PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health

Senate Select Committee on COVID-19

Inquiry into Australian Government's response to the COVID-19 pandemic

29 January 2021

PDR Number: IQ21-000003

Consequences if vaccine does not achieve herd immunity

Written

Senator: Rachel Siewert

Question:
What are the health consequences if the vaccine rollout does not achieve herd immunity?

Answer:
The vaccines that Australia has advance purchase agreements with have all demonstrated that they are highly effective in preventing severe COVID-19.

Vaccination against COVID-19 will therefore not only prevent severe illness and save lives; it will limit pressure on the services critical to the functioning of society, effected through hospitalisation, serious ongoing health conditions, or even death.

Achieving community protection through immunisation would see people connecting with family and friends, transitioning back to their workplaces and other vital components to improving the lives of many Australians. The goal of the Australian Government is to have as high an uptake of the vaccine as possible.

Determining herd immunity, the indirect protection from COVID-19 provided either by natural infection with the virus that causes COVID-19, or by receiving a COVID-19 vaccine, will depend on a range of factors.

At this stage, there is insufficient data to determine at what level the vaccines will limit community transmission to support the long-term goal of herd immunity.

Preliminary results of a new study investigating the efficacy of the AstraZeneca/Oxford vaccine (made available online in preprint on 1 February 2021) showed a 67% reduction in Polymerase Chain Reaction (PCR) positive test results for the virus that causes COVID-19 after a single standard dose of the vaccine, suggesting the potential for a substantial reduction in transmission.

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Department of Health

Senate Select Committee on COVID-19

Inquiry into Australian Government's response to the COVID-19 pandemic

Written Question on Notice, 29 January 2021

PDR Number: IQ21-000022

Collection and use data on vaccination effectiveness in Australia

Written

Senator: Rachel Siewert

Question:
How will the Government collect and use data on vaccination effectiveness, including adverse events, for each vaccine distributed in Australia?

Answer:
Following provisional approval, the Therapeutic Goods Administration (TGA) will continue to closely monitor the safety and effectiveness of COVID-19 vaccines.

The TGA collects and assesses detailed information about vaccine safety and effectiveness by:

- requiring pharmaceutical companies to submit results of ongoing and planned safety and efficacy studies as a condition of approval
- requiring pharmaceutical companies to report serious adverse events (which include lack of effectiveness) and significant safety issues (which include effectiveness concerns occurring in or outside Australia that may have implications for public health) within mandated timeframes
- requiring pharmaceutical companies to submit monthly summaries of worldwide safety data and regular risk-benefit analyses
- working closely with international regulators to assess significant safety and effectiveness concerns detected overseas
- reviewing medical and scientific literature
- collecting reports of suspected adverse events occurring in Australia that are submitted by health professionals and consumers, which may include suspected instances of lack of effectiveness. Adverse event reports that the TGA receives are entered into the TGA Adverse Event Management System.

In addition the TGA will receive reports on effectiveness from overseas countries that are currently vaccinating significant numbers of individuals.

All of this information is used daily by TGA's clinical and safety experts to help identify, analyse and investigate safety signals. A safety signal is a 'flag' for a possible safety concern. When the TGA identifies a signal, it undertakes a detailed evaluation to establish the possible role of the vaccine in causing the adverse event.

If the TGA identifies a significant safety or effectiveness concern, it will be rapidly responded to. Depending on the situation this might include requiring new warnings or instructions for use to be included in the Product Information for the vaccine, requiring changes to labelling or packaging, providing alerts to health professionals and consumers, and in extreme cases a recall or removing the vaccine from the market.

The Australian Technical Advisory Group on Immunisation (ATAGI) COVID-19 Working Group provides advice to the Minister for Health on the immunisation program for COVID-19 vaccines as they become available in Australia.

ATAGI is providing advice to Government on the effective and equitable use of COVID-19 vaccines available in Australia, as directed by the Department of Health.

ATAGI will continue to monitor all vaccine candidates as further clinical trial data becomes available, may update its advice taking into account new public health, medical, and epidemiological data.

The Department of Health is providing modelling for the evaluation of different vaccination strategies on health outcomes such as disease severity, and transmission if there was another COVID-19 outbreak. ATAGI is providing direction on the scenarios to be modelled and receives weekly updates on progress through its working groups.

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Department of Health

Senate Select Committee on COVID-19

Inquiry into Australian Government's response to the COVID-19 pandemic

Written Question on Notice, 29 January 2021

PDR Number: IQ21-000028

Tracking vaccines at every stage in their journey

Written

Senator: Rachel Siewert

Question:
In QON SQ20-000612, the Department said that they are engaging software and data specialists to ensure vaccines can be tracked at every stage in their journey - from manufacture to post-immunisation. Where is this work up to? What systems are being developed and who will be responsible for monitoring this information?

Answer:
The Department of Health engaged Accenture in December 2020 to design, develop and implement the Vaccine Data Solution (VDS).

The Vaccine Data Solution (VDS) supports reporting and operational management of COVID-19 vaccines. This includes where doses are throughout the supply chain, from entry to Australia to the point of vaccination. The VDS incorporates data from:

- logistics providers, DHL and Linfox, for the supply chain component; and
- the Australian Immunisation Register (AIR) for immunisation administration data.

The VDS is in place and supporting operations of the program. It is being enhanced to support the rollout as it progresses.