



Australian Government

Department of Health and Aged Care

Dr Melissa McCann
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Dear Dr McCann

I am writing to convey my serious concerns about false and misleading claims being made by you about the safety of COVID-19 vaccines. In particular, I wish to directly address a false claim that has been reported following your presentation at the 'COVID-19 Vaccine Conferences' in February 2023 which appears to relate to information provided to you under the *Freedom of Information Act 1982* (the FOI Act).

The misleading assertion that children have died as a result of COVID-19 vaccination in Australia is false. The TGA has not linked the death of any child with a COVID-19 vaccination. It appears that the use of the word 'causality' in template text is being intentionally misconstrued to imply a causal relationship.

I understand that senior officers at the TGA have taken considerable time to explain the TGA processes to you, as part of our response to your FOI requests.

As previously explained, the TGA takes its safety role very seriously and we work closely with all stakeholders, including the states and territories, to ensure information about suspected adverse events is provided to us. Anyone can make an adverse event report and follow-up information can be provided at any time.

We encourage everyone (including health professionals) to report adverse events even if they are unsure or think an event is unlikely to be related to vaccination.

As you would be aware, spontaneous adverse event reporting systems have limitations. Chiefly this is because reporting an adverse event following vaccination does not mean it is causally linked to the vaccine. With rapid, whole-population vaccination programs it is expected that some people will develop new symptoms or illnesses within days or weeks after vaccination, but a temporal relationship alone does not necessarily confirm a causal link. The adverse event could be a coincidence, due to underlying illness or other factors. In many cases, the very limited information provided precludes a detailed assessment, which is why we always seek and welcome additional information and will undertake re-assessment as necessary.

We also maintain clear close channels with state and territory health services and coroners in their important role.

Suggestions that the TGA intentionally withheld information from the public are simply untrue. Throughout the pandemic we have proactively published up-to-date safety reports on our website, including aggregate information about the reports received and more detailed information on serious and fatal cases.

Though the information was released to you under FOI, we did not publish them in the disclosure log because of their sensitive nature. While personal information was redacted, it remains possible that a family member or another individual could identify that the document relates to their loved one. A careful and sensitive approach to publishing the information in the disclosure log was taken, given the potential for causing distress to the family of the deceased. This approach was consistent with the TGA's legal obligations, as there are exemptions from publishing documents released under the FOI Act in circumstances such as these.

Medical practitioners continue to play a tremendously important role in using their professional judgement, expertise and influence to promote public health practice based on the best available evidence. Sadly, some have used their position of influence to spread misinformation about the safety of vaccines, which threatens to dangerously undermine public confidence. The Australian Health Practitioner Regulation Agency recognises the important responsibility of medical practitioners in ensuring sound and scientific messaging for the community in its Position Statement, which includes:

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.

I implore you to ensure any presentation you make is balanced and based on the best available evidence to ensure optimum outcomes for all Australians.

Yours sincerely



Adjunct Professor Robyn Langham AM
Chief Medical Adviser
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