Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Vaccines

Meeting Statement 13 – Wednesday 3 April 2019

Section A: Submissions for registration

The committee's advice was sought on one application to register a new vaccine and one application seeking to extend the indication for a vaccine.

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

The committee provided advice on two safety issues.

Fontanelle bulging following vaccine administration – vaccines administered at 2, 4 and 6 months of age

The TGA has been monitoring the issue of fontanelle bulging following vaccine administration.

As at March 2019, the TGA held 16 reports of Adverse Events Following Immunisation (AEFI) coded with both a vaccine and the reaction term 'bulging fontanelle'. The earliest report is from 2006, and since then 0-3 reports have been received each year.

There was no evidence clearly associating fontanelle bulging with one specific vaccine, due to the administration of more than one vaccine to 2, 4 and 6 month old infants, as per the National Immunisation Program (NIP) Schedule.

A bulging fontanelle reflects elevated intracranial pressure or volume in infants with open cranial sutures (which typically close around 5-7 months of age but can persist up to 12 to 24 months of age). Urgent medical attention may be required for some causes of bulging fontanelle (e.g. meningitis), however it can also be an incidental finding on physical examination in an otherwise well child.

The ACV advised that there is not sufficient evidence to confirm an association between the administration of vaccinations on the NIP for 2, 4 and 6 month olds and the development of fontanelle bulging.

The background rate of fontanelle bulging in infants unrelated to vaccination is not negligible, and the reporting rate to the TGA of 0-3 cases per year associated with infant vaccines is very low.

The ACV recommended that the TGA request follow-up information from the reporter, where possible to determine how the cases resolved.

The ACV suggested analysis of recent cases in the American Vaccine Adverse Event Reporting System (VAERS). Freedman et al[1] have previously conducted a review of cases of transient bulging fontanelle reported through to 2002 in the VAERS.

The ACV advised that a communication to vaccine providers is not warranted at this time.

Pandemic influenza vaccine and Pregnancy categorisation

The ACV has previously provided advice on Pregnancy categorisation of inactivated influenza vaccines including pandemic influenza vaccine (see ACV meeting statement, Meeting 8, 30 May 2018). At the current meeting the committee advised that Use in pregnancy Category B2 should be retained for the inactivated pandemic influenza vaccine containing aluminium phosphate as adjuvant. The criterion for Category A, that the vaccine has been taken by a large number of pregnant women and women of childbearing age, has not yet been established for the vaccine.

Section C: Immunisation Programs

No matter related to the immunisation programs was discussed.

Further information

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

[1] Freedman SB, Reed J, Burwen DR, Wise RP, Weiss A, Ball R. Transient Bulging Fontanelle After Vaccination: Case Report And Review Of The Vaccine Adverse Event Reporting System. J Pediatr. 2005;147:640-4. Doi 10.1016/J.Jpeds.2005.06.009