Commonwealth Government COVID-19 Response Inquiry – Public Submission 10.12.2023

Terms of Reference: Key health response measures (for example across COVID-19 vaccinations and treatments, key medical supplies such as personal protective equipment, quarantine facilities, and public health messaging).

Not So '*SAFE and EFFECTIVE*' (10 mins. read)

SUMMARY

Safety warnings ignored by the Commonwealth, Health Depts./Ministers etc. including TGA (and AHPRA etc.) following the publicly available European Medicines Agency Assessment Reports on [redacted].

Evidence from EMA website (3 links & [redacted] report image) listing identified safety risks & missing information (no data).

Research on [redacted] = 910 reported TGA DAEN cases of reactions (88% children affected) including 43 cases deemed "*Serious*" as per TGA FOI 4769 (published 17/11/2023). Reported child jab deaths - all listed on TGA DAEN and TGA FOI 3545, FOI 4077 and FOI 4769. GOVERNMENT PUBLIC DATA (DAMNING EVIDENCE OF JAB HARM).

Currently 139,579 adverse reactions cases listed on TGA DAEN following COVID-19 jabs from 21/12/2020 to 25/11/2023, including 5,863 cases reported of Australian children aged under 18. ReferTGA DAEN website as evidence.

1,005 reported jab deaths on DAEN consisting of approx. [redacted] TGA DAEN https://daen.tga.gov.au/medicines-search/

Of these 1,005 COVID-19 jab reported deaths, [redacted] child reported deaths aged from 5 - 17 (5 boys and 4 girls). See page 3.

Researched links as evidence of revealing public Government data on TGA FOI Disclosure Log (FOI 3545, 4077 and 4769).

JAB SAFETY WARNINGS IGNORED

The TGA (Therapeutic Goods Administration) provisionally approved the COVID-19 vaccinations, which were developed and manufactured at '*warp speed*' within approx. 9 months; whereas most vaccines take years for approval i.e. study trials, long term data and safety assessments etc. For example, as from the 1st July, 2023, the TGA approved release of a vaccine, called [redacted] for Australian babies aged 6 weeks old. It was initially assessed by the European Medicines Agency in their report dated 17th December 2015, despite there being **7 baby deaths reported in the trial *("All vaccinated Subjects")***. Refer page 124 as evidence of baby deaths plus safety concerns, identified risks and "*Missing information*" pages 128-130. [redacted]

The COVID-19 global trial experimental vaccines were also assessed by the European Medicines Agency (EMA) with reports in early 2021, prior to the TGA giving "provisional approval' ahead of the jab rollout in Australia. Alarmingly, these 3 publicly-available reports showed **SERIOUS safety concerns** with *important identified risks* e.g. anaphylaxis and *"Missing information"* (no data): • "*Use during pregnancy and while breast feeding* • *Use in immunocompromised patients* • *Use in frail patients with co-morbidities (e.g. chronic obstructive pulmonary disease, diabetes, chronic neurological disease, cardiovascular disorders)* • *Use in patients with autoimmune or inflammatory disorders* • *Interactions with other vaccines* • *Long-term safety*". As researched evidence, see 3 x EMA assessment report links and 2 uploaded reports (highlighted pages - quick scrolling) as part of submission. See page no's for key information. Safety concerns image [redacted]

[redacted] epar-public-assessment-report_en.pdf [redacted] 29.01.2021 - pages 48, 53, 75, 77, 117, 125, 137, 141, with **142 & 143** "***Summary of safety concerns***", 166, 168 and 172.

[redacted] 19.02.2021 – pages 30 & 115 "Biological", **55 (genotoxicity & carcinogenicity risks)**, 56, 68, 94 (only 5 study participants of the elderly aged 85+), 97 (Pfizer trial ends Dec. 2023) and **key page 115** "***Summary of safety concerns***" with "***Missing information***". See screenprint over as evidence of EMA report page 115 i.e. a table showing risks identified.

[redacted]

2.7. Risk Management Plan

Safety Specification

Summary of safety concerns

The applicant has submitted an RMP including the following summary of safety concerns:

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-associated enhanced disease (VAED) including Vaccine-associated enhanced respiratory disease (VAERD)
Missing information	Use during pregnancy and while breast feeding Use in immunocompromised patients Use in frail patients with co-morbidities (e.g. chronic obstructive pulmonary disease (COPD), diabetes, chronic neurological disease, cardiovascular disorders) Use in patients with autoimmune or inflammatory disorders Interaction with other vaccines Long term safety data

Risks considered important for inclusion of the summary of safety concerns

The review of available safety data, including post-marketing data emerging from use in the UK and US, the experience with biological products and other vaccines leads to the conclusion that anaphylaxis is an important identified risk for [redacted] This safety concern will be followed up via routine pharmacovigilance activities and in the planned and ongoing safety studies and reported in the monthly summary safety reports and PSURs.

Any important potential risks that may be specific to vaccination for COVID-19 (e.g. vaccine associated enhanced respiratory disease) should be taken into account. The Applicant has included VAED/VAERD as an important potential risk and will further investigate it in the ongoing pivotal study and a post-authorisation safety study.

Missing information

Since pregnant and breast-feeding women were excluded from the study, no information is available for those populations. It is agreed to include use during pregnancy and while breastfeeding as missing information in the RMP.

At the data cut-off of 14 Nov-20, 10-14 weeks safety data are available. Thus, long-term safety is included as missing information and will be characterised as part of the continuation of the pivotal clinical trial and the PASS.

Interaction with other vaccines, has not been evaluated in clinical trials and may be of interest to prescribers. As elderly individuals will be one target group for vaccination, and they often may need vaccination with other vaccines such as influenza and pneumococcus vaccines, further data is

Following the [redacted] jab, the very first 4 reported cases involving Australian children, with adverse reactions (jab harm), are publicly listed on the TGA DAEN (government data) https://daen.tga.gov.au/medicines-search/

1. **520591** - 25/02/2021 aged 17, Female, ***Syncope*** [loss of consciousness, fainting/ blackout].
2. **523510** - 1/03/2021 aged 15, Male, ***Chest pain, Dyspnoea*** **(breathing difficulty),** ***Electrocardiogram abnormal, Pericarditis*** [inflammation of the pericardium, a sac-like structure that surrounds the heart].
3. **524950** - 22/03/2021 aged 1, Male, ***Cough, Dyspnoea, Exposure via breast milk, Wheezing.***
4. **526666** - 25/03/2021 aged 9, Female, ***Headache, Myalgia*** **[muscle pain],** ***Product administered to patient of inappropriate age.***

[redacted]

FOI 4077 is a publicly available pdf document (5 pages) released 21/12/2022 under the TGA Freedom of Information Disclosure Log https://www.tga.gov.au/sites/default/files/2022-12/foi-4077-01.pdf This pdf shows 194 rows of COVID-19 vaccine reported deaths in Australia from 10/01/2022 to 08/11/2022, but only 20% show batch numbers/doses with the associated TGA DAEN case numbers. Notably, on page 3 of this FOI 4077 pdf, it reveals 2 reported deaths @ row 96 case no. **733723** and row 99 case no. **734187** - **BOTH these 2 death cases show the** [redacted]

FOI 4769 was released on 17/11/2023 and shows 946 pages on a pdf document issued by the TGA on their Disclosure Log. https://www.tga.gov.au/sites/default/files/2023-11/FOI%204769.pdf The first 437 pages relate to DAEN COVID-19 vax **"Serious"** cases (including deaths reported). **There are 22,000+ DAEN case reports listed (various COVID jabs) from 21/12/2020 to 19/10/2023 (FOI 4769)**. From pages 438 to 946, C-19 vax batch numbers and doses are listed from 16/01/2022 to 19/10/2023 (where shown). [redacted] is shown in hundreds of cases reported in FOI 4769. Also, the 2 deaths reported following [redacted], highlighted in **red** above, are also included in this FOI 4769 i.e. page 786 of 946 shows case no. 733723 (Dose 2 batch no. FP1430) and page 789 of 946 shows case no. 734187 [redacted], listed on the TGA DAEN, are shown below in an excel document (screenprint), amongst the current **7 x COVID jab reported child deaths**; sourced from TGA DAEN government website (accessed on 09/12/2023). The 2 jab reported death cases (5.2022), are 2 boys. **733723 is a 10-year-old boy who got dose 2 of FP1430 and 734187 is a 5-year-old boy (the youngest Australian child jab death reported) who got the same** [redacted] These 2 young boys whose deaths were reported following the [redacted] are included within the TGA's **FOI 4769** list of **"Serious"** cases. [redacted] out of 910 reported jab adverse report cases on the TGA DAEN, there are **43 "Serious" cases listed i.e. 42 children aged 4 to 12 and 1 teenager aged 19**. Via FOI 3545 and FOI 4769, there are 910 cases relating to [redacted] of which 798 cases (88%) are on the TGA DAEN with reactions (kids aged 0 - 14). Underreporting factor also applies. Not so '*safe and effective*'.

Case number	[redacted]	Age	Sex	Medicines reported as bei	MedDRA reaction terms	Serious (Y/N)	Death (Y/N)	Batches & Doses	Batch confirmed by
616124	2/9/21	17	Male	[redacted]	• Headache • Malaise • Viral myocarditis	Yes	Yes	FF0884 (1)	FOI 3545
647663	20/10/21	14	Female		• Brain injury • Cardiac arrest • Dizziness • Encephalitis • Headache • Multiple organ dysfunction syndrome • Nausea • Pyrexia	Yes	Yes	3005842 (1)	FOI 3545
695048	15/1/22	15	Male		• Adverse event following immunisation • Head banging	Yes	Yes	- (-), - (-)	FOI 4077
719838	11/3/22	7	Male		• Cardiac arrest • Generalised tonic-clonic seizure	Yes	Yes	- (1)	FOI 4769 & FOI 4077
724023	25/3/22	9	Female		• Cardiac arrest	Yes	Yes	- (-)	FOI 4769 & FOI 4077
733723	6/5/22	10	Male		• Adverse event following immunisation	Yes	Yes	FP1430 (2)	FOI 4769 & FOI 4077
734187	10/5/22	5	Male		• Abdominal pain • Cardiac arrest • Eosinophilia • Eosinophilic myocarditis	Yes	Yes	FP1430 (1)	FOI 4769 & FOI 4077
744306	11/7/22	14	Female		• Immunisation reaction	Yes	Yes	unknown (1)	FOI 4769 & FOI 4077
762472	20/12/22	17	Female		• Arrhythmogenic right ventricular dysplasia • Escherichia sepsis • Vomiting	Yes	Yes	- (2)	FOI 4769 & FOI 4334

RECOMMENDATIONS - Key health response measures (COVID-19 vaccinations & public health messaging).

1. Stop the fearmongering of COVID. Start changing public health messaging from wrongful narrative '*safe and effective*'.
2. Stop giving "provisional approval" a.k.a. 'back-door' access to Pharmaceuticals via the TGA. Start with adopting a 'safe passage' procedure and being thoroughly vigilant with reading assessment reports, studying trial information and long-term safety data of vaccines (and medicines). NB. [redacted] was rejected in USA as an unsafe product 1960's.
3. Stop all conflict of interests involving funds being given from 'big Pharma' to TGA and Governments etc.
4. Stop giving legal indemnity to pharmaceutical companies. Change the conditions or refuse these commercial contracts that have bound up the Commonwealth (including 'rogue' State/Territory Governments). Ensure proper and easier compensation channels for the jab-injured and families of the jab-deceased; with transparency and compassion.