



Australian Government

Department of Health and Aged Care

Deputy Secretary

Ms Sophie Dunstone
Committee Secretary
Senate Legal and Constitutional Affairs References Committee
legcon.sen@aph.gov.au

Dear Ms Dunstone

Thank you for your correspondence dated 21 March 2024 regarding the Senate Legal and Constitutional Affairs References Committee's inquiry into a COVID-19 Royal Commission, including an answer received from the People's Terms of Reference to questions on notice. I appreciate you providing the chance for the TGA to respond.

If the reference in the People's Terms of Reference response is to the "[Joint statement on COVID-19 and COVID-19 vaccines from nation's regulators](#)", we have reviewed the statement in question.

In terms of the assertion that the public statement is "*further emphasising limitations on independent advice on Covid vaccines*", the only "limitations" we can detect in the Statement are:

- "health practitioners have a professional obligation to only share information that is evidence-based, in line with the best available health advice, and is consistent with public health campaigns such as the Australian COVID-19 Vaccination Policy"
- "They also must meet their profession's code of conduct"
- "Only people with relevant training, qualifications and expertise are a reliable source of advice on COVID-19 or vaccines"

On review and consideration, these are reasonable expectations of a registered health professional, and we stand by them.

Of particular note, there was no mention in the joint statement that could be taken to discourage reporting of Adverse Events Following Immunisation (AEFIs). Indeed, TGA communication has been clear that patients and practitioners should have a low threshold for reporting AEFIs. Our pharmacovigilance functions are strengthened by this, and the volume of reports indicates that many practitioners and patients clearly understood this to be the case.

Throughout the pandemic, the TGA actively encouraged adverse event reporting through our various communication channels. As an example, in June 2021 the TGA ran a paid social media campaign to raise awareness of the importance of reporting side effects to medicines, vaccines and medical devices that reached 2.2 million people.

Yours sincerely

Professor Anthony Lawler
Health Products Regulation Group

25 March 2024