Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Vaccines

Meeting Statement 16 – Wednesday 30 September 2020

Section A: Submissions for registration

The committee provided advice on two applications to register new vaccines.

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 matters relating to pharmacovigilance.

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

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.

Two deaths from Oka/Merck strain virus following Zostavax immunisation have been reported to the TGA; see Safety Advisory published March 2017 and Safety Advisory published July 2020. At the time of the ACV meeting, a possible third death from Oka/Merck strain virus following Zostavax immunisation recently reported to the TGA was under investigation. Data from the TGA's Adverse Events Monitoring System database shows that up to June 2020 there were 97 cases of vaccination error reported for Zostavax, including 21 reports of administration of the vaccine to persons with compromised immune function.

The ACV provided advice on whether additional risk minimisation activities suggested by the TGA would adequately further reduce the risk of inappropriate administration to a person with compromised immune function. Such activities could include letters to healthcare providers, a mandatory checklist to screen potential patients for contraindications, prescriber education, a boxed warning on the Product Information document, or additional labelling.

The ACV also advised that a more comprehensive review of all Adverse Events Following Immunisation (AEFI) reports and benefit-risk should be considered, and asked that an update be provided at the next meeting in December.

COVID Vaccine Pharmacovigilance Plan

No specific vaccine was discussed.

The ACV was informed that the Department of Health is developing a COVID Vaccine Pharmacovigilance Plan ('Plan') to prepare the existing national pharmacovigilance system for the registration of vaccines against SARS-CoV-2 infection.

The Plan builds on Australia's already robust passive and active surveillance methodologies, including existing highly effective pharmacovigilance systems at the Department of Health (including the TGA), the National Centre for Immunisation Research and Surveillance (NCIRS), and regional pharmacovigilance centres such as state and territory health departments. The Plan falls under the Australian Government COVID-19 Vaccine and Treatment Strategy.

The Plan focuses on the early detection and investigation of Adverse Events Following Immunisation (AEFI), and timely responses to potential safety signals to minimise negative impacts on both the health of individuals and public confidence in vaccination. The draft Plan addresses potential safety signals in the context of limited baseline safety data relating to novel vaccines and vaccine technologies, expedited vaccine development, and rapid production and delivery.

The ACV provided advice on enhancements to the draft Plan regarding:

- enhanced reporting of Adverse Events Following Immunisation (AEFI)
- enhanced safety signal detection and investigation
- regulatory and programmatic actions
- communications
- collaborations.

Section C: Immunisation Programs

No matter related to 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.