Australian Government

Department of Health and Aged Care

Deputy Secretary

Sophie Dunstone
Committee Secretary
The Senate Legal and Constitutional Affairs References Committee
PO Box 6100, Parliament House
CANBERRA ACT 2600

Dear Ms Dunstone

The Therapeutic Goods Administration (TGA) thanks the Committee for the opportunity to address the potentially adverse reflection made by Senator Rennick regarding COVID-19 vaccines.

The TGA is disappointed that the Senator has chosen to allege that false statements were made by the TGA. This disappointment is amplified by the fact that the TGA has, on multiple occasions and in direct response to the questions and statements of Senator Rennick and his colleagues, explained that the Pfizer vaccine has never been approved by the TGA as being indicated for the prevention of transmission of COVID-19.

The TGA provisionally registered the Pfizer COVID-19 vaccine (Comirnaty) in 2021 for the indication "*Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2, in individuals 12 years of age and older*".

This approval, and the publicly available Australian Public Assessment Report (AusPAR)[1] published by the TGA, make no reference to this vaccine being approved to prevent transmission of COVID-19. Indeed, several of the COVID-19 vaccine AusPARs specifically mention the lack of clinical trial data about prevention of transmission in the regulatory submissions.

It is not clear whether the Senator, in describing the "product assessment report" (or AusPAR), is referencing the January 2021 AusPAR from the provisional registration

[1] https://www.tga.gov.au/resources/auspar/auspar-bnt162b2-mrna-comirnaty

of the Pfizer vaccine, the August 2023 AusPAR from its transition from provisional to full registration, or other AusPARs relating to indication extensions.

Fortunately, this distinction is not material, given:

- Both the 2021 and the 2023 AusPARs give the approved indication of the vaccine as *Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2*
- Further, the January 2021 AusPAR specifically indicated that, at that time, the question of *"vaccine efficacy against asymptomatic infection and viral transmission"* had not yet been addressed. It is clear from this statement that the initial AusPAR had no approved indication relating to the prevention of transmission.
- The 2023 AusPAR makes no reference to transmission at all.

The TGA has responded, including to Senator Rennick, on the issue of the approved indication for the COVID-19 vaccines on multiple occasions, including at Senate Estimates hearings and in multiple Questions on Notice. This includes, as a sample, in responses to:

- SQ21-001217- asked by Senator Rennick, which notably included the response:
  - *"Importantly, all provisionally approved COVID-19 vaccines are highly effective at preventing the priority public health outcomes of severe disease, hospitalisation and death."*
- IQ23-000143, which notably included the response:
  - *"…transmission effects are not an approved indication of any COVID-19 vaccine. The approved indication of COVID-19 vaccines is: "Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2".*
- SQ22-000421, which reflected specifically on the fact that the approved indication for COVID-19 vaccines was for the effect of the disease, not for the prevention of transmission.

Perhaps most relevant is Senator Babet's question, SQ23-002146, in which it was acknowledged and reaffirmed by the TGA that transmission effects are not an approved indication of any COVID-19 vaccine.

Despite this frequent correction of the record, including in specific response to Senator Rennick's questions, the Senator has made a statement regarding the TGA-approved indication of the Pfizer vaccine that has no factual basis. This represents either a fundamental misunderstanding or a misrepresentation of the role of vaccines in controlling epidemic disease, and the process of evaluation and approval of indications.

The TGA is aware that during the COVID-19 pandemic there was considerable public commentary by politicians, public health experts and officials from various levels of government. This is likely to have included a discussion of the role of COVID-19 vaccination in reducing transmission of COVID-19 in the community.

It is possible that the Senator has confused these statements with the process of official regulatory approval by the TGA. However, by citing the AusPAR, the Senator

has focussed specifically on the process of regulatory approval, and it is important that the Senator understand that his statement is without factual basis.

The Senator appears to have misconstrued '*transmission*' to mean a reduction in the chance of a vaccinated person transmitting COVID-19 if they should happen to acquire the infection. These are usually called '*breakthrough*' infections, and there are studies conducted in close-contact settings such as homes, health care settings and prisons which demonstrate a reduction of secondary transmission from vaccinated and infected people. The means by which this occurs is sometimes not clear, but there is evidence that vaccinated people may '*shed*' lower levels of virus when they are infected than do unvaccinated people. However, given that the intent of vaccination is to prevent a person contracting COVID-19 in the first place, this secondary effect, while welcome, is not the main purpose for vaccination- and nor is it the indication approved by the TGA.

The TGA appreciates the opportunity to correct the public record on the matter of COVID-19 vaccines reducing transmission of COVID-19 in the community. The TGA has not made any claims for a direct effect of COVID-19 vaccines in preventing COVID-19 transmission.

Yours sincerely

Professor Anthony Lawler
Health Products Regulation Group

17 April 2024