Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Vaccines

Meeting Statement 27 – Wednesday 1 December 2021

Section A: Submissions for registration

The committee provided advice on: one application for a new vaccine; one application for an extension of indication, new strength and new formulation for a vaccine with provisional registration; and one application for major variation (dosage) and changes to the Product Information for a vaccine with provisional registration.

Further details of the ACV discussion and advice associated with these pre-market items may be released within the Australian Public Assessment Report (AusPAR). Please note that there is a delay between when an application is considered by the ACV and the publication of the AusPAR. To browse all AusPARs see AusPAR search.

Section B: Safety

Zostavax and disseminated varicella zoster virus (Oka vaccine strain) infection

The ACV previously provided advice on Zostavax and disseminated varicella zoster virus infection on 2 August 2017 (Meeting 3) and 30 September 2020 (Meeting 16).

Zostavax is a vaccine that contains live virus, the Oka/Merck strain of varicella-zoster virus.

The vaccine is used for the prevention of herpes zoster (shingles) in individuals 50 years of age and older, and for the prevention of postherpetic neuralgia and for reduction of acute and chronic zoster-associated pain in individuals 60 years of age and older.

Disseminated varicella zoster disease due to infection with Oka/Merck strain is an important risk with Zostavax in people with compromised immune function. The Product Information for Zostavax advises that immunisation is contraindicated in patients who may be without adequate immune function due to deficiency or suppression.

The ACV noted risk minimisation actions implemented since April 2021:

- a boxed warning in the Australian Product Information and the Consumer Medicine Information documents
- a 'Dear Healthcare Professional' letter
- a safety alert on the TGA website
- a patient alert card for distribution at the time of vaccination
- warning stickers to be placed on the refrigerator where the vaccine is stored.

The ACV advised that current risk mitigation activities do not appear adequate, as there is evidence of ongoing inadvertent administration to immunocompromised individuals. 'Near-misses' of inappropriate administration were also likely underreported to regulatory bodies.

However, benefits in preventing herpes zoster, including severe cases, still appear to outweigh risks of disseminated zoster infection with the vaccine strain.

The ACV supported inclusion of warning labels on vaccine boxes and vial labels, though acknowledged the risk mitigation measures introduced in the last 6 months may not yet be fully effective, both due to the short timeframe and the marked decline in utilisation of Zostavax as the catch-up program under the National Immunisation Program progresses.

The ACV acknowledged that the main area of difficulty is not a lack of awareness that this live-attenuated vaccine should not be given to immunocompromised persons, but the difficulty surrounding the assessment and definition of 'immunocompromise'. The ACV supported the notion that the default position in the face of any uncertainty should be to not administer the vaccine.

The ACV noted that simplification of clinical criteria and clinical guidance from ATAGI may assist in the decision to identify an immunocompromised person who should not be vaccinated.

The ACV noted that the public health issue is prevention of the harms of shingles, and a wider strategy should inform any actions considered for any particular vaccine and its place in prevention of shingles.

Further information

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

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