From: SKERRITT, John
To: Christensen, George (MP)
Cc: [redacted]
Subject: Response to Mr George Christensen MP [SEC=OFFICIAL]
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Skerritt to Christensen 9 6 21.pdf

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From: [redacted] (G. Christensen, MP) [redacted] **On Behalf Of** Christensen, George (MP)
Sent: Monday, 7 June 2021 11:14 AM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Subject: Letter from Mr George Christensen MP

Good morning Professor Skerritt

Please find attached letter from Mr George Christensen MP regarding the Covid-19 virus and vaccines regarding that virus.

Regards

[redacted]
Ph: [redacted] **E:** [redacted]
Office of GEORGE CHRISTENSEN MP
Federal Member for Dawson

Australian Government

Department of Health

Deputy Secretary

Mr George Christensen MP
Member for Dawson
2/21 Milton Street
Mackay QLD 4740

Our Reference: D21-2708515

Dear Mr Christensen

COVID-19 virus and the vaccines for that virus

Thank you for your correspondence of 7 June 2021, regarding the TGA safety update report published on 27 May 2021.

Reports of adverse events from health professionals and consumers are a key source of information used by regulators like the TGA to monitor the safety of medicines and vaccines. However reporting of an adverse event to the TGA does not mean that the event was caused by the vaccine; in many cases the timing may be just coincidental.

We encourage health professionals to report even if they are unsure whether the vaccine caused an adverse event. In some states, it is mandatory for health professionals to report adverse events and for all states and territories we have had quite comprehensive reporting of adverse events. In preparation for the COVID-19 vaccine rollout we extensively promoted adverse event reporting to consumers and health professionals and have received a number of reports directly from these groups.

A team of health professionals and scientists at the TGA undertake detailed analysis of adverse event report data, using internationally accepted approaches. If a safety issue is confirmed, we rapidly communicate this to the public and take required regulatory action to maintain the safety, quality and efficacy of vaccines available in Australia.

As of 8 June 2021, the TGA has received over 26,000 reports of adverse events following COVID-19 vaccines. This results from the high number (over 5 million doses) of COVID-19 vaccines given thus far and the high awareness of adverse event reporting amongst the Australian public. About 80% of these reports are for expected vaccine side effects such as headache, fever, muscle and joint pain and injection site reactions.

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The TGA is transparent about adverse events reported, by publishing a weekly report on COVID-19 vaccine safety and undertaking a program of media conferences and press briefings on vaccines, including vaccine safety. We also make available publicly a "Database of Adverse Event Notifications" with summary information of individual adverse events following immunisation. This includes the number of cases for each reaction where death was the reported outcome. This de-identified adverse event information is published 90 days after a report is received to enable assessment of reports, including seeking external medical specialist advice when required.

The TGA publishes information about reports of death following COVID-19 vaccination in the weekly safety report. Stating that there has been "210 deaths and 24000 adverse events after COVID-19 vaccinations" would suggest that each of these deaths and adverse events has been caused by treatment with COVID-19 vaccines. This is totally incorrect.

The TGA investigates reported adverse events and has found only one case where an individual with vaccine related thrombosis with thrombocytopenia syndrome (TTS) or any other related condition has passed away. I have undertaken to communicate promptly to the public through the broadcast media and our website if any other deaths are found to be causally related to a COVID-19 vaccine.

Sadly, about 160,000 people die in Australia every year - almost 3000 each week - and therefore it is quite expected that there have been some deaths reported within days or a few weeks of vaccination. A high proportion of reported deaths were in older people as the vaccine rollout began in aged care.

All deaths and serious illnesses that are reported as possibly being linked to vaccination are reviewed by an expert team of clinical staff and advice is obtained on particular cases from a panel of external medical specialists and community representatives. Analysis includes comparing expected natural death rates to observed death rates following immunisation as well as in depth reviews of the patient histories. The review may include gathering and considering relevant clinical information on the patient's current and past medical history, risk factors, and medications at the time of vaccination, as well as any tests such as pathology and clinical notes. Where necessary this may also involve discussion with the relevant state and territory health departments, the individual's health professionals and/or the coroner. In some cases the TGA seeks advice from a panel of external medical specialists and community representatives. Analysis also includes comparing expected natural death rates to observed death rates following immunisation as well as in depth reviews of patient histories.

In some jurisdictions it is mandatory to report a death within a defined time period after vaccination, even when the reporter does not suspect the death was related to the vaccine. In approximately 20% of cases with death as a reported outcome, the reporter did not identify an adverse reaction other than the death.

Up to 6 June 2021 the TGA received a total of 278 reports of deaths following immunisation: 137 have been reported for the Pfizer vaccine, 130 for the AstraZeneca

vaccine and 11 where the vaccine was not specified. Where reported, the time between vaccination and death ranged from 2 days to over 7 weeks.

Due to patient confidentiality, we are unable to provide you the primary and non-primary causes of death for each death. Furthermore, detailed investigation of the cause of death is generally the role of the State or Territory Coroner.

The TGA identified case definitions for these adverse events and calculated background population rates so that the reported number of cases of these events could be rapidly compared with the expected number in the population to identify safety signals for investigation.

Approximately 6% of reports to the TGA relate to adverse events of special interest (i.e. typically more serious adverse events). Significant new information about any of these adverse events, such as confirmation that one of the adverse events is likely to be caused by one of the COVID-19 vaccines, will be included in the weekly report. Adverse events of special interest being monitored for both COVID-19 vaccines at present include:

- clotting disorders without thrombocytopenia (low platelets) including stroke, pulmonary embolism and deep vein thrombosis
- anaphylaxis
- thrombocytopenia without thrombosis
- seizures
- acute cardiac injury, for example myocarditis and pericarditis, heart failure and cardiogenic shock, arrhythmia
- facial weakness or paralysis, for example Bell's palsy
- loss of sense of taste or smell (also called ageusia or anosmia)
- Guillain-Barre syndrome.

Due to patient confidentiality, and limitations in the data provided to the TGA, we cannot detail the adverse events for each patient with an adverse event of special interest.

Thank you for writing on this matter.

Yours sincerely

Adj. Professor John Skerritt
Health Products Regulation Group

8 June 2021