



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Ms Anita Coles
Committee Secretary
Parliamentary Joint Committee on Human Rights
Parliament House
CANBERRA ACT 2600

Dear Ms Coles

I am writing in relation to the Parliamentary Joint Committee on Human Rights inquiry into Australia's Human Rights Framework, July 2023.

It has been brought to my attention that the Committee has received a submission from Ashley, Francina, Leonard & Associates, which contains adverse comment about the Therapeutic Goods Administration (TGA). I wish to correct this submission provided to the Committee as part of its examination of the Department of Health and Aged Care.

The TGA emphatically rejects the claim that we have suppressed any information relating to the safety of COVID-19 vaccines. The TGA's commitment to transparency, especially in relation to COVID-19 vaccines, is incontestable. In addition to publication of COVID-19 vaccine adverse event reports in our Database of Adverse Event Notifications (DAEN), we have published a regular (initially weekly and then fortnightly) COVID-19 vaccine safety report for more than 2 years. In each report, we provide clear and accurate information about our safety monitoring activities, including details of our scientific and evidence-based evaluations of suspected side effects associated with COVID-19 vaccines.

The TGA has received more than 139,000 adverse event reports for COVID-19 vaccines. This high number reflects the scale of the vaccination program, with more than 68 million doses of COVID-19 administered in Australia to 20 August 2023, and our markedly enhanced safety monitoring activities. Importantly, the most frequently reported adverse events include headache, muscle pain, fever, fatigue and nausea. These are recognised side effects of vaccination and are usually transient and mild.

The information released under a Freedom of Information request from Dr Melissa McCann, referenced in the submission, has been misinterpreted and misrepresented. It is simply not true to claim that the documents show cases of children who have died due to a vaccine related cause. In fact, the documents show that the TGA has not found such cases. Those making false claims about the documents have misinterpreted a sub-heading of the document and the use of internationally accepted World Health Organisation (WHO) causality assessment terminology.

As reported in our COVID-19 vaccine safety report, to 20 August 2023, the TGA has received and reviewed 997 reports of death in people what have been vaccinated. Of these, 14 have been identified as linked to vaccination.

None of the 9 deaths in children or adolescents (<18 years) reported to the TGA have been found to be linked to COVID-19 vaccination. This includes the cases referred to in the submission, which are currently assessed in the TGA's internal database as 'unclassifiable', as there is insufficient information to classify causality under the WHO causality assessment framework. The TGA has provided further information on these cases through Question on Notice and multiple Freedom of Information requests, including FOI 4240 and 4215, which are published in the TGA disclosure log on our website. As such, it is patently incorrect to state that the '*TGA hid number vaccine-induced deaths from the public view*' – all reports remain in the TGA's database and are used in the TGA's ongoing safety monitoring activities.

The TGA is committed to safeguarding and enhancing the health of the Australian community through effective and timely regulation of therapeutic goods. Vaccination against COVID-19 is the most effective way to reduce severe illness, hospitalisation and death from infection. Evidence from more than 13 billion vaccine doses given worldwide shows that COVID-19 vaccines have a very good safety profile in all age groups. The protective benefits of vaccination far outweigh the potential risks.

Yours sincerely

Nick Henderson
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
7 September 2023