Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advisory Committee on Vaccines

Meeting Statement 37 – Wednesday 7 September 2022

Section A: Submissions for registration

The committee provided advice on 3 submissions:

- Variation to include booster dose for individuals from 5 to less than 12 years of age for Comirnaty, which has provisional registration for active immunisation to prevent COVID-19 (active ingredient tozinameran; sponsor Pfizer Australia Pty Ltd)
- Extension of indication of primary series to individuals 6 months to 5 years of age, and new strength, for Comirnaty, which has provisional registration for active immunisation to prevent COVID-19 (active ingredient tozinameran; sponsor Pfizer Australia Pty Ltd)
- Change to a vaccine's dosing recommendations (a major variation).

Details of the ACV advice associated with these premarket items has been or will be released within the Australian Public Assessment Report (AusPAR). To browse all AusPARs see AusPAR search.

Section B: Safety

The committee was not asked to provide advice on any safety matter.

Section C: Other items for advice

The ACV was asked to provide advice on the clinical data requirement for influenza vaccine strain update if there is a change in the composition of influenza vaccines.

Quadrivalent seasonal influenza vaccines contain antigens from 4 strains of the influenza virus: two A strains (H1N1, H3N2) and two B strains (Victoria and Yamagata lineage).

Substantially reduced or nil circulation of B Yamagata lineage virus has been observed globally for the last 2 years, raising the possibility that this virus lineage may/has become extinct. In the future it is possible that quadrivalent formulations could change to remove the B Yamagata and add another A strain.

The ACV noted that the significance of such a change is not well understood at this time and suggested that the following 2 questions be explored.

1. Is the change in vaccine composition likely to change any significant process in the manufacture of the vaccine?
2. Is there likely to be any change in immunogenicity or reactogenicity?

At this stage the ACV advised that it was not in a position to provide advice on the implications of a change in seasonal influenza vaccine away from the now-established composition of two influenza A strains (H1N1 and H3N2) and two influenza B strains. The committee would need additional information before providing detailed advice on the clinical immunogenicity and safety data requirement for any potential vaccine strain change.

Further information

For further information on the ACV, please visit Advisory Committee on Vaccines

or contact the ACV by email ACV@health.gov.au.