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

Spoken Question on Notice, 28 January 2021

PDR Number: IQ21-000001

Countries that have done formal regulatory approval:

Spoken

Hansard Page number: 18

Senator: Katy Gallagher

Question:
CHAIR: Are we at the front of the queue of countries who are going through normal regulatory processes? I'm trying to understand the Prime Minister's and the health minister's public comment. It's very important that we are factually correct and truthful to the Australian people. We were told that we were at the front of the queue and that we would be amongst the first in the world to receive a vaccine. Approximately 70 million people have received the vaccine. Both those facts—61 countries running a program and 70 million people having the vaccine—don't seem to line up with the comments that our health minister and our Prime Minister have told the Australian people.
Dr Murphy: As I said, I think we are as advanced as we could possibly be with our regulatory process. New Zealand is a very similar country, and we're starting our vaccination before them. They haven't finished their regulatory process. I would have to take on notice which of those countries have done formal regulatory approval, but I'm not sure that they're all as high quality and rigorous as Professor Skerritt's processes are.
CHAIR: So we're at the front of a queue of two—Australia and New Zealand?
Dr Murphy: I didn't say that. I'm just saying that we are as advanced as we can be, given our commitment to doing the full safety and regulatory process.

Answer:

- Australia is one of the only countries in the world to have issued a formal regulatory approval for the Pfizer COVID-19 vaccine and AstraZeneca COVID-19 vaccine (see table 1, below) and this approach of formal approval will be followed for other COVID-19 vaccine candidates, if they are submitted to the Therapeutic Goods Administration (TGA).

- Two comparable jurisdictions issued conditional regulatory approvals for the Pfizer vaccine prior to Australia's provisional approval on 25 January 2021 - the European Union (21 December 2020) and Switzerland (19 December 2020).

- One comparable jurisdiction issued conditional regulatory approval for the AstraZeneca vaccine prior to Australia's provisional approval on 16 February 2021 - the European Union (29 January 2021).

- Some other countries, e.g. Middle Eastern and South American countries that are not considered comparable overseas regulators, have also provided conditional or emergency use authorisations for the Pfizer and other vaccines.

- To date, most access to COVID-19 vaccines in comparable countries (including the Pfizer, Moderna and AstraZeneca candidates) has been under temporary emergency use authorisations (EUAs) which remain in place in the United States, the United Kingdom, Canada and Singapore.

- EUAs are not the same as regulatory approval, and have been made in response to the very high COVID-19 disease burden and risk in those countries. In these cases, the potential benefits of early access are balanced with risks associated with the uncertainties of not having evaluated a full regulatory data set on safety, quality and effectiveness.

- Most jurisdictions that are using EUAs are continuing a formal review of the vaccines with the aim of achieving regulatory approval to support ongoing vaccination.

Table 1 – Regulatory status of COVID-19 vaccines in comparable overseas jurisdictions

Formal Regulatory Approval					
	Pfizer	**AstraZeneca**	**Moderna**	**Novavax**	**Janssen**
Australia	✓	✓		Provisional designation - Awaiting application	Provisional designation - Under rolling review
European Union	✓	✓	✓		
Switzerland	✓				
Temporary Emergency Use Authorisations					
United States	✓		✓		
United Kingdom	✓	✓	✓		
Canada	✓		✓		
Singapore	✓				

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Department of Health

Senate Select Committee on COVID-19

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

Spoken Question on Notice, 28 January 2021

PDR Number: IQ21-000006

Planning scenario of expected timeline to supply vaccine to four million people:

Spoken

Hansard Page number: 22

Senator: Katy Gallagher

Question:

Ms Peisley: We had a scenario where we were looking at four million people by March. That didn't seem to be possible for reasons outside our control. We're saying it might be in April before we meet that benchmark and we will hope to ramp up. We can provide it on notice but these are planning purposes only.

Answer:
As of 28 January 2021, the modelling indicated that over the weeks to 31 March 2021 the Department of Health anticipated 4 million Australians will have received their first vaccination. This estimate was indicative and subject to global uncertainty.