Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Vaccines

Meeting Statement

Meeting 2, Wednesday 31 May 2017

Role of the Advisory Committee on Vaccines (ACV) in the TGA's regulatory decision making process

The ACV is a statutory advisory committee established by the *Therapeutic Goods Regulations 1990*.

The TGA currently has seven statutory advisory committees from which it can obtain independent expert advice on specific scientific and technical matters to aid the TGA's regulatory decision making and other regulatory processes. The ACV provides advice to the TGA on, amongst other things, the safety, quality and efficacy of vaccines, including in relation to pharmacovigilance.

The advice provided by the ACV is an important element in the undertaking of the regulatory functions of the TGA. However, it forms only part of the information that is available to a TGA delegate making a regulatory decision under the *Therapeutic Goods Act 1989*. While appropriate consideration will be given to such advice, it is important to note that neither a TGA delegate nor the TGA is obliged to seek this advice in making a decision or to follow it.

The ACV also provides advice to the Office of Health Protection on post-market monitoring and safe use of vaccines in national immunisation programs.

The purpose of this Meeting Statement is to describe in general terms the matters considered by the committee at each meeting and for it to be available as soon as reasonably practical after the relevant meeting.

Submissions for registration

The sponsoring company of a vaccine is required to submit an application to the TGA, including data that support the quality, safety and efficacy of the product for its intended use. The committee provided advice on a new biological entity and on an extension of indication for an approved vaccine.

Pharmacovigilance

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other vaccine or medicine-related problem. The committee was not asked to provide advice on a pharmacovigilance matter.

Risk Management Plans

A Risk Management Plan (RMP) is a set of pharmacovigilance activities and interventions designed to identify, characterise and manage risks relating to a vaccine. The committee was not asked to provide advice on a RMP.

Immunisation Program

The committee was asked to provide advice on pathways for notification and investigation of serious adverse events following immunisation (AEFI).

The ACV advised that the trigger for a 'serious' AEFI to enter the pathway should be any 'potential signal' that could shake confidence in a national vaccination program and/or a vaccine, and suggested consideration of effective communication and other key enablers for effective responses.

Update on matters where the committee previously provided advice

No relevant publication or vaccine approval has been made that utilised advice previously provided by this committee.

Further information

Meeting statements are made publicly available after each meeting.

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

or contact ACV@health.gov.au.