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File Title:	ANTHONY LEITH ROSE & ORS v THE SECRETARY OF THE DEPARTMENT OF HEALTH AGED CARE, BRENDAN MURPHY & ORS
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Form 17

Rule 8.05(1)(a)

Third Further Amended Statement of Claim

Amended pursuant to orders of Justice Katzmann dated 17 April 2024

No. NSD349 of 2023

Federal Court of Australia

District Registry: NSW

Division: GENERAL

ANTHONY LEITH ROSE

First Applicant

ANTONIO DEROSE

Second Applicant

GARETH O'GRADIE

Third Applicant

GROUP MEMBERS AND SUB-GROUP MEMBERS OF THE CLASS

Fourth Applicants

THE SECRETARY OF THE DEPARTMENT OF HEALTH AND AGED CARE BRENDAN MURPHY

First Respondent

JOHN SKERRITT

Second Respondent

PAUL KELLY, CHIEF MEDICAL OFFICER

Third Respondent

GREG HUNT, MINISTER OF THE DEPARTMENT OF HEALTH AND AGED CARE (FORMERLY THE DEPARTMENT OF HEALTH)

Fourth Respondent

THE COMMONWEALTH OF AUSTRALIA

Fifth Respondent

Filed on behalf of	The Applicants, Anthony Leith Rose and others
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PART A – INTRODUCTION

GROUP MEMBERS

1. The applicants bring this proceeding as a representative proceeding pursuant to Part IVA of the *Federal Court of Australia Act 1976* (Cth):
    a) in their own right; and
    b) on behalf of all natural persons, being persons who at any time up to and including the date on which this Statement of Claim is filed **("the Group Members")**:
        i) were injected with one or more of the following products **("the Vaccines")** identified below as:
            (1) any of the following Vaccines sponsored by Pfizer Australia Pty Ltd, by which a Group Member is also a **Pfizer Sub-Group Member**:
                a) "COMIRNATY" product containing active ingredient BNT162b2 messenger ribonucleic acid mRNA sponsored by Pfizer Australia Pty Ltd **("the Pfizer Vaccine")**, at any time on or after:
                    i) 25 January 2021 in persons 16 years of age or older;
                    ii) 23 July 2021 in persons 12 years of age or older;
                b) the Pfizer Vaccine product produced in the formulation for paediatric use in children aged 5 to 11 years of age sponsored by Pfizer Australia Pty Ltd **("the Pfizer Child Vaccine")** at any time on or after 6 December 2021 in persons 5 to 11 years of age;
                c) The Pfizer Bivalent vaccine product (Comirnaty) Bivalent Original/Omicron BA.1), tonzinameran/riltozinameran, **("The Pfizer Bivalent Product")** at any time on or after 27 October 2022 in people aged 18 years and older;
                d) The Pfizer Bivalent vaccine product (Comirnaty Bivalent Omicron BA.4/BA.5) tozinameran and famtozinameran)

("The Pfizer Bivalent BA 4/5 Product") at any time on or after 20 January 2023 in people aged 12 years and older.

(2) any of the following Vaccines sponsored by AstraZeneca Pty Ltd, by which a Group Member is also an **AstraZeneca Sub-Group Member**:

a) "VAXZEVRIA" product containing active ingredient ChAdOx1-S sponsored by AstraZeneca Pty Ltd **("the AstraZeneca Vaccine")** at any time on or after 16 February 2021 in persons 18 years of age or older;

(3) any of the following Vaccines sponsored by Moderna Australia Pty Ltd, by which a Group Member is also a **Moderna Sub-Group Member:**

a) "SPIKEVAX" product containing active ingredient Elasomeran sponsored by Moderna Australia Pty Ltd **("the Moderna Vaccine")** at any time on or after 9 August 2021 in persons 18 years of age or older;

b) the Moderna Vaccine product produced in the formulation for paediatric use in children:

i) on or after 4 September, 2021 in persons aged 12 years or older **("the Moderna Adolescent Vaccine")**;

ii) on or after 22 February, 2022 aged 6 to 11 years of age **("the Moderna Child Vaccine")**; and

iii) on or after 21 October, 2022 in infants aged 6 months to 5 years of age **("the Moderna Infant Vaccine")**;

(4) on or after, as to:

a) the Pfizer Vaccine - 25 January 2021;

b) the Pfizer Child Vaccine - 3 December 2021;

c) the AstraZeneca Vaccine – 15 February, 2021;

d) the Moderna Vaccine - 9 August 2021;

e) the Moderna Child Vaccine – 17 February, 2022;

f) the Pfizer Bivalent vaccine -– 27 October 2022;

g) the Pfizer Bivalent BA.4/5 vaccine – 20 January 2023.

(5) in Australia; and

(6) by a suitably qualified:

a) medical practitioner;

b) health professional; or

c) any other person legally qualified or authorised to administer the Vaccines; and

ii) suffered a serious adverse event either partly or wholly by reason of injection with one or more of the Vaccines, such serious adverse event being one or more of the following events:

(1) death;

(2) a life-threatening event;

(3) an event which required in-patient hospitalisation;

(4) an event which prolonged existing hospitalisation;

(5) an event which resulted in persistent or significant disability or incapacity, including:

a) permanent impairment of a body function; or

b) permanent damage to a body structure;

(6) an event which necessitated medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure;

(7) caused a congenital anomaly, birth defect or stillbirth;

(8) was a medically important or significant event;

(9) was an event that made one or more of the outcomes above more likely; or

(10) was an event that required intervention to prevent one or more of the above outcomes, including events that required intensive treatment in an emergency department or at home but did not result in hospitalisation.

2. The following persons are not Group Members for purposes of this proceeding:

a) any current minister of the Commonwealth of Australia, a State or Territories; or

b) any judicial officer of the Commonwealth of Australia, a State or Territories.

3. The claims advanced by the applicants, on their own behalf, and on behalf of Group Members, in this proceeding, include claims for:

a) damages for personal injury;

b) general damages; and

c) damages for economic loss.

4. As at the time of the commencement of this proceeding, there are seven or more persons who are Group Members having claims against each of the respondents as pleaded and particularised in this, the Third Further Amended Statement of Claim **("SOC")** herein.

COMMON QUESTIONS OF FACT AND LAW

5. The questions of law or fact common to the claims of Group Members in this proceeding are (adopting the definitions as are pleaded below in this, the SOC):

a) whether at all material times the first respondent, the Secretary possessed the authority and undertook the responsibilities and functions and was subject to the duty alleged in paragraph 10;

b) whether at all material times the second respondent (John Skerritt) possessed the authority and undertook the responsibilities and functions and was subject to the duty alleged in paragraph 11;

c) whether at all material times the third respondent, Chief Medical Officer, Paul Kelly possessed the authority and undertook the responsibilities and functions and was subject to the duty alleged in paragraph 12;

d) whether at all material times the fourth respondent, Minister Greg Hunt possessed the authority and undertook the responsibilities and functions and was subject to the duty alleged in paragraph 13;

e) whether, and at which times, in relation to the acts and omissions pleaded in this statement of claim, the Public Officers (namely, the Secretary, Skerritt, the Chief Medical Officer Kelly and Hunt) acted:

i) in the performance or exercise of:

(1) their functions, duties or powers under the Act or the Regulations;

(2) their functions, duties or powers, whether formal or informal, incident to their respective offices;

ii) purportedly in the performance or exercise in relation to:

(1) their functions, duties or powers under the Act or the Regulations; and/or

(2) their functions, duties or powers, whether formal or informal, incident to their respective offices;

iii) while subject to:

(1) a duty to act for the public good;

(2) the Conduct Legislation;

(3) the TGA Policies;

(4) the Act; and/or

(5) the Regulations;

f) whether the material acts and omissions of each or any of the Public Officers occurred as alleged herein as:

i) as to Skerritt exclusively:

(1) the Skerritt Approvals;

(2) the Skerritt Continuing Approvals;

(3) the Skerritt Issued Misleading Vaccines Statements;

ii) as to the Secretary exclusively:

(1) the Secretary Approvals;

(2) the Secretary Continuing Approvals;

(3) the Secretary Issued Misleading Vaccines Statements;

iii) as to the Chief Medical Officer exclusively:

(1) the Chief Medical Officer Pre-Approval Conduct;

(2) the Chief Medical Officer Post-Approval Conduct;

(3) the Chief Medical Officer Issued Misleading Vaccines Statements;

iv) as to Hunt exclusively, the Minister Issued Misleading Vaccines Statements;

v) the Known Serious Vaccines Risks and Conduct – Pre-Approvals;

vi) the Known Serious Vaccines Risks and Conduct – Post-Approvals;

vii) Respondents' Control of Therapeutic Goods;

viii) the Reckless Conduct - Approvals;

ix) the Reckless Failures – Continuing Approvals;

x) the Reckless Conduct – Misleading Public Message;

xi) the Public Officers' Voluntary Assumption of Risk;

xii) the Known Approvals Assessment Failures;

xiii) the Known Post-Approvals Assessment Failures;

g) whether the Misleading Vaccines Statements:

i) manifested the Misleading Public Message;

ii) were made for the purpose of the Misleading Vaccines Statements Purpose;

h) whether the Respondents' publicly promulgated intended purposes for the Vaccines was the Vaccines Purposes;

i) whether and when the Known Serious Vaccines Risks and Conduct - Pre-

Approvals:

i) rationally established the Pre-Approval Established Critical Defects;

ii) made rationally known to the Respondents the Pre-Approval Established Critical Defects;

j) whether and when the Known Serious Vaccines Risks and Conduct - Post-Approvals:

i) rationally established the Post-Approval Established Critical Defects;

ii) made rationally known to the Respondents the Post-Approval Established Critical Defects;

k) whether the Public Officers acted as alleged upon the:

i) Purported Bases of Approvals;

ii) Purported Bases of Continuing Approvals;

l) whether and when the Respondents exercised the Respondents' Control of Therapeutic Goods in Australia;

m) whether and when the Australian population:

i) held the Public's Reasonable Expectation and Reliance;

ii) held the Public Expectation of Skill;

iii) were subject to the Known Vulnerability of the Australian Public;

n) whether the Impugned Conduct entailed:

i) the Known Gravity of the Approvals;

ii) the Foreseeability of Risk and Harm;

o) whether, and at what times, the material knowledge was held by each of the respondents as alleged in:

i) the Known Serious Vaccines Risks and Conduct – Pre-Approvals;

ii) the Known Serious Vaccines Risks and Conduct – Post-Approvals;

iii) the Pre-Approval Established Critical Defects;

iv) the Post-Approval Established Critical Defects;

v) the Misleading Vaccines Statements;

vi) the Reckless Conduct - Approvals;

vii) the Reckless Failures – Continuing Approvals;

viii) Respondents' Knowledge of Public Reliance;

ix) the Respondents' Control of Therapeutic Goods in Australia;

x) Public's Reasonable Expectation and Reliance;

xi) the Public Expectation of Skill;

xii) the Known Gravity of the Approvals;

xiii) the Known Vulnerability of the Australian Public;

xiv) the Respondents Duty;

xv) the Approvals Breach;

xvi) the Known Approvals Assessment Failures;

xvii) the Known Post-Approvals Assessment Failures;

xviii) the Known Established Falsity of the Misleading Public Message;

xix) the Clinical Testing Failures;

p) whether the Impugned Conduct were undertaken by any or all of the Respondents extraneous to any power provided:

i) under the Act and/or the Regulations;

ii) formally or informally, incident to their respective offices; or

iii) at all;

q) whether it was reasonably foreseeable that the following may cause or contribute to harm to the Group Members **("the Impugned Conduct, Misfeasance and Breaches")**:

i) the Impugned Conduct;

ii) the Skerritt Approvals Misfeasance;

iii) the Skerritt Continuing Approvals Misfeasance;

iv) the Skerritt Misleading Statements Misfeasance;

v) the Secretary Approvals Misfeasance;

vi) the Secretary Continuing Approvals Misfeasance;

vii) the Secretary Misleading Statements Misfeasance;

viii) the Chief Medical Officer Pre-Approvals Misfeasance;

ix) the Chief Medical Officer Continuing Approvals Misfeasance;

x) the Chief Medical Officer Misleading Statements Misfeasance;

xi) Hunt Misleading Statements Misfeasance;

xii) the Approvals Breach;

xiii) the Continuing Approvals Breach;

xiv) Misleading Public Message Breach;

r) whether one or more of the Impugned Conduct of the Respondents, being the Skerritt Approvals, the Secretary Approvals and the Chief Medical Officer Pre-Approval Conduct, caused or contributed to:

i) the granting of the Approvals;

ii) the wide distribution of the Vaccines to the Australian population;

iii) the injection of one or more of the Vaccines by the Group Members;

iv) the harm to the Group Members pleaded herein as the Loss and Damage or at all.

s) whether one or more of the Impugned Conduct of the Respondents being the Skerritt Continuing Approvals, the Secretary Continuing Approvals and the Chief Medical Officer Post-Approval Conduct caused or materially contributed to:

i) the Continuing Approvals;

ii) none of the Approvals being subjected to revocation or cancellation;

iii) the wide distribution of the Vaccines to the Australian population;

iv) the injection of one or more of the Vaccines by the Group Members;

v) the harm to the Group Members pleaded herein as the Loss and Damage or at all;

t) whether one or more of the Impugned Conduct of the Respondents constituted by the Skerritt Issued Misleading Vaccines Statements, the Secretary Issued Misleading Vaccines Statements, the Chief Medical Officer Issued Misleading Vaccines Statements, or the Hunt Issued Misleading Vaccines Statements caused or materially contributed to:

i) the publication of the Misleading Public Message;

ii) the reliance by the Group Members upon the Misleading Public Message;

iii) the injection of one or more of the Vaccines by the Group Members;

iv) the harm to the Group Members pleaded herein as the Loss and Damage or at all;

u) whether the following were undertaken by the respective Public Officers while not acting in performance or purported performance of, or in relation to any exercise of any duties or powers arising under the Act or the Regulations:

i) Skerritt causing the making and publication of the Skerritt Issued Misleading Vaccines Statements;

ii) the Secretary causing the making and publication of the Secretary Issued Misleading Vaccines Statements;

iii) the Chief Medical Officer undertaking:

(1) the Chief Medical Officer Pre-Approval Conduct;

(2) the Chief Medical Officer Post-Approval Conduct;

(3) the making and publication of the Chief Medical Officer Issued Misleading Vaccines Statements;

(4) the Chief Medical Officer Pre-Approval Advices; and

(5) the Chief Medical Officer Post-Approval Advices;

iv) Hunt causing the making and publication of the Hunt Misleading Vaccines Statements;

v) whether the Impugned Conduct was undertaken by the Respondents with:

i) knowledge that such was:

(1) extraneous to any power under the Act; and

(2) likely to cause harm to the Group Members;

ii) further or alternatively, reckless indifference:

(1) to whether such was extraneous to any power under the Act; and

(2) to the likelihood of harm to the Group Members;

w) whether the Respondents owed the Respondents' Duty to the Group Members;

x) whether the acts and/or omissions constituted by the Impugned Conduct of any or all of the Respondents caused:

i) the Approvals Breach;

ii) the Continuing Approvals Breach; and/or

iii) Misleading Public Message Breach.

y) whether each of the Impugned Conduct, Misfeasance and Breaches occurred;

z) whether the Impugned Conduct of the Respondents respectively caused:

i) as to Skerritt:

(1) the Skerritt Approval Breaches;

(2) the Skerritt Continuing Approval Breaches;

ii) as to the Secretary:

(1) the Secretary Approval Breaches;

(2) the Secretary Continuing Approval Breaches;

iii) as to the Chief Medical Officer:

(1) the Chief Medical Officer Pre-Approval Breaches;

(2) the Chief Medical Officer Post-Approval Breaches;

aa) whether each of the following constituted misfeasance in public office:

i) the Skerritt Approvals Misfeasance;

ii) the Skerritt Continuing Approvals Misfeasance;

iii) the Skerritt Misleading Statements Misfeasance;

iv) the Secretary Approvals Misfeasance;

v) the Secretary Continuing Approvals Misfeasance;

vi) the Secretary Misleading Statements Misfeasance;

vii) the Chief Medical Officer Pre-Approvals Misfeasance;

viii) the Chief Medical Officer Continuing Approvals Misfeasance;

ix) the Chief Medical Officer Misleading Statements Misfeasance;

x) the Hunt Misleading Statements Misfeasance;

bb) whether one or more of the Impugned Conduct, Misfeasance and Breaches caused or contributed to injury, loss or harm and damage to the Group Members;

cc) whether and to what extent the Commonwealth is vicariously liable for the actions (tortious or otherwise) of the Public Officers alleged in the proceedings.

APPLICANTS

6. The First Applicant, Anthony Leith Rose **("Mr Rose")**:

a) is a Group Member of the Moderna Sub-Group;

b) was born on 7 October 1976 in New South Wales;

c) is unmarried, formerly married;

d) has two children;

e) is an Australian citizen;

f) resides in New South Wales;

g) received an injection of a single dose of the Moderna Vaccine **("Mr Rose Vaccination")**:

i) by a medical health professional;

ii) on 8 October 2021;

iii) in Sydney, New South Wales;

h) Mr Rose Vaccination caused Mr Rose to suffer by 9 October, 2021, chronic and ongoing **("the Rose Injuries")**:

i) severe cognitive impairment;

ii) severe chest pain;

iii) severe headaches;

iv) shortness of breath;

v) painful left arm;

vi) leg weakness;

vii) vision changes;

viii) altered cardiac function; and

ix) severe chronic fatigue.

7. The Second Applicant, Antonio Derose **("Mr Derose")**:

a) is a Group Member of the AstraZeneca Sub-Group;

b) was born on 7 November 1957 in Italy;

c) is unmarried, formerly married;

d) has 3 children;

e) is an Australian permanent resident;

f) resides in South Australia;

g) received an injection of a single dose of the AstraZeneca Vaccine **("Mr Derose Vaccination")**:

   i) by a medical health professional;

   ii) on 9 October 2021;

   iii) in Adelaide, South Australia;

h) Mr Derose Vaccination caused Mr Derose to suffer by 18 October 2021, chronic and ongoing **("the Derose Injuries")**:

   i) Acute Disseminated Encephalomyelitis;

   ii) lower back pain;

   iii) lower limb numbness and weakness;

   iv) neurogenic bladder and bowel;

   v) inability to walk unassisted;

   vi) wheelchair dependency;

   vii) left lower leg venous thrombosis.

8. The Third Applicant, Gareth O'Gradie **("Mr O'Gradie")**:

a) is a Group Member of the Pfizer Sub-Group;

b) was born on 19 September 1981;

c) is married;

d) has 2 children;

e) is an Australian citizen;

f) resides in Victoria;

g) received an injection of a single dose of the Pfizer Vaccine **("Mr O'Gradie Vaccination")**:

   i) by a medical health professional;

   ii) on 24 July 2021;

   iii) in Melbourne, Victoria.

h) Mr O'Gradie Vaccination caused Mr O'Gradie to suffer by 31 July 2021 **("the O'Gradie Injuries")**:

i) chronic;

(1) myopericarditis requiring pericardiectomy;

(2) pericarditis;

(3) myocarditis;

(4) lethargy;

(5) shortness of breath;

(6) back pain;

(7) psychological illness:

(8) anxiety;

(9) depression;

(10) PTSD;

(11) social isolation.

ii) chronic from treatment:

(1) disfiguring scarring;

(2) numbness of the chest wall due to median sternotomy for pericardiectomy;

(3) steroid induced diabetes;

(4) injection site reactions to immunosuppressive injection therapy.

iii) acute:

(1) chest pain;

(2) palpitations;

(3) shortness of breath; and

(4) fever.

9. Each and every one of the applicants is capable of suing:

a) in their own right; and

b) on behalf of the Group Members.

PART B – THE RESPONDENTS

THE FIRST RESPONDENT

10. At all material times, the first respondent, the Secretary of the Department of Health and Aged Care **("the Secretary")**:

a) is identified in the person of Brendan Murphy;

b) was secretary of the Department of Health and Aged Care (formerly the Department of Health) being a department of the Australian Government executive **("the Department")**;

c) represented and acted for the Commonwealth in his role as secretary of the Department;

d) was "Secretary" as defined by and pursuant to s. 3 of the *Therapeutic Goods Act 1989* (Cth), and thereby Secretary for the purposes of:

   i) the *Therapeutic Goods Act 1989* (Cth) **("the Act")**;

   ii) the *Therapeutic Goods Regulations 1990* (Cth) **("the Regulations")**;

e) maintained the Australian Register of Therapeutic Goods **("the Register")**:

   i) required by s.9A(1) of the Act to be for the purpose of compiling information related to, and providing evaluation of therapeutic goods for use in humans;

   ii) purportedly pursuant to the Act and Regulations;

f) dealt with the matters to which the Act relates and/or matters incident to his office as the secretary of the Department;

g) was appointed to the role of secretary by the Fourth Respondent, Greg Hunt, the Minister of the Department Of Health And Aged Care (formerly, the Department of Health) **("the Minister")**;

h) directed and was responsible for the functions of:

   i) the Department;

   ii) the Therapeutic Goods Administration **("the TGA")** acting pursuant to the Act;

i) undertook the functions of the TGA and the Department by:

   i) direct action and/or directive;

   ii) by directions to authorised persons:

      (1) empowered to act in accordance with the authority delegated by the Secretary; and/or

      (2) pursuant to whose instructions the following were required to act or customarily acted:

         a) TGA members, officers and staff;

         b) the Department officers and staff.

j) was the head of The National Covid-19 Vaccine Taskforce **("the National Vaccine Taskforce")** which:

i) implemented the mass distribution of the Vaccines to the Australian population;

ii) conducted a public information campaign to motivate the Australian public to receive the Vaccines;

iii) promoted and caused the highest possible uptake of the Vaccines by the Australian public;

iv) collects and monitors all available Covid and Vaccines data;

v) regularly informed the Minister of all available and accumulated data relating to Covid and the Vaccines;

k) was an officer of the Commonwealth belonging to the Commonwealth Public Service, acting as a representative of and acting on behalf of the Commonwealth;

l) was a Commonwealth Officer as defined by s. 3 of the Act;

m) in all acts and omissions doing so purportedly pursuant to and insofar as the duties and authorities conferred on him:

i) as an officer of the Commonwealth; and/or

ii) by legislation, including the Act and Regulations;

n) was subject to and bound by, in his conduct **("the Conduct Legislation")**:

i) the *Public Service Act 1999* (Cth);

ii) the *Public Governance, Performance and Accountability Act 2013* (Cth);

iii) the *Parliamentary Service Act 1999* (Cth);

o) was, for the purposes of the Conduct Legislation an:

i) "Agency Head" and "Secretary", as defined by s. 7 of the *Public Service Act 1999* (Cth);

ii) "Accountable Authority", as defined by s. 12 of the *Public Governance, Performance And Accountability Act 2013* (Cth);

iii) "Secretary", as defined by s. 7 of the *Parliamentary Service Act 1999* (Cth).

p) was a member of the Department's executive body;

q) reported to the Minister;

r) was empowered to delegate his authority and powers under the Act, wherein such persons to whom authority is delegated remained subject to his direction pursuant to s. 57(4) of the Act;

s) was chairman of the Commonwealth Science and Industry Technical Advisory Group;

t) wherein the Secretary delegated any power under any legislation, the exercise or purported exercise of power by that person in every instance and at all material

times, such were pursuant to s. 34AB(1)(c) of the *Acts Interpretation Act 1901* (Cth), were:

i) exercises of the purported power of the Secretary;

ii) the acts of the Secretary.

u) by reason of the factual matters pleaded at (a) to (t) above, was at all times in the course of undertaking acts and omissions incident to his office under a positive duty to so act for the public good.

THE SECOND RESPONDENT

11. At all material times until 18 April 2023, the second respondent, John Skerritt **("Skerritt")**:

a) led the TGA acting purportedly pursuant to the powers conferred under the Act and the Regulations;

b) directed and was responsible for undertaking the functions of the TGA and the Department consistently with the direction of the Secretary;

c) undertook the functions of the TGA and the Department by:

i) direct action and/or directive; and/or

ii) directions to:

(1) authorised persons empowered to act in accordance with the authority delegated by Skerritt or the Secretary;

(2) persons whom were required to act or customarily acted in respect of the instructions of Skerritt, including:

a) TGA members, officers and staff;

b) the Department's officers and staff.

d) was a person pursuant to whose instructions TGA members, officers and staff were required to act or customarily acted;

e) dealt with the matters to which the Act relates and/or matters incident to his office as an officer of the Department;

f) was Deputy Secretary of Health Products Regulation Group (HPRG) which:

i) is part of the Department;

ii) includes the whole of the TGA;

g) duly authorised by the Secretary as a person:

i) authorised to exercise powers under the Act pursuant to s. 7A of the Act;

ii) as an authorised officer to exercise powers under the Regulations;

h) was a member of the HPRG executive body;

i) had direct responsibility for the overall management of:
    i) the TGA; and
    ii) the Office of Drug Control;
j) was the most senior officer within the TGA:
    i) to whom TGA members reported;
    ii) pursuant to whose instructions TGA members, officers and staff were required to act or customarily acted;
    iii) with responsibility for the conduct of the TGA;
k1) was a member of the National Vaccine Taskforce;
k) was an officer of the Commonwealth belonging to the Commonwealth Public Service, acting as a representative of and on behalf of the Commonwealth;
l) was a Commonwealth Officer as defined by s. 3 of the Act;
m) in all acts and omissions doing so purportedly pursuant to and insofar as the duties and authorities conferred on him:
    i) as an officer of the Commonwealth; and/or
    ii) legislation, including the Act and Regulations.
n) was subject to and bound in his conduct by the Conduct Legislation;
o) was, for the purposes of the Conduct Legislation an:
    i) "APS Employee", for the purposes of and as defined by s. 7 of the *Public Service Act 1999* (Cth);
    ii) "Official", for the for the purposes of and as defined by s. 8 of the *Public Governance, Performance And Accountability Act 2013* (Cth);
    iii) "SES Employee", for the purposes of and as defined by s. 7 of the *Parliamentary Service Act 1999* (Cth);
p) was a member of the Department's executive body;
q) wherein Skerritt delegated any power under any legislation, the exercise or purported exercise of power by that person in every instance and at all material times, such were pursuant to s. 34AB(1)(c) of the *Acts Interpretation Act 1901* (Cth), were:
    i) exercises of the purported power of Skerritt;
    ii) the acts of Skerritt.
r) by reason of the factual matters pleaded at (a) to (q) above, was at all times in the course of undertaking acts and omissions incident to his office under a positive duty to so act for the public good.

THE THIRD RESPONDENT

12. At all material times, the third respondent, the Chief Medical Officer **("the Chief Medical Officer")**:

    a) was identified in the person of Professor Paul Kelly;

    b) was an officer of the Commonwealth Public Service and represented and acted for the Commonwealth in his role as Chief Medical Officer;

    c) was the principal medical advisor to:

        i) the Minister of the Department

        ii) the Department;

        iii) the Australian Government; and

        iv) the Secretary;

    d) was directed by and reported to the Secretary;

    e) dealt with the matters to which the Act relates and incident to his office as chief medical officer of the Commonwealth;

    f) was directly responsible for the division of the Department:

        i) called the Office of Health Protection and Response Division;

        ii) providing advices relating to:

            (1) epidemiology;

            (2) infectious disease; and

            (3) immunisation of the Australian population;

    g) was tasked with assisting the Australian Government and Australian population to:

        i) understand how coronavirus spreads through the community;

        ii) understand what the Australian population and Australian Government could do to stop the spread of coronavirus; and

        iii) distribute the Vaccines to the entire Australian population;

    h) was an officer of the Commonwealth belonging to the Commonwealth Public Service, acting as a representative of and on behalf of the Commonwealth;

    i) was a Commonwealth Officer as defined by s. 3 of the Act;

    j) in all acts and omissions was doing so purportedly pursuant to and insofar as the duties and authorities conferred on him:

        i) as an officer of the Commonwealth; and/or

        ii) by legislation, including the Act and the Regulations;

    k) was subject to and bound in his conduct by the Conduct Legislation;

l) was for the purposes of the Conduct Legislation an:

i) "APS Employee", for the purposes of and as defined by s. 7 of the *Public Service Act 1999* (Cth);

ii) "Official", for the for the purposes of and as defined by s. 8 of the *Public Governance, Performance and Accountability Act 2013* (Cth);

iii) "SES Employee", for the purposes of and as defined by s. 7 of the *Parliamentary Service Act 1999* (Cth);

m) was a member of the Department's executive body;

n) was the deputy chair of the Commonwealth Science and Industry Technical Advisory Group;

o) wherein the Chief Medical Officer delegated any power under any legislation, the exercise or purported exercise of power by that person in every instance and at all material times were, pursuant to s. 34AB(1)(c) of the *Acts Interpretation Act 1901* (Cth):

i) exercises of the purported power of the Chief Medical Officer;

ii) the acts of the Chief Medical Officer.

p) by reason of the factual matters pleaded at (a) to (o) above, was at all times in the course of undertaking acts and omissions incident to his office under a positive duty to so act for the public good.

THE FOURTH RESPONDENT

13. At all material times the fourth respondent, Greg Hunt **("Hunt")**:

a) was minister for the Department until 23 May 2022;

b) was an officer and representative of the Commonwealth acting on behalf of the Commonwealth;

c) was a Minister for the purposes of the Act;

d) was the Minister responsible for administration of the Act;

e) dealt with the matters to which the Act relates and matters incident to his office as a minister of the Commonwealth;

f) was a Commonwealth Officer as defined by s. 3 of the Act;

g) was regularly advised by the National Vaccine Taskforce as to all available and accumulated data relating to Covid and the Vaccines;

h) in all acts and omissions doing so purportedly pursuant and insofar as to the duties and authorities conferred on him:

i) as an officer and minister of the Commonwealth; and/or

ii) legislation.

i) by reason of the factual matters pleaded at (a) to (h) above, was at all times in the course of undertaking acts and omissions incident to his office under a positive duty to so act for the public good.

THE FIFTH RESPONDENT

14. At all material times, the fifth respondent, the Commonwealth was and is liable for the actions and omissions in their respective capacities as officers of the Commonwealth of **("the Public Officers")**:

a) the Secretary;

b) Skerritt;

c) the Chief Medical Officer; and

d) Hunt.

ACTIONS THROUGH THE TGA, THE DEPARTMENT, OFFICERS AND EMPLOYEES OF THE DEPARTMENT AND OTHER AUTHORISED PERSONS

15. At all material times, the Public Officers, when acting through the body of the TGA or the Department, either directly or by exercising acts or omissions by the grant of authority to or direction of any employee, officer, contractor or servant of the TGA, the Department, or any other person acting under the authority or at the direction of the Public Officer were acting:

a) for the purposes of the allegations of acts and omissions in this pleading; and

b) in fact, to facilitate and bring about that act or omission.

RESPONDENTS' LIABILITY

16. Each act or omission pleaded by reference to the personal respondents identified in this proceeding was an act or omission:

a) carried out by them or purportedly pursuant to the duties and authorities conferred on them as officers of the Commonwealth;

b) wherein the Commonwealth is responsible in law for the actions of those persons;

c) performed whilst the respective respondent was under a positive duty to act for the public good in those acts and omissions.

THE DEPARTMENT

17. The Department was at all material times and is:

a) responsible for:

i) the health and wellbeing of the Australian population including the Group Members;

ii) the Australian health system;

iii) the priorities of the government of the Commonwealth;

iv) the overall administration of the Act and the Regulations **("the Department Functional Responsibilities")**;

b) a department of the Commonwealth;

c) regulating medicines and medical devices in Australia, including the Vaccines, through the approved functions of the TGA under the Act;

d) comprised of departments which included the HPRG;

e) managed by:

i) the Secretary; and

ii) the Minister.

f) was created and continues to exist for the purported overarching purpose of the betterment of the health and wellbeing of the Australian population **("the Department Overarching Purpose")**.

Particulars

Para. 17 in Schedule D of the SOC.

THE TGA

18. The TGA was at all material times:

a) a part and a division of:

i) the Department; and

ii) the Health Products Regulation Group **("the HPRG")** being a sub-division of the Department;

b) a statutory body empowered in its functions by:

i) the Act;

ii) the Regulations;

c) empowered by the Act and the Regulations to provide for the establishment and maintenance of a national system of controls of therapeutic goods used in

Australia regardless of the place of production, including the Vaccines, in respect of their:

i) safety;

ii) efficacy;

iii) quality;

d) directed in its daily functions by:

i) Skerritt, in his position as the Deputy Secretary of the HPRG; and

ii) the Secretary, in his position as secretary of the Department;

e) acting in all of its conduct under the direction and authority of:

i) Skerritt;

ii) the Secretary;

iii) Hunt; and

iv) the Commonwealth;

f) operating as the Australian regulatory authority in respect of therapeutic goods including the Vaccines;

g) regularly carrying out and tasked with conducting assessment and monitoring activities to ensure therapeutic goods available in Australia, including the Vaccines:

i) are of an acceptable standard; and

ii) with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances;

h) possessed of, and publicly declared by the TGA to be possessed of, the following responsibilities relevant to the Vaccines authorisation and use in Australia **("the TGA Functional Responsibilities")**:

i) the evaluation of applications to approve new medicines and vaccines for supply in Australia, including the Vaccines, for their:

(1) safety;

(2) efficacy;

(3) quality;

(4) risk-benefit profile;

ii) undertaking safety monitoring of medicines and vaccines approved for supply in Australia after they are on the market, including the Vaccines, for their ongoing:

(1) safety;

(2) efficacy;

(3) quality;

(4) risk-benefit profile;

iii) regulation of therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products;

iv) ensuring that therapeutic goods available for supply in Australia are safe and fit for their intended purpose;

v) creation and maintenance of the Register for the purpose of compiling information in relation to, and providing for evaluation of, therapeutic goods for use in humans;

vi) evaluation of applications to approve new medicines for supply in Australia;

vii) safety monitoring of medicines and vaccines approved for supply in Australia after they are on the market by:

(1) pre-market assessment; and

(2) post-market monitoring and enforcement of standards including withdrawal of a product from use;

viii) undertaking risk assessment of new medicines as a primary function in the process by application of the TGA's scientific and clinical expertise to its decision-making to ensure that the benefits of a product outweigh any risk;

ix) in assessing the level of risk of therapeutic goods including vaccines, taking account of:

(1) side effects;

(2) potential harm through prolonged use;

(3) toxicity; and

(4) the seriousness of the medical condition for which the product is intended to be used;

x) managing the risks of approval of therapeutic products including vaccines by:

(1) identifying, assessing and evaluating the risks posed by therapeutic products;

(2) applying any measures necessary for treating the risks posed; and

(3) monitoring and reviewing risks over time;

xi) adopting a risk-benefit approach by balancing:

(1) assurances to consumers that the products they take are safe for their intended use; and

(2) providing access to products that are essential to their health needs;

xii) obtaining and using risk information in relation to a therapeutic product including vaccines in determining:

(1) whether to approve a medication for supply; and

(2) the conditions that might be imposed on that approval;

xiii) in direct proportion to the level of risk the medicine poses to the consumer:

(1) increasing the level of TGA regulatory control; and

(2) determining how and whether consumers can access the medicine by exercising TGA controls or approvals;

xiv) determining a therapeutic product's risk by assessing whether:

(1) the product contains a substance or substances:

a) scheduled in the Poisons Standard;

b) previously unknown or untested in humans:

i) for the purpose proposed; or

ii) at all;

(2) the product's use can result in significant adverse effects;

(3) the product is used to treat life-threatening or very serious illnesses;

xv) the regulation of medicines available to the Australian population by:

(1) classifying the medicine based on different levels of risk to consumer of the medicine;

(2) implementing appropriate regulatory controls for the manufacturing processes of those medicines;

(3) assessing and evaluating medicines for and based upon quality, safety and efficacy where the medicine:

a) is assessed as having a higher level of risk;

b) consequently and typically subject to supply and consumption by prescription only;

xvi) act in the event of evident safety or efficacy issues with approved and registered medicines to:

(1) closely monitor the safety of the product;

(2) withdraw the product from:

a) the Register;

b) access to the general population;

Particulars

Para. 18(h) in Schedule D of the SOC.

i) undertaking, and publicly declared to be undertaking, inter alia, the following functions relevant to the Vaccines and authorisation and use in Australia **("the TGA Functions")**:

i) evaluating new prescription medicines;

ii) approving or rejecting medicines based upon evaluation;

iii) approving applications to market biologicals and generic medicines in Australia;

iv) providing internal scientific advice to support the decisions made by the Medicines Regulation Division;

v) evaluating toxicological and pharmaceutical chemistry aspects of therapeutic products;

vi) providing internal expertise in the biological sciences;

vii) overseeing medicines and vaccines to ensure they maintain an appropriate level of quality, safety and efficacy following entry into the Australian marketplace;

viii) evaluating and authorising clinical trials for therapeutic products;

ix) monitoring and managing medicine shortages;

x) supporting the Governments COVID-19 vaccine compensation scheme;

xi) conducting laboratory testing, quality assessment and test procedure development in disciplines such as:

(1) microbiology;

(2) immunobiology;

(3) molecular biology;

(4) biochemistry;

(5) chemistry;

(6) biomaterials engineering;

xii) contributing to post market monitoring and the evaluation of a range of therapeutic products for market authorisation including vaccines;

xiii) ensuring manufacturers of medicines meet appropriate quality standards by:

(1) physically inspecting manufacturing facilities in Australia and abroad;

(2) providing clearances for facilities where suitable inspections have

been carried out by comparable overseas regulators;

(3) coordinating therapeutic product recalls when considered necessary;

(4) providing internal technical advice to support Medicines Regulation Division's decisions including on matters relating to:

a) manufacturing practice; and

b) quality management;

xiv) providing efficient, best practice regulatory operations;

xv) communications with the public and health professionals through websites, social media, media releases, direct communications, and responding to direct enquiries.

Particulars

Para. 18(i) in Schedule D of the SOC.

PART C - THE VACCINES APPROVALS AND CONTINUING APPROVALS

COVID AND THE VIRUS

19. SARS-CoV-2 **("the Virus")** is known to be a virus that causes the disease known as Coronavirus Disease (COVID-19) **("Covid")**.

APPROVAL OF THE VACCINES

20. Approval of and the undertaking of provisional registration for each of the Vaccines, pursuant to and as defined by s. 23AA of the Act, occurred as follows **("the Approvals")**:

a) the Pfizer Vaccine **("the Pfizer Approval")**:

i) for use in persons 16 years of age or older;

ii) approved on 24 January 2021;

iii) entered onto the Register: 25 January 2021;

iv) sponsored by Pfizer Australia Pty Ltd **("Pfizer")**;

b) the Pfizer Vaccine **("the Pfizer Adolescent Approval")**:

i) extension of the Pfizer Approval for indicated use of the Pfizer Vaccine in persons 12 years of age or older;

ii) approved on 22 July 2021;

iii) entered onto the Register on 23 July 2021;

iv) sponsored by Pfizer;

c) the Pfizer Child Vaccine **("the Pfizer Child Approval")**

i) extension of the Pfizer Approval and change to formulation (excipients) for indicated use of the Pfizer Vaccine in children aged 5 years to 11 years;

ii) approved on 3 December 2021;

iii) entered onto the Register on 6 December 2021;

iv) sponsored by Pfizer;

c1) the Pfizer Bivalent Vaccine **("the Pfizer Bivalent Approval")**

i) approved for use in persons 18 years of age or older as a booster dose;

ii) approved on 20 January 2023;

iii) entered onto the Register on 23 January 2023;

iv) sponsored by Pfizer;

d) the AstraZeneca Vaccine **("the AstraZeneca Approval")**

i) for use in persons 18 years of age or older;

ii) approved on 15 February 2021;

iii) entered onto the Register on 16 February 2021;

iv) sponsored by AstraZeneca Pty Ltd **("AstraZeneca")**;

e) the Moderna Vaccine **("the Moderna Approval")**

i) for use in persons 18 years of age or older;

ii) approved on 9 August 2021;

iii) entered onto the Register on 9 August 2021:

iv) sponsored by Moderna Australia Pty Ltd **("Moderna")**;

f) the Moderna Adolescent Vaccine **("the Moderna Adolescent Approval")**

i) extension of the Moderna Approval for indicated use of the Moderna Vaccine in persons 12 years of age or older;

ii) approved on 3 September 2021;

iii) entered onto the Register on 4 September 2021;

iv) sponsored by Moderna;

g) the Moderna Child Vaccine **("the Moderna Child Approval")**

i) extension of the Moderna Approval for indicated use of the Moderna Vaccine in persons 6 years of age or older;

ii) approved on 17 February 2022;

iii) entered onto the Register on 22 February 2022;

iv) sponsored by Moderna;

h) the Moderna Infant Vaccine **("the Moderna Infant Approval")**

i) extension of the Moderna Approval for indicated use of the Moderna Vaccine in persons 6 months of age or older;
ii) approved on 19 October 2022;
iii) entered onto the Register on 21 October 2022;
iv) sponsored by Moderna.

21. Each and every one of the Approvals remains in effect from the date of the respective Approvals until the time of the commencement of these proceedings **("the Continuing Approvals").**

22. Pfizer, Moderna and AstraZeneca **("the Sponsors")** undertook studies or trials **("the Sponsors' Trials")** from which the resultant data was gathered and provided directly or made available to the TGA and to the Secretary and Skerritt **("the TGA Respondents")** and they were subsequently provided directly or made available to the Chief Medical Officer and Hunt prior to the respective Approvals **("the Sponsors' Study Data")**.

Particulars

Schedule E of the SOC.

TRIAL PROTOCOLS

23. The following trial protocols were produced by the Sponsors and provided and made available to the TGA and the TGA Respondents and subsequently provided and made available to the Chief Medical Officer and Hunt prior to the Approvals as the purported basis for the conduct of the Sponsors' Trials **("the Trial Protocols")**:

a) A phase 1/2/3, placebo-controlled, randomized, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity, and efficacy of SARS-CoV-2 RNA vaccine candidates against Covid-19 in healthy individuals. Protocol Number C4591001, Trial ID NCT04368728. Final version dated Nov, 2020. Sponsored by BioNTech SE, Collaborator: Pfizer.
https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf
Earliest version dated 15 April, 2020
https://www.nejm.org/doi/suppl/10.1056/NEJMoa2034577/suppl_file/nejmoa2034577_protocol.pdf

b) A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to

Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older. Protocol Number: mRNA-1273-P301. Dated 20 August, 2020. Sponsored by: ModernaTX, Inc. https://covid19crc.org/wp-content/uploads/2020/09/mRNA-1273-P301-Protocol-2020.pdf

c) A phase III randomised, double-blind, placebo-controlled multicentre study in adults to determine the safety, efficacy and immunogenicity of AZD1222, a non-replicating ChAdOx1 vector vaccine, for the prevention of Covid-19. Trial ID: NCT04516746. Dated 17 September, 2020. Sponsored by AstraZeneca. https://s3.amazonaws.com/ctr-med-7111/D8110C00001/52bec400-80f6-4c1b-8791-0483923d0867/c8070a4e-6a9d-46f9-8c32-cece903592b9/D8110C00001_CSP-v2.pdf

Particulars

Para. 23 in Schedule D of the SOC.

TGA APPROVAL DOCUMENTS

24. The TGA and the TGA Respondents produced, possessed and/or authorised documents prior to the Approvals, relating to the matters and data provided directly to or made available to the Respondents and the conclusions drawn therefrom as to the Vaccines' safety and efficacy, including by reference to the Sponsors' Study Data **("the TGA Vaccine Approval Documents")**.

Particulars

Schedule F of the SOC.

PART D - THERPAEUTIC GOODS ADMINISTRATION AND THE ACT

25. The Act:

a) is an Act of the Commonwealth providing for a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods in Australia;

b) s. 5 - binds the Crown in the right of the Commonwealth in civil proceedings.

THE ACT - GUIDING OBJECTS

26. The Act relevantly contained the following provisions at all material times in respect of the objects of the Act, applicable to the Approvals and use of the Vaccines in Australia **("the TGA's Statutory Purpose")**:

a) s. 4(1)(a) - an object of the Act is to provide for the establishment and maintenance of a national system of controls relating to the following in respect of therapeutic goods used in Australia:

i) quality;

ii) safety;

iii) efficacy;

iv) timely availability.

THE ACT - REGISTER

27. The Act relevantly contained the following provisions at the relevant times in respect of the establishment and conduct of the Register, applicable to the Approvals and use of the Vaccines in Australia **("the Register's Statutory Purpose")**:

a) s. 9A(1) - the Secretary is to maintain the Register, for the purpose of:

i) compiling information regarding therapeutic goods for use in humans;

ii) providing for evaluation of therapeutic goods for use in humans;

b) s. 9A(2)(aa) - the Register to contain a part for provisionally registered goods.

PROVISIONAL DETERMINATION – REGISTRATION OF VACCINES

28. The Act relevantly contained the following provisions at the relevant times in respect of a provisional application and determination by the Secretary in respect of the registration of vaccines upon the Register, applicable to the Approvals and use of the Vaccines in Australia:

a) s. 22C(1) - a person may make an application to the Secretary for a provisional determination relating to (as prescribed by reg. 10K of the Regulations) **("Provisional Determination Application")**:

i) a new prescription medicine; and/or

ii) a new indications medicine.

b) s. 22D(1) – the Secretary must decide to make, or to refuse to make, the determination in response to a Provisional Determination Application **("Provisional Determination")**;

c) s. 22D(2) – the Secretary may make the determination after receiving the

Provisional Determination Application only if the Secretary is satisfied that all of the following criteria are met in relation to the medicine (as prescribed by reg. 10L of the Regulations) **("the Provisional Determination Criteria")**:

i) an indication of the medicine is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;

ii) there are no therapeutic goods that are intended to treat, prevent or diagnose the condition included in the Register (except provisionally registered goods) or if one or more are, that there is preliminary clinical data demonstrating that the medicine is likely to provide a significant improvement in the efficacy or safety of the treatment, prevention or diagnosis of the condition compared to those goods;

iii) there is preliminary clinical data demonstrating that the medicine is likely to provide a major therapeutic advance;

iv) the person who made the application has provided sufficient evidence of the person's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years that would start on the day that provisional registration of the medicine would commence if the Secretary were to provisionally register the medicine.

THE ACT - REGISTRATION OF VACCINES

29. The Act relevantly contained the following provisions at the relevant times in respect of the registration of vaccines upon the Register, including provisionally, applicable to the Approvals and use of the Vaccines in Australia:

a) s. 23 - a person may make an application to the Secretary for registration or listing of therapeutic goods **("Registration Application")**;

b) s. 23AA(1) - if a person makes a Registration Application and a Provisional Determination relating to the person, the medicine and the indication to which the Registration Application relates is in force when the application is made, the application is taken to be an application for provisional registration of the medicine **("Provisional Registration")**;

c) s. 25(1)(d)(i) – the Secretary must evaluate the vaccine for Provisional Registration by having regard to whether, based on preliminary clinical data the following has been satisfactorily established **("the Provisional Registration Statutory Standard")**:

i) the safety of the vaccine for the purposes for which it is to be used;

ii) the efficacy of the vaccine for the purposes for which it is to be used;

d) s. 25(3) – after evaluation of the vaccine in accordance with s. 25 including the Provisional Registration Standard, the Secretary must register the vaccine or not register the vaccine on the Register.

THE ACT - REQUIREMENT FOR GENE TECHNOLOGY REGULATOR ADVICE

30. The Act relevantly contained the following provisions at the relevant times in respect of the Secretary's obligation to seek advice in respect of a Registration Application, applicable to the Approvals and use of the Vaccines in Australia:

a) s. 30C(2)(b) – where the vaccine has been Provisionally Registered, the Secretary must give written notice to the Gene Technology Regulator requesting the Gene Technology Regulator to give advice about the application **("Requirement to Seek Gene Technology Regulator Advice")**;

b) s. 30E – the Secretary must ensure that the advice received by the Secretary pursuant to the Requirement to Seek Gene Technology Regulator Advice is taken into account in making a decision on the application for Registration that the advice relates to **("Requirement to Consider Gene Technology Regulator Advice")**.

LAPSING REGISTRATION APPLICATION – INACCURATE OR MISLEADING INFORMATION

31. The Act relevantly contained the following provisions at the relevant times in respect of the lapsing of a Registration Application, including provisionally, applicable to the Approvals and use of the Vaccines in Australia:

a) s. 24(2)(b) – a Registration Application lapses if it contains information that is inaccurate or misleading in a material particular:

i) including information given under s. 31 of the Act; and

ii) the failure to give information consisting of individual patient data in relation to the vaccine required under s. 31 of the Act.

PROVISIONAL DETERMINATION – REVOCATION

32. The Act relevantly contained the following provisions at the relevant times in respect of the revocation of provisional application and determination by the Secretary in respect of the registration of vaccines upon the Register, applicable to the Approvals and use of the Vaccines in Australia:

a) s. 22F(1) - the Secretary may revoke a Provisional Determination if the Secretary is satisfied that the Provisional Determination Criteria are no longer met in relation to the medicine.

SECRETARY'S POWER TO REQUIRE INFORMATION OR DOCUMENTS

33. The Act relevantly contained the following provisions at the relevant times in respect of the power of the Secretary to require from the person applying for or having received Registration Approval, applicable to the Approvals and use of the Vaccines in Australia.

a) s. 8(1) - the Secretary may request that a person who has imported into Australia or has supplied in Australia therapeutic goods give to an officer of the Department within a reasonable period information required concerning the goods':

i) composition;

ii) indications;

iii) directions for use or labelling of the goods; or

iv) advertising material relating to the goods;

b) s.31(1) – the Secretary may require from a person whom is an applicant under a Registration Application or in relation to a Registered medicine registered currently or in the preceding 5 years any information or documents as provided for under s. 31(1) of the Act **("the TGA Power to Obtain Information")**.

SECRETARY'S POWER TO SUSPEND OR CANCEL REGISTRATION

34. The Act relevantly contained the following provisions at all material times in respect of the power of the Secretary to suspend or cancel Registration of a vaccine, applicable to the Approvals and use of the Vaccines in Australia **("the Secretary's Power to Suspend or Cancel")**:

a) s.29D(1) - the Secretary may suspend the registration or listing of a registered vaccine if:

i) the Secretary is satisfied that there is a potential risk of death, serious illness or serious injury if the vaccine continues to be included in the Register; and

ii) it is likely that the person will, within the period of the suspension, be able to take the action necessary to ensure that the therapeutic goods would not cause a potential risk of death, serious illness or serious injury if the therapeutic goods were to continue to be included in the Register; or

iii) the Secretary is satisfied that it is likely that there are grounds for cancelling the registration or listing of the goods under paragraph 30(1)(da), (e), (ea), (f), (fa), (fb) or (g) or subsection 30(1A), (1C), (1D) or (2) of the Act.

b) s. 30(1)(d) - the Secretary may cancel the registration of a vaccine if it appears to the Secretary that failure to cancel the registration or listing would create an imminent risk of death, serious illness or serious injury **("the Cancellation Standard")**.

DELEGATION OF THE MINISTER'S OR SECRETARY'S POWERS

35. The Act relevantly contained the following provisions at the relevant times in respect of the power of the Minister or the Secretary to delegate all or any of their powers and functions under the Act, applicable to the Approvals and use of the Vaccines in Australia:

a) s. 57(1) - the Minister or the Secretary may, by signed instrument, delegate to an officer of the Department; an officer of an authority of the Commonwealth that has functions in relation to therapeutic goods, an APS employee in an Agency (within the meaning of the Public Service Act 1999) that has functions in relation to therapeutic goods; a person occupying or acting in an office, or holding an appointment, declared by the regulations to be an office or appointment the occupant or holder of which may be a delegate under this section or a person seconded to the Department from those places provided for at sub-section (d), all or any of his or her powers and functions under this Act.

OBLIGATION TO ACT IN ACCORDANCE WITH STATUTE

36. The TGA Respondents were required at all times when purporting to or actually exercising their respective powers, functions and discretion under the Act, to act in accordance with the statutory obligations and principles pleaded herein at paragraphs 25 to 35 **("the Statutory Obligations")**.

PART E - TGA VACCINES REGULATORY APPROVAL POLICIES

TGA POLICIES - VACCINES APPROVAL & REGULATION

37. The TGA prior to, at the time of and at all material times since the Approvals adopted and publicly declared that it functioned under and applied the following procedures in respect of definition, approval and regulation of vaccines in Australia, including the Vaccines **("the TGA Policies")**:

a) the TGA is responsible for assessing vaccines and other medicines before they can be used in Australia;

b) the TGA will only register a vaccine for use in Australia if the benefits of the vaccine outweigh the risks for the group of people in which it is intended to be used;

c) the TGA defines vaccines as medicines that:

   i) protect the vaccine recipient against specific diseases;

   ii) protect the vaccine recipient and those who come into contact with the vaccine recipient from serious and life-threatening diseases;

d) the TGA rigorously assesses vaccines for safety, quality and efficacy before they can be used in Australia;

e) the TGA only uses the best available scientific evidence to assess the risks and benefits of each vaccine before approval;

f) the TGA's evidence requirements in assessing and approving vaccines for use are based on international guidelines developed by the European Medicines Agency;

g) the TGA carefully assesses:

   i) the results of clinical trials; and

   ii) the way in which the trials were conducted, including:

      (1) if they were conducted for a sufficient amount of time; and

      (2) if there were enough participants in the trial that represented the people for whom the vaccine is intended;

h) the TGA before approving a vaccine requires well-designed trials:

   i) of a sufficient length;

   ii) with a sufficient number of people who represent the people for whom the vaccine is intended;

i) the TGA requires before approving a vaccine that the results of trials must demonstrate that the benefits of the vaccine greatly outweigh the risks;

j) the TGA's decision of whether to register a vaccine for use in Australia is informed by the advice of the Advisory Committee on Vaccines;

k) the TGA monitors vaccines for safety after they are supplied in Australia;

l) the TGA receives adverse event reports in relation to approved vaccines from:

    i) consumers;

    ii) health professionals;

    iii) sponsors; and

    iv) state and territory health departments;

m) for regulatory purposes, spontaneous reports of adverse events:

    i) are considered to have implied causality; and

    ii) where it is not clear whether a causal association exists:

        (1) are presumed to mean that the vaccine and the adverse event are possibly related; and

        (2) meet the definition of an adverse reaction, unless the reporter explicitly states otherwise;

n) the TGA publishes reports of adverse event reports in relation to approved vaccines in the publicly available Database of Adverse Event Notifications **("DAEN")**;

o) the TGA requires mandatory submission of Serious Adverse Events reports to the TGA by sponsors of vaccines in Australia;

p) if the TGA suspects that there is a problem with a vaccine, the TGA:

    i) will launch an investigation;

    ii) may suspend use of the vaccine during the investigation;

    iii) will notify the community of safety concerns through the publication of alerts on the TGA website;

q) before it registers any vaccine for use in Australia, the TGA considers every ingredient in a vaccine for:

    i) safety;

    ii) quality; and

    iii) efficacy;

r) when a new or changing risk associated with a vaccine is identified, the TGA must:

    i) re-evaluate the benefits of the vaccine using all available data, such benefits including prevention of:

        (1) the target disease;

(2) severity of symptoms;

(3) hospitalisation;

(4) complications;

(5) effect of target disease on offspring (in case of vaccination of pregnant women); and

(6) any other clinical outcome relevant for individual patients; and

ii) estimate the impact of the new or changing risk on the benefit-risk balance of the vaccine;

s) where provisionally registering vaccines, the TGA:

i) does so on the basis of preliminary clinical data which must demonstrate that the benefit of early availability of the vaccine outweighs the risk inherent in the fact that additional data is still required;

ii) will base its decision to grant time-limited provisional registration of a vaccine upon the TGA's assessment of whether:

(1) the preliminary clinical data satisfactorily establishes the safety and efficacy of the vaccine;

(2) the quality of the vaccine has been satisfactorily established; and

(3) the TGA is satisfied with the sponsor's plan to submit comprehensive clinical data on the safety and efficacy of the vaccine after approval is granted;

iii) will re-assess risks related to the absence of evidence through data provided after provisional approval as part of the confirmatory data;

iv) must use the confirmatory data obtained to confirm the relationship between:

(1) outcomes predicted by the surrogate endpoint or other preliminary data in relation to the safety and efficacy of the vaccine; and

(2) the clinical benefit as demonstrated by direct clinical outcomes;

t) all adverse events arising in approved vaccines:

i) are risk assessed and entered into the appropriate database for future reference;

ii) are used by the TGA to identify safety signals;

u) a safety signal in a vaccine:

i) is a 'flag' for a possible safety concern;

ii) when identified by the TGA, prompts the TGA to conduct a detailed evaluation to establish the possible role of the vaccine in causing the

adverse event;

v) signal detection:

i) involves identifying patterns of adverse events associated with a particular medicine or vaccine that warrant further investigation;

ii) may arise from:

(1) a previously unrecognised safety issue;

(2) a change in the frequency or severity of a known safety issue;

(3) identification of a new 'at risk' group;

w) if a safety concern is identified relating to a vaccine, the TGA:

i) can take regulatory action to ensure that the vaccine continues to have for its intended use acceptable:

(1) safety;

(2) efficacy/performance; and

(3) quality;

ii) will issue safety alerts **("Safety Alerts")** to notify the Australian public and health professionals about the safety concern including:

(1) known safety problems;

(2) changes in the reporting pattern of known problems;

(3) new problems; and

(4) coincidental events;

x) in regards to approving and regulating the Vaccines, the TGA will:

i) not register a Covid vaccine unless the vaccine has well-conducted clinical trials in humans that demonstrate the vaccine:

(1) very significantly reduces the incidence of Covid disease in people who are vaccinated with the vaccine compared to a control group of people who did not receive the vaccine, effectively being the absolute risk reduction rate; and

(2) reduces the transmission of disease between individuals, including from asymptomatic to uninfected individuals;

ii) prior to approving any Covid vaccine, consider:

(1) the availability of alternative vaccines and treatments;

(2) the status of the pandemic; and

(3) the epidemiology of the Virus in Australia and worldwide;

iii) require all participants in clinical trials to be followed up by the Sponsors for a median of 6 months to assess the potential risk of:

(1) late-onset adverse events; and

(2) vaccine-associated enhanced respiratory disease;

iv) require all participants in clinical trials to be followed by the Sponsors:

(1) for at least 1 year; and

(2) ideally longer to assess the:

a) duration of vaccine efficacy; and

b) longer-term safety of the Vaccine;

v) strengthen the existing vaccine vigilance system for early detection and investigation of suspected side effects in order for the TGA to:

(1) enhance Vaccine safety signal detection and investigation;

(2) undertake worldwide environmental scanning for safety material in relation to the Vaccines by ongoing review of worldwide:

a) medical literature; and

b) data;

(3) manage any emerging safety issues arising in the Vaccines;

(4) inform the public of emerging Vaccines safety information;

(5) maintain public confidence in the Vaccines immunisation program;

vi) thoroughly investigate all adverse event reports to determine causality if within days to weeks after vaccination with the Vaccines:

(1) a person dies; or

(2) has a serious event requiring hospitalisation;

vii) subsequent to their thorough investigation of all serious adverse events following vaccination with the Vaccines, the TGA will:

(1) publish the results of the independent assessments performed on the TGA website, accompanied by:

a) a summary of the case; and

b) extra clinical advice for health professionals.

Particulars

The TGA Policies adopted by the TGA and thereby those acting as officers and employees of the TGA are contained in in the respective policy documents particularised in Schedule A of the SOC.

The TGA Policies were widely publicised by the Commonwealth by public website declaration and by the voluminous oral declarations of the Respondents at the time

of and subsequent to the Approvals as being the basis upon which the Commonwealth through the TGA would undertake the Approvals and Continuing Approvals.

38. At all material times, in performance of powers, functions and discretion under the Act, the TGA Respondents were reasonably expected by the Group Members to and they were obliged to adhere to the TGA Policies:
    a) with reasonable care; and
    b) in good faith; and
    c) pursuant to the Conduct Legislation.

39. *deleted*

40. *deleted*

PLEADING – THE AUSTRALIAN PUBLIC

41. In all instances when the "Australian public" or "Australian population" is referred to in this pleading, such includes, in each and every instance, reference expressly to each and all of the Group Members.

PART F – KNOWLEDGE

RESPONDENTS' KNOWLEDGE ARISING FROM KNOWN FACTUAL MATTERS

42. The respondents knew, or alternatively had reckless disregard as to the existence of, factual matters prior to the Approvals **("the Known Serious Vaccines Risks and Conduct - Pre-Approvals")** which rationally established in fact and made manifestly known that **("the Pre-Approval Established Critical Defects")**:
    a) the Vaccines were not rationally established to:
        i) be safe for any of the purported vaccine purposes, being the **("the Vaccine Purposes")**:
            (1) prevention of transmission of the Virus;
            (2) prevention of infection with the Virus;
            (3) prevention of Covid;

(4) prevention of severe Covid;

(5) prevention of hospitalisation from Covid; and

(6) prevention from death from Covid;

ii) be efficacious for any of the Vaccine Purposes;

iii) be necessary for any of the Vaccine Purposes;

iv) provide benefits which outweighed their risks for any of the Vaccine Purposes;

v) be likely to provide a major therapeutic advance;

b) further or in the alternative, the Vaccines were rationally established to:

i) be unsafe for any of the Vaccine Purposes;

ii) be inefficacious for any of the Vaccine Purposes;

iii) be unnecessary for any of the Vaccine Purposes;

iv) possess risks which outweighed their benefits for any of the Vaccine Purposes;

v) be unlikely to provide a major therapeutic advance;

c) Covid was:

i) not rationally established to be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

ii) further or in the alternative, rationally established to not be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

d) by reason of (a) to (c) herein above, the following factual matters had not been rationally established **("the Critical Vaccine Requirements")**:

i) the Vaccines were safe for any of the Vaccine Purposes;

ii) the Vaccines were efficacious for any of the Vaccine Purposes;

iii) the Vaccines were necessary for any of the Vaccine Purposes;

iv) the Vaccines would provide benefits which outweighed their risks for any of the Vaccine Purposes;

v) the Vaccines were likely to provide a major therapeutic advance;

vi) Covid was a life-threatening or seriously debilitating condition for all persons in Australia including those under 70 years of age;

vii) the respective Approvals as granted and the conduct in granting them:

(1) satisfied the following legislation:

a) the TGA' Statutory Purpose;

b) the Register's Statutory Purpose;

c) s. 25(1)(d)(i) of the Act;

d) s. 22D(2) of the Act;

e) r. 10L(1)(a) and (c) of the Regulations; and

f) the Conduct Legislation;

(2) were lawful;

viii) that sufficient evidence existed to rationally establish (i) to (vii) above;

ix) that the respective Approvals would in each instance be in accordance with the Department Overarching Purpose.

Particulars

The Known Serious Vaccines Risks and Conduct - Pre-Approvals are contained in Paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.

The circumstances of knowledge of the Known Serious Vaccines Risks and Conduct – Pre-Approvals are particularised in Schedule C of the SOC.

Particulars of the Pre-Approval Established Critical Defects are contained in Para. 42 in Schedule D of the SOC.

43. The respondents knew, or alternatively had reckless disregard as to the existence of, factual matters subsequent to the Approvals **("the Known Serious Vaccines Risks and Conduct - Post-Approvals")** which rationally established in fact and made manifestly known that **("the Post-Approval Established Critical Defects")**:

a) the Vaccines were not rationally established to:

i) be safe for any of the Vaccine Purposes;

ii) be efficacious for any of the Vaccine Purposes;

iii) be necessary for any of the Vaccine Purposes;

iv) provide benefits which outweighed their risks for any of the Vaccine Purposes;

v) be likely to provide a major therapeutic advance;

b) further or in the alternative, the Vaccines were rationally established to:

i) be unsafe for any of the Vaccine Purposes;

ii) be inefficacious for any of the Vaccine Purposes;

iii) be unnecessary for any of the Vaccine Purposes;

iv) possess risks which outweighed their benefits for any of the Vaccine Purposes;

v) rationally established to be unlikely to provide a major therapeutic advance;

c) Covid was:

i) rationally established to not be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

ii) further or in the alternative, not rationally established to be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

d) by reason of (a) to (c) herein above, the Critical Vaccine Requirements had not been rationally established.

Particulars

The Known Serious Vaccines Risks and Conduct - Post-Approvals are contained in Paragraphs 75 to 155 (inclusive) in Schedule B of the SOC.

The circumstances of knowledge of the Known Serious Vaccines Risks and Conduct – Post-Approvals are particularised in Schedule C of the SOC.

Particulars of the Post-Approval Established Critical Defects are contained in Para. 43 in Schedule D of the SOC.

PART G - MISLEADING STATEMENTS

SKERRITT – MISLEADING STATEMENTS

44. Prior to and subsequent to the Approvals, Skerritt made public statements in respect of the safety, efficacy and necessity of the Vaccines to the Australian population **("the Skerritt Misleading Vaccines Statements")**.

Particulars

Paragraph 44 in Schedule G of the SOC.

SECRETARY – MISLEADING STATEMENTS

45. Prior to and subsequent to the Approvals, the Secretary made public statements in respect

of the safety, efficacy and necessity of the Vaccines to the Australian population **("the Secretary Misleading Vaccines Statements")**.

Particulars

Paragraph 45 in Schedule G of the SOC.

TGA – MISLEADING STATEMENTS

46. Prior to and subsequent to the Approvals, the TGA Respondents through the TGA made public statements in respect of the testing, reporting, oversight, safety, efficacy and necessity of the Vaccines to the Australian population **("the TGA Misleading Vaccines Statements")**.

Particulars

Paragraph 46 in Schedule D of the SOC.

Paragraph 46 in Schedule G of the SOC.

CHIEF MEDICAL OFFICER – MISLEADING STATEMENTS

47. Prior to and subsequent to the Approvals, the Chief Medical Officer made public statements in respect of the safety, efficacy and necessity of the Vaccines to the Australian population **("the Chief Medical Officer Misleading Vaccines Statements")**.

Particulars

Paragraph 47 in Schedule G of the SOC.

HUNT – MISLEADING STATEMENTS

48. Prior to and subsequent to the Approvals, Hunt made public statements in respect of the safety, efficacy and necessity of the Vaccines to the Australian population **("the Hunt Misleading Vaccines Statements")**.

Particulars

Paragraph 48 in Schedule G of the SOC.

THE DEPARTMENT – MISLEADING STATEMENTS

49. Prior to and subsequent to the Approvals, the Respondents, through the Department, made public statements in respect of the safety, efficacy and necessity of the Vaccines to the

Australian population **("the Department Misleading Vaccines Statements")**.

Particulars

Paragraph 49 in Schedule D of the SOC.

Paragraph 49 in Schedule G of the SOC.

MISLEADING PUBLIC MESSAGE

50. The statements pleaded at paragraphs 44 to 49 (inclusive) herein **("the Misleading Vaccines Statements")**:

a) individually and in confluence represented to the Australian population (including the Group Members) either expressly or impliedly that **("the Misleading Public Message")**:

i) the Vaccines were unquestionably safe;

ii) the Vaccines were so safe that anything other than the most mild of side effects almost never occurred;

iii) the purposes of the Vaccines were for the Vaccine Purposes;

iv) the Vaccines were completely or almost completely effective in providing the Vaccine Purposes in recipients;

v) prior and subsequent to the Approvals, the Vaccines would be, were and continued to be subjected to:

(1) the most rigorous oversight, reporting, vigilance, assessment and ongoing reporting, vigilance and assessment for safety and efficacy possible;

(2) an assessment procedure equivalent to that applied all other approved therapeutic products in Australia;

(3) strict application of all provision of the TGA Policies to assessment and ongoing assessment of the Vaccines' safety, efficacy, necessity and risk-benefit profile.

vi) nothing known by the Respondents in respect of testing prior to the Approvals or known data in respect of the safety or efficacy of the Vaccines were of any concern;

vii) if people did not take the Vaccines they would be at a high risk of dying or becoming seriously ill;

viii) for everyone in Australia the risks of serious illness and death from not taking the Vaccines were significantly higher than the risks of injury from

taking the Vaccines;

ix) taking the Vaccines was essential to protect others from Covid;

x) nothing in the known data in respect of post-Approvals side effects from the Vaccines was of any material concern to the Australian public;

xi) public reporting and statements of the Respondents pre-Approvals and post-Approvals in respect of the safety, efficacy and risk-benefit profile of the Vaccines discloses to the Australian public the most accurate and comprehensively evident representation of those matters;

b) individually and in confluence, represented to the Australian population (including the Group Members), either expressly or impliedly, that prior to the respective Approvals those authorised to assess the Vaccines and grant the Approvals rationally established and were satisfied that **("the Purported Bases of Approval")**:

i) the Vaccines were safe for any of the Vaccine Purposes;

ii) the Vaccines were efficacious for any of the Vaccine Purposes;

iii) the Vaccines were necessary for any of the Vaccine Purposes;

iv) the Vaccines would provide benefits which outweighed their risks for any of the Vaccine Purposes;

v) Covid was a life-threatening or seriously debilitating condition for all persons in Australia;

vi) the respective Approvals as granted and the conduct in granting them satisfied all relevant legislation and was lawful;

vii) that sufficient evidence existed to rationally establish (i) to (vi) above;

c) individually and in confluence represented to the Australian population (including the Group Members), either expressly or impliedly, that at all times since the respective Approvals **("the Purported Bases of Continuing Approval")**:

i) the Purported Bases of Approval continued to be met;

ii) the available data after the respective Approvals continued to rationally establish the Purported Bases of Approval;

iii) those persons authorised to assess the Vaccines and grant the Approvals and Continuing Approvals were rationally satisfied as to (i) and (ii);

iv) that the Vaccines should be rolled out to the entire Australian population for use as soon as possible;

d) contained the Misleading Public Message which was misleading because in truth, it was contrary to the balance of data and evidences in the possession of, known to,

and/or reasonably available to the persons who made them and authorised them, being the Respondents and those acting under their direction and authority;

e) were made for the purposes and with the intention, by each of the Public Officers **("the Misleading Vaccines Statements Purpose")**:

i) of inducing the Australian population to receive one or more of the Vaccines:

(1) in the greatest numbers possible;

(2) with the minimal hesitation possible; and

(3) with the minimal delay possible;

ii) that the Australian Public would rely upon the truth of the Misleading Public Message in deciding whether or not to receive one or more of the Vaccines;

iii) to convey:

(1) the Misleading Public Message;

(2) the Vaccine Purposes;

(3) the Purported Bases of Approval;

(4) the Purported Bases of Continuing Approval;

f) were made in the circumstances of the following knowledge and conduct of the Respondents, where, having occurred at the relevant point in time, as pleaded and particularised herein:

i) the Known Serious Vaccines Risks And Conduct - Pre-Approvals;

ii) the Known Serious Vaccines Risks And Conduct - Post-Approvals; and

iii) the knowledge and conduct pleaded and particularised in the Misleading Vaccines Statements.

Particulars

Para. 50 in Schedule D of the SOC.

PART H - RELEVANT CONDUCT OF THE RESPONDENTS

SKERRITT - APPROVALS

51. Skerritt granted, caused or materially contributed to the grant of each of the respective Approvals **("the Skerritt Approvals")**:

a) personally and directly pursuant to a purported power to grant the Approvals delegated to him under the Act by the Secretary and/or the purported power incident to his office;

b) further or alternatively, by either directly or through direction given to an employee of the Commonwealth, expressly or impliedly advising the Secretary and Hunt and/or advising, sanctioning or directing any other person imbued with the actual or delegated authority to grant the Approvals that:

    i) the Approvals be granted or ought to be granted;

    ii) the grant of the Approvals would satisfy the requirements of legislation including the Act and the Regulations;

    iii) as at the date of the respective Approvals that the Critical Vaccine Requirements had been rationally established;

    iv) all available and relevant information, data and materials accumulated by the TGA, the Department and Skerritt and/or reasonably available to Skerritt rationally established that the Vaccines at the times of the Approvals met the Critical Vaccine Requirements;

    v) he was rationally satisfied as to the matters contained in sub-paragraphs (i) to (iv) herein;

c) further or alternatively, by failing or refusing at any time up to the time of the respective Approvals to expressly or impliedly, either directly or through direction given to an employee of the Commonwealth, advise the Secretary and Hunt and/or advise, sanction or direct any other person imbued with the actual or delegated authority to grant the Approvals that:

    i) the Approvals not be or ought not be granted;

    ii) the grant of the Approvals would not satisfy the requirements of legislation including the Act and the Regulations;

    iii) as at the date of the respective Approvals that in fact the Critical Vaccine Requirements had not been rationally established;

    iv) he was rationally satisfied as to the matters contained in sub-paragraphs (i) to (iii) herein;

d) wherein Skerritt undertook any or all of the acts and/or omissions pleaded at sub-paragraphs (a) to (c) herein, in each instance he:

    i) intended, knew, expected and considered it likely that as a natural and probable consequence of those acts or omissions that:

        (1) the respective Approvals would be granted;

(2) the Vaccines would be widely distributed to the Australian population for use; and

(3) the Vaccines would be received by the Australian population;

ii) caused as a direct consequence the respective Approvals to be granted;

iii) caused as a direct consequence the Vaccines to be widely distributed to the Australian population for use;

iv) caused as a direct consequence the Vaccines to be received by the Group Members.

Particulars

Para. 51 in Schedule D of the SOC.

SKERRITT – CONTINUING APPROVALS

52. Skerritt, in respect of each of the respective Continuing Approvals from the time of the respective Approvals and on a continuing basis until he ceased acting as an officer of the Department on 18 April 2023 **("the Skerritt Continuing Approvals")**:

a) failed or refused to personally:

i) revoke any or all of the Approvals; or

ii) cancel any or all of the Approvals;

b) further or in the alternative, failed or refused to, expressly or impliedly, either directly or through direction given to an employee of the Commonwealth, expressly or impliedly advising the Secretary and Hunt and/or advising, sanctioning or directing any other person imbued with the actual or delegated authority to cancel or revoke the Approvals that:

i) the Approvals be or ought to be revoked;

ii) the Approvals be or ought to be cancelled;

c) further or alternatively, by either directly or through direction given to an employee of the Commonwealth, expressly or impliedly advising the Secretary and Hunt and/or advising, sanctioning or directing any other person imbued with the actual or delegated authority to cancel or revoke the Approvals that:

i) the Approvals ought not be revoked or cancelled;

ii) the Critical Vaccine Requirements continued at all times to be rationally established;

iii) all available and relevant post-Approvals information, data and materials accumulated by the TGA, the Department and Skerritt and/or reasonably

available to Skerritt rationally established that the Vaccines at all times since the Approvals continued to meet the Critical Vaccine Requirements;

iv) he continued at all times to be rationally satisfied as to the matters contained in sub-paragraphs (i) to (iii) herein;

d) further or in the alternative, failing or refusing to, expressly or impliedly, either directly or through direction given to an employee of the Commonwealth, failed to advise the Secretary, Hunt, the Commonwealth or anyone that:

i) the Approvals be or ought to be revoked;

ii) the Approvals be or ought to be cancelled;

iii) the Approvals did not satisfy the requirements of legislation including the Act and the Regulations;

iv) the Continuing Approvals occurred in circumstances wherein:

(1) the criteria prescribed by s. 10L of the Regulation for the purposes of subsection 22D(2) were not met;

(2) in breach of s. 25(1)(d)(i) of the Act, the Vaccines were not rationally established to be safe or effective based upon preliminary clinical data or at all;

(3) a failure to cancel the Approvals would create an imminent risk of death, serious illness or serious injury to the Australian population;

(4) the Approvals were unlawful;

e) wherein Skerritt engaged in the omissions pleaded at (a) to (d) herein:

i) he intended, knew, expected and considered it likely that as a natural and probable consequence of those omissions that:

(1) the respective Continuing Approvals would occur;

(2) the respective Approvals would not be cancelled or revoked;

(3) the Vaccines would continue to be widely distributed to the Australian population for use;

(4) the Vaccines would continue to be received by the Group Members;

ii) the respective Continuing Approvals occurred as a direct consequence;

iii) the respective Approvals were as a direct consequence in fact not cancelled or revoked;

iv) the Vaccines as a direct consequence were and continued to be widely distributed to the Australian population for use;

v) the Vaccines as a direct consequence were and continued to be received by the Group Members.

Particulars

Para. 52 in Schedule D of the SOC.

SKERRITT – MISLEADING STATEMENTS

53. Skerritt, with respect to the Misleading Vaccines Statements:

a) caused the following statements to be publicly and widely made to the Australian population **("the Skerritt Issued Misleading Vaccines Statements")**:

i) the Skerritt Misleading Vaccines Statements - by personally making and causing those statements to be published;

ii) the TGA Misleading Vaccines Statements – by:

(1) directing or advising one or more employees or officers of the TGA that the statements were acceptable for publication and/or to publish the statements;

(2) further or in the alternative, by failing or refusing to direct or advising any employees or officers of the TGA or anyone that the statements not be published;

iii) in the premises of (i) and (ii):

(1) intending, knowing, expecting and considering it likely that as a natural and probable consequence of those acts or omissions the respective statements would be widely published to the Australian population;

(2) as a direct consequence, those statements were in fact published widely to the Australian population.

Particulars

Para. 53(a) in Schedule D of the SOC.

b) the Skerritt Issued Misleading Vaccines Statements individually and in confluence in every instance:

i) were intended by Skerritt to:

(1) convey to the Australian population the Misleading Public Message;

(2) be received and relied upon by the whole Australian population;

(3) cause the Australian population to take the Vaccines;

ii) did in fact convey to the Australian population the Misleading Public Message;

iii) were in fact received and relied upon by the Australian population;

iv) did in fact cause the Australian population to take the Vaccines.

Particulars

Para. 53(b) in Schedule D of the SOC.

c) in causing the Skerritt Issued Misleading Vaccines Statements to be made and published, Skerritt:

i) was not acting in performance or purported performance of, or in relation to any exercise of Skerritt's duties or powers arising under the Act or the Regulations;

ii) by reason of the contents of those statements and the factual matters pleaded in paragraph 50 herein, personally assumed responsibility to positively exercise at all times the power incident to his office to protect the Group Members from harm arising from receiving the Vaccines.

Particulars

Para. 53(b) in Schedule D of the SOC.

SECRETARY – APPROVAL

54. The Secretary granted, caused or materially contributed to the grant of each of the respective Approvals **("the Secretary Approvals")**:

a) personally and directly pursuant to a purported power to grant the Approvals under the Act and/or the power incident to his office;

b) further or alternatively by, expressly or impliedly, either directly or through direction given to an employee of the Commonwealth, delegating such power to Skerritt or other person to grant the respective Approvals;

c) further or alternatively, by acting under his authority as secretary of the Department, causing the respective Approvals to be granted by either directly or through direction given to an employee of the Commonwealth, expressly or impliedly advising Hunt, and/or advising, sanctioning or directing any other person imbued with the actual or delegated authority to grant the Approvals that:

i) the Approvals be granted or ought to be granted;

ii) the grant of the Approvals would satisfy the requirements of legislation including the Act and the Regulations;

iii) all available and relevant information, data and materials accumulated by the TGA, the Department and the Secretary and/or reasonably available to the Secretary rationally established that the Vaccines at the times of the Approvals met the Critical Vaccine Requirements;

iv) that as at the date of the respective Approvals that the Critical Vaccine Requirements had been rationally established;

v) he continued at all times to be rationally satisfied as to the matters contained in sub-paragraphs (i) to (iv) above;

d) further or alternatively, failing or refusing at any time up to the time of the respective Approvals to expressly or impliedly, either directly or through direction given to an employee of the Commonwealth, advise Hunt, Skerritt, and/or advise, sanction or direct any other person imbued with the actual or delegated authority to grant the Approvals that:

i) the Approvals not be or ought not be granted;

ii) the grant of the Approvals would not satisfy the requirements of legislation including the Act and the Regulations;

iii) as at the date of the respective Approvals:

(1) that the Critical Vaccine Requirements had not been rationally established;

(2) he had knowledge of the Known Serious Vaccines Risks and Conduct - Pre-Approvals, details of those matters, and that those matters were in fact true;

(3) he had knowledge of the Pre-Approval Established Critical Defects details of those matters, and that those matters were in fact rationally established.

e) in respect of the delegation of authority pleaded at (b) or (c) herein and the exercise of purported power in the grant of the Approvals therefrom, in every instance and at all material times such purported exercises of power were:

i) subject to the direction of the Secretary;

ii) exercises of the purported power of the Secretary;

iii) the acts of the Secretary.

Particulars

Para. 54(e) in Schedule D of the SOC.

f) wherein the Secretary undertook any or all of the acts and/or omissions pleaded at sub-paragraphs (a) to (e) herein, in each instance he:

i) intended, knew, expected and considered it likely that as a natural and probable consequence of those omissions that:

(1) the respective Approvals would be granted;

(2) the Vaccines would be widely distributed to the Australian population for use;

(3) the Vaccines would be received by the Australian population;

ii) caused as a direct consequence the respective Approvals to be granted;

iii) caused as a direct consequence the Vaccines to be widely distributed to the Australian population for use;

iv) caused as a direct consequence the Vaccines to be received by the Group Members.

Particulars

Para. 54(f) in Schedule D of the SOC.

THE SECRETARY - CONTINUING APPROVALS

55. The Secretary, in respect of each of the respective Continuing Approvals from the time of the respective Approvals and on a continuing basis **("the Secretary Continuing Approvals")**:

a) failed or refused to cause or personally:

i) revoke any or all of the Approvals;

ii) cancel any or all of the Approvals; or

iii) exercise the Secretary's Power to Suspend or Cancel

b) further or in the alternative, failed or refused to, expressly or impliedly, either directly or through direction given to an employee of the Commonwealth, expressly or impliedly advising Hunt and advising, sanctioning or directing Skerritt and/or any other person imbued with the actual or delegated authority to cancel or revoke the Approvals that:

i) the Approvals be or ought to be revoked;

ii) the Approvals be or ought to be cancelled; or

iii) the Secretary's Power to Suspend or Cancel ought to be exercised;

c) further or alternatively, by either directly or through direction given to an employee of the Commonwealth, expressly or impliedly advising the Skerritt and Hunt and/or advising, sanctioning or directing any other person imbued with the actual or delegated authority to cancel or revoke the Approvals that:

i) the Approvals ought not be revoked or cancelled;

ii) the Critical Vaccine Requirements continued at all times to be rationally established;

iii) all available and relevant post-Approvals information, data and materials accumulated by the TGA, the Department and the Secretary and/or reasonably available to the Secretary rationally established that the Vaccines at all times since the Approvals continued to meet the Critical Vaccine Requirements;

iv) he continued at all times to be rationally satisfied as to the matters contained in sub-paragraphs (i) to (iii) herein;

d) further or in the alternative, failing or refusing to, expressly or impliedly, either directly or through direction given to an employee of the Commonwealth, failed to advise Skerritt, Hunt, the Commonwealth or anyone that:

i) the Approvals be or ought to be revoked;

ii) the Approvals be or ought to be cancelled;

iii) the Secretary's Power to Suspend or Cancel ought to be exercised;

iv) the Approvals did not satisfy the requirements of legislation including the Act and the Regulations;

v) the Continuing Approvals occurred in circumstances wherein:

(1) the criteria prescribed by s. 10L of the Regulations for the purposes of subsection 22D(2) of the Act were not met;

(2) in breach of s. 25(1)(d)(i) of the Act, the Vaccines were not rationally established to be safe or effective based upon preliminary clinical data or at all;

(3) a failure to cancel the Approvals would create an imminent risk of death, serious illness or serious injury to the Australian population;

(4) the Approvals were unlawful;

vi) the Pre-Approval Established Critical Defects subsisted at the date of the respective Approvals;

vii) at all times since the date of the Approvals, the Post-Approval Established Critical Defects had arisen and continued to subsist at the times of the respective Continuing Approvals.

e) wherein the Secretary engaged in the omissions pleaded at sub-paragraphs (a) to (d) herein:

i) he intended, knew, expected and considered it likely that as a natural and probable consequence of those omissions that:
   (1) the respective Continuing Approvals would occur;
   (2) the respective Approvals would not be cancelled or revoked;
   (3) the Secretary's Power to Suspend or Cancel would not be exercised;
   (4) the Vaccines would continue to be widely distributed to the Australian population for use;
   (5) the Vaccines would continue to be received by the Group Members;

ii) the respective Continuing Approvals occurred as a direct consequence;

iii) the respective Approvals were as a direct consequence in fact not cancelled or revoked;

iv) the Vaccines as a direct consequence continued to be widely distributed to the Australian population for use;

v) the Vaccines as a direct consequence continued to be received by the Group Members.

Particulars

Para. 55 in Schedule D of the SOC.

THE SECRETARY – MISLEADING STATEMENTS

56. The Secretary, with respect to the Misleading Vaccines Statements:

a) caused the following statements to be publicly and widely made to the Australian population **("the Secretary Issued Misleading Vaccines Statements")**:

   i) the Secretary Misleading Vaccines Statements - by personally making and causing those statements to be published;

   ii) the TGA Misleading Vaccines Statements – by:
      (1) directing or advising one or more employees or officers of the TGA that the statements were acceptable for publication and/or to publish the statements;
      (2) further or in the alternative, by failing or refusing to direct or advising any employees or officers of the TGA or anyone that the statements not be published;

Particulars

Para. 56(a)(i)-(ii) in Schedule D of the SOC.

iii) the Department Misleading Vaccines Statements – by:

(1) directing or advising one or more employees or officers of the Department that the statements were acceptable for publication and/or to publish the statements;

(2) further or in the alternative, by failing or refusing to direct or advising any employees or officers of the Department or anyone that the statements not be published;

iv) in undertaking the acts and/or omission at sub-paragraphs (i) to (iii) herein above:

(1) intending, knowing, expecting and considering it likely that as a natural and probable consequence of those acts or omissions the respective statements would be widely published to the Australian population;

(2) as a direct consequence, those statements were in fact published widely to the Australian population;

b) the Secretary Issued Misleading Vaccines Statements individually and in confluence in every instance:

i) were intended by the Secretary to:

(1) convey to the Australian population the Misleading Public Message;

(2) be received and relied upon by the whole Australian population;

(3) cause the Australian population to take the Vaccines;

ii) did in fact convey to the Australian population the Misleading Public Message;

iii) were in fact received and relied upon by the Australian population;

iv) did in fact cause the Australian population to take the Vaccines.

c) in causing the Secretary Issued Misleading Vaccines Statements to be made and published, the Secretary:

i) was not acting in performance or purported performance of, or in relation to any exercise of the Secretary's duties or powers arising under the Act or the Regulations;

ii) by reason of the contents of those statements and the factual matters pleaded in paragraph 50 herein, personally assumed responsibility to positively exercise at all times the power incident to his office to protect the Group Members from harm arising from receiving the Vaccines.

Particulars

Para. 56(c) in Schedule D of the SOC.

CHIEF MEDICAL OFFICER - APPROVALS

57. The Chief Medical Officer, at all relevant times prior to the respective Approvals and on or about the time of the respective Approvals acting under his purported authority as Chief Medical Officer of the Commonwealth:

a) advised the Commonwealth, the Secretary, and Hunt directly or alternatively through the employees and officers of the Commonwealth either expressly or impliedly that **("the Chief Medical Officer Pre-Approval Advices")**:

i) each of the respective Vaccines at the time of the respective Approvals:

(1) was rationally determined by him to have met the Critical Vaccine Requirements;

(2) to have been rationally established in fact to have met the Critical Vaccine Requirements;

ii) sufficient evidence existed such that the respective Vaccines could be rationally determined to in fact have met the Critical Vaccine Requirements;

iii) further or in the alternative, insufficient evidence existed such that the respective Vaccines could be rationally determined not to in fact have met the Critical Vaccine Requirements;

iv) all available and relevant post-Approvals information, data and materials accumulated by the TGA, the Department and the Chief Medical Officer and/or reasonably available to the Chief Medical Officer rationally established that the Vaccines at the times of the Approvals met the Critical Vaccine Requirements;

v) wide distribution of the Vaccines to, and consumption of the Vaccines by, the Australian population:

(1) should proceed as soon as possible;

(2) would be in accordance with the Department Overarching Purpose to further the health and wellbeing of the Australian population;

(vi) he continued at all times to be rationally satisfied as to the matters contained in sub-paragraphs at (i) to (v).

b) further or alternatively, failed or refused at any time up to the time of the respective Approvals to expressly or impliedly, either directly or through direction given to an employee of the Commonwealth, to advise the Secretary and Hunt and/or advise or direct any other person imbued with the actual or delegated authority to grant the Approvals, that **("the Chief Medical Officer Pre-Approval Failures to Advise")**:

i) each of the respective Vaccines at the time of the respective Approvals:

(1) had not been rationally determined by him to have met the Critical Vaccine Requirements;

(2) had not been rationally established in fact to have met the Critical Vaccine Requirements;

ii) insufficient evidence existed such that the respective Vaccines could be rationally determined to in fact have met the Critical Vaccine Requirements;

iii) further or in the alternative, sufficient evidence existed such that the respective Vaccines could be rationally determined not to in fact have met the Critical Vaccine Requirements;

iv) wide distribution of the Vaccines to, and consumption of the Vaccines by, the Australian population:

(1) should not proceed as soon as possible or at all;

(2) would be contrary to the Department Overarching Purpose to further the health and wellbeing of the Australian population;

c) in undertaking the act of the Chief Medical Officer Pre-Approval Advices and the omission of the Chief Medical Officer Pre-Approval Failures to Advise (together, "**the Chief Medical Officer Pre-Approval Conduct")**, the Chief Medical Officer in each instance:

i) intended, knew, expected and considered it likely that as a natural and probable consequence of those acts or omissions that:

(1) the respective Approvals would be granted; and

(2) the Vaccines would be widely distributed to the Australian population for use;

ii) caused as a direct consequence the Vaccines to be widely distributed to the Australian population for use;

iii) caused as a direct consequence the receipt of the Vaccines by the Group Members;

d) in undertaking the Chief Medical Officer Pre-Approval Conduct the Chief Medical Officer was not acting in performance or purported performance of, or in relation to

any exercise of the Chief Medical Officer's duties or powers arising under the Act or the Regulations.

Particulars

Para. 57 in Schedule D of the SOC.

CHIEF MEDICAL OFFICER - CONTINUING APPROVALS

58. The Chief Medical Officer, at all relevant times subsequent to the respective Approvals and at all times from the time of the respective Approvals, acting under his purported authority as chief medical officer of the Commonwealth:

a) advised, either directly or through direction given to an employee of the Commonwealth, the Secretary, and Hunt and/or advised or directed any other person imbued with the actual or delegated authority to grant the Approvals, the Continuing Approvals or distribute the Vaccines that **("the Chief Medical Officer Post-Approval Advices")**:

i) the Chief Medical Officer Pre-Approval Advices continued to be true and correct;

ii) all available and relevant post-Approvals information, data and materials accumulated by the TGA, the Department and the Chief Medical Officer and/or reasonably available to the Chief Medical Officer rationally established that the Vaccines at all times since the Approvals continued to meet the Critical Vaccine Requirements;

iii) the Vaccines should be distributed for use by the Australian population because in every instance they continued to meet the Critical Vaccine Requirements;

iv) the Vaccines should be used by all of the Australian population where of the indicated age range because in every instance they continued to meet the Critical Vaccine Requirements;

v) he continued at all times to be rationally satisfied as to the matters contained in sub-paragraphs (i) to (iv) above;

b) acting under his authority as Chief Medical Officer of the Commonwealth, either directly or through direction given to an employee of the Commonwealth:

i) directing that the Vaccines be distributed to the Australian Public;

ii) advising, sanctioning, and/or directing a person imbued with the actual or delegated authority to do so, that the Vaccines be distributed to the Australian Public;

c) further or alternatively, failed or refused to expressly or impliedly, either directly or through direction given to an employee of the Commonwealth, to advise the Secretary and Hunt and/or advise or direct any other person imbued with the actual or delegated authority to grant the Approvals, the Continuing Approvals or distribute the Vaccines that **("the Chief Medical Officer Post-Approval Failures to Advise")**:

i) each of the respective Vaccines at all times subsequent to the respective Approvals was rationally determined by him to have, and in fact had, not met the Critical Vaccine Requirements;

ii) he had directly, or that he knew that the TGA or other entity of the Commonwealth had in fact failed to:

(1) undertake a properly conducted risk-benefit analysis in respect of the respective Vaccines which rationally established that the benefits of the Vaccines were significantly greater than the risks for the segment of population for which the respective Vaccines were approved;

(2) rigorously assess the Vaccines for safety and efficacy before they could be used in Australia which rationally established that the Vaccines met the Critical Vaccine Requirements;

(3) examine or consider the reasonably available scientific evidence to assess the risks and benefits of each Vaccine before approval which rationally established that the Vaccines met the Critical Vaccine Requirements;

(4) carefully assess the results of the respective Vaccines' clinical trials which rationally established that the Vaccines met the Critical Vaccine Requirements;

iii) that insufficient evidence existed such that the respective Vaccines could be rationally determined to in fact have met the Critical Vaccine Requirements;

iv) further or in the alternative, sufficient evidence existed such that the respective Vaccines could be rationally determined to in fact have failed to meet the Critical Vaccine Requirements;

v) that wide distribution of the Vaccines to, and consumption of any of the Vaccines should not occur;

vi) that the Australian public should not consume the Vaccines;

vii) that the respective Approvals should not have been granted;

viii) that the respective Approvals should be revoked or cancelled;

d) in undertaking the acts of the Chief Medical Officer Post-Approval Advices and the omissions of the Chief Medical Officer Post-Approval Failures to Advise (together, "**the Chief Medical Officer Post-Approval Conduct"**) the Chief Medical Officer:

i) intended, knew, expected and considered it likely that as a natural and probable consequence of those acts or omissions that:

(1) the respective Continuing Approvals would occur;

(2) the respective Approvals would not be cancelled or revoked;

(3) the Vaccines would continue to be widely distributed to the Australian population for use;

(4) the Vaccines would continue to be received by the Group Members;

ii) caused as a direct consequence in fact:

(1) the respective Continuing Approvals to occur;

(2) the respective Approvals were not cancelled or revoked;

(3) the Vaccines continued to be widely distributed to the Australian population for use;

(4) the Vaccines continued to be received by the Group Members;

e) in undertaking the Chief Medical Officer Post-Approval Conduct the Chief Medical Officer was not acting in performance or purported performance of, or in relation to any exercise of Chief Medical Officer's duties or powers arising under the Act or the Regulations.

Particulars

Para. 58 in Schedule D of the SOC.

CHIEF MEDICAL OFFICER – MISLEADING STATEMENTS

59. The Chief Medical Officer, with respect to the Misleading Vaccines Statements:

a) caused the following statements to be publicly and widely made to the Australian population **("the Chief Medical Officer Issued Misleading Vaccines Statements")**:

i) the Chief Medical Officer Misleading Vaccines Statements - by personally making and causing those statements to be published;

ii) further and alternatively, the Department Misleading Vaccines Statements by:

(1) directing or advising one or more employees or officers of the Department that the statements were acceptable for publication and/or to publish the statements;

(2) further or in the alternative, by failing or refusing to direct or advising any employees or officers of the Department or anyone that the statements not be published;

iii) in undertaking the acts and/or omissions pleaded at sub-paragraphs (i) to (ii) herein above:

(1) intending, knowing, expecting and considering it likely that as a natural and probable consequence of those acts or omissions the respective statements would be widely published to the Australian population;

(2) as a direct consequence, those statements were in fact published widely to the Australian population;

Particulars

Para 59(a)(i)-(iii) in Schedule D of the SOC.

b) the Chief Medical Officer Issued Vaccines Statements individually and in confluence in every instance:

i) were intended by the Chief Medical Officer to:

(1) convey to the Australian population the Misleading Public Message;

(2) be received and relied upon by the whole Australian population;

(3) cause the Australian population to take the Vaccines;

ii) did in fact convey to the Australian population the Misleading Public Message;

iii) were in fact received and relied upon by the Australian population;

iv) did in fact cause the Australian population to take the Vaccines.

c) in causing the Chief Medical Officer Issued Misleading Vaccines Statements to be made and published, the Chief Medical Officer:

i) was not acting in performance or purported performance of, or in relation to any exercise of the Chief Medical Officer's duties or powers arising under the Act or the Regulations;

ii) by reason of the contents of those statements and the factual matters pleaded in paragraph 50 herein, personally assumed responsibility to positively exercise at all times the power incident to his office to protect the Group Members from harm arising from receiving the Vaccines.

Particulars

Para. 59(c) in Schedule D of the SOC.

MINISTER – MISLEADING STATEMENTS

60. Hunt, with respect to the Misleading Vaccines Statements:

a) caused the Hunt Misleading Vaccines Statements to be publicly made **("the Hunt Issued Misleading Vaccines Statements")**:

i) by personally making and publishing those statements;

ii) further or in the alternative, by directing or advising one or more employees or officers of the Department that the statements were acceptable for publication and/or to publish the statements on his behalf;

iii) further or in the alternative, by failing or refusing to direct or advise any employees or officers of the Department or anyone that the statements not be published on his behalf;

iv) in undertaking the acts and/or omissions pleaded at sub-paragraphs (i) to (iii) herein above:

(1) intending, knowing, expecting and considering it likely that as a natural and probable consequence of those acts or omissions the respective statements would be widely published to the Australian population;

(2) as a direct consequence, those statements were in fact published widely to the Australian population.

Particulars

Para. 60(a) in Schedule D of the SOC.

b) in the making of the Hunt Issued Misleading Vaccines Statements individually and in confluence, Hunt:

i) intended:

(1) to convey to the Australian population the Misleading Public Message;

(2) that the Misleading Public Message be received and relied upon by the whole Australian population;

(3) that the Australian population take the Vaccines;

ii) in fact:

(1) conveyed to the Australian population the Misleading Public Message;

(2) caused the Misleading Public Message to be received and relied upon by the whole Australian population;

(3) caused the Australian population to take the Vaccines;

c) in causing the Hunt Issued Misleading Vaccines Statements to be made and published, Hunt:

i) was not acting in performance or purported performance of, or in relation to any exercise of Hunt's duties or powers arising under the Act or the Regulations;

ii) by reason of the contents of those statements and the factual matters pleaded in paragraph 50 herein, personally assumed responsibility to positively exercise at all times the power incident to his office to protect the Group Members from harm arising from receiving the Vaccines.

Particulars

Para. 60(c) in Schedule D of the SOC.

PART I - NEGLIGENCE CLAIM

CONTROL OF THERAPEUTIC GOODS AND STATEMENTS

61. By reason of the factual matters pleaded at 10 to 18 and 25 to 56 (inclusive) herein, the Public Officers, whether through the TGA or otherwise by purported or actual powers incident to their office, at all material times **("the Respondents' Control of Therapeutic Goods in Australia")**:

a) were in a position to control, and did control absolutely, whether or not a therapeutic good in Australia (including the Vaccines) could be lawfully or otherwise authorised for use in and widely distributed to the general Australian public (including the Group Members) in Australia (including by causing,

directly or indirectly, the Approvals, Continuing Approvals and the wide distribution of the Vaccines to the Australian population) and, if so authorised:

i) under what conditions; and

ii) for what period of time.

Particulars

Para. 61(a) in Schedule D of the SOC.

b) were in a position to control and did control absolutely, direct, lawful and practical access to the Vaccines by the Australian public (including the Group Members) by reason of their direct or indirect influence and control of :

i) the grant of the Approvals;

ii) the occurrence of the Continuing Approvals;

iii) the wide distribution of the Vaccines to the Australian population;

Particulars

Para. 61(b) in Schedule D of the SOC.

c) were in a position to, and did, control and direct absolutely all statements to the Australian public (including the Group Members), for and on behalf of the Commonwealth:

i) by the Public Officers themselves or any other officer of the TGA, the Department or the Commonwealth as to:

(1) the Vaccines':

a) safety;

b) efficacy;

c) risk-benefit profile;

d) necessity for use by the Australian public (including the Group Members);

(2) any other matter relating to the Approvals, the Continuing Approvals and the Vaccines.

ii) relied upon and accepted by the Australian population as to the best, and most reliable, comprehensive and authoritative source of information in respect of the matters contained in sub-paragraph (1) herein above, such reliance being:

(1) known at all times by the Public Officers;

(2) actively promoted and encouraged by the Public Officers and other officers and employees of the Department at all material times.

Particulars

Para. 61(c) in Schedule D of the SOC.

d) were in a position to control, and did control absolutely, whether a therapeutic good in Australia (including the Vaccines) could be withdrawn from lawful or otherwise use by, and wide distribution to, the general Australian public (including the Group Members) in Australia (including in the Approvals and the Continuing Approvals and wide distribution of the Vaccines to the Australian population);

Particulars

Para. 61(d) in Schedule D of the SOC.

e) in determining whether or not to lawfully or otherwise authorise (including in the Approvals and Continuing Approvals) and distribute for use by the general Australian public (including the Group Members) a therapeutic good in Australia (including the Vaccines) and/or to advise those persons and entities so authorised in respect of all matters relevant to such authorisation, were in a position to control and did control absolutely:

   i) the information and data to which they would and did have regard or otherwise;

   ii) the procedure by which they would make any such determinations.

Particulars

Para. 61(e) in Schedule D of the SOC.

62. The Respondents' Control of Therapeutic Goods in Australia were:

a) generally known by the Group Members and the Australian Public;

b) promoted publicly by the TGA and the Public Officers.

Particulars

Para. 62 in Schedule D of the SOC.

KNOWLEDGE OF THE GROUP MEMBERS' RELIANCE

63. By reason of the Respondents Control of Therapeutic Goods in Australia and the public knowledge of that fact, the Respondents knew and the Australian public (including the Group Members) did in fact, reasonably expect and rely upon the fact that the Public Officers, in performing their functions regarding the Approvals, the Continuing Approvals, the wide distribution of the Vaccines to the Australian population and the publication of the

Misleading Public Message, would **("the Public's Reasonable Expectation and Reliance")**:

a) do so in accordance with and adherence to:
    i) a positive duty to act for the public good;
    ii) as to Skerritt and the Secretary, the Act and Regulations and the Statutory Obligations;
    iii) as to Skerritt and the Secretary the TGA Policies;
    iv) good practice;
    v) the Department Overarching Purpose;
    vi) the requirements of good conduct of the Respondents in the provisions of the Conduct Legislation;
    vii) would, in all the circumstances, do so:
        (1) with reasonable care;
        (2) in good faith;
        (3) in fulfilment of the objects of the Act;
        (4) for the public good;
b) as regards statements constituting the Misleading Public Message made by the Public Officers (or on their behalf, at their direction and/or under their authority) being the Misleading Vaccines Statements, have provided:
    i) true and accurate representation of those matters;
    ii) exhaustive representations as to what was known by them about those matters;
    iii) representations solely based upon rationally determined matters in which the respective Public Officer had formed a rational belief.

PUBLIC EXPECTATION OF RESPONDENTS' TECHNICAL SKILL IN APPROVALS

64. The Public Officers knew at all material times that they, those acting on their authority, and the TGA were invested with powers, discretions and functions **("the Public Expectation of Skill")**:

a) in a highly technical and complex area of national health care;
b) pursuant to which it was reasonably expected that, in the exercise of such powers, discretions and functions, they would be, in fact:
    i) undertaken by, and understood by the Australian public (including the Group Members) to be undertaken by professionally qualified persons, having skill, experience and the necessary expertise in their areas of work;

ii) thereby necessarily giving such actions and omissions exceptional force and authority.

c) in the exercise of which were responsible for compliance with, where applicable to such exercise of power:
   i) the Act and Regulations and the Statutory Obligations;
   ii) the TGA Policies;
   iii) the Department Overarching Purpose;
   iv) the requirements of good conduct of the Public Officers in the provisions of the Conduct Legislation;

d) in such an important, sensitive, and publicly known function, that would be reasonably expected and accepted by the Australian population (including the Group Members) to be:
   i) undertaken:
      (1) with reasonable care, professionally and in good faith;
      (2) in adherence to and compliance with:
         a) empowering legislation including the Act and the Regulations;
         b) publicly declared policy including the TGA Policies.
   ii) thereby relied upon as such in the exercise of their functions as such, including and specifically **("the Impugned Conduct")**:
      (1) as to Skerritt;
         a) the Skerritt Approvals;
         b) the Skerritt Continuing Approvals; and
         c) the Skerritt Issued Misleading Vaccines Statements;
      (2) as to the Secretary;
         a) the Secretary Approvals;
         b) the Secretary Continuing Approvals;
         c) the Secretary Issued Misleading Vaccines Statements;
      (3) as to the Chief Medical Officer:
         a) the Chief Medical Officer Pre-Approval Conduct;
         b) the Chief Medical Officer Post-Approval Conduct;
         c) the Chief Medical Officer Issued Misleading Vaccines Statements;
      (4) as to Hunt, the Hunt Misleading Vaccines Statements.

Particulars

Such knowledge arises in the circumstances of the factual

matters pleaded at 10 to 18 and 25 to 56 (inclusive) herein, the nature and effect of the Impugned Conduct and the Respondents' Control of Therapeutic Goods in Australia.

IMPUGNED CONDUCT NOT UNDERTAKEN PURSUANT TO THE ACT

65. In causing the Skerritt Issued Misleading Vaccines Statements to be made and published, Skerritt was not acting in performance or purported performance of, or in relation to any exercise of Skerritt's duties or powers arising under the Act or the Regulations.

Particulars

Para. 65 in Schedule D of the SOC.

66. In causing the Secretary Issued Misleading Vaccines Statements to be made and published, the Secretary was not acting in performance or purported performance of, or in relation to any exercise of the Secretary's duties or powers arising under the Act or the Regulations.

Particulars

Para. 66 in Schedule D of the SOC.

67. In undertaking the Chief Medical Officer Pre-Approval Conduct, the Chief Medical Officer Post-Approval Conduct, the Chief Medical Officer Pre-Approval Advices, the Chief Medical Officer Post-Approval Advices, and causing the Chief Medical Officer Issued Misleading Vaccines Statements to be made and published, the Chief Medical Officer was not acting in performance or purported performance of, or in relation to any exercise of the Chief Medical Officer's duties or powers arising under the Act or the Regulations.

Particulars

Para. 67 in Schedule D of the SOC.

68. In causing the Hunt Misleading Vaccines Statements to be made and published, Hunt was not acting in performance or purported performance of, or in relation to any exercise of Hunt's duties or powers arising under the Act or the Regulations. Alternatively, he failed to observe the limits of his powers.

Particulars

Para. 68 in Schedule D of the SOC.

GRAVITY OF THE GRANTING OF THE VACCINES APPROVALS

69. The Public Officers and the Australian public knew that the Public Officers and those acting under authority **("the Known Gravity of the Approvals")**:

a) were invested with the power, functions and discretion relating to the approval of, the provision of advices and public statements in respect of, and the widespread distribution to the Australian population of therapeutic goods in Australia (including the Vaccines);
b) in the conduct of those functions undertaken in respect of the Impugned Conduct would:
    i) be significant and material to the Australian population (including the Group Members);
    ii) expose the Australian population (including the Group Members) to a deleterious and extreme risk of harm if those functions and powers were exercised:
        i) without reasonable care;
        ii) extraneous to power;
        iii) for an ulterior or improper purpose contrary to the public good, being a purpose inconsistent with an honest attempt to act lawfully or in accordance with the purpose for which the power to act was conferred, being the public good; and/or
        iv) with knowledge or reckless indifference to:
            a) the absence of statutory power or otherwise to undertake those functions;
            b) the occurrence of resultant injury or damage to the Group Members which may arise;
            c) the misleading or false nature of statements made;
        v) in bad faith.

KNOWLEDGE OF VULNERABILITY OF AUSTRALIAN PUBLIC TO TGA ACTIONS

70. The Public Officers knew at all material times that any decision, act or omission undertaken

by them or those under their authority and direction in respect of the Impugned Conduct would **("the Known Vulnerability of the Australian Public")**:

a) directly affect whether or not the Australian population (including the Group Members) had lawful access to any or all of the Vaccines;
b) directly affect whether or not the Australian population (including the Group Members) were injected with any or all of the Vaccines;
c) directly affect whether or not the Vaccines being injected by the Australian Population once approved were in truth:
    i) safe for their intended use;
    ii) effective for their intended use;
    iii) possessive of a positive risk-benefit profile.
d) directly affect the health and well-being of those injected with the Vaccines;
e) directly affect the likelihood of serious personal injury and harm to those injected with the Vaccines.

Particulars

Para. 70 in Schedule D of the SOC.

FORESEEABILITY OF RISK AND HARM

71. In the premises, it was reasonably foreseeable that **("the Foreseeability of Risk and Harm")**:

a) the Group Members would:
    i) rely upon and act upon the Misleading Vaccines Statements;
    ii) apprehend and believe the Misleading Public Message;
    iii) determine thereby to take one or more of the Vaccines.
b) the Impugned Conduct would cause:
    i) the availability of access to the Vaccines by the Group Members for use not otherwise available;
    ii) the Group Members to use the Vaccines which would not otherwise have occurred;
    iii) the Group Members to suffer injury, loss and damage;
    iv) pervasive and serious negative consequences upon the health and well-being of the Australian population (including the Group Members).
c) that when undertaking the Impugned Conduct, where not undertaken with reasonable care, such acts or omissions carried the real probability and likelihood

that the Group Members would suffer:

i) serious or catastrophic personal injuries;

ii) loss and damage.

Particulars

Para. 71 in Schedule D of the SOC.

PUBLIC OFFICERS - ASSUMED RISK OF HARM TO GROUP MEMBERS

72. By reason of the nature of the Misleading Vaccines Statements, the Misleading Public Message which those statements conveyed, and the factual matters pleaded and particularised at paragraphs 61 to 71 (inclusive) herein, the Public Officers publicly and unequivocally:

a) claimed the Vaccines to be safe, effective and necessary for the Group Members;

b) thereby personally assumed responsibility for:

i) the safety, efficacy and necessity of the Vaccines for the Group Members;

ii) harm to the Group Members arising as a consequence of receiving any of the Vaccines.

RESPONDENTS' DUTY TO THE GROUP MEMBERS

73. By reason of the factual matters and the circumstances of the relationship between the Public Officers and the Group Members pleaded herein, the Public Officers were under a duty to the Group Members to exercise reasonable care and skill and to avoid or minimise the risk of harm when undertaking acts and omissions which would directly or indirectly cause **("the Respondents' Duty")**:

a) a therapeutic good to become lawfully available to the Group Members;

b) a therapeutic good to remain lawfully available to the Group Members;

c) the distribution of a therapeutic good to the Group Members;

d) public statements to the Group Members as to the safety, efficacy and necessity of a therapeutic good.

Particulars

Para. 73 in Schedule D of the SOC.

RESPONDENTS' CONDUCT – NEGLIGENCE AND BREACH OF DUTY IN APPROVALS

74. Skerritt, the Secretary and the Chief Medical Officer undertook conduct constituted by the Impugned Conduct prior to and at the time of the respective Approvals as follows **("the Reckless Conduct - Approvals")**:

a) as to Skerritt – he undertook the conduct comprising the Skerritt Approvals, wherein:

i) such conduct caused, and further or alternatively materially contributed to the granting of the Approvals, the distribution of the Vaccines to the Australian public (including the Group Members) and the receipt of the Vaccines by the Group Members;

Particulars

The factual matters pleaded and particularised at paragraph 51 herein.

ii) the resultant granting of the Approvals arising from such conduct were in breach of and contrary to the legislation under which they were purportedly made, being the Act and the Regulations;

Particulars

The Approvals Statutory Breaches and the factual matters pleaded and particularised at paragraph 90(d) and (g)(i) herein below.

iii) such conduct was contrary to the Department Overarching Purpose;

Particulars

The factual matters pleaded and particularised at paragraph 90(e) herein below.

iv) such conduct was in breach of the TGA Functional Responsibilities;

Particulars

The Approvals TGA Functions Breaches and the factual matters pleaded and particularised at paragraph 90(d) and (g)(ii) herein below.

v) such conduct was in breach of the legislation by which Skerritt's conduct as an officer of the Commonwealth was regulated;

Particulars

The Skerritt Public Governance Breaches and the factual matters pleaded and particularised at paragraph 90(d) and (g)(iii) herein below.

vi) such conduct was in breach of the express provisions of the TGA Policies regulating Skerritt's conduct within the TGA;

Particulars

The TGA Policies Approvals Breaches and the factual matters pleaded and particularised at paragraph 90(d) and (g)(iv) herein below.

vii) such conduct was undertaken in the circumstances of the rationally established facts and knowledge of Skerritt pleaded and particularised at paragraphs 90(a) to (h) herein below as to:

(1) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

(2) the Pre-Approval Established Critical Defects;

(3) the known failures of the Vaccines to meet the Critical Vaccine Requirements;

(4) the unlawfulness of the conduct; and

(5) the breach of a duty to act for the public good in such conduct.

viii) by reason of the factual matters and knowledge pleaded at sub-paragraph (vii) above, in fact, and such facts being known to Skerritt, and further or alternatively facts to which he had reckless disregard:

(1) the Vaccines were:

a) not rationally established to be safe for any of the Vaccine Purposes;

b) not rationally established to be efficacious for any of the Vaccine Purposes;

c) not rationally established to be necessary for any of the Vaccine Purposes;

d) not rationally established to provide benefits which outweighed their risks for any of the Vaccine Purposes;

e) not rationally established to be likely to provide a major therapeutic advance;

(2) further or in the alternative, the Vaccines were:

a) rationally established to be unsafe for any of the Vaccine Purposes;

b) rationally established to be inefficacious for any of the Vaccine Purposes;

c) rationally established to be unnecessary for any of the Vaccine Purposes;

d) rationally established to possess risks which outweighed their

benefits for any of the Vaccine Purposes;

e) rationally established to be unlikely to provide a major therapeutic advance;

(3) Covid was:

a) not rationally established to be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

b) further or in the alternative, rationally established to not be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

b) as to the Secretary – he undertook the conduct comprising the Secretary Approvals wherein:

i) such conduct caused, and further or alternatively materially contributed to the granting of the Approvals, the distribution of the Vaccines to the Australian public (including the Group Members) and the receipt of the Vaccines by the Group Members;

Particulars

The factual matters pleaded and particularised at paragraph 54 herein.

ii) the resultant granting of the Approvals arising from such conduct were in breach of and contrary to the legislation under which they were purportedly made, being the Act and the Regulations;

Particulars

The Approvals Statutory Breaches and the factual matters pleaded and particularised at paragraph 96(d) and (g)(i) herein below.

iii) such conduct was contrary to the Department Overarching Purpose;

Particulars

The factual matters pleaded and particularised at paragraph 96(e) herein below.

iv) such conduct was in breach of the TGA Functional Responsibilities;

Particulars

The Approvals TGA Functions Breaches and the factual matters pleaded and particularised at paragraph 96(d) and (g)(ii) herein below.

v) such conduct was in breach of the legislation by which the Secretary's

conduct as an officer of the Commonwealth and secretary of the Department was regulated;

Particulars

The Secretary Public Governance Breaches and the factual matters pleaded and particularised at paragraph 96 (d) and (g)(iii) herein below.

vi) such conduct was in breach of the express provisions of the TGA Policies regulating the Secretary's conduct within the TGA;

Particulars

The TGA Policies Approvals Breaches and the factual matters pleaded and particularised at paragraph 96 (d) and (g)(iv) herein below.

vii) such conduct was undertaken in the circumstances of the rationally established facts and knowledge of the Secretary pleaded and particularised at paragraphs 96(a) to (h) herein below as to:

(1) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

(2) the Pre-Approval Established Critical Defects;

(3) the known failures of the Vaccines to meet the Critical Vaccine Requirements;

(4) the unlawfulness of the conduct; and

(5) the breach of a duty to act for the public good in such conduct.

viii) by reason of the factual matters and knowledge pleaded at sub-paragraph (vii) above, in fact, and such facts being known to the Secretary, and further or alternatively facts to which he had reckless disregard:

(1) the Vaccines were:

a) not rationally established to be safe for any of the Vaccine Purposes;

b) not rationally established to be efficacious for any of the Vaccine Purposes;

c) not rationally established to be necessary for any of the Vaccine Purposes;

d) not rationally established to provide benefits which outweighed their risks for any of the Vaccine Purposes;

e) not rationally established to be likely to provide a major therapeutic advance;

(2) further or in the alternative, the Vaccines were:

a) rationally established to be unsafe for any of the Vaccine Purposes;

b) rationally established to be inefficacious for any of the Vaccine Purposes;

c) rationally established to be unnecessary for any of the Vaccine Purposes;

d) rationally established to possess risks which outweighed their benefits for any of the Vaccine Purposes;

e) rationally established to be unlikely to provide a major therapeutic advance;

(3) Covid was:

a) not rationally established to be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

b) further or in the alternative, rationally established to not be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

c) as to the Chief Medical Officer - he undertook the conduct comprising the Chief Medical Officer Pre-Approval Conduct which included the Chief Medical Officer Pre-Approval Advices and the Chief Medical Officer Pre-Approval Failures to Advise wherein:

i) such conduct caused, and further or alternatively materially contributed to the granting of the Approvals, the distribution of the Vaccines to the Australian public (including the Group Members) and the receipt of the Vaccines by the Group Members;

Particulars

The factual matters pleaded and particularised at paragraph 57 herein.

ii) such conduct was contrary to the Department Overarching Purpose;

Particulars

The factual matter pleaded and particularised at paragraph 102(e) herein below.

iii) such conduct was in breach of the legislation by which the Chief Medical Officer's conduct as an officer of the Commonwealth was regulated;

Particulars

The Chief Medical Officer Public Governance Breaches and the factual matters pleaded and particularised at paragraph 102(c), (d), (e), (f), (g) (h) and 102(i)(i) to (v) herein below.

iv) such conduct was undertaken in the circumstances of the rationally established facts and knowledge of the Chief Medical Officer pleaded and particularised at paragraphs 102(a) to (h) herein below as to:

(1) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

(2) the Pre-Approval Established Critical Defects;

(3) the known failures of the Vaccines to meet the Critical Vaccine Requirements;

(4) the unlawfulness of the conduct; and

(5) the breach of a duty to act for the public good in such conduct.

v) wherein, by reason of the factual matters and knowledge pleaded at sub-paragraph (iv) above, in fact, and such facts being known to the Chief Medical Officer, and further or alternatively facts to which he had reckless disregard:

(1) the Vaccines were:

a) not rationally established to be safe for any of the Vaccine Purposes;

b) not rationally established to be efficacious for any of the Vaccine Purposes;

c) not rationally established to be necessary for any of the Vaccine Purposes;

d) not rationally established to provide benefits which outweighed their risks for any of the Vaccine Purposes;

e) not rationally established to be likely to provide a major therapeutic advance;

(2) further or in the alternative, the Vaccines were:

a) rationally established to be unsafe for any of the Vaccine Purposes;

b) rationally established to be inefficacious for any of the Vaccine Purposes;

c) rationally established to be unnecessary for any of the Vaccine Purposes;

d) rationally established to possess risks which outweighed their benefits for any of the Vaccine Purposes;

e) rationally established to be unlikely to provide a major therapeutic advance;

(3) Covid was:

a) not rationally established to be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

b) further or in the alternative, rationally established to not be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

d) at the time of the Impugned Conduct of Skerritt, the Secretary and the Chief Medical Officer pleaded and particularised at sub-paragraphs (a) to (c) above herein:

i) the following facts had been rationally established:

(1) the Known Serious Vaccines Risks and Conduct - Pre-Approval;

(2) the Pre-Approval Established Critical Defects;

(3) the Vaccines failed to meet the Critical Vaccine Requirements;

ii) Skerritt, the Secretary and the Chief Medical Officer knew or alternatively were recklessly indifferent to the factual matters pleaded at sub-paragraph (i) herein above;

iii) the following failures in the assessment processes of the Vaccines were in every instance known to Skerritt, the Secretary and the Chief Medical Officer and further or alternatively to which they had reckless disregard **("the Known Approvals Assessment Failures")**:

(1) the studies undertaken by the Sponsors and data for the purposes of application for the grant of the Approvals disclosed:

a) that there was no clinical testing or data establishing in any of the Vaccines the effect of:

i) prevention of transmission of the Virus;

ii) prevention of infection with the Virus;

iii) prevention of serious illness from Covid;

iv) prevention of hospitalisation from Covid;

v) prevention of death from Covid;

vi) use of the Vaccines in those for whom use was intended being the Untested Groups, including in:

a) pregnant women;
b) immunocompromised people;
c) people with certain pre-existing health conditions;
d) people receiving other vaccines concurrently;
e) people with natural immunity resultant from prior infection with the Virus;

vii) long-term efficacy;
viii) genotoxicity;
ix) carcinogenicity;
x) long-term safety.
xi) extraordinary and unacceptable risks associated with the Vaccines being:
a) risks of serious adverse events;
b) risk of death;
c) unquantified and known risk of incorporation of the mRNA in the mRNA Vaccines into the human genome with the potential to cause intergenerational effects;
d) risk of carcinogenicity;
e) risk of extreme and unquantified proliferation of the spike protein in the human body with the mRNA Vaccines;
f) known and unquantified distribution and concentration of the Vaccines' lipid nanoparticle in the entire human body including the human organs for an untested and unquantified period;
g) risk of Vaccine Associated Enhanced Disease;
h) risk of use in pregnancy.

b) there were such deficiencies in the scope and nature of the evidence provided by the Sponsors in support of the Applications so as to render a rational determination establishing safety, efficacy and positive risk-benefit in the Vaccines impossible;
c) there were known factual matters which provided a reasonable

basis to doubt the accuracy and quality of the data provided by the Sponsors;

d) the TGA or none of the Respondents did not at any time receive the patient-level data in respect of the Vaccines Clinical Trials such that:

(1) the TGA and the TGA Respondents accepted the Sponsors' summaries and characterisations of the actual trial data thereby ignoring the importance of patient-level data;

(2) the TGA and the TGA Respondents could not have rationally determined the Vaccines to possess a positive risk-benefit profile for use by all sectors of the Australian population;

(3) risk-benefit analysis in respect of the stratification of risk by age and other sectors could not be accurately performed in the circumstances where Covid was known to disproportionately affect the elderly and the risks from Covid disease was negligible in the under 50 years sector of the population.

(2) the TGA or anyone did not seek or receive the provision of further studies or data from the Sponsors:

a) to remedy the deficiencies pleaded at (a) to (d) herein above prior to the Approvals or at all;

b) that would or did in fact remedy those deficiencies;

c) by generally seeking and accepting an explanation from the Sponsor as to some of those deficiencies which were invariably accepted by the TGA and the TGA Respondents in lieu of any further data;

(3) no special consideration or application was given to or caution exercised in respect of the substantially heightened risks of injury and harm associated with the known novel and unique properties of the Vaccines being:

a) first ever in-human use and unknown effect of mRNA technologies in the mRNA Vaccines **("the mRNA Vaccines" is defined in para. 27 in Schedule B of the SOC)**;

b) the novel use of lipid nanoparticles in the Vaccines;
c) the known fact that coronaviruses had never before been the subject of mass vaccination;
d) the intention that and subsequent fact that the Vaccines were to be used on a mass scale to the Australian population;
e) the reduction of the time taken for analysis and testing of the Vaccines to a fraction of that established historically and scientifically as appropriate for such analysis;

(4) the TGA, the TGA Respondents and those officers and employees acting or being directed to assess the Vaccines for the purposes of the respective Approvals possessed no rational basis to be rationally satisfied or rationally declare the Vaccines to be:

a) safe for intended use;
b) efficacious for intended use;
c) possessing of a positive risk-benefit profile;
d) necessary for use in the Australian population under the age of 70 years old.

Particulars

Para. 74 in Schedule D of the SOC.

75. By reason of the factual matters and knowledge pleaded and particularised in paragraph 74 herein above, the Reckless Conduct – Approvals undertaken by Skerritt, the Secretary and the Chief Medical Officer respectively failed to observe the limits of their respective powers and their said actions were:

a) so unreasonable that no reasonable person could have so acted or failed to act, or in the alternative, they were legally unreasonable;
b) conducted in bad faith.

Particulars

Para. 75 in Schedule D of the SOC.

BREACH OF DUTY – APPROVALS

76. By reason of the factual matters and knowledge pleaded and particularised in paragraphs 42, 43, 51, 54, 57 and 61 to 75 (inclusive) herein above, the acts and omissions of Skerritt, the Secretary and the Chief Medical Officer, respectively, in the Reckless Conduct - Approvals

were undertaken in breach of the Respondents' Duty **("the Approvals Breach")**.

RESPONDENTS' CONDUCT – NEGLIGENCE AND BREACH OF DUTY IN CONTINUING APPROVALS

77. Skerritt, the Secretary and the Chief Medical Officer undertook conduct constituted by the Impugned Conduct subsequent to the respective Approvals as follows **("the Reckless Failures - Continuing Approvals")**:

a) as to Skerritt - undertook the conduct comprising the Skerritt Continuing Approvals wherein:

i) such conduct caused, and further or alternatively materially contributed to the occurrence of the Continuing Approval, the distribution of the Vaccines to the Australian public (including the Group Members) and the receipt of the Vaccines by the Group Members;

Particulars

The factual matters pleaded and particularised at paragraph 52 herein.

ii) the resultant occurrence of the Continuing Approvals arising from such conduct were in breach of and contrary to the legislation under which they were purportedly made, being the Act and the Regulations;

Particulars

The Continuing Approvals Statutory Breaches caused by the Skerritt Continuing Approvals and the factual matters pleaded and particularised at paragraphs 90(d) and (g)(i) and the Skerritt Continuing Approval Breaches pleaded and particularised at paragraphs 92(d) and (g)(i) and herein below.

iii) such conduct was contrary to the Department Overarching Purpose;

Particulars

The factual matters pleaded and particularised at paragraph 92(e) herein below.

iv) such conduct was in breach of the TGA Functional Responsibilities;

Particulars

The continuing Approvals TGA Functions Breaches caused by the Skerritt Continuing Approvals and the factual matters pleaded and particularised at paragraph 90(d) and (g)(ii) and the Skerritt

Continuing Approval Breaches pleaded and particularised at paragraphs 92(d) and (g)(i) herein below.

v) such conduct was in breach of the legislation by which Skerritt's conduct as an officer of the Commonwealth was regulated;

Particulars

The continuing Skerritt Public Governance Breaches caused by the Skerritt Continuing Approvals and the factual matters pleaded and particularised at paragraph 90(d) and (g)(iii) and the Skerritt Continuing Approval Breaches pleaded and particularised at paragraphs 92(d) and (g)(i) herein below.

vi) such conduct was in breach of the express provisions of the TGA Policies regulating Skerritt's conduct within the TGA;

Particulars

The continuing TGA Policies Approvals Breaches caused by the Skerritt Continuing Approvals and the further breaches of the TGA Policies arising by reason of the Skerritt Continuing Approvals pleaded and particularised at paragraph 92(d) and (g)(ii) to (ix) (inclusive) herein below.

vii) such conduct was undertaken in the circumstances of the rationally established facts and knowledge of Skerritt pleaded and particularised at paragraphs 92(a) to (h) herein below as to:

(1) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

(2) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

(3) the Pre-Approval Established Critical Defects;

(4) the Post-Approval Established Critical Defects;

(5) the known failures of the Vaccines to meet the Critical Vaccine Requirements;

(6) the unlawfulness of the conduct; and

(7) the breach of a duty to act for the public good in such conduct.

viii) by reason of the factual matters and knowledge pleaded at sub-paragraph (vii) above, in fact, and such facts being known to Skerritt, and further or alternatively facts to which he had reckless disregard:

(1) the Vaccines were:

a) not rationally established to be safe for any of the Vaccine Purposes;

b) not rationally established to be efficacious for any of the Vaccine Purposes;

c) not rationally established to be necessary for any of the Vaccine Purposes;

d) not rationally established to provide benefits which outweighed their risks for any of the Vaccine Purposes;

e) not rationally established to be likely to provide a major therapeutic advance;

(2) further or in the alternative, the Vaccines were:

a) rationally established to be unsafe for any of the Vaccine Purposes;

b) rationally established to be inefficacious for any of the Vaccine Purposes;

c) rationally established to be unnecessary for any of the Vaccine Purposes;

d) rationally established to possess risks which outweighed their benefits for any of the Vaccine Purposes;

e) rationally established to be unlikely to provide a major therapeutic advance;

(3) Covid was:

a) not rationally established to be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

b) further or in the alternative, rationally established to not be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

b) as to the Secretary - undertook the conduct comprising the Secretary Continuing Approvals wherein:

i) such conduct caused, and further or alternatively materially contributed to the occurrence of the Continuing Approvals, the distribution of the Vaccines to the Australian public (including the Group Members) and the receipt of the Vaccines by the Group Members;

Particulars

The factual matters pleaded and particularised at paragraph 55 herein.

ii) the resultant occurrence of the Continuing Approvals arising from such conduct were in breach of and contrary to the legislation under which they were purportedly made, being the Act and the Regulations;

Particulars

The continuing Approvals Statutory Breaches caused by the Secretary Continuing Approvals and the factual matters pleaded and particularised at paragraphs 96(d) and (g)(i) and the Secretary Continuing Approval Breaches pleaded and particularised at paragraphs 98(d) and (g)(i) and herein below.

iii) such conduct was contrary to the Department Overarching Purpose;

Particulars

The factual matters pleaded and particularised at paragraph 92(e) herein below.

iv) such conduct was in breach of the TGA Functional Responsibilities;

Particulars

The continuing Approvals TGA Functions Breaches caused by the Secretary Continuing Approvals and the factual matters pleaded and particularised at paragraph 96(d) and (g)(ii) and the Secretary Continuing Approval Breaches pleaded and particularised at paragraphs 98(d) and (g)(i) herein below.

v) such conduct was in breach of the legislation by which the Secretary's conduct as an officer of the Commonwealth was regulated;

Particulars

The continuing Secretary Public Governance Breaches caused by the Secretary Continuing Approvals and the factual matters pleaded and particularised at paragraph 96(d) and (g)(iii) and the Secretary Continuing Approval Breaches pleaded and particularised at paragraphs 98(d) and (g)(i) herein below.

vi) such conduct was in breach of the express provisions of the TGA Policies regulating the Secretary's conduct within the TGA;

Particulars

The continuing TGA Policies Approvals Breaches caused by the Secretary Continuing Approvals and the further breaches of the TGA Policies arising by reason of the Secretary Continuing Approvals referred to in paragraph 98(g) and pleaded and particularised at

paragraph 92(d) and (g)(ii) to (iv) (inclusive) herein below.

vii) such conduct was undertaken in the circumstances of the rationally established facts and knowledge of the Secretary pleaded and particularised at paragraphs 98(a) to (h) herein below as to:

(1) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

(2) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

(3) the Pre-Approval Established Critical Defects;

(4) the Post-Approval Established Critical Defects;

(5) the known failures of the Vaccines to meet the Critical Vaccine Requirements;

(6) the unlawfulness of the conduct; and

(7) the breach of a duty to act for the public good in such conduct.

viii) by reason of the factual matters and knowledge pleaded at sub-paragraph (vii) above, in fact, and such facts being known to the Secretary, and further or alternatively facts to which he had reckless disregard:

(1) the Vaccines were:

a) not rationally established to be safe for any of the Vaccine Purposes;

b) not rationally established to be efficacious for any of the Vaccine Purposes;

c) not rationally established to be necessary for any of the Vaccine Purposes;

d) not rationally established to provide benefits which outweighed their risks for any of the Vaccine Purposes;

e) not rationally established to be likely to provide a major therapeutic advance;

(2) further or in the alternative, the Vaccines were:

a) rationally established to be unsafe for any of the Vaccine Purposes;

b) rationally established to be inefficacious for any of the Vaccine Purposes;

c) rationally established to be unnecessary for any of the Vaccine Purposes;

d) rationally established to possess risks which outweighed their benefits for any of the Vaccine Purposes;

e) rationally established to be unlikely to provide a major therapeutic advance;

(3) Covid was:

a) not rationally established to be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

b) further or in the alternative, rationally established to not be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

c) as to the Chief Medical Officer - undertook the conduct comprising the Chief Medical Officer Post-Approval Conduct which included the Chief Medical Officer Post-Approval Advices and the Chief Medical Officer Post-Approval Failures to Advise wherein:

i) such conduct caused, and further or alternatively materially contributed to the granting of the Approvals, the distribution of the Vaccines to the Australian public (including the Group Members) and the receipt of the Vaccines by the Group Members;

Particulars

The factual matters pleaded and particularised at paragraph 58 herein.

ii) such conduct was contrary to the Department Overarching Purpose;

Particulars

The factual matters pleaded and particularised at paragraph 104(e) herein below.

iii) such conduct was in breach of the legislation by which the Chief Medical Officer ’s conduct as an officer of the Commonwealth was regulated;

Particulars

The continuing Chief Medical Officer Public Governance Breaches caused by the Chief Medical Officer Post-Approval Conduct and the factual matters pleaded and particularised at paragraph 102(d) and (g)(i) herein below and referred to in paragraph 104(d) and (g)(i) herein below.

iv) such conduct was undertaken in the circumstances of the rationally

established facts and knowledge of the Chief Medical Officer pleaded and particularised at paragraphs 104(a) to (h) herein below as to:

(1) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

(2) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

(3) the Pre-Approval Established Critical Defects;

(4) the Post-Approval Established Critical Defects;

(5) the known failures of the Vaccines to meet the Critical Vaccine Requirements;

(6) the unlawfulness of the conduct; and

(7) the breach of a duty to act for the public good in such conduct.

v) by reason of the factual matters and knowledge pleaded at sub-paragraph (iv) above, in fact, and such facts being known to the Chief Medical Officer, and further or alternatively facts to which he had reckless disregard:

(1) the Vaccines were:

i) not rationally established to be safe for any of the Vaccine Purposes;

ii) not rationally established to be efficacious for any of the Vaccine Purposes;

iii) not rationally established to be necessary for any of the Vaccine Purposes;

iv) not rationally established to provide benefits which outweighed their risks for any of the Vaccine Purposes;

v) not rationally established to be likely to provide a major therapeutic advance;

(2) further or in the alternative, the Vaccines were:

a) rationally established to be unsafe for any of the Vaccine Purposes;

b) rationally established to be inefficacious for any of the Vaccine Purposes;

c) rationally established to be unnecessary for any of the Vaccine Purposes;

d) rationally established to possess risks which

outweighed their benefits for any of the Vaccine Purposes;

e) rationally established to be unlikely to provide a major therapeutic advance;

(3) Covid was:

a) not rationally established to be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

b) further or in the alternative, rationally established to not be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

d) at the time of the Impugned Conduct of Skerritt, the Secretary and the Chief Medical Officer pleaded and particularised at sub-paragraphs (a) to (c) above herein:

i) the following facts had been rationally established:

(1) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

(2) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

(3) the Pre-Approval Established Critical Defects;

(4) the Post-Approval Established Critical Defects;

(5) the Vaccines failed to meet the Critical Vaccine Requirements;

ii) Skerritt, the Secretary and the Chief Medical Officer knew or alternatively were recklessly indifferent to the factual matters pleaded at sub-paragraph (i) herein above;

iii) the following failures in the assessment processes of the Vaccines were in every instance known to Skerritt, the Secretary and the Chief Medical Officer, and further or alternatively to which they had reckless disregard **("the Known Post-Approvals Assessment Failures")**:

(1) the Known Approvals Assessment Failures;

(2) the further factual matters becoming known to Skerritt, the Secretary and the Chief Medical Officer subsequent to the Approvals further establishing:

a) the Known Approvals Assessment Failures; and

b) that there was from that time and since a known proliferation of never-before seen volume and rate of adverse events reported in respect of the Vaccines both in Australia and internationally;

c) that the TGA and the TGA Respondents have on an ongoing basis since the Approvals engaged in denial of the known causality of reported adverse events arising in connection with the Vaccines by adopting a measure of causality:
    i. in abrogation of TGA Policies in respect of causation determination;
    ii. unknown to the internationally accepted standards of adverse event causality assessment including:
        a) Bradford Hill Analysis;
        b) WHO-UMC Standard;
        c) the Naranjo Scale.
    iii. adopting an erroneous standard for causality predicated upon the false presumption that causality, even where temporally associated with the Vaccines and reported to the DAEN:
        1) is at best unlikely or lower;
        2) unless and until the TGA and the TGA Respondents are satisfied by further data establishing positive causality in the mind of the TGA and the TGA Respondents;
    iv. so as to deny the vast number of adverse events and deaths reported as temporally associated with the Vaccines by:
        1) failing or refusing to conduct proper investigation in respect of those known adverse events and deaths;
        2) where conducting any investigation, leaving open for prolonged and continuing periods any purported investigations of causality such that the Respondents continue to assert that causality has still not been established;
d) that each of the Vaccines represents an evident and known risk of death, serious illness or serious injury, the scope of which:
    i. based upon the evidence already before or reasonably

available to the TGA and the TGA Respondents, has not been fully disclosed to the Australian public;

ii. vastly exceeded from the time of the Approvals, any benefits of the Vaccines;

e) the power arising pursuant to the Cancellation Standard and the obligation upon the Respondents under the TGA Policies and Statutory Requirements relevant to the Approvals pleaded herein:

i. to suspend or cancel the Approval of each of the Vaccines;

ii. pursuant to the Secretary's Power to Suspend or Cancel by application;

iii. from the time of the Approvals, and at all times subsequent to the date of the Approvals.

f) the ongoing safety surveillance data obtained by the TGA and the TGA Respondents after the time of the Approvals demonstrating the extraordinary risks and negative risk-benefit profile data of the Vaccines established by:

i. the proportional reporting ratios in respect of almost all manner of adverse reactions related to the Vaccines demonstrating the occurrence of adverse events at a rate exponentially higher than:

1) similarly classified vaccines historically;

2) the point at which the TGA and the TGA Respondents had previously declared to be a cause for safety concern;

ii. the unprecedented proliferation of the rate of adverse event reporting temporally associated with the Vaccines as compared to historical data uniformly dismissed by the TGA and the TGA Respondents as of no concern on the erroneous bases that:

1) the data is purportedly in line with "background rates" of illness and death;

2) the reported deaths and events not being causally established by the TGA and the TGA

Respondents based upon erroneous causality assessment or alternatively failures or delays in causality assessments by the TGA and the TGA Respondents;

g) the TGA and the TGA Respondents failure to issue safety alerts arising from the known data to the Australian public such that:
    i. the Australian public has been under-informed or misinformed as to the true extent of safety issues and risks surrounding the Vaccines;

h) Skerritt, the Secretary and the Chief Medical Officer continue to undertake the Skerritt Continuing Approvals, the Secretary Continuing Approvals and the Chief Medical Officer Post-Approval Conduct respectively upon the basis that the Vaccines are safe, effective and necessary;

i) from the time of the Approvals, based upon the data known to Skerritt, the Secretary and the Chief Medical Officer the following have been rationally established and known to them:
    1) that since that time the Vaccines were not demonstrated by the evidence known to Skerritt, the Secretary and the Chief Medical Officer to be reasonably or otherwise:
        a) safe for their intended purpose;
        b) effective for their intended purpose;
        c) possessing of a positive risk-benefit profile.
    2) that since that time the data and evidence known to Skerritt, the Secretary and the Chief Medical Officer and reasonably available evidence globally obviously demonstrated that the Vaccines were in truth:
        a) unsafe for their intended use;
        b) ineffective for their intended use;
        c) possessive of a grossly negative risk-benefit profile.
    3) since the time of the Approvals, Skerritt, the

Secretary and the Chief Medical Officer knew that the studies undertaken by the Sponsors and further surveillance data provided to the TGA and the TGA Respondents disclosed subsequently to the Approvals that:

1) the testing and ongoing data does not establish in any of the Vaccines the effect of:
    a) prevention of transmission of the Virus;
    b) prevention of infection with the Virus;
    c) prevention of serious illness from Covid;
    d) prevention of hospitalisation from Covid;
    e) prevention of death from Covid;
2) absence of safety, efficacy, or positive risk-benefit in use of the Vaccines in those for whom use was intended including in:
    a) pregnant women;
    b) immunocompromised people;
    c) people with certain pre-existing health conditions;
    d) people receiving other vaccines concurrently;
    e) people with natural immunity resultant from prior infection with the Virus;
    f) long-term efficacy;
    g) long-term safety.
3) there were extraordinary and unacceptable risks associated with the Vaccines being:
    a) risks of Serious Adverse Events **("Serious Adverse Events" is defined in para. 17 in Schedule B of the SOC)**;
    b) risk of death;
4) the Vaccines displayed an exponentially negative risk-benefit profile for:
    a) the entire population of Australia;

b) further or in the alternative, those persons under 70 years of age;

5) that the Vaccines:
   a) are not safe for their intended use;
   b) are not effective for their intended use;
   c) possess significantly higher risk than benefit:
      i) in all recipients of the Vaccines;
      ii) further or in the alternative, recipients under the age of 70 years.

Particulars

Para. 77 in Schedule D of the SOC.

78. By reason of the factual matters and knowledge pleaded and particularised in paragraph 77 herein above, the Reckless Failures – Continuing Approvals undertaken by Skerritt, the Secretary and the Chief Medical Officer respectively failed to observe the limits of their respective powers and were:

a) so unreasonable that no reasonable person could have so acted or failed to act, or in the alternative were legally unreasonable;

b) conducted in bad faith.

Particulars

Para. 78 in Schedule D of the SOC.

BREACH OF DUTY – CONTINUING APPROVALS

79. By reason of the factual matters and knowledge pleaded and particularised in paragraphs 42, 43, 52, 55, 58 and 61 to 78 (inclusive) herein above, the acts and omissions of Skerritt, the Secretary and the Chief Medical Officer, respectively, in the Reckless Conduct – Approvals were undertaken in breach of the Respondents' Duty **("the Continuing Approvals Breach")**.

Particulars

Para. 79 in Schedule D of the SOC.

RESPONDENT'S CONDUCT – NEGLIGENCE AND BREACH OF DUTY IN MISLEADING PUBLIC MESSAGE

80. The Public Officers undertook conduct constituted by the Impugned Conduct causing the publication of the Misleading Public Message subsequent to the respective Approvals as follows:

a) the Public Officers undertook the conduct causing the publication to the Australian population of the Misleading Public Message by:

i) as to Skerritt - Skerritt Issued Misleading Vaccines Statements;

ii) as to the Secretary - the Secretary Issued Misleading Vaccines Statements;

iii) as to the Chief Medical Officer - the Chief Medical Officer Issued Misleading Vaccines Statements; and

iv) as to Hunt - the Hunt Misleading Vaccines Statements;

b) the Public Officers undertook such conduct respectively in circumstances wherein:

i) such conduct caused, and further or alternatively materially contributed to taking of the Vaccines by the Group Members;

Particulars

The factual matters pleaded and particularised at paragraph 53 herein.

ii) each and every one of the Public Officers prior to and at the time of the publication of the statements, possessed the knowledge of, and further or alternatively were recklessly indifferent to the factual matters constituting:

(1) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

(2) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

(3) the Pre-Approval Established Critical Defects;

(4) the Post-Approval Established Critical Defects.

iii) by reason of the factual matters and knowledge pleaded at sub-paragraph (ii) above, in fact, and such facts being known to the Public Officers, and further or alternatively facts to which they had reckless disregard:

(1) the Vaccines were:

a) not rationally established to be safe for any of the Vaccine Purposes;

b) not rationally established to be efficacious for any of the Vaccine Purposes;

c) not rationally established to be necessary for any of the Vaccine Purposes;

d) not rationally established to provide benefits which outweighed

their risks for any of the Vaccine Purposes;

e) not rationally established to be likely to provide a major therapeutic advance;

(2) further or in the alternative, the Vaccines were:

a) rationally established to be unsafe for any of the Vaccine Purposes;

b) rationally established to be inefficacious for any of the Vaccine Purposes;

c) rationally established to be unnecessary for any of the Vaccine Purposes;

d) rationally established to possess risks which outweighed their benefits for any of the Vaccine Purposes;

e) rationally established to be unlikely to provide a major therapeutic advance;

(3) Covid was:

a) not rationally established to be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

b) further or in the alternative, rationally established to not be a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age;

Particulars

Para. 80(b)(iii) in Schedule D of the SOC.

iv) the Public Officers caused the Misleading Public Message to be published **("the Known Established Falsity of the Misleading Public Message")**:

(1) which was in every respect at all relevant times:

a) rationally established to be false, and further or in the alternative not rationally established to be true;

b) known by each and every one of the Public Officers to be rationally established to be false and further or alternatively not rationally established to be true;

c) further or in the alternative, each and every one of the Public Officers recklessly disregarded the facts that the Misleading Public Message was rationally established to be false and further or alternatively not rationally established to be true.

Particulars

Para. 80(b)(iv) in Schedule D of the SOC.

v) the knowledge and facts of the Known Established Falsity of the Misleading Public Message by reason of the following rationally established factual matters were known to each and every one of the Public Officers at the relevant time of publication, and further or alternatively to which they had reckless disregard:

(1) the Vaccines were not unquestionably or otherwise safe because the Vaccines were:

a) rationally established to be unsafe;

b) further or alternatively, not rationally established to be safe.

Particulars

The facts were rationally established and known as particularised in the following paragraphs:

1. Pre-Approvals: para. 67-75, 79 to 85, 85F to 89, 91 to 130 (inclusive) of Schedule B of the SOC.
2. Post-Approvals: para. 134 to 136, 143, 150 to 179, 181, 183 to 188, 192 to 211 (inclusive) of Schedule B of the SOC.

(2) the Vaccines were not so safe that anything other than the most mild of side effects almost never occurred because in fact the Vaccines were:

a) rationally established to:

i) not infrequently cause serious side effects, permanent injury, and death; and

ii) cause unprecedented volumes of side effects;

b) further or alternatively, did not rationally establish that the Vaccines:

i) infrequently caused serious side effects, permanent injury, and death; and

ii) did not cause unprecedented volumes of side effects;

Particulars

The facts were rationally established and known as particularised in the following paragraphs:

1. Pre-Approvals: para. 3 to 10, 14 to 20, 26 to 33, 35 to 74 (inclusive) of Schedule B of the SOC.

2. Post-Approvals: para. 80 to 82, 89, 96 to 125, 127, 129 to 133, 137 to 155 (inclusive) of Schedule B of the SOC.

(3) the Vaccines were not completely or almost completely effective to prevent infection from the Virus because in fact the Vaccines were:

a) rationally established to not be at least substantially effective to prevent infection from the Virus;

b) further or alternatively were not rationally established to be at least substantially effective to prevent infection from the Virus;

Particulars

The facts were rationally established and known as particularised in the following paragraphs:

1. Pre-Approvals: para. 21, 22, 24, 25, 28, 32 and 36 of Schedule B of the SOC.
2. Post-Approvals: para. 81, 83, 84, 86, 87, 90, 92 to 95 (inclusive) of Schedule B of the SOC.

(4) the Vaccines were not completely or almost completely effective to prevent transmission of the Virus because in fact the Vaccines were:

a) rationally established to not be at least substantially effective to prevent transmission of the Virus;

b) further or alternatively were not rationally established to be at least substantially effective to prevent transmission of the Virus;

Particulars

The facts were rationally established and known as particularised in the following paragraphs:

1. Pre-Approvals: para. 9, 22, 25, 28, 32, 36, 62, 73 and 74 of Schedule B of the SOC.
2. Post-Approvals: para. 83, 88, 90 and 92 of Schedule B of the SOC.

(5) the Vaccines were not completely or almost completely effective to prevent serious Covid because in fact the Vaccines were:

a) rationally established to not be at least substantially effective to prevent serious Covid; or alternatively

b) not rationally established to be at least substantially effective

to prevent serious Covid;

Particulars

The facts were rationally established and known as particularised in the following paragraphs:

1. Pre-Approvals: para. 9, 22, 25, 28, 32 and 60 of Schedule B of the SOC.
2. Post-Approvals: para. 83, 90, 92 and 94 of Schedule B of the SOC.

(6) the Vaccines were not completely or almost completely effective to prevent death from Covid because in fact the Vaccines were:

a) rationally established to not be at least substantially effective to prevent death from Covid; or alternatively

b) not rationally established to be at least substantially effective to prevent death from Covid;

Particulars

The facts were rationally established and known as particularised in the following paragraphs:

1. Pre-Approvals: para. 9, 22, 25, 28, 32 and 60 of Schedule B of the SOC.
2. Post-Approvals: para. 81 to 84, 90, 92 and 94 of Schedule B of the SOC.

(7) prior to the Approvals, the Vaccines had not been subjected to the most rigorous assessment for safety and efficacy possible because at the relevant times it was rationally established, that the assessment of the Vaccines involved:

a) assessment which was limited to the data provided by the Sponsors absent any independent testing by the TGA or the TGA Respondents;

b) no patient level data being provided to the TGA or the TGA Respondents in the course of the Approvals processes or at all;

c) assessed data being limited solely to short-term data;

d) no clinical testing of:

i) prevention of transmission of the Virus;

ii) prevention of infection with the Virus;

iii) prevention of serious illness from Covid;

iv) prevention of hospitalisation from Covid;

v) prevention of death from Covid;

vi) use of the Vaccines in those for whom use was intended being the Untested Groups, including in:

1) pregnant women;

2) immunocompromised people;

3) people with certain pre-existing health conditions;

4) people receiving other vaccines concurrently;

5) people with natural immunity resultant from prior infection with the Virus;

vii) long-term efficacy;

viii) genotoxicity;

ix) carcinogenicity;

x) long-term safety.

e) extraordinary and unacceptable risks associated with the Vaccines being:

i) risks of Serious Adverse Events;

ii) risk of death;

f) unquantified and known risk of incorporation of the mRNA in the mRNA Vaccines into the human genome with the potential to cause intergenerational effects;

Particulars

Para. 80(b)(v)(7) in Schedule D of the SOC.

(8) prior to the Approvals, the Vaccines had not been subjected to an assessment procedure equivalent to that applied all other approved therapeutic products in Australia because in fact, it was rationally established that:

a) the approval assessment process under the Act for provisional approval of the Vaccines as in the Approvals was profoundly different and less rigorous as allowed by s. 25(1)(d)(i) in that unlike the regular approvals process, provisional approval evaluation was based only upon limited and short-term preliminary clinical data as opposed to fulsome and long-term data;

b) the Approvals were undertaken:

i) in an unprecedentedly truncated time frame;

ii) with unprecedented limitations of evidence for the Approvals being short-term and lacking fundamental evidence pleaded above at sub-paragraph (iv) herein;

Particulars

Para. 80(b)(v)(8) in Schedule D of the SOC.

(9) matters in fact known by the Public Officers in respect of testing prior to the Approvals or known data in respect of safety and efficacy of the Vaccines were of objective cause for concern because in fact, and the facts known to the Public Officers or alternatively to which the Public Officers had reckless indifference at the relevant times rationally established, that:

a) the Vaccines were:

i) not established to be safe for any of the Vaccine Purposes;

ii) not established to be effective for any of the Vaccine Purposes;

b) further or in the alternative, the Vaccines were:

i) established to be unsafe for any of the Vaccine Purposes;

ii) established to be ineffective for any of the Vaccine Purposes;

Particulars

The facts were rationally established and known as particularised in the following paragraphs:

1. Pre-Approvals: para. 3 to 20, 22, 24, 25, 26 to 33, 35 to 74 (inclusive) of Schedule B of the SOC.
2. Post-Approvals: para. 80 to 125, 127, 129 to 133 and 137 to 155 (inclusive) of Schedule B of the SOC.

(10) people who did not take the Vaccines would not generally be at a high risk of dying or becoming seriously ill from Covid because in fact:

a) it was rationally established that:

i) the Vaccines were not at least substantially effective to

prevent death or serious illness from Covid;

ii) the unvaccinated were not more likely than the vaccinated to become seriously ill or die from Covid;

b) that Covid disease itself was generally not causative of a high risk of serious illness or death in the general population at any time;

c) further or alternatively, it was not rationally established that:

i) the Vaccines were at least substantially effective to prevent death or serious illness from Covid;

ii) the unvaccinated were more likely than the vaccinated to become seriously ill or die from Covid;

iii) Covid disease itself was generally causative of a high risk of serious illness or death in the general population at any time;

Particulars

The facts were rationally established and known as particularised in the following paragraphs:

1. Pre-Approvals: para. 1, 9, 23, 25, 28 and 74 of Schedule B of the SOC.
2. Post-Approvals: para. 81 to 88, 90, 92 to 95 and 108 (inclusive) of Schedule B of the SOC.

(11) for everyone in Australia the risks of serious illness and death from not taking the Vaccines were not significantly higher than the risks of injury from taking the Vaccines because in fact:

a) it was rationally established, that the risk of injury from the Vaccines was significantly higher than the risks of serious illness or death from Covid at all times:

i) for the entirety of the Australian population; and

ii) further or alternatively, at least those under the age of 70 years;

b) further or alternatively, it was not rationally established that the risks of serious illness and death from not taking the Vaccines were not significantly higher than the risks of injury from taking the Vaccines at all times:

i) for the entirety of the Australian population; and

ii) or alternatively, at least those under the age of 70 years.

Particulars

The facts were rationally established and known as particularised in the following paragraphs:

1. Pre-Approvals: para. 1 to 74 (inclusive) of Schedule B of the SOC.
2. Post-Approvals: para. 77 to 125, 127, 129 to 133 and 137 to 155 (inclusive) of Schedule B of the SOC.

(12) taking the Vaccines was not essential to protect others from Covid because in fact:

a) it was rationally established, that the Vaccines did not prevent transmission of or infection with the Virus;

b) further or alternatively, it was not rationally established that the Vaccines prevented transmission of or infection with the Virus;

Particulars

The facts were rationally established and known as particularised in the following paragraphs:

1. Pre-Approvals: para. 1, 9, 23, 25, 28, 32, 36, 62, 73 and 74 of Schedule B of the SOC.
2. Post-Approvals: para. 82 to 86, 88, 90, 92 to 95 (inclusive) of Schedule B of the SOC.

(13) the data in respect of post-Approvals side effects from the Vaccines was of any actual material concern to the Australian public because in fact, and the facts known to the Public Officers or alternatively to which the Public Officers had reckless indifference at the relevant times rationally established:

a) an unprecedented rate of side effects and injury to recipients being caused by the Vaccines post-release to the Australian population;

b) a rate of side effects and injury to recipients exponentially higher than similar vaccines being caused by the Vaccines post-release to the Australian population;

c) prolific numbers of reported adverse events, Serious Adverse Events and deaths associated with the Vaccines;

d) the occurrence of a rate of injury amongst recipients of the Vaccines significantly higher than the rate of serious illness and death from Covid;

Particulars

The facts were rationally established and known as particularised in the following paragraphs:

Post-Approvals: para. 80 to 82, 89, 96 to 125, 127, 129 to 133 and 137 to 155 (inclusive) of Schedule B of the SOC.

(14) that public reporting and statements of the Respondents pre-Approvals and post-Approvals in respect of the safety, efficacy and risk-benefit profile of the Vaccines does not disclose to the Australian public the most accurate and comprehensively evident representation of those matters because:

a) in fact, and the facts known to the Respondents or alternatively to which the Respondents had reckless indifference at the relevant times rationally established:

i) the Pre-Approval Established Critical Defects;

ii) the Post-Approval Established Critical Defects;

iii) the Respondents at no time published accurately or at all those matters pleaded in (i) and (ii) herein above to the Australian public.

Particulars

The facts were rationally established and known as particularised in the following paragraphs:

1. Pre-Approvals: para. 1 to 74 (inclusive) of Schedule B of the SOC;
2. Post-Approvals: para. 77 to 125, 127, 129 to 133 and 137 to 155 (inclusive) of Schedule B of the SOC.

(15) in each and every instance of the publication of the respective statements, such statement was caused by the respective Public Officer:

a) for the purposes of and intent of the Misleading Vaccines

Statements Purpose;

Particulars

Particulars of the Misleading Vaccines Statements Purpose as defined at Para. 50 in Schedule D of the SOC.

b) wherein he intended, knew, expected and considered it likely that as a natural and probable consequence of the publication of those respective statements, that the Australian population would, and did in fact:

i) rely upon those statements in determining whether to take one or more of the Vaccines;

ii) determine to take one or more of the Vaccines;

iii) take one or more of the Vaccines.

Particulars

Para. 80(b)(v)(15) in Schedule D of the SOC.

c) the conduct of the Public Officers was in every instance contrary to the Overarching Department Purpose because the Misleading Public Message promulgated by the Public Officers in the publication of the respective public statements was in fact detrimental to the health and wellbeing of the Australian Public;

Particulars

Para. 80(c) in Schedule D of the SOC.

d) the conduct of the Public Officers was in every instance in breach of the binding legislation and duties applicable to their respective conduct, unlawful, in breach of a duty to act for the public good, and the said officers failed to observe the limits of their respective powers, specifically:

i) as to Skerritt – the relevant circumstances and breaches in conduct pleaded and particularised at (a) to (c) above and paragraph 94(e) herein below;

ii) as to the Secretary – the relevant circumstances and breaches in conduct pleaded and particularised at (a) to (c) above and paragraph 100(e) herein below;

iii) as to the Chief Medical Officer – the relevant circumstances and breaches in conduct pleaded and particularised at (a) to (c) above and paragraph 106(e) herein below; and

iv) as to the Minister – the relevant circumstances and breaches in conduct pleaded and particularised at (a) to (c) above and paragraph 108(e), (h)(v) and (vii), herein below.

Particulars

Para. 80(d) in Schedule D of the SOC.

Such breaches occur by reason of the factual matters and knowledge pleaded at sub-paragraphs (a) to (c) herein above.

81. By reason of the factual matters and knowledge pleaded and particularised in paragraph 80 herein above, the Reckless Conduct – Misleading Public Message undertaken by the Public Officers respectively were:

    a) so unreasonable that no reasonable person could have so acted or failed to act or alternatively, the conduct was legally unreasonable;

    b) conducted in breach of a duty to act in such conduct for the public good, unlawfully and in bad faith.

BREACH OF DUTY – MISLEADING STATEMENTS

82. By reason of the factual matters and knowledge pleaded in paragraphs 42, 43, 53, 56, 59, 60 and 61 to 81 (inclusive) herein above, the acts and omissions of the Public Officers respectively in the Reckless Conduct – Misleading Public Message were undertaken in breach of the Respondents' Duty **("the Misleading Public Message Breach")**.

BREACHES OF DUTY – CAUSATION OF LOSS AND DAMAGE

83. But for one or more of the Approvals Breaches, the Continuing Approvals Breaches and the Misleading Public Message Breaches **("the Breaches")**, the Group Members would not have:

    a) had access to the Vaccines;

    b) received one or more of the Vaccines;

    c) suffered injury, loss and damage.

84. By reason of one or more of the Breaches, the Group Members:

    a) had access to the Vaccines;

    b) received one or more of the Vaccines;

    c) suffered injury, loss and damage **("the Loss and Damage")**.

Particulars

PART J - MISFEASANCE CLAIM

ALTERNATIVE CLAIM

84A . The misfeasance claim pleaded herein below at paragraphs 85 to 112 (inclusive) is pleaded in the alternative to the negligence claim pleaded herein above at paragraphs 61 to 84 (inclusive) except where either claim expressly relies upon those facts or conclusions of law pleaded and particularised in the alternative claim.

PUBLIC OFFICERS

85. The Public Officers were at all material times:
    a) officers of the Commonwealth;
    b) acting for and on behalf of the Commonwealth;
    c) in their respective positions:
        i) holding public office;
        ii) discharging a public duty.

86. While acting in their respective capacities as officers of the Commonwealth and acting with power incident to their office and/or to administer the Act and the Regulations, the Public officers were exercising:
    a) the executive power of the Commonwealth;
    b) maintaining and executing a law of the Commonwealth.

87. The Public Officers, in undertaking the Impugned Conduct, were each purportedly discharging a public duty in acting in their respective capacities as officer of the Commonwealth, acting with power incident to their office and/or administering the Act and associated legislative instruments in exercising powers, functions and discretions under those instruments, including:

a) undertaking all matters connected with the consideration of and granting of approvals for registration of therapeutic goods in Australia relevantly, including:
    i) the Approvals;
    ii) maintaining the Vaccines upon the Register subsequent to the Approvals;
    iii) undertaking matters connected with the ongoing monitoring, assessment and pharmacovigilance after the Approvals in respect of the Vaccines;
b) making public statements in respect of those matters;
c) undertaking all matters connected with the distribution of the Vaccines widely to the Australian population;
d) providing advices to the Commonwealth and its officers, employees and agents in respect of:
    i) the safety, efficacy and necessity of the Vaccines for the Australian population;
    ii) the lawfulness of the Approvals and Continuing Approvals and compliance of the Vaccines with legislation;
    iii) the distribution of the Vaccines to the Australian population for widespread use.

Particulars

Para. 87 in Schedule D of the SOC.

88. The powers or purported powers to perform the Impugned Conduct were at all material times conferred on the Public Officers by means of:
a) direct or delegation of a statutory power under the Act;
b) designation as an authorised person for the purpose of express powers under the Act;
c) the Commonwealth acting through the Department giving full allowance to the TGA and the Public Officers to exercise the executive power of the Commonwealth under section 61 of the Constitution in the maintenance and execution of the Act; and/or
d) further and without limiting the above, the Commonwealth, so acting, giving full allowance to the Public Officers to determine when to exercise informal powers instead of, or in addition to, formal powers conferred under the Act or any other legislation.

89. By reason of the matters pleaded herein, when respectively undertaking the Impugned Conduct each of the Public Officers:
a) were at all material times public officers exercising the executive power of the Commonwealth;

b) owed a duty to exercise the powers for the public good and not for any ulterior purpose;

c) owed that duty to the Group Members.

Particulars

The factual matters pleaded at paragraphs 10 to 18 (inclusive) and 85 to 88 (inclusive) herein.

SKERRITT – APPROVALS MISFEASANCE

90. Skerritt, in respect of the respective Approvals **("the Skerritt Approvals Misfeasance")**:

a) engaged in the conduct constituted by the Skerritt Approvals;

b) undertook the Skerritt Approvals upon the Purported Bases of Approval at the time of the respective Approvals;

Particulars

The Particulars of the Purported Bases of Approval and Continuing Approval as defined at Para. 50 in Schedule D of the SOC.

c) possessed no later than at the time of the respective Approvals the knowledge of the factual matters constituting:

i) the Known Serious Vaccines Risks and Conduct - Pre-Approval;

ii) the Pre-Approval Established Critical Defects; and

iii) the Known Approvals Assessment Failures.

Particulars

Para. 90(c) in Schedule D of the SOC.

d) undertook the Skerritt Approvals in circumstances wherein Skerritt at all material times as an officer of the Commonwealth:

i) was subject to and bound by, and knew that he was subject to and bound by the obligations and positive duties in respect of such conduct arising under the relevant express and implied provisions of:

(1) the Act;

(2) the Regulations;

(3) the Conduct Legislation;

(4) the TGA Policies, in circumstances where those policies were and are:

a) adopted and widely publicised by the Commonwealth as being for the purposes of ensuring compliance with the powers and

responsibilities contained expressly and impliedly under the Act and good government;

b) widely publicised by the Commonwealth and the Respondents as being the basis upon which the Approvals and the Continuing Approvals would be made;

c) in accordance with which Skerritt was bound to act:

i) where acting in good faith and with reasonable care;

ii) pursuant to the conduct provisions of the Conduct Legislation.

Particulars

Para. 90(d)(i) in Schedule D of the SOC.

ii) was at all material times in respect of the Skerritt Approvals:

(1) acting purportedly pursuant to his duties, obligations and responsibilities pleaded at paragraph 11 herein;

(2) acting purportedly pursuant to a power incident to his office as deputy secretary of the Health Products Regulation Group (HPRG) within the Department and head of the TGA;

(3) acting purportedly pursuant to powers and in accordance with his obligations arising in the exercise of such powers:

a) under the Conduct Legislation;

b) in accordance with the publicly promulgated TGA Policies;

(4) providing advices and support to the Secretary, Minister and the Department across the full range of matters relating to the Vaccines including the:

a) safety and efficacy of the Vaccines; and

b) compliance of the Applications with the provisions of the Act;

Particulars

The factual matters and circumstances pleaded and particularised at paragraphs 10, 11, 13, 14, 15, 17, 18, 36 and 90(d)(ii) of the SOC.

(5) when such power was being exercised by a person delegated by Skerritt to do so under any act of parliament:

a) Skerritt in that instance in fact personally exercising his power or purported power; and

b) Skerritt in that instance in fact personally taking those actions.

(6) personally directing the actions of any person acting pursuant to a power or purported power delegated by him under the Act.

Particulars

Act s. 57(4)

Acts Interpretation Act 1901 (Cth) s. 34AB(1)(c)

e) the Skerritt Approvals were undertaken by Skerritt:

i) purportedly for the proper purpose incident to his office that his actions in that office be undertaken consistently with:

(1) the Department Overarching Purpose;

(2) the TGA's Statutory Purpose;

(3) his duty to act for the public good;

ii) in circumstances wherein, the Skerritt Approvals were in fact inconsistent with the Department Overarching Purpose and the TGA's Statutory Purpose because they were made in the circumstances of the facts of and Skerritt's knowledge of the Pre-Approval Established Critical Defects;

iii) thereby for an improper purpose:

(1) contrary to the public good;

(2) in breach of a duty to act for the public good.

Particulars

Para. 90(e) in Schedule D of the SOC.

f) at no time prior to the Skerritt Approvals or at all did Skerritt:

i) rationally establish the Critical Vaccine Requirements;

ii) hold the rational belief that the Critical Vaccine Requirements had been rationally and satisfactorily established;

Particulars

Para. 90(f) in Schedule D of the SOC.

g) undertook the Skerritt Approvals in the circumstances of the factual matters and knowledge pleaded at sub-paragraphs (a) to (f) herein, thereby undertaking the Skerritt Approvals **("the Skerritt Approval Breaches")**:

i) in, causing or materially contributing to breaches of the express provisions of the Act, specifically the Statutory Obligations, and thereby acting unlawfully by causing approval and registration of the Vaccines for use by the Australian Public in the known circumstances of **("the Approvals Statutory Breaches")**:

(1) the failure to institute proper controls because the Approvals were undertaken in the absence of any rationally demonstrable safety or efficacy in breach of the TGA's Statutory Purpose;

(2) the failure to maintain the Register as providing for properly evaluated therapeutic goods for use in humans because the Approvals were undertaken without proper evaluation of the Vaccines in breach of the Register's Statutory Purpose;

(3) breaches of s. 22D(2) of the Act and r. 10L(1)(a) and (c) of the Regulations because the Approvals were made wherein:

a) the Known Serious Vaccines Risks and Conduct - Pre-Approvals rationally established that Covid was not in fact a life-threatening or seriously debilitating condition in the Australian population under 70 years of age;

b) the preliminary clinical data or any data for the Vaccines did not rationally establish that the Vaccines were likely to provide a major therapeutic advance because the known preliminary clinical data known at the time of the Approvals did not rationally establish the Critical Vaccine Requirements;

(4) breach of s. 25(1)(d)(i) of the Act, specifically by the failure of the Vaccines' safety and efficacy for the purposes for which it was used to be rationally established based upon preliminary clinical data because the factual matters known at the time of the respective Approvals, whether the preliminary clinical data or otherwise did not rationally establish the Critical Vaccine Requirements;

(5) the absence of any preliminary clinical trials or testing undertaken for the specific purposes for which the Vaccines were to be used **("the Clinical Testing Failures")**:

a) being any of the Vaccine Purposes;

b) other than protection against symptomatic Covid;

Particulars

Para. 90(g)(i)(3)-(5) in Schedule D of the SOC.

(6) the absence at any time prior to the Approvals of:

a) rational establishment in fact of any of the Critical Vaccine Requirements;

b) the rational belief that:

i) the TGA' Statutory Purpose was or would be rationally and satisfactorily established by the Approvals;

ii) the Register's Statutory Purpose was or would be rationally and satisfactorily established by the Approvals;

iii) the Critical Vaccine Requirements had been rationally and satisfactorily established in respect of the Vaccines;

iv) s. 22D(2) of the Act r. 10L(1)(a) and (c) of the Regulations had been rationally and satisfactorily established in respect of the Vaccines;

v) s. 25(1)(d)(i) of the Act had been rationally and satisfactorily established in respect of the Vaccines;

Particulars

Para. 90(g)(i)(6) in Schedule D of the SOC.

(7) the failure to act in accordance with the Requirement to Seek Gene Technology Regulator Advice by failing to give written notice to the Gene Technology Regulator requesting the Gene Technology Regulator to give advice about the Provisional Application, in breach of s. 30C(2)(b) of the Act;

(8) the failure to act in accordance with the Requirement to Consider Gene Technology Regulator Advice by failing to take into account in making a decision on the Applications any advice of the Gene Technology Regulator about the Provisional Application, in breach of s. 30E of the Act;

(9) the granting of the respective Approvals in breach of s. 24(2)(b) of the Act wherein the applications for registration had in fact lapsed in circumstances of the respective applications containing misleading material particulars, specifically, assertions by the Sponsors that the Vaccines were safe and efficacious for any of the Vaccine Purposes, known to him at the time to be demonstrably false by reason of the established knowledge and facts of the Pre-Approval Established Critical Defects;

(10) in the Approvals, the failure to exercise the power pursuant to s. 31(1) of the Act that the Sponsors provided the individual patient level data in respect of the Clinical Trials:

a) failing which the respective Approvals lapsed pursuant to s. 24(2)(d) of the Act because such data was and remains essential to rationally establishing the safety and efficacy of the Vaccines for their intended use;

b) thereby manifesting a positive legal obligation to have done so.

ii) in, causing or materially contributing to the breach of the widely publicised TGA responsibilities and obligations relating to the Approvals, specifically the TGA Functional Responsibilities, in **("the Approvals TGA Functions Breaches")**:

(1) the failure to evaluate the applications manifesting the respective Approvals so as to establish the Vaccines' safety, efficacy or positive risk-benefit profile;

(2) the failure to undertake proper risk assessment of the Vaccines by the application of the TGA's scientific and clinical expertise to its decision-making in the Approvals;

(3) the failure to ensure that the benefits of the Vaccines outweigh any risk;

(4) the failure to properly assess the level of risk of the Vaccines by failing to take account of the known:

a) Vaccines' side effects;

b) Vaccines' potential harm through prolonged use;

c) Vaccines' toxicity; and

d) seriousness of the medical condition for which the product is intended to be used, specifically Covid infection.

(5) the failure to manage the risks of Approvals by:

a) failing to identify, assess and evaluate the risks posed by the Vaccines;

b) failing to apply all measures necessary for treating the risks posed by the Vaccines;

c) failing to properly assess whether the Vaccines contained ingredients:

i) which were previously unknown and untested in humans for the intended use; and

ii) the use of which could result in significant adverse effects;

(6) the grant of the respective Approvals in circumstances wherein the risk-benefit ratio was negative;

(7) the failure to adequately obtain, consider or apply risk information in relation to the Vaccines in determining to grant the respective Approvals and/or that the respective Approvals ought to be granted;

Particulars

Para. 90(g)(ii) in Schedule D of the SOC.

iii) in breach of the express provisions of the Conduct Legislation to which he was at all times bound in undertaking the Skerritt Approvals, specifically undertaking the Skerritt Approvals in the circumstances of the matters pleaded at sub-paragraphs (a) to (g)(ii) herein thereby **("the Skerritt Public Governance Breaches")**:

(1) failing to provide the Commonwealth with advice that is frank, honest, timely and based upon the best available evidence;

Particulars

Para. 90(g)(iii)(1) in Schedule D of the SOC.

(2) acting in breach of the statutory legal obligations of the *Public Service Act 1999* and/or the and the *Parliamentary Service Act 1999* and the relevant Code of Conduct, under which his genuine belief or intent that the actions were proper is irrelevant to such breach, by:

Particulars

Para. 90(g)(iii)(2) in Schedule D of the SOC.

a) failing to act honestly and with integrity in connection with his position within the Department;

Particulars

Para. 90(g)(iii)(2)(a) in Schedule D of the SOC.

b) failing to act with care and diligence in connection with those acts and omissions by failing to act:

i) with serious attention and solicitude to those matters;

ii) earnest effort to accomplish the purposes for which the powers are granted;

iii) reasonably, such that Skerritt's actions were so unreasonable that no reasonable person could have taken them;

Particulars

Para. 90(g)(iii)(2)(b) in Schedule D of the SOC.

iv) within Australian law;

Particulars

s.13(4) of the *Public Service Act 1999* and the *Parliamentary Service Act 1999*.

(3) acting in breach of the statutory legal obligations of the *Public Governance, Performance and Accountability Act 2013* (Cth), by:

a) acting unlawfully by failing, pursuant to his statutory duty, to exercise his powers, perform his functions and discharge his duties:

i) with the degree of care and diligence that a reasonable person would exercise;

ii) honestly, in good faith and for a proper purpose;

Particulars

Para. 90(g)(iii)(3) in Schedule D of the SOC.

iv) acting in breach of the express provisions of the TGA Policies by undertaking the Approvals thereby undertaking, causing or materially contributing to **("the TGA Policies Approvals Breaches")**:

Particulars

Para. 90(g)(iv) in Schedule D of the SOC.

(1) the granting of the Registration of the Vaccines for use in Australia wherein their benefits were not, and were known by Skerritt not to be, significantly greater than their risks;

Particulars

Para. 90(g)(iv)(1) in Schedule D of the SOC.

(2) the granting of the respective Approvals wherein the Vaccines did not, and were known by Skerritt not to, prevent the transmission of or infection by the Virus and thereby did not protect the recipient or those around them from contracting Covid;

Particulars

The TGA Policies breached arise specifically from the Vaccine Regulation Policy document particularised in Schedule A of the SOC

(3) the granting of the Approvals wherein the TGA did not and were known by Skerritt at the time of the respective Approvals not to have rigorously assessed the Vaccines for safety and efficacy before such Approvals allowing for their use in Australia;

Particulars

Para. 90(g)(iv)(3) in Schedule D of the SOC.

(4) the granting of the Approvals wherein the TGA failed and were known by Skerritt to have failed to have only used the best available scientific evidence to assess the risks and benefits of each of the Vaccines before the respective Approvals;

Particulars

The TGA Policies breached arise specifically from the Vaccine Regulation Policy document particularised in Schedule A of the SOC.

(5) the granting of the Approvals wherein the TGA failed and were known by Skerritt to have failed to have acted upon a rigorous evaluation of the totality of scientific and clinical evidence provided by Sponsors of the Covid vaccines as well as other evidence available, including that which may be specific to other countries before the granting of the respective Approvals;

Particulars

The TGA Policies breached arise specifically from the TGA Covid Vaccine Evidence Policy document particularised in Schedule A of the SOC.

(6) the granting of the Approvals wherein the TGA failed and were known by Skerritt to have failed to have carefully assessed the results of the Clinical Trials and the way in which the trials were conducted;

Particulars

Para. 90(g)(iv)(6) in Schedule D of the SOC.

(7) the granting of the Approvals wherein the TGA failed and were known by Skerritt to have failed to have ensured that the Clinical Trials had continued for an adequate period of time and not stopped too early to answer its scientific questions including the lipid nanoparticle biodistribution studies being stopped at 48 hours despite rising concentration levels and also the unblinding of the control group in the Pfizer study;

Particulars

The TGA Policies breached arise specifically from adopted the Clinical Trials Oversight Policy (EMA) particularised in Schedule A of the SOC.

(8) the granting of the Approvals wherein the TGA failed and were known by Skerritt to have failed to have rationally determined that the Clinical Trials were properly constructed so as to detect common and uncommon adverse reactions of the Vaccines and to address long-term risks of the Vaccines by utilising an appropriate sample size and duration;

Particulars

The TGA Policies breached arise specifically from the adopted Pharmacovigilance in Vaccine Approvals Policy (EMA) particularised in Schedule A of the SOC.

(9) the granting of the Approvals wherein the TGA failed and were known by Skerritt to have failed to have rationally determined that the Clinical Trials were properly constructed such that inclusion and exclusion criteria was relevant to the target population for vaccination as proposed and effected in Australia and as per the Vaccines' indicated recipient group;

Particulars

The TGA Policies breached arise specifically from the adopted Pharmacovigilance in Vaccine Approvals Policy (EMA) particularised in Schedule A of the SOC.

(10) the granting of the Approvals wherein the TGA failed and were known by Skerritt to have failed to have rationally determined that the results of the Clinical Trials established that the benefits of the Vaccine greatly outweighed the risks;

Particulars

Para. 90(g)(iv)(10) in Schedule D of the SOC.

(11) the granting of the Approvals wherein the TGA failed and were known by Skerritt to have failed to have required or obtained a high level of evidence from the Sponsor prior to Approvals;

Particulars

The TGA Policies breached arise specifically from the TGA Covid Vaccine Evidence Policy document particularised in Schedule A of the SOC.

(12) the granting of the Approvals wherein the TGA failed and were known by Skerritt to have failed to have established that the Vaccines prevent Covid disease through well-conducted clinical trials in humans by the Sponsors;

Particulars

The TGA Policies breached arise specifically from the TGA Covid Vaccine Evidence Policy document particularised in Schedule A of the SOC.

(13) the granting of the Approvals wherein the TGA had and were known by Skerritt to have had such data as to rationally determine or at least suspect that:

a) there were serious problems with the Vaccines;

b) an investigation was warranted but failed to do so;

c) suspension of the use of the Vaccines was warranted during the investigation but failed to do so;

d) notify the Australian population of safety concerns of the Vaccines through the publication of alerts on the TGA website, but failed to do so;

Particulars

The TGA Policies breached arise specifically from the Vaccine Regulation Policy document particularised in Schedule A of the SOC.

(14) the granting of the Approvals wherein the TGA failed and were known by Skerritt to have failed to have considered every ingredient of the Vaccines for safety or efficacy;

Particulars

Para. 90(g)(iv)(14) in Schedule D of the SOC.

(15) the granting of the Approvals provisionally wherein the TGA failed and were known by Skerritt to have failed to have obtained or considered preliminary clinical data in the Clinical Trials which rationally or otherwise established at the time of the Approvals that the benefit of early availability of the Vaccines outweighed the risk inherent in the fact that additional data was still required;

Particulars

Para. 90(g)(iv)(15) in Schedule D of the SOC.

(16) the granting of the Approvals provisionally wherein the TGA failed and were known by Skerritt to have failed to have properly considered:

a) the availability of alternative treatments for Covid;

b) the status of the pandemic; and

c) the epidemiology of the Virus in Australia and worldwide;

Particulars

The TGA Policies breached arise specifically from the TGA Covid Vaccine Evidence Policy document particularised in Schedule A of the SOC.

(17) the granting of the Approvals provisionally wherein the TGA failed and were known by Skerritt to have failed to have before the Approvals obtained and considered data which rationally established that the Clinical Trials established that the Vaccines:

a) very significantly reduced the incidence of Covid disease; and

b) reduced the transmission of disease between individuals, including from asymptomatic to uninfected individuals;

Particulars

The TGA Policies breached arise specifically from the TGA Covid Vaccine Evidence Policy document particularised in Schedule A of the SOC.

(18) the granting of the Approvals provisionally wherein the TGA failed and were known by Skerritt to have failed to have before the Approvals satisfactorily established the Vaccines' safety, efficacy and a positive risk/benefit balance based upon preliminary data from the Clinical Trials;

Particulars

Para. 90(g)(iv)(18) in Schedule D of the SOC.

(19) the granting of the Approvals provisionally wherein the TGA failed and were known by Skerritt to have failed to have before the Approvals rationally established the safety and efficacy of the Vaccines based upon data from the Clinical Trials provided by the Sponsors which was insufficient to allow the benefits of the Vaccines to be assessed against the risks identified by the evidence;

Particulars

Para. 90(g)(iv)(19) in Schedule D of the SOC.

(20) the granting of the Approvals provisionally wherein the TGA failed and were known by Skerritt to have failed to act upon properly and continuously reviewed safety and efficaciousness information collected from use in mass vaccination programs worldwide;

Particulars

Para. 90(g)(iv)(20) in Schedule D of the SOC.

(21) the granting of the Approvals wherein the TGA failed and were known by Skerritt to have failed to have before the Approvals rationally established a high level of safety as required for the Vaccines, so required because tolerance to risk is low as vaccines, including the Vaccines, are usually and in fact intended to be and were administered in Australia under the Department's control and management:

a) to otherwise healthy individuals;

b) to very young or vulnerable persons;

c) to almost the entire adult population of Australia; and

d) by mandate of vaccination with the Vaccines;

Particulars

The TGA Policies breached arise specifically from the adopted Pharmacovigilance in Vaccine Approvals Policy (EMA) particularised in Schedule A of the SOC.

(22) the granting of the Approvals spanning almost the entire age range of the Australian population wherein the TGA failed and were known by Skerritt to have failed to have prior to or after the Approvals, properly and rationally:

a) established the safety profile of the Vaccines within the various age categories which differ substantially within the target population;

b) addressed such variation by calculating the disproportionality of the risk of the Vaccines as compared to the background risk for illness from Covid in a similar age-specific group;

Particulars

Para. 90(g)(iv)(22) in Schedule D of the SOC.

h) undertook the Skerritt Approvals wherein in the circumstances of the factual matters pleaded at sub-paragraphs (a) to (g) herein:

i) the Purported Bases of Approval were in fact false;

ii) the procedures that were required by law to be observed in relation to the Skerritt Approvals, were not observed, being the Skerritt Approval Breaches;

iii) Skerritt did not have jurisdiction to undertake the Skerritt Approvals;

iv) there was no evidence or other material to rationally:

(1) justify the Skerritt Approvals;

(2) establish the Critical Vaccine Requirements; or

(3) establish the Purported Bases of Approvals;

v) the Skerritt Approvals was a purported exercise of a power:

(1) for a purpose other than a purpose for which the power was conferred, being to act for the public good;

(2) in excess of any power conferred;

(3) contrary to the public good;

(4) so unreasonable that no reasonable person could so exercise the power or alternatively, were legally unreasonable;

(5) inconsistent with an honest attempt to perform the functions of a public office;

vi) the Skerritt Approvals in the circumstances would cause the Vaccines to be distributed to and received by the Group Members:

(1) in the circumstances of the rationally established facts and knowledge of:

a) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

b) the Pre-Approval Established Critical Defects;

(2) thereby likely to cause harm to the Group Members.

vii) at no time had Skerritt:

(1) rationally established in fact the Critical Vaccine Requirements;

(2) held the rational belief that:

a) the Critical Vaccine Requirements had been rationally and satisfactorily established;

b) the relevant requirements of the provisions of the Act and Regulations in respect of the Approvals had been rationally and satisfactorily established;

viii) by reason of (i) to (vii) herein, the Skerritt Approvals undertaken by Skerritt were:

(1) patently unlawful and extraneous to power;

(2) likely to cause harm to the Group Members; and

(3) in breach of the duty to act for the public good;

i) in the premises, in undertaking the Skerritt Approvals, Skerritt:

i) knew of the factual matters pleaded at sub-paragraph (h) herein, or alternatively was recklessly indifferent as to the existence of those factual matters;

ii) was actuated by improper purposes contrary to the public good and thereby acted in bad faith;

iii) knew the Skerritt Approvals were unlawful and undertaken without any power to do so, or alternatively was recklessly indifferent as to whether the Skerritt Approvals were unlawful and undertaken without any power to do so;

iv) knew the Skerritt Approvals were likely to cause harm to the Group Members, or alternatively was recklessly indifferent as to whether the Skerritt Approvals likely to cause harm to the Group Members.

Particulars

Para. 90(i) in Schedule D of the SOC.

91. By reason of the factual matters pleaded in paragraph 90 herein, the acts, omissions and knowledge of Skerritt in the Skerritt Approvals in the circumstances of the Skerritt Approvals Misfeasance constituted misfeasance in public office.

SKERRITT - CONTINUING APPROVALS MISFEASANCE

92. Skerritt, in respect of each of the respective Continuing Approvals **("the Skerritt Continuing Approvals Misfeasance")**:

a) engaged in the conduct constituted by the Skerritt Continuing Approvals;

b) undertook the Skerritt Continuing Approvals upon the Purported Bases of Continuing Approval at the time of the respective Continuing Approvals;

Particulars

The Particulars of the Purported Bases of Approval and Continuing Approval as defined at Para. 50 in Schedule D of the SOC.

c) possessed no later than at the time of the respective Continuing Approvals the knowledge of the factual matters constituting:

i) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

ii) the Pre-Approval Established Critical Defects;

iii) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

iv) the Post-Approval Established Critical Defects;

v) the Known Approvals Assessment Failures;

vi) the Clinical Testing Failures.

Particulars

Para. 92(c) in Schedule D of the SOC.

d) undertook the Skerritt Continuing Approvals in circumstances wherein Skerritt at all material times from the time of the respective Approvals as an officer of the Commonwealth:

i) was subject to and bound by, and knew that he was subject to and bound by the obligations and positive duties in respect of such conduct arising under the relevant express and implied provisions of:

(1) the Act;

(2) the Regulations;

(3) the Conduct Legislation; and

(4) the TGA Policies.

Particulars

Acts Interpretation Act 1901 (Cth), s. 34AAA

Particulars of Adherence to TGA Policies as defined at Para. 90(d)(i) in Schedule D of the SOC.

ii) was at all times in respect of the Skerritt Continuing Approvals:

(1) purportedly acting pursuant to and in accordance with Skerritt's duties, responsibilities and obligations pleaded at paragraph 11 herein;

(2) where having empowered a person to act pursuant to authority delegated to them by Skerritt:

a) such person at law was thereby exercising Skerritt's power or purported power; and

b) such actions of that person thereby at law constituting the actions of Skerritt himself.

Particulars

Acts Interpretation Act 1901 (Cth) s. 34AB(1)(c)

iii) was empowered to, and further or alternatively, knew that the Secretary and any other person delegated the authority by the Secretary to exercise the Secretary's powers under s. 22F(1) and s. 30(1)(a) of the Act was empowered to:

(1) revoke the Approvals pursuant to s.22F(1) of the Act because at all times and continuously since the time of the Approvals the criteria prescribed by the regulations for the purposes of subsection 22D(2) were not, and at no time were, met in relation to the Vaccines, specifically because:

a) contrary to r. 10L(1)(a) of the Regulations:

i) it was at no time rationally established that Covid was in fact a life-threatening or seriously debilitating condition in the Australian population under 70 years of age;

ii) further or in the alternative it was rationally established that Covid was not in fact a life-threatening or seriously debilitating condition in the Australian population under 70 years of age;

b) contrary to r. 10L(1)(c) of the Regulations:

i) the preliminary clinical data nor any data for the Vaccines did not rationally establish that the Vaccines were likely to provide a major therapeutic advance because the known preliminary clinical data known at the time of and since the Approvals:

1) did not rationally establish the Critical Vaccine Requirements;

2) further or in the alternative, rationally established the Critical Vaccine Failures;

3) at no time tested for the specific purposes for which the Vaccines were to be used:

a) being any of the Vaccine Purposes;

b) other than protection against symptomatic Covid;

c) Skerritt, at no time held the rational belief that the criteria prescribed by r. 10L(1)(a) or r. 10L(1)(c) of the Regulations had been rationally or satisfactorily established;

Particulars

Para. 92(d)(iii)(1) in Schedule D of the SOC.

(2) cancel the Approvals pursuant to s.30(1)(a) of the Act because at all times and continuously since the time of the Approvals:

a) it was rationally established that a failure to cancel the Approvals would create an imminent risk of death, serious illness or serious injury to the Australian population;

b) by reason of sub-paragraph (a) herein, Skerritt knew and was rationally satisfied that a failure to cancel the Approvals would create an imminent risk of death, serious illness or serious injury to the Australian population.

Particulars

Para. 92(d)(iii)(2) in Schedule D of the SOC.

e) the Skerritt Continuing Approvals were undertaken by Skerritt:

i) purportedly for the proper purpose incident to his office that his actions in that office be undertaken consistently with:

(1) the Department Overarching Purpose;

(2) the TGA's Statutory Purpose;

(3) his duty to act for the public good;

ii) in circumstances wherein, the Skerritt Continuing Approvals were in fact inconsistent with the Department Overarching Purpose and the TGA's Statutory Purpose because they were made in the circumstances of Skerritt's knowledge of the Pre-Approval Established Critical Defects and the Post-Approval Established Critical Defects;

iii) thereby for an improper purpose:

(1) contrary to the public good;

(2) in breach of a duty to act for the public good;

Particulars

Para. 92(e) in Schedule D of the SOC.

f) at no time prior to the Skerritt Continuing Approvals or at all did Skerritt:

i) rationally establish in fact the Critical Vaccine Requirements;

ii) hold the rational belief that the Critical Vaccine Requirements had been rationally and satisfactorily established.

Particulars

Para. 92(f) in Schedule D of the SOC.

g) undertook the Skerritt Continuing Approvals in the circumstances of the factual matters and knowledge pleaded at sub-paragraphs (a) to (f) herein, thereby undertaking the Skerritt Continuing Approvals in, causing or materially contributing to the following breaches of the Conduct Legislation and TGA Policies

after the Approvals known to Skerritt **("the Skerritt Continuing Approval Breaches")**:

i) the ongoing and unresolved Skerritt Approval Breaches;

ii) the TGA failure to properly collaborate in monitoring the safety and effectiveness of Covid vaccines to assess new safety issues and take quick action to mitigate risks;

Particulars

The TGA Policies breached arise specifically from the TGA Covid Vaccine Evidence Policy document particularised in Schedule A of the SOC.

iii) the TGA failure to act upon the conclusions arising from the monitoring and assessment of the safety of Covid Vaccines after the Approvals by working closely on an ongoing basis with:

(1) health care professionals;

(2) public health authorities;

(3) the Sponsors.

Particulars

The TGA Policies breached arise specifically from the TGA Covid Vaccine Evidence Policy document particularised in Schedule A of the SOC.

iv) the TGA failure to act upon any additional pharmacovigilance activities required to:

(1) establish evidence of safety of the Vaccines as they are novel and contain a novel adjuvant;

(2) assess the risk of occurrence of rare or delayed onset local or systemic adverse reactions;

(3) detect the occurrence of auto-immune diseases and immune-mediated reactions resulting from a synergistic action of the adjuvant in the Vaccines and the biologically active antigen in the Virus;

(4) assess the effectiveness of the Vaccines in circumstances wherein the pre-Approvals data was limited;

(5) properly consider and understand the spontaneous reports to the adverse events registers including the DAEN and AusVaxSafety raising concerns that a higher than expected rate of vaccine failures

and breakthrough infections in certain risk groups exists in the Vaccines;

Particulars

The TGA Policies breached arise specifically from the adopted Pharmacovigilance in Vaccine Approvals Policy (EMA) particularised in Schedule A of the SOC.

v) the TGA failure to engage in post-Approvals assessment of Vaccines' efficacy and immunogenicity in order to obtain additional critical information on:

(1) waning immunity;

(2) long-term protection;

(3) cross-protective efficacy; and

(4) the most appropriate use of the vaccine.

Particulars

The TGA Policies breached arise specifically from the adopted Pharmacovigilance in Vaccine Approvals Policy (EMA) particularised in Schedule A of the SOC.

vi) the TGA failure in the known circumstances of newly identified risks and adverse events associated with the Vaccines evident in voluminous reporting, to:

(1) engage in any proper re-evaluation of the benefit of the Vaccines using all available data;

(2) estimate the impact of the new or changing risk on the benefit-risk profile of the Vaccines;

Particulars

The TGA Policies breached arise specifically from the adopted Pharmacovigilance in Vaccine Approvals Policy (EMA) particularised in Schedule A of the SOC.

vii) the TGA failure to properly and rationally classify reported adverse events associated with the Vaccines as causal:

(1) by dismissing such adverse events, including deaths, as not causally linked to the Vaccines;

(2) in breach of and contrary to the universally accepted benchmark of causality wherein a causally associated adverse event is any undesirable medical event:

a) that occurs during or after the administration or use of the Vaccines; and

b) for which there is at least a reasonable possibility of a causal relationship between the use of the vaccines and the event;

(3) in breach of and contrary to the universally accepted position that any spontaneous report of a TGA Defined Adverse Event by health professionals, patients or consumers are considered to be related adverse events as they convey the suspicions of the person reporting the information that there is a causal relationship;

(4) in breach of the universally accepted obligation to properly risk assess and enter into the appropriate database for future reference those adverse events which can then be used by the TGA to identify safety signals;

(5) failure or refusal to implement the regulatory standard of causality that:

a) spontaneous adverse events reports are considered to have implied causality;

b) where it is not clear whether a causal association is suspected, spontaneous reports are presumed to mean that the Vaccines and the adverse event are possibly related and meet the definition of an adverse reaction, unless the reporter explicitly states otherwise;

c) a safety signal can arise from a single report of a Serious Adverse Event **("Serious Adverse Event" - defined para. 27 Schedule B)** if there is a possible causal association to the Vaccines;

Particulars

Para. 92(g)(vii) in Schedule D of the SOC.

viii) the TGA failure to properly and rationally:

(1) identify the safety signals which arose in respect of the Vaccines evident in the data reported post-Approvals in respect of the Vaccines which indicated:

a) safety concerns;

b) reduced efficacy or effectiveness; and/or

c) Vaccines' failures;

(2) undertake a detailed evaluation to establish the possible role of the Vaccines in causing adverse events;

(3) take regulatory action to ensure that the Vaccines continue to possess acceptable safety and efficacy/performance for their intended use where safety concerns relating to the Vaccines were identified;

(4) communicate with the public in a timely way or at all regarding the emerging vaccine safety signals arising from reports of adverse events following the Vaccines;

Particulars

Para. 92(g)(viii) in Schedule D of the SOC.

ix) the TGA failure to properly and rationally:

(1) act upon safety material in relation to the Vaccines obtained through worldwide medical literature and data;

(2) act upon obvious safety signals evident in patterns of adverse events that warranted further investigation arising from:

a) previously unrecognised safety issues associated with the Vaccines;

b) a change in the frequency or severity of a known safety issue associated with the Vaccines; or

c) identification of a new 'at risk' group associated with the Vaccines.

Particulars

Para. 92(g)(ix) in Schedule D of the SOC.

xi) the TGA and the Department failure to properly and rationally:

(1) undertake further investigations wherein deaths or serious events needing hospitalisation occurred within days to weeks after vaccination with the Vaccines;

(2) gather as much information as possible about those persons in sub-paragraph (1) herein above including by:

a) liaising with the person's treating general practitioner, treating medical specialists and hospital at which they received treatment post-vaccination with the Vaccines;

b) convening an expert panel of doctors to compile a full clinical dossier on the injured or deceased person;

(3) review the full clinical dossier of those persons in sub-paragraph (1) herein above and to determine whether VSIG needed to:

a) review the case in detail; and

b) assess if the Vaccines caused the adverse event;

Particulars

The TGA Policies breached arise specifically from the National Vaccines Adverse Events Reporting Procedure document particularised in Schedule A of the SOC.

Particulars of the Skerritt Continuing Approvals Breaches are contained in Para. 92(g) in Schedule D of the SOC.

h) undertook the Skerritt Continuing Approvals wherein in the circumstances of the factual matters pleaded at sub-paragraphs (a) to (g) herein:

i) the Purported Bases of Continuing Approval were in fact false;

ii) the procedures that were required by law to be observed in relation to the Skerritt Approvals and the Skerritt Continuing Approvals were not observed, being the Skerritt Continuing Approval Breaches;

iii) Skerritt did not have jurisdiction to undertake the Skerritt Approvals and the Skerritt Continuing Approvals;

iv) there was no evidence or other material to rationally:

(1) justify the Skerritt Approvals or Skerritt Continuing Approvals;

(2) establish the Critical Vaccine Requirements; or

(3) establish the Purported Bases of Approvals;

v) the Skerritt Continuing Approvals was a purported exercise of a power:

(1) for a purpose other than a purpose for which the power was conferred, being to act for the public good;

(2) in excess of any power conferred;

(3) contrary to the public good;

(4) so unreasonable that no reasonable person could so exercise the power or alternatively, were legally unreasonable;

(5) inconsistent with an honest attempt to perform the functions of a public office;

vi) the Skerritt Continuing Approvals in the circumstances would cause the Vaccines to be distributed to and received by the Group Members:

(1) in the circumstances of the rationally established facts and knowledge of:

a) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

b) the Pre-Approval Established Critical Defects;

c) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

d) the Post-Approval Established Critical Defects;

(2) thereby likely to cause harm to the Group Members.

vii) at no time had Skerritt:

(1) rationally established in fact the Critical Vaccine Requirements;

(2) held the rational belief that:

a) the Critical Vaccine Requirements had been rationally and satisfactorily established;

b) the relevant requirements of the provisions of the Act and Regulations in respect of the Approvals had been rationally and satisfactorily established;

viii) by reason of the matters pleaded at sub-paragraphs (i) to (vii) herein, the Skerritt Continuing Approvals undertaken by Skerritt were:

(1) patently unlawful and extraneous to power;

(2) likely to cause harm to the Group Members; and

(3) in breach of the duty to act for the public good;

i) in the premises, in undertaking the Skerritt Continuing Approvals, Skerritt:

i) knew of the factual matters pleaded at sub-paragraph (h) herein, or alternatively was recklessly indifferent as to the existence of those factual matters;

ii) was actuated by improper purposes contrary to the public good and thereby acted in bad faith;

iii) knew the Skerritt Continuing Approvals were unlawful and undertaken without any power to do so, or alternatively was recklessly indifferent as to whether the Skerritt Continuing Approvals were unlawful and undertaken without any power to do so;

iv) knew the Skerritt Continuing Approvals were likely to cause harm to the Group Members, or alternatively was recklessly indifferent as to whether the Skerritt Continuing Approvals were likely to cause harm to the Group Members.

Particulars

Para. 92(i) in Schedule D of the SOC.

93. By reason of the factual matters pleaded in paragraph 92 herein, the acts, omissions and knowledge of Skerritt in the Skerritt Continuing Approvals in the circumstances of the Skerritt Continuing Approvals Misfeasance constituted misfeasance in public office.

SKERRITT – MISLEADING STATEMENTS MISFEASANCE

94. Skerritt, with respect to the Misleading Vaccines Statements **("the Skerritt Misleading Statements Misfeasance")**:

a) engaged in the conduct constituted by the Skerritt Issued Misleading Vaccines Statements;

b) Skerritt prior to and at the time of the publication of the Skerritt Issued Misleading Vaccines Statements, possessed the knowledge of the factual matters constituting:

i) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

ii) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

iii) the Pre-Approval Established Critical Defects;

iv) the Post-Approval Established Critical Defects;

Particulars

Para. 94(b) in Schedule D of the SOC.

c) caused the Skerritt Issued Misleading Vaccines Statements to be made and thereby the Misleading Public Message to be made **("the Known Established Falsity of the Misleading Public Message")**:

i) which was in every respect at all relevant times:

(1) rationally established to be false, and further or alternatively not rationally established to be true;

(2) known by him to be rationally established to be false and further or alternatively not rationally established to be true;

Particulars

Para. 94(c)(i) in Schedule D of the SOC.

ii) in the circumstances of sub-paragraph (i) herein above because of the following factual matters:

(1) the Vaccines were not unquestionably or otherwise safe because the Vaccines were:

a) rationally established to be unsafe;

b) further or alternatively, not rationally established to be safe.

Particulars

Para. 94(c)(ii)(1) in Schedule D of the SOC.

(2) the Vaccines were not so safe that anything other than the most mild of side effects almost never occurred because in fact the Vaccines were:

a) rationally established to:

i) not infrequently cause serious side effects, permanent injury, and death; and

ii) cause unprecedented volumes of side effects;

b) further or alternatively, did not rationally establish that the Vaccines:

i) infrequently caused serious side effects, permanent injury, and death; and

ii) did not cause unprecedented volumes of side effects;

Particulars

Para. 94(c)(ii)(2) in Schedule D of the SOC.

(3) the Vaccines were not completely or almost completely effective to prevent infection from the Virus because in fact the Vaccines were:

a) rationally established to not be at least substantially effective to prevent infection from the Virus;

b) further or alternatively, not rationally established to be at least substantially effective to prevent infection from the Virus;

Particulars

Para. 94(c)(ii)(3) in Schedule D of the SOC.

(4) the Vaccines were not completely or almost completely effective to prevent transmission of the Virus because in fact the Vaccines were:

a) rationally established to not be at least substantially effective to prevent transmission of the Virus;

b) further or alternatively were not rationally established to be at least substantially effective to prevent transmission of the Virus;

Particulars

Para. 94(c)(ii)(4) in Schedule D of the SOC.

(5) the Vaccines were not completely or almost completely effective to prevent serious Covid because in fact the Vaccines were:

a) rationally established to not be at least substantially effective to prevent serious Covid;

b) further or alternatively not rationally established to be at least substantially effective to prevent serious Covid;

Particulars

Para. 94(c)(ii)(5) in Schedule D of the SOC.

(6) the Vaccines were not completely or almost completely effective to prevent death from Covid because in fact the Vaccines were:

a) rationally established to not be at least substantially effective to prevent death from Covid;

b) further or alternatively not rationally established to be at least substantially effective to prevent death from Covid;

Particulars

Para. 94(c)(ii)(6) in Schedule D of the SOC.

(7) prior to the Approvals, the Vaccines had not been subjected to the most rigorous assessment for safety and efficacy possible because at the relevant times it was rationally established that the assessment of the Vaccines involved:

a) assessment which was limited to the data provided by the Sponsors absent any independent testing by the TGA or the Respondents;

b) no patient level data being provided to the Respondents in the course of the Approvals processes or at all;

c) assessed data being limited solely to short-term data;

d) no clinical testing of:

i) prevention of transmission of the Virus;

ii) prevention of infection with the Virus;

iii) prevention of serious illness from Covid;

iv) prevention of hospitalisation from Covid;

v) prevention of death from Covid;

vi) use of the Vaccines in those for whom use was intended being the Untested Groups, including in:

1) pregnant women;

2) immunocompromised people;

3) people with certain pre-existing health conditions;

4) people receiving other vaccines concurrently;

5) people with natural immunity resultant from prior infection with the Virus;

vii) long-term efficacy;

viii) genotoxicity;

ix) carcinogenicity;

x) long-term safety.

xi) extraordinary and unacceptable risks associated with the Vaccines being:

1) risks of serious adverse events;

2) risk of death;

3) unquantified and known risk of incorporation of the mRNA in the mRNA Vaccines into the human genome with the potential to cause intergenerational effects;

Particulars

Para. 94(c)(ii)(7) in Schedule D of the SOC.

(8) prior to the Approvals, the Vaccines not had been subjected to an assessment procedure equivalent to that applied all other approved therapeutic products in Australia because in fact, it was rationally established that:

a) the approval assessment process under the Act for provisional approval of the Vaccines as in the Approvals was profoundly different and less rigorous as allowed by s. 25(1)(d)(i) in that unlike the regular approvals process, provisional approval evaluation was based only upon limited and short-term preliminary clinical data as opposed to fulsome and long term data;

b) the Approvals were undertaken:

i) in an unprecedentedly truncated time frame;

ii) with unprecedented limitations of evidence for the Approvals being short-term and lacking fundamental evidence pleaded above at sub-paragraph (9) herein;

Particulars

Para. 94(c)(ii)(8) in Schedule D of the SOC.

(9) matters known by Skerritt or alternatively to which he had reckless indifference in respect of testing prior to the Approvals or known data in respect of safety or efficacy of the Vaccines were of objective cause for concern because at the relevant times they rationally established that:

a) the Vaccines were:

i) not established to be safe for any of the Vaccine Purposes;

ii) not established to be effective for any of the Vaccine Purposes;

b) further or in the alternative, the Vaccines were:

i) established to be unsafe for any of the Vaccine Purposes;

ii) established to be ineffective for any of the Vaccine Purposes;

Particulars

Para. 94(c)(ii)(9) in Schedule D of the SOC.

(10) people who did not take the Vaccines would not generally be at a high risk of dying or becoming seriously ill from Covid because in fact:

a) it was rationally established that:

i) the Vaccines were not at least substantially effective to prevent death or serious illness from Covid;

ii) the unvaccinated were not more likely than the vaccinated to become seriously ill or die from Covid;

iii) Covid disease itself was generally not causative of a high risk of serious illness or death in the general population at any time;

b) further or alternatively, it was not rationally established that:

i) the Vaccines were at least substantially effective to prevent death or serious illness from Covid;

ii) the unvaccinated were more likely than the vaccinated to become seriously ill or die from Covid;

iii) Covid disease itself was generally causative of a high risk of serious illness or death in the general population at any time;

Particulars

Para. 94(c)(ii)(10) in Schedule D of the SOC.

(11) for everyone in Australia the risks of serious illness and death from not taking the Vaccines were not significantly higher than the risks of injury from taking the Vaccines because in fact:

a) it was rationally established, that the risk of injury from the Vaccines was significantly higher than the risks of serious illness or death from Covid at all times:

i) for the entirety of the Australian population; and

ii) further or alternatively, at least those under the age of 70 years; or alternatively;

b) further or alternatively it was not rationally established that the risks of serious illness and death from not taking the Vaccines were not significantly higher than the risks of injury from taking the Vaccines at all times:

i) for the entirety of the Australian population; and

ii) further or alternatively, at least those under the age of 70 years;

Particulars

Para. 94(c)(ii)(11) in Schedule D of the SOC.

(12) taking the Vaccines was not essential to protect others from Covid because in fact:

a) it was rationally established that the Vaccines did not prevent transmission of or infection with the Virus;

b) further or alternatively, it was not rationally established that the Vaccines prevented transmission of or infection with the Virus;

Particulars

Para. 94(c)(ii)(12) in Schedule D of the SOC.

(13) the data known by Skerritt or alternatively to which he had reckless indifference in respect of post-Approvals side effects from the Vaccines was of actual material concern to the Australian public because at the relevant times they rationally established:

a) an unprecedented rate of side effects and injury to recipients being caused by the Vaccines post-release to the Australian population;

b) a rate of side effects and injury amongst recipients of the Vaccines that was exponentially higher than other similar vaccines;

c) prolific numbers of reported adverse events, serious adverse events and deaths associated with the Vaccines;

d) the occurrence of a rate of injury amongst recipients of the Vaccines significantly higher than the rate of serious illness and death from Covid;

Particulars

Para. 94(c)(ii)(13) in Schedule D of the SOC.

(14) that public reporting and statements of the Respondents pre-Approvals and post-Approvals in respect of the safety, efficacy and risk-benefit profile of the Vaccines does not disclose to the Australian public the most accurate and comprehensively evident representation of those matters because:

a) in fact, and the facts known to the Respondents or alternatively to which the Respondents had reckless indifference at the relevant times rationally established:

i) the Pre-Approval Established Critical Defects;

ii) the Post-Approval Established Critical Defects;

b) the Respondents at no time published accurately or at all those matters pleaded in (a) above to the Australian public;

Particulars

Para. 94(c)(ii)(14) in Schedule D of the SOC.

d) in each and every instance of the Skerritt Issued Misleading Vaccines Statements, such statement was made by Skerritt in circumstances wherein:

i) they were made for the purposes and intent of the Misleading Vaccines Statements Purpose;

Particulars

Particulars of the Misleading Vaccines Statements Purpose as defined at Para. 50 in Schedule D of the SOC.

ii) he intended, knew, expected and considered it likely that as a natural and probable consequence of the publication of those respective statements, that the Australian population would, and did in fact:

(1) rely upon those statements in determining whether to take one or more of the Vaccines;

(2) determine to take one or more of the Vaccines;

(3) take one or more of the Vaccines;

Particulars

Para. 94(d) in Schedule D of the SOC.

e) the Skerritt Issued Misleading Vaccines Statements were made by Skerritt:

i) purportedly incident to the powers granted to Skerritt in his office;

ii) purportedly acting pursuant to and in accordance with Skerritt's duties, responsibilities and obligations pleaded at paragraph 11 herein;

iii) whilst Skerritt remained subject to and bound by, and knew that he was subject to and bound by the obligations and positive duties in respect of such conduct arising under the relevant express and implied provisions of the Conduct Legislation;

iv) whilst not acting in the making of those statement in performance or purported performance of, or in relation to any exercise of Skerritt's duties or powers arising under the Act or the Regulations;

v) purportedly for the proper purpose incident to his office of the Department Overarching Purpose and the public good;

vi) in circumstances wherein, Skerritt undertook the Skerritt Issued Misleading Vaccines Statements:

(1) for the Misleading Statements Purpose;

(2) that were in circumstances of the facts and knowledge pleaded and particularised at sub-paragraphs (b) to (d) herein above, contrary to:

a) the Department Overarching Purpose;

b) the Conduct Legislation, in breaches constituted by the Skerritt Public Governance Breaches;

c) the public good;

vii) thereby, for an improper purpose being:

(1) contrary to the public good; and

(2) in breach of a duty to act for the public good.

f) at no time prior to each of the Skerritt Issued Misleading Vaccines Statements or at all did Skerritt:

i) rationally establish in fact:

(1) the Critical Vaccine Requirements;

(2) the Misleading Public Message.

ii) hold the rational belief that:

(1) the Critical Vaccine Requirements had been rationally and satisfactorily established;

(2) the Misleading Public Message was in fact rationally established in fact as true.

Particulars

Para. 94(f) in Schedule D of the SOC.

g) the making of the Skerritt Issued Misleading Vaccines Statements undertaken by Skerritt in every case were:

i) misleading to the Australian public including the Group Members;

ii) likely to induce the Group Members to:

(1) consider the Vaccines to have satisfactorily established the Critical Vaccine Requirements; and

(2) receive the Vaccines, and

(3) suffer loss and damage.

Particulars

Para. 94(g) in Schedule D of the SOC.

h) undertook the Skerritt Issued Misleading Vaccines Statements wherein in the circumstances of the factual matters and knowledge pleaded at sub-paragraphs (a) to (g) herein:

i) the Misleading Public Message was in fact false;

ii) the statements were made in breach of the duty to act for the public good;

iii) Skerritt did not have jurisdiction to undertake the Skerritt Issued Misleading Vaccines Statements;

iv) there was no evidence or other material to rationally justify the Misleading Public Message or the making of the Skerritt Issued Misleading Vaccines Statements;

v) the Skerritt Issued Misleading Vaccines Statements were in breach of the Conduct Legislation;

vi) the Skerritt Issued Misleading Vaccines Statements was a purported exercise of a power:

(1) for a purpose other than a purpose for which the power was conferred, being to act for the public good;

(2) in excess of any power conferred;

(3) contrary to the public good;

(4) so unreasonable that no reasonable person could so exercise the power or alternatively, were legally unreasonable;

(5) inconsistent with an honest attempt to perform the functions of a public office;

Particulars

Para. 94(h)(vi) in Schedule D of the SOC

vii) the Skerritt Issued Misleading Vaccines Statements in the circumstances would cause the Vaccines to be distributed to and received by the Group Members:

(1) in the circumstances of the rationally established facts and knowledge of:

a) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

b) the Pre-Approval Established Critical Defects;

c) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

d) the Post-Approval Established Critical Defects;

(2) thereby likely to loss and cause harm to the Group Members.

viii) at no time had Skerritt:

(1) rationally established in fact the Critical Vaccine Requirements or the veracity of the Misleading Public Message;

(2) held the rational belief that:

a) the Critical Vaccine Requirements had been rationally and satisfactorily established;

b) the Misleading Public Message was true;

ix) by reason of the matters pleaded at sub-paragraphs (i) to (ix) herein, the Skerritt Issued Misleading Vaccines Statements undertaken by Skerritt were:

(1) patently unlawful and extraneous to power;

(2) likely to cause harm to the Group Members; and

(3) in breach of the duty to act for the public good;

i) in the premises, in undertaking the Skerritt Issued Misleading Vaccines Statements, Skerritt:

i) knew of the factual matters pleaded at sub-paragraph (h) herein, or alternatively was recklessly indifferent as to the existence of those factual matters;

ii) was actuated by improper purposes contrary to the public good and thereby acted in bad faith;

iii) knew the making of the Skerritt Issued Misleading Vaccines Statements were unlawful and undertaken without any power to do so, or alternatively was recklessly indifferent as to whether the making of the Skerritt Issued Misleading Vaccines Statements were unlawful and undertaken without any power to do so;

iv) knew the making of the Skerritt Issued Misleading Vaccines Statements were likely to cause harm to the Group Members, or alternatively was recklessly indifferent as to whether the making of the Skerritt Issued Misleading Vaccines Statements was likely to cause harm to the Group Members.

Particulars

Para. 94(i) in Schedule D of the SOC.

95. By reason of the factual matters pleaded in paragraph 94 herein, the acts and knowledge of Skerritt in the Skerritt Issued Misleading Statements in the circumstances of the Skerritt Misleading Statements Misfeasance constituted misfeasance in public office.

THE SECRETARY - APPROVALS MISFEASANCE

96. The Secretary, in respect of the respective Approvals **("the Secretary Approvals Misfeasance")**:

a) engaged in the conduct constituted by the Secretary Approvals;

b) undertook the Secretary Approvals upon the Purported Bases of Approval at the time of the respective Approvals;

Particulars

Particulars of the Purported Bases of Approval and Continuing Approval as defined at Para. 50 in Schedule D

of the SOC.

c) possessed no later than at the time of the respective Approvals the knowledge of the factual matters constituting:

i) the Known Serious Vaccines Risks and Conduct - Pre-Approval;

ii) the Pre-Approval Established Critical Defects; and

iii) the Known Approvals Assessment Failures.

Particulars

Para. 96(c) in Schedule D of the SOC.

d) undertook the Secretary Approvals in circumstances wherein the Secretary at all material times as an officer of the Commonwealth:

i) was subject to and bound by, and knew that he was subject to and bound by the obligations and positive duties in respect of such conduct arising under the relevant express and implied provisions of:

(1) the Act;

(2) the Regulations;

(3) the Conduct Legislation;

(4) the TGA Policies, in circumstances where those policies were and are:

a) adopted and widely publicised by the Commonwealth as being for the purposes of ensuring compliance with the powers and responsibilities contained expressly and impliedly under the Act and good government;

b) widely publicised by the Commonwealth and the Respondents as being the basis upon which the Approvals and the Continuing Approvals would be made;

c) in accordance with which the Secretary was bound to act:

i) in good faith and with reasonable care;

ii) pursuant to the conduct provisions of the Conduct Legislation;

iii) pursuant to s. 57(2)(g) of the *Public Service Act 1999* (Cth).

Particulars

Para. 96(d)(i) in Schedule D of the SOC.

ii) was at all material times in respect of the Secretary Approvals:

(1) purportedly acting pursuant to and in accordance with the Secretary's duties, obligations and responsibilities pleaded at paragraph 10 herein;

(2) purportedly acting pursuant to a power incident to the Secretary's office as secretary of the Department;

(3) acting purportedly pursuant to powers and in accordance with the Secretary's obligations arising in the exercise of such powers:

a) under the Conduct Legislation;

b) in accordance with the publicly promulgated TGA Policies;

(4) providing advices and support to Hunt, the Department and the Commonwealth across the full range of matters relating to the Vaccines including the:

a) safety and efficacy of the Vaccines; and

b) compliance of the Applications with the provisions of the Act;

(5) the "public face of Australia's fight against Covid";

(6) chairman of the Science and Industry Technical Advisory Group which was at all times tasked with and in fact providing advice to the Commonwealth as to the scientific validity or otherwise of research into the safety and effectiveness of potential Covid-19 vaccines;

(7) when such power was being exercised by a person delegated by the Secretary to do so under any act of parliament:

a) the Secretary in that instance in fact personally exercising his power or purported power; and

b) the Secretary in that instance in fact personally taking those actions;

(8) personally directing the actions of any person acting pursuant to a power or purported power delegated by him under the Act;

Particulars

Act s. 57(4)

Acts Interpretation Act 1901 (Cth) s. 34AB(1)(c)

e) the Secretary Approvals were undertaken by the Secretary:

i) purportedly for the proper purpose incident to his office that his actions in that office be undertaken consistently with:

(1) the Department Overarching Purpose;

(2) the TGA's Statutory Purpose;

(3) his duty to act for the public good;

ii) in circumstances wherein, the Secretary Approvals were in fact inconsistent with the Department Overarching Purpose and the TGA's Statutory Purpose

because they were made in the circumstances of the facts of and the Secretary's knowledge of the Pre-Approval Established Critical Defects;

iii) thereby for an improper purpose:

(1) contrary to the public good;

(2) in breach of a duty to act for the public good.

Particulars

Para. 96(e) in Schedule D of the SOC.

f) at no time prior to the Secretary Approvals or at all did the Secretary:

i) rationally establish the Critical Vaccine Requirements;

ii) hold the rational belief that the Critical Vaccine Requirements had been rationally and satisfactorily established;

Particulars

Para. 96(f) in Schedule D of the SOC.

g) undertook the Secretary Approvals in the circumstances of the factual matters and knowledge pleaded at sub-paragraphs (a) to (f) herein, thereby undertaking the Secretary Approvals **("the Secretary Approval Breaches")**:

i) in, causing or materially contributing to breaches of the express provisions of the Act, specifically the Statutory Obligations, and thereby acting unlawfully by causing approval and registration of the Vaccines for use by the Australian public in the known circumstances of the Approvals Statutory Breaches;

Particulars

Para. 96(g)(i) in Schedule D of the SOC.

ii) in, causing or materially contributing to the breach of the widely publicised TGA responsibilities and obligations relating to the Approvals, being the Approvals TGA Functions Breaches;

Particulars

Para. 96(g)(ii) in Schedule D of the SOC.

iii) in breach of the express provisions of the Conduct Legislation to which he was at all times bound in undertaking the Secretary Approvals, specifically undertaking the Secretary Approvals in the circumstances of the matters pleaded at sub-paragraphs (a) to (g)(ii) herein thereby **("the Secretary Public Governance Breaches")**:

(1) failing to provide the Commonwealth with advice that is frank, honest, timely and based upon the best available evidence;

Particulars

Para. 96(g)(iii)(1) in Schedule D of the SOC.

(2) acting in breach of the statutory legal obligations of the *Public Service Act 1999* and/or the and the *Parliamentary Service Act 1999* and the relevant Code of Conduct, under which his genuine belief or intent that the actions were proper is irrelevant to such breach, by:

Particulars

Para. 96(g)(iii)(2) in Schedule D of the SOC.

a) failing to act honestly and with integrity in connection with his position within the Department;

Particulars

Para. 96(g)(iii)(2)(a) in Schedule D of the SOC.

b) failing to act with care and diligence in connection with those acts and omissions by failing to act:

i) with serious attention and solicitude to those matters;

ii) earnest effort to accomplish the purposes for which the powers are granted;

iii) reasonably, such that the Secretary's actions were so unreasonable that no reasonable person could have taken them;

Particulars

Para. 96(g)(iii)(2)(b) in Schedule D of the SOC.

iv) within Australian law;

Particulars

s.13(4) of the *Public Service Act 1999* (Cth) and the *Parliamentary Service Act 1999* (Cth).

(3) acting in breach of the statutory legal obligations of the *Public Governance, Performance and Accountability Act 2013*(Cth), by:

a) acting unlawfully by failing, pursuant to his statutory duty, to exercise his powers, perform his functions and discharge his duties:

i. with the degree of care and diligence that a reasonable person would exercise;

ii. honestly, in good faith and for a proper purpose;

Particulars

Para. 96(g)(iii)(3) in Schedule D of the SOC.

(4) further acting unlawfully as secretary of the Department by:

a) managing the affairs of the Department in a manner which was not effective or ethical;

Particulars

In breach of s. 57(2)(a) of the *Public Service Act 1999*

b) failing to advise Hunt or the Commonwealth as to the critical and dangerous matters arising in respect of the Approvals relating to safety, efficacy, necessity and risk-benefit pleaded at sub-paragraphs (c) and (f) herein above;

Particulars

In breach of s. 57(2)(b) of the *Public Service Act 1999*

c) failing to implement measures that ensured the Department complied with the law in respect of the Approvals;

Particulars

In breach of s. 57(2)(c) of the *Public Service Act 1999*

d) failing to manage the Department in a way that was not inconsistent with Commonwealth policies, specifically the TGA Policies;

Particulars

In breach of s. 57(2)(g) of the *Public Service Act 1999*

e) failing in his duty to govern the Department in a way that promotes the achievement of the purposes of the entity, being a failure to promote the health and wellbeing of the Australian public;

Particulars

In breach of s.15(1)(b) of the *Public Governance, Performance and Accountability Act 2013* (Cth)

See also para. 96(g)(iii)(4) in Schedule D of the SOC.

iv) acting in breach of the express provisions of the TGA Policies by undertaking the Approvals manifesting the TGA Policies Approvals Breaches;

Particulars

Para. 96(g)(iv) in Schedule D of the SOC.

h) undertook the Secretary Approvals wherein in the circumstances of the factual matters pleaded at sub-paragraphs (a) to (g) herein:

i) the Purported Bases of Approval were in fact false;

ii) the procedures that were required by law to be observed in relation to the Secretary Approvals were not observed, being the Secretary Approval Breaches;

iii) the Secretary did not have jurisdiction to undertake the Secretary Approvals;

iv) there was no evidence or other material to rationally:

(1) justify the Secretary Approvals;

(2) establish the Critical Vaccine Requirements; or

(3) establish the Purported Bases of Approvals;

v) the Secretary Approvals was a purported exercise of a power:

(1) for a purpose other than a purpose for which the power was conferred, being to act for the public good;

(2) in excess of any power conferred;

(3) contrary to the public good;

(4) so unreasonable that no reasonable person could so exercise the power or alternatively, were legally unreasonable;

(5) inconsistent with an honest attempt to perform the functions of a public office;

vi) the Secretary Approvals in the circumstances would cause the Vaccines to be distributed to and received by the Group Members:

(1) in the circumstances of the rationally established facts and knowledge of:

a) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

b) the Pre-Approval Established Critical Defects;

(2) thereby likely to cause harm to the Group Members.

vii) at no time had the Secretary:

(1) rationally established in fact the Critical Vaccine Requirements;

(2) held the rational belief that:

a) the Critical Vaccine Requirements had been rationally and satisfactorily established;

b) the relevant requirements of the provisions of the Act and Regulations in respect of the Approvals had been rationally and satisfactorily established;

viii) by reason of (i) to (vii) herein, the Secretary Approvals undertaken by the Secretary were:

(1) patently unlawful and extraneous to power;

(2) likely to cause harm to the Group Members; and

(3) in breach of the duty to act for the public good;

i) in the premises, in undertaking the Secretary Approvals, the Secretary:

i) knew of the factual matters pleaded at sub-paragraph (h) herein, or alternatively was recklessly indifferent as to the existence of those factual matters;

ii) was actuated by improper purposes contrary to the public good and thereby acted in bad faith;

iii) knew the Secretary Approvals were unlawful and undertaken without any power to do so, or alternatively was recklessly indifferent as to whether the Secretary Approvals were unlawful and undertaken without any power to do so;

iv) knew the Secretary Approvals were likely to cause harm to the Group Members, or alternatively was recklessly indifferent as to whether the Secretary Approvals were likely to cause harm to the Group Members.

Particulars

Para. 96(i) in Schedule D of the SOC.

97. By reason of the factual matters pleaded in paragraph 96 herein, the acts, omissions and knowledge of the Secretary in the Secretary Approvals in the circumstances of the Secretary Approvals Misfeasance constituted misfeasance in public office.

THE SECRETARY - CONTINUING APPROVALS MISFEASANCE

98. The Secretary, in respect of each of the respective Continuing Approvals **("the Secretary Continuing Approvals Misfeasance")**:

a) engaged in the conduct constituted by the Secretary Continuing Approvals;

b) undertook the Secretary Continuing Approvals upon the Purported Bases of Continuing Approval at the time of the respective Continuing Approvals;

Particulars

The Particulars of the Purported Bases of Approval and Continuing Approval as defined at Para. 50 in Schedule D of the SOC.

c) possessed no later than at the time of the respective Continuing Approvals the knowledge of the factual matters constituting:

i) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

ii) the Pre-Approval Established Critical Defects;

iii) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

iv) the Post-Approval Established Critical Defects;

v) the Known Approvals Assessment Failures;

vi) the Clinical Testing Failures.

Particulars

Para. 98(c) in Schedule D of the SOC.

d) undertook the Secretary Continuing Approvals in circumstances wherein the Secretary at all material times from the time of the respective Approvals as an officer of the Commonwealth:

i) was subject to and bound by, and knew that he was subject to and bound by the obligations and positive duties in respect of such conduct arising under the relevant express and implied provisions of:

(1) the Act, particularly the express discretion to exercise the Secretary's Power to Suspend or Cancel, which carried with it an implied obligation to exercise that power where there is imminent risk of death, serious illness or serious injury to the Australian population;

(2) the Regulations;

(3) the Conduct Legislation; and

(4) the TGA Policies;

Particulars

Para. 98(d)(i) in Schedule D of the SOC.

ii) was at all times in respect of the Secretary Continuing Approvals:

(1) purportedly acting pursuant to and in accordance with the Secretary's duties, obligations and responsibilities pleaded at paragraph 10 herein;

(2) acting purportedly pursuant to a power incident to his office as secretary of the Department;

(3) acting purportedly pursuant to powers and in accordance with his obligations arising in the exercise of such powers:

a) under the Conduct Legislation;

b) in accordance with the publicly promulgated TGA Policies;

(4) providing advices and support to Hunt, the Department and the Commonwealth across the full range of matters relating to the Vaccines including the:

a) safety and efficacy of the Vaccines; and
b) compliance of the Applications with the provisions of the Act;

(5) the "public face of Australia's fight against Covid";

(6) chairman of the Science and Industry Technical Advisory Group which was at all times tasked with and in fact providing advice to the Commonwealth as to the scientific validity or otherwise of research into the safety and effectiveness of potential COVID-19 vaccines;

(7) in fact personally exercising his power or purported power under any act of parliament when such power was being exercised by a person delegated by him to do so; and

(8) deemed to be personally taking the actions of any person acting pursuant to a power or purported power delegated by him under any act of parliament and actually or purportedly exercising that power;

(9) personally directing the actions of any person acting pursuant to a power or purported power delegated by him under the Act.

Particulars

Act s. 57(4)

Acts Interpretation Act 1901 (Cth) s. 34AB(1)(c)

iii) was empowered, and further or alternatively, delegated the authority to exercise the Secretary's powers, under s. 22F(1) and s. 30(1)(a) of the Act to another person to:

(1) revoke the Approvals pursuant to s.22F(1) of the Act because at all times and continuously since the time of the Approvals the criteria prescribed by the Regulations for the purposes of subsection 22D(2) were not, and at no time were, met in relation to the Vaccines, specifically because:

a) contrary to r. 10L(1)(a) of the Regulations:

i) it was at no time rationally established that Covid was in fact a life-threatening or seriously debilitating condition in the Australian population under 70 years of age;

ii) further or in the alternative it was rationally established that Covid was not in fact a life-threatening or seriously debilitating condition in the Australian population under 70 years of age;

b) contrary to r. 10L(1)(c) of the Regulations:

i) the preliminary clinical data nor any data for the Vaccines did not rationally establish that the Vaccines were likely to provide a major therapeutic advance because the preliminary clinical data known at the time of and since the Approvals:

1. did not rationally establish the Critical Vaccine Requirements;
2. further or in the alternative, rationally established the Critical Vaccine Failures;
3. at no time tested for the specific purposes for which the Vaccines were to be used:
    a. being any of the Vaccine Purposes;
    b. other than protection against symptomatic Covid;

c) the Secretary, at no time held the rational belief that the criteria prescribed by r. 10L(1)(a) or r. 10L(1)(c) of the Regulations had been rationally or satisfactorily established;

(2) exercise the power to cancel the Approvals pursuant to s.30(1)(a) of the Act because at all times and continuously since the time of the Approvals:

a) it was rationally established that a failure to exercise the power to cancel the Approvals would create an imminent risk of death, serious illness or serious injury to the Australian population;

b) by reason of sub-paragraph (a) herein, the Secretary knew and was rationally satisfied that a failure exercise the power to cancel the Approvals would create an imminent risk of death, serious illness or serious injury to the Australian population;

Particulars

Para. 98(d)(iii) in Schedule D of the SOC.

e) the omissions characterised by the Secretary Continuing Approvals were undertaken by the Secretary:

i) purportedly for the proper purpose incident to the Secretary's office, and in accordance with the obligation that his actions in that office be undertaken consistently with:

(1) the Department Overarching Purpose;

(2) the TGA's Statutory Purpose; and

(3) his duty to act for the public good;

ii) in circumstances wherein, the Secretary Continuing Approvals were in fact inconsistent with the Department Overarching Purpose and the TGA's Statutory Purpose because they were made in the circumstances of the Secretary's knowledge of the Pre-Approval Established Critical Defects and the Post-Approval Established Critical Defects;

iii) thereby for an improper purpose:

(1) contrary to the public good;

(2) in breach of a duty to act for the public good.

Particulars

Para. 98(e) in Schedule D of the SOC.

f) at no time prior to the Secretary Continuing Approvals or at all did the Secretary:

i) rationally establish in fact the Critical Vaccine Requirements;

ii) hold the rational belief that the Critical Vaccine Requirements had been rationally and satisfactorily established.

Particulars

Para. 98(f) in Schedule D of the SOC.

g) undertook the Secretary Continuing Approvals in the circumstances of the factual matters and knowledge pleaded at sub-paragraphs (a) to (f) herein, thereby undertaking the Secretary Continuing Approvals in, causing or materially contributing to the following breaches of the Conduct Legislation and TGA Policies **("the Secretary Continuing Approval Breaches")**:

i) the ongoing and unresolved Secretary Approval Breaches;

ii) the breaches of the TGA Policies pleaded and particularised at paragraph 92(g);

Particulars

Para. 98(g) in Schedule D of the SOC.

h) undertook the Secretary Continuing Approvals wherein in the circumstances of the factual matters pleaded at sub-paragraphs (a) to (g) herein:

i) the Purported Bases of Continuing Approval were in fact false;

ii) the procedures that were required by law to be observed in relation to the Secretary Approvals and the Secretary Continuing Approvals were not observed, being the Secretary Continuing Approval Breaches;

iii) the Secretary did not have jurisdiction to undertake the Secretary Approvals and the Secretary Continuing Approvals;

iv) there was no evidence or other material from which the Secretary could be rationally satisfied to:

(1) rationally establish the Critical Vaccine Requirements or the Purported Bases of Continuing Approvals; or

(2) rationally justify the Secretary Continuing Approvals;

v) the Skerritt Continuing Approvals was a purported exercise of a power:

(1) for a purpose other than a purpose for which the power was conferred, being to act for the public good;

(2) in excess of any power conferred;

(3) contrary to the public good;

(4) so unreasonable that no reasonable person could so exercise the power or alternatively, were legally unreasonable;

(5) inconsistent with an honest attempt to perform the functions of a public office;

vi) the Secretary Continuing Approvals in the circumstances would cause the Vaccines to be distributed to and received by the Group Members:

(1) in the circumstances of the rationally established facts and knowledge of:

a) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

b) the Pre-Approval Established Critical Defects;

c) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

d) the Post-Approval Established Critical Defects;

(2) thereby likely to cause harm to the Group Members.

vii) at no time had the Secretary:

(1) rationally established in fact the Critical Vaccine Requirements;

(2) held the rational belief that:

a) the Critical Vaccine Requirements had been rationally and satisfactorily established;

b) the relevant requirements of the provisions of the Act and Regulations in respect of the Approvals had been rationally and satisfactorily established;

viii) by reason of the matters pleaded at sub-paragraphs (i) to (vii) herein, the Secretary Continuing Approvals undertaken by the Secretary were:

(1) patently unlawful and extraneous to power;

(2) a failure to exercise the Secretary's Power to Suspend or Cancel in circumstances where the Secretary was obliged to do so;

(3) likely to cause harm to the Group Members; and

(4) in breach of the duty to act for the public good;

i) in the premises, in undertaking the Secretary Continuing Approvals, the Secretary:

i) knew of the factual matters pleaded at sub-paragraphs (h) herein, or alternatively was recklessly indifferent as to the existence of those factual matters;

ii) was actuated by improper purposes contrary to the public good and thereby acted in bad faith;

iii) knew the Secretary Continuing Approvals were unlawful and undertaken without any power to do so, or alternatively was recklessly indifferent as to whether the Secretary Continuing Approvals were unlawful and undertaken without any power to do so;

iv) knew the Secretary Continuing Approvals were likely to cause harm to the Group Members, or alternatively was recklessly indifferent as to whether the Secretary Continuing Approvals were likely to cause harm to the Group Members.

Particulars

Para. 98(i) in Schedule D of the SOC.

99. By reason of the factual matters pleaded in paragraph 98 herein, the acts, omissions and knowledge of the Secretary in the Secretary Continuing Approvals in the circumstances of the Secretary Continuing Approvals Misfeasance constituted misfeasance in public office.

THE SECRETARY – MISLEADING STATEMENTS MISFEASANCE

100. The Secretary, with respect to the Misleading Vaccines Statements **("the Secretary Misleading Statements Misfeasance")**:

a) engaged in the conduct constituted by the Secretary Issued Misleading Vaccines Statements;

b) the Secretary prior to and at the time of the publication of the Secretary Issued Misleading Vaccines Statements, possessed the knowledge of the factual matters constituting:

i) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

ii) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

iii) the Pre-Approval Established Critical Defects;

iv) the Post-Approval Established Critical Defects.

Particulars

Para. 100(b) in Schedule D of the SOC.

c) caused the Secretary Issued Misleading Vaccines Statements to be made and thereby the Misleading Public Message to be made which was in every respect at all relevant times in circumstances of the Known Established Falsity of the Misleading Public Message;

Particulars

Para. 100(c) in Schedule D of the SOC.

d) in each and every instance of the Secretary Issued Misleading Vaccines Statements, such statement was made by the Secretary in circumstances wherein:

i) they were made for the purposes and intent of the Misleading Vaccines Statements Purpose;

Particulars

Particulars of the Misleading Vaccines Statements Purpose as defined at Para. 50 in Schedule D of the SOC.

ii) he intended, knew, expected and considered it likely that as a natural and probable consequence of the publication of those respective statements, that the Australian population would, and did in fact:

(1) rely upon those statements in determining whether to take one or more of the Vaccines;

(2) determine to take one or more of the Vaccines;

(3) take one or more of the Vaccines.

Particulars

Para. 100(d)(ii) in Schedule D of the SOC.

e) the Secretary Issued Misleading Vaccines Statements were made by the Secretary:

i) purportedly incident to the powers granted to the Secretary in his office;

ii) purportedly acting pursuant to and in accordance with the Secretary's duties, responsibilities and obligations pleaded at paragraph 10 herein;

iii) whilst the Secretary remained subject to and bound by, and knew that he was subject to and bound by the obligations and positive duties in respect of such conduct arising under the relevant express and implied provisions of the Conduct Legislation;

iv) whilst not acting in the making of those statement in performance or purported performance of, or in relation to any exercise of the Secretary's duties or powers arising under the Act or the Regulations;

v) purportedly for the proper purpose incident to his office of the Department Overarching Purpose and the public good;

vi) in circumstances wherein, the Secretary undertook the Secretary Issued Misleading Vaccines Statements:

(1) for the Misleading Statements Purpose;

(2) that were in circumstances of the facts and knowledge pleaded and particularised at sub-paragraphs (b) to (d) herein above, contrary to:

a) the Department Overarching Purpose;

b) the Conduct Legislation, in breaches constituted by the Secretary Public Governance Breaches; and

c) the public good;

vii) thereby, for an improper purpose:

(1) contrary to the public good; and

(2) in breach of a duty to act for the public good.

Particulars

Para. 100(e) in Schedule D of the SOC.

f) at no time prior to each of the Secretary Issued Misleading Vaccines Statements or at all did the Secretary:

i) rationally establish in fact:

(1) the Critical Vaccine Requirements;

(2) the Misleading Public Message.

ii) hold the rational belief that:

(1) the Critical Vaccine Requirements had been rationally and satisfactorily established;

(2) the Misleading Public Message was in fact rationally established as true.

Particulars

Para. 100(f) in Schedule D of the SOC.

g) the making of the Secretary Issued Misleading Vaccines Statements undertaken by the Secretary in every case were:

i) misleading to the Australian public including the Group Members;

ii) likely to induce the Group Members to:

(1) consider the Vaccines to have satisfactorily established the Critical Vaccine Requirements;
(2) receive the Vaccines; and
(3) suffer loss and damage;

Particulars

Para. 100(g) in Schedule D of the SOC.

h) undertook the Secretary Issued Misleading Vaccines Statements wherein in the circumstances of the factual matters and knowledge pleaded at sub-paragraphs (a) to (g) herein:

i) the Misleading Public Message was in fact false;
ii) the statements were made in breach of the duty to act for the public good;
iii) the Secretary did not have jurisdiction to undertake the Secretary Issued Misleading Vaccines Statements;
iv) there was no evidence or other material to rationally justify the Misleading Public Message or the making of the Secretary Issued Misleading Vaccines Statements;
v) the Secretary Issued Misleading Vaccines Statements were in breach of the Conduct Legislation;
vi) the Secretary Issued Misleading Vaccines Statements was a purported exercise of a power:
(1) for a purpose other than a purpose for which the power was conferred, being to act for the public good;
(2) in excess of any power conferred;
(3) contrary to the public good;
(4) so unreasonable that no reasonable person could so exercise the power or alternatively, were legally unreasonable;
(5) inconsistent with an honest attempt to perform the functions of a public office;

Particulars

Para. 100(h)(vi) in Schedule D of the SOC.

vii) the Secretary Issued Misleading Vaccines Statements in the circumstances would cause the Vaccines to be distributed to and received by the Group Members:

(1) in the circumstances of the rationally established facts and knowledge of:

a) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

b) the Pre-Approval Established Critical Defects;

c) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

d) the Post-Approval Established Critical Defects;

(2) thereby likely to cause loss and harm to the Group Members.

viii) at no time had the Secretary:

(1) rationally established in fact the Critical Vaccine Requirements or the veracity of the Misleading Public Message;

(2) held the rational belief that:

a) the Critical Vaccine Requirements had been rationally and satisfactorily established;

b) the Misleading Public Message was true;

ix) by reason of the matters pleaded at sub-paragraphs (i) to (viii) herein, the Secretary Issued Misleading Vaccines Statements undertaken by the Secretary were:

(1) patently unlawful and extraneous to power;

(2) likely to cause harm to the Group Members; and

(3) in breach of the duty to act for the public good;

i) in the premises, in undertaking the Secretary Issued Misleading Vaccines Statements, the Secretary:

i) knew of the factual matters pleaded at sub-paragraph (h) herein, or alternatively was recklessly indifferent as to the existence of those factual matters;

ii) was actuated by improper purposes contrary to the public good and thereby acted in bad faith;

iii) knew the making of the Secretary Issued Misleading Vaccines Statements were unlawful and undertaken without any power to do so, or alternatively was recklessly indifferent as to whether the making of the Secretary Issued Misleading Vaccines Statements were unlawful and undertaken without any power to do so;

iv) knew the making of the making of the Secretary Issued Misleading Vaccines Statements were likely to cause harm to the Group Members, or alternatively

was recklessly indifferent as to whether the making of the Secretary Issued Misleading Vaccines Statements were likely to cause harm to the Group Members.

Particulars

Para. 100(i) in Schedule D of the SOC.

101. By reason of the factual matters pleaded in paragraph 100 herein, the acts and knowledge of the Secretary in the Secretary Issued Misleading Vaccines Statements in the circumstances of the Secretary Misleading Statements Misfeasance constituted misfeasance in public office.

THE CHIEF MEDICAL OFFICER - APPROVALS MISFEASANCE

102. The Chief Medical Officer, at all relevant times prior to the respective Approvals and on or about the time of the respective Approvals purportedly acting under his authority as chief medical officer of the Commonwealth **("the Chief Medical Officer Pre-Approvals Misfeasance")**:

a) engaged in the conduct constituted by the Chief Medical Officer Pre-Approval Conduct;

b) undertook the Chief Medical Officer Pre-Approval Conduct upon the purported bases that **("the Chief Medical Officer Purported Bases of Pre-Approval Conduct")**:

i) the matters comprising the Chief Medical Officer's Vaccines Advices were in fact true;

ii) that the Chief Medical Officer Pre-Approval Conduct:

(1) accorded with the Department Overarching Purpose; and

(2) was for the public good.

Particulars

Particulars of the Purported Bases of Approval and Continuing Approval as defined at Para. 50 in Schedule D of the SOC.

c) possessed no later than at the time of the respective Approvals and prior to the distribution of the respective Vaccines to the Australian population the knowledge of the factual matters constituting:

i) the Known Serious Vaccines Risks and Conduct - Pre-Approval;

ii) the Pre-Approval Established Critical Defects.

Particulars

Para. 102(c) in Schedule D of the SOC.

d) undertook the Chief Medical Officer Pre-Approval Conduct in circumstances wherein the Chief Medical Officer at all material times as an officer of the Commonwealth:

i) was subject to and bound by, and knew that he was subject to and bound by the obligations and positive duties in respect of such conduct arising under the relevant express and implied provisions of the Conduct Legislation;

Particulars

Para. 102(d)(i) in Schedule D of the SOC.

ii) was at all material times in respect of the Chief Medical Officer Pre-Approval Conduct:

(1) acting purportedly pursuant to his duties, obligations and responsibilities pleaded at paragraph 12 herein;

(2) acting purportedly incident to his office as chief medical officer of the Commonwealth;

(3) acting as the principal medical advisor providing advice to Hunt, the Department and the Commonwealth relating to:

a) immunisation of the Australian population; and

b) epidemiology and infectious disease;

(4) acting purportedly pursuant to powers and in accordance with his obligations arising in the exercise of such powers under the Conduct Legislation;

(5) not acting in such conduct in performance or purported performance of, or in relation to any exercise of any duties or powers arising under the Act or the Regulations;

(6) providing advices and support to the Secretary, Minister and the Department across the full range of matters relating to the Vaccines including the safety and efficacy of the Vaccines;

(7) the Deputy–Chair of the Science and Industry Technical Advisory Group being at all times tasked with and in fact providing advice to the Commonwealth as to the scientific validity or otherwise of research into the safety and effectiveness of potential Covid-19 vaccines;

(8) in fact personally exercising his power or purported power under any act of parliament when such power was being exercised by a person delegated by the Chief Medical Officer to do so; and

(9) personally taking the actions of any person acting pursuant to a power or purported power delegated by the Chief Medical Officer under any act of parliament and actually or purportedly exercising that power.

Particulars

Acts Interpretation Act 1901 (Cth) s. 34AB(1)(c)

e) the Chief Medical Officer Pre-Approval Conduct was undertaken by the Chief Medical Officer:

i) purportedly for the proper purpose incident to his office that his actions in that office be undertaken consistently with:

(1) the Department Overarching Purpose; and

(2) his duty to act for the public good;

ii) in circumstances wherein, the Chief Medical Officer Pre-Approval Conduct were in fact inconsistent with the Department Overarching Purpose because they were made in the circumstances of the facts of and the Chief Medical Officer's knowledge of the Pre-Approval Established Critical Defects;

Particulars

The Chief Medical Officer Pre-Approval Conduct were known by the Chief Medical Officer to be inconsistent with the Department Overarching Purpose by reason of the factual matters and knowledge pleaded at sub-paragraph (c) and (d) herein.

iii) for an improper purpose:

(1) contrary to the public good;

(2) in breach of a duty to act for the public good.

Particulars

Para. 102(e) in Schedule D of the SOC.

f) at no time prior to the Chief Medical Officer Pre-Approval Conduct or at all did the Chief Medical Officer:

i) rationally establish the Critical Vaccine Requirements;

ii) hold the rational belief that the Critical Vaccine Requirements had been rationally and satisfactorily established.

Particulars

Para. 102(f) in Schedule D of the SOC.

g) undertook the Chief Medical Officer Pre-Approval Conduct in the circumstances of the factual matters and knowledge pleaded at sub-paragraphs (a) to (f) herein, thereby undertaking the Chief Medical Officer Pre-Approval Conduct **("the Chief Medical Officer Pre-Approval Breaches")**:

i) in breach of the Conduct Legislation by **("the Chief Medical Officer Public Governance Breaches")**:

(1) failing to provide the Commonwealth with advice that is frank, honest, timely and based upon the best available evidence;

Particulars

Para. 102(g)(i)(1) in Schedule D of the SOC.

(2) acting in breach of the statutory legal obligations of the *Public Service Act 1999* and/or the and the *Parliamentary Service Act 1999* and the relevant Code of Conduct, under which his genuine belief or intent that the actions were proper is irrelevant to such breach, by:

Particulars

Para. 102(g)(i)(2) in Schedule D of the SOC.

a) failing to act honestly and with integrity in connection with his position within the Department;

Particulars

Para. 102(g)(i)(2)(a) in Schedule D of the SOC.

b) failing to act with care and diligence in connection with those acts and omissions by failing to act:

i) with serious attention and solicitude to those matters;

ii) earnest effort to accomplish the purposes for which the powers are granted;

iii) reasonably, such that the Chief Medical Officer actions were so unreasonable that no reasonable person could have taken them;

Particulars

Para. 102(g)(i)(2)(b)(i)-(iii) in Schedule D of the SOC.

iv) within Australian law;

Particulars

s.13(4) of the *Public Service Act 1999* (Cth) and the *Parliamentary Service Act 1999* (Cth).

(3) acting in breach of the statutory legal obligations of the *Public Governance, Performance and Accountability Act 2013* (Cth), by:

a) acting unlawfully by failing, pursuant to his statutory duty, to exercise his powers, perform his functions and discharge his duties:

i) with the degree of care and diligence that a reasonable person would exercise;

ii) honestly, in good faith and for a proper purpose;

Particulars

Para. 102(g)(i)(3) in Schedule D of the SOC.

ii) while actuated by an improper purpose contrary to the public good.

Particulars

Para. 102(g)(ii) in Schedule D of the SOC.

h) undertook the Chief Medical Officer Pre-Approval Conduct wherein in the circumstances of the factual matters pleaded at sub-paragraphs (a) to (g) herein:

i) the Chief Medical Officer Purported Bases of Pre-Approval Conduct were in fact false;

ii) the Chief Medical Officer did not have jurisdiction to undertake the Chief Medical Officer Pre-Approval Conduct;

iii) such conduct being undertaken in breach of legislation constituted by the Chief Medical Officer Public Governance Breaches;

iv) there was no evidence or other material from which the Chief Medical Officer could be rationally satisfied to have established:

(1) the Critical Vaccine Requirements;

(2) the truth of the Chief Medical Officer Pre-Approval Advices; and

(3) the Chief Medical Officer Purported Bases of Pre-Approval Conduct;

v) the Chief Medical Officer Pre-Approval Conduct was a purported exercise of a power:

(1) for a purpose other than a purpose for which the power was conferred, being to act for the public good;

(2) in excess of any power conferred;

(3) contrary to the public good;

(4) so unreasonable that no reasonable person could so exercise the power or alternatively, were legally unreasonable;

(5) inconsistent with an honest attempt to perform the functions of a public office;

vi) the Chief Medical Officer Pre-Approval Conduct in the circumstances would cause the Vaccines to be distributed to and received by the Group Members:

(1) in the circumstances of the rationally established facts and knowledge of:

a) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

b) the Pre-Approval Established Critical Defects;

(2) thereby likely to cause harm to the Group Members.

vii) at no time had the Chief Medical Officer:

(1) rationally established in fact the Critical Vaccine Requirements;

(2) held the rational belief that the Critical Vaccine Requirements had been rationally and satisfactorily established;

(3) held the rational belief that the Chief Medical Officer Pre-Approval Advices were true;

viii) by reason of (i) to (vii) herein, the Chief Medical Officer Approvals rendered the Chief Medical Officer Approvals to be:

(1) patently unlawful and extraneous to power;

(2) likely to cause harm to the Group Members;

(3) in breach of the duty to act for the public good;

i) in the premises, in undertaking the Chief Medical Officer Pre-Approval Conduct, the Chief Medical Officer:

i) knew of the factual matters pleaded at sub-paragraph (h) herein, or alternatively was recklessly indifferent as to the existence of those factual matters;

ii) knew the Chief Medical Officer Vaccines Pre-Approval Advices were false, or alternatively was recklessly indifferent as to the falsity of the Chief Medical Officer's Vaccine Advices;

iii) knew the Chief Medical Officer Purported Bases of Pre-Approval Conduct were false, or alternatively was recklessly indifferent as to the falsity of the Chief Medical Officer Purported Bases of Pre-Approval Conduct;

iv) was actuated by improper purposes contrary to the public good and thereby acted in bad faith;

v) knew the Chief Medical Officer Pre-Approval Conduct were unlawful and undertaken without any power to do so, or alternatively was recklessly indifferent as to whether the Chief Medical Officer Pre-Approval Conduct were unlawful and undertaken without any power to do so;

vi) knew the Chief Medical Officer Pre-Approval Conduct were likely to cause harm to the Group Members, or alternatively was recklessly indifferent as to whether the Chief Medical Officer Pre-Approval Conduct were likely to cause harm to the Group Members.

Particulars

Para. 102(i) in Schedule D of the SOC.

103. By reason of the factual matters pleaded in paragraph 102 herein, the acts and omissions of the Chief Medical Officer in the Chief Medical Officer Pre-Approval Conduct in the circumstances of the Chief Medical Officer Approvals Misfeasance constituted misfeasance in public office.

THE CHIEF MEDICAL OFFICER - CONTINUING APPROVALS MISFEASANCE

104. The Chief Medical Officer, at all relevant times subsequent to the respective Approvals and at all times from the time of the respective Approvals, purportedly acting under his authority as Chief Medical Officer of the Commonwealth **("the Chief Medical Officer Continuing Approvals Misfeasance")**:

a) engaged in the conduct constituted by the Chief Medical Officer Post-Approval Conduct;

b) undertook the Chief Medical Officer Post-Approval Conduct upon the purported bases that **("the Chief Medical Officer Purported Bases of Post-Approval Conduct")**:

i) the matters comprising the Chief Medical Officer Pre-Approval Advices and the Chief Medical Officer Post-Approval Advices were in fact true;

ii) the Chief Medical Officer Post-Approval Conduct:

(1) accorded with the Department Overarching Purpose; and

(2) was for the public good.

Particulars

Particulars of the Purported Bases of Approval and Continuing Approval as defined at Para. 50 in Schedule D of the SOC.

c) possessed no later than at the time of the respective Continuing Approvals the knowledge of the factual matters constituting:

i) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

ii) the Pre-Approval Established Critical Defects;

iii) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

iv) the Post-Approval Established Critical Defects;

v) the Known Approvals Assessment Failures;

vi) the Clinical Testing Failures.

Particulars

Para. 104(c) in Schedule D of the SOC.

d) undertook the Chief Medical Officer Post-Approval Conduct in circumstances wherein the Chief Medical Officer at all material times as an officer of the Commonwealth:

i) was subject to and bound by, and knew that he was subject to and bound by the obligations and positive duties in respect of such conduct arising under relevant express and implied provisions of the Conduct Legislation;

Particulars

Para. 104(d)(i) in Schedule D of the SOC.

ii) was at all times in respect of the Chief Medical Officer Post-Approval Conduct purportedly acting pursuant to and in accordance with his duties, responsibilities and obligations as pleaded and particularised at paragraph 12 herein;

iii) was not acting in such conduct in performance or purported performance of, or in relation to any exercise of any duties or powers arising under the Act or the Regulations;

iv) where having empowered a person to act pursuant to authority delegated to them by the Chief Medical Officer:

(1) such person at law was thereby exercising the Chief Medical Officer's power or purported power; and

(2) such actions of that person thereby at law constituting the actions of the Chief Medical Officer himself;

Particulars

Acts Interpretation Act 1901 (Cth) s. 34AB(1)(c)

e) the Chief Medical Officer Post-Approval Conduct were undertaken by the Chief Medical Officer:

   i) purportedly for the proper purpose incident to his office that his actions in that office be undertaken consistently with:

      (1) the Department Overarching Purpose; and

      (2) his duty to act for the public good;

   ii) in circumstances of the facts and the Chief Medical Officer's knowledge of the Pre-Approval Established Critical Defects and Post-Approval Established Critical Defects;

   iii) thereby inconsistent with the Department Overarching Purpose and an improper purpose because such conduct was in fact and known to be detrimental to the health and wellbeing of the Australian population;

Particulars

Para. 104(e) in Schedule D of the SOC.

f) at no time prior to the Chief Medical Officer Post-Approval Conduct or at all did the Chief Medical Officer:

   i) rationally establish in fact the Critical Vaccine Requirements;

   ii) hold the rational belief that the Critical Vaccine Requirements had been rationally and satisfactorily established;

Particulars

Para. 104(f) in Schedule D of the SOC.

g) undertook the Chief Medical Officer Post-Approval Conduct in the circumstances of the factual matters and knowledge pleaded at sub-paragraphs (a) to (f) herein, thereby undertaking the Chief Medical Officer Post-Approval Conduct **("the Chief Medical Officer Post-Approval Breaches")**:

   i) in breach of the Conduct Legislation, specifically the Chief Medical Officer Public Governance Breaches;

   ii) contrary to the public good and thereby in breach of a duty to act for the public good;

Particulars

Para. 104(g) in Schedule D of the SOC.

h) undertook the Chief Medical Officer Post-Approval Conduct wherein in the circumstances of the factual matters pleaded at sub-paragraphs (a) to (g) herein:

i) the Chief Medical Officer Purported Bases of Post-Approval Conduct were in fact false;

ii) the Chief Medical Officer did not have jurisdiction to undertake the Chief Medical Officer Post-Approval Conduct;

iii) there was no evidence or other material from which the Chief Medical Officer could be rationally satisfied to have established:

(1) the Critical Vaccine Requirements;

(2) the truth of the Chief Medical Officer Post-Approval Advices;

(3) Chief Medical Officer Purported Bases of Post-Approval Conduct;

iv) the Chief Medical Officer Post-Approval Conduct was a purported exercise of a power:

(1) for a purpose other than a purpose for which the power is conferred, being to act for the public good;

(2) in excess of any power conferred;

(3) contrary to the public good;

(4) so unreasonable that no reasonable person could have so acted or failed to act;

(5) inconsistent with an honest attempt to perform the functions of a public office.

v) the Chief Medical Officer Post-Approval Conduct in the circumstances would cause the Vaccines to be distributed to and received by the Group Members:

(1) in the circumstances of the rationally established facts and knowledge of:

a) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

b) the Pre-Approval Established Critical Defects;

c) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

d) the Post-Approval Established Critical Defects;

(2) thereby likely to cause harm to the Group Members.

vi) the Chief Medical Officer at no time:

(1) rationally established in fact the Critical Vaccine Requirements;

(2) rationally believed that the Critical Vaccine Requirements had been established;

vii) by reason of the matters pleaded at sub-paragraphs (i) to (vi) herein, the Chief Medical Officer Post-Approval Conduct was:

(1) patently unlawful and extraneous to power;

(2) likely to cause harm to the Group Members; and

(3) in breach of the duty to act for the public good;

i) undertaking the Chief Medical Officer Post-Approval Conduct, wherein the Chief Medical Officer:

i) knew of the factual matters pleaded at sub-paragraph (h) herein, or alternatively was recklessly indifferent as to the existence of those factual matters;

ii) was actuated by improper purposes contrary to the public good and thereby acted in bad faith;

iii) knew the Chief Medical Officer Post-Approval Conduct was unlawful and undertaken without any power to do so, or alternatively was recklessly indifferent as to whether the Chief Medical Officer Post-Approval Conduct were unlawful and undertaken without any power to do so;

iv) knew the Chief Medical Officer Post-Approval Conduct were likely to cause harm to the Group Members, or alternatively was recklessly indifferent as to whether the Chief Medical Officer Post-Approval Conduct were likely to cause harm to the Group Members.

Particulars

Para. 104(i) in Schedule D of the SOC.

105. By reason of the factual matters pleaded in paragraph 104 herein, the acts and/or omissions of Chief Medical Officer in the Chief Medical Officer Post-Approval Conduct in the circumstances of the Chief Medical Officer Continuing Approvals Misfeasance constituted misfeasance in public office.

THE CHIEF MEDICAL OFFICER – MISLEADING STATEMENTS MISFEASANCE

106. The Chief Medical Officer, with respect to the Misleading Vaccines Statements **("the Chief Medical Officer Misleading Statements Misfeasance")**:

a) engaged in the conduct constituted by the Chief Medical Officer Issued Misleading Vaccines Statements;

b) the Chief Medical Officer prior to and at the time of the publication of the Chief Medical Officer Issued Misleading Vaccines Statements, possessed the knowledge of the factual matters constituting:

i) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

ii) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

iii) the Pre-Approval Established Critical Defects;

iv) the Post-Approval Established Critical Defects;

Particulars

Para. 106(b) in Schedule D of the SOC.

c) caused the Chief Medical Officer Issued Misleading Vaccines Statements to be made and thereby the Misleading Public Message to be made which was in every respect at all relevant times in circumstances of the Known Established Falsity of the Misleading Public Message;

Particulars

Para. 106(c) in Schedule D of the SOC.

d) in each and every instance of the Chief Medical Officer Issued Misleading Vaccines Statements, such statement was made by the Chief Medical Officer in circumstances wherein:

i) they were made for the purposes of and intent of the Misleading Vaccines Statements Purpose;

Particulars

Particulars of the Misleading Vaccines Statements Purpose as defined at Para. 50 in Schedule D of the SOC.

ii) he intended, knew, expected and considered it likely that as a natural and probable consequence of the publication of those respective statements, that the Australian population would, and did in fact:

(1) rely upon those statements in determining whether to take one or more of the Vaccines;

(2) determine to take one or more of the Vaccines;

(3) take one or more of the Vaccines;

Particulars

Para. 106(d) in Schedule D of the SOC.

e) the Chief Medical Officer Issued Misleading Vaccines Statements were made:

i) purportedly incident to the powers granted to the Chief Medical Officer in his office within the Department and as Chief Medical Officer of the Commonwealth responsible for the health of the Australian population;

ii) by the Chief Medical Officer purportedly acting pursuant to and in accordance with his duties, responsibilities and obligations pleaded and particularised at paragraph 12 herein;

iii) whilst the Chief Medical Officer remained subject to and bound by, and knew that he was subject to and bound by the obligations and positive duties in respect of such conduct arising under the relevant express and implied provisions of the Conduct Legislation;

iv) whilst not acting in the making of those statements in performance or purported performance of, or in relation to any exercise of the Chief Medical Officer's duties or powers arising under the Act or the Regulations;

Particulars

Para. 106(e)(i)-(iv) in Schedule D of the SOC.

v) purportedly for the proper purpose incident to his office of the Department Overarching Purpose and the public good;

vi) in circumstances wherein, the Chief Medical Officer undertook the Chief Medical Officer Issued Misleading Vaccines Statements:

(1) for the Misleading Statements Purpose;

(2) that were in circumstances of the facts and knowledge pleaded and particularised at sub-paragraphs (b) to (d) herein above contrary to:

a) the Department Overarching Purpose;

b) the Conduct Legislation, in breaches constituted by the Chief Medical Officer Public Governance Breaches; and

c) the public good;

(3) thereby, for an improper purpose:

a) contrary to the public good;

b) in breach of a duty to act for the public good.

Particulars

Para. 106(e)(v)-(vi) in Schedule D of the SOC.

f) at no time prior to each of the Chief Medical Officer Issued Misleading Vaccines Statements or at all did the Chief Medical Officer:

i) rationally establish in fact:

(1) the Critical Vaccine Requirements;

(2) the Misleading Public Message.

ii) hold the rational belief that:

(1) the Critical Vaccine Requirements had been rationally and satisfactorily established;

(2) the Misleading Public Message was in fact rationally established as true.

Particulars

Para. 106(f) in Schedule D of the SOC.

g) the making of the Chief Medical Officer Issued Misleading Vaccines Statements undertaken by the Chief Medical Officer in every case were:

i) misleading to the Australian public including the Group Members;

ii) likely to induce the Group Members to:

(1) consider the Vaccines to have satisfactorily established the Critical Vaccine Requirements;

(2) receive the Vaccines; and

(3) suffer loss and damage;

Particulars

Para. 106(g) in Schedule D of the SOC.

h) undertook the Chief Medical Officer Issued Misleading Vaccines Statements in the circumstances of the factual matters and knowledge pleaded at sub-paragraphs (a) to (g) herein:

i) the Misleading Public Message was in fact false;

ii) the statements were made in breach of the duty to act for the public good;

iii) the Chief Medical Officer did not have jurisdiction to undertake the Chief Medical Officer Issued Misleading Vaccines Statements;

iv) there was no evidence or other material to rationally justify the Misleading Public Message or the making of the Chief Medical Officer Issued Misleading Vaccines Statements;

v) the Chief Medical Officer Issued Misleading Vaccines Statements were in breach of the Conduct Legislation;

vi) the Chief Medical Officer Issued Misleading Vaccines Statements was an purported exercise of a power:

(1) for a purpose other than a purpose for which the power is conferred, being to act for the public good;

(2) in excess of any power conferred;

(3) contrary to the public good;

(4) so unreasonable that no reasonable person could have so acted or failed to act or, in the alternative was legally unreasonable;

(5) inconsistent with an honest attempt to perform the functions of a public office;

Particulars

Para. 100(h)(vi) in Schedule D of the SOC.

vii) the Chief Medical Officer Issued Misleading Vaccines Statements in the circumstances would cause the Vaccines to be distributed to and received by the Group Members:

(1) in the circumstances of the rationally established facts and knowledge of:

a) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

b) the Pre-Approval Established Critical Defects;

c) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

d) the Post-Approval Established Critical Defects;

(2) thereby likely to cause harm to the Group Members.

viii) at no time had the Chief Medical Officer:

(1) rationally established in fact the Critical Vaccine Requirements or the veracity of the Misleading Public Message;

(2) held the rational belief that:

a) the Critical Vaccine Requirements had been rationally and satisfactorily established;

b) that the Misleading Public Message was true;

ix) by reason of the matters pleaded at sub-paragraphs (i) to (viii) herein, the Chief Medical Officer Issued Misleading Vaccines Statements undertaken by the Chief Medical Officer were:

(1) patently unlawful and extraneous to power;

(2) likely to cause harm to the Group Members; and

(3) in breach of the duty to act for the public good;

i) in the premises, in undertaking the Chief Medical Officer Issued Misleading Vaccines Statements, the Chief Medical Officer:

i) knew of the factual matters pleaded at sub-paragraph (h) herein, or alternatively was recklessly indifferent as to the existence of those factual matters;

ii) was actuated by improper purposes contrary to the public good and thereby acted in bad faith;

iii) knew the making of the Chief Medical Officer Issued Misleading Vaccines Statements were unlawful and undertaken without any power to do so, or alternatively was recklessly indifferent as to whether the making of the Chief Medical Officer Issued Misleading Vaccines Statements were unlawful and undertaken without any power to do so;

iv) knew the making of the making of the Chief Medical Officer Issued Misleading Vaccines Statements were likely to cause harm to the Group Members, or alternatively was recklessly indifferent as to whether the making of the Chief Medical Officer Issued Misleading Vaccines Statements were likely to cause harm to the Group Members.

Particulars

Para. 106(i) in Schedule D of the SOC.

107. By reason of the factual matters pleaded in paragraph 106, the acts of the Chief Medical Officer in the Chief Medical Officer Issued Misleading Vaccines made in the circumstances of the Chief Medical Officer Misleading Statements Misfeasance constituted misfeasance in public office.

MINISTER – MISLEADING STATEMENTS MISFEASANCE

108. Hunt, with respect to the Misleading Vaccines Statements **("the Hunt Misleading Statements Misfeasance")**:

a) engaged in the conduct constituted by the Hunt Issued Misleading Vaccines Statements;

b) Hunt prior to and at the time of the publication of the Hunt Issued Misleading Vaccines Statements, possessed the knowledge of the factual matters constituting:

i) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

ii) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

iii) the Pre-Approval Established Critical Defects;

iv) the Post-Approval Established Critical Defects;

Particulars

Para. 108(b) in Schedule D of the SOC.

c) caused the Hunt Issued Misleading Vaccines Statements to be made and thereby the Misleading Public Message to be made which was in every respect at all relevant times in circumstances of the Known Established Falsity of the Misleading Public Message.

Particulars

Para. 108(c) in Schedule D of the SOC.

d) in each and every instance of the Hunt Issued Misleading Vaccines Statements, such statement was made by Hunt in circumstances wherein:

i) they were made for the purposes of and intent of the Misleading Vaccines Statements Purpose;

Particulars

Particulars of the Misleading Vaccines Statements Purpose as defined at Para. 50 in Schedule D of the SOC.

ii) he intended, knew, expected and considered it likely that as a natural and probable consequence of the publication of those respective statements, that the Australian population would, and did in fact:

(1) rely upon those statements in determining whether to take one or more of the Vaccines;

(2) determine to take one or more of the Vaccines;

(3) take one or more of the Vaccines;

Particulars

Para. 108(d) in Schedule D of the SOC.

e) the Hunt Issued Misleading Vaccines Statements were made:

i) purportedly incident to the powers granted to his office as minister of the Department;

ii) purportedly acting pursuant to and in accordance with the Department Overarching Purpose and Hunt's duties, responsibilities and obligations pleaded at paragraph 10 herein;

iii) while not acting in the making of those statements in performance or purported performance of, or in relation to any exercise of Hunt's duties or powers arising under the Act or the Regulations;

iv) in circumstances wherein at all material times:

(1) the Secretary, Skerritt, the Chief Medical Officer or any other person imbued with the actual or purported authority to grant the Approvals, the Continuing Approvals, or undertake distribution of the Vaccines to

the Australian population was at all times subject to the direction of Hunt as minister responsible for the Department;

(2) Hunt was subject to and bound by, and knew that he was subject to and bound by the obligation and positive duty to act as minister responsible for the Department for the purpose of the betterment of the health and wellbeing of the Australian population, being the Department Overarching Purpose and for the public good;

Particulars

The Department Overarching Purpose pleaded and particularised at paragraph 17(f) of the SOC.

(3) Hunt was required to be and was in fact continually informed as to, and thereby at all material times aware of:

a) the activities of the Department including:

i) the granting of each of the respective Approvals and Continuing Approvals;

ii) the distribution of the Vaccines to the Australian population;

b) all of the matters in connection with the granting of the Approvals and Continuing Approvals including:

i) the bases upon which the Approvals and Continuing Approvals were purportedly granted;

ii) the known matters relevant to:

1) the granting of the Approvals and Continuing Approvals;

2) the safety, efficacy, necessity and risk-benefit profile of the Vaccines;

Particulars

Para. 108(e) in Schedule D of the SOC.

f) at no time prior to each of the Hunt Issued Misleading Vaccines Statements or at all did Hunt:

i) rationally establish in fact:

(1) the Critical Vaccine Requirements;

(2) the Misleading Public Message.

ii) hold the rational belief that:

(1) the Critical Vaccine Requirements had been rationally and satisfactorily established;

(2) the Misleading Public Message was in fact rationally established as true;

Particulars

Para. 108(f) in Schedule D of the SOC.

g) the making of the Hunt Issued Misleading Vaccines Statements undertaken by Hunt in every case were:

i) misleading to the Australian public including the Group Members;

ii) likely to induce the Group Members to:

(1) consider the Vaccines to have satisfactorily established the Critical Vaccine Requirements;

(2) receive the Vaccines; and

(3) suffer loss and damage;

Particulars

Para. 108(g) in Schedule D of the SOC.

h) undertook the Hunt Issued Misleading Vaccines Statements in the circumstances of the factual matters and knowledge pleaded at sub-paragraphs (a) to (g) herein:

i) the Misleading Public Message was in fact false;

ii) the statements were made in breach of the duty to act for the public good;

iii) Hunt did not have jurisdiction to undertake the Hunt Issued Misleading Vaccines Statements;

iv) there was no evidence or other material to rationally justify the Misleading Public Message or the making of the Hunt Issued Misleading Vaccines Statements;

.

v) the Hunt Issued Misleading Vaccines Statements was an exercise of a power:

(1) for a purpose other than a purpose for which the power is conferred, being to act for the public good;

(2) in excess of any power conferred;

(3) contrary to the public good;

(4) so unreasonable that no reasonable person could have so acted or failed to act or in the alternative it was legally unreasonable;

(3) inconsistent with an honest attempt to perform the functions of a public office;

Particulars

Para. 108(h)(v) in Schedule D of the SOC

vi) the Hunt Issued Misleading Vaccines Statements in the circumstances would cause the Vaccines to be distributed to and received by the Group Members:

(1) in the circumstances of the rationally established facts and knowledge of:

a) the Known Serious Vaccines Risks and Conduct - Pre-Approvals;

b) the Pre-Approval Established Critical Defects;

c) the Known Serious Vaccines Risks and Conduct - Post-Approvals;

d) the Post-Approval Established Critical Defects;

(2) thereby likely to cause harm to the Group Members;

vii) at no time had Hunt:

(1) rationally established in fact the Critical Vaccine Requirements or the veracity of the Misleading Public Message;

(2) held the rational belief that:

a) the Critical Vaccine Requirements had been rationally and satisfactorily established;

b) that the Misleading Public Message was true;

viii) by reason of the matters pleaded at sub-paragraphs (i) to (vii) herein, the Hunt Issued Misleading Vaccines Statements undertaken Hunt were:

(1) patently unlawful and extraneous to power;

(2) likely to cause harm to the Group Members; and

(3) in breach of the duty to act for the public good;

i) in the premises, in undertaking the Hunt Issued Misleading Vaccines Statements, Hunt:

i) knew of the factual matters pleaded at sub-paragraph (h) herein, or alternatively was recklessly indifferent as to the existence of those factual matters;

ii) was actuated by improper purposes contrary to the public good and thereby acted in bad faith;

iii) knew the making of the Hunt Issued Misleading Vaccines Statements were unlawful and undertaken without any power to do so, or alternatively was recklessly indifferent as to whether the making of the Hunt Issued

Misleading Vaccines Statements were unlawful and undertaken without any power to do so;

iv) knew the making of the Hunt Issued Misleading Vaccines Statements were likely to cause harm to the Group Members, or alternatively was recklessly indifferent as to whether the making of the Hunt Issued Misleading Vaccines Statements were likely to cause harm to the Group Members.

Particulars

Para. 108(i) in Schedule D of the SOC.

109. By reason of the factual matters pleaded in paragraph 108, the acts of Hunt in the Hunt Issued Misleading Vaccines Statements made in the circumstances of the Hunt Misleading Statements Misfeasance constituted misfeasance in public office.

CAUSATION AND HARM - MISFEASANCE

110. The acts and omissions of:

a) Skerritt – by the Skerritt Approvals in the circumstances of the Skerritt Approvals Misfeasance;

b) the Secretary – by the Secretary Approvals in the circumstances of the Secretary Approvals Misfeasance;

c) the Chief Medical Officer – by the Chief Medical Officer Pre-Approval Conduct in the circumstances of the Chief Medical Officer Approvals Misfeasance;

d) all or alternatively, any one or more of them at sub-paragraphs (a) to (c) above, respectively, caused and, further or alternatively, materially contributed to:

i) the granting of the Approvals;

ii) the wide distribution of the Vaccines to the Australian population;

iii) the injection of one or more of the Vaccines by the Group Members;

iv) the harm to the Group Members pleaded herein as the Loss and Damage.

Particulars

Para. 110 in Schedule D of the SOC.

111. The acts and omissions of:

a) Skerritt – by the Skerritt Continuing Approvals in the circumstances of the Skerritt Continuing Approvals Misfeasance;

b) the Secretary – by the Secretary Continuing Approvals in the circumstances of the Secretary Continuing Approvals Misfeasance;

c) the Chief Medical Officer – by the Chief Medical Officer Post-Approval Conduct in the circumstances of the Chief Medical Officer Continuing Approvals Misfeasance;

d) all or alternatively, any one or more of them at sub-paragraphs (a) to (c) above, respectively, caused and, further or alternatively, materially contributed to:

i) the occurrence of the Continuing Approvals;

ii) none of the Approvals being subjected to revocation or cancellation;

iii) the wide distribution of the Vaccines to the Australian population;

iv) the injection of one or more of the Vaccines by the Group Members;

v) the harm to the Group Members pleaded herein as the Loss and Damage.

Particulars

Para. 111 in Schedule D of the SOC.

112. The acts and omissions of:

a) Skerritt – by the Skerritt Issued Misleading Vaccines Statements in the circumstances of the Skerritt Misleading Statements Misfeasance;

b) the Secretary – by the Secretary Issued Misleading Vaccines Statements in the circumstances of the Secretary Misleading Statements Misfeasance;

c) the Chief Medical Officer – by the Chief Medical Officer Issued Misleading Vaccines Statements in the circumstances of the Chief Medical Officer Misleading Statements Misfeasance;

d) Hunt – by the Hunt Issued Misleading Vaccines Statements in the circumstances of the Hunt Misleading Statements Misfeasance;

e) all or alternatively, any one or more of them at sub-paragraphs (a) to (d) above, respectively, caused and, further or alternatively, materially contributed to:

i) the publication of the Misleading Public Message;

ii) the reliance by the Group Members upon the Misleading Public Message;

iii) the injection of one or more of the Vaccines by the Group Members;

iv) the harm to the Group Members pleaded herein as the Loss and Damage.

Particulars

Para. 112 in Schedule D of the SOC.

VICARIOUS LIABILITY OF THE COMMONWEALTH

113. At all material times, the Commonwealth was and is vicariously liable for any and all tortious actions by the Public Officers in this proceeding pleaded herein because those actions:

a) were undertaken in the purported administration of the Act and/or in the exercise of powers incident to their respective offices;

b) the Commonwealth through the Department gave full allowance to the Public Officers, the TGA and to its various senior officers, to make decisions in respect of the execution and maintenance of the Act and/or the exercise of powers incident to their respective offices, subject to the general direction of the Commonwealth;

c) the executive power of the Commonwealth under s. 61 of the Constitution was exercised by the TGA in general and the Public Officers in particular so far as it concerned the execution and maintenance of the Act and/or the exercise of powers incident to their respective offices;

d) by way of appointment to their positions, the Public Officers had actual *de facto* authority to make decisions concerning the execution and maintenance of the Act and/or the exercise of powers incident to their respective offices on behalf of the Commonwealth;

e) by conferring the office and title on each of the Public Officers and permitting them to hold themselves out as such and/or holding senior positions within the TGA and/or the Department, bodies in turn held out as being responsible for the administering of the Act and/or the health and wellbeing of the Australian population, pursuant to the Department Overarching Purpose:

    i) the Commonwealth clothed each of the Public Officers with authority:

        (1) to act and speak for and on behalf of the Commonwealth in respect of matters concerning the Act and/or the Vaccines; and

        (2) thereby to act as representative of the Commonwealth;

f) the tortious acts alleged against the Public Officers in this proceeding occurred in all instances and at all material times within the scope of the authority alleged above;

g) further, or in the alternative, the Applicants:

    i) will contend that in all of the circumstances pleaded and particularised herein, the conduct of the Public Officers was the conduct of the Commonwealth;

    ii) will rely on:

        (1) s. 61 and s. 64 of the *Constitution*;

        (2) s. 56 and s. 64 of the *Judiciary Act 1903* (Cth)*;* and

        (3) the unwritten law of vicarious liability.

114. In the premises each of the said actions was done so as to render the Commonwealth liable in law for the actions of the Public Officers and any and all unidentified officers of the Commonwealth.

115. By reason of the matters pleaded at paragraphs 113 and 114 above, the Commonwealth is liable for any damages, including exemplary damages that would be awarded in favour of the Applicants as against the Public Officers for their conduct as pleaded in this proceeding.

116. By reason of the matters pleaded at paragraph 115, the Applicants are entitled to claim each loss, including the loss reflective of the Applicants' loss, against the Commonwealth of Australia for the conduct of the Public Officers as pleaded in this proceeding.

DAMAGES

117. By reason of the above matters, the applicants and the Group Members have suffered the Loss and Damage.

118. The applicants on their own behalf and on behalf of other Group Members, claim relief as follows from each of the Respondents:
    a) Damages;
    b) Exemplary Damages;
    c) Interest in pursuant to s. 51A and s. 52 of the *Federal Court of Australia Act 1976* (Cth);
    d) Costs.

Date: 7 May 2024

Signed by Natalie Strijland
Lawyer for the Applicant

This pleading was prepared by M.A. Robinson of Senior Counsel and J.M. Manner of Counsel.

Certificate of Lawyer

I, Natalie Strijland, certify to the Court that, in relation to the statement of claim filed on behalf of the Applicant, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 7 May 2024

Signed by Natalie Strijland
Lawyer for the Applicant

SCHEDULE A - TGA POLICIES

TGA POLICIES - VACCINES APPROVAL & REGULATION

The following are the particulars of the individual policies adopted by the TGA manifesting the TGA Policies, the date upon which they respectively came into effect in respect of the TGA and its officers and employees, and the circumstances of their respective adoption, implementation and public declaration:

1. The TGA, from at least May, 2019 and current at the time of the Approvals, publicly declared and the Public Officers thereby knew that the TGA, including the TGA Respondents, functioned under the following policies in respect of definition, approval and regulation of vaccines in Australia, including the Vaccines **("the TGA Vaccine Regulation Policy")**:

    a) the TGA is responsible for assessing vaccines and other medicines before they can be used in Australia;

    b) the TGA will only register a vaccine for use in Australia if its benefits are much greater than its risks;

    c) the TGA defines vaccines as medicines that:

        i) protect the vaccine recipient against specific diseases;

        ii) protect the vaccine recipient and those who come into contact with the vaccine recipient from serious and life-threatening diseases;

    d) the TGA rigorously assesses vaccines for safety, quality and efficacy before they can be used in Australia;

    e) the TGA only uses the best available scientific evidence to assess the risks and benefits of each vaccine before approval;

f) the TGA's evidence requirements in assessing and approving vaccines for use are based on international guidelines developed by the European Medicines Agency;

g) the TGA carefully assesses the results of clinical trials and the way in which the trials were conducted;

h) the TGA before approving a vaccine requires well-designed trials:

   i) of a sufficient length;

   ii) with a sufficient number of people who represent the people for whom the vaccine is intended;

i) the TGA requires before approving a vaccine that that the results of trials must demonstrate that the benefits of the vaccine greatly outweigh the risks;

j) the TGA's decision of whether to register a vaccine for use in Australia is informed by the advice of the Advisory Committee on Vaccines;

k) the TGA monitors vaccines for safety after they are supplied in Australia;

l) the TGA receives adverse event reports in relation to approved vaccines from consumers, health professionals, the companies who supply vaccines, and state and territory health departments;

m) the TGA publishes reports of adverse event reports in relation to approved vaccines in the publicly available Database of Adverse Event Notifications;

n) the TGA maintains that reporting Serious Adverse Events is mandatory for the companies who supply vaccines in Australia which must also develop and implement risk management plans for their vaccines;

o) if the TGA suspects that there is a problem with a vaccine the TGA:

i) will launch an investigation;

ii) may suspend use of the vaccine during the investigation;

iii) notify the community of safety concerns through the publication of alerts on the TGA website;

p) before it registers any vaccine for use in Australia the TGA considers every ingredient in a vaccine for:

i) safety;

ii) quality; and

iii) efficacy.

Source

TGA Policy Document - "TGA Vaccine Overview – How the TGA defines, approves and regulates vaccines in Australia May 2019"
https://www.tga.gov.au/vaccines-overview

TGA - DEFINITION OF THE VACCINES

2. The TGA Respondents, through the TGA, have defined the Vaccines, for regulatory purposes, as:

a) biologicals; and

b) new biological entities.

Source

The Pfizer Original AUSPAR – pg. 7, 9, 30.
The Moderna Original AUSPAR – pg. 7, 10.

The AstraZeneca Original AUSPAR – pg. 7, 9, 10.

TGA POLICY - PROVISIONAL APPROVAL

3. The TGA, from at least August, 2018, publicly declared and the Public Officers thereby knew that the TGA and the TGA Respondents functioned under the Act according to the following policy in respect of the process for provisional registration of vaccines by the TGA in Australia, including the Vaccines **("the TGA Provisional Approval Policy")**:

    a) the TGA can provisionally register medicines;

    b) the TGA, where provisionally registering vaccines, does so on the basis of preliminary clinical data which must demonstrate that the benefit of early availability of the vaccine outweighs the risk inherent in the fact that additional data are still required.

    c) any applicant and application to the TGA for provisional registration of a vaccine must satisfactorily establish the vaccine's:

        i) safety;

        ii) efficacy;

        iii) positive risk/benefit balance based upon preliminary clinical data.

    d) in order for the TGA to establish safety and efficacy of a vaccine, the preliminary clinical evidence provided by the applicant in support of the provisional registration application must be sufficient to allow the benefits of the vaccine to be assessed against the risks identified by the evidence;

    e) the TGA will re-assess risks related to the absence of evidence through data provided at a later stage as part of the confirmatory data;

f) the confirmatory data obtained by the TGA must confirm the relationship between:

   i) outcomes predicted by the surrogate endpoint or other preliminary data in relation to the safety and efficacy of the vaccine; and

   ii) the clinical benefit as demonstrated by direct clinical outcomes.

g) in an application for provisional approval of a vaccine the TGA actively seeks the submission from the applicant of:

   i) reports from acceptable overseas regulators to supplement the provisional submission for registration;

   ii) reports including where the vaccine has been conditionally registered overseas.

h) in addition to the standard requirements for registration of a vaccine, the TGA will base its decision to grant time-limited provisional registration of a vaccine upon the TGA's assessment of whether:

   i) the preliminary clinical data satisfactorily establishes the safety and efficacy of the vaccine;

   ii) the quality of the vaccine has been satisfactorily established; and

   iii) the TGA is satisfied with the sponsor's plan to submit comprehensive clinical data on the safety and efficacy of the vaccine:

      (1) before the end of the provisional registration period; and

      (2) starting on the day that registration would commence.

Source

TGA Policy Document - "Provisional Registration Process – For

prescription medicines with provisional determination" 2 August, 2018.
https://www.tga.gov.au/resources/resource/guidance/provisional-registration-process

TGA POLICY – ADVERSE EVENTS IDENTIFICATION

4. The TGA, from at least December 2017 and from the time of the Approvals, publicly declared and the Public Officers thereby knew that the TGA and the TGA Respondents functioned under the Act according to the following policy in respect of the identification of adverse events and serious threats to public health associated with approved biologicals in Australia, including the Vaccines, which states that **("the TGA Adverse Events Identification Policy"):**

    a) for biovigilance, an adverse event is defined as any **("TGA Defined Adverse Event")**:

        i) undesirable medical event that occurs during or after the administration or use of a biological;

        ii) undesirable medical event for which there is at least a reasonable possibility of a causal relationship between the use of the biological and the event, which is thereby:

            (1) considered an adverse event related to the biological;

            (2) reportable;

    b) a spontaneous report is an unsolicited communication by a health professional or consumer to a sponsor, manufacturer, regulatory authority or other organisation that describes one or more suspected TGA Defined Adverse Events in a patient who was given a biological;

c) any spontaneous report of a TGA Defined Adverse Event by health professionals, patients or consumers are considered to be related adverse events as they convey the suspicions of the person reporting the information that there is a causal relationship.

Source

TGA Policy Document - Identifying adverse events and serious threats to public health - Australian requirements and recommendations - 13 December 2017
https://www.tga.gov.au/resources/publication/publications/biovigilance-responsibilities-sponsors-biologicals/identifying-adverse-events-and-serious-threats-public-health

TGA POLICY - ADVERSE EVENTS REPORTING

5. The TGA, from at least August, 2021, publicly declared and the Public Officers thereby knew that the TGA and the TGA Respondents functioned under the Act according to the following policy in respect of the reporting of adverse events associated with approved vaccines in Australia, including the Vaccines which states that **("the TGA Adverse Events Reporting Policy")**:

a) all adverse events arising in approved vaccines:

i) are risk assessed and entered into the appropriate database for future reference;

ii) are used by the TGA to identify safety signals;

b) a safety signal in a vaccine:

i) is a 'flag' for a possible safety concern;

ii) when identified by the TGA, the TGA undertakes a detailed evaluation to establish the possible role of the vaccine in causing the adverse event.

c) if the TGA identifies a safety concern relating to a vaccine:

i) the TGA can take regulatory action to ensure that the vaccine continues to have for its intended use acceptable:

(1) safety;

(2) efficacy/performance; and

(3) quality.

ii) the TGA seeks to ensure that health professionals and the public are aware of:

(1) the safety concern; and

(2) any changes to the availability and recommended use of the product.

d) actions that the TGA can take in response to a safety concern include:

i) informing health professionals and consumers through alerts and articles in publications such as Medicines Safety Update;

ii) requiring changes to product labelling, or adding warnings, precautions and adverse event information to the Product Information and Consumer Medicine Information;

iii) cancelling the registration of the product, or limiting the population in which it can be used;

iv) requiring the sponsor to undertake post-marketing studies to investigate the safety concern if more information is needed before a judgment can be made about the need for further action.

Source

TGA Policy Document - "TGA Reporting Adverse Events August 2021": https://www.tga.gov.au/resources/resource/guidance/reporting-adverse-events#:~:text=All%20adverse%20events%20are%20risk,for%20a%20possible%20safety%20concern

TGA POLICY - SAFETY MONITORING

6. The TGA, from at least 9 February, 2021, publicly declared and the Public Officers thereby knew that the TGA and the TGA Respondents functioned under the Act according to the following policy in respect of the process for provisional registration of vaccines by the TGA in Australia, including the Vaccines **("the TGA Safety Monitoring Policy")**:

a) the TGA's decision to approve a new vaccine is always made on the basis that the benefits outweigh the risks for the group of people in which it is intended to be used;

b) clinical studies that are conducted before vaccines are approved by the TGA provide extensive information about the safety of the vaccine;

c) the TGA:

i) is the Government body responsible for ensuring that medicines and vaccines supplied in Australia continue to meet the required standards of:

(1) safety;

(2) effectiveness; and

(3) quality for their intended use;

ii) is responsible for the oversight of sponsors of vaccines and medicines who are legally responsible for monitoring the safety, quality and effectiveness of their products.

d) the rapid development of COVID-19 vaccines due to the urgent global need to effectively combat this pandemic has meant that the typical regulatory approval and production processes are being expedited;

e) the provisional approval pathway allows for temporary registration of promising new medicines and vaccines where the need for early access outweighs the risks;

f) information from ongoing clinical trials and safety studies will continue to be collected and analysed after provisional approval;

g) the TGA, other international regulators, and vaccine sponsors will also continuously review safety and effectiveness information collected from use in mass vaccination programs worldwide;

h) the TGA aims to:

i) strengthen the existing vaccine vigilance system for early detection and investigation of suspected side effects;

ii) enable it to:

(1) manage any emerging safety issues arising in approved vaccines; and

(2) maintain public confidence in the immunisation program.

i) the TGA's objectives are:

i) timely:

(1) collection and management of reports of Vaccine AEFI;

(2) detection and investigation of vaccine safety signals;

(3) action to address any vaccine safety signals;

(4) communications that:

a) inform the public of emerging vaccine safety information; and

b) support public confidence in vaccines.

ii) close collaboration and coordination of effort with other vaccine safety stakeholder groups.

iii) enhanced reporting of Adverse Events Following Immunisation with approved vaccines;

iv) enhanced vaccine safety signal detection and investigation;

v) understanding Covid-19 vaccine safety profiles;

vi) enhanced capacity and capability for investigating individual reports of Adverse Events Following Immunisation with approved Covid 19 vaccines;

vii) enhanced cumulative data reviews for each approved Covid 19 vaccine;

viii) active surveillance of vaccine adverse events through AusVaxSafety;

ix) ongoing analysis of clinical studies and reports;

x) the production of monthly safety summary reports;

xi) worldwide environmental scanning for safety material in relation to Covid vaccines by ongoing review of worldwide:

(1) medical literature; and

(2) data.

xii) ongoing review of worldwide safety signals in Covid vaccines including sharing information on Covid vaccine safety signals between international regulators;

xiii) receiving expert advice including from:

(1) the Advisory Committee on Vaccines **("the ACV")**; and

(2) the Australian Technical Advisory Group on Immunisation **("ATAGI")**.

j) signal detection:

i) involves identifying patterns of adverse events associated with a particular medicine or vaccine that warrant further investigation;

ii) may arise from:

(1) a previously unrecognised safety issue;

(2) a change in the frequency or severity of a known safety issue;

(3) identification of a new ‘at risk’ group.

k) when a safety signal in relation to an approved medicine or vaccine is identified, the TGA will conduct a thorough investigation:

i) to determine what, if any, action is required;

ii) with the aim to determine whether vaccination could be the cause of the adverse event;

iii) which includes assessment of the ‘background rate’ of the adverse event in the population to see if the reported rate is higher than expected;

l) when a safety concern in relation to an approved medicine or vaccine arises, the TGA:

i) may use:

(1) legislative provisions to achieve effective and timely regulatory action in response to emerging Vaccine safety concerns;

(2) non-regulatory action that may help to address or reduce the risk of a safety concern.

ii) must communicate the safety concerns in a timely way to:

(1) consumers;

(2) health professionals; and

(3) media.

m) The TGA must collaborate actively with in safety monitoring activities of approved vaccines:

i) national vaccine safety stakeholders including:

(1) ATAGI;

(2) the ACV; and

(3) the National Centre for Immunisation Research and Surveillance **("the NCIRS")**;

ii) international entities including:

(1) overseas regulators; and

(2) the WHO global advisory committee on vaccines working group.

7. The NCIRS advised on 11 May, 2021 the following procedure adopted by the TGA, known at that time and from that time to the Public Officers and applying to the conduct of the TGA Respondents, for the reporting and investigation of adverse events following vaccination with the Vaccines **("National Vaccines Adverse Events Reporting Procedure")**:

a) reports of adverse events related to the Vaccines can be made by anyone to:

i) the TGA; or

ii) when prompted with a survey via the AusVaxSafety system.

b) further investigations are made by the state health department and the TGA if within days to weeks after vaccination with the Vaccines:

i) a person dies; or

ii) has a serious event needing hospitalisation.

c) the relevant health department and TGA gather as much information as possible about the person including:

i) their medical history;

ii) risk factors;

iii) any medications they are on;

iv) details and timing of the vaccine;

v) hospitalisation records;

vi) any laboratory test results and

vii) whether they have subsequently recovered or have any ongoing issues.

d) the investigation process necessarily involves liaising with the person's:

i) treating general practitioner;

ii) treating medical specialists;

iii) hospital at which they received treatment post-vaccination.

e) an expert panel of doctors is convened:

i) to discuss a serious case in detail;

ii) which often includes the treating doctor to discuss the case and may advise extra tests that may help them understand the event.

f) a full clinical dossier is subsequently provided to the TGA which:

i) then further reviews the case;

ii) decides whether a group of independent expert advisors, known as a Vaccine Safety Investigation Group **("VSIG")** is needed to review the case in detail; and

iii) assess if the relevant Vaccine(s) caused the adverse event.

g) VSIG often includes independent medical experts in:

i) vaccine safety;

ii) infectious diseases;

iii) haematology;

iv) public health and vaccine confidence;

v) other medical specialists; and

vi) a consumer representative.

h) an independent panel of advisers:

i) meet to review the case in detail;

ii) review the clinical details of the event;

iii) report to the TGA.

i) the TGA subsequently uses an internationally accepted method to rate the level of certainty of a link between the serious event and the relevant vaccine;

j) the TGA subsequently:

i) publishes the results of these independent assessments on its website, which is accompanied by:

(1) a summary of the case; and

(2) extra clinical advice for doctors.

ii) provides the results of the assessment back to:

(1) the state or territory health department; and

(2) treating doctor.

Source

National Centre for Immunisation Research and Surveillance Website page: How do we actually investigate rate COVID-19 vaccine side-effects? https://www.ncirs.org.au/how-do-we-actually-investigate-rare-covid-19-vaccine-side-effects

TGA AEFI REPORTING STANDARD

8. The Department publicly declared, and the Public Officers thereby knew, the following to be the basis of reporting adverse events to the TGA in respect of Adverse Events Following Immunisation **("AEFI")**, as to when a vaccine recipient should or should not report an AEFI to the state and territory AEFI contacts:

a) they should be reported:

i) when a recipient has concerns about an adverse event that:

(1) appears to be getting worse;

(2) does not fit the common reactions for that vaccine.

ii) in cases of anaphylaxis.

b) they do not need to report low-grade fever or pain at the spot where the needle went in as they are usually mild and short-lived;

9. The TGA publicly declared, and the Public Officers thereby knew, that as to the reporting of suspected side effects associated with a Covid vaccine, this should be reported by the consumer in circumstances where:

a) they are worried about the side effect;

b) they suspect the side effect is related to the Vaccine;

c) they seek advice from a health professional; and

d) either they or their doctor believe that a COVID-19 vaccine has caused the side effect, especially when the relevant side effect was:

i) unexpected; or

ii) significant.

e) In confluence, the TGA and the Department publicly promote and seek reporting of AEFI only where:

i) the adverse event is temporally associated with receiving the Vaccine;

ii) either they or their doctor or both suspect or believe that the AEFI is related to the Vaccine;

iii) the AEFI is significant and/or unexpected.

Source

"Reporting and managing adverse vaccination events". https://www.health.gov.au/topics/immunisation/immunisation-information-for-health-professionals/reporting-and-managing-adverse-vaccination-events

"Reporting suspected side effects associated with a COVID-19 vaccine". https://www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccine-safety-monitoring-and-reporting/reporting-suspected-side-effects-associated-covid-19-vaccine

TGA POLICY – SAFETY ALERTS

10. The TGA, from at least prior to the Approvals, publicly declared, and the Public Officers thereby knew, that the TGA and the TGA Respondents functioned under the Act according to the following policy in respect of information for consumers and health professionals relating to possible risks or action needed, including the Vaccines **("the TGA Safety Alert Policy")**:

a) safety alerts are triggered by any potential safety problem linked to a medicine **("Safety Alerts")**;

b) Safety Alerts' purpose is to notify and inform the Australian public about:

i) a possible risk for a health product;

ii) an action needed to be taken in respect of a health product;

c) Safety Alerts are defined as including:

i) known safety problems;

ii) changes in the reporting pattern of known problems;

iii) new problems; and

iv) coincidental events.

d) Safety Alerts may be in the form of:

i) safety advisories;

ii) alert/advisories; and

iii) monitoring communications;

e) Safety Alerts advices should be followed by the public;

f) at the time the safety concern manifesting the Safety Alert is detected, the TGA may not know if the concern is really caused by the medicine.

Source

TGA Policy Document - TGA Safety Alerts

https://www.tga.gov.au/news/safety-alerts

TGA POLICY ON COVID INFORMATION - CONSUMERS AND HEALTH PROFESSIONALS

11. The TGA, from at least 28 September, 2021, publicly declared, and the Public Officers thereby knew, that the TGA and the TGA Respondents functioned under the Act according to the following policy in respect of information for consumers and health

professionals relating to Covid vaccines, including the Vaccines **("the TGA Safety Covid Information Policy")**:

a) the TGA will formally evaluate the information provided by the Covid vaccine's sponsor which includes data on:

   i) clinical studies;

   ii) non-clinical/toxicology studies;

   iii) chemistry;

   iv) manufacturing;

   v) risk management; and

   vi) other information.

b) the TGA's evaluation of Covid vaccines is also informed by the advice of the Advisory Committee on Vaccines, being an independent committee of external experts;

c) the decision to approve a new vaccine is always made by the TGA on the basis that the benefits outweigh the risks for the intended population;

d) the TGA considers the safety, quality and effectiveness of every ingredient in a vaccine before registering the vaccine for use in Australia;

e) the TGA carefully assesses:

   i) the results of clinical trials of the Covid vaccines; and

   ii) the way in which those trials were designed and conducted including:

(1) if they were conducted for a sufficient amount of time; and

(2) if there were enough participants in the trial that represented the people for whom the vaccine is intended;

f) an evaluation of the Covid vaccines under the provisional pathway is:

i) is still a full review of the safety, efficacy, risks and benefits of the vaccines; and

ii) is not in the nature of an emergency use authorisation.

g) in the provisional approval process for the Covid vaccines, the TGA requires that the following be made available to all healthcare professionals and consumers those vaccines:

i) a comprehensive Consumer Medicine Information leaflet; and

ii) a comprehensive Product Information document.

h) the TGA will before and after any approval of a Covid vaccine:

i) meet regularly with international regulators to discuss the development of Covid vaccines;

ii) utilise work-sharing arrangements with comparable international regulators to expedite the evaluation of any new vaccines without compromising on strict standards of:

(1) safety;

(2) quality; and

(3) effectiveness.

i) the TGA's safety monitoring processes for Covid vaccines are well established and include:

i) reviewing and analysing reports of suspected Covid vaccine adverse events submitted by health professionals and consumers;

ii) requiring pharmaceutical companies to have risk management plans for their supplied Covid vaccines;

iii) working with international regulators to assess significant Covid vaccine adverse events detected overseas;

iv) working with state and territory health departments and clinical experts to ensure a coordinated approach

v) reviewing medical literature and other potential sources of new safety information in respect of Covid vaccines;

vi) pharmaceutical companies also have legal obligations to monitor, collect, manage and report on safety data;

vii) monitoring of approved Covid vaccines will be ongoing including:

(1) quick evaluation of new information as soon as it becomes available;

(2) ensuring that the benefits of Covid vaccines continue to outweigh the risks; and

(3) taking appropriate action to safeguard the health and safety of the Australian public.

viii) even when a suspected side effect of a vaccine is serious:

(1) it is possible - even likely - that it may not have been caused by the vaccine;

(2) the timing may be coincidental;

(3) there is an expected 'background rate' of coincidental adverse events;

(4) the TGA investigates the reports it receives to determine if there is a genuine safety concern related to the vaccine.

j) whilst undertaking every effort to expedite the availability of one or more Covid vaccines, the TGA's rigorous safety standards will not be compromised.

k) if the TGA suspects that there is a safety issue with a Covid vaccine the TGA will immediately conduct a thorough investigation of the issue;

l) if the TGA determines that the safety concern is significant it will respond appropriately including:

i) requiring the sponsor to add warnings to the Product Information for the Covid vaccine;

ii) providing safety information to vaccine providers;

iii) making changes to labelling or packaging;

iv) in very serious cases suspend use of the vaccine during the investigation;

v) notify the community of safety concerns through alerts published on:

(1) the TGA website; and

(2) state and territory health department websites.

Source

TGA Policy Document – "COVID-19 vaccine: Information for consumers and health professionals": https://www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccine-information-consumers-and-health-professionals.

TGA POLICY - SPONSOR PHARMACOVIGILANCE POLICY

12. The TGA, from at least 19 January, 2021, publicly declared, and the Public Officers thereby knew, that the TGA and the TGA Respondents functioned under the Act according to the following policy in respect of the Sponsors' Pharmacovigilance System relating to Covid vaccines, including the Vaccines **("the TGA Sponsors' Pharmacovigilance Policy")**:

a) the TGA Pharmacovigilance Policy must:

i) be followed by all Sponsors;

ii) be ensured by the TGA to in fact have been followed by the Sponsors.

b) the Sponsor's pharmacovigilance system must ensure that it:

i) allows all pharmacovigilance requirements described in the TGA's policies and applicable legislation to be met;

ii) allows investigation and reporting of product quality issues associated with Covid vaccines:

(1) Serious Adverse Events; and

(2) significant safety issues.

iii) allows critical analysis of:

(1) adverse events associated with Covid vaccines; and

(2) other safety and quality information;

iv) allow the taking of any action necessary to mitigate an identified safety issue in the approved Covid vaccines.

c) the Sponsors must identify and collect all information related to the safety of their vaccines from all possible sources, including:

i) spontaneous reports of adverse reactions including consumer reports to:

(1) the Sponsor; or

(2) to people who work for or have a contractual relationship with the Sponsor;

ii) internet and social media reports;

iii) reports from non-medical sources;

iv) solicited reports, such as from post-registration studies or post-market initiatives;

v) reports in international and local literature;

vi) individual adverse drug reaction reports in the DAEN;

vii) gathering sufficient information to scientifically evaluate reports of adverse reactions and any other safety issues associated with the medicine;

viii) validating suspected adverse reactions and report them to the TGA within the required time frame.

d) the Sponsor must report adverse reactions associated with the Covid vaccines:

i) if they are considered serious;

ii) even if the Sponsor does not agree with the reporter's assessment of the cause.

e) for regulatory purposes, spontaneous reports:

i) are considered to have implied causality;

ii) where it is not clear whether a causal association is suspected:

(1) are presumed to mean that the Covid vaccine and the adverse event are possibly related; and

(2) meet the definition of an adverse reaction, unless the reporter explicitly states otherwise.

f) the Sponsor must exercise due diligence in ensuring that reports of adverse events associated with the Covid vaccine are complete and are of high quality:

i) because reports provided by consumers may often lack sufficient clinical detail required for assessing causality or seriousness; and

ii) by accurately recording, clarifying, analysing and following up on any information received.

g) the Sponsors must:

i) obtain as much information as necessary to determine the nature and seriousness of the adverse reaction to the Covid vaccine; and

ii) seek the reporter's voluntary informed consent to contact the treating doctor for medical confirmation of the adverse reaction and any additional relevant information;

iii) if consent is not obtainable use clinical judgement to:

(1) assess how serious the reaction was from the available information; and

(2) guide the subsequent handling of it.

iv) if the adverse reaction is serious:

(1) make additional attempts as reasonable either to:

a) obtain the reporter's voluntary consent to contact the treating doctor; or

b) ask the consumer to provide relevant medical documentation to allow you to assess causality.

h) the Sponsors must:

i) regularly screen internet sources such as websites, webpages, blogs, vlogs, social networks, internet forums, chat rooms and health portals) or digital media that the Sponsors own, fund, manage or are responsible for, for potential reports of suspected adverse reactions;

ii) if they become aware of an adverse experience on an internet or digital site that it does not sponsor:

(1) review the available information; and

(2) attempt to follow up the report to determine if it must be reported to the TGA.

iii) make reasonable attempts to contact the reporter wherever possible to:

(1) confirm the event and patient details; and

(2) collect any additional information;

i) international and local scientific and medical literature are a significant source of information for monitoring:

i) the safety profile of the vaccines; and

ii) benefit-risk balance of the vaccines;

iii) particularly in relation to the detection of new safety signals or emerging safety issues.

j) the Sponsors must:

i) undertake regular and no less than weekly systematic literature review of widely used reference databases such as Medline, Excerpta Medica

or Embase, including those that contain the largest number of articles about:

(1) the vaccine;

(2) all of vaccine's active ingredients; and

(3) the vaccine's properties.

ii) monitor ongoing safety and efficacy studies relating to the Covid vaccine including non-human teratogenicity and/or carcinogenicity studies for any relevant safety findings;

iii) review and assess both worldwide and relevant local scientific and medical literature articles including abstracts from meetings and draft manuscripts to identify, report and record adverse reaction reports and significant safety issues.

iv) follow up and validate any Serious Adverse Events that are reported in the literature:

(1) by contacting the study's author to obtain further information where possible;

(2) specifically any information needed to assess causality and patient identifiers.

k) proper pharmacovigilance in respect of the Covid vaccine requires that:

i) the Sponsors collect information on adverse reactions and significant safety issues; and

ii) critically analyse and evaluate such information to monitor the on-going benefit-risk profile of the vaccine.

l) proper safety monitoring activities by the Sponsors requires:

i) a review of cumulative safety issue cases:

(1) in order to allow for a comprehensive review of potential safety issues;

(2) because safety issues may come from one or multiple sources which may suggest:

a) a new risk; or

b) a change in the nature of a known risk associated with the vaccine.

ii) where identifying a safety signal that may change the benefit–risk balance of the vaccine, reporting:

(1) the matter to the TGA as a significant safety issue; and

(2) any actions the Sponsor proposes to take, or justification for no further action.

Source

TGA Policy Document - "TGA Pharmacovigilance System – Australian Recommendations and Requirements January 2021": https://www.tga.gov.au/resources/resource/guidance/pharmacovigilance-responsibilities-medicine-sponsors/your-pharmacovigilance-system - dated 19 January, 2021.

13. The TGA, from at least 19 January, 2021, publicly declared, and the Public Officers thereby knew, that the TGA and the TGA Respondents functioned under the Act

according to the following policy in respect of the Pharmacovigilance System of sponsors relating to Covid vaccines, including the Vaccines **("the TGA Sponsors' Pharmacovigilance Policy 2")**:

a) the TGA Pharmacovigilance Policy 2 must:

   i) be followed by all Sponsors;

   ii) be ensured by the TGA to in fact have been followed by the Sponsors.

b) spontaneous reports of adverse events are considered to be adverse reactions for regulatory purposes;

c) a significant safety issue:

   i) is a new safety issue or validated signal considered by the Sponsor in relation to their vaccine which requires urgent attention of the TGA;

   ii) can be identified by ongoing review and analysis of all information that is pertinent to the vaccine's:

      (1) safety; or

      (2) benefit-risk balance;

   iii) includes:

      (1) safety-related actions by comparable international regulatory agencies;

      (2) changes in the nature, severity or frequency of known serious adverse reactions which are medically significant;

(3) detection of new risk factors for the development of a known adverse reaction or a new serious adverse reaction that may impact on the safety or benefit-risk balance of the medicine;

(4) series of reports of similar or linked adverse reactions reported at the same time;

(5) an unusual and significant lack of efficacy occurring in or outside Australia that may have implications for public health;

(6) major safety findings from a newly completed non-clinical study, post-registration study or clinical trial that may impact the benefit-risk balance of the medicine;

(7) a signal of a possible teratogenic effect or of significant hazard to public health;

(8) safety issues related to any raw materials used in the medicine that may impact the safety of the medicine and/or have implications for public health;

(9) safety issues due to misinformation in the Product Information or label that may impact the safety of the medicine;

(10) safety issues related to use outside the approved indication or intended use that may impact the safety or benefit-risk balance of the medicine.

iv) where reported by the Sponsor to the TGA:

(1) is used by the TGA to take appropriate action;

(2) may be the basis of:

a) further safety information to the public;

b) updates to Product Information documents and labels;

c) the imposition of additional risk management interventions or pharmacovigilance activities;

d) removal of the vaccine from the market.

v) is to be, where doubted by the Sponsor, treated as significant.

d) the Sponsor must report the following to the TGA:

i) expected and unexpected serious adverse reactions associated with the use of the vaccine that occurred in Australia;

ii) expected and unexpected serious adverse reactions associated with the use of the vaccine that occurred in Australia and were reported in the published international or local scientific and medical literature;

iii) all clinical and medically relevant follow-up information related to serious adverse reaction reports related to the vaccine occurring in Australia;

iv) all serious adverse reaction reports which must be:

(1) validated;

(2) followed up as necessary; and

(3) submitted to the TGA within the 15 calendar day time frame;

v) all significant safety issues related to the vaccine within 72 hours of awareness;

vi) all serious adverse reaction cases occurring in Australia that are identified through screening the worldwide literature:

(1) as soon as possible; and

(2) no later than 15 calendar days from receipt.

e) in respect of reports involving pregnancies where the embryo or foetus could have been exposed to the vaccine, the Sponsor must:

i) make reasonable attempts to follow up all individual cases;

ii) collect information on the outcome of the pregnancy and development of the child after birth;

iii) collect as much information as possible to enable assessment of the causal relationship between any reported adverse event(s) and exposure to the vaccine;

iv) consider whether the vaccine may have been taken prior to conception or during pregnancy;

v) take into account whether any active substance or one of the metabolites in the vaccine has a long half-life;

vi) report pregnancies that result in abnormal outcomes suspected to be related to the vaccine as serious adverse reactions, including:

(1) congenital anomalies or developmental delay in the foetus or the child;

(2) foetal death and spontaneous abortion;

(3) serious adverse reactions in the neonate.

vii) report suspected serious adverse reactions in infants following exposure to the vaccine in breastmilk in accordance with the reporting requirements for serious adverse reactions;

viii) report any signal of a possible teratogenic effect, such as a cluster of similar abnormal outcomes, as a significant safety issue.

f) the Sponsor must:

i) record and follow up all reports of a lack of therapeutic efficacy in the vaccine;

ii) treat reports of unusual or unexpected lack of efficacy in the vaccine as serious adverse reactions for reporting purposes;

iii) assess causality for all solicited reports including AusVaxSafety to decide if it is a serious adverse reaction in which case it must be reported to the TGA.

Source

TGA Document – "Pharmacovigilance responsibilities of medicine sponsors - Australian recommendations and requirements". https://www.tga.gov.au/sites/default/files/190214_pharmacovigilance-responsibilities-medicine-sponsors.pdf. Dated 18 January, 2021.

TGA POLICY - COVID VACCINE APPROVALS

14. The TGA, from at least 6 July, 2021, publicly declared, and the Public Officers thereby knew, that the TGA and the TGA Respondents functioned under the Act according to the

following policy in respect of the TGA Approval Process for Covid vaccines, including the Vaccines **("the TGA Covid Vaccine Approvals Policy")**:

a) the TGA's decision to grant provisional registration to the Covid vaccines is based on a number of factors including the established vaccine's:

   i) safety;

   ii) quality; and

   iii) effectiveness, for intended use.

b) the TGA, after approval of the Covid vaccine:

   i) will continue to play an active role in the ongoing monitoring of any vaccines available in Australia including the Vaccines; and

   ii) has robust procedures in place to investigate any potential new safety issues in vaccines, including the Vaccines.

c) the TGA's vaccine safety monitoring system can rapidly detect, investigate and respond to any emerging safety issues identified for Covid vaccines;

d) post-market monitoring of safety and efficacy issues in respect of the Covid vaccines by the TGA relies upon:

   i) reviewing and analysing adverse events reports;

   ii) working with international regulators; and

   iii) reviewing medical literature, media and other potential sources of new safety information.

Source

TGA Document - "TGA Covid Vaccine Approval Process July

2021" Dated 6 July, 2021.
https://www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccine-approval-process

TGA POLICY - COVID VACCINE EVIDENCE

15. The TGA, from at least 4 December, 2020, publicly declared, and the Public Officers thereby knew, that the TGA and the TGA Respondents functioned under the Act according to the following policy in respect of evidence relating to Covid vaccines, including the Vaccines **("the TGA Covid Vaccine Evidence Policy")**:

    a) the TGA will rigorously evaluate the totality of scientific and clinical evidence provided by sponsors of Covid vaccines as well as other evidence available, including that which may be specific to other countries;

    b) the TGA will only authorise a Covid vaccine if its benefits outweigh the risks, based on the required evidence provided by sponsors;

    c) the TGA will require a high level of evidence from the sponsor prior to approval of any Covid vaccine;

    d) the TGA will continually monitor approved Covid vaccines for safety, efficacy and quality;

    e) the TGA will not register a Covid vaccine unless it is demonstrated that the vaccine prevents Covid disease:

        i) through well-conducted clinical trials in humans;

        ii) by the Sponsor.

    f) before approving any Covid vaccine the TGA must consider:

        i) the availability of alternative vaccines and treatments;

ii) the status of the pandemic; and

iii) the epidemiology of the Virus in Australia and worldwide.

g) before the TGA approves any Covid vaccine:

i) clinical trials must:

(1) demonstrate that the vaccine:

a) very significantly reduces the incidence of Covid disease in people who are vaccinated with the vaccine compared to a control group of people who did not receive the vaccine; and

b) reduces the transmission of disease between individuals, including from asymptomatic to uninfected individuals;

(2) be based upon a reduction in the rate of symptomatic laboratory-confirmed Covid infections;

ii) sponsors must demonstrate robust evidence of safety;

h) after approval of a Covid vaccine:

i) the TGA will monitor the continued evidence of safety of the vaccine;

ii) evidence of Covid vaccine safety will require a database:

(1) to detect infrequent side effects;

(2) which must adequately monitor the safety of the Covid vaccines;

iii) participants in clinical trials must be followed for a median of at least 2 months after receiving their final Covid vaccine dose;

iv) participants in clinical trials must be followed up for a median of 6 months to assess the potential risks of:

(1) late-onset adverse events; and

(2) vaccine-associated enhanced respiratory disease.

v) participants in clinical trials must continue to be followed:

(1) for at least 1 year; and

(2) ideally longer to assess the duration of protection and longer-term safety of the Covid vaccine;

vi) the TGA must access the follow-up data from the:

(1) clinical studies;

(2) non-clinical studies;

(3) studies assessing the risk of vaccine-associated enhanced respiratory disease.

vii) the TGA must:

(1) continuously monitor, assess and strengthen Covid vaccine safety to ensure that the benefits of the vaccine continue to outweigh the risks; and

(2) collaborate in monitoring the safety and effectiveness of Covid vaccines to:

a) assess new safety issues; and

b) take quick action to mitigate risks.

(3) work closely on an ongoing basis with health care professionals, public health authorities, vaccine sponsors to monitor and assess the safety of Covid vaccines after authorisation.

i) continuing trials of the Covid vaccines by sponsors is essential to providing robust evidence of long-term safety and protection against the Virus which may not be adequately demonstrated through post-authorisation surveillance studies.

Source

TGA Document – "Access Consortium statement on COVID-19 vaccines evidence" Dated 4 December, 2020.
https://www.tga.gov.au/access-consortium-statement-covid-19-vaccines-evidence

ADOPTED STANDARDS & POLICIES - EUROPEAN MEDICINES AGENCY

16. Prior to the Approvals, the TGA and the TGA Respondents adopted and continue to have adopted, in respect of their functions under the Act, the following policies and principles produced and published by the European Medicines Agency **("the EMA")** relevant to the Approvals and the continuing use of the Vaccines:

a) Guideline Nonclinical Testing For Inadvertent Germline Transmission Gene Transfer Vectors dated 16 November, 2006;

b) Guideline M3(R2) Nonclinical Safety Studies For Conduct of Human Clinical Trials and Marketing Authorisation For Pharmaceuticals dated

December, 2009;

c) Guideline M4S Registration of Pharmaceuticals For Human Use dated 20 February 2003;

d) Guideline on Clinical Evaluation of New Vaccines dated 18 October 2006;

e) Guideline on Clinical Evaluation of Vaccines dated March 2017 (since updated – current update agreed by Vaccine Working Party January 2020);

f) Guideline on Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk dated July 2017;

g) Guideline S2(R1) on Genotoxicity Testing and Data Interpretation Pharmaceuticals Intended For Human dated June 2012;

h) Note for Guidance On Preclinical Pharmacological and Toxicological Testing of Vaccines dated 17 December, 1997;

i) Guideline on Strategies to Identify and Mitigate Risks for First-in-Human and Early Clinical Trials with Investigational Medicinal Products dated 20 July, 2017;

j) Guideline on the Need for Nonclinical Testing in Juvenile Animals of Pharmaceuticals for Paediatric Indications dated 24 January, 2008;

k) Guideline on Adjuvants in Vaccines for Human Use dated January, 2005;

l) Guideline on Good Pharmacovigilance Practices dated December, 2013.

MITIGATING RISK IN FIRST-IN-HUMAN MEDICINES – ADOPTED EMA POLICY

17. The TGA and the TGA Respondents adopted prior to the Approvals, in respect of their functions under the Act, the EMA Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products published on 20 July, 2017, which expressly states that:

a) toxicity can be the result of exaggerated pharmacological actions which should not be ignored when establishing a safe starting dose for humans;

b) the exposures at which these toxicities are observed should be considered for the definition of the dose escalation range to be investigated in humans;

c) an evaluation as to whether the target organs identified in the non-clinical studies warrant particular monitoring in the clinical trials should be undertaken;

d) serious toxicity should lead to a more cautious approach when setting doses and applying risk mitigation strategies in the clinical setting;

e) when serious toxicity or mortality is observed, these effects if not been possible to clarify within the studies undertaken:

i) require follow up studies to determine:

(1) the cause of death; or

(2) the mechanism of toxicity and

ii) must be examined for relevance to:

(1) the clinical trial design; or

(2) safety monitoring plan.

f) usually driven by exposures where serious toxicity/mortality is observed.

Source

European Medicines Agency - 20 July 2017. Rev. 1 Committee for Medicinal Products for Human Use (CHMP) - "Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products". Pg. 10.
https://web.archive.org.au/awa/20220816022520mp_/https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigational_en.pdf

SAFETY SURVEILLANCE – ADOPTED EMA POLICY

18. The Council for International Organisations for Medical Sciences (CIOMS) Guide on Vaccine Safety Surveillance referenced in the EMA Guideline on good pharmacovigilance practices stated, as from January, 2017 and known to and adopted by the TGA and the TGA Respondents prior to the Approvals:

a) it is the responsibility of each national regulatory authority (NRA) to assure the safety of vaccines licensed in its country;

b) safety surveillance is a fundamental pharmacovigilance tool used to assess the safety of licensed vaccines and to promptly identify and address any unexpected safety concerns arising from their use;

c) the cornerstone of vaccine pharmacovigilance is passive surveillance. In passive surveillance systems, the primary responsibility for identification and reporting AEFIs falls upon the health care provider, the patient, or the patient's family or carers.

d) the role of those responsible for overseeing the passive surveillance system focuses primarily on assuring the accuracy and completeness of reports that are received, and on analysis of the AEFI reports for necessary action.

e) following vaccine introduction in a country, there may be a need for Active Vaccine Safety Surveillance because:

i) a concern has arisen on account of a safety signal detected through passive surveillance;

ii) a new population or circumstance (e.g. expanded use in an outbreak setting) may benefit from timely impact assessment;

iii) international or local concerns have been raised about the vaccine's safety;

iv) each of the above may prompt stakeholders to question:

(1) whether passive surveillance is sufficient; or

(2) if indeed Active Vaccine Safety Surveillance would be warranted; and

(3) whether additional data would be needed to inform the benefit-risk assessment for the vaccine's use.

f) spontaneous reporting pharmacovigilance:

i) offers the potential for detecting rare events because of the broad pool of reporters;

ii) using a passive surveillance system allows a case series to be assembled to detect:

(1) patterns of adverse events connected with vaccines; and

(2) possible associations between a vaccine and an adverse event.

Source

EMA Guideline on good pharmacovigilance practices: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-product-population-specific-considerations-i-vaccines_en.pdf

Council for International Organisations for Medical Sciences (CIOMS) - Guide to Active Vaccine Safety Surveillance, Geneva 2017. https://cioms.ch/wp-content/uploads/2020/04/240WEB-CIOMS-Guide-AVSS-20170202-protected.pdf (Page 2, 9, 20)

PHARMACOVIGILANCE - APPROVALS AND REPORTING – ADOPTED EMA POLICY

19. Pharmacovigilance approvals and reporting guidelines specific to vaccines and directly applicable to the Vaccines, published in or about February, 2013, known to and adopted by the TGA and the TGA Respondents at the time of the Approvals in respect of their functions under the Act, states as requirements of good pharmacovigilance in the testing, analysis and approval of vaccines, including the Vaccines ("**Pharmacovigilance in Vaccine Approvals Policy (EMA)**"):

a) robust systems and procedures must be in place to continuously monitor quality, safety and efficacy of vaccines;

b) a high level of safety is required for vaccines and tolerance to risk is low because vaccines, as in the case of the Vaccines:

i) are usually administered to otherwise healthy individuals, often very young or vulnerable;

ii) may be administered to a large fraction of the population and vaccination is mandatory in some countries;

c) the risk-benefit balance of many vaccines:

i) is dynamic and may change over time which may impact on pharmacovigilance activities;

ii) is such that the balance of risks and benefits may shift such that:

(1) the risk may outweigh the benefits over time; and

(2) the tolerance to the risks of vaccines is decreased.

d) factors affecting risk-benefit balance include:

i) efficacy and effectiveness in vaccination programs;

ii) biological variability.

e) vaccines are highly complex multi-component products manufactured from biological systems that are inherently variable over time and between Sponsors;

f) the safety, quality and efficacy of vaccines are as dependent on the product-specific manufacturing process as on the inherent profile of active antigens and excipients;

g) clinical trials must be constructed to:

i) detect common and uncommon adverse reactions and to address long-term risks by utilising appropriate sample size and duration;

ii) only be limited such that inclusion and exclusion criteria are relevant to the target population for vaccination;

h) risk to the developing foetus from vaccination of the mother with an inactivated vaccine during pregnancy:

i) means that live attenuated vaccines are contraindicated in pregnant women due to the known or suspected risk of transplacental infection of the foetus;

ii) should be discussed, including data collected in the post-authorisation phase if available.

i) additional pharmacovigilance activities may be needed in the following circumstances:

i) to establish evidence of safety for novel vaccines or for vaccines with a novel adjuvant, in order to:

(1) assess the risk of occurrence of rare or delayed onset adverse reactions, local or systemic;

(2) detect occurrence of auto-immune diseases and immune-mediated reactions resulting from a synergistic action of the adjuvant and the biologically active antigen;

ii) to assess the effectiveness of the vaccine, especially where pre-authorisation data are limited;

iii) to investigate clusters of reported adverse events/reactions;

iv) where spontaneous reports raise concerns that a higher than expected rate of vaccine failures and breakthrough infections in certain risk groups exists;

j) a pregnancy register may be needed to address risks of the vaccine in pregnant women to allow identification of spontaneous abortions, stillbirths and congenital malformations with an adequate duration of follow-up of the offspring;

k) where AESI are presented in the safety specification as important potential risks and baseline/background incidence rates of those AESI in the target population are not available, it may be necessary to design a study to collect this information in order to provide rapid answers to vaccine safety concerns emerging from spontaneous reports of suspected adverse reactions;

l) plans for post-authorisation efficacy studies (PAES) may include the assessment of vaccine efficacy/effectiveness and immunogenicity in order to get additional information on waning immunity, long-term protection, cross-protective efficacy/effectiveness and the most appropriate use of the vaccine;

m) the potential for local and systemic adverse reactions should be analysed for different doses of the vaccine and also across different vaccination schedules by summarisation of the following data in the PSUR:

i) reports of:

(1) vaccine failure; and

(2) lack of efficacy/effectiveness;

(3) vaccination errors;

(4) vaccination anxiety-related reactions such as syncope;

(5) literature data with information relevant to other similar vaccines and vaccine components such as stabilisers, preservatives and adjuvants.

n) when a new or changing risk is identified, the regulatory body must:

i) re-evaluate the benefit of the medicinal product using all available data, such benefits including prevention of:

(1) the target disease;

(2) severity of symptoms;

(3) hospitalisation;

(4) complications;

(5) effect of target disease on offspring (in case of vaccination of pregnant women); and

(6) any other clinical outcome relevant for individual patients;

ii) estimate the impact of the new or changing risk on the benefit-risk balance of the vaccine.

o) non-clinical studies and experimental investigations should be considered to address safety concerns and to elucidate the aetiology of an adverse reaction including:

i) virological;

ii) bacteriological;

iii) immunological experiments; and

iv) other methods.

p) a safety signal:

i) is information arising from one or multiple sources which suggests:

(1) a new potentially causal association; or

(2) a new aspect of a known association between an intervention and an event; or

(3) a set of related events that is judged to be of sufficient likelihood to justify verificatory action;

ii) includes observations and experiments;

iii) in vaccines may also relate to:

(1) evidence of reduced efficacy or effectiveness;

(2) vaccine failures; and

(3) quality deviations with potential impact on:

a) safety;

b) efficacy; or

c) effectiveness (which may be batch-specific).

q) a safety signal:

i) can arise from a single report of a Serious Adverse Event if there is a possible causal association to the vaccine which review of:

(1) adequate information on the clinical course of the event (time to onset, signs and symptoms, results of relevant laboratory and diagnostic tests, evolution, and treatment of the event);

(2) medical history;

(3) vaccination history;

(4) co-medication; and

(5) details of the vaccine(s) administered (including brand name, batch number, route of administration and dose).

ii) is based upon contextual information, such relevant data being:

(1) the number of reported cases of a similar event; and

(2) the probability of occurrence of the event in a non-vaccinated population of the same age category calculated from:

a) clinical trials; and

b) observational studies.

(3) if adequate data is available, the number of vaccinated individuals of the same age category, the observed and expected numbers of cases should be estimated.

r) in mass vaccination programs which involve large exposure over a relatively short time period, safety signal detection:

i) should be as real-time as possible;

ii) inform decision-making as the vaccination progresses;

iii) occurs by quickly analysing and communicating the significance of spontaneously reported adverse reactions;

iv) requires rapid:

(1) identification of possible new signals;

(2) assessment of the likelihood that the number of reports may be consistent with the expected background incidence in the vaccinated cohort, and thereby possibly coincidental.

s) the safety profile of a vaccine may differ substantially within the target population (for example, higher risks in the youngest age groups) which should be addressed by:

i) calculating the disproportionality of the risk of those vaccines as compared to the background risk for illness in a similar age-specific group;

ii) examining the results of statistical methods using both comparator groups; and

iii) using reports for other vaccines as the comparator group with a stratification made at least by age.

t) when there is little time to validate safety signals it is essential to make best use of suspected adverse reaction reports as:

i) although such analyses cannot exclude risks or determine causality:

(1) they can put suspected adverse reaction reports into context; and

(2) should be used as a routine tool for real-time surveillance;

ii) they can be used in safety signal validation;

iii) in the absence of robust epidemiological data, they can be used in preliminary signal evaluation.

u) the shorter the time that has elapsed between the vaccination procedure and the event, the more likely it is to be perceived as a safety trigger and subsequently be reported;

v) events that are expected, common and mild, or occur late after vaccination, are less likely to be reported;

w) given uncertainties around the observed number of adverse events cases sensitivity analyses should be applied in statistical analyses accounting for:

i) the levels of diagnostic certainty;

ii) the level of vaccine exposure;

iii) the background incidence rates;

iv) properly assumed levels of under-reporting of adverse events;

v) numbers of confirmed and non-confirmed cases (using several categories of diagnostic certainty as appropriate);

vi) numbers of vaccinated individuals or vaccine doses administered; and

vii) confidence intervals of incidence rates.

x) appropriate follow-up of serious suspected adverse reactions is essential, including data on possible alternative causes;

y) safety signal evaluation requires attention to the following matters:

i) the incidence of the natural disease in the target population for vaccination and its seasonality;

ii) additives and excipients used for the production, inactivation, preservation, and stabilisation of the vaccine;

iii) past experience with similar vaccines, adjuvants and types of antigens, in order to identify adverse reactions which are unexpected and for which a causal relationship remains to be elucidated;

iv) distinction between suspected adverse reactions to the vaccine and those reflecting the clinical picture of the disease for which vaccination has been given (e.g. rash following measles vaccination);

v) public information (public campaign, press) that may favour certain reports in some periods.

z) the principle of public health protection:

i) is particularly relevant in situations such as the approval of vaccines for healthy children, particularly in case of a localised adverse event incident;

ii) requires in those circumstances consideration of a vaccine batch recall or quarantine:

(1) in the absence of the full facts; and

(2) evidence and before the assessment of the issue is finalised.

aa) when considering a batch recall or quarantine where indicated following the relevant adverse event the following matters are to be considered:

i) detailed description of the cases presented in CIOMS format with narrative;

ii) any additional information as appropriate including:

(1) laboratory results;

(2) autopsy reports;

(3) literature.

iii) the characteristics of the adverse event including:

(1) severity;

(2) expectedness (new adverse reaction vs. increased frequency of a known adverse reaction);

(3) outcome;

iv) the characteristics of patients presenting the adverse event including:

(1) age;

(2) concomitant diseases;

(3) concomitant vaccination;

v) the crude number of cases and reporting rate or incidence rate of the adverse event in the vaccinated population using actual vaccine usage

data rather than sales data and observed vs. expected calculations of the event observed;

vi) the time and space clustering of cases, e.g. cases reported by a single hospital, physician or region;

vii) the geographical distribution (both spatial and numbers of doses used) of the suspected batch(es);

viii) the manufacturing records of the suspected batch(es) (certificates of analysis, information on deviations observed at in-process controls or manufacturing steps, documentation of recent changes to the manufacturing process);

ix) the storage and administration conditions of the suspected batch(es);

x) re-analysis of retained samples of the suspected batch(es), focusing, if necessary, on additional parameters to those required for the release of the product;

xi) investigation of any other available source of information that may promptly provide information on similar events (including batch-related information) and provide a preliminary assessment of all available data within a short timeframe.

bb) for single fatal adverse events, particularly where the cause of death is unknown, the reporting rate of the event relative to both the usage of the vaccine batch and the expected age-specific all-cause mortality should be considered before deciding on a recall or quarantine action;

cc) regulatory authorities must engage in:

i) appropriate communication about the benefit-risk balance and safe use of vaccines by regulators to:

(1) the target population;

(2) vaccinated individuals;

(3) parents / carers;

(4) healthcare professionals;

(5) health policy makers; and

(6) the general public;

dd) principles and guidance on safety communication entails:

i) transparency;

ii) providing explicit information in lay language to the public regarding the use of vaccines which is fundamental to the communication approach;

iii) public confidence in vaccination programs being only attained by implementation of and knowledge that systems are in place to ensure complete and rapid assessment and to take precautionary measures if needed;

iv) safety communication about vaccines may also profit from describing key functions of the pharmacovigilance systems;

v) communication about vaccine should include:

(1) informing vaccinators and healthcare professionals on the management of vaccine-related anxiety and associated reactions, particularly in individuals with special conditions:

a) including pregnancy, puberty, immunosensitive conditions, general anxiety or other mood disorders, epilepsy;

b) for the purpose of quantifying safety concerns, relevant background rates, by age group and sex;

c) of up-to-date signs and symptoms which are present in adverse events, whether:

   i) known to be causally related;

   ii) suspected to be causally related or

   iii) likely to be coincidental.

d) preparing standard frequently needed explanations tested by representatives of likely target audiences;

e) addressing concerns raised by the public by proactively communicating results of benefit-risk evaluations;

f) ensuring appropriate communication with the public and in particular the media which should be monitored;

g) giving information to the media in a timely and meaningful manner.

Source

Guideline on good pharmacovigilance practices (GVP) Product- or Population-Specific Considerations

I: Vaccines for prophylaxis against infectious diseases. HMA Heads of Medicines Agencies and European Medicines Agency as an agency of the European Union. Dated 9 December, 2013. Pg. 4,5,6,8,12-20. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-product-population-specific-considerations-i-vaccines_en.pdf

MONITORING OF DATA IN CLINICAL TRIALS – ADOPTED EMA POLICY

20. Guidelines requiring the establishment of data monitoring committees in drug clinical studies directly applicable to the Clinical Trials and the Vaccines published in or about 2005, known to and adopted by the TGA and the TGA Respondents in respect of their functions under the Act at the time of the Approvals states **("Clinical Trials Oversight Policy (EMA)")**:

    a) it is important to ensure that a trial:

        i) continues for an adequate period of time;

        ii) is not stopped too early to answer its scientific questions;

    b) an independent Data Monitoring Committee (DMC):

        i) is appointed as a group of experts external to a study that reviews accumulating data from an ongoing clinical trial to serve the task of answering scientific questions;

        ii) should in general have the predominant purpose of monitoring safety in the study data;

        iii) might also assess other aspects of a clinical trial including:

(1) study integrity; and

(2) study design.

iv) should be set up in relation to a study:

(1) upon consideration of:

a) the vaccine's indication;

b) study endpoints;

c) study duration;

d) study population.

(2) where there is:

a) a lack of available knowledge about the drug;

b) the drug concerns a life-threatening disease usually the implementation, indicated:

i) from an ethical point of view;

ii) whether or not:

1. the treatment aims to reduce mortality or morbidity; or

2. is intended to relieve the patients' situation.

c) would only in very rare cases not be necessary where there exists the circumstances of:

i) a lack of available knowledge about the drug; or

ii) the drug concerns a life-threatening disease usually the implementation.

Source

European Medicines Agency Pre-authorisation Evaluation of Medicines for Human Use London, 27 July 2005 - Doc. Ref. EMEA/CHMP/EWP/5872/03 COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP) - GUIDELINE ON DATA MONITORING COMMITTEES. Pg. 3-4.
https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-data-monitoring-committees_en.pdf

SCHEDULE B - PARTICULARS OF THE KNOWN SERIOUS VACCINES RISKS AND CONDUCT – PRE-APPROVALS AND THE KNOWN SERIOUS RISKS AND CONDUCT – POST-APPROVALS

PART A - RESPONDENTS KNOWLEDGE OF ACTUAL COVID THREAT AND VACCINE NECESSITY

KNOWN ACTUAL THREAT OF COVID TO AUSTRALIAN POPULATION

1. Prior to the Approvals, scientific data rationally establishing the risks and threat of Covid infection to the Australian population was widely and globally published disclosing the following **("the Known Actual Threat of Covid")**:

    a) the Covid infection case fatality rate estimated by the US Government Center for Disease Control was known to the Respondents at least from May, 2020 and at the time of the Approvals and was:

        i) in the overall population - 0.004;

        ii) in people 0-49 years old – 0.0005;

        iii) in people 50-64 years old – 0.002;

        iv) in people 65 years old and over – 0.013.

Source

CDC. Coronavirus disease 2019 (COVID-19). COVID-19 Pandemic Planning Scenarios. Updated May 20, 2020. http://web.archive.org/web/20200709001525/https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html

b) the statistics produced by the Commonwealth as to the scale of Covid infections in the Australian population was obviously exaggerated because **("the Publicly Inflated Covid Infections")**:

i) there was a known and widespread Australian Government approval and use of the polymerase chain reaction test used to detect purported active cases of Covid infection in Australia and internationally **("the PCR Test")** which:

(1) was uniformly set to cycle threshold value **("CTV")** of greater than 35 which was:

a) so unreasonably sensitive as to produce erroneous results;

b) could and did produce a positive result where:

i) no live virus was present; or

ii) only a fragment of a single viral particle was present;

c) even when set to a CTV of 35, produced positive results in which a positive culture was present in only 3% of those instances;

d) was at no time intended or purposed by its creator and producer for use in public health practice to be a diagnostic instrument for detection of Covid infection;

e) was wholly unfit for purpose, inappropriate and misleading in its operation for the purpose to which it was applied as a diagnostic instrument for detection of Covid infection;

(2) frequently provided positive results in persons:

a) with very low viral loads of the Virus;

b) who were asymptomatic;

c) incapable of transmission of the Virus due to their low viral loads;

(3) in 97% of positive results by PCR testing for the Virus:

a) no Virus was detected in subsequent culture tests;

b) the positive result was false.

(4) was publicly notified on 21 July, 2021 by the CDC:

a) to be subject to CDC's withdrawal of the request to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel;

b) to be inappropriate for the stated purpose of testing for infection with the Virus;

(5) is and was at all material times ineffective and misleading as a specific diagnostic tool to identify the Virus or Covid infection;

Source

Jaafar R, et al - Correlation Between 3790 Quantitative Polymerase Chain Reaction-Positives Samples and Positive Cell Cultures, Including 1941 Severe Acute Respiratory Syndrome Coronavirus 2 Isolates. Clin Infect Dis. 2021 Jun 1;72(11):e921. doi: 10.1093/cid/ciaa1491. Erratum in: Clin Infect Dis. 2021 Nov

2;73(9):1745. PMID: 32986798; PMCID: PMC7543373. https://pubmed.ncbi.nlm.nih.gov/32986798/

CDC 07/21/2021: Lab Alert: Changes to CDC RT-PCR for SARS-CoV-2 Testing https://www.cdc.gov/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html

External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results November 2020 DOI:10.5281/zenodo.4298004. Pieter Borger https://www.researchgate.net/publication/346483715_External_peer_review_of_the_RTPCR_test_to_detect_SARS-CoV-2_reveals_10_major_scientific_flaws_at_the_molecular_and_methodological_level_consequences_for_false_positive_results

c) there was a known inflation of the reporting of Covid - related deaths by the Commonwealth known to the Respondents at the time of the Approvals obviously arising because **("the Inflated Covid Deaths")**:

i) the quantum of Covid-related deaths reported was at all material times defined to include any person who was determined at the time of death to have been infected with the Virus whether or not Covid was determined to be the actual cause of death, thereby:

(1) allowing for excessive coincidental findings of death unrelated to Covid in a high proportion such that the claimed deaths from Covid were in fact in respect of the most virulent strain of Covid:

a) only 41% causally related to Covid;

b) 2.5 times the actual deaths causally related to Covid;

(2) in no manner genuinely ascribing causality of the deaths to Covid;

(3) the number of Covid-related deaths reported were based upon a causality assessment process unknown to science;

(4) no statistic has been produced by the Respondents or was known to the Respondents prior to the Approvals or at all as to the number of Australians whose death was caused by Covid in circumstances where in truth:

a) the cases of Australians reportedly determined at the time of death to have been infected with the Virus:

i) had co-existing co-morbidities at the time of death in 93% of those cases;

ii) were listed with Covid as the sole cause of death in only 7% of those cases;

b) the total number of Australians whose death was actually caused by Covid was materially smaller than the reported Covid-related deaths.

Source

"Deaths in children and young people in England after SARS-CoV-2 infection during the first pandemic year". Smith, C et al. 2022. Nature Medicine; Vol 28, 185-192. https://doi.org/10.1038/s41591-021-01578-1

"COVID infection severity in children under 5 years old before and after Omicron emergence in the US".WANG, L. et al. Posted 13 January, 2022. https://doi.org/10.1101/2022.01.12.22269179

See e.g. NSW COVID-19 WEEKLY DATA OVERVIEW: www.health.nsw.gov.au/coronavirus

d) based upon Commonwealth reporting recorded from on or about the time of the Approvals at 31 January, 2021 and to the present time:

i) that the median age of death from Covid was at that time and remains until the present **("the Known Median Age of Covid Deaths")**:

(1) 81.2 years for males; and

(2) 86.0 years for females;

ii) in circumstances where in truth **("the Known Non-Effect of Covid Upon Age Life Expectancy")**:

(1) the known median life expectancy at birth for people born in that same period was:

a) 81.3 years for males; and

b) 85.4 years for females.

(2) the median age of death was:

a) 79 for males; and

b) 85 for females.

(3) the expectation of significant and common co-morbidities amongst those in that age group known to be:

a) entirely causal; or

b) contributory.

Source

"Australian Government Department of Health – Data Sheet". https://www.health.gov.au/sites/default/files/documents/2021/02/coronavirus-covid-19-at-a-glance-31-january-2021-coronavirus-covid-19-at-a-glance-31-january-2021.pdf

"ABS Life expectancy hits a new high". Media Release. Released 4/11/2021. https://www.abs.gov.au/media-centre/media-releases/life-expectancy-hits-new-high

"Australian Institute of Health and Welfare. Deaths in Australia" Australian Government. Web report: https://www.aihw.gov.au/reports/life-expectancy-death/deaths-in-australia/contents/age-at-death

e) at the time of the Approvals, based upon Commonwealth reporting by the ABS **("the Known Actual Circumstances of Covid")**:

i) Covid was only the 38th leading cause of death in Australia in 2020, even adopting the Inflated Covid Deaths;

ii) influenza was a significantly greater concern in Australia, in that infection with influenza reported by the ABS in 2017:

(1) was the direct cause of 1,183 deaths in that year;

(2) in confluence with pneumonia, contributed to 4,369 deaths in that year;

(3) was the 9th leading cause of death in that year;

(4) was the 12th leading cause of death in 2018 at 3102 deaths;

iii) the impact of Covid varies materially depending upon the age group;

iv) not one person under the age of 50 years in Australia had died from Covid at the time of the Approvals;

Source

Australian Government Department of Health (2018) Communicable Diseases Intelligence. Report of the National Influenza Surveillance Scheme 2011 to 2018. Year 2022 Volume 46. Communicable Disease Epidemiology and Surveillance Section
https://doi.org/10.33321/cdi.2022.46.12

Australian Government Department of Health – Data Sheet
https://www.health.gov.au/sites/default/files/documents/2021/02/coronavirus-covid-19-at-a-glance-31-january-2021-coronavirus-covid-19-at-a-glance-31-january-2021.pdf

f) from prior to January 2021 and before the Approvals, the Respondents knew that, with respect to the fatality rate in respect of Covid infection **("the Known Actual Covid Fatality Rate")**:

i) the true infection fatality rate for Covid:

(1) across all age groups and strata of the world population at that time ranged from 0.00 to 0.0154;

(2) as an average across all age groups and global populations was 0.002;

(3) a range of less than 0.001 to 0.0058 in city and national populations globally;

(4) was 0.0003 in people below 40 years of age;

(5) in people below 70 years of age:

a) ranged from 0.00 to 0.0068;

b) was a median of 0.0005;

(6) was similar to seasonal influenza;

ii) that at that time 94% of the global population was younger than 70 years old;

iii) that the infection fatality rate data was rationally established based upon unassailable large scale and widely published scientific seroprevalence testing which determined actual previous Covid infections in the population;

iv) the median age of Covid deaths at that time:

(1) in Australia – 82 years of age;

(2) globally in developed countries between 78 and 86 years of age;

v) that comparatively, the infection fatality rate of:

(1) seasonal influenza was scientifically determined and known to be usually 0.001;

(2) influenza during the 1918-1919 influenza pandemic was greater than 0.025;

vi) the variation in the infection fatality rate of Covid infection varies due to differences in population age structure and the case-mix of infected and deceased patients and other factors.

Source

The Known Actual Covid Fatality Rate was well documented and accepted scientifically prior the Approvals including in, for example, the following studies:

1. "Seroprevalence of anti-SARS-CoV-2 IgG antibodies in Kenyan blood donors". Uyoga, S et al. Nov 2020. Science: Vol 371, Issue 6524. Pp 79-82.
https://www.science.org/doi/10.1126/science.abe1916

2. "High SARS-CoV-2 seroprevalence in health care workers but relatively low number of deaths in urban Malawi" Chibwana, M et al. 2020. Wellcome Open Res, 5:199.
https://wellcomeopenresearch.org/articles/5-199/v1

3. "What do the Delhi and Mumbai Sero-Survey Results Tell US About COVID-19 in India?". The Wire. 31 July,2020.
https://thewire.in/health/delhi-mumbai-covid-19-coronavirus-seroprevalence-survey-results

4. "Covid-19 far more widespread in Indonesia than official data show: studies". Reuters. 3 June, 2021.
https://www.reuters.com/world/asia-pacific/exclusive-covid-19-far-more-widespread-indonesia-than-official-data-show-studies-2021-06-03/

5. "Seroprevalence of SARS-CoV-2 in Guilan Province, Iran". Shakiba, M et al. April 2020. Emerging Infectious Diseases. 2021;27(2):636-638.
https://wwwnc.cdc.gov/eid/article/27/2/20-1960_article

6. “42.4 percent of the residents of Israel have antibodies against the corona virus”. The Standard. 25 June, 2020. https://www.derstandard.at/story/2000118306133/42-4-prozent-der-bewohner-ischgls-haben-antikoerper-gegen-sars

7. “COVID-19 mortality, excess mortality, deaths per million and infection fatality ratio, Belgium, 9 March 2020 to 28 June 2020”. Molenberghs, G et al. 2022. Euro Surveill. 27(7). https://doi.org/10.2807/1560-7917.ES.2022.27.7.2002060

8. “Estimation of SARS-CoV-2 Infection Fatality Rate by Real-time Antibody Screening of Blood Donors”, Erikstrup, C et al. January 2021. Clinical Infectious Diseases, Volume 72, Issue 2, Pages 249–253, https://doi.org/10.1093/cid/ciaa849

9. “Estimating the infection fatality ratio in England”. The Centre for Evidence-Based Medicine. 21 August, 2020. https://www.cebm.net/covid-19/estimating-the-infection-fatality-ratio-in-england/

10. ”SARS-CoV-2 antibody prevalence in England following the first peak of the pandemic”. Ward, H et al. 2021. Nat Commun 12, 905. https://doi.org/10.1038/s41467-021-21237-w

11. “Infection fatality rate of SARS-CoV2 in a super-spreading event in Germany”. Streeck, H et al. 2020. Nat Commun 11, 5829. https://doi.org/10.1038/s41467-020-19509-y

12. “Humoral immune response to SARS-CoV-2 in Iceland”. Gudbjartsson, DF et al. Oct 2020. New England Journal of Medicine. 383:1724-1734. https://www.nejm.org/doi/full/10.1056/NEJMoa2026116

13. “Age-specific SARS-CoV-2 infection fatality ratio and associated risk factors, Italy, February to April 2020”. Poletti, P et al. 2020. Euro Surveill. 2020;25(31)..
https://doi.org/10.2807/1560-7917.ES.2020.25.31.2001383

14. “Infection fatality risk for SARS-CoV-2 in community dwelling population of Spain: nationwide seroepidemiological study”. Pastor-Barriuso, R et al. Nov 2020. BMJ 2020; 371.
https://doi.org/10.1136/bmj.m4509

15. “Serology-informed estimates of SARS-CoV-2 infection fatality risk in Geneva, Switzerland”. Perez-Saez, J et al. April 2021. Lancet. VOLUME 21, ISSUE 4, E69-E70.
https://doi.org/10.1016/S1473-3099(20)30584-3

16. “Early peak and rapid decline of SARS-Co-V-2 seroprevalence in a Swiss metropolitan region”. Emmenegger, M et al. Posted August 2021.
https://www.medrxiv.org/content/10.1101/2020.05.31.20118554v4

17. “Population-based seroprevalence of SARS-CoV-2 is more than halfway through the herd immunity threshold in the State of Maranhão, Brazil”. Mourna da Silva, AA et al. Posted Sept 01, 2020.
https://www.medrxiv.org/content/10.1101/2020.08.28.20180463v1

18. “Three-quarters attack rate of SARS-CoV-2 in the Brazilian Amazon during a largely unmitigated epidemic”. Buss, L et al. Dec 2020. SCIENCE. Vol 371, Issue 6526 pp. 288-292
https://pubmed.ncbi.nlm.nih.gov/33293339/

19. “Using serological studies to assess Covid-19 infection fatality rate in developing countries: A case study from one Colombian department”. Alvis Guzman, N et al. Sept 2021. International Journal of Infectious Diseases. Vol 110: p 4-5.

https://www.sciencedirect.com/science/article/pii/S1201971221005075

20. “Infection fatality ratios for Covid-19 among noninstitutionalized persons 12 and older: results of a random-sample prevalence study”. Blackburn, J et al. January 2021. Annals of Internal Medicine. https://www.acpjournals.org/doi/10.7326/M20-5352

21. “Covid-19 antibody seroprevalence in Santa Clara County, California”. Bendavid, E et al. April, 2021. International Journal of Epidemiology, Volume 50, Issue 2, Pages 410–419, https://doi.org/10.1093/ije/dyab010

22. “Second round of COVID-19 community testing completed; Miami-Dade County and the University of Miami Miller School of Medicine announce initial findings”. Miami-Dade County News Release. 24 April, 2020. https://www.miamidade.gov/releases/2020-04-24-sample-testing-results.asp

23. “Preliminary results of USC-LA County COVID-19 study released”. University of Southern California Press Room. April 20, 2020. https://pressroom.usc.edu/preliminary-results-of-usc-la-county-covid-19-study-released/

24. “Infection fatality risk for SARS-CoV-2 in community dwelling population of Spain: nationwide seroepidemiological study”. Pastor-Barriuso, R et al. 2020. BMJ. 371. https://doi.org/10.1136/bmj.m4509

25. “Global perspective of COVID-19 epidemiology for a full-cycle pandemic”. Ioannidis, J Dec 2020, European Journal of Clinical Investigation. Vol 50, Issue 12.

https://onlinelibrary.wiley.com/doi/10.1111/eci.13423

26. “A systematic review and meta-analysis of published research data on Covid-19 infection fatality rates”. Meyerowitz-Katz, Dec 2020. International Journal of Infectious Diseases. Volume 101, P138-148. https://www.ijidonline.com/article/S1201-9712(20)32180-9/fulltext

27. “Estimation of SARS-CoV-2 Infection Fatality Rate by Real-time Antibody Screening of Blood Donors”.Erikstrup, C et al. January 2021. Clinical Infectious Diseases, Volume 72, Issue 2, Pages 249–253. https://doi.org/10.1093/cid/ciaa849

28. “Humoral immune response to SARS-CoV-2 in Iceland” Gudbjartsson, DF et al. Oct 2020. New England Journal of Medicine. 383:1724-1734.
https://www.nejm.org/doi/full/10.1056/NEJMoa2026116

29. “Infection fatality rate of COVID-1937 inferred from seroprevalence data”.Ioannidis, J. P. A . 2020. Bulletin of the World Health Organization. 99(1): 19-33F.
https://www.who.int/bulletin/online_first/BLT.20.265892.pdf

31. “1918 Influenza: the mother of all pandemics”. Taubenberger JK, Morens DM. 2006. Emerg Infect Dis. 12(1):15-22.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3291398/#R4

32. “All-cause mortality supports the COVID-19 mortality in Belgium and comparison with major fatal events of the last century”. Bustos 33. Sierra, N et al. Nov 2020. Arch Public Health. 13;78(1):117.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7662738/

“CDC - Weekly Updates by Select Demographic and Geographic Characteristics”.
https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm

"COVID-19 epidemiology update: Key updates". Government of Canada.
https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html

"NHS – COVID-19 Daily Deaths".
https://www.england.nhs.uk/statistics/statistical-work-areas/covid-19-daily-deaths/

"France - COVID-19: epidemiological update of May 7, 2020"
https://www.santepubliquefrance.fr/maladies-et-traumatismes/maladies-et-infections-respiratoires/infection-a-coronavirus/documents/bulletin-national/covid-19-point-epidemiologique-du-7-mai-2020

"Germany - Current situation reports, weekly reports and pandemic radar".
https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Situationsberichte/Gesamt.html

"Characteristics of patients who died positive for SARS-CoV-2 infection in Italy".
https://www.epicentro.iss.it/coronavirus/sars-cov-2-decessi-italia

"Corona virus: situation in Switzerland".
https://www.bag.admin.ch/bag/de/home/krankheiten/ausbrueche-epidemien-pandemien/aktuelle-ausbrueche-epidemien/novel-cov/situation-schweiz-und-international.html

g) as 2 April, 2021, it was conclusively determined and verified by data available publicly that **("the Known Underestimate of Previous Covid Infection in the Population")**:

i) actual cases of current or previous infection with Covid in the US population was in fact 4,416% or 44.17 times greater than the reported number of Covid cases (53,000 / 1,200);

ii) the local infection fatality rate for Covid at that time across all age groups was scientifically estimated to be approximately 0.17%.

Source

"Covid-19 Antibody Seroprevalence in Santa Clara County, California". Bendavid et al. April 2021. International Journal of Epidemiology. Vol 50, Issue 2, pages 410-419

h) the purported risk from Covid was artificially inflated by:

i) publication of case fatality rates which erroneously relied upon the number of tested cases known to be significantly less than actual numbers of infections;

ii) the number of deaths as a comparator further inflated by the Inflated Covid Deaths;

iii) Covid had an actual infection fatality rate known to the Respondents at the time of the Approvals of:

(1) no greater than 0.0057 in the general population;

(2) no greater than 0.0005 in those under the age of 70 years;

(3) far lower than early purely speculative and unsubstantiated estimates.

i) from prior to the Approvals, in respect of the question of natural extant or arising immunity from Covid in the general Australian population that **("the Known and Ignored Efficacy of Natural Covid Immunity")**:

i) the Respondents at no point in time prior to the Approvals reasonably considered or studied as an alternative to mass vaccination:

(1) the efficacy and duration of the natural immunity from Covid in people either naturally or following Covid infection **("Natural Immunity")**;

(2) Natural Immunity as a positive consideration within the context of risk-benefit analysis in Approval of any of the Vaccines;

ii) it had been scientifically established that:

(1) Natural Immunity is very durable and typically persists for 12-17 years;

(2) the world population has cross-reacting T-cells, B cells and antibodies derived from encounters with previous cold coronaviruses that can recognise and defend against Covid;

iii) the four human coronaviruses that cause common colds were at the time of the arrival of the Virus and at the time of the Approvals:

(1) endemic in the world population;

(2) never vaccinated against by humans because no such successful vaccine had ever existed;

iv) over 150 scientific studies and evidence on natural immunity as compared to the COVID-19 vaccine-induced immunity had:

(1) been produced; and

(2) disclosed a consensus that immunity caused by COVID infection is robust and long lasting.

v) prior to the Approvals in respect of Covid infection that:

(1) at least 40% to 45% of the infections were asymptomatic and in some cohorts the proportion was 96% depending upon:

a) age; and

b) cross-immunity imparted by other viruses such as beta coronaviruses HCoV-OC43 and HCoV-HKU1.

(2) 80% were mild infections.

Source

Dr Karina Reiss, Dr Sucharit Bhakdi. Book, "Corona False Alarm? Facts and Figures". Pages 101-108.

The Known and Ignored Efficacy of Natural Covid Immunity was well documented and accepted scientifically prior the Approvals including in, for example, the following studies:

1. "Covid-19: Do many people have pre-existing immunity?" Doshi, P. September 2020. BMJ: 370.
https://doi.org/10.1136/bmj.m3563

2. "Preexisting and de novo humoral immunity to SARs-CoV-2 in humans". Kevin W NG et al. 2020. Science. 370(6522): 1339-1343.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7857411/

3. "Letter to BMJ: T-cells really are the superstars in fighting COVID-19 - but why are some of us so poor at making them?" King E. Sept 2020 https://www.bmj.com/content/370/bmj.m3563/rr-6

4. “Prevalence of asymptomatic SARS-CoV-2 infection: a narrative review”. Oran DP, Topol, EJ. 2020. Annals of Internal Medicine. 173,362-367.
https://doi.org/10.7326/M20-3012

5. “160 Plus Research Studies Affirm Naturally Acquired Immunity to Covid-19: Documented, Linked, and Quoted”. Alexander, PE. October, 2021. Brownstone Institute.
https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/

j) that in the circumstances of the rationally established scientific factual matters:

i) Covid was not a threat to the Australian population such that the Respondents could assume such a low a level of risk arising to the Australian population which could only be met with an even lower level of risk in receiving the Vaccines confirmed by fully, comprehensively, and evidently establishing that the Vaccines are:

(1) safe;

(2) effective;

(3) displaying a positive risk-benefit profile.

ii) the Approvals were undertaken as a Provisional Approval by the Respondents upon the purported basis that there was an urgent need for the Vaccines early approval such that if the Vaccines were not approved in a materially expedited manner **(“the False Necessity Basis”)**:

(1) millions of the Australian population would die or require hospitalisation due to the Covid infection;

(2) there were no other therapies available in the world known to be capable of therapeutically addressing Covid infection;

(3) mass vaccination was the only way out of the Covid Pandemic;

(4) there was an urgent need for the Vaccines;

(5) the risk – benefit ratio was such that there was a greater harm in failing to approve the Vaccines and make them available to the public without full and proper testing than not.

iii) to the extent that any risk-benefit assessment was done in respect of the Vaccines prior to the Approvals, the Respondents:

(1) assumed a level of risk in respect of Covid profoundly controverted by the actual risk of Covid known and disclosed to the Respondents in the Known Actual Threat of Covid, including the False Necessity Basis;

(2) without any proper basis failed or refused to apply the Known Actual Threat of Covid to any risk-benefit analysis in respect of the Vaccines, thereby determining the Approvals:

a) on the basis of known false assumptions, including the False Necessity Basis;

b) in circumstances where in truth the Approvals ought to have been rejected where the Known Actual Threat of Covid was properly considered.

Source

TGA Documents indicating that there was an urgent need for the Vaccines in order to prevent widespread serious disease, hospitalisations and deaths from Covid in Australia:

1. The Pfizer Original AUSPAR. Page 9.

2. The Pfizer 12-15 Year Olds Extension AUSPAR. Page 8.

3. The Pfizer 5-11 Year Olds Extension AUSPAR. Page 9,10.

4. The Booster for 12-15 Year Olds AUSPAR. Page 7.

5. The Pfizer 6 months-5 Year Olds Extension AUSPAR. Page 9,10.

6. The Pfizer Booster AUSPAR For Adults >18 Years AUSPAR. Page 9.

7. The Pfizer Booster for 5-11 Year Olds Booster AUSPAR. Page 10,11.

8. The Pfizer Clinical Evaluation Report. Page 9,10.

9. The Pfizer Delegate's Overview. Page 22.

10. The AstraZeneca Delegate's Overview. Page 6.

11. The AstraZeneca Original AUSPAR. Page 9.

12. The AstraZeneca Booster in >18 Year Olds AUSPAR. Page 8.

13. The Moderna 12-17 Year Olds AUSPAR. Page 9.

The False Necessity Basis was purported on the following occasions by the Respondents in their Misleading Statements:

the Skerritt Misleading Vaccines Statements:

7 December, 2021;

1 March, 2022;

1 April, 2022.

the Secretary Misleading Vaccines Statements:

3 February, 2021;

7 March, 2021.

the TGA Misleading Vaccines Statements:

27 May, 2021;

16 September, 2021;

8 November, 2022.

the Misleading Department Vaccines Statements:

23 December, 2021.

PART B – RESPONDENTS' KNOWLEDGE OF VACCINES' SAFETY RISKS AND LACK OF EFFICACY – PRE-APPROVAL

KNOWN ALTERNATIVE THERAPIES FOR COVID

2. On or about 10 December, 2020 and prior to the Approvals scientific data and conclusions rationally establishing and disclosing the existence of effective therapeutics already available for the treatment of COVID was widely and globally published **("the Known Alternative Therapies")**:

a) including:

i) antivirals such as:

(1) interferon beta-2a;

(2) molnupiravir;

(3) lopinavir/ritonavir;

(4) remdesivir.

ii) steroids such as:

(1) dexamethasone.

iii) monoclonal cocktails such as:

(1) tocilizumab (actemra).

iv) hyperimmune plasma/convalescent plasma; and

b) known to the Respondents to have been publicly acknowledged by Pfizer at that time.

Source

The Known Alternative Therapies were disclosed by the fact that those therapies were publicly known and approved for use in humans for a significant period prior to the Approvals. Further the TGA and the TGA Respondents had provided to them the following document produced by Pfizer making the assertion expressly - Pfizer-BioNTech Covid-19 Vaccine (BNT162, PF-07302048) Vaccines And Related Biological Products Advisory Committee Briefing Document - Meeting Date: 10 December 2020. https://www.Fda.Gov/Media/144246/Download. Page 10.

The existence of the Known Alternative Therapies was well documented and accepted scientifically including in for example the following studies:

1. “Efficacy of various treatment modalities for nCOV-2019: A systematic review and meta-analysis”. Misra, S et al. 2020. Eur J Clin Invest. 50:e13383. https://doi.org/10.1111/eci.13383

2.https://www.recoverytrial.net/news/low-cost-dexamethasone-reduces-death-by-up-to-one-third-in-hospitalised-patients-with-severe-respiratory-complications-of-covid-19 June 2020. Subsequently published in Feb 21 as: “Dexamethasone in Hospitalized Patients with Covid-19”. The Recovery Collaborative Group. N Engl J Med. February 25, 2021, 384:693-704

3. “Tocilizumab for treatment patients with COVID-19: Recommended medication for novel disease”. Samaee, H et al. December 2020. Int Immunopharmacol. 89(Pt A):107018. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7494278/

4. “Convalescent plasma as a potential therapy for Covid 19”. Chen, L et al. April 2020. The Lancet. Vol 20: pp398-400. https://www.thelancet.com/action/showPdf?pii=S1473-3099%2820%2930141-9

KNOWN INHERENT VACCINES RISKS

3. Prior to the Approvals scientific data and conclusions rationally establishing the novel nature of the Vaccines was widely and globally published disclosing that the Vaccines were **(“the Known Inherent Vaccines Risks”)**:

a) each producing their intended effect in the human body by the introduction of a new or modified gene into the body for the purpose of seeking to immunise against Covid;

b) by universal and conventional definition;

i) not “vaccines”, as per the definition of a vaccine at the time of the Approvals;

ii) gene therapy products;

c) for the Pfizer and Moderna Vaccines, never evaluated under any gene therapy guidelines;

d) utilizing a pharmacological effect, action, mechanism and purpose which has never before in history been:

i) widely used in a general population;

ii) deployed in a fully approved therapeutic product;

e) by reason of their unprecedented nature, experimental;

f) using in their composition a genetic technology which has not been employed for any fully approved drug in history;

g) previously only investigated in relatively early clinical research for possible use in certain cancers and rare genetic disorders;

h) possessing of exceptional and inherent safety risks, by reason of:

i) their novel properties; and

ii) widespread intended use;

i) operating in a manner never used previously:

i) by delivery into the human cells of either:

(1) RNA in a lipid nanoparticle; or

(2) DNA genetic material contained in a viral vector;

ii) to produce a spike protein:

(1) similar to that found on the surface of the coronavirus as its most toxic element;

(2) in order to provoke an immune response.

j) in respect of the mRNA Vaccines, employing new generation nanoparticle technology using nanoparticles which:

i) are either:

(1) non-viral based; or

(2) viral based;

ii) by reason of their small size are:

(1) more readily taken up by the human body than larger sized particles;

(2) able to cross biological membranes and access cells, tissues and organs that larger sized particles normally cannot;

(3) widely and efficiently distributed throughout the human body cells and organs following administration;

(4) cross the blood-brain barrier;

(5) possessive of higher risk and implications in relation to organ and tissue toxicity as compared to conventional vaccines which largely remain at the site of injection;

(6) are associated with long term inflammation:

a) in various tissues and organs; and

b) cardiovascular adverse effects.

k) so unprecedented in their nature and mechanism and purpose so as to be:

i) reasonably expected to take more than 10-12 years to develop due to technical difficulties;

ii) having a 5% probability of proving safety and efficacy in even early Phase II clinical trials involving small numbers of individuals; and

iii) having a 2% probability of moving to larger Phase III clinical trials and demonstrating safety and efficacy before being considered for marketing.

Source

Merriam-Webster definition of vaccine at the time of the Approvals:
"Any preparation of weakened or killed bacteria or viruses introduced into the body to prevent disease by stimulating antibodies against it".
https://languagelog.ldc.upenn.edu/nll/?p=50886

Food and Drug Administration (FDA) Office of Cellular, Tissue, and Gene Therapies' definition of "gene therapy products" include:
"Introducing a new or modified gene into the body to help treat a disease".

https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy

The Known Inherent Risks were well documented and accepted scientifically including in for example the following studies:

1. “Reasons for success and lessons learnt from nanoscale vaccines against COVID-19”. Kisby et al. 2021. Nature Nanotechnology. Vol 16: 843-852. https://www.nature.com/articles/s41565-021-00946-9.pdf

2. “Research Strategies for Safety Evaluation of Nanomaterials, Part II: Toxicological and Safety Evaluation of Nanomaterials, Current Challenges and Data Needs”. 2005. Toxicological Sciences, Volume 88, Issue 1, Pages 12–17. https://doi.org/10.1093/toxsci/kfi293

3. “Health and Environmental Alliance Fact Sheet – Nanotechnology and Health Risks”. April 2008. https://www.env-health.org/IMG/pdf/17-_NANOTECHNOLOGY_AND_HEALTH_RISKS.pdf

4. Bekele, T., Gunn, A., Chapman, N., Chowdhary, V., Corrigan, K., ... Yamey, G. (2018). “Developing new health technologies for neglected diseases: a pipeline portfolio review and cost model”. Young, R et al. 2018. Gates Open Research. 2:23. https://doi.org/10.12688/gatesopenres.12817.2

The nature and effect of the Vaccines was uncontroversially disclosed to the TGA and the TGA Respondents through the Sponsors’ Provisional Applications for Registration. That the mechanism of effect of the Vaccines was unprecedented was

rationally established in the body of known vaccine products worldwide.

KNOWN AND INTENDED WIDESPREAD USE OF THE VACCINES

4. At all material times the Respondents intended and in fact acted so that subsequent to the Approvals the Vaccines would be received by a significant majority of the Australian population by **("the Known Widespread Use of Vaccines")**:

a) the Respondents' determination that the Vaccines, once approved and subsequent to the Approvals, would be as far as possible made available and distributed to the entire Australian population;

b) the widespread media and government promotional messaging that the Vaccines were:

i) safe;

ii) effective;

iii) the only way out of the Covid pandemic for the Australian population.

c) the Approvals being attended by widespread government and private industry incentive and promotion of the Vaccines as safe and effective;

d) a reasonable expectation that the Australian public would generally accept that the Vaccines are safe and effective where:

i) approved for registration and public use by the Secretary and the Australian Government;

ii) the Respondents public and consistent message that the Vaccines were and are:

(1) safe;

(2) effective;

(3) the only way out of the Covid pandemic for the Australian population.

Source

TGA Documents indicating that the Vaccines are the only way to overcome the Covid Pandemic:

1. The Pfizer Original AUSPAR. Page 9.
2. The Pfizer 12-15 Year Olds Extension AUSPAR. Page 8.
3. The Pfizer 5-11 Year Olds Extension AUSPAR. Page 9,10.
4. The Booster for 12-15 Year Olds AUSPAR. Page 7.
5. The Pfizer 6 months-5 Year Olds Extension AUSPAR. Page 9,10.
6. The Pfizer Booster AUSPAR For Adults >18 Years AUSPAR. Page 9.
7. The Pfizer Booster for 5-11 Year Olds Booster AUSPAR. Page 10,11.
8. The Pfizer Clinical Evaluation Report. Page 9,10.
9. The Pfizer Delegate's Overview. Page 22.
10. The AstraZeneca Delegate's Overview. Page 6.
11. The AstraZeneca Original AUSPAR. Page 9.
12. The AstraZeneca Booster in >18 Year Olds
13. AUSPAR. Page 8.
14. The Moderna 12-17 Year Olds AUSPAR. Page 9.

Consistent examples of the messaging of the Respondents associated with the Approvals and the release of the Vaccines to

the Australian population are pleaded and particularised herein at paragraphs 44(b), 44(g), 44(l), 45(a), 45(a1), 45(b), 45(b1), 46(a), 46(c), 46(d), 46(e), 46(f), 46(i), 47(c), 47(c2), 47(d), 48(a), 48(b), 48(c), 49(b) and 49(c) and defined as the "Misleading Statements of the Respondents".

KNOWN TYPICAL APPROVALS TIMELINE

5. Prior to the Approvals reported data and internally accumulated data of the TGA rationally establishing the typical process for authorisation of a new vaccine for use by the Australian public was widely and globally published disclosing the following **("the Known Vaccine Timeline")**:

a) that a typical vaccine development timeline:

i) takes 5 to 10 years, and sometimes longer to:

(1) assess whether the vaccine is safe and efficacious in clinical trials;

(2) complete the regulatory approval processes; and

(3) manufacture sufficient quantity of vaccine doses for widespread distribution.

ii) involves the following stages and time frames:

(1) Animal testing – years;

(2) Phase I - 3 months;

(3) Phase II - 2 years;

(4) Phase III - several years;

(5) Manufacturing;

(6) Approval.

iii) differed exponentially from the Approvals because the total amount of time taken for the Approvals from commencement, testing and trials to the time of the Approvals was:

(1) 9 months for the Pfizer vaccine;

(2) 10 months for the AstraZeneca vaccine; and

(3) 17 months for the Moderna vaccine.

Source

The Known Vaccine Timeline are a well-established and known matter of public historical record including the TGA's own records of its conduct in previous vaccine approvals and the current Approvals.

KNOWN USE AMONGST UNTESTED GROUPS

6. Prior to the Approvals scientific data rationally establishing the testing and use of the Vaccines in untested groups of people was widely and globally published and provided to the TGA and TGA Respondents by the Sponsors disclosing the following **("the Known Untested Groups")**:

a) it is not usual practice in medicine to use a therapeutic intervention on groups of people on whom the therapeutic intervention has never been tested:

b) the Vaccines were not tested on **("the Untested Groups")**:

i) pregnant women;

ii) lactating women;

iii) people with autoimmune diseases;

iv) people who had prior infection with the disease, specifically Covid;

v) people with polyethylene glycol allergies.

c) the Vaccines were each indicated by the TGA and the TGA Respondents in any case for use by the Untested Groups.

Source

The Known Untested Groups are established by:

1. the fact that a therapeutic intervention was not used on untested groups is a matter of public record in terms of regulatory historical data.

2. the fact that the Vaccines had not been tested on the Untested Groups before the Approvals is disclosed in the entirety of testing data relating to the Vaccines which was provided by the Sponsors to the TGA and the TGA Respondents prior to the Approvals;

3. the Vaccines were indicated for the Untested Groups by reason of issuance of the Approvals which included the specified indications and TGA approved Product Information.

KNOWN CORONAVIRUS MODE OF INFECTION

7. Prior to the Approvals widely and globally published scientific data and data provided to the TGA and the TGA Respondents by Pfizer relevant to coronaviruses and their mode of infection disclosed **("the Known Coronavirus Vaccine Issues")**:

a) coronaviruses:

    i) spread within an infected organism so as to avoid completely detection or neutralisation by virus-specific antibodies;

    ii) primarily infect epithelial cells within the lung;

b) it remained unknown as to the coronavirus':

    i) exact mechanism of lung injury; and

    ii) cause of severe disease in humans.

c) vaccine development for coronaviruses is rendered futile and/or hazardous because:

    i) vaccines must either:

        (1) induce better immunity than the original virus; or

        (2) lessen the disease incurred during a secondary infection;

    ii) the propensity of the coronaviruses to recombine pose a problem by rendering the vaccine:

        (1) ineffective; and

        (2) potentially increasing the evolution and diversity of the virus in the wild.

d) it has been clearly established scientifically that virus vaccination with S protein leads to enhanced disease;

e) due to the lack of effective therapeutics or vaccines for the coronaviruses the best measures to control human coronaviruses are and remain, as opposed to vaccination:

i) a strong public health surveillance system; and

ii) rapid diagnostic testing and quarantine when necessary.

f) the data contained in the Pfizer Nonclinical Studies provided to the TGA as a basis for the Pfizer Approval showed:

i) Pfizer Vaccine recipients suffering "immune stimulation and inflammatory response" the TGA (delegate) determined required further scrutiny given the known risk of Antibody-Dependent Enhancement (ADE);

ii) the Pfizer Nonclinical Study demonstrating lung histopathological changes in the Pfizer Vaccine recipients;

iii) several of the histopathological finding in immunological tissues such as spleen and lymph nodes, as well as increase in temperature, persisted beyond the end of the trial at three weeks;

iv) indications of a hyperimmune response in the Pfizer Vaccine recipients accepted by the TGA (delegate) as requiring further review.

Source

The scientific facts and conclusions were disclosed through widely published scientific studies since at least 2015 – e.g. Coronaviruses: An Overview of Their Replication and Pathogenesis, Anthony Fehr and Stanley Perlman, pg. 10, 13, 15-16. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4369385/pdf/978-1-4939-2438-7_Chapter_1.pdf

The Pfizer Nonclinical Trial Data was made available to the TGA and the TGA Respondents prior to the Approvals and summarized by the TGA in the Pfizer Nonclinical Evaluation Report.

KNOWN DEFECTS IN STUDIES AND RAW DATA RELEASE

8. Prior to the Approvals scientific data was provided to the TGA and TGA Respondents by the Sponsors rationally establishing the absence of transparency and adequacy of data provided in respect of the Approvals disclosing the following **("the Known Study Defects")**:

a) the Sponsors failed to engage in reasonable data transparency in the circumstances of the Approvals that:

i) data transparency was and is a well-established norm in biomedical research, and

ii) there was extreme importance of data transparency due to the extremely high possibility and risk of harm in the Australian population in the:

(1) use of the novel Vaccines and their respective technologies never before used in a mass vaccination setting;

(2) the broad use of the Vaccines as public health interventions being given to the vast majority of the population;

(3) the comparatively and significantly shorter period of the Approvals.

iii) the Australian populations contribution to the funding of the Approvals apparatus;

b) the Sponsors provided data upon which each of the Approvals was based which was so inadequate as to render proper determination of the following impossible in circumstances of prolific use of the Vaccines:

(1) stratified safety profile of the Vaccines;

(2) the Risk-Benefit Profile of the Vaccines;

(3) the rational basis for use of Vaccines at all.

Source

These arise based upon the entirety of the data provided to the TGA and the TGA Respondents by the Sponsors in relation to the Approvals.

KNOWN ABSENCE OF TESTING OR EVIDENCE FOR VACCINES TO PREVENT SERIOUS ILLNESS, FATALITIES OR COVID TRANSMISSION

9. Prior to the Approvals testing data provided to the TGA and TGA Respondents by the Sponsors rationally establishing the insufficient clinical trial testing of the Vaccines for the Approvals disclosed the following **("the Known Absence of Testing and Evidence for Vaccine Prevention of Transmission, Serious Illness, or Fatality")**:

a) the Vaccines Clinical Trials were at no time designed to, provide data for, or draw a conclusion as to whether or not the Vaccines were effective to:

i) prevent serious illness arising from Covid infection or at all;

ii) prevent death arising from Covid infection or at all; or

iii) prevent transmission of Covid between people.

b) there was no scientific evidence provided to the Respondents that the Vaccines:

i) prevent serious illness arising from Covid infection or at all;

ii) prevent death arising from Covid infection or at all; or

iii) prevent transmission of Covid between people.

c) in respect of the Vaccine Clinical Trials:

i) the Vaccine Clinical Trials did not reach results of statistical significance to meet the secondary trial endpoint and thereby did not in fact:

(1) detect a reduction in any serious outcome such as hospital admissions, use of intensive care, or deaths;

(2) determine whether the Vaccines can interrupt or prevent transmission of the virus.

ii) the Vaccine Clinical Trials did not reach the secondary study endpoints and thereby did not in any manner study or rationally conclude:

(1) the safety or efficacy of the Vaccines in respect of:

a) Immunocompromised patients;

b) Pregnant or Breastfeeding Women;

(2) the Vaccines' ability to **("the Efficacy Failures")**:

a) reduce or prevent severe Covid including:

i) admission to hospital or ICU;

ii) death;

b) interrupt, reduce, or prevent entirely transmission of Covid from one person to another.

iii) the following Vaccine Clinical Trials had as their protocol a primary endpoint definition of confirmed infection with Covid even with only mild symptoms:

(1) Pfizer Clinical Trial;

(2) Moderna Clinical Trial; and

(3) AstraZeneca Clinical Trial;

iv) the primary endpoint rendered a rational determination of the Efficacy Failures to be impossible.

Source

The relevant testing data evidencing the absence of testing and trial design in respect of the Vaccine Clinical Trials were provided by the Sponsors to the TGA and the TGA Respondents before the Approvals.

The Vaccine Clinical Trial Protocols provided by the Sponsors prior to the Approvals include:

1. PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines) Protocol C4591001. 2020. https://pfe-pfizercom-d8-prod.s3.amazonaws.com/202009/C4591001_Clinical_Protocol.pdf **("the Pfizer Clinical Trial Protocol")**

2. A phase 3, randomized, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine in adults aged 18 years and older [protocol No mRNA-1273-P301]. 2020. http://web.archive.org/web/20201018173405/https://www.modernatx.com/sites/default/files/mRNA-1273-P301-Protocol.pdf **("the Moderna Clinical Trial Protocol")**

3. Clinical Study Protocol - Amendment 2 AZD1222-D8110C00001. 2020. https://s3.amazonaws.com/ctr-med-7111/D8110C00001/52bec400-80f6-4c1b-8791-0483923d0867/c8070a4e-6a9d-46f9-8c32-cece903592b9/D8110C00001_CSP-v2.pdf **("the AstraZeneca Clinical Trial Protocol")**

The TGA and the TGA Respondents received the entirety of the data including the Vaccines Clinical Trial Data.

The Pfizer Original AUSPAR. Page 34.

The Moderna Original AUSPAR. Pages 56-58.

The AstraZeneca. Pages 37, 38.

KNOWN LIMITATION OF STUDY SCALE

10. Prior to the Approvals testing data provided to the TGA and the TGA Respondents by the Sponsors rationally establishing insufficient clinical trial testing of the Vaccines for the Approvals disclosed the following:

a) the Pfizer Clinical Trial, the Moderna Clinical Trial and the AstraZeneca Clinical Trial **("the Clinical Trials")** were ended after just 150 to 170 end point events occurring being the occurrence of:

i) a positive Covid infection confirmation; and

ii) any associated symptom regardless of severity;

b) the Clinical Trials were, in the circumstances of (a):

i) used to assert a conclusion of efficacy as a basis for the of the Vaccines for use by the majority of the Australian population derived from only approximately 170 recipient results;

ii) applying a disproportionately limited stopping rule in circumstances of the proposed widespread use of the Vaccines;

iii) in the circumstances of (a) and (b), the efficacy data provided in respect of the Vaccines based upon the Clinical Trials:

(1) was obviously unreliable;

(2) made impossible the rational identification of severe rare adverse events associated with the Vaccines at the time of the Approvals.

Source

These matters arise in the entirety of the data provided by the Sponsors to the TGA and the TGA Respondents for the Approvals including the Vaccines Clinical Trial Data.

KNOWN MISLEADING CONCLUSION OF PFIZER VACCINE EFFICACY

11. Prior to the Pfizer Approval, the Pfizer Vaccine clinical testing data **("the Pfizer Clinical Trial Data")** and conclusions provided to the TGA and TGA Respondents by Pfizer

asserting that the Pfizer Vaccine had demonstrably achieved a short term vaccine efficacy of 95% against Covid in persons injected with 2 doses of the Pfizer Vaccine **("the Known Misleading Pfizer Efficacy Conclusion")** disclosed that such claims were rationally misleading and unreliable because:

a) the conclusion was claimed to be based upon the Pfizer Clinical Trial having been conducted upon approximately 44,000 subjects wherein the Known Misleading Pfizer Efficacy Conclusion is in fact based upon outcomes reported in only 170 trial participants;

b) there in fact were 43,448 participants wherein:

    i) 21,720 were in the Pfizer Vaccine group;

    ii) 21,728 were in the placebo group;

c) of that number only 170 subjects tested positive for Covid and developed mild or greater Covid symptoms during the trial period, being the defined confirmed cases endpoint for the study determined by Pfizer and known to the Respondents;

d) of the "confirmed Covid cases":

    i) 8 were reported in the Pfizer Vaccine group;

    ii) 162 were reported in the placebo group;

e) clinical efficacy of 95% was erroneously concluded and determined by applying these two relative numbers to each other as follows:

    i) comparing 8/170 for the Pfizer Vaccine group and 162/170 in the placebo group;

    ii) inferring from that the Pfizer Vaccine was shown to be 95% effective;

f) wherein in fact:

i) 99.07% of the unvaccinated group in the Pfizer Clinical Trial did not develop symptomatic Covid infection;

ii) 99.95% the Pfizer Vaccine group in the Pfizer Clinical Trial did not develop symptomatic Covid infection;

iii) there was scientifically demonstrated and disclosed:

(1) an absolute risk reduction of symptomatic Covid infection of only 0.71% in the Pfizer Vaccine group;

(2) the number of doses of Pfizer Vaccine needed to treat, being the number of doses needed to prevent a single case of symptomatic Covid infection, of 141 doses.

iv) the absolute risk reduction and the number needed to treat being the correct and most accurate measure of protection from symptomatic Covid infection which may only present as mild symptoms in an uninfected population over the trial surveillance period;

v) misleadingly, the purported 95% efficacy of the Pfizer Vaccine was obtained in circumstances where in truth:

(1) in the Pfizer Clinical trial 3410 “suspected Covid-19 cases” were excluded from the calculation:

a) upon the basis of symptoms being displayed according to the trial protocol but PCR tests were not conducted by Pfizer in the following amounts:

i) 1594 occurring in the vaccine group;

ii) 1816 occurring in the placebo group;

b) undermining the veracity and reliability of the efficacy claims, of 95% efficacy;

c) but for which, inclusion of those suspected cases results in the following logically indicated risk reductions in the Pfizer Vaccine:

i) a relative risk reduction of only 18.9%;

ii) an absolute risk reduction with the Pfizer Vaccine of only 1.72%;

iii) number of doses needed to treat or needed to prevent a single case of symptomatic Covid infection of 58 doses.

(2) in the Pfizer Clinical Trial 2714 "suspected Covid-19 cases" were excluded from the calculation:

a) upon the basis of symptoms occurring within 7 days of the injection in the following amounts:

i) 1,185 occurring in the Pfizer Vaccine group; and

ii) 1,529 in the placebo group;

b) undermining the veracity and reliability of the efficacy claims of 95% efficacy;

c) but for which, inclusion of those suspected cases

results in the following logically indicated risk reductions in the Pfizer Vaccine:

i) a relative risk reduction of only of 22.44%;

ii) an absolute risk reduction with the Pfizer Vaccine of only 1.58%;

iii) number of doses needed to treat or needed to prevent a single case of symptomatic Covid infection of 63 doses.

vi) in the circumstances, the Known Misleading Pfizer Efficacy Conclusion logically:

(1) was misleading and not an accurate representation of the actual efficacy of the Pfizer Vaccine against Covid;

(2) did not reflect what the Australian population's general understanding of what 95% efficacy for the Pfizer Vaccine was;

(3) was obviously indicative of the unacceptably low efficacy rate of the Pfizer Vaccine wherein:

a) the TGA and the TGA Respondents accepted the exclusion of a number of subjects material to efficacy claims:

i) without question or request for further analysis;

ii) despite the extreme disparity in efficacy displayed as between the relative risk reduction and absolute risk reduction;

iii) in circumstances where in truth those excluded numbers profoundly and exponentially exaggerated the asserted efficacy rate of the Pfizer Vaccine.

b) Pfizer's own study protocol indicated those symptoms as:

i) being indicative of Covid infection;

ii) rendered those subjects to be "suspected" Covid cases without any follow-up testing.

(4) was an unacceptable basis for a claim and conclusion of satisfactory efficacy by the TGA and the TGA Respondents because:

a) of the matters pleaded in the above sub-paragraphs herein;

b) it was the predominant basis for the:

i) Pfizer Approval;

ii) promotion of the Pfizer Vaccine's purported 95% efficacy to the entire Australian population.

c) of the intended and consequent public promotion of the 95% efficacy figure;

d) the high potential for reporting bias in the Pfizer Clinical Trial evaluation of Pfizer Vaccine efficacy;

e) the profound disparity between the relative and absolute risk reduction measures of efficacy;

f) the non-disclosure to the Australian public of the absolute-risk reduction rate evident in the Pfizer Clinical Trial in abrogation of TGA guidelines for communicating risks and benefits to the Australian public;

g) the propensity to mislead the Australian public when cited without reference to the way in which they were determined;

h) at no time in the Pfizer Clinical Trial or at all was the Pfizer Vaccine compared to any other product other than a placebo such that at the time of the Pfizer Approval:

i) the safety or efficacy of the Pfizer Vaccine was never compared to any other product including any potential or actual therapies for the treatment of or protection against Covid;

ii) the Pfizer Vaccine could not thereby be rationally determined to be a major therapeutic advance for the treatment of or protection against Covid;

Source

The Known Misleading Pfizer Efficacy Conclusion was stated in the TGA evaluator's assessment of the Pfizer Clinical Trial Data contained in the Pfizer Original AUSPAR produced by

the TGA.

The data was provided to the TGA and the TGA Respondents by Pfizer on or before November, 2020 in the Pfizer Clinical Trial Data upon which the Known Misleading Pfizer Efficacy Conclusion was based.

KNOWN MISLEADING CONCLUSION OF PFIZER CHILD VACCINE EFFICACY

12. The Respondents knew prior to and at the time of the Pfizer Child Approval, the Pfizer Child Vaccine clinical testing data and conclusions provided to the TGA and TGA Respondents by Pfizer asserting that the Pfizer Child Vaccine had demonstrably achieved a short term vaccine efficacy of 90.7% against Covid in children 5 to 11 years of age injected with 2 doses of the Pfizer Child Vaccine **("the Known Misleading Pfizer Child Efficacy Conclusion")** disclosed that such claims were rationally misleading and unreliable because:

    a) the conclusion was claimed to be based upon the Pfizer Clinical Trial having been conducted upon approximately 4,500 subjects wherein the Known Misleading Pfizer Child Efficacy Conclusion is in fact based upon outcomes reported in only 19 trial participants;

    b) the 4,500 subjects were divided approximately into 3000 Pfizer Child Vaccine recipients and 1,500 placebo recipients;

    c) of that number only 19 subjects tested positive for Covid and developed mild or greater Covid symptoms which was the defined confirmed cases endpoint for the study determined by Pfizer from which;

        i) of the "confirmed Covid cases":

            (1) 3 were reported in the Pfizer Vaccine group;

            (2) 16 were reported in the placebo group;

ii) clinical efficacy of 90.7% was erroneously concluded and determined by applying these two relative numbers to each other as follows:

(1) comparing 3/19 for the Pfizer Vaccine group and 16/19 in the placebo group;

(2) inferring from that the Pfizer Child Vaccine was shown to be 90.7% effective;

iii) wherein in fact:

(1) 98.9% of the unvaccinated group in the Pfizer Child Clinical Trial did not develop symptomatic Covid infection;

(2) 99.9% of the Pfizer Child Vaccine group in the Pfizer Child Clinical Trial did not develop symptomatic Covid infection;

(3) there was demonstrated an absolute risk reduction of symptomatic Covid infection of only 1% in the Pfizer Vaccine group;

(4) the absolute risk reduction is the correct measure of protection from symptomatic Covid infection which may only present as mild symptoms in an uninfected population over the trial surveillance period.

iv) in the circumstances the Known Misleading Pfizer Child Efficacy Conclusion logically:

(1) was misleading and not an accurate representation of the actual efficacy of the Pfizer Child Vaccine against Covid;

(2) did not reflect what the Australian population's general understanding of what 90.7% efficacy for the Pfizer Child Vaccine was;

(3) was an unacceptable basis for a claim and conclusion of satisfactory efficacy by the Respondents because:

a) of the matters pleaded at sub-paragraphs (a) to (c)(iv)(2) herein;

b) it was the predominant basis for the:

i) Pfizer Child Approval;

ii) promotion of the Pfizer Child Vaccine's purported efficacy to the entire Australian population.

c) of the intended and consequent public promotion of the 90.7% efficacy figure;

d) of the high potential for reporting bias in the Pfizer Child Clinical Trial evaluation of Pfizer Child Vaccine efficacy;

e) of the profound disparity between the known relative and absolute risk reduction measures of efficacy;

f) of the non-disclosure to the Australian public of the absolute-risk reduction rate evident in the Pfizer Child Clinical Trial in abrogation of TGA guidelines for communicating risks and benefits to the Australian public;

g) the propensity to mislead the Australian public when cited without reference to the way in which they were determined.

Source

The Known Misleading Pfizer Child Efficacy Conclusion was stated in the TGA evaluator's assessment of the Pfizer Clinical Trial Data contained in the Pfizer Child AUSPAR produced by the TGA.

The data was provided to the TGA and the TGA Respondents by Pfizer on or before December 2021 in the Pfizer Child Clinical Trial upon which the Known Misleading Pfizer Child Efficacy Conclusion was based.

KNOWN MISLEADING CONCLUSION OF MODERNA VACCINE EFFICACY

13. Prior to the Moderna Approval, the Moderna Vaccine clinical testing data **("the Moderna Clinical Trial Data")** and conclusions provided to the TGA and the TGA Respondents by Moderna asserting that the Moderna Vaccine had demonstrably achieved a "a robust and highly protective" 94.1% against Covid in persons injected with 2 doses of the Moderna Vaccine **("the Known Misleading Pfizer Efficacy Conclusion")** disclosed that such claims were rationally misleading and unreliable because:

a) there was demonstrated an absolute risk reduction of symptomatic Covid infection of only 1.1% in the Moderna Vaccine group;

b) the absolute risk reduction is the correct measure of protection from symptomatic Covid infection which may only present as mild symptoms in an uninfected population over the trial surveillance period;

c) in the circumstances the Known Misleading Moderna Efficacy Conclusion logically:

i) was not a true or accurate representation of the actual efficacy of the Moderna Vaccine against Covid;

ii) did not reflect what the Australian population's general understanding of what 94.1% efficacy for the Pfizer Child Vaccine was;

iii) was an unacceptable basis for a claim and conclusion of satisfactory efficacy by the Respondents because:

(1) of the matters pleaded at sub-paragraphs (a) to (c)(iii) herein;

(2) it was the predominant basis for the:

a) Moderna Approval;

b) promotion of the Moderna Vaccine's purported 94.1% efficacy to the entire Australian population.

(3) the intended and consequent public promotion of the 94.1% efficacy figure;

(4) the high potential for reporting bias in the Moderna Clinical Trial evaluation of the Moderna Vaccine efficacy;

(5) the profound disparity between the known relative and absolute risk reduction measures of efficacy;

(6) the non-disclosure publicly of the absolute-risk reduction rate evident in the Moderna Clinical Trial in abrogation of TGA guidelines for communicating risks and benefits to the Australian public;

(7) the propensity to mislead the Australian public when cited

without reference to the way in which they were determined.

d) at no time in the Moderna Clinical Trial or at all was the Moderna Vaccine compared to any other product other than a placebo such that at the time of the Moderna Approval:

i) the safety or efficacy of the Moderna Vaccine was never compared to any other product including any potential or actual therapies for the treatment of or protection against Covid;

ii) the Moderna Vaccine could not be rationally determined to be a major therapeutic advance for the treatment of or protection against Covid.

Source

The Known Misleading Moderna Efficacy Conclusion was stated in the TGA evaluator's assessment of the Moderna Clinical Trial Data contained in the Moderna AUSPAR.

The data was provided to the TGA and the TGA Respondents by Moderna on or before August 2021 in the Moderna Clinical Trial Data upon which the Known Misleading Moderna Efficacy Conclusion was based.

KNOWN UNDETERMINED VACCINES RISK-BENEFIT

14. Prior to the Pfizer Approval and Moderna Approval testing data provided to the TGA and the TGA Respondents by Pfizer and Moderna respectively rationally establishing the absence of any risk-benefit analysis or any determination of a positive risk-benefit profile for the Vaccines disclosed that **("the Known Failure to Determine Vaccine Risk-Benefit")**:

a) in the Pfizer Clinical Trials and the Moderna Clinical Trials the data logically and rationally demonstrated that:

i) reevaluation of the Pfizer and Moderna Clinical Trial data using "All Cause Severe Morbidity", being the proper scientific endpoint of a clinical trial, as the primary endpoint of the trials, produced a statistically significant increase in All Cause Severe Morbidity in the participants who were vaccinated by the Vaccines over those receiving the placebo;

ii) All Cause Severe Morbidity in both the Vaccine and placebo control groups was defined as all reports of :

(1) severe infection with Covid; combined with

(2) all Serious Adverse Events.

iii) the logical and rational scientific conclusion drawn from the direct comparison of All Cause Severe Morbidity between the Vaccine and Placebo group participants, is that the Vaccines:

(1) do more harm than good;

(2) do not provide a health benefit; and

(3) fail any reasonable risk-benefit analysis.

Source

The data was provided to the TGA and the TGA Respondents by the Sponsor in November 2020 in the Pfizer Clinical Trial data and on or before August 2021 in the Moderna Clinical Trial Data upon which the Known Failure to Determine Vaccine Risk-Benefit was based.

KNOWN SERIOUS DEATHS EVENTS REPORTING IGNORED

15. In or about January, 2021, and prior to the Approvals, widely and globally published data by the Government of Norway and provided to the TGA and the TGA Respondents

disclosed that **("the Norway Data")**:

a) there were 30 fatalities causally related to the Pfizer Vaccine in 40,000 recipient elderly individuals in Norway;

b) the Norwegian regulator subsequently updated guidance for vaccination with Covid vaccines advising that caution and case-by-case judgement should be used when vaccinating frail elderly subjects.

16. In response to the Norway Data, the TGA and the TGA Respondents:

a) publicly stated without rational basis that there were no specific risks of vaccination with the Pfizer Vaccine in elderly patients;

b) in the Pfizer Product Information for health care professionals, asserted that:

i) the data for use in the frail elderly greater than 85 years of age is limited;

ii) the potential benefits of vaccination with the Pfizer Vaccine as compared to the potential risk and clinical impact of even relatively mild systemic adverse events in the frail elderly should be carefully assessed on a case-by-case basis.

iii) in circumstances wherein:

(1) in the Pfizer Product Information approved, authorised and published by the TGA and the TGA Respondents:

a) no reference to or comment on the Norway Data or any deaths in the Pfizer Product Information summary (section 4.8 Adverse effects) appears;

b) death and renal failure are not listed as adverse events;

c) the special warning suggests that there is lack of data in elderly:

i) but does not report the fact that there were reports of deaths; and

ii) is misleading to a prescriber reading the statements.

Source

"Investigation reveals no specific risk of COVID-19 vaccinations in elderly patients". 2 February, 2021. https://www.tga.gov.au/news/media-releases/investigation-reveals-no-specific-risk-covid-19-vaccinations-elderly-patients#:~:text=The%20TGA%20has%20concluded%20that,19%20vaccine%20in%20elderly%20patients.&text=On%2014%20January%202021%20the,with%20the%20Pfizer%20BioNTech%20vaccine

"Australian Product Information – Comirnaty Covid-19 Vaccine". https://www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-210125-pi.pdf

KNOWN PFIZER CLINICAL DATA DANGERS, LACK OF EFFICACY AND BENEFIT – FDA COMMENTARY

17. In December 2020 and prior to the Approvals the scientific data widely and globally published and provided to the TGA and the TGA Respondents by the FDA rationally establishing the safety risks of the Pfizer Vaccine disclosed the following **("the Known Pfizer Vaccine Efficacy and Safety Issues – FDA Analysis")**:

a) 2 Pfizer Vaccine participants died during the Pfizer Clinical Trial reporting period from April 29, 2020 (first participant, first visit) to November 14, 2020

(cut-off date) wherein it was reported that:

i) one experienced a cardiac arrest 62 days after vaccination #2 and died 3 days later;

ii) one died from arteriosclerosis 3 days after vaccination #1;

iii) wherein:

(1) the FDA irrationally and erroneously concluded the deaths to be of no concern because those deaths represent events that occur in the general population of the age groups where they occurred, at a similar rate;

(2) these events occurred after the vaccination:

a) logically indicating by scientific definition that where there was no more likely explanation, the events are at least possibly causal;

b) where no further details on these events has been provided;

c) being each dismissed on the basis that the rate of injury occurrence is in accordance with background death rates despite the fact that, in isolation, background death rates present no proper scientific basis to dismiss causality.

b) among 3410 total cases of suspected but unconfirmed Covid in the overall study population:

i) 1594 occurred in the Pfizer Vaccine group of which 409 occurred within 7 days of vaccination;

ii) 1816 in the placebo group of which 209 occurred within 7 days of vaccination;

iii) by reason of (1) and (2) negligible efficacy in the Pfizer Vaccine was thereby scientifically and logically evident;

iv) considering that subset data:

(1) the FDA erroneously and without scientific basis concluded with regard to that data that:

a) it was possible that the imbalance as between the Pfizer Vaccine group and the placebo group in suspected COVID-19 cases occurring in the 7 days post-vaccination represents:

i) vaccine reactogenicity;

ii) symptoms that overlap with those of COVID-19;

b) the data imbalance did not raise a concern that the reporting of those suspected but unconfirmed Covid cases could have masked clinically significant adverse events that would not have otherwise been detected.

(2) the data in truth presented clinical evidence of at least possible Vaccine-Associated Enhanced Respiratory Disease (VAERD);

(3) the FDA's conclusions had no logical, reasonable or scientific basis in the data;

(4) a reasonable analysis would determine that the imbalance of post

vaccination reactogenic symptoms separated by definition as 'likely but not PCR confirmed COVID-19 cases' must raise a concern.

c) in respect of the safety of the Pfizer Vaccine the severe adverse events as reported:

i) occurred in up to 4.6% of participants;

ii) were defined as an event that **("Serious Adverse Events")**:

(1) results in death;

(2) is life-threatening;

(3) requires inpatient hospitalisation;

(4) prolongs existing hospitalisation;

(5) results in persistent or significant disability or incapacity, including permanent impairment of a body function or permanent damage to a body structure;

(6) necessitates medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure;

(7) is a congenital anomaly or birth defect;

(8) makes one of the above more likely, or that requires intervention to prevent one of these outcomes.

iii) were more frequent after dose 2 than after dose 1;

iv) by age of the patient, occurred in:

(1) adults 55 years of age or older at a frequency of up to 2.8%;

(2) those under 55 years of age at a frequency of up to 4.6%.

v) logically and scientifically disclosed that:

(1) as those events occurred more frequently after dose 2 (which could be considered a 'rechallenge' by causality assessment criteria) this is indicative of likely Pfizer Vaccine causality;

(2) the rate of Serious Adverse Events is material and very high at up to 4.6%;

(3) there was a tendency for higher rates of Serious Adverse Events in younger persons;

(4) the clear risk of a Serious Adverse Event from the Pfizer Vaccine is significantly higher than the risk of a Serious Adverse Event from Covid infection thereby presenting a negative risk-benefit analysis at least in those aged under 55 years.

d) adverse events of special interest which occurred and determined to be possibly related to the Pfizer Vaccine were:

i) lymphadenopathy which was reported in:

(1) 0.3% of total recipients of the Pfizer Vaccine;

(2) 0.5% in the younger 16 to 55 years age group recipients of the Pfizer Vaccine;

(3) 0.1% in the older over 55 years age group recipients of the Pfizer

Vaccine; and

(4) 0.037% in the total placebo group.

ii) Bell's Palsy which was reported:

(1) in four of the Pfizer Vaccine group;

(2) from dose 1 through 1 month after dose 2, there were three reports of Bell's palsy in the Pfizer Vaccine group;

(3) in none in the placebo group;

iii) erroneously and without scientific basis determined by the FDA to:

(1) have occurred at a frequency consistent with the expected background rate in the general population; and

a) thereby:

i) possessing a less certain causal relationship because:

1. the number of cases was small; and

2. not more frequent than expected in the general population.

ii) of no concern;

iii) not a bar to approval without further inquiry.

iv) logically and scientifically disclosing of the following:

(1) the FDA reference to a background rate of a condition reported as evidence against causality is false;

(2) no proper assessment of causality is provided;

(3) no further data on the background rate is provided;

(4) in truth in any case the reported rate of Bell's Palsy exponentially exceeds the true background rate because:

a) given that the events occurred in a one month period, the background rate for this number of events would not be expected to be this high based on true background population rates which are generally known to be 15-30 incidences per 100,000 per year;

b) in the Pfizer Clinical Study Bell's Palsy occurred at a rate of 4 per 43,448 in one month which equates to:

i) 110 cases per 100,000 persons per year;

ii) 3.7 times to 7.4 times the background rate in general population.

e) adverse reactions in the Pfizer Vaccine group occurred as follows with the following extremely high frequency:

i) injection site reactions (84.1%);

ii) fatigue (62.9%);

iii) headache (55.1%);

iv) muscle pain (38.3%);

v) chills (31.9%);

vi) joint pain (23.6%);

vii) fever (14.2%);

f) in respect of the Pfizer Study resultant unknown risks and data gaps in certain subpopulations it was concluded by the FDA that:

i) there was insufficient data to make conclusions about the safety of the vaccine in subpopulations including:

(1) children less than 16 years of age;

(2) pregnant and lactating women; and

(3) immunocompromised individuals.

g) a numerically greater number of appendicitis cases occurred in the Pfizer Vaccine group but:

i) occurred no more frequently than expected background rate in the given age groups;

ii) it was determined for that reason by the FDA without scientific basis and erroneously:

(1) not to establish a causal relationship;

(2) not to raise a clear concern.

h) the FDA concluded that the risk of vaccine-enhanced disease over time:

i) remained unknown at that time;

ii) was potentially associated with waning immunity;

iii) needed to be evaluated further in:

(1) ongoing clinical trials; and

(2) observational studies conducted following authorization and/or licensure;

i) the conclusions evident in the FDA Briefing Document relied upon by the TGA and the TGA Respondents in granting the Pfizer Approval:

i) erroneously and without scientific basis relied consistently upon the use of background rates and small study sizes to:

(1) dismiss adverse event causality;

(2) reject the need for further consideration of causality of adverse events;

(3) dismiss concern as to those reported adverse events.

ii) were based in part upon obviously false premises;

iii) were obviously erroneous.

j) contained data in respect of the Pfizer Vaccine which brought into obvious doubt the Pfizer Vaccine's:

i) safety;

ii) efficacy;

iii) positive risk-benefit assessment.

Source

The Known Pfizer Vaccine Dangers – FDA Analysis were published to the TGA and the TGA Respondents in the document being the FDA Briefing Document **("the FDA Briefing Document")** as follows: "Vaccines and Related Biological Products Advisory Committee Meeting. December 10, 2020. FDA Briefing Document" - Pfizer-BioNTech COVID-19 Vaccine. Sponsor: Pfizer and BioNTech. https://www.fda.gov/media/144245/download pg. 41 – 43 and pg. 48-49

The rate of Bell's palsy in the world population is evident in widely published studies including, for example:

1. "Bell's Palsy: A Prospective Study". Mustafa A, Suleiman A. 2020. Int J Dent. 2160256. https://pubmed.ncbi.nlm.nih.gov/32256592/

2. "Familial idiopathic facial palsy". Döner F, Kutluhan S 2000. European Archives of Oto-Rhino-Laryngology. 257 (3): 117–19.

3. "Annualized incidence and spectrum of illness from an outbreak investigation of Bell's palsy". Morris, AM et al. 2002. Neuroepidemiology. 21 (5): 255–61.

KNOWN SAFETY AND RISK-BENEFIT ISSUES – PFIZER CLINICAL TRIAL DATA

18. On or about 25 January, 2021 and prior to the Pfizer Approval the Pfizer Clinical Trial Data rationally establishing significant safety risk and risk-benefit deficit in respect of

the Pfizer Vaccine provided to the TGA and the TGA Respondents by Pfizer disclosed that:

a) Lymphadenopathy was reported as an adverse event:

i) in 64 participants or 0.3% of the Pfizer Vaccine group:

(1) comprised of:

a) 54 participants in the younger age group; and

b) 10 in the older age group;

(2) at a rate of more than 10 times more than the placebo group having 6 reports;

(3) 73% of which were determined by the Respondents' investigator to be causally related to the Pfizer Vaccine;

(4) with a mean duration of 10 days;

(5) 12 of which were ongoing at the time of the data cut-off date;

(6) reported in most instances within 2 to 4 days after vaccination;

b) Hypersensitivity was reported as an adverse event in:

i) two cases in the Pfizer Vaccine Group; and

ii) one case in the placebo group.

c) Drug Hypersensitivity was reported as an adverse event:

i) in six cases in the Pfizer Vaccine Group;

ii) in one case in the placebo group;

iii) causing the Respondents to determine and assert that post-market monitoring for hypersensitivity events should be conducted.

d) Bell's Palsy was reported as an adverse event in:

i) four cases in the Pfizer Vaccine Group; and

ii) none in the placebo group.

e) Serious Adverse Events were reported and found by the TGA and the TGA Respondents to be causally related to the Pfizer Vaccine in:

i) 3 of the Pfizer Vaccine group to the Pfizer Vaccine, which involved:

(1) shoulder injury related to vaccine administration;

(2) ventricular arrhythmia; and

(3) lymphadenopathy;

(4) none of the placebo group.

f) 12 cases of appendicitis were reported, comprised of:

i) 8 in the Pfizer Vaccine Group; and

ii) 4 in the placebo group;

iii) all of which were assessed by Pfizer and subsequently asserted by the TGA and the TGA Respondents as unrelated to the Pfizer Vaccine:

(1) based upon the sole fact that the number of events were purportedly not greater than expected based on estimated background rates;

(2) contrary to the TGA and TGA Respondents' adopted and established methodologies of causality assessment being the:

a) Naranjo Scale; and

b) WHO Causality Assessment for Adverse Events.

g) 1 other event of lower back pain and bilateral lower extremity pain with radicular paranesthesia:

i) in the Pfizer Vaccine group;

ii) in the younger age subgroup (18 to 55 years of age); and

iii) assessed by the TGA investigator as related to the Pfizer Vaccine.

h) withdrawals from the study of trial participants due to Severe Adverse Events, Serious Adverse Events or Adverse:

i) were characterised as "few" despite being reported as:

(1) <1.2% or <521 persons for Severe Adverse Events;

(2) <0.5% or <217 persons for Serious Adverse Events;

(3) <0.2% or <86 persons for Adverse Events;

ii) were so significant as to in every instance lead to withdrawal of the participant from the study;

iii) are reported with no disclosed detail as to whether these participants

belonged to the Pfizer Vaccine or Placebo groups despite such information being obviously and logically critical to forming an accurate risk-benefit assessment of the Pfizer Vaccine;

iv) are obviously and logically disclosed in a misleading form as to the known and true incidence of Adverse Events in the Pfizer Vaccine group because:

(1) the incidence of Adverse Events in the Pfizer Vaccine group is coalesced with the Placebo group, such that:

a) the true distribution of the Adverse Events between study groups has been obfuscated;

b) it is possible and plausible that the occurrence of Adverse Events reported was entirely in the Pfizer Vaccine group;

(2) the characterisation of those events as "few" is obviously false;

(3) the bare data disclosed logically indicates a high incidence of Adverse Events leading to withdrawal of participants from the study.

Source

The Pfizer Original AUSPAR. Pages 28, 29.

KNOWN SAFETY AND RISK-BENEFIT ISSUES – MODERNA CLINICAL TRIAL DATA

19. In August, 2021 and prior to the Moderna Approval the Moderna Clinical Trial Data rationally establishing significant safety risk and risk-benefit deficit in respect of the Moderna Vaccine provided to the TGA and the TGA Respondents by Moderna disclosed

("the Known Moderna Clinical Studies Issues"):

a) that those in the Australian population receiving the Moderna Vaccine, when including the risk of a Serious Adverse Event arising from Covid infection:

i) were at a significantly higher risk of a Serious Adverse Event:

(1) than those whom did not receive the Moderna Vaccine;

(2) being an excess risk of 15.1 per 10,000 vaccinated;

ii) were at a risk of a Serious Adverse Event of at least 1 in 662.

Source

The Moderna Clinical Trial Data from the Moderna Clinical Trial was provided to the TGA and the TGA Respondents by Moderna prior to August, 2021 and prior to the Moderna Approval and is referred to in the Moderna AUSPAR produced by the TGA.

KNOWN SAFETY AND RISK-BENEFIT ISSUES – ASTRAZENECA CLINICAL TRIAL DATA

20. On or about 28 January, 2021 and prior to the AstraZeneca Approval the AstraZeneca Clinical Trial Data rationally establishing significant safety risks and risk-benefit deficit in respect of the AstraZeneca Vaccine provided to the TGA and the TGA Respondents by AstraZeneca disclosed the following **("the Known AstraZeneca Clinical Studies Issues")**:

a) sudden adverse events arising in the AstraZeneca Vaccine group were:

i) one case of Multiple Sclerosis which was highly likely to have been related to the AstraZeneca Vaccine;

ii) one case of transverse myelitis which was highly likely to have been related to the AstraZeneca Vaccine;

iii) subsequently and prior to the AstraZeneca Approval:

(1) all asserted by the TGA to be unlikely to be related to AstraZeneca Vaccine:

a) based entirely upon a bare assertion of AstraZeneca to that effect;

b) without the benefit of patient level data being disclosed to the TGA or the TGA Respondents;

c) without further request for information or investigation of causality by the TGA or anyone;

(2) the TGA should have cautiously examined each event before the AstraZeneca Approval;

(3) never subjected to scientifically sound assessment of causality or significance by the TGA or anyone;

b) at no time in the AstraZeneca Clinical Trial or at all was the AstraZeneca Vaccine compared to any other product other than a placebo such that at the time of the AstraZeneca Approval:

i) the safety or efficacy of the AstraZeneca Vaccine was never compared to any other product including any potential or actual therapies for the treatment of or protection against Covid;

ii) the AstraZeneca Vaccine could not be rationally determined to be a major therapeutic advance for the treatment of or protection against Covid.

Source

The AstraZeneca Clinical Trial Data from the AstraZeneca Clinical Trial **("the AstraZeneca Clinical Trial Data")** was provided to the TGA and the TGA Respondents by AstraZeneca prior to January, 2021 and prior to the AstraZeneca Approval.

The AstraZeneca Clinical Data and the conclusions of the Respondents pleaded are evident in the AstraZeneca Clinical Data having been provided to the Respondents in connection with the AstraZeneca Approval application and further references to that data in the following TGA Respondent produced documents:

1. the AstraZeneca Original AUSPAR;

2. the AstraZeneca Clinical Evaluation Report;

3. the ACV AstraZeneca Minutes;

4. the AstraZeneca Delegate's Overview.

KNOWN DEFECTIVE DATA IN APPROVING THE PFIZER BIVALENT VACCINE

21. Prior to the Pfizer Bivalent Approval, the data rationally establishing significant safety risk and risk-benefit deficit in respect of the Pfizer Bivalent Vaccine provided to the TGA and the TGA Respondents by Pfizer and further the actions of the TGA and ATAGI disclosed the following the Respondents knew of the following matters relating to the Pfizer Bivalent Vaccine **("the Known Defective Pfizer Bivalent Data")**:

a) on or about 27 October 2022, the TGA provisionally approved the Pfizer (Comirnaty) Bivalent Original/Omicron BA.1 vaccine **("the Pfizer Bivalent Vaccine")** for use as a booster COVID-19 vaccine in people aged 18 years and older;

b) ATAGI conducted an evaluation of the immunogenicity, efficacy, and safety data on the Pfizer Bivalent Vaccine;

c) the ATAGI evaluation pleaded at (b) disclosed prior to the Pfizer Bivalent Approval, the Pfizer Bivalent Vaccine:

i) to be 30% effective in preventing Covid infection;

ii) to have displayed no material effectiveness in clinical studies;

iii) to have no data produced as to the immunogenicity or safety of the Pfizer bivalent vaccine in people under 55 years of age;

iv) to have evidence supporting its use limited to:

(1) immunogenicity and safety data from the C4591031 trial (substudy E) at 4 weeks after a second booster dose (fourth dose);

(2) participants aged >55 years received Pfizer bivalent vaccine as their second booster dose, 5 to 12 months following a Pfizer original primary course and Pfizer original first booster dose against the Omicron BA.1 variant;

v) was tested only in people without prior infection even though:

(1) a CDC study had estimated at that time that 64% of 18-64 year old persons and 75% of all adults as at February 2022 had antibodies indicating prior infection with Covid;

(2) people without prior infection were a minority;

(3) inclusion of those individuals with prior infection would likely produce different results to those reported.

vi) wherein the Pfizer Bivalent Vaccine was advanced and approved for use as a booster in everyone aged 18 years and over despite:

(1) the only clinical trial data disclosed 4 weeks of data of participants aged 55 years and older who received their 4th dose of Pfizer vaccine;

(2) trial participants being already vaccinated with the Pfizer Vaccine 3 times wherein the trial:

a) compared the fourth dose of the bivalent Pfizer Vaccine to a fourth dose with the original Pfizer Vaccine;

b) had no unvaccinated control group;

(3) it being inappropriate to approve this vaccine as a booster in people less than 55 years of age where no data for this age group existed.

Source

The relevant data of the Known Defective Pfizer Bivalent Data was contained in the data relating to the Pfizer Bivalent Vaccine provided to the TGA and the TGA Respondents in the course of approval application and the ATAGI Statement "ATAGI recommendations on use of the Pfizer bivalent (Original/Omicron BA.1) COVID-19 vaccine Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) the Pfizer bivalent (Original/Omicron BA.1) COVID-19 vaccine", provided to the TGA and the TGA Respondents.

https://www.health.gov.au/news/atagi-recommendations-on-use-of-the-pfizer-bivalent-originalomicron-ba1-covid-19-vaccine

https://www.cdc.gov/mmwr/volumes/71/wr/mm7117e3.htm

KNOWN DEFECTIVE PFIZER STUDY PROTOCOL

22. Prior to the Pfizer Approval the actions of the TGA and the TGA Respondents and data provided to the TGA and the TGA Respondents by Pfizer rationally establishing the trial protocols adopted and utilised by Pfizer in undertaking the Clinical Pfizer Study **("the Pfizer Clinical Trial Protocol")** and significant deficiencies of reliability of results obtained under that protocol disclosed the following **("the Known Pfizer Study Protocol Deficiencies")**:

    a) the Pfizer Study Protocol was accepted by the TGA prior to the Pfizer Approval and stated in respect of the stopping rule criteria for participants in the studies **("the Pfizer Study Stopping Rules")**:

        i) the participation of the person in question in the study would be ended if:

            (1) any participant vaccinated with the Pfizer Vaccine, at any dose level, develops a Serious Adverse Event which is assessed by the investigator as:

                a) possibly related to the Pfizer Vaccine; or

                b) there is no alternative, plausible, attributable cause other than such event being related to the Pfizer Vaccine.

            (2) any participant vaccinated with the Pfizer Vaccine, at any dose level, develops a Grade 4 local reaction or systemic event after vaccination which is assessed by the investigator as:

                a) possibly related to the Pfizer Vaccine; or

                b) there is no alternative, plausible, attributable cause other than such event being related to the Pfizer Vaccine.

(3) any participant vaccinated with the Pfizer Vaccine, at any dose level, develops a fever greater than 40.0°C (104.0°F) for at least 1 daily measurement after vaccination which is assessed by the investigator as:

a) possibly related to the Pfizer Vaccine; or

b) there is no alternative, plausible, attributable cause other than such event being related to the Pfizer Vaccine.

(4) any 2 participants vaccinated with the Pfizer Vaccine, at any dose level, report the same or similar severe (Grade 3) Adverse Events (including laboratory abnormalities) after vaccination which is assessed by the investigator as:

a) possibly related to the Pfizer Vaccine; or

b) there is no alternative, plausible, attributable cause other than such event being related to the Pfizer Vaccine.

(5) any participant dies or requires ICU admission due to SARS-CoV-2 infection;

b) the Pfizer Study Stopping Rules were defective because they prevented conclusions or data substantiating the Pfizer Vaccine's:

i) efficacy in preventing death in Covid infected patients;

ii) efficacy in preventing serious disease in Covid infected patients;

iii) efficacy in preventing Covid infection;

iv) efficacy in preventing transmission of the Virus.

Source

The Pfizer Clinical Trial Protocol. Pg. 63-65 and s. 8.2.2.

KNOWN WHO DECLARED NATURAL IMMUNITY FROM COVID IN THE AUSTRALIAN POPULATION

23. Prior to the Approvals the widely and globally World Health Organisation published scientific data and conclusions rationally establishing the existing natural immunity to Covid in the Australian population at the time of the Approvals disclosed that **("the Known Pre-Approval Natural Immunity from Covid")**:

a) numerous studies demonstrate that a proportion of the population have some level of cross-reactive immunity to Covid without ever having been infected by the virus seen in 40-60% of the population;

b) neutralizing antibodies to Covid are stably produced in the naturally immune person after infection for 6-7 months after infection, even in patients who had mild symptoms;

c) most individuals develop strong protective immune responses following natural infection with the Virus;

d) natural infection provides similar protection against symptomatic disease as vaccination, at least for the available follow up period.

Source

The following paper containing the factual matters relating to natural immunity were published prior to the Approvals as follows: World Health Organisation - SAGE Working Group on COVID-19 Vaccines dated 22 December 2020. Background paper on Covid-19 disease and vaccines. Prepared by the Strategic Advisory Group of Experts (SAGE)

on Immunization Working Group on COVID-19 vaccines **("the WHO Background Paper")**. Pg. 8.

KNOWN WHO POTENTIAL EFFECTIVENESS OF COVID VACCINES

24. Prior to the Approvals the widely and globally World Health Organisation published scientific data and conclusions rationally establishing the potential effectiveness of Covid vaccines including the Vaccines disclosed that **("the Known WHO Potential Effectiveness of Covid Vaccines")**:

    a) the potential for vaccination to eliminate Covid from any population depends upon a vaccine's effectiveness against infection and virus shedding;

    b) at that time, effectiveness of the Vaccines against infection and virus shedding were unknown and never tested for in any clinical study.

Source

The WHO Background Paper, Page 15

KNOWN WHO PANDEMIC CONTROL PRINCIPLE

25. From prior to the Approvals the widely and globally World Health Organisation published scientific data and conclusions and totality of data provided by the Sponsors to the TGA and the TGA Respondents in respect of the Vaccines for the Approvals rationally establishing the mechanism by which a vaccine including the Vaccines would control Covid and end the Covid Pandemic disclosed that **("the Known WHO Means to Control Covid")*:***

    a) the World Health Organisation's overarching goal in addressing the Covid Pandemic was to control Covid by:

        i) slowing down transmission of the Virus; and

        ii) preventing associated illness and death.

b) relevantly, at the time of the respective Approvals, no data provided by the Sponsors allowed any determination as to whether the Vaccines could or would:

i) prevent infection with Covid;

ii) prevent transmission of the Virus;

iii) prevent serious illness from Covid infection;

iv) prevent death from Covid.

Source

The WHO Background Paper - Page 7.

The absence of testing is based upon the entirety of data provided by the Sponsors directly to the TGA and the TGA Respondents in respect of the Approvals.

KNOWN RISK-BENEFIT RISKS

26. Prior to the respective Approvals the totality of data provided to the TGA and the TGA Respondents by the Sponsors and matters already known to the Respondents rationally establishing the nature and proposed use of the Vaccines disclosed that **("the Vaccines Risk-Benefit Profile"):**

a) the Vaccines engaged novel therapies and ingredients:

i) never before tested for use or used:

(1) in humans;

(2) in a mass vaccination program.

ii) possessing of unknown effects in the human body.

b) the Vaccines were intended to be administered to large populations of healthy subjects, including children;

c) the Vaccines were expected to be introduced by health authorities as mandatory in certain settings including workplaces;

d) there was a known significant excess risk of Serious Adverse Events arising in the use of the mRNA Vaccines being the Known Vaccines Excess Risk Data;

e) there was no release of participant - level datasets by the Vaccine Sponsors to the TGA and the TGA Respondents prior to the Approvals.

Source

The data and concomitant conclusions and knowledge were disclosed to the TGA and the TGA Respondents in the Known Vaccines Excess Risk Data pleaded at paragraph 27 herein below and the entirety of the data provided by the Sponsors.

KNOWN EXCESS RISK – PFIZER AND MODERNA CLINICAL TRIALS

27. Prior to the Approvals the testing data provided to the TGA and the TGA Respondents rationally establishing the material excess risks of taking the Pfizer and Moderna Vaccines disclosed that **("the Known Vaccines Excess Risk Data")**:

a) as to the mRNA Phase 3 Vaccine Trials:

i) Pfizer and Moderna each undertook prior to the Approvals a single phase III randomized trial to accumulate data and advance conclusions;

ii) Pfizer and Moderna submitted the data and conclusion results of these single phase III randomized trials to the TGA in support of the

Approvals;

iii) the trials were expected to monitor participants for two years;

iv) Pfizer and Moderna reported data to the TGA at the time of the declared cut-off date being:

(1) 14 November 2020 for the Pfizer Phase 3 Trial;

(2) 25 November 2020 for Moderna Phase 3 Trial.

b) Serious Adverse Events were evident in the placebo-controlled, phase III randomized clinical trials and consequent data provided to the TGA of the Vaccines utilising mRNA mechanism, being the Pfizer Vaccine and the Moderna Vaccine **("the mRNA Vaccines")**:

i) being the Phase 3 Trial for **("the mRNA Vaccine Trials")**:

(1) the Pfizer Vaccine, being study C451001 **("the Pfizer Phase 3 Trial")**;

(2) the Moderna Vaccine, being study mRNA-1273-P301 **("the Moderna Phase 3 Trial")**.

ii) made evident by application of the internationally accepted standard of Brighton Collaboration adverse events of special interest;

c) the data contained within the mRNA Vaccine Trials disclosed the following conclusive facts based upon that data ("**the mRNA Vaccine Trial Data")**:

i) an excess of Serious Adverse Events of Special Interest occurring in:

(1) 10.1 per 10,000 Pfizer Vaccine recipients over placebo baselines in the Pfizer Phase 3 Trial ;

(2) 15.1 per 10,000 Moderna Vaccine recipients over placebo baselines in the Moderna Phase 3 Trial;

ii) combined, the mRNA Vaccines were associated with an excess risk of Serious Adverse Events of Special Interest of:

(1) 12.5 per 10,000 mRNA Vaccines recipients; and

(2) a risk ratio of 1.43.

d) the Pfizer Phase 3 Trial data disclosed that for those taking the Pfizer Vaccine:

i) as to Serious Adverse Events:

(1) a 36% higher risk of Serious Adverse Events than the unvaccinated group, wherein a Serious Adverse Event **("Serious Adverse Event")**:

a) relates to an event or occurrence that led to a death or serious deterioration in the state of health of the person;

b) is an adverse event for which one or more of the following is true for the person:

i) results in death;

ii) is life-threatening;

iii) requires inpatient hospitalisation;

iv) prolongs existing hospitalisation;

v) results in persistent or significant disability or incapacity, including permanent impairment of a body function or permanent damage to a body structure;

vi) necessitates medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure;

vii) is a congenital anomaly or birth defect;

viii) is a medically important event:

1. that make one of the outcomes above more likely, or that require intervention to prevent one of these outcomes; or

2. that require intensive treatment in an emergency department or at home but do not result in hospitalisation, such as allergic bronchospasm, a blood disorder or convulsions.

(2) a risk excess of a Serious Adverse Event of 18 per 10,000 in those receiving the Pfizer Vaccine; and

(3) a risk ratio of 1.36 of a Serious Adverse Event in those receiving the Pfizer Vaccine;

ii) in respect of the occurrence of multiple Serious Adverse Events in recipients of the Pfizer Vaccine:

(1) a 84.6% higher number than the placebo group;

(2) 24 multiple cases as compared to 13 in the placebo group.

iii) a statistically significant greater number of cardiovascular Adverse Events of Special Interest occurring in those receiving the Pfizer Vaccine than in the placebo group;

iv) as to related Serious Adverse Events of Special Interest **("Serious AESI")**:

(1) a 57% higher risk of Serious AESI wherein a Serious AESI is a Serious Adverse Event that:

a) is a pre-defined medically-significant event that may be causally connected to the vaccine; and

b) must be carefully monitored.

(2) an incidence of 27.7 Serious AESI per 10,000 reported in the Pfizer Vaccine recipients as against 17.6 per 10,000 in the placebo group; and

(3) a risk difference of 10.1 Serious AESI per 10,000 Pfizer Vaccine recipients.

e) the Moderna Phase 3 Trial data disclosed that for those taking the Moderna Vaccine:

i) as to Serious Adverse Events there was:

(1) a 6% higher risk of a Serious Adverse Event in the Moderna Vaccine recipients than the unvaccinated group;

(2) a risk excess of a Serious Adverse Event of 7.1 per 10,000 in the Moderna Vaccine recipients; and

(3) a risk ratio of 1.06 of a Serious Adverse Event in the vaccinated.

ii) as to Adverse Events of Special Interest:

(1) a 36% higher risk of Serious AESI in Moderna Vaccine recipients over the placebo group;

(2) an incidence of 57.3 AESI per 10,000 reported in the Moderna Vaccine recipients as against 42.2 per 10,000 in the placebo group; and

(3) a risk difference of 15.1 of Serious AESI per 10,000 Moderna Vaccine recipients.

f) the combined mRNA Vaccine Trials disclosed that for those taking either of the mRNA Vaccines:

i) as to Serious Adverse Events:

(1) there was a 16% higher risk of a Serious Adverse Event in mRNA Vaccines recipients than the placebo group;

(2) a risk excess of a Serious Adverse Event of 13.2 per 10,000 mRNA Vaccine recipients; and

(3) a risk ratio of 1.16 of a Serious Adverse Event in the mRNA Vaccine recipients.

ii) as to Serious AESI:

(1) a 43% higher risk of Serious AESI in the mRNA Vaccine recipients;

(2) a risk difference of 12.5 AESI per 10,000 mRNA Vaccine recipients;

(3) of the 236 Serious AESI occurring across the combined mRNA Vaccine Trials:

a) 230 out of 236 (97%) were adverse event types included as AESI because they are seen in Covid infected persons;

b) the largest excess risk occurred amongst the AESI Category of coagulation or clotting disorders.

Source

The TGA and the TGA Respondents were provided the following study documents in the course of and prior to the Approvals:

1. The Pfizer Clinical Trial; and
2. The Moderna Clinical Trial.

The above clinical trials are referenced by the TGA as the source of the data relied upon in The Pfizer Original AUSPAR and The Moderna Original AUSPAR.

The Brighton Collaboration is widely published, known and accepted internationally as a standard for the classification of AESI's.
https://brightoncollaboration.us/

KNOWN FALSE RISK-BENEFIT PRESUMPTIONS – PFIZER VACCINE

28. On or about 21 January, 2021 and prior to the Pfizer Approval scientific data provided to the TGA and the TGA Respondents by Pfizer and a purported risk-benefit analysis undertaken by the TGA and the TGA Respondents of the Pfizer Vaccine with regard the

Pfizer Nonclinical Trials and the Pfizer Clinical Trial Data disclosed the following **("the Known Pfizer Clinical & Nonclinical Trial Data Issues")**:

a) the TGA asserted the following as matters of fact supporting a favourable risk-benefit determination in respect of the Pfizer Vaccine **("the TGA Asserted Risk Benefit Considerations")**:

i) that there was an unmet public health need in respect of Covid, being a safe and effective Covid vaccine;

ii) that the incidence rate of Covid in Australia was better than other countries;

iii) that life for Australians was far from the normal life Australians led pre-Covid including travel restrictions and border closures and that these have been having a negative impact on the daily life of Australians;

iv) Covid outbreaks had been occurring frequently;

v) a safe and effective vaccine is one of the important tools in the fight against the Covid pandemic;

vi) no Covid vaccine was currently registered in Australia.

b) the TGA Asserted Risk Benefit Considerations and the TGA and the TGA Respondents' determination of a favourable risk benefit profile for the Pfizer Vaccine were made in circumstances of the following false assumptions **("the TGA Known False Risk Benefit Assumptions")**:

i) the Pfizer Vaccine was proven to be safe and effective;

ii) that a vaccine was the only known available means by which Covid could and must be addressed;

iii) that there were no known alternatives to vaccination in the treatment and mitigation of Covid infection;

iv) that the Pfizer Vaccine had established in the Pfizer Trial data that it would prevent Covid:

(1) infection;

(2) severe symptoms; and

(3) death.

v) that the loss of "normal life" and negative effects associated with the Covid pandemic was:

(1) a function of direct effect of Covid; and

(2) not solely a function of the implementation of mitigation measures made without scientific basis or positive effect.

vi) that Covid infection would be so obviously injurious to the Australian population that the mass injection of the Australian population with a never-before-used therapy of unknown long term effects was an obvious benefit and necessity.

Source

The Pfizer AUSPAR. Pg. 33-35 referring to the TGA risk benefit analysis applied based upon the Pfizer Nonclinical Trials and the Pfizer Clinical Trial data provided to the TGA and the TGA Respondents by Pfizer.

KNOWN RISK-BENEFIT ANALYSIS FAILURE AND EVIDENT VACCINES RISK-BENEFIT NEGATIVE PROFILE

29. Prior to the Approvals, the totality of data in respect of the Vaccines provided to the TGA and the TGA Respondents by the Sponsors in respect of the Approvals and the established assessment procedures of the TGA disclosed relevantly to the negative risk benefit profile of the Vaccines the following:

    a) risk - benefit analysis is the essential means by which any of the Vaccines should be considered for approval;

    b) policy formation should consider potential harms alongside potential benefits;

    c) accepted scientific protocol dictates that in respect of the harm-benefit analysis in the use of medicines including the Vaccines **("Correct Risk-Benefit Analysis")**:

        i) risk is primarily ascertained by the frequency of Serious Adverse Events;

        ii) Serious Adverse Event frequencies must be weighed against the benefit of the Vaccines being used in otherwise healthy subjects;

        iii) in the case of preventative medicines in healthy subjects including the Vaccines, consideration must be given to the comparative risk that the disease being purportedly prevented, being symptomatic Covid disease:

            (1) would ever occur; and

            (2) would, if occurring, progress to a disease with a risk of harm approaching or exceeding the risk of receiving the Vaccines;

iv) consideration must be given to the fact that the risk of Serious Adverse Events increases proportionally to the volume of doses administered;

v) risk-benefit analysis is appropriately applied in a stratified manner accounting for the differing levels of risk and benefit in each group by, inter alia, age, physical condition, and pregnancy status;

d) Correct Risk-Benefit Analysis:

i) is the appropriate methodology by which the TGA and any person was required to determine whether or not to grant or advise in support of the Approvals for any or all of the Vaccines for use by the Australian public;

ii) was at no stage prior to the Approvals:

(1) undertaken by any of the Vaccine Sponsors;

(2) undertaken by any of the Respondents upon the data available to or provided to them prior to or subsequent to the Approvals;

(3) applied to the data provided by the Sponsors, available to the Respondents, or within the Respondents possession **("the Available Risk-Benefit Data")**;

(4) sought by the Respondents from the Sponsors;

(5) sought to be facilitated by the Respondents by obtaining a reasonably sufficient degree of data to effect Correct Risk-Benefit Analysis.

e) by reason of (a) to (d), the Respondents failed to fulfil its obligations to **("the Failure to Undertake Required Risk Benefit Analysis")**:

i) undertake Correct Risk-Benefit Analysis or any reasonable risk-benefit analysis in respect of the Vaccines;

ii) only register the Vaccines for use in Australia where it had properly determined that the benefits of the Vaccines are much greater than its risks;

iii) rigorously assess the Vaccines for safety, quality and efficacy before they can be used in Australia;

iv) use the best available scientific evidence to assess the risks and benefits of each Vaccine before approval;

v) carefully assess the results of the Vaccines' clinical trials;

vi) only grant the Approvals where the Vaccines trials demonstrated that the benefits of the Vaccines greatly outweighed the risks.

f) the Available Risk-Benefit Data disclosed that **("the Failure to Consider the Serious Vaccines Risks")**:

i) obligatory risk benefit analysis in respect of the Vaccines required of the Respondents:

(1) a comparison between:

a. the Known Vaccines Excess Risk Data and documented counts of Serious Adverse Events in the Vaccines prior to the Approvals; and

b. severe and critical Covid cases in of each the Vaccines and comparison control group in each of the respective Vaccines Clinical Trial; and

(2) examination of the comparable data extending from after the full vaccination of the subjects with the Vaccines or placebo until the end of the study data.

ii) the short-term risk-benefit performance of:

(1) the Pfizer Vaccine was demonstrated to be:

a. harmful;

b. entirely unbalanced in favour of harm;

c. possessing of a harm-benefit ratio of 25, wherein:

i. a harm-benefit ratio of 0.1 or less is acceptable for approval;

ii. a harm-benefit ratio of 1 indicates literally more harm than good with every dose.

(2) the Moderna Vaccine was demonstrated to be:

a. harmful;

b. entirely unbalanced in favour of harm;

c. possessing of a harm-benefit ratio of 1.1, wherein:

i. a harm-benefit ratio of 0.1 or less is acceptable for approval;

ii. a harm-benefit ratio of 1 indicates literally more harm than good with every dose.

(3) the AstraZeneca Vaccine was unknown and unable to be demonstrated due to the absence of sufficient data made available by the Sponsors prior to and at the time of the AstraZeneca Approvals.

Source

Risk-benefit analysis applied the totality of data in respect of the Vaccines provided to the TGA and the TGA Respondents in respect of the Approvals.

The requirement upon the TGA and the TGA Respondents to establish safety, efficacy and positive risk-benefit of any medicine prior to approval is contained within:

1. The TGA Policies;
2. The Adopted EMA Policies; and
3. The Statutory Obligations.

KNOWN ISSUES OF PFIZER NONCLINICAL TRIALS

30. On or about 15 January, 2021 and prior to the Pfizer Approval the Pfizer Nonclinical Trial data provided to the TGA and the TGA Respondents by Pfizer and widely and globally published scientific studies rationally establishing the significant safety and efficacy risks and risk-benefit deficit in respect of the Pfizer Vaccine disclosed that **("the Known Pfizer Nonclinical Studies Issues")**:

a) almost the same lung inflammation was found in monkeys in control and Pfizer Vaccine groups, demonstrating negligible benefit of the Pfizer Vaccine;

b) Pfizer did not in the Pfizer Nonclinical Trial or at all compare the antibody response between Pfizer Vaccine group and the control group;

c) Pfizer did not study any autoimmune diseases that may have been induced by the Pfizer Vaccine, nor was any data of that nature provided;

d) Pfizer did not study pharmacokinetic data in relation to the Pfizer Vaccine nor was any data of that nature provided;

e) Pfizer asserted to the TGA that those studies referred to in (b) to (d) above were not necessary:

    i. on the erroneous basis that the Pfizer Vaccines were a "vaccine" in the established use and definition of that scientific term;

    ii. an assertion which the TGA and the TGA Respondents unconditionally accepted as a valid basis for those refusals to study those matters;

    iii. in circumstances where in truth the Pfizer Vaccine was a never-before used gene therapy and not a "vaccine" in the established use and definition of that scientific term at that time.

f) no material distribution data of the Pfizer mRNA or s-protein in the human body was conducted because the trial:

    i. was stopped by Pfizer after 2 days;

    ii. at the 2 day mark showed lipids, mRNA and protein of the Pfizer Vaccine in that group:

        (1) present in multiple organs; and

        (2) still increasing in concentration in certain organs in the body at that point;

g) no data as to the degradation of the protein was provided by Pfizer;

h) the antibody and T-cell response which was present initially:

i. decreased significantly over 5 weeks;

ii. made apparent the fact that any response elicited by the Pfizer Vaccine was short-lived;

i) long-term immunity of the Pfizer Vaccine was not studied nor was any data of that nature provided by Pfizer;

j) Vaccine-induced autoimmune diseases were not studied nor was any data of that nature provided by Pfizer;

k) Pfizer had not performed any study nor provided any safety data in respect of the following:

i. toxicity studies on lipid nanoparticle formulation;

ii. secondary species toxicology;

iii. genotoxicity studies;

iv. carcinogenicity studies;

v. immunotoxicology studies;

vi. juvenile animal studies;

vii. studies conducted on the novel excipients used in the Pfizer Vaccine.

l) no study of mucosal immunity was undertaken nor data provided by Pfizer in relation to mucosal immunity in Pfizer Vaccine recipients in circumstances where in truth:

i. Covid is an infection of the mucosal space and the airway;

ii. mucosal infections are typified by Ig-A in secretions which is where the immune response:

(1) is required and should occur;

(2) should be examined to prove efficacy of the Pfizer Vaccine or any Covid Vaccine.

iii. the failure to undertake such a study and accept the absence of such data rationally indicates an obvious neglect of the biology of the condition of Covid infection by Pfizer;

m) the data from the Pfizer Nonclinical Trial unquestionably disclosed that:

i. the mRNA codon in the Pfizer Vaccine had been optimised to make more spike protein;

ii. the spike protein and the LNP encasing the spike protein has been contrived by Pfizer is to facilitate its entry into the cells of the recipient to produce the antigen;

iii. the resultant effect of the Pfizer Vaccine in recipients is that cells in recipients can and do produce antigens in:

(1) an indiscriminate manner;

(2) a completely unknown amount;

(3) a completely unknown distribution.

iv. the Pfizer Vaccine Lipid Nanoparticle would go into:

(1) all body cells;

(2) significantly more cells than the Virus itself could go into physiologically because the Virus did not possess the receptors to do so;

v. the Pfizer Vaccine produces more protein than the actual Virus would, which:

(1) is unprecedented in any previously produced vaccine;

(2) is the precise opposite of typical vaccines which are normally attenuated and weaker than the actual virus being immunised against.

vi. one of the four lipids in the Pfizer Vaccine lipid nanoparticles is slightly ionised, which:

(1) allows the Pfizer Vaccine to enter any cell within the human body;

(2) renders the lipid to be more infectious in humans than the Virus;

vii. the poly-A tail of the Pfizer Vaccine's mRNA:

(1) was modified to be about 3 times the length of the virus' mRNA poly-A tail;

(2) degrades significantly more slowly than the Virus' mRNA;

n) the mice and monkeys used in the Pfizer Nonclinical Study (and other studies) were not appropriate animal models for a Pfizer Vaccine because:

i. those animals are known not to be affected by the Virus in the same way as humans;

ii. serious disease from Covid infection does not occur in monkeys.

o) the TGA and the TGA Respondents' conclusion and acceptance of Pfizer's assertion that large amounts of the Pfizer Nonclinical Trial data are not required because the Pfizer Vaccine is "a vaccine" like any other were rationally and obviously false in the case of the Pfizer Vaccine because:

i. the Pfizer Vaccine is not a vaccine like any other that has successfully been used before;

ii. traditionally a vaccine is an antigen or deactivated virus that is no longer able to infect the recipient but can trigger an immune response;

iii. the Pfizer Vaccine instead carries and injects genetic information designed to instruct the body's cells to create the antigen;

iv. as a result of the Pfizer Vaccine's mechanism of effect, every cell throughout the body may make the antigen;

v. the prolific production of antigen in the body of the recipient caused by the Pfizer Vaccine is profoundly different to a traditional vaccine wherein the antigen stays in the injection site;

vi. mRNA would as a result of the Pfizer Vaccine be produced potentially in every cell in the body;

vii. the intentionally and excessively limited distribution data showed the nanolipid Vaccine adjuvant present in numerous organs in the body.

p) the reproductive/fertility study undertaken by Pfizer prior to the Pfizer Approval undertaken as part of the Pfizer Nonclinical Trial:

i. was of rational and obvious profound importance in respect of the safety of the Pfizer Vaccine because of the known distribution of the Pfizer mRNA to the ovaries of recipients;

ii. showed implantation loss in the mice:

(1) at a rate of:

a. 4.1% in the control group;

b. 9.8% or 139% higher in Pfizer Vaccine group;

(2) which was justified and excused as of no significance by the TGA and the TGA Respondents:

a. on the basis that historical controls have shown similar rates of miscarriage;

b. on the basis at (a.) which is rationally, obviously and profoundly inappropriate and wrong because:

i. historical studies cannot be compared to contemporary data due to the variance to an unknowable degree as between historical and current control groups;

ii. a contemporaneous prospective study control group is in every case required as a true measure of baseline as they possess precisely the same characteristics as the Pfizer Vaccine group.

q) the foetal abnormalities study undertaken by Pfizer prior to the Pfizer Approval undertaken as part of the Pfizer Nonclinical Trial:

i. was of obvious profound importance because a vaccine of the kind which the Pfizer Vaccine is was never before used as a vaccine;

ii. revealed 9 occurrences of foetal abnormalities in the Pfizer Vaccine Group being significantly higher than in the control group;

iii. produced results of significantly higher abnormalities in the Pfizer Vaccine group than the control group which:

(1) were asserted by Pfizer, the TGA and the TGA Respondents to be of no consequence, concern or bar to approval;

(2) were never sought to be further understood or clarified by the TGA or the TGA Respondents as further studies of that nature were:

a. not conducted by Pfizer; or

b. not requested by the TGA or the TGA Respondents;

c. asserted by Pfizer to not be required;

d. found to be acceptable by the TGA and the TGA Respondents by accepting and justifying Pfizer's assertions without any sound or scientific basis.

r) T-cell studies undertaken by Pfizer as part of the Pfizer Nonclinical Trial, which examined cytokine production in Pfizer Vaccine recipients, showed a significant variation in immune response, and demonstrated an obvious and rational:

i. unpredictable and different response in individual Pfizer Vaccine recipients depending on many factors which determine how much any individual will produce the antigen;

ii. amount of antigen production in Pfizer Vaccine recipients which is uncontrolled because it is dependent upon the individual's own immune response and will differ from person to person.

s) cytokine studies undertaken by Pfizer as part of the Pfizer Nonclinical Trials, which examined cytokine production in Pfizer Vaccine recipients obviously and rationally demonstrated:

i. the dominant cytokine produced in Pfizer Vaccine recipients was IL-10 which is the main cytokine produced by the T-suppressor cells that turn off the immune response in the human body;

ii. a short-acting duration of antibody response to the Pfizer Vaccine in the body;

iii. the downregulation of immune response occurred such that:

(1) with a small antigen load, the IL-10 cytokine was produced in relatively small amounts; and

(2) with increased antigen load, the IL-10 cytokine production increased significantly;

iv. a lack of safety and efficacy in the Pfizer Vaccine.

t) the Pfizer Nonclinical Trial undertaken by Pfizer and associated data in confluence rationally and obviously disclosed prior to the Pfizer Approval that the Pfizer Vaccine:

i. possesses the propensity to have affect future generations of the recipients;

ii. disclosed no evidence of better efficacy or speed of production over traditional vaccines;

iii. disclosed no evident basis to have been used over traditional vaccines;

iv. disclosed a significantly higher risk than traditional vaccines;

v. displayed an unpredictable and different response depending on many factors which determine how much any individual will produce the antigen;

vi. displayed an amount of antigen production which is uncontrolled because it is dependent upon the individual's own immune response and differs from person to person.

u) the limited studies showed that the ALC-0315 novel excipient used in the Pfizer Vaccine was:

i. only slowly eliminated; and

ii. retained in the liver.

v) that the TGA and Respondents had determined that:

i. there were shortcomings in the repeat dose toxicity study design implemented by Pfizer in respect of the Pfizer Vaccine for the Pfizer Approval;

ii. those shortcomings should not preclude approval of the Pfizer Vaccine.

iii. a proper and complete repeat dose toxicity study from Pfizer prior to the Pfizer Approval was not required.

w) the novel excipients in the Pfizer Vaccine were subject to:

i. no repeat dose studies;

ii. no reproductive toxicity studies

x) the TGA and the TGA Respondents determined that findings in the studies with the Pfizer lipid nanoparticle formulation were due to the lipid excipients in the case of hepatocyte vacuolation, which was probably a manifestation of hepatocyte uptake of lipids;

y) the potential of the Pfizer LNP or the vaccine formulation for complement activation or stimulation of cytokine release was not adequately assessed in nonclinical studies;

z) there was no data provided by Pfizer relating to the kinetics of Pfizer mRNA degradation;

aa) there was unknown metabolism of the lipid nanoparticle adjuvants in the liver and that the metabolic studies in vitro:

i. were stopped at between 2 hours and 4 hours at which time:

(1) almost none of the lipids had been metabolised from the liver at all;

(2) levels in many cases were still increasing in the liver;

(3) the half-life of the lipid nanoparticle in the liver, was determined to be:

a. somewhere between 4 hours and forever;

b. unknown.

bb) how long these products stay in the body or their metabolic pathway was and remains entirely unknown;

cc) the Pfizer Vaccine was highly inflammatory, crossed the blood-brain barrier and into the neuro tissues, into the spinal cord and into the ovaries and testes;

dd) a single-dose intravenous study in rats disclosed that both novel lipid excipients - ALC-0159 and ALC-0315 - in the Pfizer LNP formulation rapidly distributed from plasma to the liver being the only organ collected for analysis;

ee) the elimination of both lipids from the recipients were slow;

ff) the study cited in the Pfizer Vaccine Approval Application:

i. indicated lipid nanoparticles in:

(1) the injection site;

(2) liver;

(3) spleen;

(4) adrenal glands; and

(5) ovaries;

ii. did not investigate draining lymph nodes;

iii. did not involve any analysis of:

(1) faeces;

(2) urine;

(3) carcass; and

(4) cage-wash samples.

iv. was erroneously asserted by Pfizer to the TGA and the TGA Respondents to have included the standard panel of tissues but excluded the draining lymph nodes;

v. such study erroneously accepted by the TGA and the TGA Respondents as being sufficient in circumstances of:

(1) metabolic studies having not been adequately performed to determine how either the mRNA, the produced spike protein or lipids were metabolised or excreted

(2) the possibility of toxic metabolites having not been adequately assessed.

gg) that in assessing toxicity of the Pfizer Vaccine in the Pfizer Nonclinical Trial Data provided by Pfizer:

i. the TGA and the TGA Respondents determined that the dosing interval utilised by Pfizer in the study was not optimal; and

ii. repeat dose toxicity studies with a dosing interval of 2 or 3 weeks not utilised by Pfizer would be more appropriate for investigating the potential toxicity of the vaccine.

hh) the TGA and the TGA Respondents determined that:

i. another repeat dose study in animals is not considered necessary because of "the availability of clinical data"; and

ii. the deficiencies in the provided repeat dose toxicity study design should not preclude approval of the Pfizer Vaccine;

ii) the TGA and the TGA Respondents accepting and determining "given the availability of clinical data" as justification for why another repeat dose study was not necessary, rationally meant that the TGA and the TGA Respondents had in fact determined that the Australian public at large were the suitable test subjects for the Vaccines;

jj) as to major toxicities identified in the Pfizer Nonclinical Trial Data**:**

i. treatment related findings in the repeat dose study in rats with the Pfizer Vaccine (V9) were:

(1) increased body temperature;

(2) acute inflammation at the injected site with oedema and erythema,

(3) increased white blood cells;

(4) neutrophils;

(5) large unstained cells (LUC);

(6) eosinophils;

(7) basophils; and

(8) fibrinogen;

ii. the albumin to globulin ratio was decreased;

iii. acute phase proteins, α2-macroglobulin and α1-acid glycoprotein increased;

iv. transient lower reticulocytes;

v. lower red cell mass;

vi. spleen weights increased, associated with enlarged spleen and lymph nodes.

kk) treatment related microscopic findings were seen at:

i. the injection sites and surrounding tissues (mixed cell inflammation, mostly neutrophils);

ii. draining lymph nodes (hypercellularity of germinal centre and increased plasma cells, mostly plasmablasts);

iii. bone marrow (hypercellularity of hematopoietic cells, primarily myeloid cells);

iv. the spleen (increased hematopoiesis and germinal centre); and

v. the liver (vacuolation of hepatocytes in the portal region).

ll) the findings were erroneously determined by the TGA and the TGA Respondents to be of no concern:

i. and to be consistent with:

(1) immune stimulation and responses; and

(2) inflammatory reactions and responses;

(3) except for hepatocyte vacuolation deemed to probably be lipid vacuoles;

ii. in circumstances where in truth:

(1) it was scientifically established since at least 2019 in respect of the meaning of these Adverse Events in the Pfizer Nonclinical Trial data that:

a. in the context of a preclinical toxicity study:

i. an adverse effect is:

1. a test item-related change in the morphology, physiology, growth, development, reproduction or life span of the animal model;

2. likely to result in an impairment of functional capacity to maintain:

a. homeostasis; and

b. an impairment of the capacity to respond to an additional challenge;

b. as the most abundant plasma protein, albumin is largely responsible for producing the oncotic pressure that keeps fluid within the vascular system:

i. severe hypoalbuminemia results in loss of oncotic pressure causing edema and ascites due to accumulation of fluid in interstitial spaces;

ii. marked or severe decreases in albumin are associated with clinical edema are Adverse Events;

c. hypoalbuminemia:

i. results from and reflects the inflammatory state;

ii. interferes with adequate responses to events like surgery or chemotherapy;

iii. is associated with:

1. poor quality of life;

2. reduced longevity;

3. liver failure;

iv. is an adequate indicator of deterioration of the clinical state of a patient.

d. the lowered albumin outcome:

i. was erroneously dismissed by Pfizer as an expected inflammatory response;

ii. was accepted by the TGA and the TGA Respondents as an acceptable inflammatory

response of no consequence to the Pfizer Approval;

iii. was in fact, as in the Pfizer Nonclinical Trial, when coupled with oedema or swelling, which was present in the toxicology animal studies, rationally and obviously:

1. an adverse finding;

2. associated with liver failure; or

3. indicative of clinical deterioration; and

4. a serious safety finding which:

a. required further investigation;

b. is not appropriately dismissed as an inconsequential observation;

c. is indicative of a safety issue in the Pfizer Vaccine.

mm) by reason of the factual matters at (a) to (ii) herein above, the utilization of the Pfizer Nonclinical Trial data as a basis for establishing safety and efficacy in the Pfizer Vaccine and granting the Approval of the Pfizer Vaccine, obviously and logically involved:

i. a failure to obtain data essential to establishing the safety or efficacy of the Pfizer Vaccine;

ii. a failure to identify and make public the obvious safety and efficacy issues made evident by the data and lack of data contained in the Pfizer Nonclinical Trial;

iii. an acceptance of excuses for the non-production of essential data from Pfizer in the Pfizer Nonclinical Trial without any proper or scientific basis for doing so;

iv. a failure to establish the safety or efficacy of the Pfizer Vaccine prior to the Pfizer Approval or at all.

Source

The above matters are referred to in the document produced by the TGA and the TGA Respondents dated 8 January, 2021 (revised 15 January, 2021) – the Pfizer Nonclinical Evaluation Report. Pages: 4, 5, 6, 10, 11, 12-14, 18-19, 47, 55; and the Pfizer Original AUSPAR.

The requirement to establish safety, efficacy and positive risk-benefit of any medicine prior to approval is contained within:

1. The TGA Policies;
2. The Adopted EMA Policies; and
3. The Statutory Obligations.

The scientifically established approach to the observed adverse events in the trial is exemplified for example in:

"Principles for Assessing Adversity in Toxicologic Clinical Pathology" - Lila Ramaiah. Toxicologic Pathology 2017, Vol. 45(2) 260-266. 2017, pg. 261.

Hypoalbuminemia: Pathogenesis and Clinical Significance. Soeters, P.B., Wolfe, R.R. and Shenkin, A. (2019). Journal of Parenteral and Enteral Nutrition, 43: 181-193. Pg. 181.

KNOWN EVIDENCE OF PFIZER ADJUVANT DISTRIBUTION THROUGHOUT THE BODY

31. From 9 November, 2020 and prior to the Approvals the widely and globally published scientific data and conclusions and data provided by Pfizer to the TGA and the TGA Respondents rationally establishing the extreme dangers and risk associated with Lipid Nanoparticles **("LNP")** used as the delivery vehicle for the synthetic mRNA in the Pfizer Vaccine disclosed that the LNP in the Pfizer Vaccine **("the Early Known Pfizer Biodistribution Danger Data")**:

a) extensively bio-distribute throughout the human body;

b) accumulates in various organs including:

i) kidney;

ii) spleen;

iii) adrenal glands;

iv) testes; and

v) ovaries;

c) in distribution testing, were assessed for only 48 hours before stopping, at which time:

i) the adrenal glands and ovaries:

(1) displayed their highest mean concentrations;

(2) the concentration of LNP was still increasing;

d) possessed effects from the delivered synthetic mRNA upon the various organs studied which were and are unknown;

b) were and are toxic to humans;

c) caused significant and unquantified danger and effects in human recipients of the Pfizer Vaccine.

Source

The Early Known Pfizer Biodistribution Danger Data was contained in the following data provided by Pfizer to the TGA and the TGA Respondents:

1. the biodistribution of Lipid Nanoparticle-mRNA as from 9 November, 2020, the paper published on or about that date in the FDA released document: Acuitas Therapeutics Inc / Pfizer "A Tissue Distribution Study of a [3 H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats" at pg. 21.
https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf

2. as at on or about 28 February, 2021 the data contained in the Pfizer Post-Marketing Data pg. 9 and 12;

The toxicity of lipid nanoparticles in humans including those used in the Vaccines was well documented and accepted scientifically including for example, rationally established in the following published and widely known studies:

1. "Oxygen Radical-Mediated Pulmonary Toxicity Induced by Some Cationic Liposomes". Dokka, S et al. 2000. Pharm Res 17, 521–525: https://doi.org/10.1023/A:1007504613351;

2. "Toxicity of cationic lipids and cationic polymers in gene delivery". Hongtao, LV et al. 2006. Journal of Controlled Release, Volume 114, Issue 1, Pages 100-109. https://doi.org/10.1016/j.jconrel.2006.04.014;

3. "The systemic toxicity of positively charged lipid nanoparticles and the role of Toll-like receptor 4 in immune activation". Ranit, K et al. 2010. Biomaterials, Volume 31, Issue 26, Pages 6867-6875. https://doi.org/10.1016/j.biomaterials.2010.05.027;

4. "Toxicity and immunomodulatory activity of liposomal vectors formulated with cationic lipids toward immune effector cells". Filion, M., Phillips, N. 1997. Biochemical et Biophysica Acta (BBA) – Biomembranes, Volume 1329, Issue 2, Pages 345-356. https://doi.org/10.1016/S0005-2736(97)00126-0.

KNOWN PFIZER CLINICAL TRIAL ISSUES – TGA EVALUATION

32. On or about 8 January, 2021 and prior to the Pfizer Approval the Pfizer Clinical Trial data provided to the TGA and the TGA Respondents by Pfizer rationally establishing the

significant safety and efficacy risks and dangers and risk-benefit deficit in respect of the Pfizer Vaccine disclosed that **("the Known Pfizer Clinical Data Issues")**:

a) at no time prior to the Pfizer Approval did Pfizer provide immunogenicity data in respect of the Pfizer Vaccine in the Pfizer Clinical Trial **("the Known Pfizer Immune Response Failures")**;

b) the TGA and the TGA Respondents knew prior to the Pfizer Approval that the Pfizer Vaccine (described by Pfizer as "V9") that would be and was finally supplied to Australia differed from the concurrently tested version (described by Pfizer as "V8") **("the Alternate Pfizer Vaccine")** in the circumstances:

   i. the Pfizer Vaccine was produced in a materially different manner to the Alternate Pfizer Vaccine;

   ii. the Pfizer Vaccine and the Alternate Pfizer Vaccine were and are materially different therapeutics because they possess different:

      (1) nucleotide sequences; and

      (2) codon optimisation sequences;

   iii. the Pfizer Approval proceeded upon testing data which:

      (1) had been derived from the Alternate Pfizer Vaccine which were never undertaken on the Pfizer Vaccine, specifically studies:

         a. R-20-0054; and

         b. VR-VTR-10741;

      (2) was unknown as to whether the data received from Pfizer had been derived from the Alternate Pfizer Vaccine or the Pfizer Vaccine, specifically studies:

a. R-20-0112; and

b. R-20-0211;

iv. the Pfizer Approval proceeded upon testing data to approve the Pfizer Vaccine which was:

(1) known to be unrelated to the Pfizer Vaccine; and

(2) not known as to whether it was the Pfizer Vaccine.

Source

"Pfizer/BioNTechCOVID-19 mRNA vaccine (BNT162, PF-07302048) TGA Pre-Submission Meeting September 18, 2020" produced by Pfizer and presented to the TGA on 18 September 2020. Pg. 20, 21, 61 and 113. https://www.tga.gov.au/sites/default/files/foi-2389-03-1.pdf

Pfizer Nonclinical Evaluation Report, Pg. 7

c) the entirety of the Pfizer Clinical Trial Data provided by Pfizer in respect of the Pfizer Vaccine **("the Known Pfizer Clinical Data Efficacy Failures")**:

i. failed to rationally demonstrate the pre-specified success criterion for true efficacy in the Pfizer Vaccine;

ii. disclosed that the Pfizer Clinical Trial did not test for or provide data and thereby no conclusions could be or were drawn or demonstrated as to Pfizer Vaccine efficacy in prevention of:

(1) severe illness from Covid infection;

(2) transmission of the Virus between persons;

(3) death from Covid infection;

(4) Covid infection at all.

d) that **("the Known Declining Pfizer Efficacy")**:

i. changes in Covid pandemic characteristics would change the efficacy of the Pfizer Vaccine over time;

ii. sustained protective efficacy for Pfizer Vaccine could not be concluded;

e) that in defining the Virus, Pfizer cited scientific literature **("the Known Failure to Examine Identified Effective Alternatives")**:

i. which scientifically concluded and established that:

(1) the serine protease inhibitor blocks the Virus from entering and infecting lung cells;

(2) full inhibition of the Virus was attained when camostat mesylate and E-64d, and inhibitor of CatB/l, were added.

ii. which despite establishing the efficacy of those compounds as pleaded in (i) herein above, the TGA and the TGA Respondents did not consider or explore those therapies:

(1) for use against Covid;

(2) which were prior to the Approvals:

a. already in use and production for clinical use;

b. able to block the Virus entry into cells.

Source

The above matters were evident in the Pfizer Clinical Evaluation Report. Pages 8, 24, 27, 39, 41, 42.

The study cited in defining the Virus is: "SARS-CoV-2 Cell Entry Depends on ACE2 and TMPRSS2 and Is Blocked by a Clinically Proven Protease Inhibitor", Hoffmann M et al, Cell. 2020; 181(2):271-280.e278 at section entitled "The Cellular Serine Protease TMPRSS2 Primes SARS-2 for Entry, and Serine Protease Inhibitor Blocks SARS-CoV-2 Infection of Lung Cells"

KNOWN PFIZER CLINICAL TRIAL ISSUES – TGA AUSPAR

33. On or about 21 January, 2021 and prior to the Pfizer Approval the Pfizer Clinical Trial Data provided to the TGA and the TGA Respondents by Pfizer rationally establishing the significant safety and efficacy risks and dangers and risk-benefit deficit in respect of the Pfizer Vaccine disclosed that **("the Known Pfizer Vaccine Trial Data Issues")**:

a) the long term effect of the Pfizer Vaccine was not evident as:

i. antibodies and T-Cells produced as a consequence of the Pfizer Vaccine declined quickly over 5 weeks;

ii. the TGA and the TGA Respondents expressly doubted that any long-term immunity would be afforded by the Pfizer Vaccine;

b) the totality of data provided by Pfizer for assessment by the TGA and the TGA Respondents in respect of the Pfizer Approval disclosed:

i. only short term evaluation of protection by the Pfizer Vaccine;

ii. a lack of any pharmacokinetic data for the S antigen-encoding in the mRNA of the Pfizer Vaccine (v.9);

iii. suboptimal dosing intervals undertaken in the repeat dose study;

iv. a lack of any repeat dose toxicity studies in a second species;

v. a lack of any genotoxicity studies with the novel excipients in the Pfizer Vaccine being used which had never before been tested or approved by the TGA;

vi. a lack of any studies investigating potential for autoimmune diseases from the Pfizer Vaccine;

vii. a lack of any studies of long-term immunity in the Pfizer Nonclinical Trial;

viii. a lack of any studies of vaccine induced autoimmune diseases in the Pfizer Nonclinical Trial;

ix. a lack of complement activation in the Pfizer Nonclinical Trial;

x. a lack of stimulation of cytokine release studies in the Pfizer Nonclinical Trial;

xi. numerous adverse events of special interest **("AESI")** and adverse events in the vaccine group that were absent in the placebo group assessed by the investigator as "unrelated to study intervention" and "none were assessed as related to study intervention by the investigators" which was accepted by the TGA and the TGA Respondents thereby rationally evidencing:

(1) a disregard for the purpose and function required of the TGA and the TGA Respondents; and

(2) a tendency to simply accept any justifications or explanations of the

Sponsors despite the clear risk to the public that such an approach may create;

(3) failure or refusal by the TGA and the TGA Respondents to:

a. review individual case data for any of the adverse events reported in the study; or

b. enquire further when no further information on individual cases was provided.

xii. multiple cases of Serious Adverse Events were reported in the Pfizer Trials in the Pfizer Vaccine group only which:

(1) should have triggered the stopping rules for the trial;

(2) represented a safety signal;

(3) were assessed and accepted by the TGA and the TGA Respondents as not related to the Pfizer Vaccine;

(4) should have:

a. prompted a review of the investigators assessments of the adverse events but were not;

b. alerted the TGA and the TGA Respondents to independently review the investigators assessments against Brighton Collaboration case definitions, but were not.

c) that from a clinical point of view:

i. the entire data set provided by Pfizer in respect of the Pfizer Approval was a single clinical trial (Study C4591001) for which interim findings for a median follow up period of around 2 months only were made available;

ii. short follow-up duration limits in the Pfizer Trials limited any possible conclusions in respect of:

(1) persistence of efficacy of the Pfizer Vaccine;

(2) late onset adverse events;

(3) rare adverse events.

Source

The above matters are evident in the Pfizer Original AUSPAR - Pages 14, 15, 30.

The stopping criteria for the Pfizer Clinical Trial are found in the Pfizer Clinical Trial Protocol. Page 63-64.

The requirement of the Respondents to establish safety, efficacy and positive risk-benefit of any medicine prior to approval is contained within:

1. The TGA Policies;
2. The Adopted EMA Policies; and
3. The Statutory Obligations.

KNOWN CONFLICTS OF INTEREST – PFIZER ANALYSIS STUDY

34. In December, 2020 the analysis of the Pfizer Clinical Trial Data provided to the TGA and the TGA Respondents and widely and globally published **("the Pfizer Vaccine Analysis Study")** rationally establishing the efficacy and safety risks and dangers of the

Pfizer Vaccine and upon which the TGA and the TGA Respondents relied in the Approvals disclosed that the analysis **("the Known Conflicts of Interest")**:

a) was conducted by 29 authors, of which:

   i) 21 had direct conflicts of interest;

   ii) 19 were employees of Pfizer;

   iii) 18 held stock in Pfizer;

   iv) 2 had received research grants for their institutions or sites from Pfizer;

   v) 1 was a grant recipient from Pfizer and retained personal fees from Pfizer; and

   vi) 1 obtained fees for their involvement in the Pfizer Clinical Study.

b) the Pfizer Vaccine Analysis Study:

   i) was relied upon by the TGA including its conclusions in relation to the Pfizer Approval;

   ii) was funded by BioNTech and Pfizer.

Source

Polack, FP et al "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine" New England Journal of Medicine. December 2020. DOI: 10.1056/NEJMoa2034577

https://www.nejm.org/doi/10.1056/NEJMoa2034577?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

TGA Response to FOI request listing the Pfizer Vaccine

Analysis Study as evidence provided by the TGA as to the safety and efficacy of the Pfizer Vaccine. https://www.tga.gov.au/sites/default/files/foi-request-response.pdf

KNOWN ASTRAZENECA NONCLINICAL TRIAL ISSUES

35. On or about 15 February, 2021 and prior to the AstraZeneca Approval the AstraZeneca Nonclinical Trial data **("AstraZeneca Nonclinical Trial Data")** provided to the TGA and the TGA Respondents by AstraZeneca rationally establishing significant safety and efficacy risks and dangers and risk-benefit deficit in respect of the AstraZeneca Vaccine disclosed that **("the Known AstraZeneca Nonclinical Trial Data Issues")**:

a) antibodies decrease rapidly within 2 weeks after the 2nd dose of the AstraZeneca Vaccine;

b) no long-term immunity in respect of the AstraZeneca Vaccine was assessed in nonclinical studies**;**

c) immunogenicity of the AstraZeneca Vaccine may decrease with repeated vaccination;

d) the AstraZeneca Nonclinical Trial data disclosed an obvious lack of immunity with the AstraZeneca Vaccine beyond 2 weeks affecting profoundly the risk-benefit analysis;

e) because a reproductive toxicity study of the AstraZeneca Vaccine was ongoing at that time by AstraZeneca, a Pregnancy Category B2 was considered acceptable;

f) the TGA and the TGA Respondents determined that without adequate assessment of the effects upon embryo foetal development the AstraZeneca Vaccine was not recommended for use in pregnant women, in circumstances where in truth:

i. the AstraZeneca Vaccine was claimed by the TGA and the TGA Respondents at the time of the Approvals to be safe for use in pregnant women;

ii. a B2 Pregnancy Category is incorrect in the circumstances according to the AstraZeneca Protocol as there were neither nonclinical animal studies nor human study results made available to the TGA and the TGA Respondents by AstraZeneca as the trials were ongoing;

iii. subsequent data indicated high toxicity in pregnancy.

g) there were unexpected and unexplained findings of significantly higher viral RNA load in the intestinal tissues of animals vaccinated with a 2nd dose of the AstraZeneca Vaccine over the 1st dose at 7 days after the injection;

h) by reason of (g), animals receiving the 2nd dose of the AstraZeneca Vaccine as compared to 1st dose only required further investigation, which was not undertaken;

i) the lack of boosting of antibody or protective responses following 2nd dose of the AstraZeneca Vaccine in animals tested required further investigation;

j) the TGA and the TGA Respondents adopted a conclusion that there was no evidence of vaccine associated enhanced disease despite subjective findings of the TGA and the TGA Respondents:

i. of a 'surprising' and 'unexplained' finding involving potential T cell exhaustion;

ii. of evidence of a small set of cytokines not being elevated by the booster;

iii. that identified phenomena occurring post-vaccination could not be excluded by:

(1) the absence of a single cytokine being elevated;

(2) the T cell exhaustion theory; and

(3) abnormal response to booster vaccination which required careful assessment and scrutiny.

k) the data from the AstraZeneca Nonclinical Trial disclosing an obvious and rational failure to establish AstraZeneca Vaccine's:

i. safety;

ii. efficacy; or

iii. positive risk-benefit profile.

Source

The above matters are evident in the AstraZeneca Nonclinical Evaluation Report, pg. 5 and 8.

KNOWN ASTRAZENECA CLINICAL TRIAL ISSUES

36. On or about 27 January, 2021 and prior to the AstraZeneca Approval the AstraZeneca Clinical Trial Data provided to the TGA and the TGA Respondents by AstraZeneca rationally establishing significant safety and efficacy risks and dangers and risk-benefit deficit in respect of the AstraZeneca Vaccine disclosed **("the Known AstraZeneca Clinical Trial Data Issues")**:

a) that the TGA and the TGA Respondents considered that:

i. for provisional registration of a medicine including the Vaccines the role of the TGA is to assess whether:

(1) quality of the Vaccine has been adequately established for the purpose for which the Vaccine is to be used;

(2) safety of the Vaccine has been adequately established for the purpose for which the Vaccine is to be used;

(3) efficacy has been adequately established for the purpose for which the Vaccine is to be used;

ii. in approving a medicine including the Vaccines, for a vaccination to be rolled out with the aim of protecting the Australian population, the context of this use needs to be considered;

iii. there needs to be consideration as to whether the efficacy demonstrated by the Vaccines is sufficient:

(1) for use in the Australian context where Covid was at that time less prevalent;

(2) that expert advice in this respect be sought.

b) the AstraZeneca Clinical Trial data disclosed that:

i. AstraZeneca reported neurological disorders:

(1) including headaches which occurred in:

a) 9.3% of subjects who received the AstraZeneca Vaccine; and

b) 6.1% of the control group;

c) the first 7 days after vaccination; and

d) which AstraZeneca purportedly considered, and the TGA and the TGA Respondents accepted without any evident basis, to be due reactogenicity.

(2) including tremor which:

a) was more commonly seen in the AstraZeneca Vaccine group than the control group;

b) tended to be in the first 7 days after vaccination; and

c) which AstraZeneca purportedly considered, and the TGA and the TGA Respondents accepted without any evident basis, to be due reactogenicity.

(3) in circumstances where in truth it was known to the Respondents that higher reactogenicity:

a) indicates an obvious risk of Vaccine-Associated Enhanced Respiratory Disease;

b) should properly have been have further investigated as an adverse finding by the TGA and the TGA Respondents but was not;

ii. AstraZeneca reported that 2 participants in the AstraZeneca Vaccine group suffered Serious Adverse Events:

(1) being:

a) pyrexia; and

b) transverse myelitis.

(2) which the TGA and the TGA Respondents considered may have been causally associated with the AstraZeneca Vaccine;

iii. AstraZeneca reported angina:

(1) in 3 cases in the AstraZeneca Vaccine group;

(2) as not occurring in the control group at all;

(3) as occurring between 16 and 17 days after the AstraZeneca vaccination;

(4) the causality of which was:

a) purportedly considered by AstraZeneca to be unlikely to be related to the AstraZeneca Vaccine;

b) accepted by the TGA and the TGA Respondents without proper basis to be unlikely to be related to the AstraZeneca Vaccine;

iv. AstraZeneca reported death occurring in 2 of the AstraZeneca Vaccine group:

(1) 1 reportedly due to fungal pneumonia in a patient with HIV; and

(2) 1 reportedly due to malignant neoplasm;

(3) as to causality of the deaths, relevantly:

a) purportedly considered by AstraZeneca not to be causally related to the AstraZeneca Vaccine;

b) accepted by the TGA and the TGA Respondents without proper basis as not causally related to the AstraZeneca Vaccine;

c) using the causality assessment probability scales and WHO criteria, the deaths:

i. are at least possible;

ii. more likely probable or certain causal.

d) there were exclusion criteria for anyone with serious medical conditions, or any chronic condition unless it was stable and well controlled;

i. wherein, a stable HIV patient died of reported fungal pneumonia, and:

1. for the event to have occurred after the product with a temporal relationship;

2. the death is in fact obviously indicative of immune interference from the AstraZeneca Vaccine triggering disease progression and immunodeficiency.

e) the malignant neoplasia required closer and further evaluation because:

i. malignant neoplasms were also reported in the Pfizer Clinical Trial;

ii. no mutagenicity studies were conducted; and

iii. the patient would have been excluded from the AstraZeneca Clinical Trial if they had malignant neoplasia prior to the study;

iv. to have developed neoplasia and succumbed to this during the study period is evidence obviously and rationally indicative of a highly concerning causality for aggressive malignancy.

v. AstraZeneca reported in 2 cases of sudden adverse events in the AstraZeneca group:

(1) transverse myelitis in a 37 year old subject wherein it was reportedly concluded by AstraZeneca and accepted by the TGA and the TGA Respondents that there was uncertainty as to whether the Serious Adverse Event was causally:

a) inflammatory (and drug related); or

b) vascular; or

c) multiple sclerosis; and

d) possibly and to an unknown degree attributable causally to the patient's family history of Charcot-Marie-Tooth Disease type 1a;

e) in circumstances where in truth in fact:

i. Charcot-Marie-Tooth type 1a family history is likely irrelevant and obviously not a better causal answer to AstraZeneca Vaccine causality;

ii. no details on the degree of relatedness of this family history were given to or by the Respondents in suggesting this alternative causality;

iii. no details of the gene mutation for the family member were provided by AstraZeneca or anyone suggesting this alternative causality;

iv. no details of any genetic testing on the patient were provided by AstraZeneca or anyone suggesting this alternative causality;

v. the rejection of AstraZeneca Vaccine causality by the TGA and the TGA Respondents in the circumstances is made without any evident basis.

(2) multiple sclerosis in a 37 year old subject wherein it was reportedly concluded by AstraZeneca and accepted by the TGA and TGA Respondents that:

a) the patient's brain had multiple lesions;

b) most of the patient's brain lesions were thought to pre-date the vaccination; and

c) the multiple sclerosis was considered not related to the AstraZeneca Vaccine;

d) in circumstances where in truth in fact:

i. the TGA asserted that the MRI results disclose that the brain lesions for MS mostly were thought to pre-date the vaccination;

ii. no details are provided and no evident basis as to how AstraZeneca or the TGA came to this conclusion;

iii. it is impossible to 'date' MS lesions on an MRI unless a previous MRI has been reviewed for comparison;

iv. the rejection of AstraZeneca Vaccine as being causal by the TGA and the TGA Respondents in the circumstances was made without any evident basis.

vi. the control group in the study improperly used either meningococcus vaccine or saline without any further detail as to the proportion of each or reason for using another vaccine as the control;

vii. AstraZeneca concluded and the TGA and the TGA Respondents accepted the conclusion that there was a clinically meaningful imbalance in the incidence of Adverse Events of Special Interest being Vaccine-Associated Enhanced Respiratory Disease;

viii. AstraZeneca reported that there was a case of transverse myelitis and multiple sclerosis in the AstraZeneca Vaccine group;

ix. there was a reported case of chronic inflammatory demyelinating polyneuropathy:

(1) in the ongoing US study of the AstraZeneca Vaccine;

(2) for which causality in respect the AstraZeneca Vaccine was determined to have remained uncertain;

x. the safety data in the elderly was determined by the TGA and the TGA Respondents to be:

(1) important as applying to at-risk individuals;

(2) relatively limited and small in sample size and quantity;

(3) derived from only 8.9% of participants who were over 65 years old; and

(4) derived from only 6.1% of all study participants were over 70 years old;

xi. reactogenicity was reported as less severe in the elderly than in the younger population;

c) the AstraZeneca Clinical Trial Data was so limited that the TGA and the TGA Respondents had determined at the time of the AstraZeneca Approval:

i. no conclusions could be drawn from the data in respect of the efficacy of the AstraZeneca Vaccine;

ii. the results in respect of efficacy of the AstraZeneca Vaccine were uninterpretable;

iii. the data was incapable of secondary analysis;

iv. animal studies of the AstraZeneca Vaccine demonstrated persistent spreading of the Virus in the upper respiratory tract in the AstraZeneca Vaccine group;

v. efficacy of the AstraZeneca Vaccine in preventing asymptomatic disease was unknown;

vi. efficacy of the AstraZeneca Vaccine in preventing transmission of the Virus was unknown;

d) that the TGA and the TGA Respondents asserted at that time in respect of the AstraZeneca Vaccine that:

i. it is important that the Australian population understand the facts about:

(1) the efficacy of the AstraZeneca Vaccine;

(2) the limitations of the AstraZeneca Vaccine efficacy data; and

(3) the need to continue other public health measures to prevent the spread of disease until more information about vaccine efficacy is available;

ii. the duration of follow up, and reasons for missing data in follow up, are important in determining efficacy;

iii. lower duration of follow up may be from drop outs or the censoring of cases by the Sponsor;

iv. longer duration of follow up increases the time of exposure and increases the opportunity for true effectiveness (or non-effectiveness) to be demonstrated;

v. one of the major limitations of the AstraZeneca Clinical Study in respect of efficacy is the short and variable duration of follow up.

e) that in the AstraZeneca Clinical Trials those at high risk of Covid **("the High Risk Groups")** were excluded or insufficiently represented to conclude safety or efficacy in those groups including:

i. the elderly;

ii. pregnant women; and

iii. those with significant co-morbidities.

f) in the TGA and the TGA Respondents' asserted opinion:

i. the standard for approval for registration is a different assessment to a risk/benefit analysis as the potential risks of vaccination are small, and the potential benefits in this population large;

ii. identified high risk populations should not be excluded from the indication:

(1) because:

a) it is reasonable to extrapolate efficacy in those groups; and

b) the risks of Covid outweigh potential risks of the vaccine;

(2) notwithstanding:

a) the entire absence of evidence indicating efficacy in those groups;

b) the TGA and the TGA Respondents' complete absence of assessment or quantification of the actual risks of Covid; and

c) the obvious failure to establish safety and thereby risk in respect of the AstraZeneca Vaccine.

iii. the TGA and the TGA Respondents must ensure:

(1) adequate warning about the limitations of the data in the AstraZeneca Product Information; and

(2) a recommendation to prescribers that the potential risks and benefits to an individual be considered prior to proceeding to vaccinate with the AstraZeneca Vaccine.

iv. in respect of the High Risk Groups, the totality of data provided by AstraZeneca for the AstraZeneca Approval contained:

(1) insufficient patients in the study; and

(2) incomplete pre-clinical studies.

g) the TGA and the TGA Respondents asserted to have determined the following in respect of the AstraZeneca Vaccine and recommended that for potential users of the AstraZeneca Vaccine, the following warnings were appropriate:

i. vaccination with the AstraZeneca Vaccine or any other vaccine may not protect all recipients of that vaccine;

ii. the AstraZeneca Vaccine or any other vaccine should be used along with other infection control measures to prevent acquiring Covid;

iii. immunisation with AstraZeneca Vaccine reduces the risk of symptomatic disease but does not eliminate the risk of acquiring Covid;

iv. individuals who test positive for Covid on PCR swab may still be infectious and require isolation even though vaccinated with the AstraZeneca Vaccine;

h) the totality of data provided by AstraZeneca for the AstraZeneca Approval in fact disclosed:

i. no real understanding as to the actual risks to AstraZeneca Vaccine recipients;

ii. no real understanding as to the actual efficacy or benefit of the AstraZeneca Vaccine to recipients;

iii. no possible conclusion as to the AstraZeneca Vaccine:

(1) safety;

(2) efficacy;

(3) risk-benefit profile.

i) the conclusions by the TGA and the TGA Respondents drawn from that totality of data submitted provided by AstraZeneca for the AstraZeneca Approval involved:

i. assumptions by the TGA and the TGA Respondents as to efficacy and safety of the AstraZeneca Vaccine without any scientific basis;

ii. no application of risk-benefit analysis by the TGA and TGA Respondents by comparing actual threat of Covid to risks associated with AstraZeneca Vaccine; and

iii. an obvious and complete misunderstanding by the TGA and the TGA Respondents of an appropriate risk-benefit evaluation.

Source

The matters are evident in the following documents produced by and for the TGA and the TGA Respondents dated 28 January, 2021 as follows:

1. The AstraZeneca Delegate Report, pg. 6, 21, 22, 24.

2. The AstraZeneca Clinical Evaluation Report, pg. 5, 8, 20, 44, 47, 48, 49, 51, 54, 58, 59.

GENOTOXICITY/CARCINOGENICTY - KNOWN EXTREME RISK OF PFIZER MRNA VACCINE

37. Prior to the Pfizer Vaccine Approval data provided by Pfizer to the TGA and the TGA Respondents and widely and globally published scientific data and studies rationally establishing significant safety issues in respect of the Pfizer Vaccine in their known configuration upon humans disclosed:

a) that the active ingredient in the Pfizer Vaccine is a single-stranded, 5'-capped messenger RNA (mRNA) **("the Pfizer Vaccine mRNA")**:

i. produced using a cell-free in vitro transcription from the corresponding DNA templates;

ii. encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);

b) the Pfizer 3’ Untranslated Region (UTR) provides a coding sequence:

   i. homologous for mitochondrial human RNA for the mitochondrial 12S protein;

   ii. which is a nucleoside modified sequence wherein each uridine is replaced with pseudouridine.

c) the full sequence of the Messenger RNA encoding the full-length SARS-CoV-2 spike glycoprotein of the Pfizer Vaccine **(“the Pfizer Vaccine mRNA”) (“the Known Untranslated mRNA”)**:

   i. the 3´UTR region of the Pfizer mRNA comprises two sequence elements derived from the amino-terminal enhancer of split (AES) mRNA and the mitochondrial encoded 12S ribosomal RNA to confer RNA stability and high total protein expression;

   ii. the untranslated regions thereby contain mitochondrial RNA;

   iii. the coding sequence for the Pfizer Vaccine contains several regions:

      (1) in addition to the mRNA encoding the spike protein;

      (2) includes the untranslated regions.

d) the Pfizer coded sequence for the Pfizer mRNA has a long polyA tail;

e) it was scientifically established from March 2020 in respect of considerations of gene therapy for mitochondrial diseases that **(“the Known Mitochondrial RNA Risks”)**:

   i. the consequences of mutations in the mitochondrial genome (mtDNA) and mitochondria-related nuclear genes are:

(1) often severe;

(2) are attended by a poor prognosis;

ii. the mtDNA encodes a small but critical subset of genes;

iii. mitochondrial DNA is exclusively inherited from the mother;

iv. therefore a woman with mutant mtDNA can:

(1) pass the disease directly through female offspring;

(2) transmit heritable genetic afflictions for multiple generations down the maternal line;

v. mtDNA variants can have devastating consequences for the health of the patient by disrupting mitochondrial function;

vi. the overproduction of mitochondrial proteins (whether encoded by mtDNA or nDNA) may, in and of itself, cause severe defects in:

(1) mitochondrial function; and

(2) metabolism.

vii. production of defective and/or misfolded mitochondrial proteins encoded from the nuclear genome can lead to:

(1) a toxic accumulation of mitochondrial protein precursors in the cytosol (mitochondrial precursor over-accumulation stress); and

(2) dysfunction within the mitochondria itself**;**

viii. the overexpression of homologous repair and DNA repair enzymes can lead to:

(1) genome instability;

(2) significant harm to the patient.

f) the potential harm arising from the use of mitochondrial RNA in sequence as used in the Pfizer mRNA contained in the Pfizer Vaccines is potentially:

i. intergenerational;

ii. catastrophic;

iii. causing transfection which is species significant;

g) the presence of non-coding sequences such as microRNA in the untranslated regions has potential clinical significance;

h) integrating vectors and mutagens containing polyA signals either engineered or endogenous as in the Pfizer mRNA may:

i. induce cancer by mutating host genes in a number of different ways;

ii. elicit premature termination of gene transcription;

i) the risk of mutagenesis and oncogenic potential thereby arising in the Pfizer Vaccine;

j) despite these significant intergenerational known risks, neither Pfizer, nor the TGA and TGA Respondents nor anyone, undertook nor sought studies to understand these risks in respect of the Pfizer Vaccine, being:

i. genotoxicity studies; and

ii. carcinogenicity studies.

k) despite the Known Mitochondrial RNA Risks being rationally established prior to the Pfizer Approval, the TGA, the TGA Respondents or anyone have not prior to the Pfizer Approval, or at any time:

i. conducted a detailed examination or consideration of the untranslated regions of the Pfizer mRNA, nor sought or been provided evidence of such examination or consideration by Pfizer;

ii. evaluated or considered the risks associated with, nor sought or having been provided with such evaluation or consideration from Pfizer:

(1) the use of mitochondrial RNA in the Pfizer Vaccine;

(2) the presence of non-coding sequences such as microRNA in the Pfizer Vaccine.

iii. evaluated or considered the impact of the replacement of every uridine with a pseudouridine, nor sought or having been provided with such evaluation or consideration by Pfizer;

iv. evaluated or considered the impacts on stabilisation of function, translation of protein and splicing regulation in the Pfizer Vaccine, nor sought or having been provided with such evaluation or consideration by Pfizer;

v. evaluated or considered the genetic sequence data in the Pfizer mRNA implications in respect of potential mutagenesis and oncogenic potential, nor sought or having been provided with such evaluation or consideration by Pfizer;

vi. evaluated or considered the genetic sequence data in the Pfizer mRNA implications in respect of potential inflammatory or oncogenic risks, nor

sought or having been provided with such evaluation or consideration by Pfizer;

vii. evaluated or considered the potential for the long polyA tail in the Pfizer mRNA, nor sought or having been provided with such evaluation or consideration by Pfizer, to:

(1) induce cancer by mutating host genes;

(2) elicit premature termination of gene transcription.

viii. had knowledge of or had sought the answer to, the following matters in respect of the Pfizer mRNA of critical medical consequence for recipients of the Pfizer Vaccine:

(1) whether or not those non-coding regions enter the nucleus for translations as would usually occur with an RNA virus;

(2) by what process the mRNA segment is spliced or removed from the remaining RNA;

(3) by what process are the nucleotide sequences degraded;

(4) the potential for micro RNA inclusion in the UTR;

(5) the nucleotide sequence was NOT solely the mRNA coding for the spike protein:

a) despite the presumption and public pronouncements by the TGA and the TGA Respondents that that nucleotide sequence was only the mRNA encoding the spike protein.

Source

These matters are based upon the following:

1. the knowledge and conclusions of the TGA and the TGA Respondents in the following documents prepared by and/or for the TGA and the TGA Respondents prior to the mRNA Vaccine Approvals:

    1. the Pfizer Original AUSPAR
    2. the Pfizer Product Information, pg. 1.
    3. the Pfizer Nonclinical Evaluation Report

2. the Known Mitochondrial RNA Risks arises from the uncontroversial scientific literature published prior to the MRNA Vaccine Approvals, including for example:

    1. Slone, J., Huang, T. "The special considerations of gene therapy for mitochondrial diseases". npj Genom. Med. 5, 7 (2020). https://doi.org/10.1038/s41525-020-0116-5

    2. "Cancer Gene Discovery: exploiting insertional mutagenesis", Ranzani et all, Mol Cancer Res 2013 October; 11(10) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3836224/pdf/emss-54324.pdf

3. the Known Untranslated mRNA is contained in the published World Health Organisation document: WHO International Nonproprietary Names Programme 11889 – Description Messenger RNA encoding the full-length SARS-CoV-2 spike glycoprotein. https://web.archive.org/web/20210105162941/https://mednet-communities.net/inn/db/media/docs/11889.doc published in or about September, 2020.

4. The relevant details of the Pfizer mRNA was contained in the Pfizer Product Information approved, authorised and published by the TGA and the TGA Respondents on or about January, 2021 and before the Pfizer Approval.

5. The TGA and TGA Respondents' failure to ascertain the risks pleaded herein is evident in the TGA FOI response to the following questions as "no such documents exist relating to the following" (refer FOI 3604):

    a. the risk of and/or presence of micro-RNA sequences (miRNA) comprised within the Comirnaty mRNA active ingredient (mRNA genomic sequence).

    b. the risk of and/or presence of Oncomirs (oncogenic miRNA - microRNA) comprised within the Comirnaty mRNA active ingredient (mRNA genomic sequence).

    c. the risk of and/or presence of Stop Codon read-through (suppression of stop codon activity) arising as a result of the use of pseudo uridine in the Comirnaty miRNA active ingredient (mRNA genomic sequence).

    d. the composition of the final protein product (molecular weight and amino acid sequence) produced following injection of the Comirnaty mRNA product in human subjects.

    e. the risk of the use of the AES-mtRNR1 3' untranslated region of the Comirnaty mRNA product in human subjects.

KNOWN FAILURE TO REFER PFIZER AND MODERNA VACCINE TO OFFICE OF THE GENE TECHNOLOGY REGULATOR

38. Prior to the Pfizer Approval and the Moderna Approval the TGA and the Secretary were obliged to refer the the mRNA Vaccines to the Office of the Gene Technology Regulator **("the OGTR")** prior to granting the Approvals because:

a) there were and are binding obligations under the Act being the Requirement to Seek Gene Technology Regulator Advice and the Requirement to Consider Gene Technology Regulator Advice which require the TGA and the TGA Respondents to:

i. give written notice to the Gene Technology Regulator requesting the Gene Technology Regulator to give advice about the Pfizer Application and the Moderna Application;

ii. ensure that the advice received by the Secretary pursuant to Requirement to Seek Gene Technology Regulator Advice is taken into account in making a decision on the application for Registration that the advice relates to, being the Pfizer Application and the Moderna Application;

b) the OGTR regulates therapies that involve in-vivo genetic manipulation of human cells as prescription medicines under s. 23 of the *Gene Technology Act 2000* (Cth), including:

i. small silencing RNAs;

ii. CRISPR;

iii. other gene editing technologies; and

iv. gene therapies administered by vectors.

c) the Department-produced document for the Office of the Gene Technology Regulator published in October, 2021 stated that **("the OGTR GMO Definitions Document")**:

i. the document was prepared to assist regulated organisations to understand which new technologies, including gene editing techniques, result in genetically modified organisms **("GMOs")** that are regulated under the *Gene Technology Act 2000* (Cth);

ii. exclusion of RNAi techniques from being properly regarded as gene technology can only occur if:

(1) the genomic DNA sequence cannot be changed by the technique; and

(2) if the introduced RNA cannot be translated into a protein or lead to production of infectious agents.

d) the mRNA Vaccines are GMO for the purposes of and therefore subject to **("the GMO Requirements")**:

i. the requirements of section 30C of the Act whereby the Gene Technology Regulator should have undertaken or commissioned research in relation to risk assessment and the biosafety of the GMOs in the Pfizer Vaccine and the Moderna Vaccine;

ii. the Act provisions and particularly the:

(1) Requirement to Seek Gene Technology Regulator Advice; and

(2) the Requirement to Consider Gene Technology Regulator Advice.

e) despite the matters pleaded in paragraph (a) to (d) above:

i. no critical safety advice was obtained from the OGTR in respect of the mRNA Vaccines prior to their approvals;

ii. the mRNA Vaccines were approved in circumstances where:

(1) the mRNA Vaccines are in substance gene therapies; and

(2) in the absence of any knowledge or understanding as to the effects of the active mRNA ingredients of each of the mRNA Vaccines.

Source

The OGTR GMO Definitions Document - Aust Gov, Dept of Health, Office of Gene Technology Regulator produced in Oct 2021 document entitled "Overview - status of organisms modified using gene editing and other new technologies". https://www.ogtr.gov.au/sites/default/files/2021-11/overview_-_status_of_gene_editing_and_other_new_technologies.pdf

The Requirement to Seek Gene Technology Regulator Advice and the Requirement to Consider Gene Technology Regulator Advice are contained in s. 30C(2)(b) and s. 30E of the Act.

KNOWN GENOTOXICITY OF THE VACCINES

39. Prior to the mRNA Approvals data provided to the TGA and the TGA Respondents by Pfizer and Moderna rationally establishing genotoxicity, safety and mutagenicity risks in the mRNA Vaccines disclosed that **("the Known mRNA Vaccine Risks and Failures")**:

a) genotoxicity and mutagenicity are a material and serious risk in those receiving the mRNA Vaccines by reason of:

i. the presence in each of the mRNA Vaccines:

(1) novel nano-lipid compounds;

(2) micronuclei in genotoxicity studies described for the lipids in the Moderna mRNA Vaccines;

ii. the presence of micronuclei in genotoxicity studies being causally connected with in humans:

(1) chromosomal aberrations;

(2) highly inflammatory reaction;

(3) genotoxicity; and

(4) mutagenicity.

iii. the novel excipient used in the mRNA Vaccines.

b) related risk and prevalence data was at no time before or after the mRNA Approvals:

i. obtained or produced by Pfizer or Moderna;

ii. provided to or considered by the TGA and the TGA Respondents.

c) the novel excipients in the mRNA Vaccines:

i. have not been assessed for safety by the TGA and the TGA Respondents; and

ii. are not approved for use by registration in the Register.

d) analysis of potential for both genotoxicity (damage to genes) and mutagenicity (potential to cause cancer) are:

i. among the highest priorities from a regulatory perspective;

ii. particularly warranted in the mRNA Vaccines wherein:

(1) the mRNA Vaccines are genetic therapeutics;

(2) it was always contemplated that the mRNA Vaccines would be approved and promoted for use:

a) in healthy individuals of all ages;

b) for the entire adult population of Australia.

e) in approving the mRNA Vaccines, the TGA and the TGA Respondents:

i. approved, authorised and published Product Information statements in respect of those mRNA Vaccines which acknowledge the omission of this important pre-clinical (in-vitro and/or animal) genotoxicity and mutagenicity safety data;

ii. granted the Approvals in respect of the mRNA Vaccines wherein a possibility existed that:

(1) the mRNA contained in the mRNA Vaccines may be reverse transcribed or incorporated into the recipient's DNA around the body including in a wide variety of tissues and organs including eggs in the ovary;

(2) the mRNA Vaccines may induce cancers;

(3) adverse effects may be inherited into future generations;

(4) which in total were, prior to the mRNA Vaccine Approvals:

a) contrary to the assumptions and statements made by the TGA and the TGA Respondents;

b) indicative of an extreme need for further investigation of the mRNA Vaccines by the TGA and the TGA Respondents;

c) of such extreme importance and concern so as to obviously:

    i. preclude the mRNA Vaccines from being considered safe for use in humans; and

    ii. indicate immediate withdrawal of the mRNA Vaccines from authorised use in humans from and at the time of the mRNA Vaccine Approvals granted by the TGA and the TGA Respondents.

Source

The absence of genotoxicity and carcinogenicity studies is acknowledged in:

1. The Pfizer Clinical Evaluation Report;
2. The Pfizer Original AUSPAR;
3. The Moderna Original AUSPAR.

The requirement to consider genotoxicity and mutagenicity in respect of the safety of the mRNA Vaccines in granting the mRNA Approvals, arises from:

1. The TGA Policies;
2. The Statutory Obligations;
3. The Adopted EMA Policies.

KNOWN GENOTOXICITY AND CARCINOGENICITY ISSUES – PFIZER VACCINE

40. On or about 25 January, 2021 and prior to the Pfizer Approval the data provided to the TGA and the TGA Respondents by Pfizer and the widely and globally published scientific data and studies rationally establishing the significant genotoxicity and carcinogenicity risks of the Pfizer Vaccine disclosed **("the Known Pfizer Genotoxicity Issues")**:

a) in respect of potential genotoxicity of the Pfizer Vaccine:

i. no genotoxicity studies were conducted for the Pfizer Vaccine;

ii. no genotoxicity studies were undertaken on the novel excipients contained in the Pfizer Vaccine;

b) Pfizer asserted, and the TGA and the TGA Respondents accepted without further consideration or evidence that **("the Pfizer Genotoxicity Assertions")**:

i. the novel lipid excipients were not expected to be genotoxic based on in silico analysis of the novel lipids and their primary metabolites for which reports were not provided;

ii. the absence of genotoxicity studies with the novel lipid exposures were justified on the basis that:

(1) the threshold of toxicological concern (TTC) concept was satisfied; and

(2) the lipid excipients in the Pfizer Vaccine - ALC-0159 and ALC-0315 **("the Pfizer Excipients")** - were structurally and functionally similar to the two lipid excipients - PEG-2000-C-DMG and DLin-MC3-DMA - used in the drug Patisiran **("the Patisiran Excipients")**;

(3) both of the Patisiran Excipients were found to be safe in a full genotoxicity test battery of Patisiran.

c) that based solely upon the Pfizer Genotoxicity Assertions, the TGA and the TGA Respondents were thereby satisfied that **("the TGA Pfizer Genotoxicity Conclusions")**:

i. genotoxicity studies in respect of the Pfizer Vaccine were not required;

ii. genotoxicity studies in respect of the Pfizer Excipients were not required;

iii. the Pfizer Excipients were not expected to pose a genotoxic risk;

iv. neither the mRNA nor the lipid excipients of the LNP formulation are expected to have genotoxic potential;

d) contrary to the Pfizer Genotoxicity Assertions and the TGA Pfizer Genotoxicity Conclusions, in fact:

i. in animal studies intravenous administration of Patisiran lipid complex resulted in:

(1) developmental toxicity including:

a) embryo foetal mortality; and

b) reduced foetal body weight;

(2) maternal toxicity;

ii. it is not scientifically acceptable and obviously erroneous to compare and rely upon a non-clinical genotoxicity test for structurally dissimilar lipids in Patisiran:

(1) as it was known to be utilised solely for a terminal condition in humans not healthy subjects as in the Pfizer Vaccine;

(2) it was known and proven to be teratogenic in animal studies;

a) whilst Pfizer did not provide to the TGA, the TGA Respondents or anyone, the reports of the in-silico analysis;

b) when those presumptions were based on having two vaccines per year, and now up to 5 doses are being used in many patients without any re-evaluation of the safety data.

(3) the justification in respect of the satisfaction by the Pfizer Vaccine as satisfying the threshold of toxicological concern was rationally and obviously false because:

a) Pfizer justified and the TGA and the TGA Respondents accepted and similarly asserted without proper basis the absence of genotoxicity studies with the novel lipid exposures based on the threshold of toxicological concern (TTC) concept;

b) Pfizer falsely claimed and the TGA and the TGA Respondents accepted and similarly asserted that the Toxicological Threshold of Concern (TTC) concept was much higher than someone having twice yearly vaccines for 70 years would be exposed to;

c) the claim was and is obviously false because their calculations of TTC were invalid as:

i. Pfizer calculated the exposure of the two novel excipients as follows:

1. per dose per day being **("the Pfizer Novel Excipient Levels")**:

a. ALC-0159 – 53.4 mcg; and

b. ALC-0315 – 430 mcg;

2. calculated a less than lifetime total exposure of threshold of toxicological concern to be 19.16 mg per day by:

    a. multiplying the TTC of a mutagenic substance of 1.5 mcg per day projected over 70 years at 365 days per year divided by 2 days;

    b. allowing then that the acceptable threshold per year to compare to the Pfizer Vaccine is 19.16 mg per day;

3. then comparing the per injection day rate of the excipients in the Pfizer Vaccine with the calculated less than lifetime total exposure of threshold of toxicological concern to be 19.16 mg per day **("the Concern Threshold Day Rate")** as follows:

    a. the volume of ALC-0159 at 53.4 mcg per injection day received is 360 fold lower than the Concern Threshold Day Rate;

    b. the volume of ALC-0315 at 430 mcg per injection day received is 45 fold lower than the Concern Threshold Day Rate.

ii. the European Medicines Agency's Scientific guideline published at the time of the Pfizer Approval requires that when calculating the threshold:

    1. the number of days is taken to be the number of **dosing** days;

2. not the time interval over which the doses were administered.

iii. as Pfizer used the interval time (so the number of days over 70 years of exposure = 25,550 days) in their calculation of TTC, it calculated the TTC level as over 19,000 mcg which is 45-360 times the exposure that someone would have from twice yearly vaccines for 70 years;

iv. however using the above EMA guideline, the TTC is in fact 20mcg calculated at 140 days for the 70 years at twice yearly dosing;

v. at dose levels of 53.5mcg and 430 mcg, the Pfizer Novel Excipient Levels far exceed the true Toxicological Threshold of Concern in a single dose;

d) accordingly at that time it was rationally established that there was:

i. an unstated genotoxic risk in the Pfizer Vaccine;

ii. a failure to require genotoxicity testing predicated upon false reasoning and false assumptions.

e) the distribution of LNP-BNT162b2 (V9) mRNA or expressed S protein was not studied nor such data provided to or sought by the Respondents;

f) the distribution of lipid nanoparticles in the Pfizer Vaccine was investigated by monitoring of a radio-labelled lipid-marker after intramuscular administration in rats, disclosing that:

i. the mean concentration of radioactivity in sexes combined in tissue and blood following single intramuscular dose of 50mcg RNA in a rat in the same report showed:

(1) in the ovaries of females:

a) a total lipid concentration of 0.104 mcg/g or ml of the Pfizer Vaccine lipid within 25 minutes of vaccination;

b) an increase in concentration by 11,788% within 48 hours of vaccination at which point testing did, and was known by the TGA and the TGA Respondents to be stopped by Pfizer;

(2) in the testes of males:

a) a total lipid concentration of 0.031 mcg/g or ml of the Pfizer Vaccine lipid within 25 minutes of vaccination;

b) an increase in concentration by 1,032% within 48 hours of vaccination at which point testing did, and was known by the TGA to be stopped by Pfizer;

(3) distribution studies for the mRNA nucleotide or spike antigen from the Pfizer Vaccine were not provided to the Respondents;

(4) the surrogate distribution marker of the Liquid Nanoparticle distribution from the Pfizer Vaccine demonstrated distribution to the gonads in males and females; and

(5) examination of the concentration of the distribution marker was stopped by Pfizer at the 48 hour post-vaccination mark at which point concentrations were rising exponentially.

g) it was thereby rationally and scientifically established that:

i. the TGA Pfizer Genotoxicity Conclusions were:

(1) made without basis in the evidence provided to the TGA, the TGA Respondents or anyone;

(2) opposed to the evidence presented to the TGA, the TGA Respondents or anyone.

ii. the Pfizer Vaccine was demonstrably:

(1) not safe;

(2) subject to significant genotoxicity and carcinogenicity risks.

Source

The Pfizer Nonclinical Evaluation Report - pg. 13, 40, 43, pg. 45 - Table 4.2

The Pfizer Original AUSPAR – pg. 14,15.

Publicly Available - Patisiran Product Information - pg. 6, 7.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210922s000lbl.pdf

"ICH M7 Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk - Scientific guideline" Pg. 12 – s. 7.3.
https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-m7r1-assessment-control-dna-reactive-mutagenic-impurities-pharmaceuticals-limit_en.pdf
Published since 3 February, 2018.

KNOWN GENOTOXICITY AND CARCINOGENICITY ISSUES – MODERNA VACCINE

41. On or about 9 August 2021 and prior to the Moderna Approval the data provided to the TGA and the TGA Respondents by Moderna rationally establishing significant genotoxicity and carcinogenicity risks in respect of the Moderna Vaccine disclosed **("the Known Moderna Genotoxicity Issues")**:

    a) no genotoxicity studies were:

        i. conducted for the Moderna Vaccine;

        ii. sought by the TGA or the TGA Respondents or anyone prior to the Moderna Approval or at all.

    b) that Moderna has asserted that and the TGA and the TGA Respondents accepted that the Moderna Vaccine mRNA and lipid components were not expected to be genotoxic:

        i. without any evidentiary or scientific basis;

        ii. as a basis for explanation of the absence of genotoxicity studies.

    c) the TGA and the TGA Respondents had made the following determinations and determined that they were appropriate for publication in the Moderna Product Information **("the TGA Moderna Genotoxicity Determinations")**:

        i. the novel lipid components of the Moderna Vaccine were negative in the bacterial reverse mutation Ames test and in vitro micronucleus test in human peripheral blood lymphocytes;

        ii. a luciferase mRNA in SM102-containing lipid nanoparticles was negative in a rat bone marrow micronucleus assay (IV dose of SM-102 28.5 mg/kg, PEG-2000-DMG 2.8 mg/kg);

iii. a surrogate ZIKA mRNA-based vaccine formulated in SM-102-containing lipid nanoparticles induced micronuclei in male rats but not in females (IV dose of SM-102 60 mg/kg, PEG-2000-DMG 6 mg/kg;

iv. the weight of evidence suggests the genotoxicity potential of the novel lipid components SM-102 and PEG-2000-DMG is very low;

v. the other components of Moderna Vaccine (other lipids and mRNA) are not expected to be genotoxic.

d) the TGA Moderna Genotoxicity Determinations were made in circumstances where in truth:

i. the genotoxicity study result for the Moderna Vaccine published in the Moderna Product Information was not reported or considered in the Moderna Original AUSPAR produced by the TGA and the TGA Respondents;

ii. studies performed on the Moderna lipid nanoparticles showed a marker for genotoxic potential in the micronuclei in male rats indicating positive genotoxicity potential in the Moderna Vaccine;

iii. further information on the studies performed and further detail on genotoxicity nonclinical on data:

(1) was required to be requested and evaluated by the TGA and the TGA Respondents;

(2) was not sought by the TGA and the TGA Respondents before the Moderna Approval or at all.

Source

1. The Moderna Original AUSPAR - Pg. 15.
2. The Moderna Product Information - Pg. 24.

KNOWN GENOTOXICITY AND CARCINOGENICITY ISSUES – ASTRAZENECA VACCINE

42. On or about 28 January, 2021 and prior to the AstraZeneca Approval the data provided to the TGA and the TGA Respondents by AstraZeneca and the widely and globally published scientific studies rationally establishing significant genotoxicity and carcinogenicity risks in respect of the AstraZeneca Vaccine disclosed that **("the Known AstraZeneca Genotoxicity Issues")**:

a) three different animal studies using three different AstraZeneca Vaccine vectors examined the biodistribution in the bodies of the mice post-vaccination which found in one of the studies that the vector was found to have migrated to the subject's:

i. heart;

ii. liver;

iii. ovaries;

iv. testes; and

v. lymph nodes.

b) no genotoxicity studies were performed in respect of the AstraZeneca Vaccine;

c) no carcinogenicity studies were performed in respect of the AstraZeneca Vaccine;

d) that the absence of genotoxicity and carcinogenicity studies in the AstraZeneca Vaccine were determined by the TGA and the TGA Respondents to be justified on the erroneous bases that the AstraZeneca Vaccine was a vaccine in circumstances where in truth:

i. it was concluded by the TGA and the TGA Respondents to be:

(1) the first ever GMO vaccine to be used in Australia;

(2) the first vaccine of its kind in Australia;

ii. was acknowledged thereby the AstraZeneca Vaccine to be completely novel in nature;

iii. thereby incapable of being approached on the basis of being a known therapy.

e) the TGA and the TGA Respondents through the OGTR had determined by 8 February, 2021 and prior to the AstraZeneca Approvals that:

i. adenoviruses as used in the AstraZeneca Vaccine have led to random integration of the virus DNA into the host genome;

ii. experimental studies in cell lines and mice have described possible integration of adenovirus vectors as used in the AstraZeneca Vaccine into host genomes at very low frequencies;

iii. the GMO in the AstraZeneca Vaccine is expected to be confined to the intra-muscular injection site and the draining lymph nodes of the human host;

iv. adenoviral vectors including the AstraZeneca Vaccine vector have been used extensively in clinical studies as a vaccine and gene therapy for almost 30 years and there is no evidence of integration of viral DNA into the host genome and so the consequences of integration of viral DNA into a host cell genome will not be further discussed;

f) the determinations referred to in (e) being made by the TGA and the TGA Respondents:

i. despite a risk of genome integration this were dismissed and not further evaluated;

ii. despite biodistribution studies demonstrating distribution to the ovaries and testes, thereby further genome integration, genotoxicity and germ cell integration studies should have been performed;

iii. known and published clinical evidence of:

(1) integration of foreign DNA into the host human genome;

(2) the use of Adenoviral Vector DNA such as is used in the AstraZeneca Vaccine can possibly lead to:

a) integration of foreign DNA into host genomes;

b) the disruption of genes in the host chromosome;

c) mutations of the host chromosome.

(3) foreign DNA integration can alter cellular DNA epigenetic signals immediately at the site of insertion;

(4) extreme caution being required when injecting adenoviral vectors into humans;

(5) modern adenovirus vectors as used in the AstraZeneca Vaccine are not dissimilar from older vectors which caused catastrophic experiences;

(6) that as opposed to the AstraZeneca Vaccine more careful consideration of conventional vaccines based on recombinant spike protein to have been a safer choice.

iv. biodistribution data referenced did not take into account the study where distribution to gonads was demonstrated.

g) the TGA and the TGA Respondents determined that the AstraZeneca vector had negligible risks of **("the TGA AstraZeneca Genotoxicity Conclusions")**:

i. integrating into the human genome; or

ii. recombination with human adenovirus.

h) it was thereby obvious to the TGA and the TGA Respondents that:

i. the TGA AstraZeneca Genotoxicity Conclusions were:

(1) made without basis in the evidence known to the TGA and the TGA Respondents;

(2) opposed to the evidence known to the TGA and the TGA Respondents;

(3) made in circumstances where in truth the matters asserted could not be known to the TGA and the TGA Respondents.

ii. the AstraZeneca Vaccine was:

(1) not demonstrably safe;

(2) subject to significant known genotoxicity risks.

Source

The AstraZeneca Delegate's Overview, pg. 8, 9
The AstraZeneca AusPAR, pg. 10.

Risk Assessment And Management Plan – full version, Department of Health and Aged Care, Office of the Gene Regulator, Licence number DIR 180.
https://www.ogtr.gov.au/sites/default/files/2021-06/dir180-

full_risk_assessment_and_risk_management_plan.pdf - DIR 180. Pg. 2, 6, 9.
Commercial supply of a genetically modified COVID-19 vaccine, dated 8 February 2021, https://www.ogtr.gov.au/gmo-dealings/dealings-involving-intentional-release/dir-180

Study of the known possibility of integration of foreign DNA into the host human genome citing scientific data and studies to this effect since 2000 and known to the Respondents at the time of the AstraZeneca Approval: "Adenoviral Vector DNA- and SARS-CoV-2 mRNA-Based Covid-19 Vaccines: Possible Integration into the Human Genome - Are Adenoviral Genes Expressed in Vector-based Vaccines?" Doerfler W. Virus Res. 2021 Sep;302:198466.

DETERMINING VACCINE GENOTOXICITY AND CARCINOGENICITY – INTERNATIONAL GUIDELINES AND TGA FAILURES

43. At all material time prior to the Approvals the WHO Guidelines published in 2014 and prior to the Approvals **("the WHO Genotoxicity and Carcinogenicity Guidelines")** disclosed that good practice requires that a standard battery of genotoxicity studies is generally recommended for safety assessment of most novel adjuvants that are (or contain) new chemical entities.

Source

"Guidelines on the nonclinical evaluation of vaccine adjuvants and adjuvanted vaccines" WHO Technical Report Series No. 987, 2014 – World Health Organisation - Annex 2 https://cdn.who.int/media/docs/default-source/biologicals/vaccine-standardization/trs_987_annex2.pdf?sfvrsn=ea91caca_3&down

load=true Page 85: D.2.5 Genotoxicity and carcinogenicity studies.

44. Despite the widely and globally published provisions of the WHO Genotoxicity and Carcinogenicity Guidelines and the presence of novel adjuvants in the Vaccines, the TGA and the TGA Respondents at no point obtained or sought genotoxicity and carcinogenicity studies from the Sponsors without:

a) explanation as to why those studies were not sought or obtained; or

b) evident basis as to why those studies were not sought or obtained.

45. At all material times prior to the Approvals the European Agency for the Evaluation of Medicinal Products widely and globally published guidance on carcinogenic potential in medicines seeking registration **("the EMA Carcinogenicity Guidelines")** disclosed that good practice requires that the objective of carcinogenicity studies is to identify a tumorigenic potential in animals as part of the assessment of the relevant risk in humans.

Source

"Note for Guidance on Carcinogenic Potential" Committee for Proprietary Medicinal Products. The European Agency for the Evaluation of Medicinal Products – Evaluation of Medicines for Human Use. Dated 25 July, 2002 and commencing operation in January, 2003.

46. Despite the provisions of the EMA Carcinogenicity Guidelines and the presence of novel adjuvants in the Vaccines, the TGA and the TGA Respondents at no point obtained or sought genotoxicity and carcinogenicity studies from the Sponsors:

a) without:

i. explanation as to why those studies were not sought or obtained; or

ii. evident basis as to why those studies were not sought or obtained;

b) contrary to the EMA Carcinogenicity Guidelines by:

i. not regarding or applying the true objective of carcinogenicity testing being to identify and determine the potential of carcinogenicity in the Vaccines;

ii. abrogating the purpose of and requirement for the study on the basis of mere postulation, without basis, that the risk was unlikely.

TGA GENE THERAPY GUIDELINES

47. At all material times prior to the Approvals the following widely and globally published international guidelines were applicable to the conduct of the TGA and the TGA Respondents in considering and granting the Approvals upon the data provided by the Sponsors **("the TGA and International Gene Therapy Guidelines")**:

a) The TGA guideline in respect of medicines produced by genetic manipulation, applicable to the mRNA Vaccines and the Approvals relevantly states **("the TGA Genetically Manipulated Medicines Guidelines")**:

i. medicines produced by genetic manipulation consist of:

(1) medicines derived or produced from GMOs (biological medicines);

(2) GMOs that are intended for use as medicinal agents (GMO medicines);

(3) regulation of genetically modified organisms in Australia and dealings with GMOs, including their research, manufacture, propagation and importation, are prohibited:

a) unless explicitly authorised under the *Gene Technology Act 2000* (Cth); and

b) in order to protect human health and safety, and the environment;

c) including:

i. all dealings with live, viable GMOs;

ii. those GMOs intended for use as, or in the manufacturing or testing of medicines.

(4) the Office of the Gene Technology Regulator (OGTR):

a) administers the *Gene Technology Act 2000* (Cth);

b) maintains a publicly accessible record of all dealings in Australia that involve GMOs or GM products (the Record).

(5) the Record includes information on all GM products that are approved for supply in Australia under a number of Acts, including therapeutic goods containing GM products that are approved for supply under the *Therapeutic Goods Act 1989* (Cth);

(6) the TGA and the TGA Respondents are required to inform the Office of Gene Technology Regulator about applications for the supply of therapeutic goods that contain GMOs;

(7) guidance on quality issues for recombinant or biotechnological medicines is provided in European Union guidelines **("the European GMO Guidelines")**, which includes production and quality control of medicinal products derived by recombinant DNA technology, and states expressly that:

a) appropriate attention needs to be given to the quality of all reagents used in production, including components of fermentation media;

b) specifications for these are to be included in documentation and they must comply with any relevant European recommendations;

c) tests for potency, abnormal toxicity, pyrogenicity and sterility etc., which apply to products made by conventional methods, will also apply to products made by rDNA technology;

d) the purpose of molecular genetic studies is to establish that:

    i. the correct sequence has been made and incorporated in the host cell; and

    ii. that both the structure and the number of copies of the inserted sequence are maintained within the cell during culture to the end of production.

e) products expressed in foreign hosts:

    i. may deviate structurally, biologically or immunologically from their natural counterparts;

    ii. may suffer alterations leading to undesirable clinical effects which can arise:

        1. at posttranslational level; or

        2. during production or purification.

    iii. presence must be justified and shown to be consistently controlled.

f) unintended variability in the culture during production may lead to changes:

i. which favour the expression of other genes in the host/vector system; or

ii. which cause alteration in the product, resulting in:

1. differing yield;

2. change to the product itself (e.g. in the nature and degree of glycosylation); and/or

3. quantitative and qualitative differences in the impurities present.

g) procedures to ensure consistency of production conditions as well as the final product are imperative;

h) full details of the nucleotide sequence of the gene of interest and of the flanking control regions of the expression vector should be provided to confirm that the construction is identical to that desired;

i) southern blot analysis should be used, in addition to sequence analysis of mRNA or cDNA molecules in order to provide convincing data on the integrity of the expressed gene(s);

j) sufficient sequence information to characterise the gene product adequately should be obtained by the regulator.

b) the EMA Guideline on non-clinical testing for inadvertent germline transmission of gene transfer vectors in effect from May, 2007 requires that:

i. no gene therapy trials may be carried out which result in modifications to the subject´s germline genetic identity;

ii. it is important to appropriately assess if there is a risk of inadvertent germline transmission;

iii. in vivo use of naked DNA, genetically modified viruses, viral or non-viral vectors may be associated with a risk of vertical germline transmission of vector DNA which should be assessed;

iv. the relative risk for germline transmission of each vector should be based on its:

(1) biodistribution profile;

(2) vector replication; and

(3) integration ability.

v. the route of administration is an important parameter as parenteral administration of vector could potentially lead to the presence of vector DNA within the gonads;

vi. if a vector is detected in gonads, more detailed information will be needed;

vii. a positive signal in the germline cells will require elucidation of whether stem cells are transduced;

viii. if a positive signal is observed in gonadal tissues, additional testing will be needed;

ix. the next consideration should be what type of population will be treated;

x. in the case of definitely sterile patients there is no need to perform germline transmission studies before the first use in man - in all other cases germline transmission studies should be performed;

xi. prior to marketing authorisation application biodistribution studies should be performed:

(1) using the final vector construct with the gene of interest;

(2) with two dose levels at minimum;

(3) in at least two species, one of which should be a non-rodent species;

(4) using both sexes.

xii. any deviation from this principle needs to be justified;

xiii. general principles for non-clinical germline transmission studies require:

(1) non clinical pharmacological studies, biodistribution studies in animals (2 different species and 2 sexes), one rodent and one non-rodent;

(2) no gene therapy trials may be carried out which result in modifications to the subject´s germline genetic identity where:

a) the vector is distributed to the gonads;

b) the population intended to be treated are not sterile;

c) the vector-derived DNA is detected within oocytes or sperm cells (cell fractionation studies).

c) the World Health Organisation in its COVID-19 Vaccines: Safety Surveillance Manual published on 22 December, 2020 stated that:

i. in developing a potential mRNA vaccine in respect of Covid including the mRNA Vaccines, developers were seeking to use genetic instructions in the form of DNA or RNA:

(1) wherein nucleic acid is inserted into human cells;

(2) which produces copies of the virus protein;

(3) in vaccines:

a) which will encode the virus's spike protein;

b) the production of which involves making genetic material only, not the virus;

c) which are unproven;

d) using technology which no other licensed vaccine uses.

ii. the proposed mRNA Vaccines for Covid being developed at that time including the mRNA Vaccines:

(1) carried theoretical risks relating to:

a) immune-mediated events;

b) local and systemic reactions due to pro-inflammatory properties of the plasmids carrying the DNA sequence or the mRNA segment.

(2) are based on mRNA coding for an antigenic protein that poses the risk of integration into host cell DNA;

(3) introduce into the recipient residual molecules, originating from raw materials, which could induce unexpected immune responses.

d) the European Medicines Agency ICH Guideline on Non-Clinical Safety Studies For The Conduct Of Human Clinical Trials and Marketing Authorisation For Pharmaceuticals published in December, 2009 required that:

i. a complete battery of tests for genotoxicity should be completed before initiation of Phase II trials;

ii. if a positive finding occurs, an assessment, and then possibly additional testing, should be conducted to determine if further administration to humans is still appropriate;

iii. before the inclusion of pregnant women in clinical trials, all female reproduction toxicity studies and the standard battery of genotoxicity tests should be conducted;

iv. safety data from previous human exposure should be evaluated.

Source

TGA Guidance 21: Medicines produced by genetic manipulation Previously ARGPM Appendix 21: Medicines produced by genetic manipulation, Version 1.0, July 2013. pg. 5 - 6. https://www.tga.gov.au/sites/default/files/pm-argpm-guidance-21.pdf.

European Medicines Agency - Pre-authorisation Evaluation of Medicines for Human Use - Committee For Medicinal Products For Human Use. "Guideline On Non-Clinical Testing For Inadvertent Germline Transmission Of Gene Transfer Vectors". https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-non-clinical-testing-inadvertent-germline-transmission-gene-transfer-vectors_en.pdf. Annexed as Appendix 13. dated 16 November 2006 and coming into operation on May 2007. Pg. 3, 4, 5, 6, 8

World Health Organisation – "Covid-19 vaccines: safety surveillance manual" 22 December 2020. https://www.who.int/publications/i/item/9789240032781. Pg. 5, 8,

The European Medicines Agency "ICH Guideline on non-clinical safety studies for the conduct of human clinical trials and marketing authorisation for pharmaceuticals" published in December, 2009. https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-m3r2-non-clinical-safety-studies-conduct-human-clinical-trials-marketing-authorisation_en.pdf. Pg. 18, 20

Production And Quality Control Of Medicinal Products Derived By Recombinant DNA Technology Guideline Title Production and Quality Control of Medicinal Products derived by recombinant DNA Technology Legislative basis Directive 75/318/EEC as amended Date of first adoption First adopted June 1987 This version adopted December 1994 Date of entry into force July 1995. https://www.ema.europa.eu/en/documents/scientific-guideline/production-quality-control-medicinal-products-derived-recombinant-dna-technology_en.pdf. Pg. 205–216 of Rules 1998 (3A)–3AB1a).

48. The granting of the Approvals abrogated the TGA and International Gene Therapy Guidelines because prior to the Approvals:

a) there was a known risk of germline integration based on WHO guideline for nucleic acid COVID 19 vaccines, and with mRNA vaccines first in human use in this clinical trial, the risk of germline integration was definitively unknown;

b) novel lipid adjuvants did not undergo genotoxicity studies, with justification referencing studies performed that were not made available to the TGA or the TGA Respondents, and that were performed on a dissimilar lipid compound which demonstrated teratogenicity in animal studies;

c) there was known evidence of distribution to gonads based on lipid distribution studies of the Vaccines;

d) studies on distribution or elimination of the nucleic acid or on the produced spike protein were not performed on the Vaccines nor sought by the TGA or the TGA Respondents;

e) no studies to assess for presence of nucleic acid in the oocytes/ sperm cells were performed nor sought by the TGA or the TGA Respondents;

f) no evaluation for chromosomal integration in oocytes and / or sperm cells were performed nor sought by the TGA or the TGA Respondents;

g) according to International Gene Therapy Guidelines the Vaccines in the known circumstances:

   i. should never had even been approved for human trials;

   ii. should never have been granted the Approvals.

Source

The Pfizer Original AUSPAR;
The Moderna Original AUSPAR;
The AstraZeneca Original AUSPAR.

KNOWN NOVEL EXCIPIENT GUIDELINES

49. From prior to the Approvals the following widely and globally published guidelines and obligations relevant to the approval of vaccines containing novel excipients as in the case

of the Vaccines were published and in effect **("the Novel Excipient Guideline Requirements")**:

a) the EMA guideline adopted by the TGA in respect of repeated dose toxicity published on 18 March, 2010 states that:

    i. the toxicology and pharmacokinetics of an excipient used for the first time in the pharmaceutical field must be investigated;

    ii. the same pivotal studies as for a new active substance should be performed;

    iii. studies with the active substance together with the excipients used in the final product may be needed.

b) the TGA guideline published in February, 2018 in respect of administrative information and prescribing information in Australia applicable to the Applications received by the TGA from 9 February 2018 states that:

    i. nonclinical overview is required when the product includes a novel excipient or involves the novel use of an excipient;

    ii. where the applicant claims essentially similarity to a registered product the nonclinical overview should focus on:

        (1) the grounds for claiming essential similarity; and, if applicable;

        (2) the additional data to demonstrate evidence of the equivalence of safety and efficacy properties.

c) the European Agency for the Evaluation of Medicinal Products stated in a technical document in respect of the registration of pharmaceuticals for human use on 20 February, 2003 that in respect of non-clinical overview of a vaccine that where a drug product includes a novel excipient an assessment of the information regarding the safety of that novel excipient should be provided.

d) the TGA and the TGA Respondents failed to abide by the guidelines pleaded at (a) to (c) above by granting the Approvals in the absence of studies in respect of the adjuvants contained in the Vaccines.

Source

Committee for Human Medicinal Products (CHMP) Guideline on repeated dose toxicity. 18 March 2010. https://web.archive.org.au/awa/20220816022836mp_/https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-repeated-dose-toxicity-revision-1_en.pdf Page 4 s. 5.2.

CTD Module 1.4.2 Administrative information and prescribing information for Australia Applicable to applications received by the TGA from 9 February 2018 Version 4.0, February 2018. Therapeutic Goods Administration. https://www.tga.gov.au/sites/default/files/ctd-module-1-180219.pdf Page 31 Module 2.4.

The European Agency for Evaluation of Medicinal Products. 20 February, 2003. ICH M4S Common Technical Document for the Registration of Pharmaceuticals for Human Use – Safety. Non-Clinical Overview and Nonclinical Summaries of Module 2 – Organisation of Module 4. Pg. 5.

KNOWN FAILURE TO EXAMINE PFIZER mRNA SEQUENCING – UNKNOWN mRNA

50. Prior to the mRNA Vaccine Approvals data provided by Pfizer and Moderna to the TGA and the TGA Respondents in respect of the mRNA Vaccines rationally establishing safety risks in respect of the mRNA Vaccines disclosed that **("the Known Failure to Examine Pfizer MRNA Sequencing")**:

a) an oncomir is a microRNA that was known and established scientifically to be associated with cancer;

b) the coding sequence for the Pfizer Vaccine contains several regions:

   i. in addition to the mRNA encoding spike protein;

   ii. being 3'-UTR and 5'-UTR **("the Unknown Pfizer mRNA Regions")**;

c) the Unknown Pfizer mRNA Regions:

   i. were never examined in detail by the TGA or the TGA Respondents prior to the Pfizer Approval or at all;

   ii. were unknown to the TGA and the TGA Respondents in their contents and untranslated at the time of the Pfizer Approval and since that time;

   iii. may contain oncomirs, the answer to which:

      (1) was unknown to the TGA and the TGA Respondents at the time of the Pfizer Approval and presently;

      (2) ought to have been sought and understood by the TGA and the TGA Respondents prior to the Pfizer Approval:

      (3) must be known in order to declare the Pfizer Vaccine safe;

      (4) remains unknown to the TGA and the TGA Respondents.

Source

The Known Failure to Examine Pfizer MRNA Sequencing arises from the TGA and the TGA Respondents response to FOI3604 request which sought "all documents related to the TGA's assessment of the risk and/or presence of oncomirs (oncogenic

miRNA-microRNA) comprised within the Comirnaty mRNA active ingredient (mRNA genomic sequence)", the response being that the documents requested do not exist.

KNOWN PFIZER NOVEL EXCIPIENT SAFETY RISK

51. On or about 15 January, 2021 and prior to the Pfizer Approval the data provided by Pfizer to the TGA and the TGA Respondents rationally establishing material safety risks in the novel excipient of the Pfizer Vaccine disclosed that **("the Known Pfizer Novel Excipient Safety Risk")**:

    a) Pfizer did not study, nor did the TGA and the TGA Respondents receive, seek or require data, nor was such data known or in existence, in respect of:

        i. the toxicity of:

            (1) the Pfizer Lipid Nanoparticle Formulation;

            (2) the Pfizer Novel Excipients;

            (3) the safety of the Pfizer Novel Excipients in a second species;

    b) the TGA and the TGA Respondents determined and accepted and in fact that, in the Pfizer Nonclinical Trial there was no adequate assessment of the potential of the Pfizer Lipid Nanoparticle or the Pfizer Vaccine to produce:

        i. complement activation; or

        ii. stimulation of cytokine release.

    c) the statement and actual fact that Pfizer would provide no further data in addition to that provided in the Pfizer Nonclinical Study in relation to the safety of the Pfizer Novel Excipients:

i. was stated by Pfizer prior to the Pfizer Approval;

ii. was considered acceptable to the TGA and the TGA Respondents and accepted by the TGA and the TGA Respondents in proceeding with the Pfizer Approval.

d) in response to an enquiry by the TGA regarding the toxicity assessment of the novel excipients in the Pfizer Liquid Nanoparticle Formulation, Pfizer stated that **("the Pfizer Novel Excipient Justification")**:

i. the product Patisiran is:

(1) administered as a lipid nanoparticle formulation;

(2) approved in the US, Europe and Canada;

(3) the subject of approvals which were not reviewed by the Respondents;

(4) contains lipids DLin-MC3-DMA and PEG2000-C DMG **("the Patisiran Lipids")**;

ii. that the Pfizer Novel Excipients (ALC-0315 and ALC-0159) respectively:

(1) have a similar toxicity profile to the Patisiran Lipids;

(2) are structurally and functionally similar to the Patisiran Lipids.

iii. the matters pleaded in (i) and (ii) above were accepted by the TGA and the TGA Respondents who determined:

(1) that there was structural similarity between:

a) the Pfizer Novel Excipient ALC-0159; and

b) the Patisiran Lipid PEG2000-C DMG.

iv. the matters pleaded in (i) and (ii) above were factual in circumstances where there was in fact no similarity between the structures of **("the Novel Excipient Dissimilarity")**:

(1) the Pfizer Novel Excipient ALC-0315; and

(2) the Patisiran Lipid DLin-MC3-DMA;

a) despite the evident Novel Excipient Dissimilarity, the TGA and the TGA Respondents accepted the Pfizer Novel Excipients Justification:

i. as a basis for the determination that it was acceptable that:

1. Pfizer did not conduct repeat dose toxicity studies in a second animal species with the Pfizer Novel Excipients; and

2. the Pfizer Vaccine Approval Proceed;

ii. because the TGA and the TGA Respondents had claimed to have determined that:

1. the Pfizer Novel Excipients and the Patisiran Lipids are all amino or amino/PEG lipids; and

2. the potential lifetime exposure of a recipient to the Pfizer Novel Excipients is expected to be low.

e) the Pfizer Novel Excipient Justification undertaken by the TGA and the TGA Respondents occurred in the known circumstances of:

i. the factual dissimilarity between the Pfizer Novel Excipients and the Patisiran Lipids;

ii. Patisiran being a drug used in terminal patients and not healthy patients as in the proposed recipients of the Pfizer Vaccine;

iii. Patisiran Lipids were found and commonly known to be toxic specifically:

(1) in animal studies, intravenous administration of Patisiran Lipids to pregnant rabbits resulted in:

a) developmental toxicity;

b) embryofoetal mortality; and

c) reduced foetal body weight;

d) maternal toxicity.

(2) in a separate study Patisiran administered to pregnant rabbits resulted in:

a) embryofoetal mortality;

b) reduced foetal body weight; and

c) maternal toxicity.

iv. the acceptance of the Pfizer Novel Excipient Justification is irrational because:

(1) spleen and lymph node histological changes did not normalise at the recovery phase;

(2) the temperature change did not recover by the 3-week recovery phase;

(3) liver vacuolation:

a) was not further investigated by the TGA, the TGA Respondents, Pfizer or anyone; and

b) was simply reported as 'recovered' without an adequate evaluation of the underlying pathophysiology of this finding and the potential risks for use in humans.

(4) the dose interval was known to be inadequate:

a) given the very long, and entirely unknown half-life of the lipid nanoparticles;

b) given that with short duration of immunity and unknown long-term protection that repeat doses were likely required; and

c) because the interval for booster doses was required to be formally examined on both efficacy and toxicity evaluations.

Source

The Pfizer Nonclinical Evaluation Report – Pg. 5, 12.
Patisiran Product / Prescribing Information - Pg. 6 -7.

KNOWN PFIZER NONCLINICAL IMMUNUE RESPONSE ISSUES

52. On or about 15 January, 2021 and prior to the Pfizer Approval the data provided to the TGA and the TGA Respondents rationally establishing material safety risks in immune responses caused by the Pfizer Vaccine **("the Known Pfizer Immune Response Risks")**:

a) Pfizer had asserted to have determined that the findings in the Pfizer Nonclinical Trial Data presented to and then accepted and adopted by the TGA and the TGA Respondents of large unstained cells in the Pfizer Vaccine rat recipients were **("the**

False Pixatimod Justification”):

i. consistent with:

(1) immune stimulation; and

(2) inflammatory responses.

ii. claimed to be determined by the TGA and the TGA Respondents to be of no consequence or bar to the Pfizer Approval based upon the erroneous assertion that increased large unstained cells has been reported for Pixatimod:

(1) being an immune stimulating agent;

(2) citing as a basis for the assertion, the study “Hammond et al. 2018” **(“the Hammond Study”)**; or

(3) acute viral infections;

(4) in circumstances where in truth the Hammond Study disclosed that:

a) the experiment that was the subject of the Hammond Study was terminated on day 18 post-treatment initiation or 25 days post-inoculation due to emerging toxicities in all treatment groups;

b) following exposure to Pixatimod there were striking and the significant increases in large unstained cells in recipients;

c) the authors of the Hammond Study concluded that given the potent immune stimulatory activity of Pixatimod:

i. it is important to characterize toxicologic responses that could be associated with excessive activation of the immune system; and

ii. the elevations in body temperature and large unstained cells in recipients were particularly noteworthy.

b) the False Pixatimod Justification:

i. was accepted and advanced by the TGA and the TGA Respondents as:

(1) an adequate explanation for the adverse finding of large unstained cells in the Pfizer Nonclinical Study; and

(2) as a basis to proceed to the Pfizer Approval.

ii. occurred in circumstances where:

(1) the Hammond Study expressly described the importance of characterising the toxicological responses that could be associated with excessive activation of the immune system;

(2) immune toxicity studies were:

a) not performed by Pfizer; or

b) not required to be performed or sought by the TGA or the TGA Respondents;

(3) the Phase I monotherapy clinical trial of Pixatimod:

a) was for the treatment of advanced metastatic cancer:

i. that had relapsed; and

ii. for which there were no further treatment options;

b) for palliative patients with almost zero survival prospect;

c) produced data which was from a Phase 1 trial;

(4) the Pfizer Vaccine was for use on a healthy population;

(5) accepting data from the trial of such a product in the Hammond Study as a basis for regulatory approval for a healthy population was completely irrational and obviously dangerous;

(6) it was and is a known scientifically established and accepted fact–that increases in large unstained cell numbers are an indication typically only of either:

a) viral disease; or

b) leukemia.

(7) the finding of large unstained cell in the Pfizer Nonclinical Trial notified the TGA and the TGA Respondents that:

a) there was a problem with the Pfizer Lipid Nanoparticle;

b) further investigation was warranted;

(8) the purported acceptance of the False Pixatimod Justification without further investigation was irrational and obviously dangerous.

Source

The Pfizer Nonclinical Evaluation Report – pg. 11.

The Hammond Study - "Immunomodulatory activities of pixatimod: emerging nonclinical and clinical data, and its potential utility in combination with PD-1 inhibitors".

Hammond et al. J Immunother Cancer 2018 Jun 14;6(1):54. doi: 10.1186/s40425-018-0363-5. https://jitc.bmj.com/content/6/1/54.long.

The known pathology related to Large Unstained Cell numbers as in the Pfizer Nonclinical Study is exemplified in such studies as follows:

The Mouse Adult Gross Anatomy Ontology and Mammalian Phenotype Ontology rate genome browser (a clinical database and website describing rat models in clinical trials) - https://rgd.mcw.edu/rgdweb/ontology/annot.html?acc_id=MP:0012362– wherein the indication applied to the term "increased large unstained cell (LUC) number" states: Aberrations in the count of large unstained cells may be indicative of viral disease or leukemia.

KNOWN VACCINES' NOVEL ADJUVANT OIL CARCINOGEN

53. Prior to the Approvals the following data provided to the TGA and the TGA Respondents in respect of the Vaccines and widely and globally published scientific data rationally establishing safety risks relating to the Vaccines' used adjuvants disclosed that **("the Known Oil Adjuvant Risk")**:

    a) a mineral or synthetic oil adjuvant:

        i. is used in each of the Vaccines **("the Vaccines Adjuvants")**;

        ii. is scientifically known and established to have carcinogenic potential in the animal host due to minimal metabolism of the oils;

        iii. where used in the Vaccines is the first time a mineral or synthetic oil adjuvant has been utilised in vaccines for human use; and

iv. the use of mineral or synthetic oil adjuvant in the Vaccines indicated that rigorous evaluation for the known risks was reasonably and logically required before the Approvals.

b) no testing of the Vaccines Adjuvants has been:

i. undertaken by the Sponsors or anyone;

ii. sought or obtained by the TGA or the TGA Respondents prior to the Approvals or at all.

Source

See - US Patent 3149036, Patented Sept 15 1964, for a novel vaccine adjuvant. "The need therefore exists for an adjuvant which is relatively nontoxic to the host and which will potentiate the antibody response to all antigens and additionally will maintain the titre over a long period of time thus endowing the host with a long period of immunity. In an attempt to satisfy the current needs, it had been proposed to use a mineral oil emulsion in which the antigen was incorporated in the aqueous phase. While this seemed to present some promise of providing an adjuvant type composition, it was found that it was not in fact a suitable solution because the mineral oil was not metabolized by the animal host and therefore could be a carcinogen."

The presence of Vaccine Adjuvants in the Vaccines was disclosed by way of the data provided by the Sponsors before and in support of the Approvals of the Vaccines to the TGA and the TGA Respondents.

KNOWN VACCINES' POLYETHYLENE GLYCOL RISK

54. Prior to the Approvals the following data provided to the TGA and the TGA Respondents in respect of the Vaccines and widely and globally published scientific data rationally

establishing safety issues in respect of the use of polyethylene glycol in the mRNA Vaccines disclosed that **("the Known PEG Risk")**:

a) polyethylene glycol **("PEG")**:

i. is a lipid shell, is used in, and has a triple role in the mRNA Vaccines being:

(1) to protect the genetic material from degradation prior to cellular uptake;

(2) facilitate cellular uptake; and

(3) act as an adjuvant.

ii. has been scientifically known since at least the time of the Approvals to have a high prevalence in national populations:

(1) of up to 72% in populations with no prior exposure to PEG-based medical therapy; and

(2) which can have important consequences for any PEG-based therapeutics; and

(3) the existence of which is correlated with:

a) a prevalence in populations of anti-PEG antibodies;

b) consequently in PEGylated-based therapeutics such as the Vaccines:

i. an impairment of therapeutic efficacy;

ii. the development of severe adverse effects; and

iii. more common and more severe reactions upon re-exposure.

Source

The Known PEG Risk was well documented and accepted scientifically including in for example the following studies:

1. "Antibodies Against Polyethylene Glycol in Human Blood: A Literature Review". Hong, L., Wang, Z., Wei, X., Shi, J. & Li, C. (2020). Journal of Pharmacological and Toxicological Methods 102: 106678. https://doi.org/10.1016/j.vascn.2020.106678

2. "PEGylation and Anti-PEG Antibodies. Engineering of Biomaterials for Drug Delivery Systems". Lila, A. S., Shimizu, A. T. & Ishida, T. (2018). Woodhead Publishing 51-68. https://doi.org/10.1016/B978-0-08-101750-0.00003-9

3. "Pre-existing Anti–Polyethylene Glycol Antibody Linked to First-Exposure Allergic Reactions to Pegnivacogin, A PEGylated RNA Aptamer". Ganson, N. J., Povsic, T. J., Sullenger, B. A., Alexander, J. H., Zelenkofske, S. L., ... Hershfield, M. S. (2016). Journal of Allergy and Clinical Immunology 137(5): 1610-1613. https://doi.org/10.1016/j.jaci.2015.10.034

The use of PEG in the mRNA Vaccines was disclosed by the Sponsors in the provided data provided to the TGA and the TGA Respondents prior to Approvals.

KNOWN mRNA SPIKE PROTEIN RISKS

55. On or about 15 January, 2021 and prior to the mRNA Vaccines Approvals data provided by Pfizer and Moderna to the TGA and the TGA Respondents and widely and globally published EMA assessment rationally establishing significant safety efficacy risks and risk-benefit deficit in respect of the mRNA spike proteins produced by the mRNA

Vaccines **("the mRNA Spike Proteins")**:

a) the immunofluorescence staining of cells transfected with the Pfizer Vaccine displayed:

   i. a reduction to the endoplasmic reticulum immunofluorescence staining;

   ii. some form of change to proteins;

   iii. the matters pleaded in (i) and (ii) herein above, in circumstances where in truth at that time it was a known scientific fact, including such fact being known to the Respondents that:

      (1) it was a known scientific fact that the observed reduced fluorescence (red) on the endoplasmic reticulum:

         a) obviously indicated less endoplasmic reticulum/ Golgi protein; and

         b) is a known response to cellular stress; and

         c) is a sign of impending cell death;

         d) would consequentially lead to ER/ cytoplasmic vacuolation, which was disclosed as, and in fact, found in the histopathology in the liver cells in the Pfizer Vaccine animal studies;

      (2) Pfizer's assertion was accepted and adopted by the TGA and the TGA Respondents that this was likely due to lipid uptake within the cells:

         a) insinuated that small globules of lipid were seen in the cells or similar:

            i. despite the fact that the lipids encapsulating the product were nano lipids which would be impossible to see on plain

microscopy;

ii. which if visible through coalescence, would suggest an unstable nano lipid structure;

b) which by reason of (a) was an irrational, illogical and unacceptable explanation.

(3) the data provided by Pfizer indicated an obvious and extreme safety issue in the use of the mRNA Vaccines with respect to the mRNA Spike Proteins.

b) there was no data or testing by Pfizer provided to or sought by the TGA and the TGA Respondents or anyone in respect of:

i. the distribution and degradation data on the S antigen encoding mRNA;

ii. the mRNA Spike Protein at all.

c) it was a known and intended effect of the mRNA Vaccines and disclosed by Pfizer that:

i. the mRNA Vaccines would go into the cell;

ii. then the protein that would be created can either:

(1) be put onto the surface of the cell (the membrane) which will induce an autoimmune response; or

(2) be secreted into the body.

d) from 19 February, 2021 it was publicly disclosed that the EMA had found "fragmented species" of RNA in the Pfizer Vaccine injection solution which:

i. resulted from early termination of the process of transcription from the DNA template;

ii. if translated by the human cell following injection, would generate incomplete spike proteins, resulting in:

(1) an altered and unpredictable three-dimensional structure; and

(2) a physiological impact that is:

a) at best neutral; and

b) at worst detrimental to the recipient's cellular functioning.

(3) has never been controverted in its concluded effect by any known data.

e) that the available data disclosed a significant and known safety risk in respect of the use of the mRNA Vaccines producing the mRNA Spike Protein.

Source

The Pfizer Nonclinical Evaluation Report. pg. 8, 20, 34-35.

EMA Public Assessment Report Comirnaty Common name: COVID-19 mRNA vaccine (nucleoside-modified) Procedure No. EMEA/H/C/005735/0000 dated 19 February, 2021, pg. 18.
https://ia802202.us.archive.org/5/items/assessment-report-pfizer-july/Assessment-Report-Pfizer-February.pdf

KNOWN MRNA SPIKE PROTEIN RISKS

56. Prior to the mRNA Vaccine Approvals, the totality of data provided by Moderna and Pfizer to the TGA and the TGA Respondents and widely and globally published scientific data and studies at that time rationally establishing material safety risks in the mRNA

Vaccines disclosed that the spike proteins produced by the mRNA Vaccines **("the Reasonably Known mRNA Spike Protein Risks")**:

a) possessed the long-term potential to induce autoimmune diseases in indeterminate volume; and

b) carried the risk of causing blood clotting and mitochondrial damage;

c) had no long-term safety data available in existence in connection with their use in humans;

d) interfered with the body's natural immune system including Toll Like Receptors;

e) could by their nature provoke latent viral eruptions of Herpes Zoster and Epstein-Barr viruses;

f) were profoundly different from the spike protein produced by the Virus because:

    i. the uracil nucleotide bases (there are 4 different nucleotide bases in RNA: uridine, cytosine, guanine and adenine) are replaced with pseudo uridine (a methylated derivative); and

    ii. the pseudo uridine bases remain in circulation for a longer and unknown period.

g) impart profound pharmacological characteristics to the mRNA molecule produced by the mRNA Vaccines including the ability to evade natural degradation as occurs in natural mRNA;

h) contribute to Antibody-Dependent Enhancement (ADE) provoked by prior:

    i. Covid infection; or

    ii. vaccination with the mRNA Vaccines.

i) manifest as either acute or chronic autoimmune and inflammatory conditions, such that:

    i. it is not possible to distinguish an ADE manifestation of disease from a non-ADE viral infection and consequently:

        (1) when diseases and deaths occur shortly after vaccination with an mRNA vaccine, it can never be definitively determined, even with a full investigation, that the vaccine reaction was not a proximal cause.

j) have a high binding affinity with the following which typically take years to manifest symptomatically in:

    i. tTG (associated with Celiac Disease);

    ii. TPO (Hashimoto's thyroiditis);

    iii. myelin basic protein (multiple sclerosis); and

    iv. several endogenous proteins.

k) possess the long-term potential in both children and adults who received mRNA Vaccines:

    i. to cause vascular endothelial damage; and

    ii. to trigger pro-inflammatory response in brain endothelial cells;

    iii. to behave as a prion and cause prion-like diseases by way of:

        (1) its ability to bind to many known proteins; and

        (2) induce their misfolding into potential prions;

(3) actions similar to neurodegenerative diseases, including Alzheimer's and Parkinson's disease.

Source

Scientific data and studies published before the mRNA Approvals include:

Classen JB. COVID-19 RNA Based Vaccines and the Risk of Prion Disease. Microbiol Infect Dis. 2021; 5(1): 1-3.

The production of spike proteins in the mRNA Vaccines was disclosed in the data provided by Pfizer and Moderna to the TGA and the TGA Respondents in the course of the mRNA Vaccine Approvals.

KNOWN PREGNANCY RISKS - PFIZER REPRODUCTIVE STUDY IN PFIZER NONCLINICAL EVALUATION REPORT

57. On or about 15 January, 2021 and prior to the Pfizer Approval the data provided to the TGA and the TGA Respondents by Pfizer and the widely and globally published scientific studies and data rationally establishing significant safety risks and risk-benefit deficit by reproductive risks in the Pfizer Vaccine disclosed that:

a) the Pfizer Reproductive study performed on rats was the only reproductive study performed by Pfizer in respect of the Pfizer Vaccine for which data was provided to the Respondents by Pfizer relating to the Pfizer Approval **("the Pfizer Reproductive Study")**;

b) the Pfizer Reproductive Study disclosed at that time and summarised by the TGA and the TGA Respondents in the Pfizer Nonclinical Evaluation Report that:

i. adverse findings included:

(1) swelling, which is a scientifically accepted indicator of possible:

a) liver pathology;

b) heart pathology; or

c) kidney pathology;

(2) more than double the control rate of pre-implantation loss / miscarriage in the Pfizer Vaccine recipients being:

a) 9.8% in the Pfizer Vaccine group; and

b) 4.1% in the control group.

ii. the Pfizer Reproductive Study utilised historical data:

(1) to justify that increased rate of pre-implantation loss and miscarriage seen in the Pfizer Vaccine group as being "within historical range";

(2) without providing detail of the historical data referred to;

(3) that was not subject to any quality assurance audit;

(4) with the TGA and the TGA Respondents' acceptance of that historical data as a basis for the Pfizer Approval and pregnancy classification of B1;

a) in circumstances where in truth, it had been scientifically established since prior to the Pfizer Approval that:

i. the use of historical controls is inappropriate in nearly all studies; and

ii. contemporary controls are essential; and

iii. historical data, particularly from another laboratory should be treated with considerable caution.

iii. in the Pfizer Vaccine group there was:

(1) a total of 28 anomalies or malformations in a litter size of only 21;

(2) one animal which developed a solid, dark heterogeneous mass adherent to its liver tissue that was described by the TGA in the Pfizer Nonclinical Evaluation Report as “a liver hernia”;

(3) in circumstances where in truth:

a) a ‘liver hernia’:

i. is not a recognised diagnostic term known to medicine; and

ii. required clarification.

b) a solid, dark heterogenous mass adherent to liver tissue is scientifically known to suggest cancer tumor growth and:

i. required further evaluation;

ii. is significant in evaluation of the need for carcinogenicity studies which were never performed on the Vaccines;

c) the following clinical observations were made in the Pfizer Reproductive Study but were not included, discussed or considered by the TGA or the TGA Respondents in the Pfizer Nonclinical Evaluation Report or at all:

i. the occurrence of chromodacryorrhea (associated with nutritional deficiencies, chronic physiological stress, chronic light exposure, or dacryoadenitis) was found in:

(1) 1 pup in the Pfizer Vaccine group;

(2) none in the control group.

ii. that limping was found in:

(1) 26 pups in the Pfizer Vaccine group;

(2) none in control group.

iii. that piloerection was found in:

(1) 2 of the pups in Pfizer Vaccine group;

(2) none in the control group.

iv. that swelling was found in:

(1) 92 of the pups in Pfizer Vaccine group;

(2) none in the control group.

v. significantly higher rates in the Pfizer Vaccine Group over the control group of:

(1) hair loss;

(2) red stained fur;

(3) scabs;

(4) swelling.

vi. one pup in the Pfizer Vaccine group:

(1) with symptoms being:

a) cold to touch;

b) weak;

c) thin;

d) pale;

e) cyanotic.

(2) reasonably presumed:

a) pre-terminal;

b) subsequently dying.

(3) culled from the study such that the Pfizer Reproductive Study reported no deaths.

vii. a pregnancy rate of:

(1) in the Pfizer Vaccine group: 95%;

(2) in the control group: 98%

viii. clinically significant differences in uterine weight:

(1) 5.55g in the Pfizer Vaccine group;

(2) 17.93g in the control group.

ix. clinically significant differences in late reabsorptions:

(1) 0.2 in the Pfizer Vaccine group;

(2) 0.1 in the control group.

x. reduced causal vertebra at the rates:

(1) 2 in the Pfizer Vaccine group;

(2) none in the control group;

xi. clinically significant 21% higher rate of pre-birth loss in the Pfizer Vaccine group of:

(1) 8.22% in the Pfizer Vaccine group;

(2) 6.8% in the control group.

xii. the occurrence of *situs inversus totalis* in the Pfizer Vaccine pup 255 which is:

(1) a rare congenital abnormality characterized by a mirror-image transposition of both the abdominal and the thoracic organs;

(2) not reported in:

a) any of the summary tables of the Pfizer Reproductive Study; or

b) any part of the Pfizer Nonclinical Evaluation Report prepared by the TGA and the TGA Respondents.

xiii. demonstrating a known failure by the TGA or the TGA Respondents or anyone to consider or report highly significant study findings in the Pfizer Reproductive Study:

(1) being the only study ever undertaken to examine reproductive and pregnancy risks in Pfizer Vaccine recipient;

(2) relevant to the reproductive and pregnancy risks to recipients of the Pfizer Vaccine;

(3) disclosing significant reproductive and pregnancy risks to recipients of the Pfizer Vaccine.

Source

The Pfizer Nonclinical Evaluation Report – pg. 55-56. Table 6.1.

The Pfizer Reproductive Study – pg. 62, 87, 88, 89, 97, 100, 1061.

Scientific understanding of the incorrect use of historical control data in the study is exemplified in the following scientific study:

Fest et al, "Guidelines for the Design and Statistical Analysis of Experiments Using Laboratory Animals" ILAR Journal, Vol 43, Issue 4, 2002, pages 244-258
https://doi.org/10.1093/ilar.43.4.244. 1
pg. 256
https://academic.oup.com/ilarjournal/article/43/4/244/981872?login=false

KNOWN IMPROPER APPLICATION OF PREGNANCY SAFETY CATEGORY B1 IN PFIZER VACCINE

58. On or about 19 January, 2021 and prior to the Pfizer Approval the data provided to the TGA and the TGA Respondents and the internal actions within the TGA rationally establishing significant safety concerns in pregnant recipients of the Pfizer Vaccine disclosed that **("the TGA Pregnancy Categorisation of the Pfizer Vaccine")** :

a) on or about 11 January, 2021, the TGA and the TGA Respondents had stated to have determined and asserted that in respect of the Pfizer Vaccine:

i. a Pregnancy Category of B2 was appropriate;

ii. the reason that Pregnancy Category of B2 was appropriate was because the Reproductive Study showed increased occurrence of supernumerary lumbar ribs in fetuses in treated female rats;

iii. the following wording with respect to use in pregnancy in the Pfizer Product Information was appropriate:

There is limited experience with use of COMIRNATY in pregnant women. A combined fertility and developmental toxicity study in rats showed increased occurrence of supernumerary lumbar ribs in fetuses from COMIRNATY- treated female rats. Administration of COMIRNATY in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.

b) by on or about 15 January, 2021, the TGA and the TGA Respondents had stated to have determined and asserted that in respect of the Pfizer Vaccine:

i. Pregnancy Category of B1 was appropriate;

ii. that Pregnancy Category of B1 was appropriate because **("the Basis for Pfizer Reproductive Category B1")**:

(1) because "no embryofoetal effects have been noted in a combined reproductive and development study in rats";

(2) by reference to the Pfizer Reproductive Study.

iii. the following wording with respect to use in pregnancy in the Pfizer Product Information was appropriate:

> *There is limited experience with use of COMIRNATY in pregnant women. see Effects on fertility. Administration of COMIRNATY in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus;*

c) by on or about 25 January, 2021, the TGA and the TGA Respondents stated to have determined and asserted again that in respect of the Pfizer Vaccine:

i. Pregnancy Category of B1 was appropriate; and

ii. combined reproductive and developmental study:

(1) showed no adverse effects on female fertility, embryofoetal development and post-natal development (up to weaning) in rats;

(2) by reference to the Pfizer Reproductive Study

d) the matters pleaded above herein in (a) to (c) occurring in circumstances of the TGA having defined the Pregnancy Category of B1 since May, 2011 as **("the TGA Defined B1 Pregnancy Category")**:

i. drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed;

ii. studies in animals have not shown evidence of an increased occurrence of foetal damage;

iii. the use of any medicine during pregnancy requires careful consideration of both risks and benefits by the treating health professional;

iv. this must not be used as the sole basis of decision making in the use of medicines during pregnancy;

v. TGA does not provide advice on the use of medicines in pregnancy for specific cases.

e) the TGA Pregnancy Categorisation of the Pfizer Vaccine undertaken by the TGA and the TGA Respondents:

i. proceeded upon the known and obvious falsehood that the Pfizer Reproductivity Study showed no adverse effects on female fertility, embryofoetal development and post-natal development in rats;

ii. applied an obviously erroneous Pregnancy Category of B1 to the Pfizer Vaccine based upon false interpretation of the Pfizer Reproductivity Study data;

iii. proceeded where based upon the actual data provided by Pfizer, the most appropriate Pregnancy Category of B3 was evident;

iv. resulted in:

(1) the known grant of the Pfizer Approval in circumstances of demonstrated risk to pregnant women whom received the Pfizer Vaccine;

(2) the marketing of the Pfizer Vaccine to the Australian public with Product Information which was patently false;

(3) a known and obvious breach of the TGA Pregnancy Categorisation Policy.

Source

The Pfizer Delegates Overview. pg. 26-27.
The Pfizer Nonclinical Evaluation Report, pg. 15.
The Pfizer AUSPAR. Pg. 8.

TGA Australian Categorisation System For Prescribing Medicines In Pregnancy – May, 2011 **("TGA Pregnancy Categorisation Policy")**
https://www.tga.gov.au/australian-categorisation-system-prescribing-medicines-pregnancy.

KNOWN IMPROPER APPLICATION OF PREGNANCY SAFETY CATEGORY IN ASTRAZENECA VACCINE

59. On or about 28 January, 2021 and prior to the AstraZeneca Approval the Respondents knew of the data provided to the TGA and the TGA Respondents by AstraZeneca and the internal actions within the TGA rationally establishing significant safety concerns in pregnant recipients of the AstraZeneca Vaccine disclosed that **("the TGA Pregnancy Categorisation of the AstraZeneca Vaccine")**:

a) a fertility and embryofoetal development study in respect of the AstraZeneca Vaccine had at no stage been completed prior to the AstraZeneca Approval;

b) the AstraZeneca Vaccine was at that time not recommended by the TGA and the TGA Respondents for use in pregnant women as the first Vaccine choice;

c) AstraZeneca proposed to the TGA and the TGA Respondents a Pregnancy Category of B2;

d) a Pregnancy Category B2 was asserted to be appropriate by the TGA and the TGA Respondents on the basis that animal reproductive studies had not been completed;

e) the TGA has defined the Pregnancy Category of B2 from May, 2011 as follows **("the TGA Defined B2 Pregnancy Category")**:

i. a drug has been taken:

(1) by only a limited number of pregnant women and women of childbearing age;

(2) without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed.

ii. studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of foetal damage.

f) the TGA Pregnancy Categorisation of the AstraZeneca Vaccine by the TGA and the TGA Respondents:

i. applied an obviously erroneous Pregnancy Category of B2 to the AstraZeneca Vaccine due to a total absence of any nonclinical or clinical trial reproductive results having been conducted at the time of the AstraZeneca Approval;

ii. proceeded where based upon the actual data provided by AstraZeneca the most appropriate Pregnancy Category of B3 was rationally indicated and evident;

iii. resulted in:

(1) the known grant of the AstraZeneca Approval in circumstances of demonstrated risk to pregnant women whom received the AstraZeneca;

(2) the marketing of the AstraZeneca Vaccine to the Australian public with Product Information which was patently false;

(3) a known and obvious breach of the TGA Pregnancy Categorisation Policy.

Source

The AstraZeneca Nonclinical Evaluation Report. pg. 10.
The TGA Pregnancy Categorisation Policy.

KNOWN IMMUNOTOXITY RISK - PFIZER

60. On or about 15 January, 2021 and prior to the Pfizer Approval the data provided to the TGA and the TGA Respondents by Pfizer, the internal actions within the TGA, and the widely and the globally published guidelines of the WHO, EMA and ICH rationally establishing significant immunotoxicity safety and efficacy risks and risk-benefit deficit in the Pfizer Vaccine disclosed that **("the Known Pfizer Immunotoxicity Risk")**:

a) no dedicated immunotoxicity study was conducted by Pfizer nor obtained or sought by the TGA, the TGA Respondents or anyone in respect of the Pfizer Vaccine;

b) in-vitro study on stimulation of cytokine release in human PBMC cells provided by Pfizer disclosed inconclusive results;

c) immune-stimulatory effects in the Pfizer Vaccine recipients were observed in pharmacology and repeat dose toxicity studies;

d) no vaccine-related systemic intolerance or mortality was observed in the studies;

e) contrary to the First In Human Medicine Policy **("the Known EMA Policy Breaches")**:

i. prior to the Approvals it was disclosed that:

(1) toxic effects were observed at just 3 x the proposed dose in the Pfizer Clinical Trials phase I/II;

(2) the Pfizer Vaccine displayed a narrow therapeutic window;

(3) 100mcg and 50mcg doses for Pfizer were abandoned by Pfizer in those trials due to reactogenicity and side effects, indicating:

a) high potential for toxicity especially where liver metabolism was being relied upon as the means by which the substance would be metabolised.

(4) the dose of 30mcg was subsequently chosen for the Pfizer Vaccine;

ii. in the circumstances of (i), the Pfizer Approval was made.

f) in a study for the release of cytokines in Pfizer Vaccine recipients:

i. the number of animals studied was:

(1) three animals;

(2) stated by the TGA and the TGA Respondents and were in fact, objectively "small";

ii. there was high inter-animal variation.

g) the Pfizer Nonclinical Trial data disclosed that:

i. IFN-γ has been found to play a role in autoimmunity as disclosed in studies:

(1) Lees 2015;

(2) Pollard et al. 2013;

ii. IFN-γ was increased in animals immunised with the Pfizer Vaccine; and

iii. that autoimmune diseases are and were a potential risk from use of the Pfizer Vaccine.

h) the TGA and the TGA Respondents asserted to have determined at that time that the known Pfizer Vaccine autoimmune disease risk "is addressable by the ongoing 2-year clinical studies";

i) the matters pleaded at (a) to (h) above occurred in circumstances where in truth:

i. the known lack of immunotoxicity study for the Pfizer Vaccine was in direct breach of the European Medicines Agency ICH Guideline adopted by the TGA on non-clinical safety studies for new human pharmaceuticals which requires that:

(1) all new human pharmaceuticals should be evaluated for the potential to produce immunotoxicity using standard toxicity studies and additional immunotoxicity studies;

(2) such studies should be conducted as appropriate based on a weight-of-evidence review, including immune-related signals from standard toxicity studies;

(3) if additional immunotoxicity studies are indicated these should be completed before exposure of a large population of patients (e.g., Phase III).

ii. the TGA and the TGA Respondents' acceptance in the absence of immunotoxicity study prior to the Approvals was irrational, reckless and obviously dangerous;

iii. the WHO Background document on Covid-19 disease and vaccine current at the time of the Pfizer Nonclinical Trials and the Pfizer Approval stated that:

(1) that there existed concerns of antibody-enhanced disease:

a) which could occur in individuals who have antibodies induced by immunisation;

b) which remained an important issue for:

i. vaccine development; and

ii. safety monitoring.

(2) Covid can have three stages:

a) early Covid infection is marked by viral response with mild symptoms;

b) a pulmonary phase associated with shortness of breath with or without hypoxia; and

c) a hyper-inflammation phase marked by host inflammatory response associated with acute respiratory distress syndrome, shock, and cardiac failure.

iv. the WHO declarations as to Covid prior to the Approvals rationally established that:

(1) the mild nature of early Covid infections warranted only the consideration for effective immunisation to be prevention of serious illness and death;

(2) it was irrational, reckless and obviously dangerous that the TGA and the TGA Respondents:

a) accepted that those outcomes were never tested in the clinical trials

for any of the Vaccines;

b) accepted the endpoint being set in the Vaccines clinical trials as symptomatic Covid infection, with no regard to severity of symptoms or outcomes.

v. at that time that the data provided by Pfizer disclosed:

(1) the "host inflammatory response", causing the hyper-inflammation stage is the very underlying pathophysiology of severe disease;

(2) the response rationally required careful evaluation of clinical markers for inflammatory hyper response, such as injection site inflammation findings, lymph node finding, cytokines etc. after administration of the Vaccines;

(3) several adverse findings in the Vaccines Nonclinical Trials were explained by the Sponsors and accepted and asserted by the TGA and the TGA Respondents to be "due to inflammatory response" when:

a) this explanation should reasonably have immediately raised a safety signal with the TGA and the TGA Respondents:

i. for high risk of VAED based on the cytokine release pattern in the provided data;

ii. indicating that immunotoxicity studies were required;

iii. that there was a potential for autoimmune disease.

Source

The Pfizer Nonclinical Evaluation Report – pg. 10, 14

The Known EMA Policy Breaches arose by the adoption of the EMA policies and further the disclosure of the entirety of the Pfizer Clinical Trials data prior to the Approvals.

EMA ICH Note for Guidance on Immunity Toxicity Studies for Human Pharmaceuticals. https://www.ema.europa.eu/en/documents/scientific-guideline/ich-s-8-immunotoxicity-studies-human-pharmaceuticals-step-5_en.pdf – pg. 4.

ICH - European Medicines Agency - December 2009 EMA/CPMP/ICH/286/1995 "ICH guideline M3(R2) on non-clinical safety studies for the conduct of human clinical trials and marketing authorisation for pharmaceuticals - Step 5" – pg. 21.

World Health Organisation. DRAFT Prepared by the SAGE Working Group on COVID-19 Vaccines 22 December 2020 Background paper on Covid-19 disease and vaccines. Prepared by the Strategic Advisory Group of Experts (SAGE) on Immunization Working Group on COVID-19 vaccines 22 December 2020. – pg. 9.

KNOWN PFIZER ISSUES – REPORTING TO ACV AND ACV RESPONSES

61. The ACV provides and at all material times provided independent medical and scientific advice:

a) to the Minister and the TGA;

b) on vaccine issues relating to:

i. the safety, quality and efficacy of vaccines supplied in Australia;

ii. pre-market assessment;

iii. post-market monitoring; and

iv. safe use in national immunisation programs.

62. On or about 11 January, 2021 and prior to the Pfizer Approval, the Secretary through a delegate advised the ACV of the following asserted determinations made by the TGA and the TGA Respondents in respect of the safety, efficacy and risk-benefit profile of the Pfizer Vaccine and data obtained through Pfizer in the Pfizer approval application, to the ACV in seeking advice relevant to approval of the Pfizer Vaccine **("the TGA Determined Deficiencies in Pfizer Vaccine Approval Data")**:

a) that there were known identified limitations of the data provided by Pfizer in respect of the Pfizer Vaccine which included that:

i. safety follow-up for the Pfizer Vaccine was limited to median two months after the second dose;

ii. the duration of immune response from the Pfizer Vaccine was not known;

iii. the duration of Pfizer Vaccine protection was not known;

iv. Pfizer Vaccine efficacy against asymptomatic infection was not known;

v. Pfizer Vaccine efficacy against viral transmission was not known;

vi. Pfizer Vaccine data in immunocompromised individuals was very limited;

vii. there was a lack of data in respect of safety and efficacy of the Pfizer Vaccine in:

(1) children;

(2) pregnant women; and

(3) lactating mothers.

viii. pharmacovigilance activities and post-market studies had been proposed by Pfizer as a means to address the data deficiencies after release of the Pfizer Vaccine.

63. Despite the TGA Determined Deficiencies in Pfizer Vaccine Approval Data, the TGA and the TGA Respondents had asserted to have determined as at 11 January, 2021 that:

a) there was no reason known to them that the application for the Pfizer Vaccine should not be approved for provisional registration; and

b) that the final decision, including Conditions for Provisional Registration would be made following ACV discussion in respect of the First TGA ACV Advice Request.

64. The ACV responded to the TGA and the TGA Respondents on or about 19 January, 2021 asserting to have determined the following in response to the advice request based upon the data, documents and correspondences provided by the TGA and data obtained from Pfizer by the TGA and the TGA Respondents in the Pfizer Approval application rationally establishing material safety concerns in the Pfizer Vaccine disclosing that **("the ACV Advised Deficiencies in Pfizer Vaccine Approval Data")**:

a) in respect of the quality of the Pfizer Vaccine:

i. the EMA Report to which the ACV had access:

(1) acknowledged the presence of truncated and/or modified forms mRNA in the Pfizer Vaccine at concentrations higher than the Pfizer Clinical Trial;

(2) acknowledged that such quality issue could impact the immune response to the Pfizer Vaccine.

ii. that:

(1) residual DNA should be part of batch testing; and

(2) increased DNA contamination has potential to increase reactogenicity to the Pfizer Vaccine;

(3) thereby rationally establishing before the time of the Pfizer Approval that:

a) DNA contamination had been observed in the Pfizer Vaccine;

b) the obligation for Office of the Gene Technology Regulator advice to have been sought by the TGA and the TGA Respondents, which was not sought;

c) the elevated risk of genome integration in the use of the Pfizer Vaccine.

iii. that there was a remaining safety concern in respect of the Pfizer Vaccine:

(1) being vaccine-associated enhanced disease (VAED) including vaccine-associated enhanced respiratory disease (VAERD);

(2) to be addressed in ongoing and planned pharmacovigilance activities;

(3) which despite being advised in the detail pleaded at (1) and (2) above, the TGA and the TGA Respondents:

a) at no time referred to VAED or VAERD in the Pfizer Product Information approved, authorised and published by the TGA and the TGA Respondents;

b) accepted and allowed that the Pfizer Approval would proceed in the face of remaining and unaddressed safety concerns which would then only be clarified by observing the effects of the

Pfizer Vaccine on the Australian population at large.

iv. that there was limited or no information regarding the efficacy and safety of the Pfizer Vaccine:

(1) in patients with:

a) autoimmune or inflammatory disorders;

b) immunocompromised individuals;

c) pregnant women; and

d) individuals with a history of anaphylaxis.

(2) to be remedied by the requirement for clinical guidance to assist the TGA and the TGA Respondents in making a determination as to the risks of taking the Pfizer Vaccine;

(3) which despite being advised in the detail pleaded at (1) and (2) above, the TGA and the TGA Respondents accepted and allowed that the Pfizer Approval would proceed in the face of remaining safety concerns which would then only be clarified by observing the effects of the Pfizer Vaccine on the Australian population at large, including those untested groups.

v. that relevant consumer information in respect of the Vaccines, including deficiencies in knowledge relating to the Vaccines' safety and efficacy, would be critical to the formation of informed consent:

(1) by users of the Vaccines in a campaign roll-out;

(2) wherein despite this advice the Pfizer Vaccine Consumer Medicine Information summary was approved by the TGA and the TGA Respondents and did not include:

a) any reference to the presence of truncated and/or modified forms mRNA in the Pfizer Vaccine;

b) any statement of knowledge as to the absence of certainty and data in respect of safety and efficacy by TGA;

c) any reference to the risk of VAED:

    i. including that it was a known special risk of concern;

    ii. not referred to in the Pfizer Product Information approved, authorised and published by the TGA and the TGA Respondents.

d) the exclusion of the above matters by the TGA and the TGA Respondents from the approved documents prepared for the purported purpose of fully informing the Australian Public was:

    i. an abrogation of informed consent in those receiving the Pfizer Vaccine;

    ii. a known refusal or failure to inform the Australian public as to safety matters to which recipients of the Pfizer Vaccine had a reasonable expectation and right to know.

Source

ACV Meeting Minutes - January 2021. https://www.tga.gov.au/sites/default/files/2023-03/foi-4093-01.pdf. Pg. 6,7,8,10,12. Advisory Committee on Vaccines Meeting 18 Minutes on Item 2.1 BNT162b2 [mRNA] COVID-

19 vaccine Proprietary Product Name: Comirnaty Sponsor: Pfizer Australia Pty Ltd. January 2021.

Document: A1b EMA – Assessment Report Dated 21 December 2020.

Documents provided to the ACV by the TGA upon which the ACV solely relied in providing the First ACV Advice.

The ACV considered the following documentation, provided at various times between 10 December 2020 and 15 January 2021:

A1 Delegate - request for ACV advice and overview – 'Delegate's Overview'
A1a Sponsor – clinical overview dated 3 December 2020
A1b EMA – assessment report dated 21 December 2020
A2 Sponsor - application letter dated 23 October 2020
M3 TGA - Quality – product summary
M3a TGA – Quality – evaluation report – active ingredient Drug Substance
M3b TGA – Quality – evaluation report – vaccine Drug Product
M3c TGA – Quality – draft consent for labels that do not comply with Labelling Order
M3d Sponsor – Labels for vial and 195 vial carton - European
M3e Sponsor – Labels for vial and 195 vial carton – Australian – FDA Emergency Use
M4 TGA - Nonclinical – summary and evaluation report
M4a TGA – Nonclinical comment on Supernumerary lumbar ribs

65. Technical and safety information in respect of a therapeutic approved for use by the Australian public formally described as the product's "Product Information" **("Product**

Information"):

a) is typically authorised and published by the TGA;

b) is required to be in a form approved by the Secretary pursuant to s. 7D(1) of the Act;

c) is created for the purposes of fully informing the user of the therapeutic as to:

i) the nature of the product;

ii) the safety of the product;

d) is required to comply with the TGA Product Information Requirements.

TGA STATUTORY REQUIRED INCLUSIONS – PRODUCT INFORMATION

66. At all material times from prior to the Approvals a prescribed and approved form for the provision of Product Information, including for the Vaccines **("the TGA Product Information Requirements")**:

a) was and remained in force at the time of the respective Approvals;

b) was approved by the Secretary pursuant to s. 7D(1) of the Act;

c) with respect to adverse effects in medicines including the Vaccines, requires the following to be expressed in the Vaccines' Product Information at s. 4.8 **("the TGA Product Information Requirements")**:

i. the Vaccine's adverse or undesirable effects:

(1) severity;

(2) clinical importance; and

(3) frequency.

ii. expressed in the following format:

(1) table of adverse events:

a) at a cut-off of, for example, 1% comparing:

i. the frequency of adverse events (n(%) or (%)) on drug; with

ii. a placebo/active comparator (if studies support this comparison) (usually very common and common);

b) a line listing of adverse reactions that fall below the cut-off:

i. by System Organ Classes (SOC);

ii. using CIOMS frequencies (usually uncommon, rare); and

c) a post-marketing section of adverse reactions by system organ class using CIOMS frequencies (usually rare or very rare).

Source

Australian Government, Department of Health and Aging, TGA - Form for providing Product Information. https://www.tga.gov.au/resources/resource/guidance/form-providing-product-information

KNOWN DEFICIENCIES – ASTRAZENECA PRODUCT INFORMATION

67. Prior to and at the time of the AstraZeneca Approval, the TGA and the TGA Respondents approved, authorised and published the AstraZeneca Product Information for the purported purposes of informing the Australian public, which excluded the following

AstraZeneca Vaccine related adverse events already disclosed in the data provided by AstraZeneca to the TGA and the TGA Respondents at that time **("the Known AstraZeneca Product Information Exclusions")**:

a) AstraZeneca reported tremor which was more commonly seen in the AstraZeneca Vaccine group than the control group and which tended to be in the first 7 days;

b) AstraZeneca reported angina:

   i. in 3 cases in the AstraZeneca Vaccine group;

   ii. as not occurring in the control group at all;

   iii. occurring between 16 and 17 days after the AstraZeneca vaccination;

c) AstraZeneca reported a sudden case of:

   i. transverse myelitis in an AstraZeneca recipient;

   ii. multiple sclerosis in an AstraZeneca recipient

d) AstraZeneca reported death in 2 of the AstraZeneca Vaccine group wherein:

   i. 1 reportedly due to fungal pneumonia; and

   ii. 1 reportedly due to malignant neoplasm.

e) AstraZeneca reported clinically meaningful incidence of Vaccine-Associated Enhanced Respiratory Disease in AstraZeneca Vaccine recipients;

f) there was an unusual case of chronic inflammatory demyelinating polyneuropathy in the ongoing US study of the AstraZeneca Vaccine;

g) in disclosing the reporting of "very rare events of demyelinating disorders have

been reported following vaccination with COVID-19 Vaccine AstraZeneca" the TGA and the TGA Respondents:

i. stated that "a causal relationship has not been established";

ii. in disclosing the comparison with controls and information about rates of events such as myelitis, wilfully excluded reference to the fact that the control used was a meningococcal vaccine which has myelitis as a known potential risk.

Source

The AstraZeneca Product Information
The AstraZeneca Clinical Evaluation Report – pg. 20, 44, 47, 48, 49, 51, 54

68. The TGA and the TGA Respondents by reason of the matters pleaded at paragraph 67 herein, engaged in the Known AstraZeneca Product Information Exclusions prior to the AstraZeneca Approval:

a) in obvious breach of the TGA Product Information Requirements;

b) by withholding from the users of the AstraZeneca Vaccine information:

i. essential to establishing informed consent for recipients of the AstraZeneca Vaccine;

ii. reasonably expected by the Australian population to have been disclosed by the TGA and the TGA Respondents;

iii. required by law.

c) where the TGA and the TGA Respondents knew that and in fact the AstraZeneca Product Information would not be in any case likely to be received by patients because:

i. the AstraZeneca Vaccine vials were typically provided in lots of large numbers of 100, with hundreds of doses in each allotment with:

(1) no box; and

(2) no Product Information provided.

Source

The AstraZeneca Product Information

The AstraZeneca Clinical Evaluation Report – pg. 20, 44, 47, 48, 49, 51, 54.

KNOWN DEFICIENCIES – PFIZER PRODUCT INFORMATION

69. Prior to and at the time of the Pfizer Approval, the TGA and the TGA Respondents approved, authorised and published the Pfizer Product Information for the purported purpose of informing the Australian public which excluded the following Pfizer Vaccine related adverse events already disclosed in the data provided by Pfizer at that time **("the Known Pfizer Product Information Exclusions")**:

a) Lymphadenopathy was reported as an adverse event:

i. in 64 participants or 0.3% of the Pfizer Vaccine group:

ii. comprised of:

(1) 54 participants in the younger age group; and

(2) 10 in the older age group.

(3) at a rate of more than 10 times more than the placebo group having 6 reports;

(4) 73% of which were determined by the Respondents' investigator to be causally related to the Pfizer Vaccine;

(5) with a mean duration of 10 days;

(6) 12 of which were ongoing at the time of the data cut-off date;

(7) reported in most instances within 2 to 4 days after vaccination;

b) Hypersensitivity was reported as an adverse event in:

i. two cases in the Pfizer Vaccine Group; and

ii. one case in the placebo group;

c) Drug Hypersensitivity was reported as an adverse event:

i. in six cases in the Pfizer Vaccine Group;

ii. in one case in the placebo group;

iii. causing the TGA and the TGA Respondents to determine and assert that post-market monitoring for hypersensitivity events should be conducted.

d) Bell's Palsy was reported as an adverse event in:

i. four cases in the Pfizer Vaccine Group; and

ii. none in the placebo group.

e) Serious Adverse Events were reported and found by the TGA and the TGA Respondents to be causally related to the Pfizer Vaccine in 3 of the Pfizer Vaccine group to the Pfizer Vaccine, which involved:

i. shoulder injury related to vaccine administration;

ii. ventricular arrhythmia; and

iii. lymphadenopathy;

iv. none of the placebo group to the study intervention;

f) Serious Adverse Events were reported in 12 cases of appendicitis comprised of:

i. 8 in the Pfizer Vaccine Group; and

ii. 4 in the placebo group;

g) 1 other event of lower back pain and bilateral lower extremity pain with radicular paranesthesia was reported in the Pfizer Vaccine group assessed by the investigator as related to the Pfizer Vaccine.

Source

The Pfizer Product Information

The Pfizer Original AUSPAR – pg. 28

70. The TGA and the TGA Respondents by reason of the matters pleaded at paragraph 69 herein, engaged in the Known Pfizer Product Information Exclusions:

a) in obvious breach of the TGA Product Information Requirements;

b) by withholding from the users of the Pfizer Vaccine information:

i. essential to establishing informed consent for recipients of the Pfizer Vaccine;

ii. reasonably expected to have been disclosed by the TGA and the TGA Respondents;

iii. required by law.

c) where the Respondents knew that and in fact the Pfizer Product Information would not be in any case likely to be received by patients because:

i. the Pfizer Vaccine vials were typically provided in lots of large numbers of 100, with hundreds of doses in each allotment with:

(1) no box; and

(2) no Product Information provided.

Source

The Pfizer Product Information

The Pfizer Original AUSPAR – pg. 28.

KNOWN CONSENT FORM DEFICIENCIES

71. The official consent form authored and published by the Department in or about August, 2022 for the purpose of properly informing the Australian population as to matters relevant to the safety, efficacy and risk-benefit of the Vaccines thereby signifying informed consent to receiving the Vaccines **("the Vaccines Consent Form")** stated that:

a) medical experts have studied the Vaccines to make sure they are safe;

b) most side effects of the Vaccines are mild;

c) side effects of the Vaccines may:

i. start on the day of vaccination; and

ii. last for one or two days.

d) the Vaccines may carry rare or unknown side effects;

e) thrombosis with thrombocytopenia syndrome:

i. is a very rare side effect of the AstraZeneca Vaccine;

ii. does not happen at all after the Pfizer Vaccine or Moderna Vaccine.

f) myocarditis and pericarditis (heart inflammation):

i. is a rare risk following vaccination with the Moderna Vaccine, Pfizer Vaccine and AstraZeneca Vaccine;

ii. risk is ranked from highest to lowest as follows:

(1) Moderna Vaccine;

(2) Pfizer Vaccine;

(3) AstraZeneca Vaccine.

Source

Australian Government – "Consent form for COVID-19 vaccination": https://www.health.gov.au/sites/default/files/documents/2022/08/covid-19-vaccination-consent-form-for-covid-19-vaccination-covid-19-vaccination-consent-form.pdf

72. The Vaccines Consent Form:

a) was composed by the Department for the express purpose of informing the reader of the risks associated with the Vaccines to a degree such that consent to receiving the Vaccines would only occur in circumstances of informed consent;

b) was publicly promoted expressly and by inference by the Department as confirming in writing a person's consent to receive one of the Vaccines and providing information therein sufficient for that consent and understanding of the safety risks of the Vaccines;

c) excluded known significant adverse event and risk information;

d) in no way provided information to the reader sufficient for the reader to have been properly informed of the risks of the Vaccines to receive the Vaccines under informed consent;

e) was grossly misleading as to the actual risks of the Vaccines known at the time of publication;

f) it was known to the Respondents at that time that it could be reasonably expected that:

i. the patient would rely upon the Vaccines Consent Form as a source of risk information; and

ii. would not visit the TGA website to find the vaccination AusPAR and associated Product Information in order to review the information themselves to make an informed decision.

Source

Australian Government – "Consent form for COVID-19 vaccination": https://www.health.gov.au/sites/default/files/documents/2022/08/covid-19-vaccination-consent-form-for-covid-19-vaccination-covid-19-vaccination-consent-form.pdf . Pg. 1 - 2 - updated on 29 August, 2022.

The knowledge of the expectation pleaded at sub-paragraphs (f)(i) and (ii) is inferred by reason of the facts pleaded at sub-

paragraphs (a) and (b) herein.

KNOWN SAFETY RISKS - PFIZER APPROVAL FOR 12 YEARS AND OLDER

73. On or about 22 July, 2021 and prior to the Pfizer Adolescent Approval data provided to the TGA and the TGA Respondents by Pfizer, the internal actions of the TGA and the TGA adopted EMA guidelines rationally establishing significant safety and efficacy risks and risk-benefit deficit in the Pfizer Adolescent Vaccine disclosed that:

a) the TGA and the TGA Respondents prior to 15 January, 2021 had determined and asserted that the Pfizer Vaccine was at that time:

i. not proposed for paediatric use; and

ii. not the subject of any specific studies in juvenile animals submitted to or known to the TGA and the TGA Respondents.

b) the TGA and the TGA Respondents on or about 22 July, 2021, determined and asserted to extend the indication for the Pfizer Vaccine to use in children 12 years of age and older, being the Pfizer Adolescent Approval, in circumstances where in truth at that time:

i. the guideline adopted by the TGA being the International Guideline, Juvenile Animals required that:

(1) even if adverse reactions on developing organ(s) can be predicted from adult human or animal data:

a) studies in juvenile animals might be warranted:

i. if there is a need to further address a specific concern; or

ii. to study reversibility or possible aggravation of the expected findings; and

iii. establish safety factors.

b) approval of medicinal products intended for paediatric patients requires a special risk/benefit assessment where the possible effects of the product on the ongoing developmental processes in the age group(s) to be treated are also taken into consideration.

(2) at a minimum, prior to the commencement of studies in a paediatric population, results of studies should be available and obtained from:

a) the core safety pharmacology package;

b) appropriate repeat dose toxicity studies;

c) the standard battery of genotoxicity tests; and

d) relevant parts of the reproductive toxicity test program.

(3) situations which would justify toxicity studies in juvenile animals include, but are not limited to:

a) findings in nonclinical studies that indicate target organ or systemic toxicity relevant for developing systems;

b) possible effects on growth and/or development in the intended age group; or

c) if a pharmacological effect of the test compound will affect developing organ(s).

ii. from prior to, on or about 22 July, 2021 and before the Pfizer Adolescent Approval rationally establishing significant safety, efficacy and risk-benefit issues in respect of the Pfizer Adolescent Vaccine were disclosed in the

totality of data provided by Pfizer:

(1) from the first dose to one month after the second dose of the Pfizer Vaccine Serious Adverse Events reported in adolescents and young adults in the study were:

a) in adolescents:

i. 0.6% in the vaccine group; and

ii. 0.2% in the placebo group;

b) in young adults:

i. 1.7% in the vaccine group;

ii. 0.5% in the placebo group

c) in one adolescent in the Pfizer Vaccine group reported as developing grade 4 pyrexia of 40.4°C:

i. two days after Dose 1;

ii. with temperature returning to normal on Day 4;

iii. causing the participant to withdraw from the study;

iv. determined by Pfizer to be related to the Pfizer Vaccine;

v. which is by definition serious; and

vi. met the stopping rules for the Pfizer Child Trial.

d) two participants in the adolescent group had life threatening Adverse

Events that:

i. occurred following the Pfizer Vaccine;

ii. occurred after they turned 16 years of age;

iii. because they turned 16 years of age during the study, they:

1. were unblinded by Pfizer;

2. were not included in analyses of blinded data;

3. were no longer reported upon or followed up by Pfizer;

4. were not the subject of further inquiry by the TGA and the TGA Respondents or the provision of any further data.

iv. were thereby evidence of two adolescent trial participants who suffered life threatening Adverse Events from the Pfizer Vaccine which were never pursued, publicly disclosed or reported by the TGA or the TGA Respondents.

(2) it was reported by Pfizer that Pfizer's safety surveillance and risk management team:

a) conducted a review of spontaneous reports of myocarditis and pericarditis;

b) provided details of the review of spontaneous reports of myocarditis and pericarditis to the TGA and the TGA Respondents in the April monthly summary safety report;

c) reported an overall conclusion purportedly based on the totality of

the available data that there was not enough evidence to currently support a causal association between the vaccine and myocarditis and pericarditis;

d) the TGA and the TGA Respondents accepted and adopted Pfizer's assertions as to the spontaneous reports of myocarditis and pericarditis in adolescent subjects:

i. on the erroneous and irrational bases that:

1. while a plausible mechanism for a causal association of myocarditis and pericarditis is not yet clear;

2. it may be postulated that myocarditis and pericarditis could be a systemic inflammatory reaction due to an immune response to the Pfizer Vaccine.

ii. in circumstances where in fact:

1. the Pfizer Vaccine in this age group should not have been approved when there was suspicion in the trials;

2. a clear sign of risk causal to the Pfizer Vaccine was dismissed without rational basis;

3. risk of myocarditis to adolescents and young adults outweigh the known risk of Covid infection in that age group;

4. thereby, risk–benefit analysis was ignored entirely by the TGA and the TGA Respondents and was never conducted in any proper form prior to the Pfizer Adolescent Approval.

(3) Pfizer Vaccine efficacy for adolescents:

a) was never a pre-specified endpoint in testing of the Pfizer Adolescent Vaccine;

b) was determined and adopted by the TGA and the TGA Respondents by improperly and irrationally using a data cut-off date of 13 March 2021 which was:

i. based on the immunogenicity and safety assessment; and

ii. not based on the number of COVID-19 cases accrued for the adolescent group.

(4) the TGA and the TGA Respondents had asserted as determining that the data submitted by Pfizer had the following limitations:

a) at that time of the Pfizer Adolescent Approval the following remained entirely unknown:

i. the long-term efficacy of the Pfizer Vaccine;

ii. the safety of the Pfizer Vaccine;

iii. the efficacy of the Pfizer Vaccine against asymptomatic infection;

iv. the efficacy of the Pfizer Vaccine against viral transmission.

b) the number of adolescents in the study was not sufficient to detect vary rare adverse events in recipients of the Pfizer Vaccine;

c) no data was available or made available in respect of co-administration of the Pfizer Vaccine with quadrivalent seasonal

influenza vaccine;

d) safety and efficacy of the Pfizer Vaccine for use in adolescents with immunodeficient status and high health risks were not assessed;

e) the efficacy of the Pfizer Vaccine against variants of concern was not assessed;

f) even apparently mild episodes of myocarditis may lead to long term sequelae such as arrhythmias.

iii. it was obviously and rationally established thereby that:

(1) the Pfizer Vaccine was demonstrably unsafe for use by Adolescents;

(2) that the Pfizer Vaccine was in no manner demonstrated to be, for use by Adolescents;

a) safe;

b) effective;

c) displaying a positive risk-benefit profile.

Source

The Pfizer Nonclinical Evaluation Report – pg. 14.

The Pfizer 12-15 Year Old Extension AUSPAR - Pg. 23, 26, 29, 32.

European Medicines Agency - 24 January 2008 Doc. Ref. EMEA/CHMP/SWP/169215/2005 Committee For Human Medicinal Products (CHMP) – "Guideline On The Need For Non-Clinical Testing In Juvenile Animals Of Pharmaceuticals

For Paediatric Indications" Guideline. Pg. 3. https://web.archive.org.au/awa/20220816022753mp_/https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-need-non-clinical-testing-juvenile-animals-pharmaceuticals-paediatric-indications_en.pdf

KNOWN SAFETY RISKS - PFIZER APPROVAL FOR 5-11 YEAR OLD CHILDREN

74. On or about 7 December, 2021 and the Pfizer Child Approval the data provided by Pfizer to the TGA and the TGA Respondents and internal actions of the TGA and the TGA Respondents rationally establishing significant safety and efficacy risks and risk-benefit deficit in the Pfizer Child Vaccine disclosed that:

a) the TGA and the TGA Respondents had asserted to having determined that children:

i. were as likely to be infected with the Virus as adults;

ii. are in most cases asymptomatic when infected with the Virus;

iii. when symptomatically infected by the Virus, have symptoms which are usually mild;

b) at the time of approval of the Pfizer Child Approval, reported deaths per reported confirmed cases of Covid was:

i. 0 out of 10,467 deaths (0.00%);

ii. zero.

c) transmission of the Virus was not tested in any clinical trial for the Pfizer Child Vaccine;

d) the Pfizer Child Trial data disclosed:

i. a total of only 48 participants which:

(1) were assigned to the Pfizer 5 Year Old Vaccine group;

(2) were administered doses of 10 μg, 20 μg, and 30 μg of BNT162b2 in numbers of 16 each;

(3) received 2 doses of Comirnaty vaccine; and

(4) completed the 1-month follow up.

ii. due to observed reactogenicity in the initial 4 out of 16 participants of the assigned 30 μg dose level group after receiving both doses:

(1) a decision was made by Pfizer for the remaining 12 participants in that dose level group:

a) that they would receive the same dose that was to be selected for Phase II/III (10 μg) at Dose 2; and

b) the 30 μg dose level was discontinued completely in the study.

iii. phase I immunogenicity results in the clinical study report were not presented to the TGA and the TGA Respondents for the 30 μg dose level group;

iv. participants assigned to the 30 μg dose level are included in safety analyses, but safety results are reported separately for those who received different dose levels at Dose 2.

e) the following factual matters rationally establishing the absence of any logical or proper risk-benefit assessment undertaken by the TGA or the TGA Respondents or any rational determination of positive risk-benefit profile in respect of the Pfizer Child Vaccine:

i. the Risk Management Plan report released by Pfizer in February 2022 reviewed all available US COVID-19 cases and deaths to 14 August 2021 showing incident of death in children who tested positive to COVID-19 in ages 0-4 and 5-11 years was listed as "<0.1%" for each group;

ii. the mortality rate in children hospitalised with COVID-19 of less than 0.18%, which is less than the mortality rate seen in children from seasonal influenza;

iii. 7% of children 0 to 18 years being asymptomatic upon infection;

iv. no children died and 4 aged 5-11 were admitted to Intensive Care Units (ICU);

v. the Inflated Covid Deaths and inflated hospitalisation figures of which:

(1) at least some of those cases are often admitted for serious co-morbidities but coincidentally tested positive for Covid;

(2) thereby such information is rendered unreliable.

vi. the risk of COVID-19 death in an otherwise healthy 5-11 year-old is virtually or statistically nil;

vii. there was a mortality rate of zero from Covid among children without a pre-existing medical condition;

viii. thereby even a minute risk in the Pfizer Child Vaccine rendered the risk-benefit analysis of the Pfizer Child Vaccines as unbalanced and objectively negative.

f) the TGA and the TGA Respondents had determined and asserted that there were no:

i. adverse events of special interest including:

(1) thrombocytopenic events;

(2) thromboembolic or intravascular coagulation events;

(3) autoimmune or demyelination events;

(4) meningitis;

(5) encephalitis;

(6) neuritis;

(7) Kawasaki disease;

(8) multisystem inflammatory syndrome in children; or

(9) acute respiratory distress syndrome.

ii. severe Covid cases;

iii. potential vaccine-associated enhanced respiratory disease; or

iv. severe or serious related rash;

v. adverse events reported as pleaded at (1) to (6) above in circumstances where in truth:

(1) at the time of those determinations and assertions, being 7 December, 2021, there were published Adverse Events in Australian young people aged under 18 years reported on DAEN related to the Vaccines which disclosed the following:

a) 399 reports of the above Adverse Events of Special Interest related to the Vaccines;

b) 2 cases where death was a reported outcome;

c) 152 cases of pericarditis;

d) 142 cases of myocarditis, 1 case of which reported death as the outcome;

e) 56 cases of myopericarditis;

f) 16 cases of anaphylactic reaction;

g) 12 cases of appendicitis;

h) 6 cases of thrombocytopenia;

i) 5 cases of Bell's Palsy;

j) 3 cases of demyelination;

k) 2 cases of immune thrombocytopenia;

l) 2 cases of multisystem inflammatory syndrome in children;

m) 2 cases of Guillain-Barre syndrome;

n) 1 cases of multi-organ dysfunction syndrome.

vi. had any rational and logical risk-benefit assessment been conducted by the TGA and the TGA Respondents, the Pfizer Child Vaccine could never have been rationally considered appropriate for use in the Australian population as:

(1) the risk of Severe Adverse Events from the Pfizer Child Vaccine substantially exceeded the benefit.

g) it was obviously and rationally established based upon the totality of matters pleaded at (a) to (h) above that:

i. the clinical data received provided no basis for assessment as to safety, efficacy or risk-benefit of the Pfizer Child Vaccine;

ii. the Pfizer Child Vaccine was demonstrably unsafe for use by children;

iii. that the Pfizer Child Vaccine was in no manner demonstrated to be, for use by Adolescents;

(1) safe;

(2) effective;

(3) displaying a positive risk-benefit profile.

iv. no risk-benefit analysis was undertaken by the TGA or the TGA Respondents;

v. risk-benefit analysis in respect of the Pfizer Child Vaccine displayed a significantly higher risk than benefit to children from the Pfizer Child Vaccine.

Source

The Pfizer 5-11 Year Old Extension AUSPAR - Pg. 10, 11, 20, 53.

The Pfizer Risk Management Plan – dated February 2022 - US COVID-19 cases and deaths to 14 August 2021 - s. 6.6,

7.1, 7.2, 7.3.

The DAEN data obtained from:
https://daen.tga.gov.au/medicines-search

PART C – RESPONDENTS' KNOWLEDGE OF VACCINES' SAFETY RISKS AND LACK OF EFFICACY – POST-APPROVAL

KNOWN RESTRICTION OF ADVICES REGARDING VACCINES - AHPRA

75. On or about 9 March, 2021, the Australian Health Practitioner Regulation Agency produced and forwarded a widely published statement to every or nearly every registered health practitioner in Australia, which contained, *inter alia*, the following admonitions **("the AHPRA Covid Vaccine Statement of Prohibited Advices")**:

a) any promotion of anti-vaccination statements or health advice which contradicts the best available scientific evidence or seeks to actively undermine the national immunisation campaign (including via social media) is not supported by National Boards and may be in breach of the codes of conduct and subject to investigation and possible regulatory action;

b) concerns about the conduct or practice of a health practitioner can be reported to AHPRA via the AHPRA concerns submission portal;

c) National Boards can consider whether the practitioner has breached their professional obligations and will treat these matters seriously and in accordance with established procedure;

d) which limited the independent advices of medical practitioners Australia wide in respect of the safety, efficacy and risk-benefit of injections with the Vaccines such that:

i. any independent advice must only have accorded with ongoing promotion and encouragement to all patients to take the Vaccines without further

consideration as only accords with AHPRA's and the Respondents' official position;

ii. the medical practitioners independently formed views as a medical professional were excluded from disclosure to any patient where it conflicted with AHPRA's and the Respondents' promotion of the Vaccines;

iii. these limitations were an obvious abrogation of the independent doctor-patient relationship such that medical practitioners were bound to advise, where arising, in direct conflict with their own professional opinion;

iv. the misconduct of the TGA and the TGA Respondents in regulating the Vaccines were unable to be rectified or controverted by the independent medical practitioner whom were required to adopt AHPRA's and the Respondents' view solely.

Source

AHPRA Position Statement on Covid-19 Vaccination dated 9 March, 2021 and distributed to every, or nearly every Australian registered health practitioner and health student.
https://www.ahpra.gov.au/documents/default.aspx?record=WD21%2f30751&dbid=AP&chksum=zrOQ56xJaaLbasNxLDyqMA%3d%3d

KNOWN RESTRICTION OF VACCINES ADVICES

76. In or about August, 2021, the TGA, the TGA Respondents and AHPRA jointly declared in a public statement to the Australian public *inter alia* that **("the TGA Covid Vaccine Statement of Prohibited Advices")**:

a) for general information about COVID-19 and vaccines, the Commonwealth and state and territory Department of Health websites are the most accurate and up to date sources of information;

b) the public can talk to their GP about the COVID-19 vaccines and what would be best for them in their circumstances;

c) the public can be safe in the knowledge that registered health practitioners must meet national standards Registered health practitioners and thereby have a professional obligation when providing care in person or sharing information online to only share information that is:

   i) evidence-based;

   ii) in line with the best available Government health advice; and

   iii) is consistent with public health campaigns such as the Australian COVID-19 Vaccination Policy;

d) action could be taken against a practitioner that doesn't meet those standards;

e) the public must not be swayed by other opinions:

   i. by inference, doing so would put the health of that individual and others around that individual at risk;

f) reliable sources of information on COVID-19 and vaccines in Australia were solely the State and Commonwealth regulatory authorities, including the Department;

g) the statements made should be relied upon as true by the Australian public, in circumstances wherein those statements rationally and obviously:

   i) limited the independent advices of medical practitioners Australia wide in respect of the safety, efficacy and risk-benefit of injection with the Vaccines such that:

      (1) any independent advice must only have accorded with ongoing promotion and encouragement to all patients to take the Vaccines

without further consideration as only accords with the Respondents' official public position;

(2) a medical practitioners' independently formed views as a medical professional were excluded from disclosure to any patient where it conflicted with the Respondents' promotion of the Vaccines;

(3) were an obvious abrogation of the independent doctor-patient relationship such that medical practitioners were bound to advise, where arising, in direct conflict with their own professional opinion;

(4) the misconduct of the TGA and the TGA Respondents in regulating the Vaccines were unable to be rectified or controverted by the independent medical practitioners whom were required to adopt the Respondents' view solely.

Source

"Joint statement on COVID-19 and COVID-19 vaccines from nation's regulators". 30 August, 2021. https://www.tga.gov.au/news/media-releases/joint-statement-covid-19-and-covid-19-vaccines-nations-regulators

77. By reason of the factual matters pleaded at paragraphs 75 and 76 above:

a) AHPRA at that time of publication of the TGA Covid Vaccine Statement of Prohibited Advices had already provided the AHPRA Covid Vaccine Statement of Prohibited Advices to all or almost all Australian Health Practitioners preventing them from conveying any information that would:

i. undermine the National Immunisation Campaign; irrespective of whether that information:

(1) was the best available scientific evidence;

(2) was relevant to the patient;

(3) was in the best interests of the patient's health;

(4) was essential for the patient to provide proper informed consent.

b) such coercion would have resulted in Australian health practitioners being:

i. unable to provide all relevant information to their patients in order to obtain proper informed consent from their patients to vaccination;

ii. reluctant to discuss openly with their patients and peers observed AEFI;

iii. reluctant to report formally observed AEFI.

Source

AHPRA Position Statement on Covid-19 Vaccination dated 9 March, 2021 and distributed to every, or almost every Australian registered health practitioner and health student.

KNOWN CORRUPTION OF LONGER TERM STUDY DATA BY SPONSORS

78. Within 2 weeks of the Pfizer Approval Pfizer disclosed through provided data to the TGA and the TGA Respondents that the ongoing Pfizer Clinical Study was producing corrupted and unreliable longer term data rationally establishing safety risks in the Pfizer Vaccine by disclosing that **("the Pfizer Longer Term Trial Corruption")**:

a) Pfizer commenced offering the Pfizer Vaccine to placebo recipients:

i) within 2 weeks of the Approvals;

ii) despite the Pfizer Clinical Trial Protocol stipulating a follow-up period of two years;

iii) thereby:

(1) eliminating follow-up after a few months of administration;

(2) eliminating the ongoing potential for longer term baseline comparison between Pfizer Vaccine and placebo recipients;

(3) ending the period of randomized follow-up;

(4) limiting understanding of the Pfizer Vaccine's benefits and harms;

(5) rendering unknown whether the Pfizer Vaccine can reduce the risk of serious Covid disease;

(6) precluding any further ability to compare adverse events in the Pfizer Vaccine recipients to the placebo recipients.

Source

the Vaccines Clinical Trial Data

KNOWN PFIZER CLINICAL TRIAL FRAUD EVIDENCE

79. On or about 10 November, 2021 reports were widely and globally published rationally establishing the unreliability of the data provided to the TGA and the TGA Respondents by Pfizer that:

a) a senior executive at a Pfizer Testing Site had made allegations relating to the Pfizer Clinical Trial of the Pfizer Vaccine that **("the Reported Pfizer Trial Fraud")**:

i) data was falsified;

ii) integrity of the data was corrupted;

iii) patients were unblended in the midst of the trial;

iv) the vaccination staff were inadequately trained;

v) protocol deviations were not reported;

vi) trial specimens were mis-labelled.

b) the circumstances of the Reported Pfizer Trial Fraud are relevantly that **("the Reported Pfizer Trial Fraud Circumstances")**:

i) the Reported Pfizer Trial Fraud were reported to have been supported by produced:

(1) internal company documents;

(2) photos;

(3) audio recordings;

(4) emails; and

(5) the corroborating oral evidence of:

a) a high-level executive at the relevant facility;

b) another two employees at the facility.

c) the regulatory body the FDA had not at the time of the TGA Pfizer Fraud Response (or at any time since) inspected the site notwithstanding a complaint having been made in respect of the Data Fraud Allegations over 1 year earlier on 25 September, 2020;

d) the subsequent trial data produced by Pfizer including data to which the Data Fraud Allegations related were accepted by the TGA and the TGA Respondents as accurate and reliable;

e) in response to the Reported Pfizer Trial Fraud, the TGA and the TGA Respondents claimed **("the TGA Pfizer Fraud Response")**:

i) that the TGA was seeking additional information from Pfizer in relation to the Reported Pfizer Trial Fraud;

ii) notwithstanding the Reported Pfizer Trial Fraud that:

(1) the Pfizer Vaccine is highly safe and effective; and

(2) Australians should not be concerned about the allegations of fraud

and other matters raised in the Reported Pfizer Trial Fraud;

(3) the benefit of the Vaccines are:

a) clear; and

b) not in dispute;

(4) all eligible Australians who are not yet vaccinated should be vaccinated with one of the Vaccines as soon as possible;

(5) given that the Reported Pfizer Trial Fraud only pertain to 2 per cent of the trial population, the overall results are not expected to be impacted;

iii) the TGA Pfizer Fraud Response occurred in circumstances where in truth, the TGA and the TGA Respondents:

(1) had not received at the time, any information as to the Reported Pfizer Trial Fraud from Pfizer or the FDA;

(2) have not at that time nor at any time since:

a) properly or reasonably investigated the extent and impact of the Reported Pfizer Trial Fraud;

b) finally determined the veracity of the Reported Pfizer Trial Fraud allegations;

c) inspected the facility in question or the operations of that facility.

Source

'BMJ Investigation – Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial". BMJ 2021; 375 (Published 02 November, 2021).

KNOWN AUSTRALIAN REPORTING DATABASE UNDERREPORTED ADVERSE EVENTS

80. At all material times from the time of the Approvals widely and globally published scientifically known data and conclusions rationally establishing the unreliability and underreporting of the DAEN reporting system including reported adverse events rate in recipients of the Vaccines disclosed the following **("the Known DAEN Structural Deficiencies")**:

a) the DAEN is a passive reporting system that is managed by the TGA in respect of reported suspected adverse events arising from the use of medicines, biological therapies and vaccines including the Vaccines;

b) such passive systems as the DAEN have been well established scientifically prior to the Approvals as to generally result in a rate of underreporting of adverse events:

i. of 95-98%;

ii. by a factor of 31.

c) reporting to passive surveillance systems including the DAEN is unsolicited;

d) doctors were dissuaded from reporting Covid-related adverse events by reason of the AHPRA Covid Vaccine Statement of Prohibited Advices and the TGA Covid Vaccine Statement of Prohibited Advices;

e) the data from the active reporting system of AusVaxSafety known to the Respondents at all relevant times as follows disclosed the following exponentially higher and more accurate reported rate of adverse events associated with the use of the Vaccines than that disclosed in the DAEN:

i. as at 31 December, 2021:

(1) the DAEN reports of Adverse Events following the Vaccines were:

a) 42,598,706 total vaccine doses administered nationally;

b) 102,763 reports of adverse events;

c) 0.24% reporting rate of adverse events.

(2) AusVaxSafety reports of Adverse Events following the Vaccines were:

a) 5,108,600 safety surveys completed;

b) 49% reported at least 1 adverse event;

(3) an indicated approximate 200-fold underreporting rate of suspected adverse events associated with the Vaccines.

Source

Published studies detailing known underreporting in passive surveillance systems include:

Electronic Support for Public Health–Vaccine Adverse Event Reporting System - 12/01/07 - 09/30/10, Lazarus, Ross, MBBS, MPH, MMed, GDCompSci, Harvard Pilgrim Health Care, Inc – see pdf Report at: https://www.icandecide.org/wp-content/uploads/2020/12/Lazarus-report.pdf

"Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System?". Rose, J. The Institute for Pure and Applied Knowledge. Vol 3:100-129, Oct. 2021: https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_0490c898f7514

df4b6fbc5935da07322.pdf

Registered health practitioners and students: What you need to know about the COVID-19 vaccine rollout.
https://www.ahpra.gov.au/News/2021-03-09-vaccination-statement.aspx

AHPRA Position Statement on Covid-19 Vaccination dated 9 March, 2021 and distributed to every Australian registered health practitioner and health student.

Australian Government COVID-19 Vaccine Roll-out - 31 December 2021
https://www.health.gov.au/sites/default/files/documents/2021/12/covid-19-vaccine-rollout-update-31-december-2021.pdf

The DAEN database
https://daen.tga.gov.au/medicines-search/

AuxVaxSafety
https://ausvaxsafety.org.au/our-work/covid-19-vaccine-safety-surveillance

KNOWN EARLY STUDIES AND DATA DISCLOSING TRUE LACK OF VACCINES EFFICACY AND SAFETY

81. From July, 2021, widely and globally published scientific studies and world data from highly vaccinated populations continuously and rationally established from that time the following:

a) an utter lack of material or lasting efficacy in preventing Covid, whether symptomatic or otherwise;

b) negative efficacy of the Vaccines in respect of the Omicron strain, that is, a person

vaccinated with the Vaccines were up to 800% more likely to suffer from symptomatic Covid infection then an unvaccinated person;

c) that the greater the number of doses received of the Vaccines, the more one becomes susceptible to COVID-19 infection;

d) countries with higher vaccination rates with the Vaccines have higher proportionate numbers of Covid cases than those with lower vaccination rates with the Vaccines; and

e) that as vaccination of a population with the Vaccines increased, there were:

   i. more COVID-19 cases per million; and

   ii. more deaths per million associated with COVID-19.

f) the unprecedented number of over 1,000 scientific studies speaking to the evident side effects arising from injection with the Vaccines;

g) that the vaccinated were showing similar very high viral loads compared to the unvaccinated and the vaccinated were therefore equally as infectious;

h) vaccinated people infected by variants such as the Delta variant who became symptomatic:

   i. were equally as infectious as symptomatic unvaccinated cases; and

   ii. contributed to the spread of COVID even in highly vaccinated communities;

i) the European Union's drug regulator warned that the boosters of the Vaccines risked adverse effects upon the immune system and may not be warranted;

j) mass vaccination campaigns with the Vaccines had failed.

Source

Published scientific studies at that time based upon reported world data included:

"Resurgence of SARS-CoV-2 infection in a highly vaccinated health system workforce." Keehner, J et al. 2021. New England Journal Medicine 385, 1330-1332. doi: 10.1056/NEJMc2112981; https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/

"An observational study of breakthrough SARS-CoV-2 Delta variant infections among vaccinated healthcare workers in Vietnam." Chau, G.V.V et al. 2021. EClinicalMedicine 41, 101143. https://doi.org/10.1016/j.eclinm.2021.101143.

"An outbreak caused by the SARS-CoV-2 Delta variant (B.1.617.2) in a secondary care hospital in Finland". Hetemäki Iivo, et al. May 2021. Euro Surveill. 2021;26(30):pii=2100636. https://doi.org/10.2807/1560-7917.ES.2021.26.30.2100636

"Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel". Shitrit, P et al. 2021. July 2021. Eurosurveillance, 26, 2100822 (2021)

"Patient betrayal: The Corruption of healthcare, informed consent and the physician – patient relationship." Thorp J.A et al. 2022. The Gaxette of Medical Sciences. https://www.doi.org/10.46766/tjegms

"New Studies Show that the COVID Vaccines Damage your Immune System, Likely Permanently," Kirsch, S. 2021. Steve

Kirsch's Newsletter, Dec. 24, 2021, https://stevekirsch.substack.com/p/new-stu-dy-shows-vaccines-must-be

"Pfizer CEO says Two Covid Vaccine Doses Aren't Enough for Omicron," Kirsch S. 2022. Steve Kirsch's Newsletter, Jan. 10, 2022, https://stevekirsch.subs-tack.com/p/pfizer-ceo-says-two-covid-vaccine

"Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States". Subramanian, S.V., Kumar, A. 2021. European Journal of Epidemiology. https://doi.org/10.1007/s10654-021-00808-7

"Worldwide Bayesian Causal Impact Analysis of Vaccine Administration on Deaths and Cases Associated with COVID-19: A Big Data Analysis of 145 Countries," Ritchie, H et al. Nov 2021 https://vector-news.github.io/editorials/CausalAnalysisReport_html.html

"Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2 delta variant". Riemersma, K et al. 2021. https://doi.org/10.1101/2021.07.31.21261387

"Viral Load Among Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups When Infected with SARS-CoV-2 Delta Variant." Acharya C.B et al. March 2022. Open Forum Infectious Diseases. Vol 9, Issue 5. https://doi.org/10.1093/ofid/ofac135

"Predominance of antibody-resistant SARS-CoV-2 variants in

vaccine breakthrough cases from the San Francisco Bay Area, California." Servellita, V et al. 2022. Nat Microbiol 7, 277–288.
https://doi.org/10.1038/s41564-021-01041-4

"EU Drug Regulator Expresses Doubt on Need for Fourth Booster Dose," Jan. 11, 2022
https://www.reuters.com/business/healthcare-pharmaceuticals/eu-drug-regulator-says-more-data--needed-impact-omicron-vaccines-2022-01-11/

"Top Israeli Immunologist Criticizes Pandemic Response in Open Letter," Kirsch S. Jan, 2022, Steve Kirsch's Newsletter
https://stevekirsch.substack.com/p/top-israeli-immunologist--criticizes?r=15hae6&utm_campaign=post&utm_medium=email

KNOWN EARLY PROVEN INEFFICACY OF THE VACCINES – AUSTRALIAN DATA

82. The Australian Bureau of Statistics **("the ABS")** published and reported in Australia the following data on 31 March, 2023 as to reported deaths from or with Covid and the concurrent injury and deaths being reported to the DAEN and AusVaxSafety as caused by the Vaccines after the Approvals rationally establishing the negative risk-benefit of the Vaccines at that time, which disclosed that:

a) the following numbers of deaths associated with Covid were reported in the respective year:

i. 2020: 906 deaths;

ii. 2021: 1,351 deaths;

iii. 2022: 10,095 deaths.

b) concurrent injury and deaths caused by the Vaccines reported:

i. to the DAEN of approximately 135,000 Adverse Events from the Approvals until the end of 2022 published by the TGA and the TGA Respondents;

ii. to AusVaxSafety of Adverse Events associated with the Vaccines reported in 49% of Vaccines recipients, with 1.2% of recipients requiring medical attendance or hospitalisation following Vaccination with the Vaccines;

c) beginning in 2021 the reported data disclosed that:

i. the proportions of hospitalisations and deaths are as high or higher among vaccinated than among unvaccinated people;

ii. there was an overall low benefit from vaccination based upon the data that:

(1) there were very low reported Infection Fatality Rates for individuals under 70 years of age;

(2) the ABS mortality data detailed a 1,114% increase in Covid;

(3) deaths in 2022 when 96% of the Australian adult population was vaccinated, as compared to 2020 which was prior to the Vaccine rollout commencing in Australia.

Source

The ABS produced "Covid-19 Mortality in Australia: Deaths registered until 28 February 2023".
https://www.abs.gov.au/articles/covid-19-mortality-australia-deaths-registered-until-28-february-2023

The DAEN database
https://daen.tga.gov.au/medicines-search/

AuxVaxSafety
https://ausvaxsafety.org.au/our-work/covid-19-vaccine-safety-surveillance

83. From at June, 2021 widely and globally published scientific studies undertaken upon globally reported and published data rationally establishing the Vaccines' lack of prevention of Covid infection, transmission, serious disease and death disclosed that:

a) the Vaccines do not prevent:

i) infection with the Virus; or

ii) person to person spread or transmission of the Virus;

iii) serious infection from Covid;

iv) death from Covid.

b) such data accruing in circumstances where the known factual matters before the Approvals disclosed that:

i) the Vaccines were not clinically tested to prevent:

(1) infection with the Virus; or

(2) person to person spread or transmission of the Virus;

(3) serious infection from Covid;

(4) death from Covid.

ii) the Vaccines, according to their respective Product Information disclosure sheets approved, authorised and published by the TGA and the TGA

Respondents for use and publication to the Australian public, were at no time indicated to prevent:

(1) infection with the Virus; or

(2) person to person spread or transmission of the Virus;

(3) serious infection from Covid;

(4) death from Covid.

iii) infection with the Virus occurs through airborne infection of viral particles entering via the mucosa of the nose;

iv) the Vaccines:

(1) do not induce mucosal immunity;

(2) do not affect the viral load in the nasal mucosa of an Infected Person;

(3) instead:

a) seek to induce blood-borne immunity;

b) are thereby wholly ineffective in countering organisms entering and multiplying in the mucosal tract;

(4) thereby from the time of the Approvals never prevented nor were ever tested, known, intended or expected to:

a) infection with the Virus; or

b) person to person spread or transmission of the Virus.

Source

Widely and globally published studies included:

"Correlation between 3790 Quantitative Polymerase Chain Reaction-Positives Samples and Positive Cell Cultures, Including 1941 Severe Acute Respiratory Syndrome Coronavirus 2 Isolates Clinical Infectious Diseases" Jaafar, R. et al (2020), Volume 72, Issue 11. https://pubmed.ncbi.nlm.nih.gov/32986798/

"Breakthrough infections with SARS-CoV-2 omicron despite mRNA vaccine booster dose". Kuhlmann, C. 2022. The Lancet Correspondence. Volume 399, Issue 10325, P625-626. https://doi.org/10.1016/S0140-6736(22)00090-3

"Transmissibility of SARS-CoV-2 among fully vaccinated individuals". Franco-Paredes, C. 2022. The Lancet Infectious Diseases Correspondence. Volume 22, Issue 1, P16. https://doi.org/10.1016/S1473-3099(21)00768-4

"COVID-19: stigmatising the unvaccinated is not justified". Kampf, G. (2021) The Lancet. Volume 398, Issue 10314, P1871. https://doi.org/10.1016/S0140-6736(21)02243-1

"Outbreak of SARS-CoV-2 infections, including COVID-19 vaccine breakthrough infections, associated with large public gatherings— Barnstable County, Massachusetts". Brown, CM et al (July 2021) CDC MMWR Morb Mortal Wkly Rep 2021;70: 1059–62. https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm

"Shedding of Infectious SARS-CoV-2 Despite Vaccination" Riemersma, KK et al. 2022. PLOS Pathogens. https://doi.org/10.1371/journal.ppat.1010876

KNOWN POST-APPROVAL VACCINES INEFFICACY DATA

84. From early 2022 the widely and globally published scientific studies and publicly available reported data of public health sources in the US, Australia, Denmark, Israel and the UK disclosed and rationally established at that time that:

a) the protective efficacy of the Vaccines had materially waned;

b) the Vaccines were displaying negative efficacy in that:

i. COVID-19 vaccination commenced in Australia early in 2021 and reached 91.4% for "fully vaccinated" individuals aged 16 years and over in December, 2021;

ii. the absolute rate of new infection Cases of Covid peaked in Australia and Worldwide in the period of December 2021 to July 2022;

iii. vaccinated persons were at a higher risk by the Omicron Strain and sub-variants of the Omicron Strain prevalent in the Australian and worldwide population at that time;

iv. the Vaccines effectiveness has been and remains negative since at least December 20, 2021 as those vaccinated persons were and remain:

(1) in publicly available data demonstrably and materially overrepresented proportionally in reported:

a) new cases of Covid;

b) new hospitalisations due to Covid;

c) deaths due to Covid.

(2) at a higher risk than Unvaccinated Persons of:

a) new cases of Covid;

b) new hospitalisations due to Covid;

c) deaths due to Covid.

(3) vaccination with the Vaccines leads to a diminished ability to protect from infection by the newer variants.

Source

Widely and globally published scientific studies and data included:

"Increasing SARS-CoV-2 cases, hospitalizations and deaths among the vaccinated elderly populations during the Omicron (B.1.1.529) variant surge in UK". Emani, V et al. 2022. medRixiV preprint https://www.medrxiv.org/content/10.1101/2022.06.28.22276926v2

"Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination". Roltgen, K et al. March 2022. Cell 185,1025-1040 https://doi.org/10.1016/j.cell.2022.01.018

Our World In Data – Coronavirus Pandemic: Explore the Global Situation https://ourworldindata.org/coronavirus#explore-the-global-situation

KNOWN INEFFICACY IN CHILDREN

85. From January, 2022 it was widely and globally published in scientific study and reported that:

a) the Swedish Health Agency reversed their recommendation on the administration of COVID Vaccines to adolescent children 5-11 on the basis that the demonstrated benefits did not outweigh the risks of vaccination with the Vaccines;

b) children were at a significantly lower risk than adults of developing Covid by infection from the Virus.

Source

Sweden decides against recommending COVID vaccines for kids aged 5-11 (27 January 2022) Reuters https://www.reuters.com/world/europe/sweden-decides-against-recommending-covid-vaccines-kids-aged-5-12-2022-01-27/

"Pre-activated antiviral innate immunity in the upper airways controls early SARS-CoV-2 infection in children." Loske, J. et al. March 2022. Nature Biotechnology: Vol 40, 319-324. https://www.nature.com/articles/s41587-021-01037-9

KNOWN DECREASING EFFICACY WITH EACH INJECTION

86. From December, 2022, widely and globally published data and scientific studies had rationally established and thereby disclosed that:

a) the Pfizer Vaccine provided decreasing protection against Covid with every dose of the Pfizer Vaccine;

b) the greater the number of Vaccine doses previously received the higher the risk of COVID-19;

c) the more recent the last prior COVID-19 episode was, the lower the risk of reinfection with the Virus;

d) previous infection with Covid provides lasting naturally acquired immunity;

e) any immunity afforded by the Vaccines wanes with increasing number of doses therefore indicating against any justification for booster doses to be administered;

f) by February 2022, prior Covid infection had occurred in (CDC Study):

(1) 64% of the 18-64 age group population the US; and

(2) 75% of children and adolescents;

(3) almost half of the infections that occurred were:

a) between December 2021 and February 2022;

b) predominantly Omicron BA.1/BA.2 lineage infections.

g) a substantial proportion of individuals may be unlikely to derive substantial benefit from ongoing vaccination with the Vaccines or booster doses of the Vaccines.

Source

Widely and globally published data and scientific studies included:

"Effectiveness of the Coronavirus Disease 2019 (COVID-19) Bivalent Vaccine" Shrestha, N et al. December, 2022. https://doi.org/10.1101/2022.12.17.22283625

"Seroprevalence of Infection-Induced SARS-CoV-2

Antibodies — United States, September 2021–February 2022". Clarke, K. 2022.

MMWR Morb Mortal Weekly Report 71. https://www.cdc.gov/mmwr/volumes/71/wr/mm7117e3.htm

KNOWN LACK OF EFFICACY – FOURTH DOSE OF mRNA VACCINES

87. From February 2022 widely and globally published data and scientific studies had rationally established and thereby disclosed that in respect of those receiving a fourth dose of the Pfizer or Moderna Vaccines that:

a) breakthrough infections after vaccination with the Vaccines were:

i. common;

ii. accompanied by high viral loads.

b) efficacy against Covid infection was displayed by the empirical evidence to be:

i. 30% for the fourth dose of the Pfizer Vaccine recipients; and

ii. 11% for the fourth dose of the Moderna Vaccine recipients;

c) local and systemic adverse reactions were being reported in:

i. 80% of the fourth dose Pfizer Vaccine recipients; and

ii. 40% of the fourth dose Moderna Vaccine cases respectively.

Source

Widely and globally published data and scientific studies included:

"4th Dose COVID mRNA Vaccines' Immunogenicity & Efficacy Against Omicron VOC." Regev-Yochay G., Gonen T.,Gilboa M. 2022. N Engl J Med; 386:1377-1380. https://www.nejm.org/doi/10.1056/NEJMc2202542

KNOWN - INEFFECTIVE TO PREVENT TRANSMISSION

88. From April 2021 widely and globally published data and scientific studies had rationally establishing the Vaccines' demonstrable inefficacy disclosed that:

a) those vaccinated with the Vaccines can still contract and transmit Covid regardless of whether they are symptomatic or not;

b) there was a concurrent increase in new Covid cases as the percentage of the population fully vaccinated increased;

c) countries with higher percentage of a population fully vaccinated have higher COVID cases per million people.

Source

Widely and globally published data and scientific studies included:

"Covid-19 Vaccinated Individuals Can Be A Source of SARS-CoV-2 Transmission – A Systematic Review". Kampf, 2021. Hygiene. 1(1):1-11.

"Increases in Covid-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States". Subramanian, SV and Kurmar, A. 2021. European Journal of Epidemiology, 36: 1237-1240.

KNOWN VACCINES REDUCED IMMUNITY SIDE EFFECT

89. From April 2021 widely and globally published data and scientific studies had rationally established and thereby disclosed in respect of the risk of injury from use of the Vaccines:

a) vaccination with an mRNA vaccine, including the mRNA Vaccines, initiates a set of biological events that are:

i. different from that induced by natural infection;

ii. in several ways demonstrably counterproductive to both short and long-term immune competence and normal cellular function;

b) mRNA vaccines including the mRNA Vaccines:

i. downregulate critical pathways related to:

(1) cancer surveillance;

(2) infection control; and

(3) cellular homeostasis.

ii. introduce into the body highly modified genetic material;

iii. produce a biological response that is demonstrably dissimilar to natural infection;

c) injection with the mRNA Vaccines:

i. induces a profound impairment in type 1 interferon signalling causing diverse adverse consequences to human health;

ii. causes immune cells to:

(1) take up the mRNA Vaccines' nanoparticles;

(2) release into circulation:

a) large numbers of exosomes containing spike protein; and

b) critical microRNAs that induce a signalling response in recipient cells at distant sites.

iii. can potentially cause profound disturbances in regulatory control of protein synthesis and cancer surveillance; and

iv. thereby have a causal link to:

(1) neurodegenerative disease;

(2) myocarditis;

(3) immune thrombocytopenia;

(4) Bell's palsy;

(5) liver disease;

(6) impaired adaptive immunity;

(7) impaired DNA damage response; and

(8) tumorigenesis.

Source

Widely and globally published data and scientific studies included:

"Innate immune suppression by SARS-CoV-2 mRNA Vaccinations: The Role of G-quadruplexes, exosomes and MicroRNAs". Seneff et al, Food Chem Toxicol. 2022 Jun.

KNOWN VACCINES INFERIORITY TO NATURAL IMMUNITY

90. Widely and globally published data and scientific studies rationally established and thereby disclosed that in respect of the Vaccines:

a) from the time of the Approvals and continuing to the present:

i. there is no evidence in existence which demonstrated that vaccination with the Vaccines provides superior immunity to natural human immunity in respect of infection with the Virus or the development of Covid;

ii. natural immunity:

(1) provides a decreased risk of re-infection and extremely low rates of hospitalisation in relation to repeat infection;

(2) provides significant protection against reinfection with Covid with an efficacy ~95% for at least seven months;

iii. the frequency of re-infection from Covid after previous infection:

(1) caused hospitalisation in only five out of 14,840 or 0.03% of those previously infected with Covid; and

(2) death in one out of 14,840 or 0.01% of those with previous infection.

b) from August 2021 and continuing to the present:

i. a person vaccinated with the Pfizer Vaccine had a 13.06-fold increased risk

for breakthrough infection with the Delta variant of the Virus and significant risk of symptomatic infection compared to unvaccinated individuals whom had previous Covid infection;

ii. naturally acquired immunity confers stronger protection against infection and symptomatic disease caused by the Delta variant of the Virus compared to Pfizer Vaccine induced immunity;

iii. the natural human immune system in those persons whom are unvaccinated following infection with Covid generally:

(1) is more effective than each of the Vaccines at preventing:

a) transmission of Covid;

b) serious illness or death arising from Covid;

c) infection or re-infection with Covid;

d) wanes at a materially slower rate than each of the Vaccines in those effects.

Source

Widely and globally published data and scientific studies included:

"Quit Ignoring Natural COVID Immunity — Antibody testing and proof of prior infection can allow more people to return to normal". Klausner, J., Kojima, N. 2021. Medpage Today, 28 May 2021.
www.medpagetoday.com/infectiousdisease/covid19/92836

150 plus research studies affirm naturally acquired immunity to Covid-19: documented, linked, and quoted.

https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/

“SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy”. Abu-Raddad, L et al. 2021. eClinicalMedicine, The Lancet Discovery Science, Vol 35, May 2021, https://doi.org/10.1016/j.eclinm.2021.100861

“SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study”. Hall, V. J. 2021. SIREN, Volume 397, Issue 10283, P1459-1469. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00675-9/fulltext

Pilz S et al (2021) SARS-CoV-2 re-infection risk in Austria. European Journal of Clinical Investigation Volume 51, Issue 4 e13520 https://doi.org/10.1111/eci.13520

“Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Naturally Acquired Immunity versus Vaccine-induced Immunity, Reinfections versus Breakthrough Infections: A Retrospective Cohort Study”. Gazit, S et a. 2021. Clinical Diseases Major Article https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9047157/pdf/ciac262.pdf

Evident from the publicly available Israeli Ministry of Health Database data in the period of August to September, 2021 from September 2021.

“Protection and waning of natural and hybrid immunity to

SARS-CoV-2". Goldberg, Y. et al. 2021. N. Eng. J. Med. 386: 2201–2212. (2022). https://doi.org/10.1038/s41467-022-33096-0

"Viral load dynamics of SARS-CoV-2 Delta and Omicron variants following multiple vaccine doses and previous infection". Woodbridge, Y et al. 2022. Nat Commun. 7;13(1):6706.

KNOWN VIRAL LOAD – VACCINATED INCREASED

91. From October 2021 widely and globally published data and scientific studies rationally establishing the inefficacy of the Vaccines disclosed in respect of Vaccines:

    a) persons vaccinated with the Vaccines who experienced breakthrough infection with the Delta Variant carry 251 times the viral load in their nostrils compared to those infected unvaccinated persons who were infected in the March-April 2020 period with older strains.

Source

Widely and globally published scientific studies and data included:

"Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers, Vietnam". Nguyen, C et al. 2021. The Lancet Preprint.

KNOWN NATURAL IMMUNITY SUPERIOR

92. From September 2021 widely and globally published data and scientific studies from Israel rationally establishing the inefficacy of the Vaccines within 70 days of vaccination with the Vaccines, the recipient generally had no or negligibly greater protection than an unvaccinated person in respect of preventing:

a) transmission of Covid;

b) serious illness or death arising from Covid; and

c) infection or re-infection with Covid.

Source

Evident from the publicly available Israeli Ministry of Health Database data in the period of August to September, 2021 from September, 2021.

93. From March 2022 widely and globally published data and scientific studies from Qatar rationally established and thereby disclosed that previous natural infection with the Virus:

a) was associated with lower incidence of Covid infection;

b) regardless of the variant, than mRNA primary-series vaccination.

Source

Widely and globally published scientific studies and data included:

"Protection of prior natural infection compared to mRNA vaccination against SARS-CoV-2 infection and severe COVID-19 in Qatar". Chemaitelly et al. The Lancet Microbe. December 22, Volume 3(12): E944-E955

94. From May, 2022 widely and globally published data and scientific studies rationally establishing the superiority of natural immunity to Covid as opposed to vaccination with the mRNA vaccines disclosed that:

a) previous natural infection was associated with lower incidence of Covid infection regardless of the variant, than 2 doses of the mRNA Vaccines;

b) effectiveness of primary natural infection against severe, critical or fatal Covid-19 re-infection was 97.3% irrespective of the variant of primary infection or reinfection.

Source

Widely and globally published scientific studies and data included:

"Protection from previous natural infection compared with mRNA vaccination against SARS-CoV-2 infection and severe COVID-19 in Qatar: a retrospective cohort study". Chemaitelly, H. 2022. Lancet Microbe 2022; 3: e944–55. https://doi.org/10.1016/S2666-5247(22)00287-7

95. From September 2022 widely published data and scientific studies in the form of 65 widely published studies in 19 countries rationally establishing the superiority of natural immunity to Covid as opposed to vaccination with the mRNA Vaccines disclosed that:

a) natural immunity was high against infection by all variants except omicron BA.1 which was substantially lower than the other variants;

b) for all variants including Omicron mean pooled effectiveness of natural immunity was greater than 78% against severe disease, including hospitalisation and death;

c) natural immunity protection from reinfection from all ancestral, Alpha and Delta variants:

i. declined over time; but

ii. remained at 78.6% at 40 weeks.

iii. protection against severe disease remained high for all variants with:

(1) 90.2% natural immunity protection for ancestral, Alpha and Delta variants; and

(2) 88.9% natural immunity protection for the Omicron BA.1 variant at 40 weeks; and

(3) despite protection from past infection waning over time the level of protection is at least as durable, if not more durable than that provided by 2-dose vaccination with the mRNA vaccines for all variants.

Source

Widely and globally published scientific studies and data referring to 65 independent studies is contained in:

"Past SARS-CoV-2 infection protection against re-infection: a systematic review and meta-analysis". Covid-19 Forecasting Team. The Lancet Articles. Volume 401, Issue 10379, P833-842.

INTERNATIONAL REPORTS OF ADVERSE EVENTS - KNOWN FDA ADVERSE EVENTS OF SPECIAL INTEREST

96. From July 2021 widely and globally published data and scientific study in the form of real-time monitoring of Serious Adverse Events reports relating to the Pfizer Vaccine by the FDA rationally establishing significant safety risks in the Pfizer Vaccine and thereby disclosed four potential adverse events of interest which were and are:

a) pulmonary embolism;

b) immune thrombocytopenia;

c) disseminated intravascular coagulation; and

d) acute myocardial infarction;

e) in respect of (a), (b) and (c) above, Brighton Adverse Events of Special Interest in the category:

(1) of coagulation disorders; and

(2) that exhibited the largest excess risk in the vaccine group in both of the mRNA Vaccine Trials.

Source

Widely and globally published scientific studies and data included:

"Initial Results of Near Real-Time Safety Monitoring of COVID-19 Vaccines in Persons Aged 65 Years and Older". US Food & Drug Administration. July, 2021. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/initial-results-near-real-time-safety-monitoring-covid-19-vaccines-persons-aged-65-years-and-older

KNOWN COUNTRIES BANNING VACCINE TREATMENT

97. The following widely and globally published data and scientific studies disclosed at those respective times those countries restricting further administration of the Vaccines in their populations following observed empirical data of injury and death associated with the Vaccines as against risk from Covid infection within those countries:

a) in September, 2022, Denmark ceased offering the Vaccines to those aged under 50 years unless they were at a higher risk of becoming severely ill from the Virus, citing as a basis the facts that:

i. the purpose of vaccination is to prevent severe illness, hospitalisation and death not to prevent infection; and

ii. people aged under 50 are generally not at higher risk of becoming severely ill from the Virus.

b) in October, 2022, Sweden ceased recommending the vaccine for 12-17 year olds, citing very low risk from infection with the Virus in that age group.

Source

Danish Health Authority – Why are people aged under 50 not to be re-vaccinated?
https://www.sst.dk/en/english/corona-eng/vaccination-against-covid-19

Sweden to stop offering Covid jabs to teenagers. September, 2022.
https://medicalxpress.com/news/2022-09-sweden-covid-jabs-teenagers.html

KNOWN FOETAL AND INFANT ADVERSE EVENTS

98. From March 2022 widely and globally published data and scientific studies reviewing 1,013 peer-reviewed publications relating to the safety of the Vaccines rationally established and thereby disclosed the following side effects, injury and death as caused by the mRNA Vaccines in foetuses and infants:

a) miscarriage;

b) foetal death;

c) foetal malformation;

d) chronic autoimmune disease;

e) permanent immune deficiency syndrome;

f) chronic permanent CNS diseases;

g) chronic cognitive disorders;

h) seizure disorders; and

i) neonatal/infant cancers.

Source

"Patient betrayal: The Corruption of healthcare, informed consent and the physician – patient relationship". Thorp J.A et al. 2022. The Gazette of Medical Sciences. https://www.thegms.co/medical-ethics/medethics-rw-22021403.pdf

KNOWN INSURANCE COMPANY DATA

99. The following were widely and globally published data reported by insurance firms globally in respect of the volume and time of precipitous increases in insurance claim related deaths in the late 2021 to early 2022 period:

a) in December, 2021, OneAmerica Insurance Company publicly disclosed that during the 3rd and 4th quarters of 2021, death in people of working age (18 to 64 years) in the U.S:

i. was 40% higher than it was before the Pandemic;

ii. was not attributed to Covid in the majority of cases; and

iii. the world was experiencing the highest death rates reporting to insurance firms in recorded history.

b) in January, 2022, it was publicly reported by Group Life Insurance company which is responsible for 90% of employer-based sickness and life insurance policies in the United States that beginning in Q3 of 2021, younger age groups were suddenly dying at historically unprecedented rates.

c) in January, 2022, it was publicly reported that as to the insurance sector globally, the life insurance industry had reported claims of:

i. $5.5billion in the first 3 quarters of 2021; compared to

ii. $3.5 billion for all of 2020.

Source

"Insurance executive says death rates among working-age people up 40 percent". 3 January, 2022. https://www.wfyi.org/news/articles/insurance-death-rates-working-age-people-up-40-percent

"SOA Research Institute (January 2022) Group Life COVID-19 Mortality Survey Report". Page 23. https://www.soa.org/48ff80/globalassets/assets/files/resources/research-report/2022/group-life-covid-19-mortality.pdf

"Life insurers adapt pandemic risk models after claims jump". 13 January, 2022. https://www.reuters.com/article/health-coronavirus-life-insurance-idCAKBN2JN0HP

INTERNATIONAL REPORTING DATA - KNOWN HIGH ADVERSE EVENTS AND DEATHS FROM VACCINES REPORTED IN US

100. From 24 December, 2021 the widely and globally published U.S. data contained in the VAERS Database and CDC data and scientific data analysis studies in respect of reported

injury and death related to the use of the Vaccines rationally establishing material safety risks in the Vaccines, disclosed that:

a) reports of Adverse Events following vaccination with the Vaccines disclosed:

    i. total number of reported adverse events: 705,991;

    ii. total number of reported serious adverse events: 126,418;

    iii. total number of reported deaths: 10,856;

b) total number of reports of hospitalisation or emergency room visits following vaccination with the Vaccines disclosed:

    i. hospitalisation: 46,202;

    ii. emergency room visits: 87,586.

c) total number of reports of cardiovascular, neurological, immunological, and reproductive Adverse Events following vaccination with the Vaccines disclosed:

    i. cardiovascular adverse events: 276,985;

    ii. neurological adverse events: 297,527;

    iii. immunological adverse events: 349,175;

    iv. reproductive adverse events: 12,277.

d) total number of reports of Adverse Events in Children following vaccination with the Vaccines disclosed:

    i. for children aged 0-18 years: 41,595;

ii. for children aged 5-11: 4,777.

e) as at 8 December, 2021 the total number of doses administered in the United States of America of the Vaccines was 119.6 million doses;

f) disclosing reported adverse events rates of:

i. 5.9 adverse events per 1,000 doses administered;

ii. 1.1 serious adverse events per 1,000 doses administered;

iii. 0.9 deaths per 10,000 doses administered.

Source

The VAERS database.

CDC Covid Data Tracker – Covid-19 Vaccinations in the United States.
https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total

g) the reports of adverse events, by way of comparison with the Vaccines, in respect of the Flu Vaccine over the preceding period, rationally establishing the exponentially higher rate of reported injury and death related to the Vaccines, the published data and analysis disclosing that:

i. the number of doses administered annually in the U.S. ranged from about 110 million per year to more than 190 million per year since 2008 being in an average single year 25% more doses than all of the Covid Vaccines doses administered to 8 December, 2021;

ii. the average number of reported deaths from all non-Covid vaccines in that period in the U.S. was 155 deaths per year which discloses that the rate of

deaths in the Covid Vaccines on average has been 7000% higher than non-Covid vaccines.

Source

"A report on US Vaccine Adverse Events Reporting system (VAERS) of the COVID-19 Messenger Ribonucleic Acid (mRNA) Biologicals". Rose, J. 2021. Science, Public Health Policy, and the Law. Volume 2:59-80. https://www.datascienceassn.org/sites/default/files/VAERS%20Report%20on%20Covid19%20Vaccine%20mRNA%20Biologicals%20-%20May%2C%202021.pdf

Centers for Disease Control and Prevention – Historical Reference of Seasonal influenza Vaccine Doses Distributed. Revised 4 August 2021. https://www.cdc.gov/flu/prevent/vaccine-supply-historical.htm

Covid-19 Vaccine Pharmacovigilance Report. World Council for Health. Updated 4 August 2022.Worldcouncilforhealth.org: https://worldcouncilforhealth.org/resources/covid-19-vaccine-pharmacovigilance-report

KNOWN EXPONENTIAL INCREASE IN ADVERSE EVENTS AND FOETAL DEATHS REPORTED SINCE APPROVAL OF THE VACCINES IN US

101. As at 11 November 2022 the widely and globally published U.S. data reported in the VAERS Database rationally establishing material safety risks in the Vaccines disclosed the following death and injury reported as related to the use of the Vaccines:

a) 4,546 foetal deaths had been reported following the Vaccines being given to pregnant women;

b) examining the preceding 32 years since the database was started in 1990:

i. the Vaccines represent 62% of all adverse events reported to VAERS for any reason in the 32 year period;

ii. the Vaccines represent 77% of all vaccine-related deaths reported to VAERS for any reason in the 32 year period.

Source

The VAERS database.

https://vaers.hhs.gov/

KNOWN EXPONENTIAL INCREASE IN ADVERSE EVENTS AND DEATHS REPORTED SINCE APPROVAL OF THE VACCINES IN US

102. From December 2021 the widely and globally published U.S. data reported in the VAERS Database in respect of the relative rate of injury and death reported as related to the use of the Vaccines rationally establishing material safety risk in the Vaccines disclosed that:

a) the mean number of adverse events reported annually from 2011 until 2020 for Conventional Vaccines was 39,218 Adverse Events per annum;

b) the number of reported Adverse Events in 2021 inclusive of the Vaccines was 705,991;

i. rationally establishing and disclosing that the reporting of adverse events had thereby increased by 1,700% compared to the 9 years prior for all vaccines in the first year after the Vaccines were approved;

c) the mean number of deaths reported annually from 2011 until 2020 for Conventional Vaccines was 155 deaths per annum;

d) the number of reported deaths in 2021 inclusive of the Vaccines was 10,856;

i. rationally establishing and disclosing that the reporting had thereby increased by 6,900% compared to the 9 years prior for all vaccines in the first year after the Vaccines were approved;

e) rationally establishing and disclosed that the increase was not attributable to excess administered doses because:

i. the Vaccines are a small proportion of all vaccines given in the US;

ii. influenza vaccines administered since the 2008/2009 flu season number 1,720,400,000;

iii. the approximate total number of doses the Vaccines administered by 31 December, 2021 was 521,620,000;

f) rationally establishing and disclosing that cumulative increases in the VAERS adverse events reporting precisely correlated with:

i. the number of people fully vaccinated against Covid-19; and

ii. the times at which people became fully vaccinated with the Vaccines cumulatively increased.

Source

The VAERS database.

Cumulative Covid Vaccinations. https://ourworldindata.org/grapher/cumulative-covid-vaccinations

KNOWN HIGH REPORTED RATES OF VACCINES ADVERSE EVENTS IN US

103. From 4 October, 2022, the widely and globally published data from the US Government V-Safe active surveillance program in respect of reported injury and death related to the use of the Vaccines rationally establishing material safety risks in the Vaccines, disclosed that:

a) 10,108,273 people reported to the V-Safe program following vaccination with the Vaccines, of which:

i. 33.2% reported an adverse event following vaccination;

ii. 6,458,751 total health impacts were reported including:

(1) 7.7% of persons reported requiring medical care following vaccination;

(2) 11.9% of persons reported being unable to undertake normal activities following vaccination;

(3) 12.9% of persons missed school or work following vaccination.

Source

V-Safe Vaccine Surveillance Program https://data.cdc.gov/Public-Health-Surveillance/v-safe/dqgu-gg5d

KNOWN HIGH REPORTED MYOCARDITIS/PERICARDITIS IN THE YOUNG IN US

104. From 31 March, 2022 widely and globally data from the US Government Vaccine Safety Datalink (VSD) of the CDC active surveillance program of the Vaccines in respect of the reported death and injury associated with the Vaccines rationally establishing significant safety risks in the mRNA Vaccines disclosed that:

a) verified myocarditis/pericarditis 0-7 days following mRNA vaccination (14 Dec, 2020 – 31 March, 2022) was reported as follows:

i. in Males aged 12-15 years after 2 Pfizer doses - 153.4 cases per 1 million doses;

ii. in Males aged 16-17 years after:

(1) 2 Pfizer doses – 139.3 cases per 1 million doses;

(2) 3 Pfizer doses – 198.1 cases per 1 million doses;

iii. in Males aged 18-29 years after:

(1) 2 Pfizer doses – 81.4 cases per 1 million doses;

(2) 3 Pfizer doses – 47.6 cases per 1 million doses;

(3) 2 Moderna doses – 97.3 cases per 1 million doses;

(4) 3 Moderna doses – 70.3 cases per 1 million doses;

iv. in Females aged 16-17 years after:

(1) 3 Pfizer doses – 43.4 cases per 1 million doses;

Source

The CDC Vaccine Safety Datalink (VSD) database. https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html

KNOWN HIGH REPORTED RATES OF VACCINES ADVERSE EVENTS IN EUROPE

105. From 25 December, 2021 the widely and globally published data from the EMA EudraVigilance System database passive surveillance program in respect of the reported death and injury associated with the Vaccines rationally establishing material safety risks in the Vaccines disclosed that:

a) there were 1,304,635 reports of adverse events related to the Vaccines detailed as follows:

i. the Moderna Vaccine:

(1) 182,225 reported adverse events;

(2) 76.5% reported in 18-64 years age group;

(3) 16.6% reported in 65-85 years age group;

ii. the Pfizer Vaccine:

(1) 654,735 reported adverse events;

(2) 2.2% reported in 12-17 years age group;

(3) 74.8% reported in 18-64 years age group;

(4) 13.9% reported in 65-85 years age group;

iii. the AstraZeneca Vaccine:

(1) 425,561 reported adverse events;

(2) 77.7% reported in 18-64 years age group;

(3) 14.3% reported in 65-85 years age group.

Source

The EudraVigilance System database.
https://www.ema.europa.eu/en/human-regulatory/research-development/pharmacovigilance/EudraVigilance

KNOWN HIGH REPORTED RATES OF VACCINES FEMALE REPRODUCTIVE SIDE EFFECTS – UK

106. From April 2022 the widely and globally published UK Government data of reported reproductive-associated injuries caused by the Pfizer Vaccine in the UK between 9 December, 2020 and 20 April, 2022 rationally establishing significant safety risks in the Pfizer Vaccine disclosed that:

a) 31,195 reproductive and breast disorders;

b) greater than 10,000 menstruation and uterine bleedings;

c) greater than 7000 menstruations with increased bleeding; and

d) 1000 breast-related signs or symptoms.

Source

COVID-19 mRNA Pfizer-BioNTech Vaccine Analysis Print.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1069177/COVID-19_Pfizer-BioNTech_Vaccine_Analysis_Print_DLP_6.04.2022.pdf

KNOWN HIGH ADVERSE DATA WORLDWIDE REPORTING

107. From June 2022 widely and globally published data and scientific studies rationally establishing significant safety risks in the Vaccines disclosed that in respect of the globally reported death and injury caused by the Vaccines:

a) the total number of adverse events related to the Vaccines on the international regulatory databases constituted by WHO VigiAccess, VAERS, EudraVigilance, and UK Yellow Card Scheme, individually were in each database unprecedented in history;

b) the magnitude of disparity in the number of adverse events from the Covid-19 Vaccines compared to other commonly administered vaccines and therapies was sufficient to indicate an alarming safety signal for these products;

c) the total number of adverse events on VigiAccess for common vaccines was as follows:

i. Tetanus vaccine:

(1) data collected since 1968;

(2) 15,381;

ii. Polio vaccine:

(1) data collected since 1968;

(2) 123,732;

iii. Influenza B vaccine;

(1) data collected since 1986;

(2) 90,044;

iv. Covid-19 Vaccines;

(1) Data collected since 2020;

(2) 4,000,000 - being 1,646% higher in 18 months than those other vaccines combined since 1968.

d) risk of death as reported in VAERS:

i. Influenza Vaccines: 1 in 5,074,171 (based on 33 deaths in 167,447,642 vaccinations);

ii. Covid-19 Vaccines: 1 in 30,041 (based on 5770 deaths in 173,335,866 vaccinations) - being a 16,791% higher rate of death reported in the Covid-19 Vaccines.

e) Total Number Adverse Events on EudraVigilance for common vaccines:

i. all measles vaccines:

(1) approximately 673,200,000 vaccinations;

(2) 48,913 adverse events;

ii. all polio vaccines:

(1) approximately 673,200,000 vaccinations;

(2) 8,982 adverse events - being a combined 0.0043% adverse event rate.

iii. Covid-19 vaccines:

(1) 341,628,772 vaccinations;

(2) 1,800,000 adverse events - being:

a) a 0.53% adverse event rate;

b) 12,200% higher than the known typical adverse event rate for the polio and measles vaccines.

iv. the above rates or reported death and injury related to the Vaccines at (i) to (iii) occurring wherein historically:

(1) in 1976, the swine flu vaccination campaign was halted after a series of adverse event reports including 53 deaths;

(2) in 1955, the polio vaccine was recalled in less than 1 year after 10 reported deaths.

Source

The World Council for Health Covid-19 Pharmacovigilance Report
https://worldcouncilforhealth.org/wp-content/uploads/2022/12/Pharmacovigilance-Report-20.12.22-LR3.pdf

KNOWN GLOBAL DATA - MORE LIKELY TO DIE FROM VACCINES THAN COVID

108. From February 2022 the widely and globally published all-cause mortality data contained in the COVID and All-Cause Mortality Data from US and U.K and widely published scientific study upon that data rationally established and thereby disclosed in respect of the reported death and injury related to the Vaccines that:

a) children under 18 are 51 times more likely to die from vaccination with the Vaccines than they are to die from COVID if not vaccinated;

b) in the age range of 18 to 29 those persons are eight times more likely to die from vaccination with the Vaccines than from COVID if not vaccinated;

c) in the age range of 30 to 39 those persons are seven times more likely to die from vaccination with the Vaccines than from COVID if not vaccinated;

d) in the age range of 40 to 49 those persons are five times more likely to die from vaccination with the Vaccines than from COVID if not vaccinated;

e) in the age range of 50 to 59 those persons are two times more likely to die from vaccination with the Vaccines than from COVID if not vaccinated;

f) in the age range of 60 years and over, those persons are equally likely to die from vaccination with the Vaccines than from COVID if not vaccinated;

g) only in the 80 years of age and over age group is a person less likely to die from vaccination with the mRNA Vaccines than from COVID if not vaccinated, being 0.13% less likely to die from vaccination with the Vaccines than from COVID if not vaccinated;

h) the risk-benefit ratio for taking the mRNA Vaccines under the age of 60 is determinatively against taking the Vaccines.

Source

"COVID-19 and All-Cause Mortality Data by Age Group Reveals Risk of COVID Vaccine-Induced Fatality is Equal to or Greater than the Risk of a COVID death for all Age Groups Under 80 Years Old as of 6 February 2022". Dopp K. and Seneff S. 2022. https://www.skirsch.com/covid/Seneff_costBenefit.pdf

KNOWN VACCINES CAUSE OF EXCESS MORTALITY - AUSTRALIAN MORTALITY DATA

109. From September 2021 to September 2022 the widely published data of Mortality in Australia statistics published by the ABS rationally established and thereby disclosed that in respect of excess mortality in Australia from the time of the mass vaccination of the Australian population with the Vaccines:

a) from the beginning of 2022 until 30 September, 2022:

i. there were 144,650 deaths of which:

(1) 19,986 deaths or 16.0% were above the historical average;

(2) only 8,160 deaths are attributed to Covid.

b) the excess mortality rates began to rise in September, 2021:

i. the mortality rate has at no time fallen back to the 5 year average range;

ii. as at 30 September, 2021, 77.8% of the Australian population aged 16 years and over had received at least one dose of the Vaccines;

c) in the period of December 2021 to March 2022:

i. the mortality rate exhibited a peak in excess deaths over the baseline average;

ii. there were less than 500 deaths attributed to Covid;

iii. there were approximately 3,800 deaths;

d) in the period of March 2022 to August 2022 a further peaking of deaths occurred;

e) prior to the highly anomalous year of 2022, the highest annual increase in deaths per population was 4.4%, which occurred in 1964;

f) on average, over the following 66 year period, there was an annual 1.6% decrease in the death rate;

g) by 30th November 2022, according to the ABS, 9,115 of the deaths were recorded as being attributed to Covid;

i. thereby rationally establishing and disclosing at and prior to that time based upon the mortality data that:

(1) Covid was not solely responsible for the excess mortality;

(2) the rollout of the Vaccines is associated with excess mortality.

Source

ABS Provisional Mortality Statistics,
https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release#covid-19-mortality

COVID-19 Vaccine Rollout - 30 September 2021
https://www.health.gov.au/sites/default/files/documents/2021/09/covid-19-vaccine-rollout-update-30-september-2021.pdf

BRADFORD HILL ANALYSIS OF AUSTRALIAN MORTALITY DATA – VACCINES CAUSAL OF EXCESS MORTALITY IN AUSTRALIA

110. From July 2021 to December 2022 the widely published data of the Mortality in Australia statistics published by the ABS through widely and globally published scientific application of Bradford Hill Analysis in causality assessment to that data, rationally established and thereby disclosed that:

a) since prior to the Approvals, the Bradford Hill Analysis was and remains one of the most widely used and superior methods of adverse event causality assessment historically and globally;

b) that reasonably applying the internationally accepted standard of causality, being the Bradford Hill Analysis Criteria (namely: correlation, consistency, specificity, temporality and dose-response relationship) to the excess mortality data, rationally establishes and thereby discloses that:

i. the significant excess mortality occurring in the Australian population at that time was 74% positively correlated with the volume of injections of the Vaccines in the Australian population;

ii. the excess mortality observed in that period is iatrogenesis caused by the Vaccines;

(1) thereby, that:

a) the increase in excess mortality in Australia at that period was causally related to the Vaccines;

b) harm, or risk of harm from the Vaccines significantly outweighs any benefit of the Vaccines.

Source

ABS Provisional Mortality Statistics
https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release#covid-19-mortality

"Australian COVID-19 pandemic: A Bradford Hill Analysis of Iatrogenic Excess Mortality." Sy, W. 2023. J Clin Exp Immunol, 8(2), 542-556.

KNOWN UK EXCESS MORTALITY IN YEAR OF VACCINES APPROVALS

111. From September 2021 widely published data and scientific studies rationally established and thereby disclosed the following significant increases in excess mortality in July to September 2021 in the UK occurring concurrently with the Approvals and release of the Vaccines:

a) aged 25-34 years: 181%;

b) aged 35-44 years: 217%;

c) aged 45-54 years: 208%;

d) aged 55-64 years: 170%.

Source

Society of Actuaries Research Institute published its COVID-19 Mortality Survey Report.
www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/deathsbyvaccinationstatusengland

KNOWN GERMANY EXCESS MORTALITY IN YEAR OF VACCINES APPROVALS

112. From August 2022 the widely and globally published data and scientific studies in respect of excess mortality rates in Germany, rationally established and thereby disclosed that whilst such excess mortality remained stable in 2020 during the pandemic but prior to the use of the Vaccines, began increasing significantly from April 2021 onwards and was:

a) almost entirely due to an increase in deaths in the age groups between 15 and 79;

b) indicative of a similar pattern for stillbirths in that period with an increase of:

i. 9.4% in the second quarter of 2021; and

ii. 19.6% in the fourth quarter of 2021.

Source

"Excess mortality in Germany 2020-2022". Kuhbandner, C and Reitzner, M. August, 2022.
DOI: 10.13140/RG.2.2.27319.19365.
https://www.researchgate.net/publication/362777743_Excess_mortality_in_Germany_2020-2022

KNOWN AUTOPSY DATA – SUDDEN DEATH AFTER VACCINATION

113. From 27 November, 2022 widely and globally published empirical data and autopsy results following autopsies of 35 cases of people with sudden death at home occurring within 20 days of injection with the Vaccines rationally establishing significant safety risks in the Vaccines disclosed that 14.3% of those fatalities were found to have:

a) died as a result of Vaccine related myocarditis;

b) died within 5 days of injection with the Vaccine;

c) not had previous Covid infection;

d) a degree and type of myocardial inflammatory infiltration and cardiac pathology never before observed in the 20 years prior autopsy service at Heidelberg University Hospital.

Source

"Autopsy-based histopathological characterization of myocarditis after anti-SARS-CoV-2-vaccination". Schwab, C et al, 2023. Clin Res Cardiol 112, 431–440.
https://doi.org/10.1007/s00392-022-02129-5

ADVERSE EVENT REPORTING TO THE TGA - KNOWN PFIZER POST-APPROVAL DATA AND SERIOUS SAFETY SIGNALS IN DEATH RATE AND MISCARRIAGE

114. From 28 February, 2021, data provided by Pfizer to the TGA and the TGA Respondents **("the Pfizer Post-Marketing Data")** in respect of injuries and deaths related to the use of the Pfizer Vaccine rationally established significant safety risk in the Pfizer Vaccine disclosing that:

a) between 1 December 2020 and 28 February 2021 (a period of 3 months):

i. 1,223 human fatalities were reported directly to Pfizer following vaccination with the Pfizer vaccine;

ii. being approximately 407 deaths per month

b) in 270 pregnant women vaccinated with the Pfizer Vaccine:

i. there was a 46% complication rate;

ii. wherein, 238 women weren't followed-up at all by Pfizer, despite the obligation to do so under the Pfizer Trial Protocol;

(1) in circumstances where in truth:

a. the TGA and the TGA Respondents did not consider Pfizer's disclosure of this extraordinary post-Approvals pregnancy complication rate to be a cause for:

i. concern; or

ii. withdrawal of the Pfizer Vaccine Approval from use in pregnant women.

Source

The Pfizer Post-Marketing Data document is entitled "5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of Pf-07302048 (Bnt162b2) Received Through 28-Feb-2021" dated 28 February, 2021. Pages 7, 12.
https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf

TGA ANNOUNCES 60-FOLD INCREASE IN POST-APPROVALS ADVERSE EVENT REPORTING

115. From 6 May, 2021 the TGA and the TGA Respondents had independently determined and were aware that subsequent to the Approvals:

a) there had been a significant increase in adverse events reported to the TGA overall as compared to 2020 as a consequence of adverse events related to the Vaccines occurring after the Approvals;

b) adverse events reported to the TGA overall as compared to 2020 had increased 60-fold as a consequence of adverse events related to the Vaccines occurring after the Approvals being reported.

Source

Announcement of Therapeutic Goods Administration, Professor John Skerritt and Commodore Eric Young's press conference on 6 May, 2021.
https://www.health.gov.au/news/therapeutic-goods-administration-professor-john-skerritt-and-commodore-eric-youngs-press-conference-on-6-may-2021

AUSVAXSAFETY – AUSTRALIAN ACTIVE ADVERSE EVENT REPORTING

116. AusVaxSafety:

a) is a national vaccine safety system in Australia;

b) is led by the NCIRS;

c) monitors adverse events following taking of the Vaccines with the stated purpose of facilitating early detection of potential vaccine safety issues;

d) states that:

i. "Post-licensure surveillance of adverse events following immunisation is an important component of any national immunisation program and is essential to maintaining the confidence of general public and immunisation providers in the national immunisation program";

ii. "Analysis of de-identified responses occurs frequently and is reviewed by vaccine experts as well as the Australian Government of Health and Aged Care, including the Therapeutic Goods Administration (TGA).

Source

"AusVaxSafety – An NCIRS led collaboration".
https://ausvaxsafety.org.au

"COVID-19 vaccine safety surveillance".
https://ausvaxsafety.org.au/our-work/covid-19-vaccine-safety-surveillance

KNOWN AUSVAXSAFETY DATA – EXTRAORDINARY RATE OF ADVERSE EVENTS

117. From 31 December, 2021 the widely published data contained in the AusVaxSafety COVID-19 Vaccine Surveillance Summary Report 2021 for the period from 22 February, 2021 to 31 December, 2021 provided to the TGA and the TGA Respondents rationally disclosing significant safety risk in the Vaccines disclosed for that period that:

a) of all recipients of the Pfizer Vaccine aged 12 years and older:

i. safety surveys were submitted by 4,094,999 people;

ii. the percentage of survey respondents who reported at least one adverse event caused by the Pfizer Vaccine within 3 days of vaccination with the Pfizer Vaccine was:

(1) after Pfizer dose 1: 37%;

(2) after Pfizer dose 2: 53%;

(3) after Pfizer dose 3: 54%;

iii. the percentage of survey respondents who reported requiring medical attendance within 3 days of vaccination with the Pfizer Vaccine was:

(1) after Pfizer dose 1: 0.7%;

(2) after Pfizer dose 2: 1.3%;

(3) after Pfizer dose 3: 0.9%;

iv. the percentage of survey respondents who reported missing work, study or routine duties in the 3 days following vaccination with the Pfizer Vaccine was:

(1) after Pfizer dose 1: 8%;

(2) after Pfizer dose 2: 21%;

(3) after Pfizer dose 3: 15%.

b) of all recipients of the AstraZeneca Vaccine aged 18 years and older:

i. safety surveys were submitted by 972,044 people;

ii. the percentage of survey respondents who reported at least one adverse event within 3 days of vaccination with the AstraZeneca Vaccine was:

(1) after AstraZeneca dose 1: 56%;

(2) after AstraZeneca dose 2: 25%;

iii. the percentage of survey respondents who reported requiring medical attendance within 3 days of vaccination with the AstraZeneca Vaccine was:

(1) after AstraZeneca dose 1: 1.1%;

(2) after AstraZeneca dose 2: 0.4%;

iv. the percentage of survey respondents who reported missing work, study or routine duties in the 3 days following vaccination with the AstraZeneca Vaccine was:

(1) after AstraZeneca dose 1: 19%;

(2) after AstraZeneca dose 2: 5%.

c) of all recipients of the Moderna Vaccine aged 12 years and older:

i. safety surveys were submitted by 41,557 people;

ii. the percentage of survey respondents who reported at least one adverse event within 3 days of vaccination with the Moderna Vaccine was:

(1) Moderna dose 1: 40%;

(2) Moderna dose 2: 65%;

(3) Moderna dose 3: 62%;

iii. the percentage of survey respondents who reported requiring medical attendance within 3 days of vaccination with the Moderna Vaccine was:

(1) Moderna dose 1: 1.4%;

(2) Moderna dose 2: 3.1%;

(3) Moderna dose 3: 0.4%;

iv. the percentage of survey respondents who reported missing work, study or routine duties in the 3 days following vaccination with the Moderna Vaccine was:

(1) Moderna dose 1: 13%;

(2) Moderna dose 2: 36%;

(3) Moderna dose 3: 19%;

d) The AusVaxSafety data in that period rationally established and thereby disclosed that the rate of adverse events reported in recipients of the Vaccines was exponentially higher than those reported for all other vaccines because in circumstances where in truth the Australian Immunisation Handbook reports that adverse reaction to vaccinations occur at an average rate of:

i. 1 in 1000 to 1 in 10,000; or

ii. 0.1% to 0.01%.

Source

National Health and Medical Research Council, "The

Australian Immunisation Handbook". 9th ed. 2008: Commonwealth Government of Australia. https://immunisationhandbook.health.gov.au/

"AusVaxSafety COVID-19 Vaccine Surveillance Summary Report 2021". https://www.health.gov.au/sites/default/files/documents/2022/09/ausvaxsafety-covid-19-vaccine-surveillance-summary-report-2021_0.pdf

KNOWN PROLIFIC ADVERSE EVENTS REPORTS LISTED IN THE DAEN DATABASE – DECEMBER 2021

118. From 31 December, 2021, the widely published DAEN database recorded in respect of the injury and death reported to the TGA in the use of the Vaccines, rationally establishing significant safety risks in the Vaccines, disclosed the following reported adverse events and deaths associated with the Vaccines:

a) Pfizer Vaccine - 25/01/2021 to 31/12/2021:

i. Adverse Events: 52,695 people;

ii. Deaths: 264 people.

b) AstraZeneca Vaccine - 16/02/201 to 31/12/2021:

i. Adverse Events: 43,874 people;

ii. Deaths: 439 people.

c) Moderna Vaccine - 09/08/2021 to 31/12/2021:

i. Adverse Events: 3,234 people;

ii. Deaths: 7 people.

d) Unspecified COVID vaccines 01/01/2021 to 31/12/2021:

i. Adverse Events: 465 people;

ii. Deaths: 25 people.

e) Total for all COVID vaccines including unspecified COVID vaccines:

i. Adverse Events: 100,268 people;

ii. Deaths: 735 people.

Source

The DAEN database.
https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen

KNOWN PROLIFIC ADVERSE EVENTS REPORTS LISTED IN THE DAEN DATABASE – JUNE 2022

119. From 8 June, 2022 the widely published data in the DAEN database in respect of injury and death reported to the TGA in recipients of the Vaccines rationally establishing significant safety risks in the Vaccines disclosed that:

a) since the rollout of the Pfizer Vaccine commenced for 5-11 year olds, in that age group there were:

i. 1,390 Adverse Events reported in recipients of the Pfizer Child Vaccine; and

ii. 5 Deaths reported in recipients of the Pfizer Child Vaccine being:

(1) a 7 year old male, caused by

a) cardiac arrest;

b) generalised tonic-clonic seizure;

(2) a 9 year old female;

a) caused by cardiac arrest;

(3) a 6 year old male;

a) caused by adverse event following immunisation;

(4) a 10 year old male;

a) caused by adverse event following immunisation;

(5) a 5 year old male;

a) caused by:

i. cardiac arrest;

ii. abdominal pain.

b) since there rollout of the Vaccines there were a total of:

i. 108,542 Adverse Events; and

ii. 723 Deaths reported in adolescents and adults following vaccination with the Vaccines;

iii. across all ages (including instances of unspecified ages), a total of:

(1) 131,991 Adverse Events reported in recipients of the Vaccines; and

(2) 884 Deaths reported following vaccination with the Vaccines.

c) on 16 June, 2022 there were reported:

i. 1,480 Adverse Events in 5-11 year olds following approximately 2.2M doses of Pfizer Vaccine; and

ii. 130,887 Adverse Events in all ages following 59,707,387 doses of Covid-19 Vaccines.

Source

The DAEN database.

"COVID-19 vaccine weekly safety report - 16-06-2022". https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-weekly-safety-report-16-06-2022

KNOWN UNPRECEDENTED EXPONENTIAL INCREASE IN REPORTED VACCINES ADVERSE EVENTS

120. From the date of the Approvals until 31 December, 2021 the widely published adverse events data reported to the TGA in DAEN rationally established the significant safety risks in the Vaccines by disclosing reported deaths and injuries associated with the Vaccines to be of a magnitude exponentially unprecedented in the history of vaccine-related adverse events recorded data in the following terms:

a) for all vaccines, excluding the Covid Vaccines, used in the 50 year period from 1 January 1971 to 31 December 2021:

i. a total number of reported adverse events of 19,330;

ii. a total number reported deaths of 59;

b) for the Vaccines in the 1 year period of 2021:

i. a total number of reported adverse events of 100,180;

ii. a total number reported deaths of 749;

c) adverse event frequency:

i. from 2010 to 2020 for the non-Covid Vaccines as being 0.9 adverse events in every 10,000 doses;

ii. in 2021, inclusive of the COVID Vaccines, as being 23 adverse events in every 10,000 doses;

iii. in the year 2021 immediately subsequent to the release of the Vaccines, an increase in adverse event frequency per dose of vaccines of 2,555%.

d) death events:

i. from 2010 to 2020 for the non-Covid Vaccines:

(1) a total of 29 reported deaths.

(2) the incidence of reported death from an adverse reaction to a vaccine was:

a) 0.22 to 0.27 reported deaths per million doses; or

b) approximately 1 death in every 4 million doses.

ii. in 2021 only inclusive of the Covid Vaccines as:

(1) a total of 749 reported deaths;

(2) 42,598,706 total vaccine doses administered nationally;

(3) the incidence of reported death from an adverse reaction to a vaccine was:

a) 17 reported deaths per million doses; or

b) approximately 1 death in every 58,823 doses.

c) an increase in the year 2021 immediately subsequent to the release of the Vaccines, in reported deaths per dose of vaccines of 30,442%.

e) the death events from vaccines data pleaded herein at (d) above indicating that receiving the Covid Vaccine is 68 times more likely to result in death than traditional vaccines;

f) the number of cases where death was a reported outcome associated with the Vaccines in 2021 was 749 as compared to ABS reports that:

i. the total reported deaths from or with Covid in 2020: 905;

ii. the total reported deaths from or with Covid in 2021: 1,306, of which:

(1) 114 occurred in January to August, 2021;

(2) 1,192 occurred in September to December, 2021;

g) the DAEN reported adverse events cases categorised by specific reaction type reported on average per annum are for:

i. Myocarditis:

(1) in the 50 year period of 1971 to 2021 for non-Covid vaccines:

a) 16 cases;

b) 0.32 cases per annum;

(2) in 2021 only for the Covid Vaccines:

a) 1110 cases;

b) 3,469 times the rate per annum of the non-Covid vaccines;

c) 69.38 times the total number of non-Covid vaccines in the preceding 50 year period.

ii. Pericarditis:

(1) in the 50 year period of 1971 to 2021 for non-Covid vaccines:

a) 12 cases;

b) 0.24 cases per annum;

(2) in 2021 only for the Covid Vaccines:

a) 2394 cases;

b) 9,975 times the rate per annum of the non-Covid vaccines;

c) 200 times the total number of non-Covid vaccines in the preceding 50 year period.

iii. Guillain-Barre Syndrome:

(1) in the 50 year period of 1971 to 2021 for non-Covid vaccines:

a) 67 cases;

b) 1.34 cases per annum;

(2) in 2021 only for the Covid Vaccines:

a) 217 cases;

b) 9,975 times the rate per annum of the non-Covid vaccines;

c) 3.24 times the total number of non-Covid vaccines in the preceding 50 year period.

iv. Immune Thrombocytopenia:

(1) in the 50 year period of 1971 to 2021 for non-Covid vaccines:

a) 21 cases;

b) 0.42 cases per annum;

(2) in 2021 only for the Covid Vaccines:

a) 114 cases;

b) 271.4 times the rate per annum of the non-Covid vaccines;

c) 5.4 times the total number of non-Covid vaccines in the preceding 50 year period.

v. Thrombosis with Thrombocytopenia Syndrome:

(1) in the 50 year period of 1971 to 2021 for non-Covid vaccines:

a) 1 case;

b) 0.02 cases per annum;

(2) in 2021 only for the Covid Vaccines:

a) 154 cases;

b) 7,700 times the rate per annum of the non-Covid vaccines;

c) 154 times the total number of non-Covid vaccines in the preceding 50 year period.

vi. Thrombocytopenia Syndrome:

(1) in the 50 year period of 1971 to 2021 for non-Covid vaccines:

a) 43 cases;

b) 0.86 cases per annum

(2) in 2021 only for the Covid Vaccines:

a) 741 cases;

b) 861 times the rate per annum of the non-Covid vaccines;

c) 17.2 times the total number of non-Covid vaccines in the preceding 50 year period.

vii. Abortions and Spontaneous miscarriages:

(1) in the 50 year period of 1971 to 2021 for non-Covid vaccines:

a) 33 cases;

b) 0.66 cases per annum;

(2) in 2021 only for the Covid Vaccines:

a) 227 cases;

b) 344 times the rate per annum of the non-Covid vaccines;

c) 6.8 times the total number of non-Covid vaccines in the preceding 50 year period.

h) As to reported adverse events to DAEN:

i. number of Adverse Events:

(1) in 1971 to 2021 related to all non-Covid vaccines: 19,330;

(2) in 2021 related to the Vaccines: 100,180.

ii. number of deaths:

(1) in 1971 to 2021 related to all non-Covid vaccines: 59;

(2) in 2021 related to the Vaccines: 749;

iii. number of adverse reactions reported per Adverse Event:

(1) in 1971 to 2021 related to all non-Covid vaccines: 2.27 Reactions per Event

(2) in 2021 related to the Vaccines: 3.26 Reactions per Event.

Source

The DAEN database. https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen

"Covid-19 Vaccine Rollout Update – 31 December, 2021". https://www.health.gov.au/sites/default/files/documents/2021/12/covid-19-vaccine-rollout-update-31-december-2021.pdf

"COVID-19 Mortality in Australia: Deaths registered until 31 March 2022". https://www.abs.gov.au/articles/covid-19-mortality-australia-deaths-registered-until-31-march-2022

KNOWN EARLY PFIZER POST APPROVAL ADVERSE EVENTS SAFETY ALARMS

121. On or about 27 August, 2021, data provided by Pfizer to the TGA and the TGA Respondents through a Periodic Safety Update Report **("the Pfizer PSUR")** and widely and globally published analysis of that data rationally established significant safety risks in the Pfizer Vaccine by disclosing the following death and injury in recipients of the Pfizer Vaccine reported to Pfizer in the period of 19 December, 2020 to 18 June, 2021:

a) the occurrence of the following adverse events in Pfizer Vaccine recipients had triggered safety signals as safety risks associated with the Pfizer Vaccine:

i. dizziness;

ii. hyperhidrosis;

iii. night sweats;

iv. asthenia;

v. lethargy;

vi. decreased appetite;

vii. vaccine stress-related responses;

viii. tachycardia;

ix. diarrhea;

x. pain in extremity (arm);

xi. anaphylaxis;

xii. vomiting;

xiii. hypersensitivity other than anaphylaxis; and

xiv. paraesthesia;

b) 327,827 recipients of Pfizer Vaccine had reported adverse reactions in reported to Pfizer in that 6 month period of which:

i. a total of 1,172,887 adverse events or 3.58 adverse events per affected recipient;

ii. 1.56% or 5,115 of affected recipients were fatalities;

iii. 30.8% were serious adverse events;

iv. 46% occurred in people 50 years old or younger;

v. 2076 were in children;

vi. 84.3% (276,437) occurred in recipients with no pre-existing co-morbidities;

c) the following adverse events in Pfizer Vaccine recipients triggered ongoing safety signals as safety risks associated with the Pfizer Vaccine:

i. immune thrombocytopenia;

ii. trigeminal neuralgia;

iii. myocarditis;

iv. pericarditis;

v. hypertensive crisis with intracranial haemorrhage;

d) contrary to the EMA Product Information Guidance, the safety issues pleaded in (a) and (c) above were not stated in Section 4.8 of the Pfizer Product Information approved, authorised and published by the TGA and the TGA Respondents either:

i. in the safety profile summary; or

ii. in the tabulated list of adverse reactions from clinical studies.

e) that Pfizer claimed had identified and was reporting that the following adverse events with safety signals which were determined not to be risks associated with the Pfizer Vaccine:

i. seizure;

ii. thromboembolic events;

iii. delayed skin reaction;

iv. delayed syncope;

v. eye pain and eye swelling;

vi. herpes zoster including ophthalmic herpes zoster;

vii. appendicitis;

viii. hearing loss and tinnitus;

ix. extensive swelling of the limbs;

x. reaction associated with dermal fillers;

xi. injection site pruritus;

xii. insomnia;

xiii. overdose;

xiv. deaths (including elderly or frail individuals);

xv. facial nerve palsy.

f) determinations pleaded at (e) above were and are irrational, obviously false and unacceptable in good faith because:

i. the evaluation of signals was ultimately the purview also of the TGA and the TGA Respondents which purported to be independently determining or addressing all safety signals;

ii. that "deaths (including elderly or frail individuals)" is listed as a signal determined not to be a risk of the Pfizer Vaccine;

iii. the TGA, the TGA Respondents and Pfizer at that time had the Norway Data detailing that deaths in the elderly and frail were a known risk;

iv. there were voluminous published reports of deaths already on the DAEN in respect of the Pfizer Vaccine;

v. Pfizer logically was not accurately reporting on safety signals associated with the Pfizer Vaccine.

g) that Pfizer reported to the TGA that during the reporting period monitoring was requested or was proposed by Pfizer in previous Summary Monthly Safety Reports for:

i. lymphopenia;

ii. immune thrombocytopenia;

iii. hearing loss and tinnitus;

iv. hypoglycaemia;

v. serious hypertension;

vi. hemophagocytic syndrome;

vii. serious arrhythmias;

viii. acute pancreatitis;

ix. acquired haemophilia; and

x. menstrual disorders.

h) contrary to the EMA Product Information Guidance, the safety issues pleaded at (g) above were not stated in Section 4.4 Special Warnings and Precautions for Use of the Pfizer Product Information that was published and approved by the TGA and the TGA Respondents:

i. as the EMA Risk Management Plan identified these adverse events as important risks;

ii. thereby failing to alert prescribers be alert for these events, and to assist in the risk-benefit evaluation of individual patients;

i) that Pfizer determined and reported to the TGA and the TGA Respondents in respect of the Pfizer Vaccine that:

i. in accordance with and as defined by the European Union Risk Management Plant (EU-RMP) in effect at the beginning of the reporting period 1.0 dated 21 December 2020:

(1) the important identified risk of the Pfizer Vaccine is anaphylaxis; and

(2) an important potential risk of the Pfizer Vaccine is Vaccine-Associated Enhanced Disease (VAED) including Vaccine-Associated Enhances Respiratory Disease (VAERD);

(3) information still entirely unknown in respect of the safety and efficacy of the Pfizer Vaccine included the complete absence of data and testing of the Pfizer Vaccine for:

a) use in pregnancy and while breast feeding;

b) use in immunocompromised patients;

c) use in frail patients with co-morbidities, including:

i. chronic obstructive pulmonary disease;

ii. diabetes;

iii. chronic neurological disorders; and

iv. cardiovascular disorders.

d) use in patients with:

i. autoimmune; or

ii. inflammatory disorders.

e) interaction with other vaccines; and

f) long term safety data.

j) the important risks associated with the Pfizer Vaccine identified in (i) above were never communicated to the Australian public by the TGA or any of the Respondents;

k) that Pfizer had claimed to have determined and reported to the TGA and the TGA Respondents that risks had been evaluated by Pfizer in the context of the benefits of the Pfizer Vaccine:

i. based upon the available safety and efficacy/effectiveness data from the reporting interval for Pfizer Vaccine; and

ii. Pfizer had determined based upon such evaluation that:

(1) the benefit-risk profile of the Pfizer Vaccine remained favourable; and

(2) no additional risk minimisation activities are warranted.

l) the claimed determinations of Pfizer pleaded at (k) above which were unchallenged by the TGA and the TGA Respondents were and are irrational, obviously false and unacceptable in good faith because the Pfizer Clinical Trial Data disclosed to the TGA and the TGA Respondents:

i. 1 in 800 Pfizer Vaccine recipients suffered Serious Adverse Events following vaccination; and

ii. the omission of approximately 4000 symptomatic patients from the analysis because they were not PCR tested;

m) Pfizer determined and reported to the TGA and the TGA Respondents that current and ongoing data from the Pfizer Clinical Trial in respect of the Pfizer Vaccine disclosed:

i. 883 Severe Adverse Events had occurred in recipients of the Pfizer Vaccine:

(1) in the 23,514 participants in the Pfizer Vaccine group;

(2) demonstrating a Severe Adverse Event rate of 3.7% in recipients of the Pfizer Vaccine;

ii. that the Severe Adverse Events in the Pfizer Vaccine group:

(1) included a case of:

a) acute myeloid leukemia;

b) anaphylactoid reaction;

c) cystitis;

d) hyperthyroidism;

e) myalgia;

f) myocardial infarction;

g) polymyalgia rheumatica;

h) portal vein thrombosis; and

i) thyroid mass.

(2) each of the Severe Adverse Events in (1) was determined by the TGA representative investigator working under the authority and direction of the TGA and the TGA Respondents to be causally linked to the Pfizer Vaccine;

(3) no aspect of the reported rate, incidence or type of these Severe Adverse Events reported and causally connected to the Pfizer Vaccine were:

a) included in the Pfizer Product Information published and approved by the TGA and the TGA Respondents;

b) disclosed to the Australian public by the Respondents.

n) that subsequent to the release of the Pfizer Vaccine into the world population for use, sourced data limited to that reported only to Pfizer directly and thereby a subset of all actual events, disclosed in respect of the recipients of the Pfizer Vaccine:

i. the occurrence of 329,919 Severe Adverse Events in Pfizer Vaccine recipients in an estimated 635.7 million doses of the Pfizer Vaccine;

ii. a rationally established rate of Severe Adverse Events of 1 in 962 persons fully vaccinated with 2 doses of the Pfizer Vaccine.

o) that the Investigator had determined almost all of the Severe Adverse Events pleaded in (n) above as being caused by the Pfizer Vaccine;

p) that Pfizer had concluded and reported to the TGA and the TGA Respondents that as to lot numbers of the Pfizer Vaccine:

i. lot numbers list several lots with materially high incidences of adverse event cases;

ii. those lots pleaded in (i) above required review according to the EMA Guideline on Good Pharmacovigilance Practices;

q) that Pfizer had concluded and reported to the TGA and the TGA Respondents in respect of a review of new safety information arising from use of the Pfizer Vaccine, Pfizer:

i. cited a study dated 1 July, 2021 relating to risk in pregnancy of the Pfizer Vaccine which stated that the following had been observed in the child or pregnant Pfizer Vaccine recipients:

(1) foetal vascular malperfusion lesion – chronic vessel with intramural fibrin deposition;

(2) placental tissue examined had a much higher rate of malperfusion lesions in the placental tissue for vaccinated patients;

a) in circumstances where in truth this should have triggered caution, and represents a foetal anomaly reported in the clinical literature.

ii. cited a study dated 31 May, 2021 that in fact reported intracranial haemorrhage in the recipients of the Pfizer Vaccine;

iii. obviously falsely stated that a search of the Medline and Embase databases

identified no new safety findings for the Pfizer Vaccine because;

(1) there existed dozens of widely published articles by that stage that raised concerns in the clinical literature;

(2) the search results were never presented by Pfizer;

(3) in fact any simple search on the subject returns results of over 1000 studies;

r) that Pfizer had concluded and reported to the TGA and the TGA Respondents that safety signals in relation to the majority of adverse event signals had been closed, or closed and refuted wherein;

i. this was accepted without question by the TGA and the TGA Respondents;

ii. details were not provided by Pfizer or the Respondents and:

iii. no inquiry by the TGA or the TGA Respondents was made.

s) that Pfizer had concluded and reported to the TGA and the TGA Respondents that the safety signal in relation to the majority of Adverse Event signals were not causal:

i. without any basis or explanation;

ii. subsequently accepted by the TGA and the TGA Respondents without question or further inquiry.

t) that Pfizer had concluded and reported to the TGA and the TGA Respondents that a safety signal in relation to serious hypertension:

i. is dismissed by Pfizer after being asked by the TGA to perform a cumulative review;

ii. has no plausible mechanism to explain any sustained elevated serious hypertension caused by the Covid Vaccine;

iii. was dismissed as pleaded at (i) and (ii) above in circumstances wherein:

(1) there are several mechanisms for serious hypertension;

(2) such cases were at that time reported on the DAEN, VAERS and in the scientific clinical literature;

(3) thereby consistent assertion that a repetitive side effect of the Vaccines is not associated with the Vaccines facilitates that continuing false assertion even when arising consistently over a long period.

u) that VAED was an ongoing safety concern in the use of the Pfizer Vaccine which the TGA and the TGA Respondents have never disclosed to the Australian public in the Product Information of the Vaccines;

v) that with respect to pregnancy, the Pfizer Vaccine trial recipients reported adverse events at the rate of:

i. 35%; or

ii. 51 recipients.

w) that of the 144 pregnancies which were recorded prospectively in the Pfizer Clinical Trial among Pfizer Vaccine recipients after commencement of the reporting period:

i. 17 (11.8%) miscarried; and

ii. 35 (24%) ended either in pregnancy loss or congenital anomaly.

x) that of the 144 pregnancies reported as pleaded at (w) above:

i. there were 73 pregnancies in Pfizer Vaccine recipients during the reporting period where the mother received the Pfizer Vaccine during the first trimester;

(1) of which 12 pregnancies (16.4%) miscarried;

y) that the miscarriage rates were profoundly higher in Pfizer Vaccine trial recipients than the scientifically established and expected typical pregnancy loss rate following diagnosis of pregnancy by ultrasound (i.e. prospectively) as follows:

i. the risk of miscarriage after diagnosis pregnancy is:

(1) 9.4% at 6 weeks of gestation;

(2) 4.2% at 7 weeks of gestation;

(3) 1.5% at 8 weeks of gestation;

(4) 0.5% at 9 weeks of gestation;

(5) 0.7% at 10 weeks of gestation.

ii. most miscarriages occur within the 1st week of gestation;

iii. an overall expected miscarriage rate after diagnosis of pregnancy (prospective) of 1.6 to 6.3% miscarriage rate;

iv. the miscarriage rate in Pfizer Vaccine recipients was between 87% and 638% higher than the scientifically established expected typical miscarriage rate;

v. that reported outcomes for a cohort from the wider population reporting an Adverse Event in pregnancy associated with the Pfizer Vaccine disclosed that:

(1) the total reported pregnancies of among Pfizer Vaccine recipients was 1089 (including both prospective and retrospective cases);

(2) miscarriages and terminations occurred in 232 (21.3%) of the Pfizer Vaccine recipients wherein 90% of terminations recorded were due to foetal defects;

(3) the total number of pregnancies wherein the Pfizer Vaccine was received in the first trimester were 215 (20%);

(4) miscarriages and terminations of 92 (43%) of the Pfizer Vaccine recipients with first trimester pregnancies wherein 83% of terminations recorded were due to foetal defects;

vi. the data thereby rationally established and disclosed that:

(1) the Pfizer Vaccine group experienced a pregnancy loss rate that was profoundly higher than expected or typical;

(2) the Pfizer Vaccine could not be reasonably or otherwise deemed safe for use in pregnant women, and in particular, in the first trimester of gestation;

(3) immediate suspension of the use of the Pfizer Vaccine in pregnant women was indicated;

z) that infants were reported to have suffered a stroke where:

i. their mother was either:

(1) vaccinated with the Pfizer Vaccine during pregnancy; or

(2) vaccinated with the Pfizer Vaccine when breastfeeding;

ii. 1 died;

iii. the outcome for 2 were not reported;

aa) that with respect to VAED in recipients of the Pfizer Vaccine:

i. there were 584 reported cases in Pfizer Vaccine recipients in the reporting period:

(1) that met the criteria for potential VAED wherein;

a) 221 of those cases were medically significant;

b) 166 of those cases required hospitalisation;

c) 37 of those cases were life threatening;

d) 160 of those cases resulted in death.

e) a wide range of severe medical conditions are reported to be associated with VAED by Pfizer;

(2) this disclosure confirmed and rationally established the Brighton Collaboration information on VAED.

bb) there were 425 confirmed breakthrough cases of Covid in the reporting period in Pfizer Vaccine recipients wherein:

i. 290 (68.2%) of the cases were severe;

ii. the severe cases resulted variously in one or more of:

(1) hospitalisation;

(2) disability;

(3) life threatening complications; or

(4) death.

iii. the particulars of those cases pleaded at (i) and (ii) above were unequivocal evidence of, and rationally established that, those cases were in fact VAED in circumstances where:

(1) the rates of severe illness and death from Covid without vaccination were very low;

(2) the Pfizer Vaccine was never indicated to prevent hospitalisation, severe illness and death;

(3) Pfizer stated that VAED remains a theoretical risk in the Pfizer Vaccine recipients accepted by the TGA and the TGA Respondents.

cc) that Covid and VAED are an Adverse Event of Special Interest, wherein:

i. there were in that period 12,058 reported cases of breakthrough infection in Pfizer Vaccine recipients;

ii. 8,633 (71.6%) of those breakthrough cases were serious;

iii. 658 (7.6%) of those breakthrough cases were reported as fatal;

iv. a 71.6% serious breakthrough rate obviously and rationally established that those cases were in fact VAED;

v. a 7.6% fatality rate obviously and rationally established that any claims of the Pfizer Vaccine reducing the incidence of death from Covid were false.

Source

The Pfizer PSUR. Pages 4, 5, 6, 22, 32, 33 (Table 6), 34, 39, 56, 81, 83, 85-87, 88, 91, 96, 100, 119-123, 128, 237, 244.

The Pfizer Post-Marketing Data. Pages 12-13.

Committee for medicinal products for human use (CHMP) ICH guideline E2C (R2) Periodic benefit-risk evaluation report. April 2012. https://www.ema.europa.eu/en/ich-e2c-r2-periodic-benefit-risk-evaluation-report-scientific-guideline

EMA Product Information Guidance – https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information-requirements

Australian Product Information – Comirnaty Covid-19 Vaccine. https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2021-PI-02442-1&d=20230418172310101

COMIRNATY, COMIRNATY ORIGINAL/OMICRON BA.1, COMIRNATY ORIGINAL/OMICRON BA.4-5 (COVID-19 mRNA VACCINE) RISK MANAGEMENT PLAN https://www.ema.europa.eu/en/documents/rmp-summary/comirnaty-epar-risk-management-plan_en.pdf

Rose, J (October 2021) Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System? The Institute for Pure and Applied Knowledge. Vol 3:100-129, Oct. 2021 https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_0490c898f7514df4b6

fbc5935da07322.pdf

EMA - Guideline on good pharmacovigilance practices https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-product-population-specific-considerations-i-vaccines_en.pdf

J Clin Invest. 2021 Jul 1; 131(13): e150319. Published online 2021 Jul 1. doi: 10.1172/JCI150319
PMCID: PMC8245182PMID: 34014840 Efficient maternal to neonatal transfer of antibodies against SARS-CoV-2 and BNT162b2 mRNA COVID-19 vaccine , Ofer Beharier et al. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8245182/.
Page 5 of study: Foetal vascular malperfusion lesion – chronic vessel with intramural fibrin deposition
Page 10 of study: the placental tissue examined had a much higher rate of malperfusion lesions in the placental tissue for vaccinated patients

Journal of Pharmaceutical Policy and Practice Commentary Open Access Published: 31 May 2021 Potential adverse events in Japanese women who received tozinameran (BNT162b2, Pfizer-BioNTech) Rumiko Shimazawa & Masayuki Ikeda Journal of Pharmaceutical Policy and Practice volume 14, Article number: 46 (2021) https://joppp.biomedcentral.com/articles/10.1186/s40545-021-00326-7

Vaccine-associated Enhanced Disease: Case Definition and Guidelines for Data Collection, Analysis, and Presentation of Immunization Safety Data October 19, 2020Case Definitions / English / News / Publications and Related Tools / Relevant for COVID-19

This is a Brighton Collaboration case definition of the term "Vaccine-associated Enhanced Disease" (VAED) to be utilized in the evaluation of adverse events following immunization. The case definition was developed by a group of experts convened by the Coalition for Epidemic Preparedness Innovations (CEPI) as part of the Safety Platform for Emergency Vaccines (SPEAC) project, in the context of active development of vaccines for COVID-19 and other emerging pathogens. The case definition format of the Brighton Collaboration was followed to develop a consensus case definition and defined levels of diagnostic certainty, after an exhaustive review of the literature and expert consultation.
https://brightoncollaboration.us/vaed/
https://brightoncollaboration.us/wp-content/uploads/2021/07/VAED-vaccine-publication.pdf

PART D - REGULATORY ACTIONS/ FAILURES

FAILURE TO ISSUE SAFETY ALERTS ISSUED - TGA

122. At all material times prior to the Approvals, the TGA and the TGA Respondents were obliged under the widely published TGA Safety Alert Policy to issue safety alerts where the medicine carries a possible risk, including:

a) known safety problems;

b) changes in the reporting pattern of known safety problems;

c) new problems; and

d) coincidental event.

Source

The TGA Safety Alert Policy

123. The TGA and the TGA Respondents have never issued a Safety Alert to the Australian public for any reason in relation to:

a) the Pfizer Vaccine;

b) the Moderna Vaccine.

124. At all material times from prior to the Approvals it was widely and globally published and common scientific knowledge and practice that with respect to causality assessment of Adverse Events in respect of any medicine, including the Vaccines and the internationally accepted standards applicable to the assessment of adverse events causality (including those relating to the Vaccines) that:

a) in practice few adverse reactions are 'certain' or 'unlikely';

b) most are 'possible' or 'probable';

c) causality assessment is a common routine procedure in pharmacovigilance;

d) systems have been developed for a structured and harmonised assessment of causality including:

i. the Naranjo Scale;

ii. the WHO Causality Assessment for Adverse Events; and

iii. Bradford Hill Criteria.

Source

Naranjo Adverse Drug Reaction Probability Scale
https://www.evidencio.com/models/show/661

"The use of the WHO-UMC system for standardised case

causality assessment".
https://who-umc.org/media/164200/who-umc-causality-assessment_new-logo.pdf

Bradford Hill Criteria
https://www.edwardtufte.com/tufte/hill

NARANJO SCALE – APPLICATION TO POPULATION AND APPLICANTS

125. At all material times prior to the Approvals, it was widely and globally published and common scientific knowledge that the international standardised assessment of causality for all adverse drug reactions is the Naranjo Adverse Drug Reaction Probability Scale **("the Naranjo Scale")** which:

a) was developed in 1991;

b) is a system developed for the structured and harmonised assessment of causality;

c) was developed to help standardise assessment of causality for all adverse drug reaction;

d) was in widespread and pervasive use and acceptance internationally as a pharmacovigilance tool to determine causality;

e) is applied to data obtained by the imposition of known and well-defined causality questions;

f) in receiving data in response to the relevant causality questions to determine a category of causality, requires that:

i. a response of "Do not know" to relevant causality question:

(1) should be used:

a) sparingly;

b) only when the quality of the data does not permit a "Yes" or "No" answer;

(2) is applicable if the information is not available; and

(3) also if the question is inapplicable to the case.

g) provided score interpretation categorised as one of:

i. definite;

ii. probable;

iii. possible; or

iv. doubtful.

h) the attribution of "possible" arises under the Naranjo Scale when the following are applicable - the reaction:

i. followed a temporal sequence after a drug;

ii. possibly followed a recognized pattern to the suspected drug; and

iii. could be explained by characteristics of the patient's disease.

i) where rationally and logically applied to those reported adverse events in respect of the Vaccines **("the Known Reported Adverse Events")**:

i. rationally manifests an adverse reaction probability score as being causally related to the Vaccines of at least possible:

(1) in all events reported to regulatory authorities in Australia, including the DAEN and AusVaxSafety;

(2) where temporally associated with receipt of the Vaccines;

(3) until other further supporting or controverting factors are investigated, identified and applied.

ii. rationally manifests a probability score of at least probable in the injuries cause to the Applicants in respect of the respective Vaccines received.

Source

"Naranjo Adverse Drug Reaction Probability Scale".
https://www.ncbi.nlm.nih.gov/books/NBK548069/

WHO SAFETY SURVEILLANCE MANUAL

126. From April 2021 and at all material times thereafter, the widely and globally published "COVID-19 Vaccines: Safety Surveillance Manual" produced by the WHO in April 2021, stated in respect of the assessment of causality and thereby disclosed that:

a) the selection of cases for causality assessment should focus on:

i. serious AEFI that:

(1) results in death;

(2) is life-threatening;

(3) requires inpatient hospitalization or prolongation of existing hospitalization;

(4) results in persistent or significant disability/incapacity; or

(5) is a congenital anomaly/birth defect;

ii. the occurrence of events above the expected rate or of unusual severity;

b) signals generated as a result of individual or clustered cases as these could signify a potential for large public health impact.

c) allegations that vaccines/vaccination cause adverse events must be dealt with rapidly and effectively;

d) appropriate action(s) must be taken to respond promptly, efficiently, and with scientific rigor to vaccine safety issues;

e) causality assessment of AEFI is a vital component of AEFI risk assessment, decision-making and the initiation of action;

f) the scientific basis for the criteria which are assessed in the process include:

i. temporal relationship;

ii. that the vaccine exposure must precede the occurrence of the event;

iii. definitive proof that the vaccine caused the event;

iv. population-based evidence for causality – i.e. what is known about “Can it?”;

v. a definitive “yes” at the population level is consistent with causality at the individual level;

vi. a strong “no” at the population level is inconsistent with causality at the individual level;

vii. no clear answer to the question at the population level, will often lead to an indeterminate conclusion at the individual level;

viii. biological plausibility: the association should be compatible with existing theory and knowledge related to how the vaccine works;

ix. consideration of alternative explanations: In doing causality assessment on an individual case report, it must be remembered that in essence one is conducting a differential diagnosis;

x. prior evidence that the vaccine in question could cause a similar event in the vaccinee.

Source

"Naranjo Adverse Drug Reaction Probability Scale".
https://www.ncbi.nlm.nih.gov/books/NBK548069/

WHO SAFETY SURVEILLANCE MANUAL – APPLICATION TO POPULATION AND APPLICANTS

127. The widely and globally published and accepted WHO-UMC System For Standardised Case Causality Assessment published as such in 2013 **("the WHO Causality Assessment for Adverse Events")**:

a) is a system developed for the structured and harmonised assessment of causality;

b) was developed to help standardise assessment of causality for all adverse drug reactions;

c) was in widespread and pervasive use and acceptance internationally at the time of the Approvals as a system for pharmacovigilance;

d) provides a score interpretation categorised as one of:

i. definite;

ii. probable/likely;

iii. possible;

iv. unlikely;

v. conditional/unclassified; and

vi. unassessable / unclassifiable.

e) has been declared by the WHO to, in practice, produce:

i. few adverse reactions defined as ‘certain’ or ‘unlikely’;

ii. most adverse reactions defined as ‘possible’ or ‘probable’;

f) was stated by the WHO when being used in the usual manner:

i. because the most frequent categories in causality assessments of case reports are ‘Possible’ or ‘Probable’:

(1) to choose one of these categories (depending on the impression of the assessor); then

(2) to test if the various criteria fit with the content of the case report; then

(3) if the report seems stronger one can go one step ‘higher’ (e.g. from ‘Possible’ to ‘Probable’); then

(4) if the evidence seems weaker one should try a ‘lower’ category.

ii. the attribution of “possible” arises under the WHO Causality Assessment for Adverse Events when the following are applicable:

(1) event or laboratory test abnormality, with reasonable time relationship to drug intake;

(2) the event could also be explained by disease or other drugs; and

(3) information on drug withdrawal may be lacking or unclear.

g) when rationally and logically applied to the Known Reported Adverse Events rationally:

i. manifests an adverse reaction probability score of causality in relation to the Vaccines of at least, "possible":

(1) where there is temporal proximity and sequence after receiving one of the Vaccines;

(2) until other further supporting or controverting factors are investigated, identified and applied.

ii. manifests a score of at least "probable" in the injuries caused to the Applicants in respect of the respective Vaccines received.

Source

"The use of the WHO-UMC system for standardised case causality assessment" Published 5 June, 2013.
https://who-umc.org/media/164200/who-umc-causality-assessment_new-logo.pdf

CAUSALITY ASSESSMENT OF REPORTED EVENTS

128. At all material times prior to the Approvals, by reason of the factual matters pleaded at paragraphs 125 to 127 (inclusive) herein and the proper and scientific application of the Naranjo Scale and the WHO Causality Assessment for Adverse Events to the adverse events and deaths reported to the TGA in recipients of the Vaccines, it was rationally

evident that:

a) adverse drug reactions are only graded as “unlikely” wherein:

   i. a clinical event, including laboratory test abnormality, with a temporal relationship to drug administration which makes a causal relationship improbable; and/or

   ii. in which other drugs, chemicals or underlying disease provide plausible explanations;

b) the temporal relationship would only allow an unlikely causality assessment where:

   i. the event occurred before the drug exposure; or

   ii. if it was so long afterwards to be considered improbable;

   iii. and when there is a more plausible alternative explanation.

c) relevantly on average over 98% of adverse events reported to the Respondents in respect of the Vaccines involved a single suspected medicine, being one of the Vaccines.

WIDESPERAD DENIAL OF CAUSALITY ASSOCIATED WITH THE VACCINES

129. From 3 April, 2022 the Australian public reported to the TGA and TGA Respondents:

a) at least 814 deaths in recipients of the Vaccines in Australia;

b) from which the TGA and the TGA Respondents claim to have only determined 11 of those cases as being “linked” to the Vaccines.

Source

COVID-19 vaccine weekly safety report - 07-04-2022 dated 7

April, 2022 produced by the TGA.
https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-weekly-safety-report-07-04-2022

KNOWN DEATHS IN CHILDREN REPORTED AFTER RECEIVING THE PFIZER AND MODERNA VACCINES

130. From 20 July, 2022 it has been reported to the TGA and the TGA Respondents by the Australian public of at least 13 deaths in children and young adults after receiving the Pfizer Vaccine and Moderna Vaccine which disclosed to the TGA and the TGA Respondents the following in respect of those deaths **("the Reported Child Deaths")**:

a) a 5 year old male died of cardiac arrest after receiving the Pfizer Vaccine;

b) a 10 year old male died after receiving the Pfizer Vaccine;

c) a 21 year old female died from myocarditis and cardiac arrest after receiving the Moderna Vaccine;

d) two 14 year old females died of cardiac arrest after receiving the Moderna Vaccine;

e) a 21 year old male died of cardiac arrest after receiving the Pfizer Vaccine;

f) a 24 year old female died of cardiac arrest after receiving the Pfizer Vaccine;

g) a 9 year old female died of cardiac arrest after receiving the Pfizer Vaccine;

h) a 7 year old male died of cardiac arrest after receiving the Pfizer Vaccine;

i) a 19 year old female died of cardiac arrest after receiving the Pfizer Vaccine;

j) a 15 year old male died after receiving the Pfizer Vaccine;

k) a 17 year old male died of myocarditis after receiving the Pfizer Vaccine;

l) a 17 year old female died of Arrhythmogenic right ventricular dysplasia after receiving the Pfizer Vaccine.

Source

FOI request response of TGA (FOI Request 3727) relating to the TGA's assessment process investigating deaths reported following vaccination with the Vaccines.

FOI request response of TGA (FOI Request 4217) relating to the deaths in children reported following vaccination with one of the Vaccines.

131. The Reported Child Deaths:

a) have at no time been disclosed to the Australian Public by the Respondents;

b) are recorded, *inter alia*, in documents produced by the TGA and the TGA Respondents produced under FOI request 3727 which were despite an automatic requirement to do so, refused by the TGA and the TGA Respondents for publication to the public TGA disclosure log on the express purported basis that disclosure of the documents could undermine public confidence and reduce the willingness of the public to report adverse events to the TGA;

c) in the circumstances of (b) above, rationally establish and disclose a willful intention by the TGA and the TGA Respondents to conceal from the Australian public:

(1) known Vaccines-related matters; or

(2) matters disclosing relevant evidence of the absence of safety in the Vaccines.

d) were at no time referred to VSIG despite being required to do so under the TGA

VSIG Policy (particularised below) in breach of that policy:

i. without proper basis;

ii. which would otherwise invoke proper application of WHO Causality Assessment;

iii. thereby circumventing the application of proper and independent causality assessment in respect of those child deaths.

Source

"Vaccine Safety Investigation Group – Work Instruction Pharmacovigilance and Special Access Branch Signal Investigation Unit". January 2019. https://www.tga.gov.au/sites/default/files/2023-01/foi-4029-06.PDF

Letter to Dr McCann from the TGA, dated 24 August 2022.

VSIG was not convened. VSIG meeting starting with the comments that: (FOI 4029 document 5, page 4) https://www.tga.gov.au/sites/default/files/2023-01/foi-4029-05.PDF

"Prior to this meeting, a TGA assessment found that this case of myocarditis demonstrated a consistent causal association with the vaccine based on the information available. It was explained that the purpose of causality assessment from a regulatory perspective is to identify and characterise the strength of the evidence supporting the likelihood of a causal association between an adverse event and a vaccine and to consider potential public health action. It was noted that a definitive causal association (or absence of association) often cannot be established for an individual event. It was

emphasised that regulatory assessment does not pre-empt or replace other reviews of this case. In particular, it was acknowledged that there is an open Coroner's investigation and there have been multiple expert panel assessments of the case at the state level."

TGA assessments (documents - FOI 3727) can and do allow for the assessment to determine a consistent causal association with the vaccine based on the information available, and that decision is recorded under the heading of 'decisions' on the Fatal Causality Documents.

"Vaccine Safety Investigation Group – Work Instruction Pharmacovigilance and Special Access Branch Signal Investigation Unit". January 2019. https://www.tga.gov.au/sites/default/files/2023-01/foi-4029-06.PDF

IMPROPER FAILURE TO REFER VACCINES RELATED CHILD DEATHS TO VSIG FOR CAUSALITY ASSESSMENT

132. Despite the occurrence of the Reported Child Deaths meeting the criteria under the TGA VSIG Policy:

a) VSIG was not convened for the children who died of cardiac arrest at the request of the TGA, the TGA Respondents or anyone to review the Reported Child Deaths;

b) the details of the Reported Child Deaths were never brought before VSIG for a determination as to causality despite an obligation to do so by the TGA and the TGA Respondents;

c) concurrently, the TGA and the TGA Respondents continue to assert that causality in respect of the Reported Child Deaths had not been determined:

i. on the improper basis that causality has still not finally been determined by the TGA and the TGA Respondents in respect of those deaths;

ii. the TGA and the TGA Respondents continue to evade a determination of causality of the Vaccines in the Reported Child Deaths by:

(1) failing to act in accord with policy;

(2) failing to take any positive steps to concluding causality assessment;

(3) maintaining a perpetually unresolved and open status on causality assessment.

iii. that the release of the Reported Child Deaths was appropriately prevented from release upon the FOI log maintained by the TGA and the TGA Respondents on the basis of 'the potential to undermine public confidence' which in and of itself requires the convening and causality assessment of VSIG under the TGA VSIG Policy;

d) by reason of the factual matters pleaded at sub-paragraphs (a) to (c) above the TGA and the TGA Respondents have thereby impeded:

i. active and independent assessment of the causality of the Reported Child Deaths;

ii. public knowledge of the causality of the Reported Child Deaths including from:

(1) the Australian population;

(2) Australian health practitioners.

iii. the possibility of regulatory action in appropriate response to the Reported Child Deaths.

Source

"Vaccine Safety Investigation Group – Work Instruction Pharmacovigilance and Special Access Branch Signal Investigation Unit". January 2019. **("the VSIG Work Instruction")**
https://www.tga.gov.au/sites/default/files/2023-01/foi-4029-06.PDF

The TGA VSIG Policy

IMPROPER FAILURE TO REFER VACCINES RELATED SAFETY ISSUES TO THE ACV FOR ASSESSMENT

133. From the time of the Approvals, in respect of the requirement of the TGA and the TGA Respondents' obligations to refer adverse events to the ACV for review and advices:

a) the TGA and the TGA Respondents have irrationally and without basis determined not to refer to ACV for review of:

i. any safety issues in respect of the Vaccines;

ii. the 1,004 reported deaths of recipients of one or more of the Vaccines;

iii. the more than 139,000 adverse events in recipients of one or more of the Vaccines, many of them serious and life changing;

b) the TGA and the TGA Respondents continue to abrogate their own policies in:

i. failing to refer extraordinarily and historically high numbers of adverse events connected with the Vaccines to the ACV; and

ii. failing or refusing to convene VSIG and referring to VSIG these serious unexpected events including the Reported Child Deaths

Source

The ACV Meeting Minutes, accessible on the TGA website. https://www.tga.gov.au/about-tga/advisory-bodies-and-committees/advisory-committee-vaccines-acv

Section B of the minutes relevantly disclose in each instance that – "The ACV was not asked to review any safety issue".

PROPORTIONAL REPORTING RATIO DATA (PRR) GENERALLY – MEASURE OF ADVERSE EVENT PROBABLITY IN VACCINES

134. At all material times from the time of the Approvals it was and is a universally known, established and accepted scientific fact that a Proportional Reporting Ratio **("PRR")**:

a) is a statistic that is used to summarise the extent to which a particular Adverse Event is reported for individuals taking a specific drug compared to the frequency at which the same adverse event is reported for patients taking some other drug;

b) is used to measure how common an Adverse Event for a particular drug is compared to how common the event is overall in the database;

c) is used to measure the strength of the statistical association between a risk factor, being the use of the drug, and a specific Adverse Event;

d) where greater than 1 for a specific medicine including the Vaccines:

i. suggests that the Adverse Event is more commonly reported for individuals taking the drug of interest, relative to the comparison drugs;

ii. is an indication that the Adverse Event is:

(1) caused by the drug of interest; and

(2) therefore a side-effect of that drug.

PRR BENCHMARK ADOPTED BY TGA RESPONDENTS – 29 SEPTEMBER, 2021

135. On or about 29 September, 2021, the TGA and the TGA Respondents:

a) adopted the use of a PRR calculation for Adverse Events following vaccination; and

b) revised the previous disproportionality analysis methods for COVID-19 vaccines to:

i. increase the frequency of PRR analysis and reporting from bimonthly to weekly; and

ii. use PRR analysis according to the vaccine trade name rather than active ingredient; and

iii. adopt a standard of:

(1) a lower threshold of a PRR > 1 **("the Benchmark PRR Rate")**; and

(2) a case count of the greater of 2 or more event-affected people to identify:

a) vaccine-event pairs for assessment;

b) safety concerns in the Vaccines specifically.

iv. adopted a standard that where adverse event data in respect of the Vaccines indicated a PRR in excess of 1 a safety concern or signal in respect of that Vaccine had arisen.

Source

"Advisory Committee on Vaccines. Minutes - Meeting 25, held 29 September 2021. COMMITTEE IN CONFIDENCE. Reference no. D21-3141615".

https://www.tga.gov.au/sites/default/files/2023-01/foi-4029-03.PDF

PRR SAFETY SIGNAL – ESSENTIAL TOOL OF DETECTION

136. From November 1, 2019 it was widely published and scientifically and publicly established and known that:

a) timely Adverse Events Following Vaccination signal event detection is essential to minimise further recipients receiving unsafe vaccines;

b) the PRR metric is:

i. a measure of disproportionality of Adverse Events Following Vaccination; and

ii. an established signal detection algorithm (SDA) in pharmacovigilance.

c) a PRR provides sensitive signal detection when calculated cumulatively by individual year or by all previous years;

d) a PRR is defined as the ratio between:

i. the frequency with which a specific Adverse Event is reported for the vaccine of interest (relative to all Adverse Events reported for the vaccine); and

ii. the frequency with which the same Adverse Event is reported for all vaccines in the comparison group (relative to all Adverse Events for vaccines in the comparison group).

e) PRR data is an important performance requirement if monitoring:

i. new vaccines;

ii. new brands or formulations;

iii. population subgroups (e.g. in pregnancy);

f) the PRR algorithm is relatively easy to implement and analyse;

g) known signal events can be detected earlier than traditional methods using PRR;

h) PRR calculation, analysis and application should be routine in any national Adverse Event surveillance system;

i) a safety "signal" can be defined as incidence of Adverse Events Following Vaccination occurring at a higher level than is normally expected;

j) safety signal detection in vaccine vigilance requires a multi-faceted approach as Adverse Events Following Vaccination range from:

i. a rare occurrence of a severe Adverse Events Following Vaccination; to

ii. increased incidence or increased severity of a known, often frequently occurring Adverse Events Following Vaccination.

k) the potential for prospective analyses to inform signal detection must also be viewed commensurate with known limitations of passive surveillance systems:

i. namely under-reporting—particularly of reactions perceived as mild; and

ii. the time lag from symptom onset to report submission.

Source

"Early signal detection of adverse events following influenza vaccination using proportional reporting ratio, Victoria, Australia". Clothier HJ et al. (2019) PLoS ONE 14(11):

e0224702.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6824574/

KNOWN EXPONENTIALLY HIGH SAFETY SIGNALS - ACTUAL PRR DATA FOR VACCINES IN AUSTRALIA

137. As from 19 July, 2021, the adverse events reported data in respect of the Vaccines collected by the TGA and the TGA Respondents rationally established and disclosed, and the TGA and TGA Respondents had independently determined, that the Proportional Reporting Ratio data in respect of the Vaccines deaths and injuries:

a) exponentially exceeded the Benchmark PRR Rate;

b) were of a magnitude exponentially in excess of comparable vaccines authorised for use in Australia and the world;

c) were unquestionably indicative of, and disclosed extreme safety risks and concern in the Vaccines;

d) were in fact as follows for the Vaccines in respect of the following adverse event types and dates **("the Vaccines PRR Data")** :

	19/07/21	**29/09/21**	**29/11/21**	**17/01/22**	**24/3/22**	**11/05/22**	**15/07/22**	**15/09/22**
Appendicitis/ appendicitis Perforated/Epiploic appendicitis	4.8	9.56	6.52	12.01	15.69	13.67	6.78	6.87
Epiploic appendagitis		7.31						
Mesenteric panniculitis		7.31						

Pancreatitis acute	11.32	5.48	3.31					
Abnormal uterine bleeding			4.14				3.79	
Blood pressure increased	3.94	4.49	3.74	3.25				
Hypertensive crisis			9.82					
Malignant hypertension							3.16	
Pulmonary hypertension		9.74	7.36					
Amenorrhoea, delayed menstrual bleeding, oligomenorrheoea	15.51	19.23	29.5	31.87	12.65	19.78	19.35	19.09
Dysmenorrhoea, mentometorrhagia	7.45	7.47	11.82	29.5	12.04	6.47	3.82	5.81
Heavy menstrual bleeding, polymennorrhoea	39.23	23.18	26.86	21.37	16.52	15.15	15.01	14.38
Irregular Menstrual bleeding, Intermenstrual bleeding	7.92	10.49	22.88	22.11	10.34	12.57	11.88	11.65

Cardiac ventricular thrombosis		9.74		13.46				
Cerebral thrombosis		6.16						
Cerebral venous sinus	21.53	24.96	14.73	16.42	17.24			
Coagulopathy	5.14	5.36		4.94	5.5	4.38		
Disseminated intravascular coagulation		3.25						
Embolism		17.05		8.08				
Peripheral artery thrombosis				29.61	35.56			
Retinal artery occlusion		17.05	8.18	7.4				
Retinal artery thrombosis		9.74						
Splenic vein thrombosis		9.74	14.73					
Portal vein thrombosis			31.91	35	39.51	32.08		
Mesenteric vein thrombosis		31.66	13.91	16.15				
Jugular vein thrombosis		19.48	22.02					
Retinal vein occlusion					7.54		7.44	
Thrombocytosis	5.87	4.06	4.91					
Thromboembolism	14.68	8.96	7.33					

Thrombosis							4.73	4.62
Pulmonary embolism	17.45	17.65	13.73	11.31	9.84	9.39	9.13	8.8
Pulmonary thrombosis	17.62	19.48				9.38	10.75	
Deep vein thrombosis	14.12	13.9	12.78	11.51	10.52	10.41	10.22	
Thrombocytopenia	5.36	9.22	10.14	10.69	10.15	9.79	9.85	9.71
Immune thrombocytopenia		3.42	2.95	3.95			3.52	
Transverse sinus thrombosis			9.82					
Venous thrombosis	7.34	8.12		6.06		11.48		
Acute myocardial infarction	15.42	9.01	9.33	6.88	5.93	4.85		3.54
Myocardial infarction	7.49	6.39	5.69	3.99	3.3	2.65		
Coronary artery thrombosis				10.77	3.56		4.56	3.26
Arteriosclerosis coronary artery		3.25		7.18	8.89			
Atrial fibrillation	4.28	5.01	4.46	4.35	3.52			
Atrial flutter	32.1	8.28	4.09			9.28		
Cardiac arrest	2.31	2.58	2.4	2.57	2.61			
Cardiac failure	2.94	3.35	3.68	3.59	2.96			
Cardiac failure	8.81	4.87		4.04				

congestive								
Cardiac flutter			12.95		6.4	5.44	5.25	5.3
Cardiac tamponade		12.33	4.14	4.23				7.8
Cardiogenic shock		6.09	5.73	3.59	3.7			
Cardiomyopathy	4.4	2.09					3.01	2.6
Carditis						22.79	17.22	17.28
Congestive cardiomyopathy								3.12
Coronary artery disease			29.41	7.54		3.85		
Coronary artery occlusion							3.23	
Acute coronary syndrome		9.74						
Myocardial ischaemia		3.25	9.82	5.05	3.36		3.21	
Myocardial strain imaging		14.61	17.18	14.13				
Myopericarditis						5.76	5.45	5.43
Pericarditis	4.95	12.33	22.39	24.02	13.93	9.17	8.71	8.44
Myocarditis		9.62	20.05	21.68	8.48	3.86	3.46	
Stress cardiomyopathy		7.31					5.07	
Blindness	3.1	2.86						
Blindness unilateral		3.65						

Basal ganglia haemorrhage			7.36					
Cerebellar infarction/ stroke				10.77	17.78			
Cerebral haemorrhage	5.03	3.99	5.11	5.03				
Cerebral infarction	6.85	5.36	4.91	4.88		6.26		
Transient ischaemic attack	5.87	6.29	12.77	5.5	5.02	4.11	4.09	
Cerebrovascular accident	7.27	6.37	3.09	5.44	4.94	4.31	4.19	4.21
Haemorrhagic stroke	5.87	7.31	3.68	4.04	4.15			
Ischaemic stroke			7.01	5.38	5.14	5.84		
Subarachnoid haemorrhage	14.68	5.68	7.36	7.54	5.56			4.62
Haemorrhage intracranial	5.87	9.74	13.91	10.77		8.22		
Subdural haematoma	8.81	14.61	27	20.19				
Subdural haemorrhage	22.63	3.25	7.36					
Embolic stroke			3.65					
Embolism		17.05						
Gastrointestinal haemorrhage	8.81	9.74	8.18					
Colitis ischaemic		21.92	24.55		11.85			
Intestinal	5.87	3.29	13.68				3.23	

ischaemia								
Pulmonary infarction		36.53	51.54	19.74				
Renal infarct				24.23				
Splenic infarction		15.83	17.18	21.54				
Thrombotic stroke		7.31						
Aneurysm	4.4	4		4.04	4.94			
Aortic aneurysm		4.31	12.27	8.08				
Aortic aneurysm rupture		7.31	9.82					
Aortic dissection	12.18		7.36					
Intracranial aneurysm	7.31		4.91		4.94	3.65		
Ruptured cerebral aneurysm		7.31						
Vertebral artery dissection		12.33	13.8	19.03				5.2
Hepatic failure	4.4	6.09	4.3	4.31				
Respiratory Failure	3.91	5.28	5.26	4.16				
Plasma cell myeloma				8.08				
Malignant melanoma		7.31	6.14			7.14		
prostate cancer				6.73	10.37			
Neoplasm		3.04	3.93	5.92	3.65	4.1	4.36	

malignant								
ovarian cancer							6.31	
Leukaemia						2.35		
Acute lymphocytic leukaemia						3.33	10.67	
Breast cancer		3.65						
Gastrointestinal cancer		7.31						
Lymphoma	5.87	3.65	6.44	6.95				
Thyroid mass				6.34				
Uterine leiomyoma					9.26			
Breast mass	11.32	6.16						
Limb mass	14.68	14.61	5.73					
Brain injury								9.19
Coma scale abnormal	15.09	5.75						
Demyelination	3.2	3.18						
Facial paralysis	3.48	3.46	3.13	3.17				
Facial paresia	4.04	3.04	3.78					
Giant cell arteritis	7.34	8.12	14.73	9.69			10.14	
Guillain- Barre syndrome						2.1		
Hemiplegia								3.18
Meningitis aseptic		3.08						
Monoplegia	3.2							
Myasthenia gravis		6.09			8.89			
Peripheral sensory				3.59				

neuropathy								
Small fibre neuropathy			3.68	6.34	8.64	8.34		
Transient global amnesia	14.68	17.05	12.27	10.77		5.07		
Vestibular disorder		14.61						
Vestibular neuronitis	3.91				3.36	3.24		
Fifth nerve paralysis		4.06		5.38		5.37		
Alopecia							5.37	
Alopecia areata							5.92	6.24
Autoimmune hepatitis			3.68					
Mast cell activation syndrome								3.34
Multisystem Inflammatory syndrome in adults						5		
Systemic immune respiratory syndrome		3.65						
Toxic epidermal necrolysis			7.36					
Endocarditis			6.9					
Mastoiditis						3.91		
Staphylococcal sepsis				8.08				

Tooth abscess		7.31						
Urosepsis		3.25						
Eosinophil count increased		7.31						
White blood cell count decreased	4.91	4.87	3.96	3.1		3.21		
Diabetic ketoacidosis			16.56	14.8	5.09	5.84		
Multiple organ dysfunction syndrome		3.04	5.04	5.38				
Multisystem Inflammatory syndrome in children					5.56	11.67		7.82
Haemophagocystic lymphosistosis			3.68	5.38		3.13	4.52	
Herpes virus infection	8.28	3.65						
Herpes zoster reactivation		6.09		3.23				
Immunodeficiency						5	7.89	9.36
Giant cell arteritis	7.34	8.12	14.73	9.69			10.14	
Mastitis			11.96	12.69	6.35	7.29		5.95
Diverticulitis	19.57	9.5	6.06	4.62				
Post-acute Covid 19 syndrome								6.63
Abortion			4	4.81	5.44	5.27	5.3	

spontaneous								
Stillbirth				4.76	6.02		4.73	
Ectopic pregnancy					8.64		6.31	
Foetal cardiac disorder							7.73	
Pre-eclampsia						8.34		

Source

PRR data released by the Respondents under FOI Request 4032.

138. The PRR Data and resultant exponential breaches of the TGA and the TGA Respondents' PRR Benchmark has never been:

a) disclosed by the Respondents to the Australian public other than by express FOI request;

b) determined or acknowledged by the Respondents as a basis for:

i. withdrawal or suspension of the use of the Vaccines in Australia or the Approvals; or

ii. concern or safety signal in respect of the Vaccines.

c) raised, *advanced or disclosed* by any of the Respondents:

i. as the basis for convening VSIG to address such data as a "safety signal of concern" as defined by VSIG arising as a result of the occurrence of the extraordinarily high PRR data associated with the Vaccines;

ii. despite a legal and ethical obligation to do so in those circumstances.

Source

PRR data released by the Respondents under FOI Request 4032.

VSIG Work Instructions, pg. 2.

KNOWN ADVERSE EVENTS OF SPECIAL INTEREST – IMPROPER REFUSAL TO RECOGNISE OR ALERT PUBLIC

139. At all material times it is a scientific and universally known and accepted fact that an Adverse Event of Special Interest is a defined condition or event that occurs in some individuals:

a) following immunisation;

b) which possesses a known potential to be causally associated with a vaccine product;

c) are required to be carefully monitored and confirmed by further research studies.

Source

AusVaxSafety NCIRS– Adverse Events of Special Interest - https://ausvaxsafety.org.au/our-work/adverse-event-special-interest-aesi-long-term-follow-program.
AusVaxSafety receives funding from the Australian Government Department of Health and Aged Care.

140. From January 2021 and before the Approvals, the CDC widely and globally published and thereby disclosed guidelines for the enhanced safety monitoring of the Vaccines which defined the following adverse events of special interest **("the CDC Reported Adverse Events of Special Interest")**:

a) death,

b) COVID19 disease;

c) Guillain-Barre Syndrome;

d) seizure;

e) stroke;

f) narcolepsy/cataplexy;

g) anaphylaxis;

h) vaccination during pregnancy;

i) acute myocardial infarction;

j) myopericarditis;

k) coagulopathy (including thrombocytopenia;

l) disseminated intravascular coagulopathy;

m) deep venous thrombosis;

n) Kawasaki's disease;

o) multisystemic inflammatory syndrome in children;

p) multisystemic inflammatory syndrome in adults;

q) transverse myelitis;

r) Bell's Palsy; and

s) appendicitis.

Source

"Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19" (as of 29 January 2021). https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf

141. From 9 September, 2022 the following widely published types and volume of adverse events in recipients of the Vaccines were reported to the TGA and the TGA Respondents by the Australian public for the period of 25 January, 2021 to 9 September, 2022 which match the CDC Reported Adverse Events of Special Interest rationally establishing those as significant known safety risks in respect of the Vaccines **("the Known AESI Occurrences")**:

DAEN Database Results Corresponding to CDC Adverse Events of Special Interest 25/01/2021 – 09/09/2022:

Adverse Event of Special Interest	**MedDRA Reaction Term**	**Number of Cases**	**Cases With a Single Suspected Medicine**	**Cases with Death as Reported Outcome**
Acute Myocardial Infarction	- Acute Myocardial Infarction - Cardiac Arrest - Myocardial Infarction	142 145 366	137 138 359	20 86 39
Anaphylaxis	- Anaphylactic Reaction - Anaphylactic Shock	1,343 27	1,317 27	0 0
Appendicitis	- Appendicitis Perforated - Appendicitis	20 248	20 246	0 1
Bell's Palsy	- Bell's Palsy	673	650	0
Coagulopathy	- Pulmonary embolism - Deep vein thrombosis - Thrombosis - Thrombosis with	1,554 1,460 497	1,489 1,399 473	72 37 11

	thrombocytopenia syndrome	162	157	9
	- Immune thrombocytopenia	133	124	7
	- Cerebral venous sinus thrombosis	76	72	4
	- Coronary artery thrombosis	12	11	3
	- Cerebral artery thrombosis	7	6	3
	- Mesenteric artery thrombosis	3	3	2
	- Mesenteric vein thrombosis	22	20	2
	- Visceral venous thrombosis	12	11	2
	- Portal vein thrombosis	45	42	2
	- Splenic thrombosis	8	8	1
	- Atrial thrombosis	2	2	1
	- Cardiac ventricular thrombosis	7	7	1
	- Basilar artery thrombosis	1	0	1
	- Carotid artery thrombosis	4	4	1
	- Cerebral venous thrombosis	7	6	1
	- Thrombotic stroke	3	3	1
	- Pulmonary thrombosis	15	14	1
	- Splenic artery thrombosis	2	2	0
	- Splenic vein thrombosis	9	9	0
	- Thrombocytosis	13	12	0
	- Retinal artery thrombosis	6	6	0
	- Retinal vascular thrombosis	2	2	0
	- Retinal vein thrombosis	6	6	0
	- Thrombosis mesenteric vessel	1	1	0
	- Hepatic vascular thrombosis	2	2	0
	- Hepatic vein thrombosis	1	1	0
	- Cavernous sinus thrombosis	1	1	0
	- Arteriovenous fistula thrombosis	1	1	0
	- Cerebellar artery thrombosis	1	1	0
	- Cerebral thrombosis	12	12	0
	- Spinal artery thrombosis	1	1	0
	- Superior sagittal sinus thrombosis	12	11	0
	- Transverse sinus thrombosis	4	2	0

	- Vertebral artery thrombosis	2	2	0
	- Foetal placental thrombosis	1	1	0
	- Renal artery thrombosis	1	1	0
	- Renal vein thrombosis	4	4	0
	- Aortic thrombosis	5	5	0
	- Arterial thrombosis	10	10	0
	- Axillary vein thrombosis	1	1	0
	- Brachiocephalic vein thrombosis	1	1	0
	- Jugular vein thrombosis	10	10	0
	- Peripheral artery thrombosis	15	15	0
	- Subclavian artery thrombosis	3	2	0
	- Subclavian vein thrombosis	4	4	0
	- Superficial vein thrombosis	262	256	0
	- Vena cava thrombosis	3	3	0
	- Venous thrombosis	13	12	0
	- Venous thrombosis limb	1	1	0
COVID-19 Disease	- COVID-19	381	191	5
	- Breakthrough COVID-19 infection	20	18	0
	- Post-acute COVID-19 syndrome	18	18	0
	- COVID-19 pneumonia	3	3	0
Guillain-Barre Syndrome	- Guillain-Barre Syndrome	267	245	7
Kawasaki's Disease	- Kawasaki's disease	8	8	0
Multisystem Inflammatory Syndrome in Children (MIS-C)	- Multisystem inflammatory syndrome in children	7	7	0
Multisystem Inflammatory Syndrome in	- Multisystem inflammatory syndrome in adults - Multisystem inflammatory	4	3	0

Adults (MIS-A)	syndrome	3	3	0
Myopericarditis	- Pericarditis	3,527	3,401	5
	- Myocarditis	1,282	1,241	14
	- Myopericarditis	425	408	1
	- Eosinophilic myocarditis	2	2	1
	- Pleuropericarditis	2	2	0
	- Giant cell myocarditis	1	1	0
	- Pericarditis constrictive	1	1	0
Narcolepsy/Cataplexy	- Narcolepsy	5	5	0
Vaccination During Pregnancy	- Abortion spontaneous	293	285	0
	- Stillbirth	16	16	0
	- Foetal hypokinesia	15	15	1
	- Ectopic pregnancy	14	14	0
	- Foetal death	12	12	1
	- Premature labour	11	10	0
	- Premature rupture of membranes	11	11	0
	- Haemorrhage in pregnancy	10	10	0
	- Pre-eclampsia	10	10	0
	- Premature baby	10	10	0
	- HELLP syndrome	4	4	0
	- Premature delivery	4	3	0
	- Foetal cardiac disorder	3	3	0
	- Premature separation of placenta	3	2	0
	- Preterm premature rupture of membranes	3	3	0
	- Complication of pregnancy	2	2	0
	- Foetal growth restriction	2	2	0
	- Gestational hypertension	2	2	0
	- Placenta praevia haemorrhage	2	2	0
	- Placental disorder	2	2	0
	- Polyhydramnios	2	2	0
	- Subchorionic haematoma	2	2	0

	- Subchorionic haemorrhage	2	2	0
	- Uterine contractions abnormal	2	2	0
	- Abortion missed	1	1	0
	- Abortion spontaneous incomplete	1	1	0
	- Anembryonic gestation	1	1	0
	- Foetal growth abnormality	1	1	0
	- Foetal placental thrombosis	1	1	0
	- Foetal-maternal haemorrhage	1	1	0
	- Haemorrhage foetal	1	1	0
	- Maternal condition affecting foetus	1	1	0
	- Postpartum haemorrhage	1	1	0
Seizure	- Seizure	816	791	8
	- Generalised tonic-clonic seizure	71	66	3
	- Partial seizures	12	10	0
Stroke	- Cerebral haemorrhage	51	48	13
	- Cerebral infarction	47	45	14
	- Ischaemic stroke	43	43	5
	- Lacunar infarction	14	14	1
	- Cerebral thrombosis	12	12	0
	- Haemorrhagic stroke	12	12	3
	- Cerebellar stroke	10	9	0
	- Embolic stroke	10	9	1
	- Cerebral artery thrombosis	7	6	3
	- Cerebral venous thrombosis	7	6	1
	- Thalamic infarction	6	6	0
	- Cerebellar infarction	5	5	2
	- Brain stem infarction	4	4	0
	- Cerebral ischaemia	3	3	0
	- Lacunar stroke	3	3	0
	- Thrombotic stroke	3	3	10
	- Basal ganglia infarction	2	2	0
	- Brain stem stroke	2	2	0

	- Cerebral artery occlusion - Haemorrhagic transformation stroke - Basal ganglia stroke - Cerebellar haemorrhage - Cerebral artery stenosis - Cerebral microhaemorrhage - Embolic cerebellar infarction - Embolic cerebral infarction - Internal capsule infarction - Spinal stroke - Vertebrobasilar stroke	2 2 1 1 1 1 1 1 1 1 1	2 2 1 1 1 1 1 1 1 1 1	0 1 0 0 0 0 0 0 0 0 1
Transverse Myelitis	- Myelitis transverse	38	36	1

142. The TGA and the TGA Respondents subsequent to the disclosure of the Reported Adverse Events of Special Interest and the Known AESI Occurrences and continuously from that time:

a) have failed or refused to add the adverse events constituting the Known AESI Occurrences **("the Unrecognised Adverse Events of Special Interest")** to the AESI register;

b) have failed or refused to disclose the Known AESI Occurrences to the Australian public;

c) have engaged in acts and omissions pleaded in (i) to (iii) above in circumstances where:

i. the TGA and the TGA Respondents were and are required to notify the public of these safety matters according to TGA Policy.

Source

The DAEN Database.
https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen

KNOWN TEMPORAL ASSOCIATION OF SHINGLES WITH THE VACCINES

143. From October, 2021:

a) widely published data and scientific studies rationally established and thereby disclosed in respect of injury caused by the Vaccines that:

i. reactivation of the dormant virus Herpes Zoster responsible for shingles has been reported in relation to vaccination with the Vaccines;

ii. 96% of patients whom developed shingles subsequently to vaccination with the Vaccines did so within a temporal timeframe defined by WHO as indicative of the shingles being caused by the Vaccine;

b) the causality of the Vaccines in respect of the development of shingles in recipients of the Vaccines:

i. has not been advised to the public;

ii. has not been raised as a safety signal, alert or AESI.

Source

Widely and globally published studies included:

"Can SARS-CoV-2 vaccine increase the risk of reactivation of Varicella zoster? A systematic review". Desai, H.D. et al. 2021. Journal of Cosmetic Dermatology Volume 20, Issue 11, Pages 3350-3361

https://doi.org/10.1111/jocd.14521

KNOWN INFLAMMATORY, VASCULAR AND BLOOD RESPONSE

144. From March 2022 widely and globally published data and scientific studies rationally established and thereby disclosed that in respect of injury caused in recipients of the Pfizer Vaccine, the Pfizer Vaccine:

a) generated a significant rise in inflammatory markers, notably after the second dose;

b) is associated with a transient worsening of endothelial function;

c) detrimentally affected vascular function;

d) through the Pfizer Spike Protein:

i. entered into the brain endothelial cells of recipients after injection ;

ii. caused the formation of microthrombi in the brain;

iii. allowed pseudo virions (spike, envelope, and membrane proteins) without viral RNA to be present in the endothelia of cerebral micro-vessels causing microvascular injury;

iv. entered cardiac pericytes and pulmonary vascular cells causing in recipients:

(1) cell signaling leading to:

a) vascular cell dysfunction; and

b) cell growth/hypertrophy.

v. entered into the plasma with unknown effects.

Source

Widely and globally published studies included:
"The effect of an mRNA vaccine against COVID-19 on endothelial function and arterial stiffness", Terentes-Printzios, D et al, Hypertension Research, 45, 846-855(2022)

KNOWN LONG TERM ILLNESS ASSOCIATED WITH VACCINES

145. From December 2020 widely and globally published data and scientific studies rationally established and thereby disclosed in respect of the mRNA Vaccines injurious effects in humans, that the mRNA Vaccines caused in recipients of that Vaccine:

a) vaccine-induced autoimmunity;

b) pathogenic priming and multisystem inflammatory disease and autoimmunity;

c) antibody dependent enhancement;

d) activation of latent viral infections;

e) neurodegeneration and prion disease;

f) inhibition of DNA damage repair;

g) increased thrombosis, cardiomyopathy and other vascular events following vaccination;

h) babies suffering enduring adverse consequences;

i) mRNA reverse transcribing intracellularly into the DNA; and

j) death due to autoimmune disease subsequent to vaccination.

Source

Widely and globally published studies included:

Kelleni M.T. 2021. SARS CoV-2 vaccination autoimmunity, antibody dependent Covid-19 enhancement and other potential risks: beneath the tip of the iceberg. International Journal of Pulmonary & Respiratory Sciences. 5, DOI: 10.19080/IJOPRS.2021.05.555658.

Seneff, S. and Nigh, G. 2021. Worse than the disease? Reviewing some possible unintended consequences of the mRNA vaccines against COVID-19. International Journal of Vaccine Theory, Practice, and Research. 2, 38 – 79.

Hasan A., Al-Mulla M.R., Abubaker J., Al-Mulla F. (2021). Early insight into antibody-dependent enhancement after SARS-CoV-2 mRNA vaccination, Human Vaccines & Immunotherapeutics,
DOI: 10.1080/21645515.2021.1969855;

Classen JB. 2021. COVID-19 RNA based vaccines and the risk of prion disease. Microbiological Infectious Diseases. 5, 1-3.
https://scivisionpub.com/pdfs/covid19-rna-based-vaccines-and-the-risk-of-prion-disease-1503.pdf

Idrees D., Kumar V. 2021. SARS-CoV-2 spike protein interactions with amyloidogenic proteins: Potential clues to neurodegeneration. Biochemical and Biophysical Research Communication 554, 94-98. doi:10.1016/j.bbrc.2021.03.100; Kuvandik A., Özcan E. Serin, S., Sungurtekin H. 2021.

Anand, P., Stahel, V.P. 2021. The safety of Covid-19 mRNA vaccines: a review. Patient Safety in Surgery 15, 20. https://doi.org/10.1186/s13037-021-00291-9

Aldén, M.; Olofsson Falla, F.; Yang, D.; Barghouth, M.; Luan, C.;
Rasmussen, M.; De Marinis, Y. 2022. Intracellular Reverse Transcription of
Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human
Liver Cell Line. Current Issues in Molecular Biology 44, 1115–1126. https://doi.org/10.3390/cimb44030073

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS – VAED

146. From May 2021 widely and globally published data and scientific studies rationally established and thereby disclosed in respect of Vaccine-Associated Enhanced Disease **("VAED")** being caused by the Vaccines, that:

a) the Brighton Collaboration case definition and guideline for VAED disclosed the following:

i. that VAED is defined under the Brighton Collaboration as an illness that occurs:

(1) in a person who receive a vaccine; and

(2) who is subsequently infected with the pathogen that the vaccine is meant to protect against;

ii. all cases of vaccine failure should be evaluated for VAED;

iii. Vaccine-associated enhanced respiratory **("VAERD")** disease refers to disease with predominant involvement of the lower respiratory tract.

b) VAED is an abnormal immune response and an exuberant immune inflammatory response that includes the following symptoms:

i. cough;

ii. tachypnoea;

iii. pulmonary haemorrhage;

iv. acute cardiac injury;

v. tachycardia;

vi. vasculitis;

vii. myocarditis;

viii. heart failure;

ix. bleeding/thrombotic events;

x. pro-inflammatory state;

xi. renal dysfunction;

xii. acute kidney injury;

xiii. abdominal pain;

xiv. diarrhea;

xv. liver dysfunction;

xvi. acute liver failure;

xvii. altered mental state;

xviii. convulsions/seizures;

xix. cranial nerve involvement;

xx. fatigue;

xxi. myalgia;

xxii. arthritis;

xxiii. multi-organ failure; and

xxiv. death.

c) VAED:

i. was an identified potential complication of the Vaccines prior to the Approvals;

ii. is a complication known to occur in other vaccines and based on the vaccine design;

iii. was confirmed by Pfizer in August, 2021 to be a theoretical risk for the vaccine requiring ongoing surveillance;

iv. has exacerbated the outcome of the Covid Pandemic;

v. is evident in the use of the Vaccines by reason of the facts that:

(1) the rate of injury from infection with Covid is materially higher in those persons Vaccinated as compared to the Unvaccinated;

(2) there are high rates of complications from Covid in the Vaccinated;

d) the rate of incidence of VAED is correlated precisely with:

   i. the uptake of the Vaccines; and

   ii. worldwide excess deaths;

e) in the Pfizer PSUR document dated 19 August, 2021 and provided to the TGA and the TGA Respondents Pfizer identified 584 cases potentially indicative of VAED-VAERD wherein:

   i. 221 cases were medically significant;

   ii. 166 cases required hospitalisation;

   iii. 37 cases were life threatening;

   iv. 160 cases resulted in death.

f) so-called "Long Covid":

   i. is defined by the Department as:

      (1) ongoing symptomatic COVID-19 – COVID-19 symptoms lasting more than 4 weeks; or

      (2) post-COVID-19 condition/syndrome – COVID-19 symptoms after 12 weeks that are not explained by an alternative diagnosis.

   ii. results in a range of medical conditions after infection with Covid;

   iii. generally affects the young and healthy;

   iv. is in fact VAED when it occurs subsequent to a vaccinated individual experiencing breakthrough infection with the Virus;

v. was at all material times in the circumstances of (i) and (ii) above rationally to be investigated and addressed as potential causes of VAED and no the recently-defined "long Covid";

vi. notwithstanding the factual matters of (i) to (v) above, has at no time been the subject of evaluation by the TGA or the TGA Respondents as possible VAED where causal in the deaths of persons vaccinated with the Vaccines.

Source

Widely and globally published studies included:

"COVID-19 mRNA vaccine (nucleoside modified) Periodic Safety Update Report (PSUR) Reporting Period 19 December 2020 through 18 June 202, Dated 19 August, 2021". Pages 119-123.

"Vaccine-associated enhanced disease: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data". Munoz, F.M et al. Vaccine. 39(2021) 3053-3066. https://brightoncollaboration.us/wp-content/uploads/2021/07/VAED-vaccine-publication.pdf

"Vaccine-associated enhanced disease: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data". Munoz, F.M et al. Vaccine. 39(2021) 3053-3066. https://brightoncollaboration.us/wp-content/uploads/2021/07/VAED-vaccine-publication.pdf

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS – MYOCARDITIS

147. At all material times from the time of the Approvals widely and globally published data and scientific studies rationally established and thereby disclosed in respect of and relevantly to increased risk of cardiac injury in recipients of the Vaccines the following:

a) myocarditis is an inflammation of the heart muscle that can lead to serious illness and is established as an Adverse Event of Special Interest arising from vaccination with the Vaccines;

b) in January 2021, the CDC listed myocarditis as an Adverse Event of Special Interest in their published guidelines for the enhanced safety monitoring for Covid 19 vaccine;

c) Myocarditis:

i. caused:

(1) permanent heart damage;

(2) death;

(3) reduced life expectancy especially in categories of:

a) younger age groups; and

b) males.

ii. can rapidly become life-threatening;

iii. can cause sudden cardiac death, with no symptoms until death;

iv. scientifically examined in a study of a multicentre cohort of 171 paediatric patients with myocarditis, caused 13% to die or undergo cardiac transplant during their initial hospitalization;

v. for those with an underlying etiology of myocarditis, the incidence of transplant or death at 5 years after diagnosis was 27%;

vi. can lead to the development of a chronic dilated cardiomyopathy (DCM), which is the leading cause of paediatric heart transplant in children older than 1 year and;

vii. in a large cohort of paediatric patients with DCM from the Paediatric Cardiomyopathy Registry, was the most common known cause of DCM;

viii. is the known cause in 46% of children diagnosed with DCM;

ix. has a prognosis for individuals which varies with the clinical presentation wherein:

(1) patients with acute myocarditis and normal cardiac function have a good prognosis overall, with a high likelihood for spontaneous recovery;

(2) those with fulminant viral myocarditis are more likely to have recovery if adequately supported with medications or MCS during the initial phase;

(3) those with giant cell myocarditis have a poor prognosis in both children and adults, with median survival of less than 6 months without cardiac transplant.

x. when evaluated from a sudden death perspective, accounts for approximately 5% to 6% of sudden deaths in young athletes in the United States;

xi. can result in life-threatening arrhythmias and conduction abnormalities, including variable degrees of:

(1) atrioventricular block;

(2) ventricular fibrillation/flutter; or

(3) ventricular tachycardia.

xii. as well as pericarditis are in every instance serious and life-threatening conditions;

xiii. cannot properly be the subject of prognosis nor or treatment without a histological based understanding of the underlying pathophysiological processes;

d) following myocarditis:

i. there is generally a 30-40% chance of progression to death or cardiac failure within 5 years;

ii. there is a 75% mortality rate within a 6 month period in some aetiologies;

iii. at least 50% of patients develop cardiomyopathy in the long term;

iv. there is a one-year mortality rate for acute myocarditis generally of 20% which increases to 56% on four-year follow-up.

v. discernible changes to a patients ECG results are rare and thereby not a reliable basis of diagnosis;

vi. reliable assessment requires a minimum of an MRI to confirm the diagnosis;

vii. proper treatment can only be guided by the result of a myocardial biopsy;

viii. outcomes of acute myocarditis are often life threatening;

ix. the risk of sudden cardiac death in patients with acute myocarditis is not always associated with the severity of myocardial inflammation and can persist after the acute phase of myocarditis is resolved;

x. acute myocarditis can cause sudden cardiac death, accounting for approximately 10% of deaths from sudden cardiac death in young individuals

aged under 35 years;

xi. life-threatening bradyarrhythmia and tachyarrhythmia can occur at any stage of the disease and lead to sudden cardiac death.

e) from August 2021 myocarditis was causally linked to the mRNA Spike Protein;

f) the Vaccines;

i. increase risk of myocarditis in those younger than 40 years of age in the mRNA Vaccines;

ii. increase the risk of myocarditis within a week of receiving the first dose of any of the Vaccines;

iii. increase the risk of myocarditis after the second dose of both mRNA vaccines;

g) myocarditis is historically underdiagnosed in practice, with clinical bias being directed towards myocardial ischemia or infarction;

h) the risk of myocarditis and pericarditis in recipients of either of the mRNA Vaccines:

i. increases both after the first and second doses;

ii. is statistically significant;

iii. is in respect of the Moderna Vaccine a 3000% increased risk;

iv. is higher in younger age groups;

v. is observable internationally.

i) Covid infection:

i. in unvaccinated patients is not associated with any materially increased risk of myocarditis and pericarditis;

ii. causes no materially increased incidence of either pericarditis nor myocarditis in adult patients post-infection.

j) at the time of the Approvals the background rate of incidence of myocarditis in children aged 15 years and under was:

i. 1.95 per 100,000 persons; or

ii. 0.00195%.

k) in the period between December 2020 and August 2021, reports of myocarditis in individuals older than 12 years old to the VAERS that occurred after administration of the mRNA Vaccines disclosed that:

i. the reported cases of myocarditis in VAERS within 7 days after vaccination exceeded the expected rates across multiple age and sex strata;

ii. rates of myocarditis were highest after the second vaccination dose in:

(1) adolescent males aged 12-15 years (70.7 per million doses of the Pfizer Vaccine);

(2) adolescent males aged 16-17 years (105.9 per million doses of the Pfizer Vaccine); and

(3) young men aged 18 to 24 years (52.4 and 56.3 per million doses of the Pfizer Vaccine and the Modern Vaccine, respectively).

l) vaccination with the Pfizer Vaccine was known from September, 2021 by the Respondents to be associated with an increased risk of myocarditis:

i. of 5 events per 100,000 persons; and

ii. which is substantially increased after Covid infection.

m) the European Medicines Agency Pharmacovigilance Risk Assessment Committee (PRAC) had by 28 October, 2021:

i. confirmed a safety signal in the Vaccines for myocarditis and pericarditis, as well as capillary leak syndrome in the Moderna Vaccine;

ii. recommended changes to the Product Information to reflect this in the Moderna Vaccine and the Pfizer Vaccine;

iii. stated that any cardiac arrest or death in young people must constitute a safety signal.

n) it was rationally and scientifically established and thereby disclosed from October 2021 that:

i. within the 28-day period post-vaccination with the mRNA Vaccines:

(1) for males and females 12 years or older combined, the second dose was associated with higher excess risk of myocarditis being:

a) 1.75 times higher risk for the Pfizer vaccine; and

b) 6.57 times higher risk for the Moderna Vaccine.

(2) for males 16 to 24 years of age, the second dose was associated with higher excess risk of myocarditis being:

a) 5.31 times higher risk for the Pfizer vaccine; and

b) 13.83 times higher risk for the Moderna Vaccine.

(3) numbers of excess events of myocarditis per 100,000 vaccinees after the second dose were:

a) 5.55 excess events for the Pfizer vaccine; and

b) 18.39 excess events for the Moderna Vaccine.

(4) similar rates as those were evident in respect of Pericarditis.

o) from April 2022 it was rationally and scientifically established and thereby disclosed that the Pfizer Vaccine caused increased risk of myocarditis in younger males as follows:

i. 1.316 per 10,000 additional instances of myocarditis among men 12–19 years old in the week following receiving the second dose of the Moderna Vaccine than those unvaccinated;

ii. 1.88 per 10,000 additional instances of myocarditis 4 weeks after receiving the second dose of the Moderna Vaccine in boys 16–24 years old compared to the unvaccinated.

p) the Commonwealth report on Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines dated 29 April, 2022, disclosed at that time that the following rates of myocarditis per million doses by age cohort and sex were reported:

i. Pfizer:

(1) 12-17 years of age:

a) males: 107;

b) females: 24;

(2) 18-29 years of age:

a) males: 67;

b) females: 20;

(3) 30-39 years of age:

a) males: 19;

b) females: 6.

ii. Moderna:

(1) 12-17 years of age:

a) males: 159;

b) females: 26;

(2) 18-29 years of age:

a) males: 142;

b) females: 12;

(3) 30-39 years of age:

a) males: 52;

b) females: 0.

q) from August, 2022 in adolescents taking two doses of the Pfizer Vaccine:

i. cardiovascular manifestations were found in 29.24% of recipients including:

(1) tachycardia - 7.64%;

(2) shortness of breath - 6.64%;

(3) palpitation - 4.32%;

(4) chest pain 4.32%; and

(5) hypertension 3.99%.

ii. confirmed or suspected myocarditis or pericarditis occurred in 2.3% of recipients.

Source

Widely and globally published studies included:

"Acute Myocarditis and Pericarditis in Children" Tunuguntla H, et al. 2019. Ped. Rev. 40(1):14-25" https://publications.aap.org/pediatricsinreview/article-abstract/40/1/14/35218/Acute-Myocarditis-and-Pericarditis-in-Children?redirectedFrom=fulltext

"Acute Myocarditis". Al-Akchar, M et al. 2022. In: StatPearls [Internet]. https://www.ncbi.nlm.nih.gov/books/NBK441847/

"Myocarditis and inflammatory cardiomyopathy: current evidence and future directions". Tschöpe, C et al. 2021. Nat Rev Cardiol. 2021;18(3):169-193.

“Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection”. Patone, M et al. 2022. Nature Medicine, 28, pages 410–422.
https://pubmed.ncbi.nlm.nih.gov/34907393/

“Age and sex-specific risks of myocarditis and pericarditis following Covid-19 messenger RNA vaccines”. Le Vu, S. 2022. NATURE COMMUNICATIONS 13, Article number: 3633. https://www.nature.com/articles/s41467-022-31401-5

“The Incidence of Myocarditis and Pericarditis in Post COVID-19 Unvaccinated Patients – a Large Population-Based Study”. Tuvali, O et al. 2022. J. Clin. Med. 2022, 11, 2219. https://doi.org/10.3390/jcm11082219

“Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection”. Patone, M et al. 2022. Nature Medicine, 28, pages 410–422.
https://pubmed.ncbi.nlm.nih.gov/34907393/

“Occurrence and Features of Childhood Myocarditis: A Nationwide Study in Finland”, Arola et al. 2017. Journal American Heath Association, v6(11).

“Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021”, Oster et al, 2022. JAMA. 327(4):331-340

“Safety of the BNT162b2 MRNA COVID-19 Vaccine in a Nationwide Setting”. Barda, N et al. 2021. N. Engl. J. Med. 385, 1078–1090

SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents, Karlstad et al. JAMA Cardiol.2022;7(6):600-612. doi:10.1001/jamacardio.2022.0583. Published online April 20, 2022. October 5, 2021 Study End – Confirmed Data on SARS-CoV-2 vaccinations, hospital diagnoses of myocarditis or pericarditis, and covariates for the participants were obtained from linked nationwide health registers in Denmark, Finland, Norway, and Sweden.

"Current Evidence in SARS-CoV-2 mRNA Vaccines and Post-Vaccination Adverse Reports: Knowns and Unknowns". Mouliou, Dimitra S. and Dardiotis, Efthimios. Diagnostics (Basel). 2022 Jun 26; 12(7):1555 citing data from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1072043/COVID-19_mRNA_Pfizer-_BioNTech_vaccine_analysis_print.pdf

"PRAC recommendations on signals", Adopted at the 25-28 October 2021 PRAC meeting. European Medicines Agency Pharmacovigilance Risk Assessment Committee.

Analysis of all UK spontaneous reports to the Yellow Card Scheme between 9 December, 2020 and 20 April, 2022 for Pfizer Vaccine.

Australian Government report (Updated 28 April 2022) "Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines". https://www.health.gov.au/sites/default/files/documents/2022/04/covid-19-vaccination-guidance-on-myocarditis-and-pericarditis-after-mrna-covid-19-vaccines.docx

"Cardiovascular Manifestation of the BNT162b2 mRNA

Covid-19 Vaccine in Adolescents", Mansanguan et al, Trop. Med. Infect. Dis. 2022, 7(8), 196.

Analysed 301 Thai adolescents aged 13-18 who received 2 doses of BNT162b2 Covid-19 vaccine. 7 cases.

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS – ANAPHYLAXIS

148. From May 2021 widely and globally published data and scientific studies rationally established and thereby disclosed in respect of and relevantly to anaphylaxis as a side-effect of the Vaccines that:

a) approximately 2.5 million doses of the Vaccines had been administered in Australia at that time;

b) anaphylaxis was being reported at a rate of 1 case per 156,250 injections of the Vaccines;

c) international long-term surveillance of vaccine-related anaphylaxis is approximately 1 in one million;

d) the rate of reported anaphylaxis related to the Vaccines was:

i. unexpectedly high as compared to the expected rate for vaccines generally;

ii. more than 6 times higher than the expected rate for vaccines generally;

iii. indicated as caused by the Vaccines;

iv. at no time stated or publicly disclosed by the TGA or the TGA Respondents to be of sufficient concern to withdraw the Vaccines from use by the Australian population.

e) anaphylaxis is:

i. a serious adverse event;

ii. as to its rate of occurrence, a critical indicator of vaccine safety;

iii. related to immunogenicity in a medication, including vaccines;

iv. indicative of a higher risk of other immunological adverse events in recipients of a medication, including vaccines.

Source

DAEN Database
https://daen.tga.gov.au/medicines-search/

Jens U. Rüggeberg, Anaphylaxis: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data, Vaccine, Volume 25, Issue 31,2007, Pages 5675-5684, ISSN 0264-410X, https://doi.org/10.1016/j.vaccine.2007.02.064.

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS – THROMBOCYTOPENIA AND THROMBOEMBOLISM

149. From April 2021 widely and globally published data and scientific studies rationally established and thereby disclosed that the mRNA Vaccines caused significantly increased risk of injury to recipients of the mRNA Vaccines by haematological and vascular events:

a) which typically caused:

i. hospital admission; or

ii. death;

b) such events being specifically:

i. thrombocytopenia;

ii. venous thromboembolism;

iii. arterial thromboembolism;

iv. cerebral venous sinus thrombosis;

v. ischaemic stroke; and

vi. other normally rare arterial thrombotic events.

c) such events occurring typically within a short time interval after first doses of the either of the mRNA Vaccines.

Source

Widely and globally published studies included:

"Risk of Thrombocytopenia and Thromboembolism after COVID-19 Vaccination and SARS-CoV-2 Positive Testing: Self-Controlled Case Series Study". Hippisley-Cox, J et al. BMJ 2021, 374, n1931

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS – THYROID EFFECTS

150. From November, 2021 widely and globally published data and scientific studies rationally established and thereby disclosed that in respect of injury caused to recipients of the Vaccines, the Vaccines:

a) caused:

i. Spontaneous Subacute Thyroiditis; and

ii. Grave's disease;

b) contained adjuvants which combine into potential cross-reactivity between the Virus and thyroid antigens to cause during and after Covid infection and injection with the mRNA Vaccines:

i. autoimmune reactions; and

ii. inflammatory reactions.

Source

Widely and globally published studies included:

"Thyroid as a Target of Adjuvant Autoimmunity/Inflammatory Syndrome Due to MRNA-Based SARS-CoV2 Vaccination: From Graves' Disease to Silent Thyroiditis". Pujol, et al. 2022. J. Endocrinol. Investig. 45, 875–882.

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS – NEUROLOGICAL EFFECTS

151. From May, 2022 widely and globally published data and scientific studies rationally established and thereby disclosed in respect of and relevantly to injury caused by neuropathy in recipients of the Vaccines that the Vaccines caused:

a) severe face and/or limb paraesthesia;

b) orthostasis, heat intolerance and palpitations; and

c) small-fibre peripheral neuropathy;

d) Bell's Palsy;

e) transverse myelitis;

f) acute disseminated encephalomyelitis;

g) Guillain-Barre Syndrome.

Source

Widely and globally published studies included:

"Neuropathic symptoms with SARS-CoV-2 vaccination". Safavi et al, medRxiv. May 17, 2022.

Allahyari, et al. "Covid-19 vaccines and neurological complications: a systematic review" *Zeitschrift für Naturforschung C*, vol. 78, no. 1-2, 2023, pp. 1-8. https://doi.org/10.1515/znc-2022-0092

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS – CANCER

152. From the period of 19 July, 2021 to 15 July, 2022, it was rationally established and thereby disclosed by the adverse events data provided to TGA and the TGA Respondents at that time that there existed an exponentially elevated propensity and risk of the Vaccines to cause injury in recipients in excess of the TGA's declared safety signal thereshold, the PRR data for cancers arising in recipients of the Vaccines which were:

a) by 19 July, 2021 a PRR for Lymphoma of 5.87;

b) by 29 September, 2021:

i. a PRR for Malignant Melanoma of 7.31;

ii. a PRR for Malignant Neoplasm of 3.04;

iii. a PRR for Breast Cancer of 3.65;

iv. a PRR for Gastrointestinal Cancer of 7.31;

v. a PRR for Lymphoma of 3.65;

c) by 29 November, 2021:

i. a PRR for Malignant Melanoma of 6.14;

ii. a PRR for Malignant Neoplasm of 3.93;

iii. a PRR for Lymphoma of 6.44;

d) by 17 January, 2021:

i. a PRR for Plasma Cell Myeloma of 8.08;

ii. a PRR for Prostate Cancer of 6.73;

iii. a PRR for Malignant Neoplasm of 5.92;

iv. a PRR for Lymphoma of 6.95;

e) 24 March, 2022

i. a PRR for Prostate Cancer of 10.37;

ii. a PRR for Malignant Neoplasm of 3.65;

f) 11 May, 2022

i. a PRR for Malignant Melanoma of 7.1;

ii. a PRR for Malignant Neoplasm of 4.1*;*

iii. a PRR for Leukaemia of 2.35;

iv. a PRR for Acute Lymphocytic Leukaemia of 3.33;

g) 15 July, 2022

i. a PRR for Malignant Neoplasm of 4.36;

ii. a PRR for Ovarian Cancer of 6.31;

iii. a PRR for Acute Lymphocytic Leukaemia of 10.67.

Source

TGA Data obtained by FOI Request 4029

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS - PREGNANT WOMEN

153. At all material times subsequent to the Approvals widely and globally published data, scientific studies and the data and documents provided by the Sponsors directly to the TGA and the TGA Respondents rationally established and thereby disclosed in respect of the risks of injury to pregnant women caused by the Vaccines that:

a) worldwide data indicated:

i. material increases in stillbirths, perinatal, and neonatal deaths from late 2021 leading into 2022;

ii. decreases in birth rates in:

(1) Germany;

(2) Taiwan;

(3) US states;

(4) Sweden;

(5) Canada;

(6) Hungary.

b) the Pfizer Post-Marketing Data dated 28 February, 2021 provided directly to the TGA and the TGA Respondents disclosed that:

i. the Vaccines were not studied for safety in pregnancy in any of the Vaccines clinical trials;

ii. the data collected in those trials for pregnant women were subjects whom incidentally became or were pregnant during the clinical trials.

iii. 270 pregnancies reported during the trial as having had exposure to the Pfizer Vaccine, from which:

(1) Pfizer failed or refused to follow-up and/or report to the TGA on the outcome of 238 pregnancies, being 88% of cases;

(2) Pfizer followed-up and reported the outcome of 32 pregnancies to the TGA wherein:

a) 23 cases (72% of those followed up) suffered spontaneous abortion with intrauterine death;

b) 2 cases (6% of those followed up) suffered premature birth with neonatal death;

c) 2 cases (6% of those followed up) suffered premature birth;

d) 1 case (3% of those followed up) of a normal;

e) 4 reported (13% of those followed up) as outcome pending.

c) VAERS reports of pregnancy-related adverse events from January 1, 1998 to June 30, 2022 calculations of PRR of adverse pregnancy events following vaccination with the Vaccines compared to Influenza vaccine found a:

i. 1200-fold higher rate of severe menstrual abnormalities;

ii. 57 fold higher rate of miscarriage;

iii. 38 fold higher rate of foetal death/stillbirth;

iv. 15 other major pregnancy complications far exceeding the regulator's safety threshold.

d) in Australia, PRR data produced by the TGA and the TGA Respondents disclosed:

i. a PRR for miscarriage of 5.3;

ii. an increase of adverse event reporting of 5.3 times higher than for any other vaccine.

e) in August, 2022 it was widely published and reported that Dr Luke McLindon, former head of fertility services at the Mater Hospital in Brisbane and former President of the Australasian Institute for Restorative Reproductive Medicine, reported miscarriages:

i. at a typical rate of occurrence of 12-15% in his cohort of patients which is higher than the usual miscarriage rate because his patients are all typically high-risk pregnancies;

ii. increasing to a rate of occurrence in excess of 70% among the subset of patients who had been injected with the Vaccines prior to conception.

f) on or about 8 October, 2022, Dr James Thorp, a board-certified OBGYN and Maternal Foetal Medicine Physician with over 43 years of clinical experience was widely published and reported as stating that:

i. in the two years prior, since the mRNA Vaccines were introduced, he has seen in his patients an "off the charts" rise among patients vaccinated with the mRNA Vaccines in:

(1) sudden foetal death;

(2) adverse pregnancy outcomes;

(3) foetal malformation;

(4) foetal cardiac arrest;

(5) severe placental problems causing inter-uterine growth restrictions.

ii. the significant increase was compared with appropriate controls like the influenza vaccine;

iii. his observations showed relative risk p-values of the mRNA Vaccines above 1,000,000;

iv. the CDC and the FDA state if you have a relative risk of (p-value) 2 or greater, that's a severe danger signal that should be looked at; and

v. the adverse events were causally related to receipt of the mRNA Vaccines by the pregnant women.

vi. the clinical standard/cardinal rule of obstetrics:

(1) is to never use a substance in pregnancy that is new, untested and even has any potential to do harm;

(2) is violated by injecting pregnant women with a novel untested vaccine was a gross violation of that cardinal rule.

Source

Widely and globally published studies included:

Guetzkow, J (July 2022) "Springtime for Stillbirths in Germany Winter for women and babies". Substack. https://jackanapes.substack.com/p/springtime-for-stillbirths-in-germany

Chudov, I (July 2022) "Hungary: Highest Vaccinated Counties Have Worst Birth Rate Drops". Substack. https://igorchudov.substack.com/p/hungary-most-vaccinated-counties

Jestre (July 2022) "Birth rate declines come to Canada". Substack. https://jestre.substack.com/p/birth-rate-declines-come-to-canada

The Pfizer Post-Marketing Data. Page 12.

COVID-19 Vaccines: The Impact on Pregnancy Outcomes and Menstrual Function. Thorp et al. Preprint Dec 2022 https://www.preprints.org/manuscript/202209.0430/v1

PRR data released under FOI Request 4032

"Brisbane doctor details how he came to be sacked by major hospital". Brisbane Times, 17 August, 2022. https://www.brisbanetimes.com.au/national/queensland/brisbane-doctor-details-how-he-came-to-be-sacked-by-major-hospital-20220817-p5baiw.html

Interview broadcast on the Ask Dr Drew Show on 8 October, 2022.

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS - CHILDREN

154. From October 2022 widely and globally published data and scientific studies rationally established and thereby disclosed in respect of injuries to children receiving the Pfizer Vaccine that in those children aged 5 years and under following taking the Pfizer Vaccine:

a) 0.9% required emergency care (ambulatory);

b) 0.1% required hospitalisation (inpatient);

c) the rate requiring emergency care was 80% higher than those in the same age group taking a vaccine which is not one of the Vaccines;

d) the rate requiring hospitalisation was 80% higher than those in the same age group taking a vaccine which is not one of the Vaccines;

e) 1.02 in every 2 children receiving the Pfizer Vaccine suffered an adverse event following vaccination;

f) the risk of children suffering an adverse event is 36% higher following the Pfizer Vaccine than it is following a vaccine which is not one of the Vaccines.

Source

Widely and globally published studies included:

"Comparative Safety of the BNT162b2 mRNA COVID-19 Vaccine vs Other Approved Vaccines in Children Younger Than 5 Years". Toepfner et al, Oct 2022. JAMA Network Open. 5(10).

KNOWN EXPLOSION IN VACCINES-RELATED ADVERSE EVENTS

155. From April 2021 widely and globally published data and scientific studies rationally established and thereby disclosed an exponential increase in adverse events and injury reported in recipients of the Vaccines at the time of subsequent Vaccine approvals as follows:

a) the Pfizer Adolescent Approval occurred on 22 July, 2021 wherein at that time the DAEN disclosed in respect of the Vaccines:

i. 45,188 reported adverse events;

ii. 427 reported deaths.

b) the Moderna Approval occurred on 9 August, 2021 wherein at that time the DAEN disclosed in respect of the Vaccines:

i. 51,489 reported adverse events;

ii. 472 reported deaths.

c) the Moderna Adolescent Approval occurred on 3 September, 2021 wherein at that time the DAEN disclosed in respect of the Vaccines:

i. 62,167 reported adverse events;

ii. 540 reported deaths.

d) the Pfizer booster dose was approved by the TGA and the TGA Respondents for use in ages 18 years and older on 26 October, 2021 wherein at that time the DAEN disclosed in respect of the Vaccines:

   i. 81,594 reported adverse events;

   ii. 641 reported deaths.

e) the Pfizer Child Approval occurred on 3 December, 2021 wherein at that time the DAEN disclosed in respect of the Vaccines:

   i. 95,384 reported adverse events;

   ii. 707 reported deaths.

f) the Moderna booster dose was approved by the TGA and the TGA Respondents for use in ages 18 years and older on 7 December, 2021 wherein at that time the DAEN disclosed in respect of the Vaccines:

   i. 96,312 reported adverse events;

   ii. 711 reported deaths.

g) the Pfizer booster dose was approved by the TGA for use in ages 16-17 year olds on 27 January, 2022 wherein at the time the DAEN disclosed in respect of the Vaccines:

   i. 110,383 reported adverse events;

   ii. 763 reported deaths.

h) the AstraZeneca booster dose was approved by the TGA and the TGA Respondents for use in ages 18 years and older on 8 February, 2022 wherein at that time the DAEN disclosed in respect of the Vaccines:

i. 114,208 reported adverse events;

ii. 769 reported deaths.

i) the Moderna Child Approval occurred on 17 February, 2021 wherein at that time the DAEN disclosed in respect of the Vaccines:

i. 116,590 reported adverse events;

ii. 774 reported deaths.

j) the Pfizer booster dose was approved by the TGA and the TGA Respondents for use in ages 12-15 year olds on 17 April, 2022 wherein at that time the DAEN disclosed in respect of the Vaccines:

i. 126,774 reported adverse events;

ii. 827 reported deaths.

k) the Moderna Infant Approval occurred on 19 July, 2022 wherein at that time the DAEN disclosed in respect of the Vaccines:

i. 134,224 reported adverse events;

ii. 908 reported deaths.

Source

DAEN Database

https://daen.tga.gov.au/medicines-search/

SCHEDULE C – PARTICULARS - CIRCUMSTANCES OF KNOWLEDGE

KNOWN SERIOUS VACCINES RISKS AND CONDUCT – PRE-APPROVALS AND KNOWN SERIOUS VACCINES RISKS AND CONDUCT – POST-APPROVALS

The Respondents' knowledge of the Known Serious Vaccines Risks and Conduct – Pre Approvals and the Known Serious Vaccines Risks and Conduct – Post-Approvals arose in each instance:

1. at and from the times pleaded as the time at which those matters were disclosed in the respective paragraphs of Schedule A;

2. by reason of being contained in the disclosed material and data in Schedule A respectively which **("the Relevant Materials and Data")** made those factual matters rationally evident and known to the recipient;

3. by way of the respective Relevant Materials and Data coming into the control, possession and knowledge of the respective Respondents by:

    a. as to the factual matters particularised at paragraphs 3, 6 to 9, 10 to 14, 18 to 22, 25 to 33, 35 to 38, 40 to 42, 50 to 52, 54 to 60, 64, 67 to 70, 73. 74, 78, 114, 121, 141 and 153 (inclusive) of Schedule A of the SOC, such data:

        i. being directly provided by the Sponsors to the Commonwealth, the TGA and the TGA Respondents in the course of and for the purposes of the Approvals, Continuing Approvals and establishing the safety and efficacy of the Vaccines being **("the Sponsors Provided Data")**:

            1. the Sponsors' Study Data provided in the circumstances of the matters pleaded at paragraph 22 of the SOC and particularised in Schedule E of the SOC;

            2. the Trial Protocols provided in the circumstances of the matters pleaded and particularised at paragraph 23 of the SOC;

3. the TGA Vaccine Approval Documents provided in the circumstances of the matters pleaded at paragraph 24 of the SOC and particularised in Schedule F of the SOC;

4. other data pleaded and particularised in those respective paragraphs as having been provided by the Sponsors directly to the TGA and TGA Respondents.

ii. as a consequence of the Sponsors Provided Data being provided directly to the TGA and the TGA Respondents, the Chief Medical Officer and Hunt receiving possession and/or knowledge of that data by:

1. direct provision of that data by one or more of the TGA Respondents, or TGA or Department employees;

2. direct access to that data being provided by an employee of the TGA or the Department.

b. as to the factual matters particularised at paragraphs 1, 3 to 14, 16, 18 to 22, to 33, 35 to 60, 62 to 77, 79, 84, 114 to 139, 141, 142 and 152 to 155 (inclusive) of Schedule A of the SOC, such data being expressly contained within documents produced internally by the TGA and the Department related to the safety, efficacy and risk-benefit of each of the Vaccines and the TGA's internal actions being thereby:

i. readily and easily accessible to any and all of the Respondents;

ii. known to all of the Respondents;

iii. directly and/or indirectly provided to all the Respondents.

c. as to the factual matters particularised at paragraphs 5, 81 to 84, 86 to 90, 95, 100, 107, 109, 110, 115 to 120, 129 to 131, 132, 133, 137, 138, 141 to 143, 144 to 150 and 208 to 211 (inclusive) of Schedule A of the SOC, such data being reported to,

collected, stored and widely published by the TGA as relating to the safety, efficacy and risk-benefit of each of the Vaccines and reported, collected, stored and published for that purpose being thereby:

i. readily and easily accessible to any and all of the Respondents;

ii. known to all of the Respondents;

iii. directly and/or indirectly provided to all the Respondents.

d. as to the factual matters particularised at paragraphs 17, 21, 24, 25, 34, 38, 43, 45, 47, 49, 55, 60 to 66, 72, 73, 75, 77, 82, 96, 97, 100 to 112, 114, 116, 117, 120, 131, 132, 133, 130 and 140 (inclusive) of Schedule A of the SOC, such data being provided directly to the TGA and the TGA Respondents by international regulatory bodies or other government departments or entities related to the safety, efficacy and risk-benefit of each of the Vaccines and published and/or directly provided for that purpose being thereby:

i. readily and easily accessible to any and all of the Respondents;

ii. known to all of the Respondents;

iii. directly provided to the TGA and TGA Respondents;

iv. indirectly and subsequently provided to Hunt and the Chief Medical Officer.

e. as to the factual matters particularised at paragraphs 1 to 3, 6, 7, 17, 23 to 25, 27, 30 to 32, 34, 37, 40, 42, 43, 45, 47, 49, 51 to 57, 79 to 95, 97 to 100, 102, 104 to 113, 121, 124 to 128, 134, 135, 139 to 141, 143 to 150, 153 to 155 (inclusive) of Schedule A of the SOC, such data being widely and globally published and known scientific studies and data in internationally acknowledged and prolific sources of scientific data and studies, related to the safety, efficacy and risk-benefit of each of the Vaccines being thereby:

i. readily and easily accessible to any and all of the Respondents;

ii. known to the Respondents;

iii. directly or indirectly provided to the Respondents by reason of the matters particularised at (g) below;

f. as to the factual matters particularised at paragraphs 6, 15, 23 to 25, 34, 43, 45, 47, 53, 60, 72 to 74, 77, 82, 96, 97, 100 to 112, 117, 120, 140, 141, 143 to 150 and 155 (inclusive) of Schedule A of the SOC, such data being widely and globally published and known international regulatory authority data related to the safety, efficacy and risk-benefit of each of the Vaccines being thereby:

i. readily and easily accessible to any and all of the Respondents;

ii. known to the Respondents;

iii. directly or indirectly provided to the Respondents by reason of the matters particularised at (g) below;

g. as to all of the factual matters particularised at paragraphs 1 to 155 (inclusive) of Schedule A of the SOC herein, such data:

i. being directly provided or alternatively being provided direct access to that data through the National Vaccine Task Force with responsibility to collect, and in fact collecting, all available Covid and Vaccine related data pleaded at paragraph 10(j) of the SOC, by reason of:

1. as to the Secretary – his position as head of the entity;

2. as to Skerritt – his position as a member of the entity;

3. as to Hunt – his position as the recipient of advices relating to all collected Covid and Vaccine related data accumulated by the entity.

ii. being directly provided or alternatively being provided direct access to that data through the Science and Industry Technical Advisory Group, which was at all times tasked with providing and, in fact, provided advice to the Commonwealth as to the scientific validity or otherwise of research into the safety and effectiveness of the Vaccines pleaded at paragraph 96(d)(ii)(6) and 102(d)(ii)(6) herein, by reason of:

1. as to the Secretary – his position as chair of the entity;

2. as to the Chief Medical Officer – his position as deputy chair of the entity;

3. as to Hunt – his position as the recipient of advices relating to the Vaccines-related data accumulated by the entity.

iii. being contained in documents, material and knowledge which:

1. by reason of the factual matters contained in paragraphs 11, 15, 17 and 18, Skerritt necessarily obtained and/or had knowledge of:

   a. as head of the TGA with functional and operational responsibility for the Approvals, Continuing Approvals; and

   b. as the maker and publisher of public declarations to the Australian population as to the safety, efficacy and necessity of the Vaccines;

2. by reason of the factual matters contained in paragraphs 10, 11 15, 17 and 18, the Secretary necessarily obtained and/or had knowledge of:

   a. as head of the Department with legal, functional and operational responsibility for the Approvals, Continuing

Approvals; and

b. as the maker and publisher of public declarations to the Australian population as to the safety, efficacy and necessity of the Vaccines;

3. by reason of the factual matters contained in paragraphs 12, 15, 17 and 18 the Chief Medical Officer necessarily obtained and/or had knowledge of:

a. as the chief medical officer of the Commonwealth with responsibility for the betterment of the health and wellbeing of the Australian population, advices to the Commonwealth for that purpose; and

b. as the maker and publisher of public declarations to the Australian population as to the safety, efficacy and necessity of the Vaccines;

4. by reason of the factual matters contained in paragraphs 10 to 18 inclusive Hunt necessarily obtained and/or had knowledge of:

a. as a minister of the Commonwealth with responsibility for the Department purposed with the betterment of the health and wellbeing of the Australian population; and

b. as the maker and publisher of public declarations to the Australian population as to the safety, efficacy and necessity of the Vaccines;

5. by reason of the factual matters contained in paragraphs 10 to 18 inclusive the Commonwealth necessarily obtained and/or had knowledge of through the Public Officers;

6. the TGA purported to, were obliged in good faith to, and/or in fact actually did actively seek to scan for and acquire all worldwide safety material in relation to Covid vaccines by ongoing review of worldwide medical literature and data pursuant to the TGA Safety Monitoring Policy particularised in Schedule A of the SOC.

iv. as to all of the Respondents, all of the data pleaded therein being in all instances contained in documents, material and knowledge to which the Respondents had, in every instance, reasonable, ongoing and unfettered access to at will;

v. as to all of the Respondents, the data contained in the documents and material directly relevant to and profoundly probative and determinative of rationally establishing:

a) the respective Vaccines efficacy, safety, necessity and risk-benefit profile;

b) whether Covid was, at any time, in fact a life- threatening or seriously debilitating condition for all persons in Australia, including those under 70 years of age;

c) whether the Vaccines were likely to provide a major therapeutic advance;

d) the matters essential to a proper determination of the respective Approvals' accordance or otherwise with the Act and applicable legislation;

e) the suitability or otherwise of the rollout of the Vaccines to the entire population of Australia;

g. As to all of the Known Serious Vaccines Risks and Conduct – Pre Approvals and the Known Serious Vaccines Risks and Conduct – Post-Approvals, those relevant matters being expressly notified to the Secretary, Skerritt, Hunt and the TGA, including the provision of voluminous supporting scientific study and documentation contained in correspondences which are particularised as follows:

RESPONDENT(S) NOTIFIED	DATE	SENDER	DESCRIPTION OF RELEVANT MATTERS AND EVIDENCE NOTIFIED
SKERRITT	18 January 2021	**Redacted, released on FOI**	**Deaths of elderly in Norway following the Vaccines (defined as the "Norway Data" in Schedule C of the SOC)**
SKERRITT	1 February 2021	**Elizabeth Hart**	**Evident failures of Vaccines to prevent transmission of the Virus and likelihood of Vaccines to drive the emergence of Virus variants**
SKERRITT	7 June 2021	**George Christensen MP**	**Proliferation of adverse events reported to the DAEN following the Vaccines**
SKERRITT	22 June 2021	**Clive Palmer**	**Proliferation of adverse events reported to the CDC following and evident lack of long term data for the Vaccines**
HUNT	2 August 2021	**Zali Steggall MP**	**Evident lack of safety of AstraZeneca Vaccine in under 40 years age group and associated risk of clotting**
HUNT, SKERRITT, SECRETARY (& ORS)	1 July 2021	**Covid Medical Network**	**Evident increased mortality risk following use of the Vaccines, potential of alternative early treatments to treat Covid, evident issues with PCR testing and**

			accuracy and evident safety issues associated with the Vaccines
TGA (ELVIRA CURRIE)	16 February 2021 12 September 2021	**Nick Shulhin**	**Detailing personal vax reaction and asking for guidance and information since doctors don't know what to do**
HUNT	21 September 2021	**Australian Chiropractic Association**	**Evident issues regarding the mandatory vaccination surrounding the Vaccines**
HUNT, SKERRITT	19 November 2021	**Dr Melissa McCann**	**Evident proliferation of reported side effects in patient cohort following vaccination with the Vaccines and need for suspension of the Vaccines program**
TGA (ELVIRA CURRIE)	9 December 2021 11 January 2022 14 January 2022 20 January 2022 1 February 2022 22 February 2022 16 March 2022 3 April 2022 5 April 2022 29 April 2022 19 October 2022 24 October 2022	**Dr Rado Faletic**	**Evident proliferation of reported adverse events following receipt of the Vaccines, failures in the post – Approvals investigation, recording and publication of adverse events after receipt of the Vaccines**
SKERRITT	21 November 2022	**Dr Melissa McCann**	**Evident proliferation of reported side effects following vaccination with the Vaccines and need for suspension of the Vaccines program**
HUNT	1 April 2022 28 April 2022 13 May 2022	**Dr Rado Faletic**	**Evident failures of TGA post-Approvals oversight of reported adverse events following receipt of the Vaccines**
SKERRITT	19 April 2022	**Clare Pain**	**Evident survey results regarding**

			non-compliance with Australian Immunisation Handbook in regard to consumption of the Vaccines in Australia
HUNT, SKERRITT	11 March 2022	**Dr Melissa McCann & 14 other Medical Practitioner co-signatories**	**Evident proliferation of reported side effects following vaccination with the Vaccines and need for suspension of the Vaccines program**
SECRETARY, SKERRITT	3 January 2023	**Dr Chris Neil on behalf of AMPS Australian Medical Professional Society**	**Evident safety issues in respect of use of the Vaccines in children**

Further particulars will be provided upon discovery.

SCHEDULE D – PARTICULARS

PARA	PARTICULARS
17	The Department Functional Responsibilities are contained in and publicly declared by the Department to be the responsibilities of the Department in documents produced by the Department in published to the Department Website at https://www.health.gov.au/. https://www.health.gov.au/about-us/what-we-do/regulation-and-compliance https://www.health.gov.au/about-us/the-australian-health-system The Department Overarching Purpose is one of the publicly self-declared purposes of the Department: 1. Department's website: https://www.health.gov.au/ 2. Department's Corporate Plan 2020-2021, pg. 6, pg.20. https://www.health.gov.au/sites/default/files/documents/2020/12/corporate-plan-2020-21_0.pdf
18(h)	The TGA Functional Responsibilities are contained in and publicly declared by the Department and the TGA to be the responsibilities of the TGA in documents produced by the Department and the TGA in published to the TGA Website at https://www.tga.gov.au/. https://www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccine-approval-process https://www.tga.gov.au/vaccines-overview https://www.tga.gov.au/sites/default/files/covid-19-vaccine-safety-monitoring-plan.pdf
18(i)	The TGA Functions are contained in and publicly declared by the

	Department and the TGA to be the functions of the TGA in documents produced by the Department and the TGA and published to the TGA Website at https://www.tga.gov.au/ https://www.tga.gov.au/about-tga/corporate-information/tga-structure
23	The trial protocols were entirely provided and made available to the Commonwealth through the Public Officers by the direct provision of the Sponsors for the purposes of apprising the Commonwealth as to the safety and efficacy of the Vaccines or through officers or employees of the Commonwealth to the Public Officers for the purposes of fulfilment of duties incident to their respective offices and the functions and purposes of the Department and the TGA, as pleaded and particularised at paragraphs 10 to 18 of the SOC. Further such information was provided to the Secretary and the Chief Medical Officer in accordance with their functions as chair and deputy-chair respectively of the Science and Industry Technical Advisory Group, which was at all times tasked with providing and, in fact, provided advice to the Commonwealth as to the scientific validity or otherwise of research into the safety and effectiveness of potential COVID-19 vaccines. Further particulars will be provided after discovery.
42	The Known Serious Vaccines Risks and Conduct – Pre-Approvals specifically and rationally establish the Pre-Approval Established Critical Defects particularised as follows **("Particulars of the Pre-Approval Established Critical Defects")**: 1. the known absence of safety of the Vaccines prior to the Approvals particularised at para. 3 to 10, 14 to 33, 35 to 74 (inclusive) in Schedule B of the SOC; 2. the known absence of efficacy of the Vaccines prior to the Approvals particularised at para. 5 to 13, 17, 31, 33, 34, 35, 30, 32 to 36, 119, 120, 62 and 74 (inclusive) in Schedule B of the SOC;

	3. the known absence of necessity of the Vaccines for those under 70 years of age prior to the Approvals particularised at para. 1, 2, 32, 36 and 74 in Schedule B of the SOC; 4. the known negative risk benefit profile of the Vaccines prior to the Approvals particularised at para. 1 to 74 (inclusive) in Schedule B of the SOC; 5. the known facts that Covid was not a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age particularised at para. 1, 2, 32 and 74 in Schedule B of the SOC; 6. that the Vaccines would not provide a major therapeutic advance rationally arise and are manifestly evident upon the entirety of the Known Serious Vaccines Risks and Conduct - Pre-Approvals particularised at paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
43	The Known Serious Vaccines Risks and Conduct – Post-Approvals specifically and rationally establish the Post-Approval Established Critical Defects particularised as follows **("Particulars of the Post-Approval Established Critical Defects")**: 1. the known absence of safety of the Vaccines continuing from the time of the Approvals particularised at para. 80 to 82, 89, 96 to 125, 127, 129 to 133, 137 to 155 (inclusive) in Schedule B of the SOC; 2. the known absence of efficacy of the Vaccines continuing from the time of the Approvals particularised at para. 81 to 88 and 90 to 95 (inclusive) in Schedule B of the SOC; 3. the known absence of necessity of the Vaccines for those under 70 years of age continuing from the time of the Approvals particularised at para. 81, 82, 84 to 86, 92 to 95 and 108 (inclusive) in Schedule B of the SOC; 4. the known negative risk benefit profile of the Vaccines continuing from the time of the Approvals particularised at para. 77 to 125, 127, 129 to 133 and 137 to 155 (inclusive) in Schedule B of the SOC;

	5. the known facts that Covid was not a life-threatening or seriously debilitating condition for those persons in Australia under 70 years of age continuing from the time of the Approvals particularised at para. 81, 82, 84 to 86, 92 to 95 and 108 (inclusive) in Schedule B of the SOC; 6. that the Vaccines would not provide a major therapeutic advance is manifestly evident upon the entirety of the Known Serious Vaccines Risks and Conduct – Post-Approvals particularised at paragraphs 75 to 155 (inclusive) in Schedule B of the SOC.
46	The relevant factual circumstances by which the TGA Respondents made the each of the TGA Misleading Vaccines Statements through employees and officers of the TGA are: 1. that those statements were prepared and published by the TGA; 2. that the TGA Respondents respectively possessed knowledge of and exercised authority, discretion and control over the preparation and publication of statements made by the TGA, including the TGA Misleading Vaccines Statements, by reason of: i. as to the Secretary, the factual matters pleaded and particularised at paragraphs 10, 15, 17, 18, 36 and 56 and of the SOC; ii. as to Skerritt, the factual matters pleaded and particularised at paragraphs 11, 15, 17, 18, 36 and 53 of the SOC; 3. the factual matters pleaded and particularised at paragraph 46 of the SOC.
49	The relevant factual circumstances by which the Respondents made each of the Department Misleading Vaccines Statements through the Department are: 1. that those statements were prepared and published by the Department; 2. that the Respondents respectively possessed knowledge of and exercised authority, discretion and control over the preparation and publication of statements made by the Department, including the Department Misleading Vaccines Statements, by reason of:

	i. as to the Secretary, the factual matters pleaded at paragraph 10, 15, 17, 18, 36 and 56 of the SOC; ii. as to Skerritt, the factual matters pleaded at paragraph 11, 15, 17, 18, 36 and 53 of the SOC; iii. as to the Chief Medical Officer, the factual matters pleaded at paragraph 12, 15, 17, 18, 36 and 59 of the SOC; iv. as to Hunt, the factual matters pleaded at paragraph 13, 15, 17 and 60 of the SOC; v. as to the Commonwealth, the factual matters pleaded at paragraph 10, 11, 12, 13, 14, 15, 16, 17, 18, 36, 53, 56, 59 and 60 of the SOC. 3. the factual matters pleaded and particularised at paragraph 49 of the SOC.
50	The Misleading Public Message arising from the Misleading Vaccines Statements was misleading by reason of the knowledge of the Respondents and acts and omissions undertaken as pleaded in the: 1. the Known Serious Vaccines Risks And Conduct - Pre-Approvals; 2. the Known Serious Vaccines Risks And Conduct - Post-Approvals; 3. the knowledge and conduct pleaded in the Misleading Vaccines Statements pleaded at paragraphs 44 to 49 (inclusive) of the SOC. The Misleading Vaccines Statements of the Respondents and applicable TGA Policies disclose the Misleading Vaccines Statements Purpose in each element as follows **("Particulars of the Misleading Vaccines Statements Purpose")**: 1. to induce the Australian population to receive one or more of the Vaccines – the Misleading Vaccines Statements particularised at paragraphs 44(a), 44(b), 44(d) to 44(n), 45(a) to 45(d1), 46(a), 46(c) to 46(j), 47(a) to 47(d), 48(aa) to 48(d) and 49 (a) to 49(c) (inclusive) in Schedule G of the SOC; 2. to induce the Australian population to receive one or more of the Vaccines in the greatest numbers possible – the Misleading Vaccines Statements particularised at paragraphs 44(b) to 44(n),

	45(a) to 45(d1), 46(a), 46(c) to 46(j), 47(a) to 47(d), 48(aa) to 48(d) and 49(a1) to 49(c) (inclusive) in Schedule G of the SOC; 3. to induce the Australian population to receive one or more of the Vaccines with the minimal hesitation possible – the Misleading Vaccines Statements particularised at paragraphs 44(a) to 44(n), 45(a) to 45(d1), 46(a), 46(c) to 46(j), 47(a) to 47(d), 48(aa) to 48(d) and 49(a1) to 49(c) (inclusive) in Schedule G of the SOC; 4. to induce the Australian population to receive one or more of the Vaccines with the minimal delay possible – the Misleading Vaccines Statements particularised at paragraphs 44(l), 45(b), 46(d), 47(c1) in Schedule G of the SOC; 5. to reassure the Australian population that the Purported Bases of Approval and Purported Continuing Bases of Approval had been met: i. the Misleading Vaccines Statements particularised at paragraphs 44(a) to 44(n), 45(a), 45(d1), 46(a), 46(c), 46(d) to 46(i), 47(a) to 47(c), 47(c2), 47(d), 48(a) to 48(c) and 49(a1) to 49(c) (inclusive) in Schedule G of the SOC; ii. further evident in the following TGA adopted policy documents particularised in Schedule A of the SOC: 1. the TGA Provisional Approval Policy; 2. the TGA Adverse Events Identification Policy; 3. the TGA Adverse Events Reporting Policy; 4. the TGA Safety Monitoring Policy; 5. the TGA Safety Covid Information Policy; 6. the TGA Sponsors' Pharmacovigilance Policy; 7. the TGA Sponsors' Pharmacovigilance Policy 2; 8. the TGA Covid Vaccine Approvals Policy; 9. the TGA Covid Vaccine Evidence Policy. 6. to reassure the Australian population that the Respondents were rationally satisfied of the Purported Bases of Approval and Purported Bases of Continuing Approval – the Misleading Vaccines Statements particularised at paragraphs 44(a) to 44(n),

	45(a), 45(b), 47(a) to 47(d), 48(a) to 48(c) and 49(a) (inclusive) in Schedule G of the SOC. 7. the intention for reliance upon the Misleading Vaccines Statements is self-evident by reason of the respective position of the Respondents and wide publication – more expressly and particularly stated in the statements particularised at paragraphs 46(c), 47(c) and 49(b) in Schedule G of the SOC. The Misleading Public Message, including the Vaccine Purposes, were promulgated by the Respondents and the TGA consistently, expansively and publicly in the Misleading Vaccines Statements pleaded and particularised at paragraphs 45 to 49 (inclusive) and Schedule G of the SOC and defined at paragraph 50 manifesting the Misleading Public Message pleaded therein. Particularly, the Respondents asserted the Misleading Public Message, including any of the Vaccine Purposes, distinctly as follows **("Particulars of the Misleading Public Message and Vaccine Purposes")**: 1. Prevention of Transmission of the Virus: a. The Misleading Vaccines Statements particularised at paragraphs 44(l), 44(n), 47(c), 47(d), 48(a), 48(c) and 49(b) in Schedule G of the SOC. b. The adopted TGA policy document TGA Covid Vaccine Evidence Policy particularised in Schedule A of the SOC. 2. Prevention of infection with the Virus: a. The Misleading Vaccines Statements particularised at paragraphs 44(f), 44(l), 46(b), 46(i), 49(b), 49(c) in Schedule G of the SOC. 3. Prevention of Covid: a. The Misleading Vaccines Statements particularised at paragraphs 44(f), 44(l), 46(c), 47(c), 47(d) and 48(a) in Schedule G of the SOC. b. The adopted TGA policy document TGA Covid Vaccine Evidence Policy particularised in Schedule A of the SOC.

	4. Prevention of severe Covid: a. The Misleading Vaccines Statements particularised at paragraphs 44(f), 44(l), 46(c), 47 (c), 48(a) and 48(c) in Schedule G of the SOC. 5. Prevention of hospitalisation from Covid: a. The Misleading Vaccines Statements particularised at paragraphs 44(l) and 48(a) in Schedule G of the SOC. 6. Prevention of death from Covid: a. The Misleading Vaccines Statements particularised at paragraphs 44(f), 44(l), 46(c), 47(c), 48 (a) and 48(c) in Schedule G of the SOC. 7. Use of the Vaccines by all persons in the Australian population within the age range indicated for the respective Vaccines: a. The Misleading Vaccines Statements particularised at paragraphs 44(j) to (m), 45(b), 46(d) to 46(f), 46(i), 47(c1), 48(a) to 48(c), 49(b) and 49(c) in Schedule G of the SOC. b. The Department - Website "Covid 19 Vaccines translated information" https://www.health.gov.au/our-work/covid-19-vaccines/covid-19-vaccines-translated-information 8. TGA published materials consistently espousing the Vaccine Purposes including the TGA website and weekly "COVID-19 vaccine weekly safety report" published by the TGA including: a. https://www.tga.gov.au/news/covid-19-vaccine-safety-reports b. http://web.archive.org/web/20210212133334/https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/getting-vaccinated-for-covid-19/why-should-i-get-vaccinated-for-covid-19 9. Engagement of a rigorous process in the Approvals and Continuing Approvals for the Vaccines: a. The Misleading Vaccines Statements particularised at 44(a), 44(d), 44(e), 44(h), 44(j), 44(l), 44(n), 45(a) to 45(b), 46(a), 46(c), 46(e), 46(f), 46(h), 47(a), 47(b) and 49(b) in Schedule G of the SOC.

	10. Engagement of a process being in accordance with TGA Policies: a. The Misleading Vaccines Statements particularised at paragraphs 44(a), 44(d), 44(e), 44(h), 44(n), 45(a), 45(b), 46(a), 46(c), 46(e), 46(f), 46(h), 47(a), 47 (b) and 49(b) in Schedule G of the SOC. 11. The Vaccines were unquestionably safe – particularised at paragraphs 44 to 49 (inclusive) in Schedule G of the SOC. 12. The Vaccines were so safe that anything other than the most mild of side effects almost never occurred – particularised at paragraphs 44 to 49 (inclusive) in Schedule G of the SOC. 13. Nothing in the known data in respect of post-Approvals side effects from the Vaccines was of any material concern to the Australian public - particularised at paragraphs 44 to 48 (inclusive) in Schedule G of the SOC. 14. Public reporting and statements of the Respondents pre-Approvals and post-Approvals in respect of the safety, efficacy and risk-benefit profile of the Vaccines discloses to the Australian public the most accurate and comprehensively evident representation of those matters - particularised at paragraphs 44 to 46 (inclusive) in Schedule G of the SOC. The Purported Bases of Approval and the Purported Bases of Continuing Approval are contained in the consistent and expansive public pronouncements of Respondents, the TGA and the Department contained in the Misleading Vaccines Statements pleaded at paragraphs 44 to 49 (inclusive) and particularised in Schedule G of the SOC and defined at paragraph 50 manifesting the Misleading Public Message pleaded therein and TGA Policies - in particular **("Particulars of the Purported Bases of Approval and Continuing Approval")**: a. the prevention of transmission of the Virus particularised at para. 44(l), 44(n), 47(c) to 47(d), 48 (a), 48(c) 49(b) in Schedule G of the SOC and the adopted TGA policy document TGA Covid Vaccine Evidence Policy particularised in Schedule A of the SOC.

	b. the prevention of infection with the Virus particularised at para. 44(f), 44(l), 46(b), 46(i), 49(b) and 49(c) in Schedule G of the SOC. c. the prevention of Covid particularised at para. 44(f), 44(l), 46(c), 46(f), 47(c), 47(d) and 48(a) in Schedule G of the SOC and the adopted TGA policy document TGA Covid Vaccine Evidence Policy particularised in Schedule A of the SOC. d. the prevention of severe Covid particularised at para. 44(f), 44(l), 46(c), 46(f), 47(c), 48(a) and 48(c) in Schedule G of the SOC. e. the prevention of hospitalisation from Covid particularised at para. 44(l) and 48(a) in Schedule G of the SOC. f. the prevention of death from Covid particularised at para. 44(f), 44(l), 46(c), 47(c), 48(a) and 48(c) in Schedule G of the SOC. g. the use by all persons in the Australian population within the age range indicated for the respective Vaccines particularised at para. 44(j), 44(l), 45(b), 46(d) to 46(f), 46(i), 47(c1), 48(a) to 48(c), 49(b), 49(c) (inclusive) in Schedule G of the SOC and the Dept of Health Website "Covid 19 Vaccines translated information": https://www.health.gov.au/our-work/covid-19-vaccines/covid-19-vaccines-translated-information h. the conduct of a rigorous process in the Approvals particularised at para. 44(a), 44(d), 44(e), 44(h), 44(j), 44(l), 44(n), 46(a), 46(c), 46(e), 46(f), 46(h), 47(a), 47(b) and 49(b) in Schedule G of the SOC. i. the conduct of the Approvals being in accordance with TGA Policies particularised at para. 44(a), 44(d), 44(e), 44(h), 44(n), 45(a), 45(b), 46(a), 46(c), 46(e), 46(f), 46(h), 47(a), 47(b) and 49(b) in Schedule G of the SOC. j. that the Purported Bases of Approval and Purported Bases of Continuing Approval were met particularised at para. 44(a) to 44(n), 45(a), 45(b), 46(a), 46(c), 46(d) to 46(i), 47(a) to 47(d),

	48(a) to 48(c), 49(a) to 49(c) (inclusive) in Schedule G of the SOC and the following adopted TGA policy documents particularised in Schedule A of the SOC: i. the TGA Provisional Approval Policy ii. the TGA Adverse Events Identification Policy iii. the TGA Adverse Events Reporting Policy iv. the TGA Safety Monitoring Policy v. the TGA Safety Covid Information Policy vi. the TGA Sponsors' Pharmacovigilance Policy vii. the TGA Sponsors' Pharmacovigilance Policy 2 viii. the TGA Covid Vaccine Approvals Policy ix. the TGA Covid Vaccine Evidence Policy k. that the makers of the Misleading Statements were rationally satisfied of the Purported Bases of Approval and Purported Bases of Continuing Approval particularised at para. 44(a) to 44(n), 45(a), 45(b), 46(f), 47(a) to 47(d), 48(a) to 48(c) and 49(a) (inclusive) in Schedule G of the SOC.
51	The particulars of Skerritt's direct acts and omissions in respect of the Approvals are pleaded and particularised at: a. paragraph 51 of the SOC and defined as the Skerritt Approvals; and b. paragraphs 74(a) and (d) of the SOC. That Skerritt, as the head of the TGA was at all material times: a. acting in the Skerritt Approvals incident to his office by reason of the factual matters pleaded at paragraphs 11, 15, 17, 18, 20, and 36 of the SOC; b. tasked with managing, directing and thereby controlling the process of evaluation, assessment and approval for use in Australia of the respective Vaccines through the TGA, including the Approvals, as pleaded and particularised at paragraphs 11, 15, 17, 18, 20 and 25 to 38 of the SOC; c. exercising the control over the approval for use of therapeutic

	goods in Australia, including the Vaccines in the Approvals, as pleaded and particularised at paragraphs 61 to 64 and 69 to 72 of the SOC; and d. thereby acting in circumstances whereby he knew that, and in fact, his actions, omissions and advices as to the suitability of the Vaccines for the Approvals would determinatively bring about the Approvals. The requirements of legislation including the Act and the Regulations pleaded at paragraph 51(b)(ii) of the SOC refers to any and all obligations arising in respect of applicable law regulating the Approvals and associated conduct of those granting the Approvals in Australia, and particularly the provisions of: a. the *Therapeutic Goods Act 1989* (Cth); b. the *Therapeutic Goods Regulations 1990* (Cth); c. the Conduct Legislation (defined at paragraph 10(n) of the SOC) being: i. the *Public Service Act 1999* (Cth); ii. the *Public Governance, Performance and Accountability Act 2013* (Cth); iii. the *Parliamentary Service Act 1999* (Cth). Further particulars of Skerritt's direct acts and omissions in respect of the Skerritt Approvals will be provided after discovery.
52	The particulars of Skerritt's direct acts and omissions in respect of the Continuing Approvals are pleaded and particularised at: i. paragraph 52 of the SOC and defined as the Skerritt Continuing Approvals; ii. paragraphs 11, 15, 17, 18, 21, 36, and 77(a) and (d) of the SOC. The factual circumstances as to Skerritt's knowledge, intention, expectation and consideration that his acts or omissions constituting the Skerritt Continuing Approvals caused the Continuing Approvals to be

	occur, the respective Approvals not to be cancelled or revoked and the Vaccines to continue to be widely distributed to the Australian population for use are: i. pleaded and particularised at paragraph 52 of the SOC; ii. that Skerritt, as the head of the TGA was at all material times: a) acting in the Skerritt Continuing Approvals incident to his office by reason of the factual matters pleaded at paragraphs 11, 15, 17, 18, 21 and 36 of the SOC; b) tasked with managing, directing and thereby controlling the process of evaluation, assessment of and ongoing approval for use in Australia of the respective Vaccines through the TGA, including the Continuing Approvals, as pleaded and particularised at paragraphs 11, 15, 17, 18, 21 and 25 to 36 of the SOC; c) exercising the control over the ongoing approval for use of therapeutic goods in Australia, including the Vaccines in the Continuing Approvals, as pleaded and particularised at paragraphs 61 to 64 and 69 to 72 of the SOC; d) thereby acting in circumstances whereby he knew that, and in fact, his actions, omissions and advices as to the suitability of the Vaccines for the Approvals would determinatively bring about the Continuing Approvals. Further particulars of Skerritt's direct acts and omissions in respect of the Skerritt Continuing Approvals will be provided after discovery.
53(a)	The relevant factual circumstances by which Skerritt is alleged to have caused the TGA Misleading Vaccines Statements to be publicly and widely made to the Australian population as pleaded at paragraphs 53(a)(ii)(1) and (2) are that: a. those statements were prepared and published by the TGA;

	b. Skerritt possessed knowledge of and exercised authority, discretion and control over the preparation and publication of statements made by the TGA, including the TGA Misleading Vaccines Statements, by reason of the factual matters pleaded and particularised at paragraphs 11, 15, 17, 18 and 53 of the SOC; c. the factual matters pleaded and particularised at paragraph 46 of the SOC.
53(b)	The Misleading Public Message arose directly from the Skerritt Issued Misleading Vaccines Statements by reason of the factual matters pleaded and particularised at paragraph 50 of the SOC. The relevant factual circumstances by which Skerritt is alleged not to be acting in performance or purported performance of or in relation to any exercise of his duties or powers arising under the Act or the Regulations is that the acts of causing the Skerritt Issued Misleading Vaccines Statements to be made and published in the factual circumstances pleaded and particularised at paragraphs 44, 46 and 53 of the SOC and paragraphs 44 and 46 in Schedule G of the SOC are acts and the performance of functions which: a. are not powers or functions provided for in any provision of the Act or the Regulations; b. are not related to any powers or functions provided for in any provision of the Act or the Regulations. The relevant factual circumstances by which Skerritt personally assumed responsibility to positively exercise at all times the power incident to his office to protect the Group Members from harm arising from receiving the Vaccines are: a. that Skerritt personally caused the Skerritt Issued Misleading Vaccines Statements to be publicly and widely made to the Australian population; b. the factual circumstances of the making of the Skerritt Issued Misleading Vaccines Statements pleaded at paragraph 44, 46, 49

	and 53 of the SOC and particularised at paragraphs 44, 46 and 49 in Schedule G of the SOC; c. the particulars of paragraph 53 of the SOC specifically: i. that Skerritt knew and that in fact, that the Misleading Public Message promulgated by Skerritt would be received and relied upon by the whole Australian population by reason of the facts that Skerritt as the head of the TGA was at all material times tasked with managing and directing the process of evaluation and assessment of the respective Vaccines through the TGA as pleaded and particularised at paragraphs 11, 15, 17, 18 and 36 of the SOC; ii. the degree of control exercised by Skerritt and the TGA and reliance upon the statements caused to be published by Skerritt, the TGA and the Department pleaded at paragraphs 61 to 64, 69 to 72 of the SOC; and iii. the wide publication of Skerritt Issued Misleading Vaccines Statements.
54(e)	s. 57(4)(a) Act *Acts Interpretation Act 1901* (Cth) s. 34AB(1)(c) The acts and omissions were made incident to the Secretary's office by reason of the factual matters pleaded at paragraphs 10, 17, 18 of the SOC. Further particulars of the Secretary's specific actions in respect of the Approvals will be provided after discovery.
54(f)	The particulars of the Secretary's direct acts and omissions in respect of the Approvals are pleaded and particularised at: a. paragraph 54 of the SOC and defined as the Secretary Approvals; b. paragraphs 10, 15, 17, 18, 20, 36, and 74(b) of the SOC. Further particulars of the Secretary's direct acts and omissions in respect of the Secretary Approvals will be provided after discovery.

	The factual circumstances as to the Secretary's knowledge, intention, expectation and consideration that his acts or omissions constituting the Secretary Approvals caused the Approvals to be granted are: a. particularised within the particulars of paragraph 54 of the SOC; b. that the Secretary, as secretary of the Department was at all material times: i. acting in the Secretary Approvals incident to his office by reason of the factual matters pleaded at paragraphs 10, 15, 17 and 18 of the SOC; ii. tasked with managing, directing and thereby controlling the process of evaluation, assessment and approval for use in Australia of the respective Vaccines through the TGA within the Department, including the Approvals, as pleaded and particularised at paragraphs 10, 15, 17, 18, 20 and 25 to 38 of the SOC; iii. exercising the control over the approval for use of therapeutic goods in Australia, including the Vaccines in the Approvals, as pleaded and particularised at paragraphs 61 to 64 and 69 to 72 of the SOC; iv. thereby acting in circumstances whereby he knew that, and in fact, his actions, omissions and advices as to the suitability of the Vaccines for the Approvals would determinatively bring about the Approvals. The requirements of legislation including the Act and the Regulations pleaded at paragraph 54.c)(ii) and d)(ii) of the SOC refers to any and all obligations arising in respect of applicable law regulating the Approvals and associated conduct of those granting the Approvals in Australia, and particularly the provisions of: a. the *Therapeutic Goods Act 1989* (Cth); b. the *Therapeutic Goods Regulations 1990* (Cth); c. the Conduct Legislation (defined at paragraph 10(n) of the SOC)

	being: i. the *Public Service Act 1999* (Cth); ii. the *Public Governance, Performance and Accountability Act 2013* (Cth); iii. the *Parliamentary Service Act 1999* (Cth).
55	The particulars of the Secretary's direct acts and omissions in respect of the Continuing Approvals are pleaded and particularised at: a. paragraph 55 of the SOC and defined as the Secretary Continuing Approvals; b. paragraphs 10, 15, 17, 18, 21, 36, and 77(b) and of the SOC. c. Further particulars of Secretary's omissions in respect of the Secretary Continuing Approvals will be provided after discovery. The factual circumstances as to Secretary's knowledge, intention, expectation and consideration that his acts or omissions constituting the Secretary Continuing Approvals caused the Continuing Approvals to be granted, the respective Approvals not to be cancelled or revoked and the Vaccines to continue to be widely distributed to the Australian population for use are: a. particularised within the particulars of paragraph 55 of the SOC; b. that the Secretary, as the secretary of the Department was at all material times: i. acting in the Secretary Continuing Approvals incident to his office by reason of the factual matters pleaded at paragraphs 10, 15, 17, 18, 21 and 36 of the SOC; ii. tasked with managing, directing and thereby controlling the process of evaluation, assessment of and ongoing approval for use in Australia of the respective Vaccines through the TGA, including the Continuing Approvals, as pleaded and particularised at paragraphs 10, 15, 17,18, 21 and 25 to 36 of the SOC; iii. exercising the control over the ongoing approval for use of therapeutic goods in Australia, including the Vaccines in the

	Continuing Approvals, as pleaded and particularised at paragraphs 61 to 64 and 69 to 72 of the SOC. iv. thereby acting in circumstances whereby he knew that, and in fact, his actions, omissions and advices as to the suitability of the Vaccines for the Approvals would determinatively bring about the Continuing Approvals. The requirements of legislation including the Act and the Regulations pleaded at paragraph 55(a)(iii)(3) of the SOC refers to any and all obligations arising in respect of applicable law regulating the Approvals and Continuing Approvals and associated conduct of those granting the Approvals and Continuing Approvals in Australia, and particularly the provisions of: a. the *Therapeutic Goods Act 1989* (Cth); b. the *Therapeutic Goods Regulations 1990* (Cth); c. the Conduct Legislation (defined at paragraph 10(n) of the SOC) being: i. the *Public Service Act 1999* (Cth); ii. the *Public Governance, Performance and Accountability Act 2013* (Cth); iii. the *Parliamentary Service Act 1999* (Cth).
56(a)(i)-(ii)	The relevant factual circumstances by which the Secretary is alleged to have caused the TGA Misleading Vaccines Statements to be publicly and widely made to the Australian population as pleaded at paragraphs 56(a)(ii)(1) and (2) are that: a. those statements were prepared and published by the TGA; b. the Secretary possessed knowledge of and exercised authority, discretion and control over the preparation and publication of statements made by the TGA, including the TGA Misleading Vaccines Statements, by reason of the factual matters pleaded at paragraph 10, 15, 17, 18, 36 and 56 of the SOC; and c. the factual matters pleaded at paragraph 46 of the SOC and particularised at paragraph 46 in Schedule G of the SOC.

56(c)	The relevant factual circumstances by which the Secretary is alleged not to be acting in performance or purported performance of or in relation to any exercise of his duties or powers arising under the Act or the Regulations is that the acts of causing the Secretary Issued Misleading Vaccines Statements to be made and published in the factual circumstances particularised at paragraphs 45, 46, 49 and 56 in Schedule G of the SOC are acts and the performance of functions which: a. are not powers or functions provided for in any provision of the Act or the Regulations; b. are not related to any powers or functions provided for in any provision of the Act or the Regulations. The relevant factual circumstances by which the Secretary personally assumed responsibility to positively exercise at all times the power incident to his office to protect the Group Members from harm arising from receiving the Vaccines are: a. that the Secretary personally caused the Secretary Issued Misleading Vaccines Statements to be publicly and widely made to the Australian population; b. the factual circumstances of the making of the Secretary Issued Misleading Vaccines Statements pleaded at paragraph 45, 46, 49 and 56 of the SOC and particularised at paragraphs 45, 46 and 49 in Schedule G of the SOC; c. the particulars of paragraph 56 of the SOC specifically: i. that the Secretary knew and that in fact, that the Misleading Public Message promulgated by the Secretary would be received and relied upon by the whole Australian population by reason of the facts that the Secretary, as the secretary of the Department, was at all material times tasked with managing and directing the process of evaluation and assessment of the respective Vaccines through the TGA as pleaded and particularised at paragraphs 10, 15, 17,18 and 36 of the SOC;

	ii. the degree of control exercised by the Secretary and the TGA and reliance upon the statements caused to be published by the Secretary, the TGA and the Department pleaded at paragraphs 61 to 64 and 69 to 72 (inclusive) of the SOC; and iii. the wide publication of the Secretary Issued Misleading Vaccines Statements. d. the nature and effect of the Misleading Vaccines Statements including the Secretary Issued Misleading Vaccines Statements pleaded and particularised at paragraph 50 of the SOC.
57	The particulars of the Chief Medical Officer's direct acts and omissions in respect of the Approvals are pleaded and particularised at: a. paragraph 57 of the SOC and defined as the Chief Medical Officer Pre-Approval Advices, the Chief Medical Officer Pre-Approval Failures to Advise, and the Chief Medical Officer Pre-Approval Conduct; b. paragraphs 12 and 17 of the SOC. Further particulars of the Chief Medical Officer Pre-Approval Advices, the Chief Medical Officer Pre-Approval Failures to Advise, and the Chief Medical Officer Pre-Approval Conduct direct acts and omissions in respect of the Approvals will be provided after discovery. The factual circumstances as to the Chief Medical Officer's knowledge, intention, expectation and consideration that his acts or omissions constituting the Chief Medical Officer Pre-Approval Advices, the Chief Medical Officer Pre-Approval Failures to Advise, and the Chief Medical Officer Pre-Approval Conduct caused the Approvals to be granted are: a. particularised within the particulars of paragraph 57 of the SOC; b. that the Chief Medical Officer, as chief medical officer of the Commonwealth, principal medical advisor to the

	Secretary, the Minister, the Department and the Commonwealth, and senior officer in the Department was at all material times: i. acting in the Chief Medical Officer Pre-Approval Advices, the Chief Medical Officer Pre-Approval Failures to Advise, and the Chief Medical Officer Conduct, incident to his office by reason of the factual matters pleaded at paragraphs 12, 15, and 17 of the SOC; ii. tasked with managing, directing and thereby controlling the process of evaluation, assessment and approval for use in Australia of the respective Vaccines through the TGA, including the Approvals, as pleaded and particularised at paragraphs 12, 15 and 17 of the SOC; iii. exercising the control over the approval for use of therapeutic goods in Australia, including the Vaccines in the Approvals, as pleaded and particularised at paragraphs 61 to 64 and 69 to 72 (inclusive) of the SOC; iv. thereby acting in circumstances whereby he knew that, and in fact, his actions and advices as to the suitability of the Vaccines for the Approvals would determinatively bring about the Approvals.
58	The particulars of the Chief Medical Officer's direct acts and omissions in respect of the Continuing Approvals are pleaded and particularised at: a. paragraph 58 of the SOC and defined as the Chief Medical Officer Post-Approval Advices, the Chief Medical Officer Post-Approval Failures to Advise, and the Chief Medical Officer Post-Approval Conduct; b. paragraphs 12, 17 and 77(c) and (d) of the SOC. Further particulars of the Chief Medical Officer's acts and omissions in

	respect of the Chief Medical Officer Post-Approval Advices, the Chief Medical Officer Post-Approval Failures to Advise, and the Chief Medical Officer Post-Approval Conduct will be provided after discovery. The factual circumstances as to the Chief Medical Officer's knowledge, intention, expectation and consideration that his acts or omissions constituting the Chief Medical Officer Post-Approval Advices, the Chief Medical Officer Post-Approval Failures to Advise, and the Chief Medical Officer Post-Approval Conduct caused the Continuing Approvals to be granted, the respective Approvals not to be cancelled or revoked and the Vaccines to continue to be widely distributed to the Australian population for use are: a. particularised within the particulars of paragraph 58 of the SOC; b. that the Chief Medical Officer, as chief medical officer of the Commonwealth, principal medical advisor to the Secretary, the Minister, the Department and the Commonwealth, and senior officer in the Department was at all material times: i. acting in the Chief Medical Officer Post-Approval Advices, the Chief Medical Officer Post-Approval Failures to Advise, and the Chief Medical Officer Post-Approval Conduct incident to his office by reason of the factual matters pleaded at paragraphs 12, 15 and 17 of the SOC; ii. tasked with the betterment of the health and wellbeing of the Australian population and the distribution of the Vaccines to the Australian public as pleaded and particularised at paragraphs 12, 15, and 17 of the SOC; iii. exercising the control over the ongoing approval for use of therapeutic goods in Australia, including the Vaccines in the Continuing Approvals, as pleaded

	and particularised at paragraphs 61 to 64 and 69 to 72 (inclusive) of the SOC; iv. thereby acting in circumstances whereby he knew that, and in fact, his actions, omissions and advices as to the suitability of the Vaccines for the Approvals would determinatively bring about the Continuing Approvals.
59(a)(i)-(iii)	The relevant factual circumstances by which the Chief Medical Officer is alleged to have caused the Department Misleading Vaccines Statements to be publicly and widely made to the Australian population as pleaded at paragraphs 59(a)(ii)(1) and (2) are that: a. those statements were prepared and published by the Department; b. the Chief Medical Officer possessed knowledge of, provided advices in respect of, and exercised authority, discretion and control over the preparation and publication of statements made by the Department, including the Department Misleading Vaccines Statements, by reason of the factual matters pleaded at paragraph 12, 15, 17 and 59 of the SOC; c. the factual matters particularised at paragraph 47 in Schedule G of the SOC.
59(c)	The relevant factual circumstances by which the Chief Medical Officer is alleged not to be acting in performance or purported performance of or in relation to any exercise of his duties or powers arising under the Act or the Regulations is that the acts of causing the Chief Medical Officer Issued Misleading Vaccines Statements to be made and published in the factual circumstances pleaded and particularised at paragraphs 47, 49 and 59 of the SOC and particularised at paragraphs 47 and 49 in Schedule G of the SOC are acts and the performance of functions which: a. are not powers or functions provided for in any provision of the Act or the Regulations; b. are not related to any powers or functions provided for in any provision of the Act or the Regulations.

	The relevant factual circumstances by which the Chief Medical Officer personally assumed responsibility to positively exercise at all times the power incident to his office to protect the Group Members from harm arising from receiving the Vaccines are: a. that the Chief Medical Officer personally caused the Chief Medical Officer Issued Misleading Vaccines Statements to be publicly and widely made to the Australian population; b. the factual circumstances of the making of the Chief Medical Officer Issued Misleading Vaccines Statements particularised at paragraphs 47, 49, and 59 in Schedule G of the SOC; c. the particulars of paragraph 59 of the SOC specifically: i. that the Chief Medical Officer knew and that in fact, that the Misleading Public Message promulgated by the Chief Medical Officer would be received and relied upon by the whole Australian population by reason of the facts that the Chief Medical Officer as chief medical officer of the Commonwealth, principal medical advisor to the Secretary, the Minister, the Department and the Commonwealth, and senior officer in the Department was at all material times tasked with the betterment of the health and wellbeing of the Australian population and the distribution of the Vaccines to the Australian public as pleaded and particularised at paragraphs 12, 15, and 17 of the SOC; ii. the degree of control exercised by the Chief Medical Officer and the Department and reliance upon the statements caused to be published by the Chief Medical Officer and the Department pleaded at paragraphs 61 to 64 and 69 to 72 (inclusive) of the SOC; and iii. the wide publication of Chief Medical Officer Issued Misleading Vaccines Statements. d. the nature and effect of the Misleading Vaccines Statements including the Chief Medical Officer Issued Misleading Vaccines

	Statements pleaded and particularised at paragraph 50 of the SOC.
60(a)	The relevant factual circumstances by which Hunt is alleged to have caused the Hunt Issued Misleading Vaccines Statements to be publicly made as pleaded at paragraphs 60(a)(ii) and (iii) of the SOC being comprised of the Ministers Misleading Vaccine Statements: a. are defined, pleaded and particularised at paragraph 48 of the SOC and paragraph 48 in Schedule G of the SOC; b. disclose that those statements were in every instance as pleaded and particularised therein: i. personally and orally made by Hunt; ii. subsequently published by the Department as attributed to Hunt. c. are that Hunt possessed knowledge of and exercised authority, discretion and control over the preparation and publication of statements made by him as then Minister of the Department, by reason of the factual matters pleaded at paragraph 13, 15, 17 and 18 of the SOC.
60(c)	The relevant factual circumstances by which the Hunt is alleged not to be acting in performance or purported performance of or in relation to any exercise of his duties or powers arising under the Act or the Regulations is that the acts of causing the Hunt Issued Misleading Vaccines Statements to be made and published in the factual circumstances pleaded and particularised at paragraphs 48, 49 and 60 of the SOC are acts and the performance of functions which: a. are not powers or functions provided for in any provision of the Act or the Regulations; b. are not related to any powers or functions provided for in any provision of the Act or the Regulations. The relevant factual circumstances by which Hunt personally assumed responsibility to positively exercise at all times the power incident to his office to protect the Group Members from harm arising from receiving the

	Vaccines are: a. that Hunt personally caused the Hunt Issued Misleading Vaccines Statements to be publicly and widely made to the Australian population; b. the factual circumstances of the making of the Hunt Issued Misleading Vaccines Statements pleaded at paragraphs 48, 49 and 60 of the SOC and particularised at paragraphs 48 and 49 in Schedule G of the SOC; c. the particulars of paragraph 60 of the SOC specifically: i. that Hunt knew and that in fact, the Misleading Public Message promulgated by Hunt would be received and relied upon by the whole Australian population by reason of the facts that Hunt as a minister of the Commonwealth and minister responsible for the Department whose purpose was the betterment of the health and wellbeing of the Australian population and the distribution of the Vaccines to the Australian public as pleaded and particularised at paragraphs 13 and 17 (inclusive) of the SOC; ii. the degree of control exercised by Hunt and the Department and reliance upon the statements caused to be published by Hunt and the Department pleaded at paragraphs 61 to 64 (inclusive) and 69 to 72 (inclusive) of the SOC; and iii. the wide publication of Hunt Issued Misleading Vaccines Statements. d. the nature and effect of the Misleading Vaccines Statements including the Hunt Issued Misleading Vaccines Statements pleaded and particularised at paragraph 50 of the SOC.
61(a)	The relevant circumstances and factual matters as to the Public Officers' control and absolute control over whether or not a therapeutic good in Australia (including the Vaccines) could be lawfully or otherwise authorised for use in Australia are pleaded and particularised at paragraphs

	10 to 18 and 25 to 38 (inclusive) of the SOC. The relevant circumstances and factual matters as to the Public Officers' position to control and absolutely control whether a therapeutic good could be widely distributed in Australia are pleaded and particularised at paragraphs 10 to 18 and 25 to 38 (inclusive) of the SOC.
61(b)	The relevant circumstances and factual matters as to the Public Officers' position to control and absolutely control direct, lawful and practical access to the Vaccines by the Australian public are pleaded and particularised at paragraphs 10 to 18 and 25 to 38 (inclusive) of the SOC. The direct and indirect control of the Public Officers pleaded at paragraph 61(b)(i) to (iii) over the grant of the Approvals, the grant of the Continuing Approvals, and the wide distribution of the Vaccines to the Australian population arose in the circumstances of the factual matters pleaded and particularised at paragraphs 10 to 18 and 25 to 38 (inclusive) of the SOC.
61(c)	The relevant circumstances and factual matters as to the Public Officers' position to, and actual, control and direct absolutely all statements to the Australian public by the Public Officers themselves or any other officer of the TGA, the Department or the Commonwealth in respect of sub-paragraphs 61(c)(i)(1)-(2) are pleaded and particularised at paragraphs 10 to 18 and 25 to 38 (inclusive) of the SOC. The relevant circumstances and factual matters as to the Australian populations' reliance upon the statements described in para 61(c) of the SOC are: a. pleaded and particularised at paragraphs 10 to 18 and 25 to 38 (inclusive) of the SOC; and b. paragraphs 63, 64, 70 and 80. The relevant circumstances and factual matters as to the Public Officers knowledge of the reliance pleaded at paragraph 61(c)(ii) of the SOC arises from:

	a. the factual matters pleaded and particularised at paragraphs 10 to 18 and 25 to 38 (inclusive) of the SOC; and b. the Public Officers' knowledge of: i. the factual matters pleaded and particularised at paragraphs 10 to 18 and 25 to 38 (inclusive) of the SOC; ii. the control exercised by the Public Officers pleaded at paragraphs 61(a)-(b), (c)(i) and (d)-(e) (inclusive) of the SOC; iii. the Respondents' knowledge of the Respondents Control of Therapeutic Goods in Australia pleaded at paragraph 63 of the SOC.
61(d)	The relevant circumstances and factual matters as to the Public Officers' position to, and actual, control and absolute control of whether or not a therapeutic good in Australia (including the Vaccines) could be withdrawn from wide distribution to, the general Australian public are pleaded and particularised at paragraphs 10 to 18, 36 and 25 to 38 (inclusive) of the SOC.
61(e)	The relevant circumstances and factual matters as to the Public Officers' position of control, and absolute control of the information and data to which they would and did have regard or otherwise, entail the personal conduct of the Public Officers, including to which information he has or had regard, and are and were undertaken at the absolute discretion of those individuals. The relevant circumstances and factual matters as to the Public Officers' position of control, and absolute control of the procedure by which they would make any determinations entails the personal conduct of the Public Officers and are and were undertaken at the absolute discretion of those individuals.
62	It was a source of common knowledge by their public pronouncements that the Public Officers were the persons empowered with and directly tasked with the assessment, approval, and distribution of the Vaccines to the

	Australian Public. Public declarations of the Public Officers and as to their position as the source of authoritative information in respect of the Vaccines is evident in for example the Misleading Vaccines Statements particularised at paragraphs 46(c), 47(c), and 48(b) in Schedule G of the SOC and the TGA Statement in the public document "COVID-19 and vaccines: Get the best advice for you and your family dated 30 August 2021 at URL https://www.ahpra.gov.au/News/2021-08-30-Joint-statement.aspx
65	The relevant factual circumstances by which Skerritt was not acting in performance or purported performance of or in relation to any exercise of his duties or powers arising under the Act or the Regulations is that the acts of causing the Skerritt Issued Misleading Vaccines Statements to be made and published in the factual circumstances pleaded and particularised at paragraphs 44, 46 and 53 and particularised in paragraphs 44 and 46 in Schedule G of the SOC are acts and the performance of functions which: a. are not powers or functions provided for in any provision of the Act or the Regulations; b. are not related to any powers or functions provided for in any provision of the Act or the Regulations.
66	The relevant factual circumstances by which the Secretary was not acting in performance or purported performance of or in relation to any exercise of his duties or powers arising under the Act or the Regulations is that the acts of causing the Secretary Issued Misleading Vaccines Statements to be made and published in the factual circumstances pleaded and particularised at paragraphs 44, 46, 49 and 56 of the SOC and particularised at paragraphs 44, 46 and 49 in Schedule G of the SOC are acts and the performance of functions which: a. are not powers or functions provided for in any provision of the Act or the Regulations; b. are not related to any powers or functions provided for in any provision of the Act or the Regulations.
67	The relevant factual circumstances by which the Chief Medical Officer

	was not acting in performance or purported performance of or in relation to any exercise of his duties or powers arising under the Act or the Regulations is that the acts of undertaking the Chief Medical Officer Pre-Approval Conduct, the Chief Medical Officer Post-Approval Conduct, the Chief Medical Officer Pre-Approval Advices, the Chief Medical Officer Post-Approval Advices, and causing the Chief Medical Officer Issued Misleading Vaccines Statements to be made and published, in the factual circumstances pleaded and particularised at paragraphs 47, 49, 57, 58 and 59 of the SOC and particularised at paragraphs 47 and 49 in Schedule G of the SOC are acts and the performance of functions which: a. are not powers or functions provided for in any provision of the Act or the Regulations; b. are not related to any powers or functions provided for in any provision of the Act or the Regulations.
68	The relevant factual circumstances by which Hunt was not acting in performance or purported performance of or in relation to any exercise of his duties or powers arising under the Act or the Regulations is that the acts of causing the Minister Issued Misleading Vaccines Statements to be made and published in the factual circumstances particularised at paragraphs 48 and 49 in Schedule G of the SOC are acts and the performance of functions which: a. are not powers or functions provided for in any provision of the Act or the Regulations; b. are not related to any powers or functions provided for in any provision of the Act or the Regulations.
70	The relevant factual acts, matters or circumstances by which each of the Public Officers knew that any decision, act or omission would directly affect the health and well-being of those injected with the Vaccines and directly affect the likelihood of serious personal injury and harm to those injected with the Vaccines are: a. particularised at paragraph 70 of the SOC; and b. that such knowledge arises in the circumstances of the factual matters pleaded and particularised at paragraphs 10 to 18, 22 to 38,

	42, 44 to 64, 69 to 75 and 77 to 84 (inclusive) of the SOC and and paragraphs 1 to 155 (inclusive) of Schedule B of the SOC. Each of the Public Officers knew the matters alleged in para 23(d) and 70(e) of the SOC: a. at all material times; and b. in each instance of the Impugned Conduct, at a time no later than prior to each of the Public Officers undertaking or engaging in each of the respective acts and omissions constituting the Impugned Conduct defined at paragraph 64(d)(ii) of the SOC and pleaded and particularised at paragraphs 51 to 60 (inclusive) of the SOC.
71	The relevant factual acts, matters or circumstances by which it was reasonably foreseeable that the alleged Impugned Conduct would cause the Group Members to suffer injury, loss and damage are the factual matters and circumstances pleaded and particularised in paragraphs 22 to 38, 42, 44 to 64, 69 to 75, 77, 78, and 80 to 84 (inclusive) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual acts, matters or circumstances by which it was reasonably foreseeable that the alleged Impugned Conduct would cause pervasive and serious negative consequences upon the health and well-being of the Australian population are the factual matters and circumstances pleaded and particularised in paragraphs 22 to 38, 42, 44 to 64, 69 to 75, 77, 78, and 80 to 84 (inclusive) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual acts, matters or circumstances by which it was reasonably foreseeable that in undertaking the Impugned Conduct, that such acts or omissions carried the high probability and likelihood that the Group Members would suffer serious or catastrophic personal injuries, loss and damage are the factual matter and circumstances pleaded and particularised in paragraphs 22 to 38, 42, 44 to 64, 69 to 75, 77, 78, and 80

	to 84 (inclusive) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.
73	1. Respondents' Control of Therapeutic Goods in Australia; 2. Public Expectation of Skill; 3. Public's Reasonable Expectation and Reliance; 4. Known Gravity of the Approvals; 5. Known Vulnerability of the Australian Public; 6. Foreseeability of Risk and Harm; 7. Public Officers' Voluntary Assumption of Risk
74	1. the Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. Particulars of the Pre-Approval Established Critical Defects; 3. the Pre-Approval Established Critical Defects; Further, the particulars of the known facts manifesting the Known Approvals Assessment Failures are contained in the factual matters pleaded in the Known Serious Vaccines Risks And Conduct - Pre-Approvals and particularised as follows **("Particulars of the Known Approvals Assessment Failures")**: 1. the known absence of clinical testing undertaken or data in respect of the Vaccines' ability to prevent transmission of the Virus prior to the Approvals particularised at para. 9 to 32, 36, 62, 73 and 74 (inclusive) in Schedule B of the SOC; 2. the known absence of clinical testing undertaken or data in respect of the Vaccines' ability to prevent infection with the Virus prior to the Approvals particularised at para. 30 to 32 and 36 (inclusive) in Schedule B of the SOC; 3. the known absence of clinical testing undertaken or data in respect of the Vaccines' ability to prevent serious illness from Covid prior to the Approvals particularised at para. 9, 20 to 32 and 60 (inclusive) in Schedule B of the SOC; 4. the known absence of clinical testing undertaken or data in respect of the Vaccines' ability to prevent hospitalisation from Covid prior to the Approvals particularised at para. 30 to 32 and 60 (inclusive)

	in Schedule B of the SOC; 5. the known absence of clinical testing undertaken or data in respect of the Vaccines' ability to prevent death from Covid prior to the Approvals particularised at para. 9, 30 to 32 and 60 (inclusive) in Schedule B of the SOC; 6. the known safety concerns regarding the use of the Vaccines in pregnant women prior to the Approvals particularised at para. 6, 9, 30, 35, 36, 40, 51, 57 to 59, 62 and 64 (inclusive) in Schedule B of the SOC; 7. the known safety concerns regarding the use of the Vaccines in immunocompromised people prior to the Approvals particularised at para. 6, 9, 17, 62 and 64 in Schedule B of the SOC; 8. the known safety concerns regarding the use of the Vaccines in people with certain pre-existing health conditions prior to the Approvals particularised at para. 3, 6, 16, 36, 54, 64 and 74 in Schedule B of the SOC; 9. the known safety concerns regarding the use of the Vaccines in people with natural immunity resultant from prior infection with the Virus prior to the Approvals particularised at para. 6 and 32 in Schedule B of the SOC; 10. the known absence of testing and data in respect of the Vaccines' long-term efficacy prior to the Approvals particularised at para. 30, 32, 33, 35, 36, 51, 62, 69 and 73 in Schedule B of the SOC; 11. the known absence of testing and data in respect of the Vaccines' genotoxicity prior to the Approvals particularised at para. 30, 33, 37 to 44, 46 to 48, 64 and 73 (inclusive) in Schedule B of the SOC; 12. the known absence of testing and data in respect of the Vaccines' carcinogenicity prior to the Approvals particularised at para. 30, 37, 39 to 47, 50, 53, 57 and 73 (inclusive) in Schedule B of the SOC; 13. the known absence of testing and data in respect of the Vaccines' long-term safety prior to the Approvals particularised at para. 3, 21, 27, 30, 33, 36, 50, 51, 55, 56, 62 and 73 in Schedule B of the

	SOC; 14. the known absence of testing and data in respect of the risk of incorporation of the mRNA in the mRNA/DNA Vaccines into the human genome with the potential to cause intergenerational effects prior to the Approvals particularised at para. 3, 30, 33, 37, 39, 41, 42, 47, 48, 54, 55 and 64 in Schedule B of the SOC; 15. the known absence of testing and data in respect of the risk of extreme and unquantified proliferation of the spike protein in the human body with the Vaccines prior to the Approvals particularised at para. 3, 30, 33, 37, 39, 40, 42, 48, 55 and 56 in Schedule B of the SOC; 16. the known distribution and concentration of the Vaccines' lipid nanoparticles throughout the human body including the human organs for an untested and unquantified period prior to the Approvals particularised at para. 3, 30, 31, 33, 40, 41, 47, 48, 51, 52 and 55 in Schedule B of the SOC; 17. the known risk of vaccine associated enhanced disease arising in the use of the vaccines prior to the Approvals particularised at para. 7, 17, 30, 33, 35, 36, 56, 60 and 64 in Schedule B of the SOC; 18. the conduct of the TGA generally seeking and accepting an explanation from the Sponsor in respect of evident issues or data deficiencies with the Vaccines, subsequently and invariably accepted in lieu of any further data or investigation prior to the Approvals particularised at para. 11, 17, 18, 20, 22, 30, 33, 35 to 37, 39 to 41, 44, 46, 48, 50 to 52, 55, 58, 60, 64 and 73 (inclusive) in Schedule B of the SOC; 19. the known facts that the Vaccines where mRNA vaccines involved the first ever in-human use of and unknown effects of mRNA technologies prior to the Approvals particularised at para. 3, 26, 30, 37 to 41, 46 to 48, 50, 55, 56 and 64 (inclusive) in Schedule B of the SOC; 20. the known novel use of lipid nanoparticles in the Vaccines prior to the Approvals particularised at para. 3, 8, 26, 30, 31, 33, 39 to 41,

	43, 44, 46, 48, 49 and 51 in Schedule B of the SOC; 21. the known fact that coronaviruses had never before been the subject of mass vaccination prior to the Approvals particularised at para. 3 and 7 in Schedule B of the SOC; 22. the known profound reduction of the time taken for analysis and testing of the Vaccines to a fraction of that established historically and scientifically and appropriate for such analysis prior to the Approvals particularised at para. 1, 5, 6 and 9 in Schedule B of the SOC; 23. the known proliferation of an unprecedented volume and rate of adverse events reporting in respect of the Vaccines prior to the Approvals particularised at para. 15, 17, 19 and 27 in Schedule B of the SOC; 24. the known facts that each of the Vaccines represents an evident and known risk of death, serious illness or serious injury which has not been fully disclosed to the Australian public prior to the Approvals particularised at para. 3, 14, 18 to 20, 27 to 33, 36, 37, 40 to 42, 51, 55, 57 to 60, 64 and 69 to 74 (inclusive) in Schedule B of the SOC; 25. the dismissal of adverse events reporting rates associated with the Vaccines based upon spurious reasons prior to the Approvals particularised at para. 16 to 18, 20, 33, 36, 73 and 74 (inclusive) in Schedule B of the SOC.
75	The relevant factual acts, matters or circumstances by which the Reckless Conduct – Approvals were undertaken by each of Skerritt, the Secretary and the Chief Medical Officer in bad faith are those factual matters and circumstances pleaded and particularised at paragraphs 22 to 38, 42, 44 to 47, 49 to 64, 69 to 75, and 77 to 84 (inclusive) of the SOC and particularised at paragraphs 1 to 74 of Schedule B of the SOC.
77	1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects;

	5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Reckless Conduct - Continuing Approvals; 8. The Known Approvals Assessment Failures; 9. The Particulars of the Known Approvals Assessment Failures; 10. The Known Post-Approvals Assessment Failures. The particulars of the known facts manifesting the Reckless Failures – Continuing Approvals are contained in the factual matters pleaded in the Known Serious Vaccines Risks And Conduct - Pre-Approvals relating to known facts and knowledge prior to the Approvals particularised in the Particulars of the Known Approvals Assessment Failures and further in the Known Serious Vaccines Risks And Conduct - Post-Approvals relating to known facts and knowledge subsequent to the Approvals particularised as follows **("Particulars of the Known Continuing Approvals Assessment Failures")**: 1. Particulars of Reckless Approvals Failures contained in the Known Serious Vaccines Risks And Conduct - Pre-Approvals 2. further, the following Post-Approvals reckless Continuing Approvals Failures contained in the Known Serious Vaccines Risks And Conduct - Post-Approvals: 3. the known absence of clinical testing undertaken or data in respect of the Vaccines' ability to prevent transmission of the Virus continuing from the time of the Approvals particularised at para. 83, 88, 90 and 92 in Schedule B of the SOC; 4. the known absence of clinical testing undertaken or data in respect of the Vaccines' ability to prevent infection with the Virus continuing from the time of the Approvals particularised at para. 81, 83, 84, 86, 87, 90 and 92 to 95 (inclusive) in Schedule B of the SOC; 5. the known absence of clinical testing undertaken or data in respect of the Vaccines' ability to prevent serious illness from Covid continuing from the time of the Approvals particularised at para.

	83, 90, 92 and 94 in Schedule B of the SOC; 6. the known absence of clinical testing undertaken or data in respect of the Vaccines' ability to prevent hospitalisation from Covid continuing from the time of the Approvals particularised at para. 82 to 84, 90 and 94 (inclusive) in Schedule B of the SOC; 7. the known absence of clinical testing undertaken or data in respect of the Vaccines' ability to prevent death from Covid continuing from the time of the Approvals particularised at para. 81 to 84, 90, 92 and 94 (inclusive) in Schedule B of the SOC; 8. the known safety concerns regarding the use of the Vaccines in pregnant women continuing from the time of the Approvals particularised at para. 98, 101, 106, 112, 114, 120, 121, 145 and 153 in Schedule B of the SOC; 9. the known safety concerns regarding the use of the Vaccines in immunocompromised people continuing from the time of the Approvals particularised at para. 121 in Schedule B of the SOC; 10. the known safety concerns regarding the use of the Vaccines in people with certain pre-existing health conditions continuing from the time of the Approvals particularised at para. 64 in Schedule B of the SOC; 11. the known safety concerns regarding the use of the Vaccines in people receiving other vaccines concurrently continuing from the time of the Approvals particularised at para. 73 in Schedule B of the SOC; 12. the known safety concerns regarding the use of the Vaccines in people with natural immunity resultant from prior infection with the Virus continuing from the time of the Approvals particularised at para. 90 and 92 in Schedule B of the SOC; 13. the known absence of testing and data in respect of the Vaccines' long-term efficacy continuing from the time of the Approvals particularised at para. 78, 83 and 90 in Schedule B of the SOC; 14. the known absence of testing and data in respect of the Vaccines' genotoxicity continuing from the time of the Approvals

	particularised at para. 89 in Schedule B of the SOC; 15. the known absence of testing and data in respect of the Vaccines' carcinogenicity continuing from the time of the Approvals particularised at para. 89 in Schedule B of the SOC; 16. the known absence of testing and data in respect of the Vaccines' long-term safety continuing from the time of the Approvals particularised at para. 73, 78, 83, 121 and 145 in Schedule B of the SOC; 17. the known absence of testing and data in respect of the risk of extreme and unquantified proliferation of the spike protein in the human body with the Vaccines continuing from the time of the Approvals particularised at para. 89, 121, 144 and 147 in Schedule B of the SOC; 18. the known risk of vaccine associated enhanced disease arising in the use of the vaccines continuing from the time of the Approvals particularised at para. 121 and 146 in Schedule B of the SOC; 19. the conduct of the TGA generally seeking and accepting an explanation from the Sponsor in respect of evident issues or data deficiencies with the Vaccines, subsequently and invariably accepted in lieu of any further data or investigation continuing from the time of the Approvals particularised at para. 121 in Schedule B of the SOC; 20. the known facts that the Vaccines where mRNA vaccines involved the first ever in-human use of and unknown effects of mRNA technologies continuing from the time of the Approvals particularised at para. 89 and 144 in Schedule B of the SOC; 21. the known novel use of lipid nanoparticles in the Vaccines continuing from the time of the Approvals particularised at para. 150 in Schedule B of the SOC; 22. the known fact that coronaviruses had never before been the subject of mass vaccination continuing from the time of the Approvals particularised at para. 3 and 7 in Schedule B of the SOC; 23. the known proliferation of an unprecedented volume and rate of

	adverse events reporting in respect of the Vaccines continuing from the time of the Approvals particularised at para. 80, 81, 96, 98 to 115, 117 to 121, 137, 195, 140, 143 to 155 (inclusive) in Schedule B of the SOC; 24. the known adoption by the TGA of an erroneous standard for causality assessment continuing from the time of the Approvals particularised at para. 125 and 127 to 133 (inclusive) in Schedule B of the SOC; 25. the known facts that each of the Vaccines represents an evident and known risk of death, serious illness or serious injury which has not been fully disclosed to the Australian public continuing from the time of the Approvals particularised at para. 83, 89, 150, 98 to 115, 117 to 123, 129, 132 and 137 to 155 (inclusive) in Schedule B of the SOC; 26. the known high proportional reporting ratios evidencing extraordinary rates of adverse events reporting in the Vaccines as compared to previously approved vaccines continuing from the time of the Approvals particularised at para. 137, 138, 152 and 153 in Schedule B of the SOC; 27. the dismissal of adverse events reporting rates associated with the Vaccines based upon spurious reasons continuing from the time of the Approvals particularised at para. 114, 121 and 129 to 186 (inclusive) in Schedule B of the SOC; 28. the failure to issue safety alerts arising from the known data to the Australian public continuing from the time of the Approvals particularised at para. 121 to 123, 138 and 142 (inclusive) in Schedule B of the SOC.
78	The relevant factual acts, matters or circumstances by which the Reckless Conduct – Continuing Approvals were undertaken by each of Skerritt, the Secretary and the Chief Medical Officer in bad faith are those factual matters and circumstances pleaded and particularised at paragraphs 22 to 38, 44 to 47, 49 to 64, 69 to 75, and 77 to 84 (inclusive) of the SOC and particularised at para 1 to 155 of Schedule B of the SOC.

79	The relevant factual acts, matters or circumstances by which the Reckless Conduct – Misleading Public Message were undertaken by each of Skerritt, the Secretary and the Chief Medical Officer in bad faith are those factual matters and circumstances pleaded and particularised at paragraphs 22 to 38, 42 to 47, 49 to 64, 69 to 75, and 77 to 84 (inclusive) of the SOC and particularised at para. 1 to 155 of Schedule B of the SOC.
80(b)(iii)	1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Known Serious Vaccines Risks and Conduct – Pre-Approvals; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Known Continuing Approvals Assessment Failures.
80(b)(iv)	1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Known Serious Vaccines Risks and Conduct – Pre-Approvals; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Known Continuing Approvals Assessment Failures.
80(b)(v)(7)	The facts were rationally established and known as particularised in the following paragraphs: 1. Pre-Approvals: para. 1 to 74 in Schedule B of the SOC. 2. Post-Approvals: para. 77 to 125, 127, 129 to 133 and 137 to 155 (inclusive) in Schedule B of the SOC. The facts are further rationally established by reason of the: 1. TGA Policies Approvals Breaches pleaded at paragraph 90(g)(iv) of the SOC;

	2. Skerritt Continuing Approval Breaches pleaded at paragraph 92(g) of the SOC.
80(b)(v)(8)	The facts were rationally established and known as particularised in the following paragraphs: 1. Pre-Approvals: para. 1, 3, 5, 6, 8 to 14, 17, 21, 22, 85F to 33, 35 to 42, 46, 48, 50 to 53, 55 to 60, 62 to 64, 73 and 74 (inclusive) in Schedule B of the SOC. The facts are further rationally established by reason of the TGA Policies Approvals Breaches pleaded at paragraph 90(g)(iv) of the SOC.
80(b)(v)(15)	The public nature of the statements and the position of Skerritt as head of TGA and the control and reliance upon the TGA and the Department pleaded at paragraphs 11, 17, 18, 44, 46, 49, 61 to 64, 69 to 70 (inclusive) of the SOC. Misleading Vaccines Statements referring to Respondents as the sole reliable source of information, arbiter of authoritative information, and determiner of Vaccines "misinformation" are pleaded and particularised at paragraphs 46(c), 47(c), and 48(b) of the SOC. Reliance as to the veracity and authoritative nature of the statements arose by reason of the respective offices of the Public Officers, and the consistent declarations of the Commonwealth and the Department that the Department was the authoritative source of accurate information as to the safety and efficacy and necessity of the Vaccines as declared for example in "COVID-19 and vaccines: Get the best advice for you and your family" Published 30 August 2021 at URL https://www.ahpra.gov.au/News/2021-08-30-Joint-statement.aspx
80(c)	The factual matters and knowledge pleaded at paragraph 80(a) and 80(b) of the SOC. Each of the Public Officers was an officer of the Department, the Secretary was the operational head of the Department, and Hunt was responsible for the conduct of the Department.

	The Overarching Department Purpose and thereby the purported guiding purpose of each acting in respect of the Department's purpose is pleaded and particularised at paragraph 17(f) of the SOC.
80(d)	1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Known Serious Vaccines Risks and Conduct – Pre-Approvals; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Known Post-Approvals Assessment Failures; 10. The Particulars of the Known Continuing Approvals Assessment Failures.
84	Particulars of the Loss and Damage to the Applicants: 1. The loss and damage to Mr Rose is the Rose Damages. 2. The loss and damage to Mr O'Gradie is the O'Gradie Damages. 3. The loss and damage to Mr Derose is the Derose Damages. Particulars of each of the other Group Members' loss and damage may be provided after the trial of common issues but is expected to include: 1. personal injury; 2. health care expenses; 3. other out of pocket expenses; 4. economic loss; 5. the need for gratuitous and in addition, or alternatively, commercial care; and 6. non-economic loss. The Breaches caused the Loss and Damage by reason of the factual matters pleaded and particularised at Para. 42 to 83 (inclusive) of the SOC.

87	The base assertion of the pleaded paragraph is that each of the Public Officers was purportedly discharging a public duty in undertaking each of the acts and omissions comprising the Impugned Conduct. The individual material facts and particulars of the Impugned Conduct undertaken by each of the Public Officers is pleaded and particularised at paragraph 51 to 60 (inclusive) of the SOC. The powers, functions and discretions exercised by each individual Respondent in undertaking the Impugned Conduct which was purportedly in discharge of a public duty in their respective capacities as officer of the Commonwealth, acting with power incident to their office and/or administering the Act and associated legislative instruments are (non-exhaustively) exemplified in paragraph 87 sub-paragraphs (a) to (d). The responsibilities of the Respondents are pleaded and particularised at paragraphs 10 to 18 (inclusive) and 36 of the SOC. Further particulars as to specific acts and omissions of the Respondents and/or their delegates may be provided after discovery.
90(c)	Skerritt knew each and every one of the factual matters constituting the Known Serious Vaccines Risks and Conduct - Pre-Approval, the Pre-Approval Established Critical Defects, and the Known Approvals Assessment Failures no later than the time of the respective Approvals. The time of the respective Approvals is pleaded and particularised at paragraph 20 of the SOC. Skerritt's knowledge of the asserted factual matters relating to the Approvals arises in the circumstances of the factual matters pleaded and particularised at: i. paragraph 90 of the SOC; and

	ii. paragraphs 11, 17, 18, 22 to 38 (inclusive) and 74(a) and (d) of the SOC and para. 1 to 74 in Schedule B of the SOC.
90(d)(i)	Skerritt was at all material times subject to and bound by the obligations and duties in his conduct arising under the Act, the Regulations, the Conduct Legislation and the TGA Policies as pleaded and particularised at: a. sub-paragraphs 90(d)(i) and 92(d)(i) of the SOC; and b. paragraphs 10(d), 10(n), 11, 17, 18, 25 to 38 (inclusive) and 90(g) of the SOC. Acts Interpretation Act 1901, s. 34AAA **("Particulars of Adherence to TGA Policies")** The TGA Policies pleaded at paragraphs 37 of the SOC were widely publicised by the Commonwealth by public website declaration and by the voluminous oral declarations of the Respondents at the time of and subsequent to the Approvals as being the basis upon which the Commonwealth through the TGA would undertake the Approvals and Continuing Approvals. See Schedule A of the SOC. Misleading Vaccines Statements of the Respondents pleaded at paragraphs 44 to 49 (inclusive) of the SOC, particularised in Schedule D of the SOC and defined at paragraph 50 of the SOC further publicly declared adherence to process and procedure in the Approvals particularised as follows: 1. the conduct of a rigorous process in the Approvals particularised at para. 44(a), 44(d), 44(e), 44(h), 44(j), 44(l), 44(n), 45(a), 45(b), 46(a), 46(c), 46(e), 46(f), 46(h), 47(a), 47(b), 48(b2), 49(a2), 49(b) in Schedule G of the SOC. 2. the conduct of the Approvals being in accordance with TGA Policies particularised at para. 44(a), 44(d), 44(e), 44(h), 44(n), 45(a), 45(b),

	45(c), 46(a), 46(c), 46(e), 46(f), 46(h), 47(a), 47(b), 48(b2), 49(a1), 49(b) in Schedule G of the SOC. 3. that the Critical Vaccine Requirements were met particularised at para. 44(a) to 44(n), 45(a), 45(b), 45(c), 46(a), 46(c), 46(d) to 46(i), 47(a) to 47(d), 48(aa) to 48(d) and 49(a) to 49(c) (inclusive) in Schedule G of the SOC. 4. the following adopted TGA policy documents particularised in Schedule A of the SOC: a. the TGA Provisional Approval Policy b. the TGA Adverse Events Identification Policy c. the TGA Adverse Events Reporting Policy d. the TGA Safety Monitoring Policy e. the TGA Safety Covid Information Policy f. the TGA Sponsors' Pharmacovigilance Policy g. the TGA Sponsors' Pharmacovigilance Policy 2 h. the TGA Covid Vaccine Approvals Policy i. the TGA Covid Vaccine Evidence Policy
90(e)	The Skerritt Approvals were in fact and known by Skerritt to be inconsistent with the Department Overarching Purpose and the TGA's Statutory Purpose by reason of the factual matters and knowledge pleaded at sub-paragraphs 90(c) and 90(d) of the SOC. The relevant factual matters and circumstances in respect of the Skerritt Approvals being undertaken by Skerritt for an improper purpose are those pleaded and particularised at: a. paragraph 90 of the SOC; and b. paragraphs 11, 17, 18, 22 to 38 (inclusive), 74(a) and 74(d) of the SOC and para. 1 to 74 (inclusive) in Schedule B of the SOC.
90(f)	1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. Particulars of the Pre-Approval Established Critical Defects; 3. The Pre-Approval Established Critical Defects; 4. The Known Approvals Assessment Failures; 5. The Particulars of the Known Approvals Assessment Failures.

90(g)(i)(3)-(5)	Skerritt directly or indirectly caused the Approvals by reason of the factual matters pleaded at paragraph 51 of the SOC. No clinical testing was undertaken and thereby no data provided in respect of the following Vaccine Purposes as contained and evident in the Known Serious Vaccines Risks and Conduct - Pre-Approvals known to all of the Respondents particularised in respect of the following ("**the Clinical Testing Failures Particulars**"): 1. Prevention - Transmission of the Virus: the factual matters particularised at paragraphs 9, 22, 25, 28, 32, 36, 62, 73 and 74 in Schedule B of the SOC; 2. Prevention - Infection with the Virus: the factual matters particularised at paragraphs 21, 22, 24, 25, 28, 32 and 36 in Schedule B of the SOC. 3. Prevention - Serious Illness from Covid: the factual matters particularised at paragraphs 9, 22, 25, 28, 32 and 60 in Schedule B of the SOC. 4. Prevention - Hospitalisation from Covid: the factual matters particularised at paragraphs 22, 28 and 60 in Schedule B of the SOC. 5. Prevention - Death from Covid: the factual matters particularised at paragraphs 9, 22, 25, 28, 32 and 60 in Schedule B of the SOC.
90(g)(i)(6)	The factual matters of fact and Skerritt's knowledge pleaded and particularised at sub-paragraphs 90(c) to 90(f) (inclusive) and sub-paragraphs 90(g)(i) to 90(g)(iii) of the SOC. 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. Particulars of the Pre-Approval Established Critical Defects; 3. The Pre-Approval Established Critical Defects; 4. The Known Approvals Assessment Failures; 5. The Particulars of the Known Approvals Assessment Failures; 6. The Clinical Testing Failures; 7. The Clinical Testing Failures Particulars.

90(g)(ii)	The relevant TGA Functional Responsibilities are pleaded and particularised at paragraph 18(h) of the SOC. The breaches arise by reason of the factual matters and knowledge pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. Particulars of the Pre-Approval Established Critical Defects; 3. The Pre-Approval Established Critical Defects; 4. The Known Approvals Assessment Failures; 5. The Particulars of the Known Approvals Assessment Failures; 6. The Clinical Testing Failures; 7. The Clinical Testing Failures Particulars.
90(g)(iii)(1)	s. 10(5) and s. 12 of the *Public Service Act 1999* and the *Parliamentary Service Act 1999.* The relevant factual matters and circumstances in respect of Skerritt's failure to provide the Commonwealth with frank, honest, timely advice are those pleaded and particularised at: a. sub-paragraphs 90(a) to (g)(iii) of the SOC; and b. paragraphs 11, 17, 18, 22 to 38(inclusive), 74(a) and 74(d) of the SOC and paragraphs 1 to 74 in Schedule B of the SOC.
90(g)(iii)(2)	Binding Code of Conduct per s. 14 of the *Public Service Act 1999* and the *Parliamentary Service Act 1999* enunciated at s. 13 of the *Public Service Act 1999* and the Parliamentary Service Act 1999. The relevant factual matters and circumstances in respect of Skerritt's breach of the statutory legal obligations of the *Public Service Act 1999*, the *Parliamentary Service Act 1999* and the relevant Code of Conduct are pleaded and particularised at: a. sub-paragraphs 90(a) to 90(g)(iv) of the SOC; and b. paragraphs 11, 17, 18, 22 to 38 (inclusive) and 74(a) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.

90(g)(iii)(2)(a)	s.13(1) of the *Public Service Act 1999* and the *Parliamentary Service Act 1999* The relevant factual matters and circumstances in respect of Skerritt's failure to act honestly and with integrity are those pleaded and particularised at: a. sub-paragraphs 90(a) to (g)(iii) of the SOC; and b. paragraphs 11, 17, 18, 22 to 38 (inclusive) and 74(a) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
90(g)(iii)(2)(b)	s.13(2) of the *Public Service Act 1999* and the *Parliamentary Service Act 1999.* The relevant factual matters and circumstances in respect of Skerritt's failure to act with care and diligence in connection with the relevant acts and omissions are those pleaded and particularised at: a. sub-paragraphs 90(a) to (g)(iii) of the SOC; and b. paragraphs 11, 17, 18, 22 to 38 (inclusive) and 74(a) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
90(g)(iii)(3)	*Public Governance, Performance and Accountability Act 2013,* s. 12, s.25, s. 26. The relevant factual matters and circumstances in respect of Skerritt's breach of the statutory legal obligations of the *Public, Governance, Performance and Accountability Act 2013* are the factual matters pleaded and particularised at: a. sub-paragraphs 90(a) to 90(g)(iii) of the SOC; and b. paragraphs 11, 17, 18, 22 to 38 (inclusive), 74(a) and 74(d) of the SOC and paragraphs 1 to 74 in Schedule B of the SOC.
90(g)(iv)	The TGA Policies pleaded at paragraph 37 of the SOC and particularised in Schedule A of the SOC were widely publicised by the Commonwealth by public website declaration and by the voluminous oral declarations of the Respondents at the time of and subsequent to the Approvals as being

	the basis upon which the Commonwealth through the TGA would undertake the Approvals and Continuing Approvals. Pleading and particulars of the Misleading Vaccines Statements at paragraph 50 of the SOC. Public declarations of the Respondents as to adherence to TGA Policies in the Approvals are particularised in the Particulars of Adherence to TGA Policies herein. The breaches below occur by reason of the factual matters and knowledge pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. Particulars of the Pre-Approval Established Critical Defects; 3. The Pre-Approval Established Critical Defects; 4. The Known Approvals Assessment Failures; 5. The Particulars of the Known Approvals Assessment Failures; 6. The Clinical Testing Failures; 7. The Clinical Testing Failures Particulars.
90(g)(iv)(1)	The TGA Policies breached arise specifically from the following adopted policy documents particularised in Schedule A of the SOC: 1. the Vaccine Regulation Policy 2. the TGA Safety Monitoring Policy 3. the TGA Covid Vaccine Evidence Policy
90(g)(iv)(3)	The TGA Policies breached arise specifically from the following adopted policy documents particularised in Schedule A of the SOC: 1. the Vaccine Regulation Policy 2. the TGA Safety Monitoring Policy 3. the TGA Covid Vaccine Approvals Policy
90(g)(iv)(6)	The TGA Policies breached arise specifically from the following adopted policy documents particularised in Schedule A of the SOC: 1. the Vaccine Regulation Policy 2. the TGA Safety Monitoring Policy

90(g)(iv)(10)	The TGA Policies breached arise specifically from the following adopted policy documents particularised in Schedule A of the SOC: 1. the Vaccine Regulation Policy 2. the TGA Safety Monitoring Policy
90(g)(iv)(14)	The TGA Policies breached arise specifically from the following adopted policy documents particularised in Schedule A of the SOC: 1. the Vaccine Regulation Policy 2. the TGA Safety Covid Information Policy
90(g)(iv)(15)	The TGA Policies breached arise specifically from the following adopted policy documents particularised in Schedule A of the SOC: 1. the TGA Provisional Approval Policy 2. the TGA Safety Covid Information Policy
90(g)(iv)(18)	The TGA Policies breached arise specifically from the following adopted policy documents particularised in Schedule A of the SOC: 1. the TGA Provisional Approval Policy 2. the TGA Safety Covid Information Policy
90(g)(iv)(19)	The TGA Policies breached arise specifically from the following adopted policy documents particularised in Schedule A of the SOC: 1. the TGA Provisional Approval Policy; 2. the TGA Safety Covid Information Policy; 3. the TGA Covid Vaccine Evidence Policy.
90(g)(iv)(20)	The TGA Policies breached arise specifically from the following adopted policy documents particularised in Schedule A of the SOC: 1. the TGA Safety Monitoring Policy 2. the TGA Safety Covid Information Policy 3. the TGA Covid Vaccine Approvals Policy 4. the TGA Covid Vaccine Evidence Policy
90(g)(iv)(22)	The TGA Policies breached arise specifically from the adopted Pharmacovigilance in Vaccine Approvals Policy (EMA) particularised in Schedule A of the SOC. In all instances, the Skerritt Approval Breaches arise by reason of the factual matters and knowledge pleaded and particularised at:

	i. sub-paragraphs 90(a) to 90(g)(iii) of the SOC; and ii. paragraphs 11, 17, 18, 22 to 38 (inclusive), 42, 74(a) and 74(d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
90(i)	The relevant factual matters and circumstances in respect of the Skerritt Approvals as undertaken by Skerritt being actuated by improper purposes are those pleaded and particularised at: a. sub-paragraphs 90(a) to (h) (inclusive) of the SOC; and b. paragraphs 11, 17, 18, 22 to 38 (inclusive), 42, 51, 74(a) and 74(d) of the SOC and 1 to 74 in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Skerritt Approvals as undertaken by Skerritt were unlawful are those pleaded and particularised at: a. sub-paragraphs 90(a) to (h) (inclusive) of the SOC; and b. paragraphs 11, 17, 18, 22 to 36 (inclusive), 42, 51, 74(a) and 74(d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Skerritt Approvals as undertaken by Skerritt would cause harm are those pleaded and particularised at: a. sub-paragraphs 90(a) to (h) (inclusive) of the SOC; and b. paragraphs 11, 15, 18, 22 to 38 (inclusive), 42, 51, 61 to 64, 69, 70, 71; 74(a) and (d) and 75, 83, 84 and 90 of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances as to Skerritt's knowledge or reckless indifference to those matters pleaded therein are those pleaded and particularised at: a. sub-paragraphs 90(a) to (h) (inclusive) of the SOC; and b. paragraphs 11, 15, 18, 22 to 38 (inclusive), 42, 51, 64 to 71 (inclusive), 74(a) and (d) and 76 of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.

92(c)	Skerritt's knowledge of the asserted factual matters relating to the Continuing Approvals arises in the circumstances of the factual matters pleaded and particularised at: i. paragraph 92 of the SOC; and ii. paragraphs 11, 17, 18, 22 to 38 (inclusive), 42, 43, 74(a) and (d), 77(a) and (d), and 90 of the SOC and 1 to 155 (inclusive) in Schedule B of the SOC. The time of the respective Approvals is pleaded and particularised at paragraph 20 of the SOC. The Continuing Approvals are defined at paragraph 21 of the SOC.
92(d)(iii)(1)	The relevant facts and knowledge arise by reason of the following factual matters pleaded and particularised in the SOC: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
92(d)(iii)(2)	The relevant facts and knowledge arise by reason of the following factual matters pleaded and particularised in the SOC: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures;

	9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
92(e)	The Skerritt Continuing Approvals were in fact, and known by Skerritt to be, inconsistent with the Department Overarching Purpose and the TGA's Statutory Purpose by reason of the factual matters and knowledge pleaded at sub-paragraphs 90(c) and (d) of the SOC. The relevant factual matters and circumstances in respect of the Skerritt Continuing Approvals being undertaken by Skerritt for an improper purpose are those pleaded and particularised: a. paragraph 92 of the SOC; and b. paragraphs 11, 17, 18, 22 to 38 (inclusive), 42, 43, 51, 51, 74(a) and (d), 77(a) and (d), and 90(g)(ii) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.
92(f)	The relevant facts and knowledge arise by reason of the factual matters and knowledge pleaded at sub-paragraph 92(c) and (d) of the SOC and in the following: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
92(g)(vii)	The TGA Policies breached arise specifically from the following adopted policy documents particularised in Schedule A of the SOC: 1. the TGA Adverse Events Identification Policy 2. the TGA Sponsors Pharmacovigilance Policy 3. the TGA Sponsors Pharmacovigilance Policy 2 4. the TGA Adverse Events Reporting Policy

	5. the TGA Safety Monitoring Policy 6. the Pharmacovigilance in Vaccine Approvals Policy (EMA)
92(g)(viii)	The TGA Policies breached arise specifically from the following adopted policy documents particularised in Schedule A of the SOC: 1. the TGA Adverse Events Reporting Policy 2. Pharmacovigilance in Vaccine Approvals Policy (EMA) 3. the TGA Safety Covid Information Policy 4. the TGA Safety Monitoring Policy 5. The TGA Covid Vaccine Approvals Policy
92(g)(ix)	The TGA Policies breached arise specifically from the following adopted policy documents particularised in Schedule A of the SOC: 1. the TGA Safety Monitoring Policy 2. the TGA Covid Vaccine Approvals Policy
92(g)	The Skerritt Continuing Approval Breaches arise by reason of the factual matters and knowledge pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
92(i)	The relevant factual matters and circumstances in respect of the Skerritt Continuing Approvals as undertaken by Skerritt being actuated by improper purposes are those pleaded and particularised at: a. sub-paragraphs 92(a) to (h) (inclusive) of the SOC; and b. paragraphs 11, 17, 18, 22 to 38 (inclusive), 42, 43, 51, 52, 74(a) and (d), 77(a) and (d), and 90(g) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.

	The relevant factual matters and circumstances in respect of the Skerritt Continuing Approvals as undertaken by Skerritt were unlawful are those pleaded and particularised at: a. sub-paragraphs 92(a) to (h) (inclusive) of the SOC; and b. paragraphs 11, 17, 18, 22 to 36 (inclusive), 42, 43, 51, 52, 74(a) and (d), and 77(a) and (d) of the SOC and 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Skerritt Continuing Approvals as undertaken by Skerritt would cause harm are those pleaded and particularised at: a. sub-paragraphs 92(a) to (h) (inclusive) of the SOC; and b. paragraphs 11, 15, 18, 22 to 38 (inclusive), 42, 43, 51, 52, 61 to 64, 69, 70, 71, 74(a) and (d), 77(a) and (d), 83, 84, 90 and 92 of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances as to Skerritt's knowledge or reckless indifference to those matters pleaded therein are those pleaded and particularised at: a. sub-paragraphs 92(a) to (h) (inclusive) of the SOC; and b. paragraphs 11, 15, 18, 22 to 38 (inclusive), 42, 43, 51, 52, 64 to 71 (inclusive), 74(a) and (d), 76, 77(a) and (d), and 90(g) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.
94(b)	The factual matters and knowledge arise by reason of the matters pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects;

	7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
94(c)(i)	The factual matters and knowledge establishing the Known Established Falsity of the Misleading Public Message are pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals 3. Particulars of the Pre-Approval Established Critical Defects 4. Particulars of the Post-Approval Established Critical Defects 5. The Pre-Approval Established Critical Defects 6. The Post-Approval Established Critical Defects 7. The Known Approvals Assessment Failures 8. The Particulars of the Known Approvals Assessment Failures 9. The Clinical Testing Failures 10. The Clinical Testing Failures Particulars
94(c)(ii)(1)	The facts were rationally established and known as particularised in the following paragraphs: 1. Pre-Approvals: para. 3 to 10, 14 to 20, 26 to 33 and 35 to 74 (inclusive) in Schedule B of the SOC. 2. Post-Approvals: para. 80 to 82, 89, 96 to 125, 127, 129 to 133 and 137 to 155 (inclusive) in Schedule B of the SOC.
94(c)(ii)(2)	The facts were rationally established and known as particularised in the following paragraphs: 1. Pre-Approvals: para. 3 to 10, 14 to 20, 26 to 33 and 35 to 74 (inclusive) in Schedule B of the SOC. 2. Post-Approvals: para. 80 to 82, 89, 96 to 125, 127, 129 to 133 and 137 to 155 (inclusive) in Schedule B of the SOC.
94(c)(ii)(3)	The facts were rationally established and known as particularised in the following paragraphs: 1. Pre-Approvals: para. 21, 22, 24, 25, 28, 32 and 36 in Schedule B of the SOC.

	2. Post-Approvals: para. 81, 83, 84, 86, 87, 90 and 92 to 95 (inclusive) in Schedule B of the SOC.
94(c)(ii)(4)	The facts were rationally established and known as particularised in the following paragraphs: 1. Pre-Approvals: para. 9, 36, 22, 25, 28, 32, 36, 62, 73 and 74 in Schedule B of the SOC. 2. Post-Approvals: para. 83, 88, 90 and 92 in Schedule B of the SOC.
94(c)(ii)(5)	The facts were rationally established and known as particularised in the following paragraphs: 1. Pre-Approvals: para. 9, 22, 25, 28, 32 and 60 in Schedule B of the SOC. 2. Post-Approvals: para. 83, 90, 92 and 94 in Schedule B of the SOC.
94(c)(ii)(6)	The facts were rationally established and known as particularised in the following paragraphs: 1. Pre-Approvals: para. 9, 22, 25, 28, 32 and 60 in Schedule B of the SOC. 2. Post-Approvals: para. 81 to 84, 90, 92 and 94 (inclusive) in Schedule B of the SOC.
94(c)(ii)(7)	The facts were rationally established and known as particularised in the following paragraphs: 1. Pre-Approvals: para. 1 to 74 (inclusive) in Schedule B of the SOC. 2. Post-Approvals: para. 77 to 125, 127, 129 to 133 and 137 to 155 (inclusive) in Schedule B of the SOC. The facts are further rationally established by reason of the: 1. TGA Policies Approvals Breaches pleaded at paragraph 90(g)(iv) of the SOC; 2. Skerritt Continuing Approval Breaches pleaded at paragraph 92(g) of the SOC.
94(c)(ii)(8)	The facts were rationally established and known as particularised in the following paragraphs: a. Pre-Approvals: para. 1, 3, 5, 6, 8 to 14, 17, 21, 22, 26 to 33, 35 to 42, 46, 48, 50 to 53, 55 to 60, 62 to 64, 73 and 74 (inclusive) in Schedule B of the SOC. The facts are further rationally established by reason of the TGA Policies

	Approvals Breaches pleaded at paragraph 90(g)(iv) of the SOC.

94(c)(ii)(9)	The relevant factual matters and circumstances in respect of that Skerritt knew or had reckless indifference to the data in respect of safety of efficacy of the Vaccines of objective cause for concern are those pleaded and particularised at paragraphs:
	a. 90(a) to (h) (inclusive) of the SOC;
	b. 92(a) to (h) (inclusive) of the SOC;
	c. 94(c)(i) of the SOC;
	d. 94(c)(ii)(9) of the SOC; and
	e. 11, 15, 18, 22 to 38 (inclusive), 42, 43, 51, 64 to 71 (inclusive), 74(a) and (d), 76 and 77(a) and (d) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.

94(c)(ii)(10)	The facts were rationally established and known as particularised in the following paragraphs: 1. Pre-Approvals: para. 1, 9, 23, 25, 28 and 74 in Schedule B of the SOC. 2. Post-Approvals: para. 81 to 88, 90, 92 to 95 and 108 (inclusive) in Schedule B of the SOC.
94(c)(ii)(11)	The facts were rationally established and known as particularised in the following paragraphs: 1. Pre-Approvals: para. 1 to 74 (inclusive) in Schedule B of the SOC. 2. Post-Approvals: para. 77 to 125, 127, 129 to 133 and 137 to 155 (inclusive) in Schedule B of the SOC.
94(c)(ii)(12)	The facts were rationally established and known as pleaded and particularised in the following paragraphs, in each and every case being known to Skerritt by the Evidentiary Basis of Skerritt's Pre-Approvals Knowledge and the Evidentiary Basis of Skerritt's Post-Approvals Knowledge particularised at: 1. Pre-Approvals: para. 1, 9, 23, 25, 28, 32, 36, 62, 73 and 74 in Schedule B of the SOC. 2. Post-Approvals: para. 81 to 86, 88, 90 and 92 to 95 (inclusive) in Schedule B of the SOC.
94(c)(ii)(13)	The relevant factual matters and circumstances in respect of the Skerritt

	knew or had reckless indifference to the data in respect of post-Approvals side effects from the Vaccines are those pleaded and particularised at:
	a. sub-paragraphs 90(a) to (h) (inclusive) of the SOC;
	b. sub-paragraphs 92(a) to (h) (inclusive) of the SOC;
	c. sub-paragraph 94(c)(i) of the SOC;
	d. sub-paragraph 94(c)(ii)(13) of the SOC;
	e. paragraphs 11, 15, 18, 22 to 38 (inclusive), 42, 43, 51, 52, 64 to 71 (inclusive), 74(a) and (d), 76 and 77(a) and (d) of the SOC and paragraphs 1 to 155 in Schedule B of the SOC.

94(c)(ii)(14)	The relevant factual matters and circumstances which Skerritt knew or had reckless indifference are pleaded and particularised at: a. sub-paragraphs 90(a) to (h) (inclusive) of the SOC; b. sub-paragraphs 92(a) to (h) (inclusive) of the SOC; and c. paragraphs 11, 15, 18, 22 to 38 (inclusive), 42, 43, 51, 52, 64 to 71 (inclusive), 74(a) and (d), 76 and 77(a) and (d) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.
94(d)	The public nature of the statements and the position of Skerritt as head of TGA and the control and reliance upon the TGA and the Department pleaded at paragraphs 11, 17, 18, 44, 46, 49 and 61 to 64 and 69 to 70 (inclusive) of the SOC. Misleading Vaccines Statements referring to Respondents as the sole reliable source of information are particularised at paragraphs 46(c), 47(c) and 48(b) in Schedule G of the SOC and the TGA Statement in the public document "COVID-19 and vaccines: Get the best advice for you and your family dated 30 August 2021 at URL: https://www.ahpra.gov.au/News/2021-08-30-Joint-statement.aspx.
94(f)	The facts and knowledge pleaded and particularised at sub-paragraphs 94(b) to (d) of the SOC. Those factual matters and knowledge arise upon the factual matters and knowledge pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals

	2. The Known Serious Vaccines Risks and Conduct - Post-Approvals 3. Particulars of the Pre-Approval Established Critical Defects 4. Particulars of the Post-Approval Established Critical Defects 5. The Pre-Approval Established Critical Defects 6. The Post-Approval Established Critical Defects
94(g)	The factual matters pleaded and particularised at sub-paragraphs 94(b) to (d) (inclusive) and (f) of the SOC. The circumstances and knowledge of the Known Established Falsity of the Misleading Public Message pleaded and particularised at paragraph 94(c) of the SOC. Knowledge of the Misleading Public Message comprising the Established Falsity of the Misleading Public Message arose by reason of the factual matters pleaded and particularised in the following: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars

94(h)(v)	The "power" in respect of the Skerritt Issued Misleading Vaccines Statements refers to a power to, in the office of the Deputy Secretary of Health Products Regulation Group and officer of the Commonwealth to produce, authorise and publish statements to the Australian public in respect of the Vaccines' safety, efficacy and necessity on behalf of the Commonwealth or at all. The "purpose" of the Skerritt Issued Misleading Vaccines Statements, contrary to the Department Overarching Purpose (pleaded and particularised at paragraph 17(f) of the SOC), was in every instance, for the Misleading Vaccines Statements Purpose defined, pleaded an particularised at paragraph 50(e) of the SOC, the basis of which is particularised in the Particulars of the Misleading Vaccines Statements Purpose.
94(i)	The relevant factual matters and circumstances in respect of the Skerritt Issued Misleading Vaccines Statements being actuated by improper purposes of Skerritt are those pleaded and particularised at: a. sub-paragraphs 94(a) to (h) (inclusive) of the SOC; and b. paragraphs 11, 15, 18, 22 to 38 (inclusive), 42, 43, 44, 46, 50 to 53 (inclusive), 64 to 71 (inclusive), 74(a) and (d), and 77(a) and (d) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Skerritt Issued Misleading Vaccines Statements being unlawful are those pleaded and particularised at: a. sub-paragraphs 94(a) to (h) (inclusive) of the SOC; and b. paragraphs 11, 15, 18, 22 to 38 (inclusive), 42, 43, 44, 46, 50 to 53 (inclusive), 64 to 71 (inclusive), 74(a) and (d), and 77(a) and (d) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of Skerritt's knowledge or alternatively, reckless indifference as to the Skerritt Issued

	Misleading Vaccines Statements being unlawful and undertaken without any power to do so, are those pleaded and particularised at: a. sub-paragraphs 94(a) to (h) (inclusive) of the SOC; and b. paragraphs 11, 15, 18, 22 to 36 (inclusive), 42, 43, 44, 46, 50 to 53 (inclusive), 64 to 71 (inclusive), 74(a) and (d), 76, and 77(a) and (d) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Skerritt Issued Misleading Vaccines Statements being likely to cause harm, are those pleaded and particularised at: a. sub-paragraphs 94(a) to (h) (inclusive) of the SOC; and b. paragraphs 11, 15, 18, 22 to 38 (inclusive), 42, 43, 44, 46, 50 to 53 (inclusive), 61 to 64 (inclusive), 69 to 71 (inclusive), 74(a) and (d), 76, 77(a) and (d) and 80 of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.. The relevant factual matters and circumstances in respect of Skerritt's knowledge or alternatively reckless indifference as to the Skerritt Issued Misleading Vaccines being likely cause harm, are those pleaded and particularised at: a. sub-paragraphs 94(a) to (h) (inclusive) of the SOC; and b. paragraphs 11, 15, 18, 22 to 38 (inclusive), 42, 43, 44, 46, 50 to 53 (inclusive), 61 to 64(inclusive), 69 to 71 (inclusive), 74(a) and (d), 76, 77(a) and (d), 80 and 90(g) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.
96(c)	The Secretary knew each and every one of the factual matters constituting Known Serious Vaccines Risks and Conduct - Pre-Approval, the Pre-Approval Established Critical Defects, and the Known Approvals Assessment Failures no later than the time of the respective Approvals. The time of the respective Approvals is pleaded and particularised at paragraph 20 of the SOC.

	The Secretary's knowledge of the asserted factual matters arises in the circumstances of the factual matters pleaded and particularised at: a. paragraph 96 of the SOC; and b. paragraphs 10, 17, 18, 22 to 38 (inclusive), 242, 74(b) and (d), and 90(g)(i) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
96(d)(i)	*Acts Interpretation Act 1901*, s. 34AAA Particulars of Adherence to TGA Policies The Secretary was at all material times subject to and bound by the obligations and duties in his conduct arising under the Act, the Regulations, The Conduct Legislation and the TGA Policies as pleaded and particularised at: a. sub-paragraphs 96(d)(i) and 98(d)(i) of the SOC; and b. paragraphs 10, 17, 18 and 25 to 38 (inclusive) of the SOC.
96(e)	The Secretary Approvals were in fact and known by the Secretary to be inconsistent with the Department Overarching Purpose and the TGA's Statutory Purpose by reason of the factual matters and knowledge pleaded at sub-paragraphs 96(c) and (d) of the SOC. The relevant factual matters and circumstances in respect of the Secretary Approvals being undertaken by the Secretary for an improper purpose are those pleaded and particularised at: a. paragraph 96 of the SOC; and b. paragraphs 10, 17, 18, 22 to 38 (inclusive), 42, 54, 74(b) and (d), and 90(g)(i) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
96(f)	The relevant knowledge and factual matters arise by reason of the following factual matters pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. Particulars of the Pre-Approval Established Critical Defects;

	3. The Pre-Approval Established Critical Defects; 4. The Known Approvals Assessment Failures; 5. The Particulars of the Known Approvals Assessment Failures; 6. The Clinical Testing Failures; 7. The Clinical Testing Failures Particulars.
96(g)(i)	The Secretary directly or indirectly caused the Approvals by reason of the factual matters pleaded at paragraph 54. The relevant factual matters and circumstances in respect of the Secretary's acting in breach of the express provisions of the Act are those pleaded and particularised at: a. paragraph 96(a) to (g) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 24 (inclusive), 25 to 36 (inclusive), 42, 54, 74(b) and (d), and 90(g)(i) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
96(g)(ii)	The relevant TGA Functional Responsibilities are pleaded and particularised at paragraph 18(h) of the SOC. The breaches arise by reason of the factual matters and knowledge pleaded and particularised as follows: The relevant knowledge and factual matters arise by reason of the following factual matters pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. Particulars of the Pre-Approval Established Critical Defects; 3. The Pre-Approval Established Critical Defects 4. The Known Approvals Assessment Failures; 5. The Particulars of the Known Approvals Assessment Failures; 6. The Clinical Testing Failures; 7. The Clinical Testing Failures Particulars.
96(g)(iii)(1)	s. 10(5) and s. 12 of the *Public Service Act 1999* and the *Parliamentary Service Act 1999.*

	The relevant factual matters and circumstances in respect of the Secretary's failure to provide the Commonwealth with frank, honest, timely advice are those pleaded and particularised at: a. sub-paragraphs 96(a) to (g)(iii)(1) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 42, 54, 74(b) and (d), and 90(g)(i) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
96(g)(iii)(2)	Binding Code of Conduct per s. 14 of the *Public Service Act 1999* and the *Parliamentary Service Act 1999* enunciated at s. 13 of the *Public Service Act 1999* and the Parliamentary Service Act 1999. The relevant factual matters and circumstances in respect of the Secretary's breach of the statutory legal obligations under the *Public Service Act 1999*, the *Parliamentary Service Act 1999* and the relevant Code of Conduct are pleaded and particularised at: a. sub-paragraphs 96(a) to 96(g)(iv) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 42, 54, 74(b) and (d), and 90(g)(i) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
96(g)(iii)(2)(a)	s.13(1) of the *Public Service Act 1999* and the *Parliamentary Service Act 1999* The relevant factual matters and circumstances in respect of the Secretary's failure to act honestly and with integrity are those pleaded and particularised at: a. sub-paragraphs 96(a) to (g)(iv) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 42, 54, 74(b) and (d), and 90(g)(i) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
96(g)(iii)(2)(b)	s.13(2) of the *Public Service Act 1999* and the *Parliamentary Service Act 1999.*

	The relevant factual matters and circumstances in respect of the Secretary's failure to act with care and diligence in connection with the relevant acts and omissions are those pleaded and particularised at: a. sub-paragraphs 90(a) to (g)(iii) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 42, 54, and 74(b) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
96(g)(iii)(3)	*Public Governance, Performance and Accountability Act 2013*, s. 12, s.25, s. 26. The relevant factual matters and circumstances in respect of the Secretary's breach of the statutory legal obligations of the Public, Governance, Performance and Accountability Act 2013 are the factual matters pleaded and particularised at: a. sub-paragraphs 96(a) to 96(g)(iii) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 42, 54, and 74(b) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
96(g)(iii)(4)	Department's Corporate Plan 2020-2021, pg. 6, pg. 20. https://www.health.gov.au/sites/default/files/documents/2020/12/corporate-plan-2020-21_0.pdf The relevant factual matters and circumstances in respect of the Secretary's acting unlawfully are the factual matters pleaded and particularised at: a. sub-paragraphs 96(a) to 96(g)(iii) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 36 (inclusive), 42, 54, and 74(b) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
96(g)(iv)	The TGA Policies pleaded at paragraphs 37 of the SOC and particularised in Schedule A of the SOC were widely publicised by the Commonwealth by public website declaration and by the voluminous oral declarations of

	the Respondents at the time of and subsequent to the Approvals as being the basis upon which the Commonwealth through the TGA would undertake the Approvals and Continuing Approvals. See pleading and particulars the Misleading Vaccines Statements at paragraph 50 of the SOC. Public declarations of the Respondents as to adherence to TGA Policies in the Approvals are particularised in the Particulars of Adherence to TGA Policies herein. The Secretary Approval Breaches arise by reason of the factual matters and knowledge pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. Particulars of the Pre-Approval Established Critical Defects; 3. The Pre-Approval Established Critical Defects; 4. The Known Approvals Assessment Failures; 5. The Particulars of the Known Approvals Assessment Failures; 6. The Clinical Testing Failures; 7. The Clinical Testing Failures Particulars.
96(i)	The relevant factual matters and circumstances in respect of the Secretary Approvals as undertaken by the Secretary being actuated by improper purposes are those pleaded and particularised at: a. sub-paragraphs 96(a) to (h) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 42, 54, and 74(b) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Secretary Approvals as undertaken by the Secretary were unlawful are those pleaded and particularised at: a. sub-paragraphs 96(a) to (h) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 36 (inclusive), 42, 54, and 74(b)

	and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Secretary Approvals as undertaken by the Secretary would cause harm are those pleaded and particularised at: a. sub-paragraphs 96(a) to (h) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 42, 54, 61 to 64 (inclusive), 69, 70, 71, 74(b) and (d), 75, 83 and 84 of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances as to the Secretary's knowledge or reckless indifference to those matters pleaded therein are those pleaded and particularised at: a. sub-paragraphs 96(a) to (h) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 42, 54, 64 to 71 (inclusive), 74(b) and (d), and 76 of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
98(c)	The Secretary's knowledge of the asserted factual matters arises in the circumstances of the factual matters pleaded and particularised at: a. paragraph 98 of the SOC; and b. paragraphs 10, 17, 18, 22 to 38 (inclusive), 42, 43, 74(b) and (d), 77(b) and (d), and 96 of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The time of the respective Approvals is pleaded and particularised at paragraph 20 of the SOC. The Continuing Approvals are defined at paragraph 21 of the SOC.
98(d)(i)	*Acts Interpretation Act 1901*, s. 34AAA Particulars of Adherence to TGA Policies

	The Secretary was at all material times subject to and bound by the obligations and duties in his conduct arising under the Act, the Regulations, The Conduct Legislation and the TGA Policies as pleaded and particularised at: a. sub-paragraphs 96(d)(i) and 98(d)(i) of the SOC; and b. paragraphs 10, 17, 18, 25 to 38 (inclusive) and 90(g) of the SOC.
98(d)(iii)	The factual matter and knowledge arise by reason of the factual matters pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
98(e)	The Secretary Continuing Approvals were in fact and known by the Secretary to be inconsistent with the Department Overarching Purpose and the TGA's Statutory Purpose by reason of the factual matters and knowledge pleaded at sub-paragraphs 98(c) and (d) of the SOC. The relevant factual matters and circumstances in respect of the Secretary Continuing Approvals being undertaken by the Secretary for an improper purpose are those pleaded and particularised at: a. paragraph 98 of the SOC; and b. paragraphs 10, 17, 18, 22 to 38 (inclusive), 42, 43, 54, 55, 74(b) and (d), and 90(g)(i) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.
98(f)	The factual matters and knowledge pleaded and particularised at sub-paragraphs 98(c) to (e) (inclusive) of the SOC.

	The factual matter and knowledge arise by reason of the factual matters pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
98(g)	The Secretary Continuing Approval Breaches arise by reason of the factual matters pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
98(i)	The relevant factual matters and circumstances in respect of the Secretary Continuing Approvals as undertaken by the Secretary being actuated by improper purposes are those pleaded and particularised at: a. sub-paragraphs 98(a) to (h) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 43, 43, 54, 55, 74(b) and (d), 77(b) and (d), and 90(g)(i) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Secretary

	Continuing Approvals as undertaken by the Secretary were unlawful are those pleaded and particularised at: a. sub-paragraphs 98(a) to (h) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 36 (inclusive), 42, 43, 54, 55, 74(b) and (d), 77(b) and (d), and 90(g)(i) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Secretary Continuing Approvals as undertaken by the Secretary would cause harm are those pleaded and particularised at: a. sub-paragraphs 98(a) to (h) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 42, 43, 54, 55, 61 to 64 (inclusive), 69, 70, 71, 74(b) and (d), 75, 77(b) and (d), 83, 84, 90(g)(i) and 96 of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances as to Secretary's knowledge or reckless indifference to those matters pleaded therein are those pleaded and particularised at: a. sub-paragraphs 98(a) to (h) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 42, 43, 54, 55, 64 to 71 (inclusive), 74(b) and (d), 76, 77(b) and (d), and 90(g)(i) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.
100(b)	The factual matters and knowledge arise by reason of the factual matters pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures;

	8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
100(c)	The circumstances and knowledge of the Known Established Falsity of the Misleading Public Message pleaded and particularised at paragraph 94(c) of the SOC. The factual falsity of the Misleading Public Message and the knowledge of that falsity arise upon the factual matters and knowledge pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
100(d)(ii)	The public nature of the statements and the position of the Secretary as head of the Department and the control and reliance upon the TGA and the Department pleaded at paragraphs 10, 17, 18, 45, 46, 49 and 61 to 64(inclusive), 69 to 71 (inclusive) of the SOC. Misleading Vaccines Statements referring to Respondents as the sole reliable source of information are particularised at paragraphs 46(c), 47(c), and 48(b) in Schedule G of the SOC and the TGA Statement in the public document "COVID-19 and vaccines: Get the best advice for you and your family dated 30 August 2021 at URL: https://www.ahpra.gov.au/News/2021-08-30-Joint-statement.aspx
100(e)	The relevant factual matters and circumstances in respect of the Secretary Issued Misleading Vaccines Statements as undertaken by the Secretary for

	an improper purpose are those pleaded and particularised at: a. sub-paragraphs 100(a) to (e)(v) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 42, 43, 45, 46, 49, 50, 54 to 56 (inclusive), 64 to 71 (inclusive), 74(b) and (d), 77(b) and (d), and 90(g)(i) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.
100(f)	The facts and knowledge pleaded and particularised at sub-paragraphs 100(b) to (d) (inclusive) of the SOC. The factual matters and knowledge arise by reason of the factual matters pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
100(g)	The factual matters pleaded at sub-paragraphs 100(b) to (d) (inclusive) of the SOC. The circumstances and knowledge of the Known Established Falsity of the Misleading Public Message pleaded and particularised at paragraph 94(c) of the SOC. Knowledge of the Misleading Public Message comprising the Established Falsity of the Misleading Public Message arose by reason of the factual matters pleaded and particularised in the following: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals;

	3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
100(h)(vi)	The "power" in respect of the Secretary Issued Misleading Vaccines Statements refers to a power to, in the office of the Secretary of the Department and officer of the Commonwealth, to produce, authorise and publish statements to the Australian public in respect of the Vaccines' safety, efficacy and necessity on behalf of the Commonwealth or at all. The purpose of the Secretary Issued Misleading Vaccines Statements, contrary to the Department Overarching Purpose (pleaded and particularised at paragraph 17(f) of the SOC), was in every instance, for the Misleading Vaccines Statements Purpose defined, pleaded and particularised at paragraph 50(e) of the SOC and the Particulars of the Misleading Vaccines Statements Purpose as defined in Schedule D of the SOC.
100(i)	The relevant factual matters and circumstances in respect of the Secretary Issued Misleading Vaccines Statements as undertaken by the Secretary being actuated by improper purposes are those pleaded and particularised at: a. sub-paragraphs 100(a) to (i)(i) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 42, 43, 45, 46, 49, 50, 54 to 56 (inclusive), 64 to 71 (inclusive), 74(b) and (d), 77(b) and (d), and 90(g)(i) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.

	The relevant factual matters and circumstances in respect of the Secretary Issued Misleading Vaccines Statements as undertaken by Secretary were unlawful are those pleaded and particularised at: a. sub-paragraphs 100(a) to (i)(ii) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 36 (inclusive), 42, 43, 45, 46, 49, 50, 54 to 56 (inclusive), 64 to 71 (inclusive), 74(b) and (d), 77(b) and (d), and 90(g)(i) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Secretary Issued Misleading Vaccines Statements being likely cause harm, are those pleaded and particularised at: a. sub- paragraphs 100(a) to (h) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 42, 43, 45, 46, 49, 50, 54 to 56 (inclusive), 61 to 64(inclusive), 69 to 71 (inclusive), 74(b) and (d), 77(b) and (d), 80 and 90(g)(i) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Secretary's knowledge or alternatively reckless indifference as to the Secretary Issued Misleading Vaccines being likely cause harm, are those pleaded and particularised at: a. sub-paragraphs 100(a) to (h) (inclusive) of the SOC; and b. paragraphs 10, 15, 17, 18, 22 to 38 (inclusive), 42, 43, 45, 46, 49, 50, 54 to 56 (inclusive), 61 to 64(inclusive), 69 to 71 (inclusive), 74(b) and (d), 76, 77(b) and (d), 80, and 90(g)(i) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.
102(c)	The Chief Medical Officer's knowledge of the asserted factual matters arises in the circumstances of the factual matters pleaded and particularised at: a. paragraph 102 of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42 and 74(c) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.

	The time of the respective Approvals is pleaded and particularised at paragraph 20 of the SOC.
102(d)(i)	*Acts Interpretation Act 1901*, s. 34AAA The Chief Medical Officer was at all material times, in respect of the CMO Approvals, subject to and bound by the obligations and duties in his conduct arising under the Act, the Regulations and the Conduct Legislation as pleaded and particularised at: a. sub-paragraph 102(d)(i) of the SOC; and b. paragraphs 10(d), 10(n), 12, 17 and 25 to 36 (inclusive) and 102(g)(i) of the SOC.
102(e)	The relevant factual matters and circumstances in respect of the Chief Medical Officer Approvals being undertaken by the Chief Medical Officer for an improper purpose are those pleaded and particularised at: a. sub-paragraphs 102(c), (d) and (e)(i) and (ii) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 57 and 74(c) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
102(f)	The factual matters and knowledge arise by reason of the factual matters pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. Particulars of the Pre-Approval Established Critical Defects; 3. The Pre-Approval Established Critical Defects; 4. The Known Approvals Assessment Failures; 5. The Particulars of the Known Approvals Assessment Failures; 6. The Clinical Testing Failures; 7. The Clinical Testing Failures Particulars.
102(g)(i)(1)	s. 10(5) and s. 12 of the *Public Service Act 1999* and the *Parliamentary Service Act 1999.* The relevant factual matters and circumstances in respect of the Chief Medical Officer's failing to provide the Commonwealth with frank,

	honest, timely advice are those pleaded and particularised at: a. sub-paragraphs 102(a) to (g) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 57 and 74(c) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
102(g)(i)(2)	Binding Code of Conduct per s. 14 of the *Public Service Act 1999* and the *Parliamentary Service Act 1999* enunciated at s. 13 of the *Public Service Act 1999* and the Parliamentary Service Act 1999. The relevant factual matters and circumstances in respect of the Chief Medical Officer's breach the statutory legal obligations of the *Public Service Act 1999*, the *Parliamentary Service Act 1999* and the relevant Code of Conduct are those pleaded and particularised at: a. sub-paragraphs 102(a) to (g) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 57, and 74(c) and (d), of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
102(g)(i)(2)(a)	s.13(1) of the *Public Service Act 1999* and the *Parliamentary Service Act 1999* The relevant factual matters and circumstances in respect of the Chief Medical Officer's failure to act honestly and with integrity are those pleaded and particularised at: a. sub-paragraphs 102(a) to (g) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 57, and 74(c) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
102(g)(i)(2)(b)(i)-(iii)	s.13(2) of the *Public Service Act 1999* and the *Parliamentary Service Act 1999.* The relevant factual matters and circumstances in respect of the Chief Medical Officer's failure to act with care and diligence are those pleaded and particularised at: a. sub-paragraphs 102(a) to (g) (inclusive) of the SOC; and

	b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 57 and 74(c) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
102(g)(i)(3)	*Public Governance, Performance and Accountability Act 2013*, s. 12, s.25, s. 26. The relevant factual matters and circumstances in respect of the Chief Medical Officer's breach of the statutory legal obligations of the *Public, Governance, Performance and Accountability Act 2013* are those pleaded and particularised at: a. sub-paragraphs 102(a) to (g) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 57 and 74(c) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Chief Medical Officer's acting unlawfully are those pleaded and particularised at: a. sub-paragraphs 102(a) to (g) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 57 and 74(c) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
102(g)(ii)	The relevant factual matters and circumstances in respect of the Chief Medical Officer's Pre-Approval Conduct being actuated by improper purposes are those pleaded and particularised at: a. sub-paragraphs 102(a) to (i) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 57 and 74(c) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
102(i)	The relevant factual matters and circumstances in respect of the Chief Medical Officer's Pre-Approval Conduct being actuated by improper purposes are those pleaded and particularised at: a. sub-paragraphs 102(a) to (i) (inclusive) of the SOC; and

	b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 57 and 74(c) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Chief Medical Officer Pre-Approval Conduct being unlawful are those pleaded and particularised at: a. sub-paragraphs 102 (a) to (i) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 57 and 74(c) and (d) of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Chief Medical Officer Pre-Approval Conduct being likely to cause harm, are those pleaded and particularised at: a. sub-paragraphs 102(a) to (h) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 44, 57, 61 to 64 (inclusive), 69, 70, 71, 74(c) and (d), 75, 83 and 84 of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances as to the Chief Medical Officer's knowledge or reckless indifference to those matters pleaded therein are those pleaded and particularised at: a. sub-paragraphs 102(a) to (i) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 57, 64 to 71 (inclusive), 74(c) and (d) and 76 of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC.
104(c)	The Chief Medical Officer's knowledge of the asserted factual matters arises in the circumstances of the factual matters pleaded and particularised at: a. paragraph 104 of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 43, 74(c) and (d) and 77(c) and (d) of the SOC and paragraphs 1 to 155 (inclusive) in

	Schedule B of the SOC. The time of the respective Approvals is pleaded and particularised at paragraph 20 of the SOC.

104(d)(i)	The Chief Medical Officer was at all material times, in respect of the CMO Continuing Approvals, subject to and bound by the obligations and duties in his conduct arising under the Conduct Legislation as pleaded and particularised at:
	a. sub-paragraph 10(n) of the SOC;
	b. sub-paragraph 102(g)(i) of the SOC;
	c. sub-paragraph 104(d)(i) of the SOC; and
	d. sub-paragraph 104(g)(i) of the SOC.

104(e)	The relevant factual matters and circumstances in respect of the Chief Medical Officer Continuing Approvals being undertaken by the Chief Medical Officer for an improper purpose are those pleaded and particularised at: a. sub-paragraphs 104(a) to (e) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 43, 57, 57, 74(c) and (d) and 77(c) and (d) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.
104(f)	The factual matters pleaded and particularised at sub-paragraph 104(c) of the SOC. The factual matters and knowledge arise by reason of the factual matters pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures;

	10. The Clinical Testing Failures Particulars.
104(g)	The Chief Medical Officer breaches arose by reason of the factual matters and knowledge pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
104(i)	The relevant factual matters and circumstances in respect of the Chief Medical Officer's Post-Approval Conduct being actuated by improper purposes are those pleaded and particularised at: a. sub-paragraphs 104(a) to (i) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 43, 57, 58, 74(c) and (d) and 77(c) and (d) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Chief Medical Officer Post-Approval Conduct being unlawful are those pleaded and particularised at: a. sub-paragraphs 104(a) to (i) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 43, 57, 57, 74(c) and (d) and 77(c) and (d) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Chief Medical Officer Post-Approval Conduct being likely to cause harm, are those pleaded and particularised at: a. sub-paragraphs 104(a) to (h) (inclusive) of the SOC; and

	b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 43, 57, 58, 61 to 64 (inclusive), 69, 70, 71, 74(c) and (d), 75, 77(c) and (d), 83, 84 and 102 of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances as to the Chief Medical Officer's knowledge or reckless indifference to those matters pleaded therein are those pleaded and particularised at: a. sub-paragraphs 104(a) to (i) (inclusive) of the SOC; b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 43, 57, 58, 64 to 71 (inclusive), 74(c) and (d), 76 and 77(c) and (d) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.
106(b)	The factual matters and knowledge arise by reason of the factual matters pleaded and particularised as follows: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
106(c)	The circumstances and knowledge of the Known Established Falsity of the Misleading Public Message pleaded and particularised at sub-paragraph 94(c) of the SOC. Knowledge of the Misleading Public Message comprising the Established Falsity of the Misleading Public Message arose by reason of the factual matters pleaded and particularised in the following: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals;

	3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
106(d)	The public nature of the statements and the position of Chief Medical Officer as the Commonwealth officer responsible for the betterment of the health and wellbeing of the Australian population and the Department pleaded at paragraphs 12, 17, 47, 49 and 61 to 64 (inclusive), 69, 70 and 71 of the SOC. It was a source of common knowledge by their public pronouncements that the Public Officers were the persons empowered with and directly tasked with the assessment, approval, and distribution of the Vaccines to the Australian Public. Public declarations of the Public Officers and as to their position as the source of authoritative information in respect of the Vaccines is evident in for example the Misleading Vaccines Statements particularised at paragraphs 46(c), 47(c), and 48(b) in Schedule G of the SOC and the TGA Statement in the public document "COVID-19 and vaccines: Get the best advice for you and your family dated 30 August 2021 at URL: https://www.ahpra.gov.au/News/2021-08-30-Joint-statement.aspx
106(e)(i)-(iv)	The acts and omissions constituting of the Chief Medical Officer in causing the Chief Medical Officer Issued Misleading Vaccines Statements to be made and published in the factual circumstances pleaded and particularised at paragraphs 12, 17, 47, 49 and 59 of the SOC are acts and the performance of functions which: a. are not powers or functions provided for in any provision of the Act or the Regulations;

	b. are not related to any powers or functions provided for in any provision of the Act or the Regulations.
106(e)(v)-(vi)	The Chief Medical Officer knew that the Chief Medical Officer Issued Misleading Vaccines Statements were in fact and known to be inconsistent with the Department Overarching Purpose by reason of the factual matters pleaded and particularised at sub-paragraphs 106(b) to (d) of the SOC. The relevant factual matters and circumstances in respect of the Chief Medical Officer causing the Issued Misleading Vaccines Statements for an improper purpose are those pleaded and particularised at: a. sub-paragraphs 106(a) to (e) (inclusive) of the SOC; b. paragraphs 12, 17, 22 to 36 (inclusive), 47, 49, 50, 57 to 59 (inclusive), 64 to 71 (inclusive), 74(c) and (d) and 77(c) and (d) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.
106(f)	The facts and knowledge pleaded and particularised at sub-paragraphs 100(b) to (d) of the SOC. The factual matters and knowledge of the Chief Medical Officer arise by reason of the factual matters pleaded and particularised in the following: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
106(g)	The factual matters pleaded at sub-paragraphs 106(b) to (d) of the SOC. The circumstances and knowledge of the Known Established Falsity of the

	Misleading Public Message pleaded and particularised at paragraph 94(c) of the SOC. Knowledge of the Misleading Public Message comprising the Established Falsity of the Misleading Public Message arose by reason of the factual matters pleaded and particularised in the following: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
106(h)(vi)	The "power" in respect of the Chief Medical Officer Issued Misleading Vaccines Statements refers to a power to, as an officer of the Commonwealth, produce, authorise and publish statements to the Australian public in respect of the Vaccines' safety, efficacy and necessity on behalf of the Commonwealth or at all.
106(i)	The relevant factual matters and circumstances in respect of the Chief Medical Officer, in causing the Chief Medical Officer Issued Misleading Vaccines Statements, was actuated by an improper purpose are those pleaded and particularised at: a. sub-paragraphs 106(a) to (i) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 43, 47, 49, 50, 57 to 59 (inclusive), 64 to 71 (inclusive), 74(c) and (d), and 77(c) and (d) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Chief Medical Officer, in causing the Chief Medical Officer Issued Misleading

	Vaccines Statements, was unlawful are those pleaded and particularised at: a. sub-paragraphs 106(a) to (i) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 43, 47, 49, 50, 57 to 59 (inclusive), 64 to 71 (inclusive), 74(c) and (d), and 77(c) and (d) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of the Chief Medical Officer Issued Misleading Vaccines Statements being likely to cause harm, are those pleaded and particularised at: a. sub-paragraphs 106(a) to (i) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 43, 47, 49, 50, 57 to 59 (inclusive), 61 to 64 (inclusive), 69, 70, 71, 74(c) and (d), 77(c) and (d) and 80 of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances as to the Chief Medical Officer's knowledge or reckless indifference to those matters pleaded at sub-paragraphs 106(i)(i), (iii) and (iv) are those pleaded and particularised at: a. sub-paragraphs 106(a) to (i) (inclusive) of the SOC; and b. paragraphs 12, 17, 22 to 36 (inclusive), 42, 43, 47, 49, 50, 57 to 59 (inclusive), 61 to 64 (inclusive), 69, 70, 71, 74(c) and (d), 76, 77(c) and (d), and 80 of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.
108(b)	The Minister knew each and every one of the factual matters constituting the Known Serious Vaccines Risks and Conduct - Pre-Approvals, the Known Serious Vaccines Risks and Conduct - Post-Approvals, the Pre-Approval Established Critical Defects and the Post-Approval Established Critical Defects: a. which arise upon the factual matters pleaded and particularised at paragraphs 1 to 155 in Schedule B of the SOC and which plead and particularise the respective date at which the knowledge of

	each was acquired; and b. no later than the time of the publication of each and every one of the Hunt Issued Misleading Vaccines Statements comprised of the Hunt Misleading Vaccines Statements. The Minister's knowledge of the asserted factual matters arises in the circumstances of the factual matters pleaded and particularised at: a. paragraph 108 of the SOC; and b. paragraphs 13, 17, 22 to 36 (inclusive), 42, and 54 of the SOC and paragraphs 1 to 74 (inclusive) in Schedule B of the SOC. The time of the respective Hunt Misleading Vaccines Statements is pleaded and particularised at paragraph 48 of the SOC.
108(c)	The circumstances and knowledge of the Known Established Falsity of the Misleading Public Message pleaded and particularised at sub-paragraph 94(c) of the SOC. Knowledge of the Misleading Public Message comprising the Established Falsity of the Misleading Public Message arose by reason of the factual matters pleaded and particularised in the following: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
108(d)	The public nature of the statements and the position of Hunt as minister responsible for the Department and the control and reliance upon the TGA

	and the Department pleaded at paragraphs 13, 17, 18 and 61 to 64, 69 to 71 (inclusive) of the SOC. Misleading Vaccines Statements referring to Respondents as the sole reliable source of information are particularised at paragraphs 46(c), 47(c), and 48(b) in Schedule G of the SOC and the TGA Statement in the public document "COVID-19 and vaccines: Get the best advice for you and your family dated 30 August 2021 at URL: https://www.ahpra.gov.au/News/2021-08-30-Joint-statement.aspx
108(e)	The relevant factual matters as to how the Minister was required to be, and was at all material times aware of matters at sub paragraphs 108(e)(iv)(3) are: a. the obligations arising under: i. s.19(1) of the *Public Governance, Performance and Accountability Act 2013*; ii. s. 57(2) of the *Public Service Act 1999*; b. the factual matters relating to Hunt's position as minister responsible for the Department pleaded and particularised at paragraphs 13 and 17 of the SOC; c. the act and circumstances in respect of Hunt making the Hunt Issued Misleading Vaccines Statements pleaded and particularised at paragraphs 48 and 60 of the SOC and paragraph 48 in Schedule G of the SOC.
108(f)	The facts and knowledge pleaded and particularised at sub-paragraphs 108(b) to (d) of the SOC. The factual matters and knowledge arise by reason of the factual matters pleaded and particularised in the following: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects;

	6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
108(g)	The factual matters pleaded at sub-paragraphs 108(b) to (d) of the SOC. The circumstances and knowledge of the Known Established Falsity of the Misleading Public Message pleaded and particularised at paragraph 94(c) of the SOC. Knowledge of the Misleading Public Message comprising the Established Falsity of the Misleading Public Message arose by reason of the factual matters pleaded and particularised in the following: 1. The Known Serious Vaccines Risks and Conduct - Pre-Approvals; 2. The Known Serious Vaccines Risks and Conduct - Post-Approvals; 3. Particulars of the Pre-Approval Established Critical Defects; 4. Particulars of the Post-Approval Established Critical Defects; 5. The Pre-Approval Established Critical Defects; 6. The Post-Approval Established Critical Defects; 7. The Known Approvals Assessment Failures; 8. The Particulars of the Known Approvals Assessment Failures; 9. The Clinical Testing Failures; 10. The Clinical Testing Failures Particulars.
108(h)(v)	The "power" in respect of the Hunt Issued Misleading Vaccines Statements refers to a power to, in the office of Minister of the Department and an officer of the Commonwealth, produce, authorise and publish statements to the Australian public in respect of the Vaccines' safety, efficacy and necessity on behalf of the Commonwealth or at all.
108(i)	The relevant factual matters and circumstances in respect of Hunt Issued Misleading Vaccines Statements being actuated by improper purposes by the Minister are those pleaded and particularised at: a. sub-paragraphs 108(a) to (i) (inclusive) of the SOC; and

	b. paragraphs 13, 17, 22 to 36 (inclusive), 42, 43, 48, 49, 50, 60 and 64 to 71 (inclusive) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of Hunt Issued Misleading Vaccines Statements being unlawful are those pleaded and particularised at: a. sub-paragraphs 108(a) to (i) (inclusive) of the SOC; and b. paragraphs 13, 17, 22 to 36 (inclusive), 42, 43, 48, 49, 50, 60 and 64 to 71 (inclusive) of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of Hunt Issued Misleading Vaccines Statements would likely cause harm are those pleaded and particularised at: a. sub-paragraphs 108(a) to (s) (inclusive) of the SOC; and b. paragraphs 13, 17, 22 to 36 (inclusive), 42, 43, 48, 49, 50, 60 to 71 (inclusive) and 80 of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC. The relevant factual matters and circumstances in respect of Hunt's knowledge or reckless indifference to those matters pleaded sub-paragraphs 108(i)(i)(1), (3) and (4) are those pleaded and particularised at: a. sub-paragraphs 108(a) to (i) (inclusive) of the SOC; and b. paragraphs 13, 17, 22 to 36 (inclusive), 42, 43, 49, 49, 50, 60 to 71 (inclusive) and 80 of the SOC and paragraphs 1 to 155 (inclusive) in Schedule B of the SOC.
110	The factual matters pleaded and particularised in paragraphs: 1. 51 - the Skerritt Approvals 2. 54 - the Secretary Approvals 3. 57 - the Chief Medical Officer Pre-Approval Conduct 4. 90 - the Skerritt Approvals Misfeasance 5. 96 - the Secretary Approvals Misfeasance

	6. 102 - the Chief Medical Officer Approvals Misfeasance The harm to the Group Members arising as a consequence of injection with the Vaccines is pleaded and particularised in paragraph 1 of the SOC.
111	The factual matters pleaded and particularised in paragraphs: 1. 52 - the Skerritt Continuing Approvals 2. 55 - the Secretary Continuing Approvals 3. 58 - the Chief Medical Officer Post-Approval Conduct 4. 92 - the Skerritt Continuing Approvals Misfeasance 5. 98 - the Secretary Continuing Approvals Misfeasance 6. 104 - the Chief Medical Officer Continuing Approvals Misfeasance The harm to the Group Members arising as a consequence of injection with the Vaccines is pleaded and particularised in paragraph 1 of the SOC.
112	The factual matters pleaded and particularised in paragraphs: 1. 53 - the Skerritt Issued Misleading Vaccines Statements 2. 56 - the Secretary Issued Misleading Vaccines Statements 3. 59 - the Chief Medical Officer Issued Misleading Vaccines Statements 4. 60 - the Hunt Issued Misleading Vaccines Statements 5. 94 - the Skerritt Misleading Statements Misfeasance 6. 100 - the Secretary Misleading Statements Misfeasance 7. 106 - the Chief Medical Officer Misleading Statements Misfeasance 8. 108 – the Hunt Misleading Statements Misfeasance The harm to the Group Members arising as a consequence of injection with the Vaccines is pleaded and particularised in paragraph 1 of the SOC. The Loss and Damage is pleaded and particularised at paragraph 84(c) of the SOC.

SCHEDULE E – SPONSORS STUDY DATA

The Sponsors' Study Data was entirely provided and made available to the Commonwealth through the Public Officers by the direct provision of the Sponsors for the purposes of apprising the Commonwealth as to the safety and efficacy of the Vaccines or through officers or employees of the Commonwealth to the Public Officers for the purposes of fulfilment of duties incident to their respective offices and the functions and purposes of the Department and the TGA, as pleaded and particularised at paragraphs 10 to 18 of the SOC.

Further such information was provided to the Secretary and the Chief Medical Officer in accordance with their functions as chair and deputy-chair respectively of the Science and Industry Technical Advisory Group, which was at all times tasked with providing and, in fact, providing advice to the Commonwealth as to the scientific validity or otherwise of research into the safety and effectiveness of potential COVID-19 vaccines.

Further such information was provided to the Secretary as head of, and Skerritt as a member of, the National Vaccine Taskforce and to Hunt who was regularly advised by the National Vaccine Taskforce as to all available accumulated data relating to Covid and the Vaccines.

The Sponsors' Trials are:

Pfizer

a) Pfizer undertook Nonclinical Trials in respect of the Pfizer Vaccine comprised of **("the Pfizer Nonclinical Trial")**:

    i) 17-day intramuscular toxicity study of BNT162B2 (v9) in wistar rats with 3-week recovery. Study number: 20GR142. Sponsored by Pfizer. 13 November, 2020

https://icandecide.org/wpcontent/uploads/2023/03/125742_S1_M4_20gr142_nsdrg.pdf
("the Pfizer Toxicity Study")

ii) a combined fertility and developmental study (including teratogenicity and postnatal investigations) of BNT162b1, BNT162b2 and BNT162b3 by intramuscular administration in the wistar rat. Sponsored by BioNTech SE. Study report 10 December, 2020 https://www.tga.gov.au/sites/default/files/foi-2289-01.pdf
("the Pfizer Reproductive Study").

iii) a repeat dosing study of three LNP-Formulated RNA platforms (BNT162b1, BNT162b2, BNT162b3) encoding viral proteins by repeat intramuscular administration to wistar han rats. Study report 1 July 2020. Study number 38166. Sponsored by Pfizer https://www.tga.gov.au/sites/default/files/foi-3093-02.pdf
("**the Pfizer Repeat Dosing Study**")

iv) a study of vaccine immunogenicity of BNT162b2 (V9) in mice. Study R-20-0085. Sponsored by Pfizer. https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf
("**the Pfizer Immunogenicity Study**")

v) a study of vaccine immunogenicity of BNT162b2 (V8) in mice. Study R-20-0054. Sponsored by Pfizer. https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf
("**the Pfizer Immunogenicity (V8) Study**")

vi) a study Characterising the immunophenotype in spleen and lymph node of mice treated with SARS-CoV-2 vaccine candidates. Study R-20-0112. Sponsored by BioNTech. https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf
("**the Pfizer Immunophenotype Study**")

vii) a study evaluating Immunogenicity and Evaluation of Protection against SARS-CoV-2 Challenge in Rhesus Macaques for BNT162b2 (V9). Sponsored by Pfizer. Study No. VR-VTR-10671. https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf
("**the Pfizer Immunogenicity and Protection Study**")

b) a phase 1/2/3, placebo-controlled, randomised, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity and efficacy of SARS-CoV-2 RNA vaccine candidates against Covid-19 in healthy individuals. Study number: C4591001. Trial ID NCT04368728. Study start date: 29 April, 2020. Sponsored by BioNTech SE, Collaborator: Pfizer. https://clinicaltrials.gov/ct2/show/NCT04368728
("the Pfizer Clinical Trial");

c) a phase 1, open-label dose-finding study to evaluate safety, tolerability, and immunogenicity and phase 2/3 placebo-controlled, observer-blinded safety, tolerability, and immunogenicity study of a SARS-CoV-2 RNA vaccine candidate against Covid-19 in healthy children and young adults. Study Number: C4591007. Trial ID NCT04816643. Commenced 24 March, 2021. Sponsored by BioNTech SE, Collaborator: Pfizer. https://clinicaltrials.gov/ct2/show/NCT04816643
("the Pfizer Child Trial");

d) a study to evaluate the safety, tolerability, efficacy and immunogenicity of BNT162b2 boosting strategies against Covid-19 in participants >12 years of age. Study Number: C4591031. Trial ID: NCT04955626. Commenced 9 July, 2021. Sponsored by BioNTech SE, Collaborator: Pfizer. https://clinicaltrials.gov/ct2/show/NCT04955626
("the Pfizer Booster Trial")

Moderna

e) a study to evaluate efficacy, safety, and immunogenicity of mRNA-1273 vaccine in adults aged 18 years and older to prevent Covid-19. Study Number: mRNA-1273-P301. Trial ID: NCT04470427. Commenced 27 July, 2020. Sponsored by Moderna TX, Inc. https://clinicaltrials.gov/ct2/show/NCT04470427
("the Moderna Clinical Trial")

f) a study to evaluate the safety, reactogenicity, and effectiveness of mRNA-1273 vaccine in adolescents 12 to <18 years old to prevent Covid-19 (TeenCove). Study Number: mRNA-1273-P203. Trial ID: NCT04649151. Commenced 2 December, 2020. Sponsored by Moderna TX, Inc. https://clinicaltrials.gov/ct2/show/NCT04649151
("the Moderna Adolescent Trial")

g) A study to evaluate safety and effectiveness of mRNA-1273 Covid-19 vaccine in healthy children between 6 months of age and less than 12 years of age". Study Number: mRNA-1273-P204. Trial ID: NCT04796896. Commenced 15 March, 2021. Sponsored by Moderna TX, Inc. https://clinicaltrials.gov/ct2/show/NCT04796896
("the Moderna Child Trial")

h) Delayed heterologous SARS-CoV-2 vaccine dosing (boost) after receipt of EUA Vaccines. Study Number: 21-0012. Trial ID: NCT04889209. Commenced May 17, 2021. Sponsored by National Institute of Allergy and Infectious Diseases (NIAID). https://clinicaltrials.gov/ct2/show/NCT04889209
("the Moderna Booster Trial")

AstraZeneca

i) AstraZeneca undertook Clinical Trials in respect of the AstraZeneca Vaccine comprised of **("the AstraZeneca Clinical Trial")**:

i) a study of a candidate Covid-19 vaccine (COV001). Study Number: COV001. Trial ID: NCT04324606. Commenced 27 March, 2020. Sponsored by: University of Oxford. https://clinicaltrials.gov/ct2/show/NCT04324606**;**

ii) Investigating a vaccine against Covid-19. Study Number: COV002. Trial ID: NCT04400838. Commenced 26 May, 2020. Sponsored by University of Oxford. https://clinicaltrials.gov/ct2/show/NCT04400838;

iii) A study of a candidate Covid-19 vaccine (COV003). Study Number: COV003. Trial ID: NCT04536051. Commenced 2 September, 2020. Sponsored by: University of Oxford. https://clinicaltrials.gov/ct2/show/NCT04536051;

iv) COVID-19 vaccine (ChAdOx1 nCoV-19) trial in South African adults with and without HIV-infection. Study Number: ChAdOx1 nCoV-19_ZA_phI/II v4.1 . Trial ID: NCT04444674. Commenced 23 June, 2020. Sponsored by: University of Oxford. https://clinicaltrials.gov/ct2/show/NCT04444674.

SCHEDULE F – TGA VACCINE APPROVAL DOCUMENTS

The TGA Vaccine Approval Documents were entirely produced by the Commonwealth and provided, made available and known to the Public Officers for the purposes of apprising the Respondents as to the safety and efficacy of the Vaccines and the fulfilment of duties incident to their respective offices and the functions and purposes of the Department and the TGA, as pleaded and particularised at paragraphs 10 to 18 herein.

Further such documents and data were provided to the Secretary and the Chief Medical Officer in accordance with their functions as chair and deputy-chair respectively of the Science and Industry Technical Advisory Group, which was at all times tasked with providing and, in fact, providing advice to the Commonwealth as to the scientific validity or otherwise of research into the safety and effectiveness of potential COVID-19 vaccines.

Further such document and data was provided to the Secretary as head of, and Skerritt as a member of, the National Vaccine Taskforce and to Hunt who was regularly advised by the National Vaccine Taskforce as to all available accumulated data relating to Covid and the Vaccines.

The TGA Vaccine Approval Documents are as follows:

PFIZER

a) Clinical Evaluation Report – Prescription Medicines Authorisation Branch. Active substance: BNT162b2 [mRNA] COVID-19 vaccine. Product Name: COMIRNATY. Sponsor: Pfizer Australia. 8 January, 2021.
("the Pfizer Clinical Evaluation Report")

b) Nonclinical Evaluation Report – BNT162b2 [mRNA] COVID-19 vaccine (COMIRNATY). Sponsor: Pfizer Australia Pty Ltd. January 2021. https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf
("the Pfizer Nonclinical Evaluation Report")

c) Delegate's Overview and Request for ACV's Advice. Active Ingredient:

BNT162b2 [mRNA]. Proprietary Product Name: Comirnaty Covid 19 vaccine. 11 January, 2021.
https://www.tga.gov.au/sites/default/files/foi-2389-01.pdf
("the Pfizer Delegate's Overview")

d) Comirnaty. Published 25 January, 2021.
https://www.tga.gov.au/resources/auspmd/comirnaty
("the Pfizer Decision Summary")

e) Australian Product Information – Comirnaty (Tozinameran) Covid-19 Vaccine dated 22 July, 2021
https://www.tga.gov.au/sites/default/files/covid-19-vaccine-pfizer-australia-comirnaty-bnt162b2-mrna-pi.pdf
("the Pfizer Product Information")

f) Comirnaty Covid-19 Vaccine Consumer Medicine Information (CMI) Summary.
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2021-CMI-02443-1
("the Pfizer Consumer Medicine Information")

g) Australian Public Assessment Report for BNT162b2 (mRNA). Sponsor: Pfizer Australia Pty Ltd. January 2021.
https://www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-210125.pdf
("the Pfizer Original AUSPAR")

h) Australian Public Assessment Report for BNT162b2 (mRNA). Sponsor: Pfizer Australia Pty Ltd. July 2021.
https://www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-210722.pdf
("the Pfizer 12-15 Year Olds Extension AUSPAR")

i) Australian Public Assessment Report for BNT162b2 (mRNA). Sponsor:

Pfizer Australia Pty Ltd. October 2021. https://www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-211029.pdf
("the Pfizer Booster for Adults >18 Years AUSPAR")

j) Australian Public Assessment Report for Tozinameran (mRNA Covid-19 vaccine). Sponsor: Pfizer Australia Pty Ltd. December 2021. https://www.tga.gov.au/sites/default/files/auspar-tozinameran-mrna-covid-19-vaccine-211207.pdf
("the Pfizer 5-11 Year Olds Extension AUSPAR")

k) Australian Public Assessment Report for Tozinameran. Sponsor: Pfizer Australia Pty Ltd. January 2022. https://www.tga.gov.au/sites/default/files/auspar-tozinameran-220128.pdf
("the Pfizer Booster for 16-17 Year Olds AUSPAR"

l) Australian Public Assessment Report for Tozinameran. Sponsor: Pfizer Australia Pty Ltd. April 2022. https://www.tga.gov.au/sites/default/files/auspar-tozinameran-220408.pdf
("the Pfizer Booster for 12-15 Year Olds AUSPAR")

m) Australian Public Assessment Report for Comirnaty COVID-19 vaccine. Sponsor: Pfizer Australia Pty Ltd. September 2022. https://www.tga.gov.au/sites/default/files/2022-10/auspar-comirnaty-20221010.pdf
("the Pfizer Booster for 5-11 Year Olds AUSPAR")

n) Australian Public Assessment Report for Comirnaty COVID-19 Vaccine. Sponsor: Pfizer Australia Pty Ltd. October 2022. https://www.tga.gov.au/sites/default/files/2022-10/auspar-tozinameran-221012.pdf
("the Pfizer 6 Months - 5 Year Olds Extension AUSPAR")

MODERNA

o) Australian Product Information – Spikevax (Elasomeran) Covid-19 Vaccine. https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2021-PI-01968-1&d=20230410172310101
("the Moderna Product Information")

p) Spikevax Covid-19 Vaccine Consumer Medicine Information (CMI) Summary. https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2021-CMI-01982-1
("the Moderna Consumer Medicines Information")

q) Spikevax. Published 9 August, 2021. https://www.tga.gov.au/resources/auspmd/spikevax
("the Moderna Decision Summary")

r) Australian Public Assessment Report for Elasomeran. Sponsor: Moderna Australia Pty Ltd. August 2021. https://www.tga.gov.au/sites/default/files/auspar-elasomeran.pdf
("the Moderna Original AUSPAR")

s) Australian Public Assessment Report for Elasomeran. Sponsor: Moderna Australia Pty Ltd. September 2021. https://www.tga.gov.au/sites/default/files/auspar-elasomeran-210903.pdf
("the Moderna 12-17 Year Olds Extension AUSPAR")

t) Australian Public Assessment Report for Elasomeran. Sponsor: Moderna Australia Pty Ltd. December 2021. https://www.tga.gov.au/sites/default/files/auspar-elasomeran-mrna-1273-211208.pdf
("the Moderna Booster for >18 Year Olds AUSPAR")

u) Australian Public Assessment Report for Elasomeran. Sponsor: Moderna

Australia Pty Ltd. February 2022.
https://www.tga.gov.au/sites/default/files/auspar-elasomeran-220221.pdf
("the Moderna 6-11 Year Olds Extension AUSPAR")

v) Australian Public Assessment Report for Elasomeran. Sponsor: Moderna Australia Pty Ltd. July 2022.
https://www.tga.gov.au/sites/default/files/2022-08/auspar-elasomeran-220727.pdf
("the Moderna 6 months and Older Extension AUSPAR")

w) Australian Public Assessment Report for Elasomeran. Sponsor: Moderna Australia Pty Ltd. November 2022.
https://www.tga.gov.au/sites/default/files/2022-11/auspar-spikevax-20221108.pdf
("the Moderna Booster for >12 Year Olds AUSPAR")

ASTRAZENECA

x) Clinical Evaluation Report - Prescription Medicines Authorisation Branch. Active Substance: ChAdOx1-S. Product name: ChAdOx1 CoV-19. Sponsor: Astra Zeneca. 27 January, 2020.
https://www.tga.gov.au/sites/default/files/foi-2494-05.pdf
("the AstraZeneca Clinical Evaluation Report")

y) Nonclinical Evaluation Report – ChAdOx1-S Covid-19 Vaccine (Covid-19 Vaccine AstraZeneca). Sponsor: AstraZeneca. January 2021.
("the AstraZeneca Nonclinical Evaluation Report")

z) Delegate's Overview. Active ingredient: ChAdOx1-S. Proprietary product name: Covid-19 vaccine AstraZeneca. Sponsor: AstraZeneca. 28 January, 2021.
https://www.tga.gov.au/sites/default/files/foi-2494-01.pdf
("the AstraZeneca Delegate's Overview")

aa) Advisory Committee on Vaccines ACV 19 Minutes on Item 2.1 ChAdOx1-S. Product name: Covid-19 vaccine AstraZeneca. Sponsor: AstraZeneca Pty Ltd. February 2021.
https://www.tga.gov.au/sites/default/files/foi-2494-04.pdf
("the ACV AstraZeneca Minutes")

bb) Australian Product Information – Vaxzevria (previously Covid-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection, dated 16 February, 2021.
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2021-PI-01194-1
("the AstraZeneca Product Information")

cc) Vaxzevria (previously Covid-19 Vaccine AstraZeneca) Consumer Medicine Information (PI) Summary.
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2021-CMI-01195-1
("the AstraZeneca Consumer Medicines Information")

dd) Covid-19 Vaccine AstraZeneca. Published 16 February, 2021.
https://www.tga.gov.au/resources/auspmd/covid-19-vaccine-AstraZeneca
("the AstraZeneca Decision Summary")

ee) Australian Public Assessment Report for ChAdOx1-S – Proprietary Product Name: Covid-19 Vaccine AstraZeneca. Sponsor: AstraZeneca Pty Ltd. February 2021.
https://www.tga.gov.au/sites/default/files/auspar-chadox1-s-covid-19-vaccine-AstraZeneca-210215.pdf
("the AstraZeneca Original AUSPAR")

ff) Australian Public Assessment Report for ChAdOx-1-S – Proprietary Product Name: Vaxzevria. Sponsor: AstraZeneca Pty Ltd. February 2022.
https://www.tga.gov.au/sites/default/files/auspar-chadox-1-s-220217.pdf
("the AstraZeneca Booster in >18 Year Olds AUSPAR")

SCHEDULE G – MISLEADING PUBLIC STATEMENTS OF THE RESPONDENTS

The following are the particulars of the misleading statements made by the respective Respondents pleaded at paragraphs 44 to 49 of the SOC:

SKERRITT – MISLEADING STATEMENTS

44. Skerritt made the following public statements expressly or by reasonable inference to the Australian public (**"the Skerritt Misleading Vaccines Statements"**):

a) on 6 February, 2021 in respect of the preliminary approval of the Vaccines, Skerritt publicly stated that:

i) the TGA had conducted a thorough investigation of the safety of the Vaccines;

ii) the adverse events observed were not causally connected with the Vaccines;

iii) the TGA was carefully examining the ongoing safety data in respect of the Vaccines to continually establish safety.

Source

Sky News Interview broadcast on 6 February, 2021

https://www.facebook.com/SkyNewsAustralia/videos/safety-evidence-for-the-pfizer-vaccine-is-pretty-thorough-tga-head/421193715601288/

b) on 16 February, 2021 that in respect of the rollout of the Vaccines Skerritt publicly stated that:

i) the objective of increasing numbers of Vaccines recipients in Australia was more important than the safety and efficacy data;

ii) the Vaccines generally are safe and effective for consumption;

iii) the actual efficacy of the Vaccines is not relevant;

iv) the Vaccines are proven safe in pregnancy.

Source

Parliament House – Press Conference, 16 February, 2021

https://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22media%2Fpressrel%2F7811446%22;src1=sm1

b1. On 17 March, 2021 Skerritt publicly stated that:

i) heart attacks and strokes after vaccination are generally coincidental and due to the statistical probability that these events are likely to occur in any case;

ii) having had a previous heart attack or stroke might be protective against the serious side of effect of 'thrombosis with thrombocytopenia' after AstraZeneca by the reasoning that such patients are 'often already on blood thinners' that might be protected against TTS.

Source

Today Show Interview broadcast on 17 March, 2021.
https://www.health.gov.au/news/therapeutic-goods-administration-adj-professor-john-skerritts-interview-on-the-today-show-on-17-march-2021

b2. On 13 April, 2021 Skerritt publicly stated that:

i) the risk of developing clotting after vaccination with the Vaccines is as unlikely as winning Lotto or approximately 1 in 300 million;

ii) clotting after vaccination with the Vaccines is in all cases most likely coincidental.

Source

Press Conference, Canberra, 13 April, 2021.
https://www.greghunt.com.au/transcript-press-conference-canberra-11/

c) on 29 April, 2021 Skerritt publicly stated that:

i) the escalating number of adverse events being reported to the TGA in respect of the Vaccines after the Approvals were merely:

(1) coincidental; and

(2) of no concern or consequence;

ii) the vaccines still remain the best way out of the pandemic.

Source

Press Conference, 29 April, 2021

https://www.abc.net.au/news/2021-04-29/health-authorities-update-covid-vaccine-deaths-bood-clot/100105130

d) on 6 May, 2021 Skerritt publicly stated that:

i) he had seen a significant 60-fold increase in adverse events reported to the TGA overall as compared to 2020 as a consequence of adverse events related to the Vaccines occurring after the Approvals being reported;

ii) the adverse events reported were of no concern;

iii) the increasing volume in reported adverse events were encouraging;

iv) the proliferation of adverse events related to the Vaccines was of no consequence or concern;

v) in no way impacted upon any determination as to the Vaccines safety for use by all Australians;

vi) that 16 cases of a severe allergic reaction to the Vaccines being anaphylaxis had been reported to the TGA which were of no particular safety concern.

Source

Press Conference, 6 May, 2021

https://www.health.gov.au/news/therapeutic-goods-administration-professor-john-skerritt-and-commodore-eric-youngs-press-conference-on-6-may-2021

e) on 8 June, 2021 Skerritt publicly stated that:

i) at that time the Vaccines had been thoroughly assessed for safety and efficacy;

ii) injecting the Vaccines involved only an extremely rare chance of

anything other than the most minor side effects being:

(1) a few in a million;

(2) 0.00001%;

iii) that on balance the risks of taking the Vaccines was so small that they were significantly outweighed by the protection against Covid that the Vaccines would provide;

iv) the risk of a serious adverse event related to taking the Vaccines was almost nil;

Source

2SM Interview, 8 June, 2021

https://www.health.gov.au/news/therapeutic-goods-administration-adj-professor-john-skerritts-interview-on-2sm-on-8-june-2021

f) on 9 August, 2021, Skerritt publicly stated that:

i) the Moderna Vaccine provides long-lasting efficacy against Covid;

ii) the Moderna Vaccine is 93% effective against Covid infection for over six months;

iii) the Moderna Vaccine is 98% effective against severe disease from Covid for over six months;

iv) the Moderna Vaccine is 100% effective against death for over six months;

Source

Press Conference at Parliament House, 9 August, 2021

https://www.theguardian.com/australia-news/live/2021/aug/09/australia-politics-business-vaccine-covid-morrison-gladys-berejiklian-sydney-brisbane-victoria-melbourne-health-moderna-pfizer-astrazeneca?page=with:block-6110caef8f0892081f6d0bf3

g) on 10 August, 2021 Skerritt publicly stated that:

i) the Vaccines mRNA technology do not alter the genes of the recipient;

ii) there have been no safety signals raised about the Vaccines with respect to pregnancy;

iii) the Moderna Vaccine is safe for pregnant women;

iv) every dose of the Vaccine is manufactured identically every time;

v) the statements made in circumstances where:

(1) Skerritt made a directly contrary statement on the same day in an interview publicly broadcast on 6PR stating:

a. where the Vaccines are being made at different sites they may be different in composition.

Source

6PR Interview, 10 August, 2021

https://www.health.gov.au/news/therapeutic-goods-administration-adj-professor-john-skerritts-interview-on-6pr-on-10-august-2021;

5AA Interview, 10 August, 2021

https://www.health.gov.au/news/therapeutic-goods-administration-adj-professor-john-skerritts-interview-on-5aa-on-10-august-2021

vi) Skerritt further on 10 August, 2021 publicly stated that:

(1) Vaccination of the entire Australian population with the Vaccines is the only means by which the entire Australian population could:

a. get out of the pandemic;

b. return to normal life.

Source

5AA Radio, 10 August 2021
https://www.health.gov.au/news/therapeutic-goods-administration-adj-professor-john-skerritts-interview-on-5aa-on-10-august-2021

vii) Skerritt further on 10 August, 2021 publicly stated that:

(1) Six months after injection with the Moderna Vaccine:

a. the efficacy of the Moderna Vaccine did not decline;

b. the Moderna Vaccine continued to provide to the recipient:

i. 93 per cent protection from infection by the Virus;

ii. between 98 and 100% per cent protection from

hospitalisation and death.

Source

ABC News Breakfast, 10 August 2021

https://www.health.gov.au/news/therapeutic-goods-administration-adj-professor-john-skerritts-interview-on-abc-news-breakfast-on-10-august-2021

h) on 7 September, 2021 Skerritt publicly stated that:

i) it could be presumed without any further evidence that deaths reported in respect of the Vaccines including the 495 deaths reported (other than 9) at that time as associated with the taking of the Vaccines were:

(1) attributable to the background death rate;

(2) not attributable to the Vaccines;

(3) are made by the reporter based upon nothing more than the fact that the death occurred after taking one of the Vaccines;

(4) coincidence;

(5) the reported deaths were of no concern or consequence in respect of the safety of the Vaccines;

(6) the Vaccines were still deemed to be safe;

(7) Panadol suffered a similarly high number of adverse events (hundreds or thousands) which were similarly of no consequence;

Source

ABC Drive Interview, 7 September, 2021

https://www.health.gov.au/news/therapeutic-goods-administration-adj-professor-john-skerritts-interview-on-abc-drive-on-7-september-2021.

i) *deleted*

j) on 5 December, 2021, Skerritt publicly stated that:

i) the Pfizer Vaccine had been extensively clinically tested;

ii) there were no safety problems identified in the clinical trials of the Pfizer Vaccine trials;

iii) the children and adults in the clinical trials of the Pfizer Vaccine only suffered adverse effects after injection:

(1) of tiredness, sore arms, headache and similarly minor adverse effects;

(2) which were invariably brief and fairly short-lived;

iv) because about one in 3,000 children developed a multi-system inflammatory condition and "can end up being very sick for months on a risk-benefit balance they should be vaccinated with the Vaccines;

v) children and adults taking the Vaccines:

(1) would suffer no serious adverse reactions;

(2) would be at higher risk of injury from Covid than the Vaccines;

(3) would protect children against multi-system inflammatory syndrome.

Source

Skerritt expressly quoted in an article published in The Guardian, 5 December, 2021.

https://www.theguardian.com/society/2021/dec/05/australian-children-aged-five-to-11-set-to-receive-pfizer-covid-vaccine-from-mid-january.

k) on 7 December, 2021 Skerritt publicly stated that:

i) the benefit of vaccination in children with the relevant child approved Vaccines is prevention of transmission to other family members;

ii) public health policies such as lockdowns justify encouragement for vaccination with the Vaccines;

iii) 1 in 3000 children contracting covid, even those who do not become very unwell, can have a long term multisystem inflammatory syndrome that would be prevented by vaccination;

iv) 'inflammation of the heart' is generally short lived;

v) the increased dose interval from 3-8 weeks was for the purposes of increased effectiveness.

Source

ABC News Breakfast, 6 December, 2021

https://www.health.gov.au/news/therapeutic-goods-administration-adj-professor-john-skerritts-interview-on-abc-news-breakfast-on-6-december-2021

k1. on 23 February, 2022 Skerritt publicly stated that in young children the risks from

Covid significantly exceeded the risks from the Vaccines for children.

Source

Press Conference, Canberra, 23 February 2023
https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/canberra-press-conference-23-february-2022-on-moderna-vaccine-for-6-11-year-olds-covid-19-vaccine-rollout-and-aged-care

l) on 1 March, 2022 Skerritt publicly stated that:

i) booster vaccination against Covid is very important because there is overwhelming evidence that a third dose of vaccination against Covid significantly reduces the risk of serious infection;

ii) booster vaccination is very important even if a person has had a recent infection with the Covid virus;

iii) the safety record of the Vaccines is impressive;

iv) serious adverse events following vaccination tend to occur 1-2 to 5-6 weeks following vaccination;

v) myocarditis is non-fatal;

vi) the risk of death or serious illness from Covid infection is significant in children;

vii) children taking the Vaccines would not:

(1) be exposed to an unnecessary risk by doing so;

(2) be infected with Covid;

(3) be hospitalised with Covid;

(4) transmit Covid to any other person;

viii) people taking a third dose of the Vaccines:

(1) would not suffer re-infection by the Covid virus;

(2) have a significantly reduced risk of serious infection;

(3) would reduce the overall number of Australians contracting Covid;

ix) Covid has a high risk of serious injury or death without vaccination;

x) people taking a third dose of the Vaccines after natural infection:

(1) gain additional immunity above acquired natural immunity against Covid by doing so;

(2) are not at any additional risk of side effects by doing so;

(3) are at a higher risk of serious infection from Covid if they do not do so as soon as they recover from the infection or within 4 months of recovering;

xi) natural acquired immunity against Covid is inferior to immunity provided by the Vaccines;

xii) the risk of Covid infection is higher than the risk of Covid vaccination in children under 12 years of age;

xiii) the Vaccines side effects suffered by children are only mild;

xiv) the risk of serious complications from Covid infection in adolescent and young adult males is higher than the risk of myocarditis from the Vaccines;

xv) the increased risk of myocarditis following Covid vaccination in adolescents who have reached puberty is acceptable;

xvi) long-term safety data on Vaccines is not necessary because most serious adverse events occur within six weeks after vaccination;

xvii) the large number of vaccinations administered globally is evidence of the safety of the Vaccine;

xviii) there has been no increase in excess deaths or disease globally since the Vaccines were first approved for use in December 2020;

xix) it is not possible to obtain long-term safety data of a vaccine without approving the use of, then administering the vaccine to the public;

xx) delaying the approval and administration of the Vaccines in order to establish their long-term safety, would have caused more hospitalisations and deaths from COVID.

Source

Press Conference, 1 March, 2022

https://www.youtube.com/watch?v=QePNjVgzYZI

SECRETARY – MISLEADING STATEMENTS

45. The Secretary made the following public statements expressly or by reasonable

inference to the Australian public (**"the Secretary Misleading Vaccines Statements"**):

a) on 3 February, 2021 the Secretary stated that:

i) there was no evidence whatsoever that any of the Vaccines:

(1) are dangerous; or

(2) could kill the recipient.

ii) the Vaccines are all extremely carefully tested by the TGA;

iii) the Vaccines are exponentially more safe and effective than the annual flu vaccines;

iv) the risks associated with contracting Covid are exponentially greater than the risks of using the Vaccines;

v) the Vaccines all had or would be subjected to the full regulatory safety and efficacy assessment before approval for use by the public;

vi) there is no risk in using the Vaccines;

vii) the Vaccines had been or would be subject to the fullest extent of safety and efficacy testing possible before release to the public.

Source

ABC Interview, 3 February, 2021

https://www.abc.net.au/7.30/dr-brendan-murphy-answers-questions-about-the/13119036

a1) on 4 February, 2021 the Secretary stated that:

i) without qualification the risks from Covid were exponentially higher than any risks from using the Vaccines;

ii) there is no evidence that the Vaccines could cause death;

iii) there is no evidence that the Vaccines are dangerous;

iv) the Vaccines were thoroughly tested by the TGA for safety and efficacy;

Source

7:30 Report Interview, Broadcast 4 February, 2021

https://www.youtube.com/watch?v=2Kg7zTG9aYM

a2) on 18 February 2021 the Secretary publicly stated that the Vaccines were proven very effective to prevent transmission of the Virus.

Source

Press Conference, Canberra, 18 February, 2021 https://www.greghunt.com.au/transcript-press-conference-canberra-6/

b) on 7 March, 2021, the Secretary stated that:

i) he has the highest confidence and trust in the Vaccines;

ii) the Vaccines are effective;

iii) every single Australia should go and be injected with one of the Vaccines as soon as it is possible to do so;

iv) the safety and efficacy of the Vaccines are beyond question for use by every single Australian without any other relevant consideration; and

v) the Secretary had personal knowledge of the veracity of these matters.

Source

Doorstop Interview, 7 March, 2021

https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/doorstop-interview-about-the-vaccine-rollout-and-vaccine-safety.

b1) on 17 March, 2021 the Secretary publicly stated that:

i) all of the available vaccine safety evidence suggests that the Vaccines do not increase the incidence of thrombotic events in recipients;

ii) thrombotic events amongst Vaccine recipients in Australia are not a significant issue;

iii) there exists no evidence whatsoever that the Vaccines are associated with a higher incidence of stroke;

iv) he is confident that the program of vaccinating Australians with the Vaccine should go ahead as planned;

v) the AstraZeneca vaccines is a very safe vaccine;

vi) the AstraZeneca vaccine is a very, very effective vaccine.

Source

Doorstop Interview, 17 March, 2021
https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/doorstop-interview-about-phase-1b-of-the-covid-vaccine-rollout

c) on 22 March, 2021 the Secretary publicly stated that:

i) the AstraZeneca Vaccine was safe and effective;

ii) reports of blood clots after receiving the AstraZeneca Vaccine were:

(1) rare;

(2) of no concern to those intending to receive that vaccine.

Source

Press Conference, Canberra, 22 March 2021
https://www.greghunt.com.au/transcript-press-conference-canberra-9/

TGA – MISLEADING STATEMENTS

46. The TGA Respondents made the following public statements through employees and officers of the TGA expressly or by reasonable inference to the Australian public (**"the**

TGA Misleading Vaccines Statements"):

a) on 27 May, 2021, in a published document entitled "COVID-19 vaccine weekly safety report" on the TGA website that:

i) if a medicine or vaccine is approved for use by the TGA including the Vaccines, it means that the benefits are considered to outweigh its risks, if used as authorised;

ii) there are no specific safety concerns from use of the Vaccines in older people;

iii) there were no new safety signals in relation to the Vaccines at that time;

iv) the TGA continues to review data from Australia and overseas relating to the safety and effectiveness of the Vaccines in older adults;

v) the TGA's monitoring had not detected any new safety signals in relation to the Vaccines at that time;

vi) the TGA reviews all deaths reported after vaccination and monitors for safety signals. Part of this analysis includes comparing expected natural death rates to observed death rates following immunisation. To date, the observed number of deaths reported after vaccination was actually less than the expected number of deaths;

vii) at that time, there was no indication that the reported cases of myocarditis and pericarditis were due to the Vaccine.

Source

TGA SAFETY REPORT – 27 May, 2021

https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-weekly-safety-report-27-05-2021

b) on 10 September, 2021 in a Media Release by the TGA titled "New restrictions on prescribing Ivermectin for COVID-19" stated:

i) vaccination provides superior protection from Covid infection than Ivermectin;

ii) taking Ivermectin for prevention of Covid is dangerous to the public;

iii) people who take Ivermectin for prevention of Covid are more likely to not comply with public health directions at that time;

iv) people who take Ivermectin for prevention of Covid are less likely to seek medical attention for symptoms of Covid;

v) taking Ivermectin for prevention of Covid increases the spread of Covid throughout the community.

Source

Media Release published on the TGA website on 10 September, 2021 titled "New restrictions on prescribing ivermectin for COVID-19"

https://www.tga.gov.au/news/media-releases/new-restrictions-prescribing-ivermectin-covid-19

c) on 16 September, 2021, in a published document entitled "COVID-19 vaccine weekly safety report -16-09-2021" on its website that:

i) vaccination against Covid is the most effective way to reduce deaths and severe illness from infection;

ii) being registered for use means that these Vaccines have met the TGA's

high standards for quality, safety and effectiveness;

iii) importantly, suspected adverse events reported to the TGA are often not caused by the Vaccines;

iv) the protective benefits of vaccination against Covid far outweighs the potential risks of vaccination;

v) the increase in the number of vaccinated people has increased reporting of fatal events which:

(1) has a coincidental association with vaccination;

(2) does not indicate a link between vaccination and the fatalities reported.

vi) review of individual reports and patterns of reporting does not suggest the Vaccines played a role in these deaths;

vii) the most authoritative safety information on the Vaccines is included in the Product Information **("Product Information" is defined at para. 65 in Schedule B of the SOC)** and Consumer Medicine Information which can be found on the TGA website;

viii) following rigorous investigations by the TGA and other international drug regulators, a clear link between Guillain Barre Syndrome and the AstraZeneca Vaccine had not been established;

ix) myocarditis and pericarditis can occur due to other causes, including common viral infections, so it is expected that many reported cases may not be related to vaccination;

x) myocarditis and pericarditis are much more common in infection with the Virus and damage to the heart is frequently severe after infection with the Virus than after the Vaccines;

xi) ATAGI have emphasised that the protective benefits of the Pfizer Vaccine greatly outweigh the risk of these rare side effects.

Source

COVID-19 vaccine weekly safety report -16-09-2021
https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-weekly-safety-report-16-09-2021

d) *deleted*

e) on 5 December, 2021, the TGA Respondents, through the TGA website, stated that:

i) in making the decision to approve the Pfizer Vaccine, the TGA carefully considered data from clinical trials conducted in the United States, Finland, Poland and Spain which included participants 5 to 11 years of age and that the study demonstrated effectiveness by showing that the immune response to the vaccine in children was similar to that seen in older age groups;

ii) clinical trials showed that the safety profile in children is similar to that seen in adults with the observed side effects being mild;

iii) the people of Australia could be confident that the TGA's review process of the Pfizer Vaccine was rigorous and of the highest standard.

Source

The TGA published on the TGA Website on 5 December, 2021: "COVID-19 vaccine: Pfizer Australia - COMIRNATY (tozinameran) (mRNA)"

https://www.tga.gov.au/covid-19-vaccine-pfizer-australia-comirnaty-tozinameran-mrna

f) on 27 August, 2021 the TGA Respondents, through the TGA website, stated the following in respect of the Pfizer Vaccine:

i) it is safe for use by anyone over the age of 16 years;

ii) it is so safe that severe adverse events or death would not occur in use of the Pfizer Vaccine;

iii) it is effective to prevent the recipient of the Pfizer Vaccines from suffering ill-effects from Covid;

iv) it meets the high safety, efficacy and quality standards required for use in Australia;

v) Australians can be confident that the TGA's review process of this vaccine was rigorous and of the highest standard;

vi) the TGA will continue to actively monitor the safety of the Pfizer vaccine both in Australia and overseas and will not hesitate to take action if safety concerns are identified.

Source

The TGA on its website expressly stated those matters on 27 August, 2021

https://www.tga.gov.au/news/media-releases/tga-provisionally-approves-pfizer-covid-19-vaccine

g) on 16 December, 2021, in a published document entitled "COVID-19 vaccine weekly safety report -16-21-2021" the TGA Respondents stated through the TGA website that myocarditis:

(1) is usually temporary;

(2) is a condition from which most people are fully recovered within a few days.

Source

COVID-19 vaccine weekly safety report - 16-12-2021
https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-weekly-safety-report-16-12-2021

h) on 16 June, 2022, in a published document entitled "COVID-19 vaccine weekly safety report -16-06-2022" on its website that:

i) the TGA closely reviews all deaths reported in the days and weeks after COVID-19 vaccination;

ii) there have been no deaths in children, adolescents or younger adults determined to be linked to COVID-19 vaccination;

iii) the risk of myocarditis and other heart effects is much higher after COVID-19 infection than after COVID-19 vaccination;

iv) myocarditis cases from the Vaccines:

(1) are often mild;

(2) usually resolve after a few days with treatment and rest.

Source

COVID-19 vaccine weekly safety report - 16-06-2022

https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-weekly-safety-report-16-06-2022

i) on 8 November, 2022, the TGA Respondents, in a published document entitled "Comirnaty original/Omicron BA.1 COVID-19 Vaccine", stated on the TGA Website that:

i) a booster dose of the Pfizer Bivalent Vaccine prevents COVID infection in individuals 18 years and older;

ii) the Pfizer Bivalent Vaccine is safe and effective in individuals 18 years and older.

Source

Published on the TGA website on 8 November, 2022
https://www.tga.gov.au/resources/auspmd/comirnaty-originalomicron-ba1-covid-19-vaccine

j) on 15 December, 2022, in a published document entitled "COVID-19 vaccine weekly safety report -15-12-2022", the TGA Respondents stated through the TGA Website that:

i) most deaths that occur after vaccination are not caused by the Vaccine;

ii) the TGA had identified 14 reports where the cause of death was linked to vaccination from 952 reports received and reviewed;

iii) there have been no deaths in children or adolescents determined to be

linked to COVID-19 vaccination;

iv) myocarditis is often mild, and cases usually resolve after a few days with treatment and rest.

Source

COVID-19 vaccine weekly safety report -15-12-2022

https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-15-12-2022

See also para. 46 in Schedule D of the SOC.

k) by the publication of the TGA Policies on the TGA Website on the respective dates particularised in Schedule A of the SOC, the TGA Respondents publicly stated expressly and/or by inference that the following matters procedures would be and were applied and followed in respect of the Approvals and Continuing Approvals of the Vaccines:

i) the TGA will only register a vaccine for use in Australia if the benefits of the vaccine outweigh the risks for the group of people in which it is intended to be used;

ii) the TGA defines vaccines as medicines that:

a. protect the vaccine recipient against specific diseases;

b. protect the vaccine recipient and those who come into contact with the vaccine recipient from serious and life-threatening diseases;

iii) the TGA rigorously assesses vaccines for safety, quality and efficacy before they can be used in Australia;

iv) the TGA only uses the best available scientific evidence to assess the risks and benefits of each vaccine before approval;

v) the TGA carefully assesses:

a. the results of clinical trials; and

b. the way in which the trials were conducted, including:

i. if they were conducted for a sufficient amount of time; and
ii. if there were enough participants in the trial that represented the people for whom the vaccine is intended;

vi) the TGA before approving a vaccine requires well-designed trials:
   a. of a sufficient length;
   b. with a sufficient number of people who represent the people for whom the vaccine is intended;

vii) the TGA requires before approving a vaccine that the results of trials must demonstrate that the benefits of the vaccine greatly outweigh the risks;

viii) for regulatory purposes, spontaneous reports of adverse events:
   a. are considered to have implied causality; and
   b. where it is not clear whether a causal association exists:
      i. are presumed to mean that the vaccine and the adverse event are possibly related; and
      ii. meet the definition of an adverse reaction, unless the reporter explicitly states otherwise;

ix) the TGA requires mandatory submission of Serious Adverse Events reports to the TGA by sponsors of vaccines in Australia;

x) if the TGA suspects that there is a problem with a vaccine, the TGA:
   a. will launch an investigation;
   b. may suspend use of the vaccine during the investigation;
   c. will notify the community of safety concerns through the publication of alerts on the TGA website;

xi) before it registers any vaccine for use in Australia, the TGA considers every ingredient in a vaccine for:
   a. safety;
   b. quality; and
   c. efficacy;

xii) when a new or changing risk associated with a vaccine is identified, the TGA must:
   a. re-evaluate the benefits of the vaccine using all available data, such benefits including prevention of:
      i. the target disease;
      ii. severity of symptoms;

iii. hospitalisation;
iv. complications;
v. effect of target disease on offspring (in case of vaccination of pregnant women); and
vi. any other clinical outcome relevant for individual patients; and

b. estimate the impact of the new or changing risk on the benefit-risk balance of the vaccine;

xiii) where provisionally registering vaccines, the TGA:

a. does so on the basis of preliminary clinical data which must demonstrate that the benefit of early availability of the vaccine outweighs the risk inherent in the fact that additional data is still required;
b. will base its decision to grant time-limited provisional registration of a vaccine upon the TGA's assessment of whether:
i. the preliminary clinical data satisfactorily establishes the safety and efficacy of the vaccine;
ii. the quality of the vaccine has been satisfactorily established; and
iii. the TGA is satisfied with the sponsor's plan to submit comprehensive clinical data on the safety and efficacy of the vaccine after approval is granted;
c. will re-assess risks related to the absence of evidence through data provided after provisional approval as part of the confirmatory data;
d. must use the confirmatory data obtained to confirm the relationship between:
i. outcomes predicted by the surrogate endpoint or other preliminary data in relation to the safety and efficacy of the vaccine; and
ii. the clinical benefit as demonstrated by direct clinical outcomes;

xiv) all adverse events arising in approved vaccines:

a. are risk assessed and entered into the appropriate database for future reference;
b. are used by the TGA to identify safety signals;

xv) a safety signal in a vaccine:

a. is a 'flag' for a possible safety concern;
b. when identified by the TGA, prompts the TGA to conduct a detailed

evaluation to establish the possible role of the vaccine in causing the adverse event;

xvi) if a safety concern is identified relating to a vaccine, the TGA:

a. can take regulatory action to ensure that the vaccine continues to have for its intended use acceptable:
    i. safety;
    ii. efficacy/performance; and
    iii. quality;
b. will issue safety alerts **("Safety Alerts")** to notify the Australian public and health professionals about the safety concern including:
    i. known safety problems;
    ii. changes in the reporting pattern of known problems;
    iii. new problems; and
    iv. coincidental events;

xvii) in regards to approving and regulating the Vaccines, the TGA will:

a. not register a Covid vaccine unless the vaccine has well-conducted clinical trials in humans that demonstrate the vaccine:
    i. very significantly reduces the incidence of Covid disease in people who are vaccinated with the vaccine compared to a control group of people who did not receive the vaccine, effectively being the absolute risk reduction rate; and
    ii. reduces the transmission of disease between individuals, including from asymptomatic to uninfected individuals;
b. prior to approving any Covid vaccine, consider:
    i. the availability of alternative vaccines and treatments;
    ii. the status of the pandemic; and
    iii. the epidemiology of the Virus in Australia and worldwide;
c. require all participants in clinical trials to be followed up by the Sponsors for a median of 6 months to assess the potential risk of:
    i. late-onset adverse events; and
    ii. vaccine-associated enhanced respiratory disease;
d. require all participants in clinical trials to be followed by the Sponsors:
    i. for at least 1 year; and
    ii. ideally longer to assess the:

1. duration of vaccine efficacy; and
2. longer-term safety of the Vaccine;

e. strengthen the existing vaccine vigilance system for early detection and investigation of suspected side effects in order for the TGA to:
   i. enhance Vaccine safety signal detection and investigation;
   ii. undertake worldwide environmental scanning for safety material in relation to the Vaccines by ongoing review of worldwide:
      1. medical literature; and
      2. data;
   iii. manage any emerging safety issues arising in the Vaccines;
   iv. inform the public of emerging Vaccines safety information;
   v. maintain public confidence in the Vaccines immunisation program;

f. thoroughly investigate all adverse event reports to determine causality if within days to weeks after vaccination with the Vaccines:
   i. a person dies; or
   ii. has a serious event requiring hospitalisation;

g. subsequent to their thorough investigation of all serious adverse events following vaccination with the Vaccines, the TGA will publish the results of the independent assessments performed on the TGA website, accompanied by:
   i. a summary of the case; and
   ii. extra clinical advice for health professionals.

Source

Website Documents particularised in Schedule A of the SOC.

CHIEF MEDICAL OFFICER – MISLEADING STATEMENTS

47. The Chief Medical Officer made the following public statements expressly or by reasonable inference to the Australian public (**"the Chief Medical Officer Misleading Vaccines Statements")**:

a) on 8 January, 2021, the Chief Medical Officer publicly stated that:

i) the TGA's Approvals will be a full approval that thoroughly investigates all aspects of the Vaccines, including:

(1) effectiveness of the Vaccines;

(2) the safety profile of the Vaccines;

(3) the quality of the manufacturing of the Vaccines;

(4) side effects of the Vaccines;

ii) the Vaccines would be fully assessed in the usual manner prior to approval;

iii) vaccine safety was the first priority of the Australian Government.

Source

ABC Breakfast News, 8 January, 2021

https://www.health.gov.au/news/chief-medical-officer-professor-paul-kellys-interview-on-abc-news-breakfast-on-8-january-2021?language=en

b) on 8 January, 2021 the Chief Medical Officer publicly stated that:

i) the TGA will expedite the Vaccines approval but will not curtail the rigorous standards of approval in order to do so;

ii) the number one priority of the Vaccines approval is to ensure their safety;

iii) the TGA will not approve of any vaccine that has not been proven to

be completely safe for use on the Australian public;

iv) the TGA will guarantee the safety, efficacy and quality of any approved Vaccines.

Source

ABC National Radio, 8 January, 2021

https://www.health.gov.au/news/chief-medical-officer-professor-paul-kellys-interview-on-abc-national-radio-on-8-january-2021?language=en

c) on 13 January, 2021 the Chief Medical Officer publicly stated that:

i) the AstraZeneca Vaccine prevents all deaths from Covid;

ii) the AstraZeneca Vaccine prevents all severe illness from Covid;

iii) the Pfizer Vaccine prevents all deaths from Covid;

iv) the Pfizer Vaccine prevents all severe illness from Covid;

v) the only authority and source of reliable information on the safety and efficacy of the Vaccines are the Australian Government and the State and Territory Governments;

vi) the medical advice conveyed by the Australian Government to the Australian people throughout the pandemic to date was flawless;

vii) the TGA are the only authority who will advise on the safety, quality and efficacy of the Vaccines;

viii) the Vaccines can assist to achieve zero community transmission of

Covid.

Source

Sky News Live – First Edition, 13 January, 2021

https://www.health.gov.au/news/chief-medical-officer-professor-paul-kellys-interview-on-sky-news-live-first-edition-on-13-january-2021

c1. on 18 February, 2021 the Chief Medical Officer publicly stated that the Pfizer and AstraZeneca Vaccines were proven to prevent severe Covid and hospitalisation from Covid in recipients.

Source

Press Conference, Canberra, 18 February, 2021
https://www.greghunt.com.au/transcript-press-conference-canberra-6/

c2. on 16 March, 2021 the Chief Medical Officer publicly stated that:

i) there is no evidence that the AstraZeneca vaccine caused blood clots;

ii) the AstraZeneca vaccine is effective;

iii) the AstraZeneca vaccine is safe.

Source

The Chief Medical Officer was expressly quoted in a news.com.au article published on 16 March, 2021.

https://7news.com.au/lifestyle/health-wellbeing/medical-boss-stands-by-astrazeneca-vaccine-c-2361544

c3. on 12 June, 2021 the Chief Medical Officer publicly stated that:

i) vaccination isn't only about making a decision to protect yourself, but protecting those around you;

ii) the fast development of the Vaccines is a huge privilege;

iii) the vaccines work very well;

iv) the vaccines are very safe for the vast majority of people;

v) the benefit for people in their 50's to have the AstraZeneca vaccine immediately significantly outweighs the risk of waiting for an alternative Vaccine.

Source

The Chief Medical Officer was expressly quoted in Canberra Times article published on 12 June, 2021.

https://www.canberratimes.com.au/story/7293963/its-an-arms-race-kelly-says-dont-wait-on-jab/

d) on 25 June, 2021 the Chief Medical Officer publicly stated that:

i) the Vaccines will protect you against Covid;

ii) the Vaccines will prevent community transmission.

Source

3AW Interview, 25 June, 2021

https://www.health.gov.au/news/chief-medical-officer-professor-paul-kellys-interview-on-3aw-on-25-june-2021?language=en

d1. on 24 December, 2021 the Chief Medical Officer publicly stated that:

i. almost everyone needing intensive care from Covid infection were unvaccinated with the Vaccines;

ii. the Vaccines were effective at preventing severe disease and death from Covid;

iii. boosters of the Vaccines protect immunocompromised people from severe disease from Covid;

iv. protection of the Vaccines:

(1) remains for many months; and

(2) against severe disease from Covid is longer lasting;

v. boosters of the Vaccines can help with preventing transmission of the Virus;

vi. patients from indigenous backgrounds and those with chronic disease will be protected for risks of severe disease by having a fourth dose of

the Vaccines;

vii. the Vaccines are proven safe in pregnancy;

viii. pregnant women and their unborn babies:

(1) are both at serious risk from Covid; and

(2) can only be protected against Covid by the Vaccines.

Source

Press Conference, Canberra, 24 December, 2021 https://www.greghunt.com.au/transcript-press-conference-canberra-43/

HUNT – MISLEADING STATEMENTS

48. Hunt stated the following public statements expressly or by reasonable inference to the Australian public (**"the Hunt Misleading Vaccines Statements")**:

aa) on 25 January, 2021 Hunt publicly stated that the Pfizer Vaccine was approved

on the basis of completely preventing severe Covid disease.

Source

Published on 25 January, 2021.
https://www.greghunt.com.au/pfizer-vaccine-approved/

a) on 21 February, 2021 Hunt publicly stated that:

i) the Vaccines are safe for breastfeeding mums;

ii) the Vaccines are up to 100% effective at preventing serious Covid;

iii) the Vaccines are up to 100% effective at preventing hospitalisations from the Virus;

iv) the Vaccines are up to 100% effective at preventing deaths from the Virus;

v) clinical trials of the Vaccines are showing that they have strong impact on transmission;

vi) the Vaccines will protect the individual from Covid;

vii) the Vaccines will protect an individual's family members from Covid;

viii) the Vaccines will protect Australia from Covid.

Source

Interview on ABC Insiders broadcast on 21 February, 2021.
https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/interview-with-david-speers-on-abc-insiders-on-the-covid-19-vaccine-rollout

b) on 7 March 2021, Hunt publicly stated that:

i) there was no evidence that the Vaccines are harmful in pregnancy;

ii) there was no need to be concerned if a person is pregnant and has taken or intends to take the Vaccines;

iii) any statements to the contrary are merely conspiracy theories

worthy of rejection;

iv) taking the Vaccines are entirely safe for pregnant recipients and their unborn child;

v) there was no known reason why the Vaccines could be considered anything other than safe in pregnancy.

Source

Doorstop Interview, 7 March, 2021
https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/doorstop-interview-about-the-vaccine-rollout-and-vaccine-safety

b1) on 5 May, 2021 Hunt publicly stated that the Vaccines are proven to prevent

transmission of the Virus and death from Covid.

Source

Press Conference, Melbourne. 5 May 2021

https://www.greghunt.com.au/14389-2/

b2) on 24 May, 2021 Hunt publicly stated that the Vaccines:

i) kept every Australian person safe from harm;

ii) had been subjected to full and thorough assessment for safety.

Source

Four Corners Interview, 24 May, 2021

https://www.greghunt.com.au/transcript-interview-four-corners/

b3) on 25 May, 2021 Hunt publicly stated that:

i) the Australian public should disregard reports of blood clotting after receiving the Vaccines;

ii) delaying in taking the Vaccines could lead to your death;

iii) the Vaccines prevent transmission of the Virus;

iv) only after full vaccination with the Vaccines can normal life return to Australia.

Source

2GB Radio interview, 25 May, 2021
https://www.greghunt.com.au/transcript-interview-jim-wilson-2gb/

c) on 27 August, 2021 Hunt publicly stated that:

i) the Vaccines can save your life;

ii) the Vaccines can protect your life;

iii) taking the Vaccines can save and protect the lives of the individual taking the Vaccines and their community.

Source

Press Conference, Canberra, 27 August, 2021

https://ministers.dese.gov.au/hunt/press-conference-canberra

d) on 24 December, 2021 Hunt publicly stated that the Vaccines were proven to protect against:

i) transmission of the Virus;

ii) severe Covid.

Source

Press Conference, Canberra, 24 December, 2021
https://www.greghunt.com.au/transcript-press-conference-canberra-43/

THE DEPARTMENT – MISLEADING STATEMENTS

49. The Respondents, through the Department, stated expressly or by reasonable inference to the Australian public that **("the Department Misleading Vaccines Statements"):**

a) the Department stated on 8 November, 2021 by publishing the document "Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines" **("the Myocarditis Concerns Guidance Document")** in the context of the admission in the document that "there are currently limited available data on the long-term outcomes of people who have had myocarditis and/or pericarditis after an mRNA COVID-19 vaccine" that:

i) short to medium term follow-up data in respect of the outcomes of those who suffer from myocarditis and/or pericarditis after an mRNA COVID-19 vaccine is reassuring for those considering taking or having taken the Vaccines;

ii) most people who have had myocarditis and/or pericarditis due to other

causes recover completely and have no ongoing impairment of cardiac function for which the data suggest this is likely for cases associated with mRNA COVID-19 vaccination, based upon the study "Tunuguntla H, et al, 'Acute Myocarditis and Pericarditis in Children' Ped. Rev. 2019; 40(1):14-25" **("the Cited Myocarditis Study")**;

iii) that even if the Vaccines recipient might suffer myocarditis or pericarditis as an effect of the Vaccines, that in all likelihood the person would recover completely with no ongoing impairment of cardiac function;

iv) the above statements made in circumstances where in truth the Respondents knew that:

(1) the Cited Myocarditis Study in fact states expressly, contrary to the Department's statements, that:

a. the myocarditis disease process can rapidly become life-threatening;

b. myocarditis can cause sudden cardiac death, with no symptoms until death;

c. in the study of 171 paediatric patients with myocarditis, 13% died or underwent cardiac transplant during their initial hospitalization;

d. for those with an underlying etiology of myocarditis, the incidence of transplant or death at 5 years after diagnosis was 27%;

e. myocarditis can also lead to the development of a chronic dilated cardiomyopathy (DCM), which is the leading cause of paediatric heart transplant in children

older than 1 year;

f. in a large cohort of paediatric patients with DCM from the Paediatric Cardiomyopathy Registry, myocarditis was the most common known cause of DCM;

g. of children with a known cause for DCM, up to 46% have been reported to be due to myocarditis;

h. 50% of those with a DCM without known myocarditis had died or undergone cardiac transplant by 5 years after diagnosis;

i. the prognosis for individuals with myocarditis is as variable as the clinical presentation wherein:

    i. patients with acute myocarditis and normal cardiac function have a good prognosis overall, with a high likelihood for spontaneous recovery;

    ii. those with fulminant viral myocarditis are more likely to have recovery if adequately supported with medications or MCS during the initial phase;

    iii. those with giant cell myocarditis have a poor prognosis in both children and adults, with median survival of less than 6 months without cardiac transplant.

j. when evaluated from a sudden death perspective, myocarditis accounts for approximately 5% to 6% of sudden deaths in young athletes in the United States;

k. myocarditis can result in life-threatening arrhythmias

and conduction abnormalities, including variable degrees of:

i. atrioventricular block;

ii. ventricular fibrillation/flutter; or

iii. ventricular tachycardia.

(2) despite the prolific and free availability of studies regarding the dangers of pericarditis and myocarditis, the Department selected the Cited Myocarditis Study as a supporting citation which:

a. was only viewable by registration and payment of a $25 USD fee;

b. consequently and obviously certain to be substantially limited in those viewing the study in its full form.

(3) the Myocarditis Concerns Guidance Document was produced:

a. for use by medical practitioners;

b. to reassure and represent to medical practitioners and their patients that:

i. regulators were carefully monitoring for these events relating to myocarditis and pericarditis;

ii. myocarditis and pericarditis after taking the Vaccines was in most cases:

1. of minimal or no concern;

2. attended only by extremely rare instances of any long term sequelae.

(4) the Respondents were entirely unaware as to:

a. the long-term outcomes of people who have had myocarditis and/or pericarditis after the Vaccines;

b. the underlying aetiology of people who have had myocarditis and/or pericarditis after the Vaccines and therefore:

i. the short or long term prognosis of people who have had myocarditis and/or pericarditis after the Vaccines; and

ii. the true risk to those who take the Vaccines of death or serious short or long term injury.

(5) myocarditis and pericarditis following injection with the mRNA based Vaccines:

a. were reasonably postulated at that time to be occurring as a result of:

i. toxic or inflammatory effects of the nano lipid delivery system used in the Vaccines; and

ii. an auto-immune response to the autologous spike protein production in those Vaccines;

b. possessed a large number of histological correlates with a variety of possible inflammatory and white blood cell infiltrates into the myocardium.

(6) the European Medicines Agency Pharmacovigilance Risk Assessment Committee (PRAC) had by 28 October, 2021, which was known to the Respondents at that time:

a. confirmed a safety signal in the Vaccines for myocarditis and pericarditis, as well as capillary leak syndrome in the Moderna Vaccine;

b. recommended changes to the Product Information to reflect this in the Moderna Vaccine and the Pfizer Vaccine;

c. stated that any cardiac arrest or death occurring in young people must constitute a safety signal;

(see particulars)

(7) it was a well-established and easily accessible scientific fact based upon extensive empirical historical data that **("Established Scientific Facts of Myocarditis")**:

a. myocarditis and pericarditis are in every instance serious and life-threatening conditions;

b. neither prognosis nor treatment can be determined without a histological based understanding of the underlying pathophysiological processes;

c. following myocarditis there is:

i. generally across all aetiologies 30-40 % chance of progression to death or cardiac failure within 5 years;

ii. some aetiologies attended by a 25% survival rate within a 6 month period;

iii. at least 50% of patients develop cardiomyopathy in the long term;

iv. a one-year mortality rate for acute myocarditis generally of 20% which increases to 56% on four-year follow-up;

v. discernible changes to a patients ECG results are rare;

vi. assessment requires a minimum of an MRI to confirm the diagnosis;

vii. proper treatment can only be guided by the result of a myocardial biopsy;

viii. outcomes of acute myocarditis are often life threatening;

ix. the risk of sudden cardiac death in patients with acute myocarditis is not always associated with the severity of myocardial inflammation and can persist after the acute phase of myocarditis is resolved;

x. acute myocarditis can also present as sudden cardiac death, accounting for approximately 10% of deaths from sudden cardiac death in young individuals aged under 35 years;

xi. life-threatening bradyarrhythmia and

tachyarrhythmia can occur at any stage of the disease and lead to sudden cardiac death.

Source

Para. 49(a) in Schedule D of the SOC.

a1. on 26 November, 2021, in a Video published to YouTube, the Department stated that:

i) vaccination with the Vaccines was the best protection against Covid of any possible measure to be taken;

ii) the DAEN database data:

(1) was being misused to deceive the public about the Vaccines safety;

(2) is reported without any assessment as to being caused by the Vaccine by the reporter;

(3) the Weekly Safety Report prepared by the TGA contains the only accurate information about the serious side effects and deaths after vaccination with the Vaccines available to the public;

(4) the Department and the TGA are the only purveyors of accurate and trustworthy information in respect of the Vaccines.

Source

The Department and TGA produced information video published to YouTube on 26 November, 2021.

https://youtu.be/PT4M9fX9sPI?feature=shared

b) in publishing the document "Pfizer COVID-19 vaccine for children aged 5 to 11: information for parents and guardians" on 23 December, 2021 the Department stated that:

i) as at that time, no specific safety concerns have been identified in the 5 – 11 year old age group in the use of the Pfizer Child Vaccine;

ii) that the Pfizer Child Vaccine would prevent transmission of Covid by recipients;

iii) that the Pfizer Child Vaccine would prevent infection of Covid in recipients;

iv) the benefits of taking the Pfizer Child Vaccine outweigh the risk; and

v) the rate and severity of myocarditis in children is expected to be lower in children aged 5 – 11 than that in adolescents, and more mild;

vi) the risks of injury in failing to vaccinate children with the Pfizer Child Vaccine are considerable and in need of mitigation;

vii) the risk of injury by injecting them with the Pfizer Child Vaccine are almost nil;

viii) myocarditis is a non-serious condition that generally people recover from fully;

ix) the Department had independently ascertained the veracity of these matters.

Source

The Department published “Pfizer COVID-19 vaccine for children aged 5 to 11: information for parents and guardians” on the Department website on 23 December, 2021.

https://www.health.gov.au/resources/publications/covid-19-vaccine-information-and-consent-form-for-parents-and-guardians-of-children-aged-5-to-11-years

c) in publishing the document “Clinical recommendations for COVID-19 vaccines” on 12 December, 2022, the Department stated that:

i) there is substantial data on the safe use of the original Pfizer Vaccine during pregnancy;

ii) there are no theoretical safety concerns relating to the use of the Novavax Vaccine during pregnancy;

iii) the AstraZeneca vaccine is not preferred in pregnancy but it can be used during pregnancy;

iv) there are no theoretical safety concerns relating to the use of the bivalent booster Vaccines during pregnancy;

v) vaccination following infection enhances natural acquired immunity;

vi) all available Vaccines are safe for use during pregnancy;

vii) there is no additional risk to the unborn child or mother if a COVID vaccine is used during pregnancy;

viii) vaccination provides superior protection against COVID infection than natural acquired immunity.

Source

The Department published “Clinical recommendations for COVID-19 vaccines” on their website on 12 December, 2022.

https://www.health.gov.au/our-work/covid-19-vaccines/advice-for-providers/clinical-guidance/clinical-recommendations

See also para. 49 in Schedule D of the SOC.