From: s47E(d)

 Sent:
 Tuesday, 3 January 2023 2:27 PM

 To:
 News; s22
 s47E(d)

Cc: GARRETT, Trish; DE TOCA, Lucas

Subject: RE: MEDIA ENQUIRY - Moderna vaccine, and advisory on the vaccine finder Health Direct

website. The Guardian Deadline 3.30pm [SEC=OFFICIAL]

Good afternoon \$22

Please find below a response to the questions provided as cleared by Trish and Lucas. Please reach out if you need anything further.

Why are the Moderna (6-11 years)' and 'Moderna (12 years +)' vaccine types no longer available in Australia? Is it because they have been replaced in the rollout by the bivalent models?

- The Australian Government advises that the Moderna (original) COVID-19 vaccine is no longer being manufactured.
 - This vaccine is being replaced by increased production and availability of the Moderna bivalent COVID-19 vaccine.
 - Children aged 6 months to under 5 years who have an increased risk of getting very sick from COVID-19 will still be able to access the Moderna (original) paediatric COVID-19 vaccine as part of a primary schedule until May 2023.

What cohort or age groups are currently eligible for the bivalent Moderna vaccine?

• The Moderna bivalent (ancestral/BA.1) vaccine is provisionally approved in Australia by the TGA for use as a booster dose for people 18 years and over.

Health Direct says the Moderna bivalent is currently available for those 18+ as a booster. Is it expected that the bivalent vaccine will be available for people under 18? And if so, when?

- The Moderna bivalent vaccine is not currently provisionally approved by the TGA for use other than as a booster dose for people aged 18 years and over.
 - For the Moderna bivalent vaccine to be available to people under 18 years of age, Moderna would need to submit an application to the TGA for assessment and provisional approval.
 - o If approved, ATAGI would then consider the available evidence to make recommendations to the Minister for Health and Aged Care on the vaccine's use in the national COVID-19 vaccine program.
 - Finally, if the Minister accepted the advice, the vaccine could then become available as part of the vaccine program.

On the current availability, people aged between 5 and 18 do not seem eligible for any Moderna vaccine. What vaccine should children seek?

- The last deliveries for the Moderna (ancestral, or original) vaccine to administration sites occurred in late November. Based on shelf-life, the Moderna (ancestral, or original) vaccine is no longer available for routine administration in Australia.
 - Children aged 6 months to under 5 years who have an increased risk of getting very sick from COVID-19 will still be able to access the Moderna (original) paediatric COVID-19 vaccine as part of a primary schedule until May 2023.
 - The Pfizer vaccines remain available for people under 18 years of age (for primary courses and boosters). The ancestral and bivalent formulations of Pfizer are also available for people 18 years and over.
 - Novavax is available for people 12 years and over and AstraZeneca for people 18 years and over, both can be used for primary courses and boosters, for individuals for whom an mRNA vaccine is not suitable.

Can you confirm explicitly that Moderna vaccines <u>are still available</u> in Australia? And that it has not been, as claimed by some critics of the vaccine rollout, "quietly pulled... from the market"?

- The Moderna COVID-19 vaccine continues to be widely available across Australia.
 - o 15 million Moderna doses, **including variant specific vaccines**, were delivered in 2022.
 - This includes all currently available formulations of the Moderna COVID-19 vaccine that have been <u>provisionally approved by the Therapeutic Goods Administration</u> for use in Australia.
- Currently available Moderna vaccines are:
 - Moderna <u>Spikevax (elasomeran)</u>
 - 6 months to less than 6 years (6 months to 5 years) 25 micrograms of elasomeran in 0.25 ml vial
 - Moderna <u>Spikevax Bivalent Original/Omicron BA.1 vaccine (elasomeran/imelasomeran)</u> 25 micrograms of elasomeran and 25 micrograms of imelasomeran in 0.5 ml vial.
 - The Moderna bivalent (ancestral/BA.1) vaccine is provisionally approved in Australia by the TGA for use as a booster dose for people 18 years and over.

Kind regards,

s22

A/g Executive Assistant to Dr Lucas de Toca, First Assistant Secretary

National COVID-19 Vaccine Taskforce, Department of Health and Aged Care.

T: 02 6289s22 | Scarborough House

We acknowledge the traditional owners of country throughout Australia, and ther continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: News <news@health.gov.au>
Sent: Tuesday, 3 January 2023 11:33 AM

To: s22 @Health.gov.au>; s47E(d) ; s22

s22 @Health.gov.au>,s47E(d) @Health.gov.au>

Cc: GARRETT, Trish <Trish.Garrett@health.gov.au>; DE TOCA, Lucas <Lucas.DeToca@health.gov.au>; News <news@health.gov.au>

Subject: MEDIA ENQUIRY - Moderna vaccine, and advisory on the vaccine finder Health Direct website. The Guardian Deadline 3.30pm [SEC=OFFICIAL]

Hi team,

Please see media request from The Guardian below in relation to advisory on Moderna vaccine, and an advisory on the vaccine finder Health Direct website that "The 'Moderna (6-11 years)' and 'Moderna (12 years +)' vaccine types will no longer be available in Australia from mid-December 2022".

Note: journalist reiterated in our discussion that the wording was confusion as did s22 from the MO when approving response.

During the holidays our response to similar questions was:

The Moderna COVID-19 vaccine continues to be widely available across Australia.

15 million Moderna doses, including variant specific vaccines, were delivered in 2022.

This includes all currently available formulations of the Moderna COVID-19 vaccine that have been <u>provisionally approved by the Therapeutic Goods Administration</u> for use in Australia.

Variant-specific versions includes:

- Moderna Spikevax (elasomeran)
 - 6 months to less than 6 years (6 months to 5 years) 25 micrograms of elasomeran in 0.25 ml vial

12 years and older - 100 micrograms of elasomeran in 0.5 ml vial

Moderna Spikevax Bivalent Original/Omicron BA.1 vaccine (elasomeran/imelasomeran) - 25 micrograms of elasomeran and 25 micrograms of imelasomeran in 0.5 ml vial.

Follow-up response:

- The Moderna (ancestral, or original vaccine) vaccine remains provisionally approved by the TGA for people 6 vears and over.
- Manufacturing of this vaccine is not continuing as the focus is now on bivalent and variant-specific vaccines.
- The Moderna bivalent (ancestral/BA.1) vaccine is provisionally approved in Australia by the TGA for use as a booster dose for people 18 years and over.
- This vaccine is widely available across thousands of locations throughout Australia
- The Moderna vaccine for people 6 months to 5 years of age is also widely available in Australia.
- The last deliveries for the Moderna (ancestral, or original) vaccine to administration sites occurred in late November. Based on shelf-life, the Moderna (ancestral, or original) vaccine is no longer available for routine administration in Australia.
 - The Pfizer vaccines remain available for people under 18 years of age (for primary courses and boosters). The ancestral and bivalent formulations of Pfizer are also available for people 18 years and over.
 - Novavax is available for people 12 years and over and AstraZeneca for people 18 years and over, both can be used for primary courses and boosters, for individuals for whom an mRNA vaccine is not suitable.

Thanks,

s22

s22

Media Unit

Australian Government, Department of Health and Aged Care

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Unless stated otherwise, this information is provided on a background basis and should not be attributed.

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

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