Australian Government

Department of Health

Ref No: MC21-040338

Dr Judy Wilyman
Ms Serene Teffaha
Mr Mani Shishineh
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Dear Dr Wilyman, Ms Teffaha and Mr Shishineh

Thank you for your correspondence of 8 December 2021 to the Minister for Health and Aged Care, the Hon Greg Hunt MP, concerning COVID-19 vaccine safety. The Minister has asked me to reply on his behalf.

I appreciate that you have very strong and passionate feelings about this topic. I would like to assure you that the Therapeutic Goods Administration's (TGA) focus is to keep Australians as safe as possible from a dangerous and very contagious virus that has killed millions of people globally.

The TGA has comprehensively evaluated each of the provisionally registered COVID-19 vaccines, including Comirnaty (Pfizer), to ensure that they meet Australia's high standards of safety, quality and efficacy. Sponsors are required to submit a wide range of information (including clinical trial data, non-clinical and toxicology studies, and chemistry, risk management and manufacturing information) as part of this process. The TGA also seeks advice from the Advisory Committee on Vaccines (an independent expert committee) before making a regulatory decision.

Prior to provisional registration of these vaccines, an Australian Public Assessment Report (AusPAR) was produced for each product. AusPARs provide transparency of the pre-market registration process and outline the scientific rationale for the TGA's regulatory decisions. They are published on the TGA website at: www.tga.gov.au/australian-public-assessment-reports-prescription-medicines-auspars.

The TGA also has a well-established and robust system in place to capture reports of suspected adverse events for vaccines once they enter the Australian market. Many of these processes have been enhanced dramatically for COVID-19 vaccines, making this the most intense safety monitoring of therapeutic goods ever conducted in Australia.

As part of this system, we receive monthly safety summaries and Periodic Safety Update Reports (PSURs) for all of the provisionally registered COVID-19 vaccines. PSURs provide a comprehensive and critical analysis of new or emerging information on the risks of the product, including global safety data. This enables us to appraise the product's overall benefit-risk profile. Based on our current assessment of this data, the benefit-risk balance of each COVID-19 vaccines remains positive.

It is important to understand how the TGA collects and uses adverse event reports, including reports of deaths. We encourage people to report suspected vaccine side effects, even if there is only a small chance that the vaccine caused them. This helps us identify trends or spikes that might reveal potential safety issues.

As you are aware, the TGA publishes all adverse event reports received in our Database of Adverse Event Notifications (DAEN) in the interests of transparency. The DAEN includes reports from 1 January 1971 up to 14 days prior to the date of access, including all other reports we have received in relation to COVID-19 vaccines during that time period. Importantly, the raw number of reports in our database cannot be used to accurately assess safety. This information is prominently displayed in the disclaimer that users must agree to before they search the database.

To 12 December 2021, more than 40 million doses of COVID-19 vaccines have been administered in Australia. Large scale vaccination means that coincidentally some people will experience a new illness or die within a few days or weeks of vaccination. Furthermore, a large proportion of the adverse events reported to the TGA following vaccination against COVID-19 are for expected and transient vaccine adverse events, such as pain at the injection site, body aches, fever and headache.

TGA staff with expertise in medicine, biostatistics and epidemiology undertake analyses of adverse event report data to detect signals for possible safety concerns. Investigations of safety signals aim to distinguish between coincidental events and adverse events that may be caused by the vaccines. If we find that a vaccine causes an adverse event, we take action and ensure that the information is available to the public. For COVID-19 vaccines, that includes putting the latest information in our weekly safety report at: www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report.

I hope this information has been helpful.

Yours sincerely

Elspeth Kay
Assistant Secretary
Pharmacovigilance Branch
Health Products Regulation Group
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