Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Vaccines

Meeting Statement 8 – Wednesday 30 May 2018

Section A: Submissions for registration

The committee's advice was sought on one application, to register a new vaccine. 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

The committee provided advice on one safety issue.

Pregnancy Categorisation of inactivated influenza vaccines

The ACV was asked to provide advice in relation to the pregnancy categorisation of influenza vaccines supplied in Australia.

Influenza vaccines change from year to year. The TGA has published information on the 2018 seasonal influenza vaccines.

The Australian categorisation system for prescribing medicines in pregnancy is directed to health professionals prescribing medicines, including vaccines, to pregnant women. The pregnancy category is usually included in the Product Information (PI) for a vaccine or medicine under the heading 'precautions'. Due to legal considerations in Australia, sponsor companies can apply a more restrictive category than can be justified on the basis of the available data.

The ACV noted that The Australian Immunisation Handbook 10th Edition (AIH) states:

> (4.7.8) Influenza vaccination is recommended for pregnant women and is safe to administer during any stage of pregnancy or while breast-feeding, *despite the product information for influenza vaccines listing pregnancy as a precaution* [emphasis added].

The ACV noted that the Office of Health Protection had proposed that the possibility of aligning the current Use in Pregnancy Categorisations of individual inactivated influenza vaccines be reviewed.

The ACV noted:

- spontaneous reporting of suspected adverse events following vaccination underestimates the incidence of such events. Notwithstanding this, routine pharmacovigilance remains very important for vaccines in all pregnancy categories

- data from product-specific, randomised controlled trials in pregnant women are scarce
- while the composition of the influenza vaccines changes each season, the pregnancy category needs to reflect accumulated experience
- Australian Technical Advisory Group on Immunisation (ATAGI) position that 'The body of evidence supports influenza vaccination during pregnancy'.

The ACV considered the following information:

- a report of a systematic review of the literature
- a review of the spontaneous reporting in Australia of adverse events following vaccination of pregnant women with inactivated influenza vaccines
- details of the extent of documented vaccination of pregnant women in Australia, provided by several states and territories
- information submitted to the TGA by several sponsors of inactivated influenza vaccines.

The ACV provided advice regarding Australian and international experience with trivalent influenza vaccines (TIVs), quadrivalent influenza vaccines (QIVs), pandemic inactivated influenza vaccines, and the labelling of inactivated influenza vaccines currently approved for use in men and women aged 65 years of age and older.

The ACV advised the adoption of Australian Pregnancy Category A should be considered by sponsors for certain inactivated influenza vaccines, reflecting the following points.

- Given the very large numbers of adult doses of TIVs distributed in the past, it is probable that substantial numbers of Australian pregnant women have been exposed to each vaccine with no signal of adverse pregnancy outcomes.
- The higher antigen dose with QIVs compared to TIVs (60 microgram vs 45 microgram) and the availability for QIV for only three completed influenza seasons means that there is less experience for QIVs than TIVs. Nonetheless, there has been substantial recent documented use of QIVs in pregnant women in Australia.
- Data to support the extrapolation to pandemic influenza vaccines from the experience with seasonal influenza vaccines are sparse. However, in the event of an influenza pandemic, the overall risk benefit would favour vaccination against non-vaccination, including for pregnant women.

The ACV advised that the wording of descriptive text associated with the Pregnancy Category A should provide a positive view of vaccination in the context of the risks of influenza infection.

The ACV noted that it was not meaningful to include a formal Use in Pregnancy category for vaccines indicated for use in women 65 years and over. The ACV supported the use of an alternative statement such as 'Not intended for use in pregnancy' together with available information about the vaccine, without a formal Use in Pregnancy category, for vaccines indicated for use in women 65 years and over.

Section C: Immunisation Programs

No item was on the agenda seeking the committee's advice on the immunisation programs.

Further information

For further information on the ACV, please visit Advisory Committee on Vaccines or contact the ACV by email ACV@health.gov.au.