Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Vaccines

Meeting Statement 3 – Wednesday 2 August 2017

Section A: Submissions for registration

The committee's advice was sought on one application for a new vaccine containing a new biological entity. The committee provided advice on a range of issues.

Further details of the ACV discussion and advice associated with this pre-market item will 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

Two pharmacovigilance items were referred to the ACV for its advice.

Influenza vaccines and anaphylaxis reports, 2016 and 2017

The TGA had received a higher than expected number of adverse events following immunisation (AEFI) in 2017 that had been coded as the adverse event 'anaphylaxis'. These included reports where early use of adrenaline (epinephrine) may have prevented the development of full blown anaphylaxis or where limited information on symptoms was provided. The TGA sought advice from the committee on how best to ensure that only true cases of anaphylaxis, rather than other conditions, were coded as such in the database of adverse event notifications.

The ACV advised that accurate terminology is important when assessing anaphylaxis cases. For example, a vasovagal episode (faint) is common after vaccine administration but is not a hypersensitivity reaction, even if adrenaline (epinephrine) is administered. The committee noted that the Brighton Collaboration Criteria should be used in the classification of anaphylaxis.

The ACV noted that egg allergy would be unlikely to increase the risk of anaphylaxis after influenza vaccine. The egg content (ovalbumin) in the currently available influenza vaccines is below that generally required to elicit an anaphylactic reaction.

The ACV advised that AEFI surveillance stratified according to vaccine brand and demonstration of differential rates of adverse reactions (if any) is important. An anaphylaxis/severe hypersensitivity reaction could be due to an excipient, including preservative, as well as the antigen.

ZOSTAVAX and disseminated herpes zoster following immunisation

ZOSTAVAX is a live virus vaccine indicated 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.

The committee considered five additional reports received by the TGA since April 2017 where ZOSTAVAX vaccine has been given to potentially immunocompromised people.

Two cases have resulted in serious disseminated disease and/or life-threatening adverse events.

There have been a higher number of serious adverse events to ZOSTAVAX in Australia compared with the USA, where the vaccine has been available for a longer period of time.

The ACV noted various actions that have been taken: an alert to general practitioners; revision of the Australian Immunisation Handbook; an NHMRC fact sheet.

The committee suggested additional activities to prevent the use of ZOSTAVAX in immunocompromised people: education of healthcare practitioners; patient education; 'pop-up' alerts in prescribing software; and checklists. Relevant clinical history extended to two years prior to the proposed vaccination with ZOSTAVAX.

The ACV noted that there may need to be revision of what the 'safe' dose of methotrexate is with regards to vaccination with ZOSTAVAX.

Section C: Immunisation Programs

Continuing from the previous meeting, the committee was asked to provide further advice on pathways for notification and investigation of serious adverse events following immunisation.

Further information

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

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