Australian Government
Department of Health

Deputy Secretary

Elizabeth Hart
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Dear Ms Hart

Re: Could COVID-19 vaccines facilitate the evolution of more virulent variants?

Thank you for your email to Adjunct Professor Skerritt, dated 6 July 2021, in which you ask whether COVID-19 vaccines could potentially facilitate the evolution of more virulent variants. I understand you also contacted the TGA on 1 February 2021 regarding this matter, and again on 21 March 2021. I apologise for the delay in responding.

Firstly, before a COVID-19 vaccine can be provisionally registered in Australia, the TGA must establish the acceptable safety, quality and efficacy of the vaccine based on the available data, which includes clinical studies, non-clinical and toxicology studies, as well as chemistry and manufacturing information. I would like to emphasise that no part of this comprehensive process has been rushed, and no data overlooked.

To date, the primary focus of COVID-19 research and development globally has been to develop vaccines that are highly effective at reducing the priority health outcomes of severe disease, hospitalisation and death. Pleasingly, evidence also continues to emerge on the effectiveness of vaccines in reducing asymptomatic disease and transmission.

All viruses are expected to naturally mutate over time and there is no credible scientific evidence to suggest that vaccination drives the evolution of variants. Indeed, widespread uptake of vaccination is critical to control the circulating virus in the community and therefore minimise the opportunity for the virus to mutate.

COVID-19 vaccines induce broad immune responses, which are expected to confer some protection against new variants, and therefore widespread vaccination is expected to mitigate the potential risk of new emerging variants. In a scenario of

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increased virulence, unvaccinated individuals would likely be adversely impacted compared to vaccinated individuals. Therefore, the vaccination of as many people as possible remains a priority for the Australian Government. Additionally, achieving herd immunity will help to protect those who cannot be vaccinated due to medical reasons.

Ongoing assessment of vaccine safety is an integral part of the provisional registration process, and the TGA has also enhanced its normal post-market surveillance activities for COVID-19 vaccines. Once vaccines have received provisional registration their safety is continuously monitored, as is the effectiveness of the vaccine against the circulating strains. The TGA continues to work closely with other international regulators, public health authorities and health care professionals to continuously assess the ongoing safety of COVID-19 vaccines available on the Australian market to ensure that the benefits of the vaccine continue to outweigh the risks.

If the TGA detects a safety concern or reduced effectiveness, rapid action will be taken to address the safety issue and promptly provide information to the public.

Yours sincerely

Tracey Duffy
A/g Deputy Secretary
Health Products Regulation Group

14 July 2021