Australian Government

Department of Health and Aged Care

Ref No: MC23-000493

Ms Emma McArthur
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Dear McArthur

Thank you for your correspondence of 04 January 2023 to the Minister for Health and Aged Care, the Hon Mark Butler MP regarding COVID-19 vaccine rollout and the safety of the vaccine. The Minister has asked me to reply.

The COVID-19 vaccine rollout is one of the single largest logistical operations this country has ever seen. This is, and continues to be, an expanding rollout with an increasing number of points of presence receiving deliveries of vaccines to support Australia's COVID-19 vaccine roll out.

The Commonwealth has in place contracts with logistic providers to operate a logistics and distribution network that will enable the efficient and secure acceptance, storage, management, monitoring and transport of vaccines to all Australians, including the delivery of vaccines and ancillary consumables necessary for the administration of COVID-19 vaccines. The goal is to protect all people in Australia from the harm caused COVID-19 infection, through preventing serious illness and death, and where possible, disease transmission.

You have asked whether the statements about the COVID-19 vaccine rollout being a clinical trial that were made by the former Minister of Health are factually correct. I would like to clarify that the use of the provisionally approved COVID-19 vaccines under the national rollout are not considered to be an extension of the clinical trials used to support the provisional registration of these vaccines. However, post-market surveillance data gathered from the real-world use of these vaccines continues to provide reassurance about their longer-term safety and efficacy.

As background, due to the urgent nature of the COVID-19 pandemic, all COVID-19 vaccines available for use and supply in Australia have been approved via the provisional approval pathway. Other countries have made COVID-19 vaccines available under ‘Emergency Use Authorisations’, which are based on the potential risks, benefits and uncertainties of the vaccine in the context of the prevailing COVID-19 situation in those countries. Temporary EUAs are different to regulatory approval pathways, such as the provisional registration pathway being used in Australia, which has enabled broader marketing authorisation and access.

I can assure you that even though the decision to provisionally approve these vaccines was made on the basis of short-term efficacy and safety data, the data submitted to the Therapeutic Goods Administration (TGA) to support the quality, safety and efficacy of the

COVID-19 vaccines showed a positive benefit-risk ratio. Waiting for data to establish the duration of protection would not have allowed these vaccines to have been available.

As part of the provisional approval, sponsors are required to continue to submit longer-term evidence to the TGA. As this implies, studies are continuing to gather data on longer-term safety and effectiveness to complement post-market monitoring and spontaneous adverse event data. It is anticipated that these will be completed by mid-2024.

Individuals who have been vaccinated can be assured that the TGA has robust procedures in place to detect and investigate signals for possible safety concerns. This involves working closely with international regulators, state and territory public health authorities, and health care professionals to continuously assess the ongoing safety of COVID-19 vaccines available in Australia.

If a safety concern is detected, rapid action will be taken to address the safety issue and promptly provide information to the public. The TGA also undertakes an independent quality assessment of every batch of vaccine supplied in Australia to ensure it meets strict quality standard. Post-market surveillance data on global real-world use of COVID-19 vaccines continue to provide reassurance about their longer-term safety. This is supported by reviews of safety data by international medicines regulators in countries with extensive COVID-19 vaccine experience.

Thank you for writing on this matter.

Yours sincerely

Radha Khiani

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