Role of the Advisory Committee on the Safety of Vaccines (ACSOV) in the TGA’s regulatory decision making process

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

The TGA currently has ten 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 ACSOV provides advice to the TGA and the Office of Health Protection (OHP) on, amongst other things, matters relating to the safety, risk assessment and risk management of vaccines supplied in Australia.

How this statement should be read

The advice provided by the ACSOV is an important element in the undertaking of the regulatory functions of the TGA. However, it forms only one part of the total body of information that is available to, for instance, a TGA delegate making a regulatory decision under the Therapeutic Goods Act 1989 (‘the Act’). Therefore, while appropriate consideration will be given to such advice, it is important to note that neither the TGA nor a TGA delegate is obliged to follow it.

It should also be noted that details of the committee’s advice may not become publicly available for some time after the committee has provided that advice. 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.

Additionally, following publication of this statement, it is most likely that further work will be undertaken by the TGA to investigate, monitor and/or evaluate the vaccines considered by the ACSOV; and this will continue for some time into the future. It is therefore possible that further information about the vaccines will become publicly available at a later time and this will be pursuant to a regulatory decision under the Act being made and following further consultation with the vaccine’s sponsor and/or manufacturer.
Overview of the safety reviews and therapeutic goods referred for advice

The TGA continually monitors therapeutic goods supplied in Australia to ensure their ongoing safety, efficacy and quality. As part of this process, the TGA routinely undertakes safety reviews of therapeutic goods.

At this meeting, there was no safety review referred to the committee for its advice.

Risk Management Plans (RMP)

A Risk Management Plan (RMP) is a set of pharmacovigilance activities and interventions designed to identify, characterise and manage risks relating to a medicine or a vaccine. At this meeting, the committee's advice was sought on two RMPs for vaccines with proposed indications relating to vaccination against an infectious disease.

The committee was asked to provide advice on matters including:

- the need for additional risk minimisation activities, namely educational materials to inform healthcare practitioners about the indications, contraindications and safety concerns associated with the vaccines
- the need to conduct additional pharmacovigilance activities, in particular an activity designed to investigate and evaluate the likely degree of off-label use of the vaccines
- the need for additional risk minimisation activities or other measures to mitigate the risk of confusion between the vaccine/s and other currently marketed vaccines.

The committee's advice will shortly be provided to the TGA for consideration as part of the TGA's regulatory decision making processes.

Following complete assessment of the application, information on the RMP evaluation will be included in the Australian Public Assessment Reports (AusPAR), which is published on the TGA website once it is finalised.

Immunisation Program advice

2016 Influenza Season Vaccine Safety Surveillance – review of the Influenza Vaccine Safety Plan (2015-2016) for extension of the program to Aboriginal and/or Torres Strait Islander children under five years of age

At its December 2014 meeting the ACSOV provided advice on the Vaccine Safety Plan (VSP) to extend the National Immunisation Program (NIP) to include trivalent influenza vaccination (TIV) for Aboriginal and/or Torres Strait Islander children aged 6 months to less than 5 years of age.

The VSP included two active surveillance components and the committee noted that in 2016, two quadrivalent influenza vaccines (QIV) will be provided under the NIP.

The committee provided advice on the effectiveness of the VSP in monitoring influenza vaccine safety in 2015 and noted that although adverse events had been reported, no safety concerns had been raised from the active surveillance component of the VSP.

The committee agreed that the execution of the VSP could be considered to have been effective regarding the administration under the NIP of the TIV to Aboriginal and/or Torres Strait Islander children aged 6 months to less than 5 years. It was also noted that work of this type provided confidence to consumers regarding vaccine safety.
Following minor amendment, the committee noted the proposed VSP for the 2016 influenza season was substantially based on the 2015 VSP. The committee agreed that the VSP under the NIP for the administration of QIVs to Aboriginal and/or Torres Strait Islander children aged 6 months to less than 5 years should be put into effect.

**Further information**

Meeting statements are made publicly available after each meeting.

For further information on the ACSOV, please visit the [ACSOV webpage](#) or contact the ACSOV Secretary: Mr Craig Davies on 02 6232 8641 (telephone) or via email: acsov@tga.gov.au