Australian Government

Department of Health

Therapeutic Goods Administration

Advisory Committee on Prescription Medicines

Meeting Statement

Meeting 308, Friday 5 February 2016

Role of the Advisory Committee on Prescription Medicines in the TGA's regulatory decision making process

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

The TGA currently has eleven 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 ACPM provides advice to the TGA on, amongst other things, matters relating to the inclusion, variation or retention of prescription medicines on the Australian Register of Therapeutic Goods.

The advice provided by the ACPM 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, for instance, a TGA delegate making a regulatory decision under the Therapeutic Goods Act. 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 follow it.

It should also be noted that information about advice provided by the committee may not become publicly available for some time after a 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.

Overview of the therapeutic goods referred for advice

At this meeting, the committee's advice was sought on 10 applications before the TGA, including: four for a new chemical entity; one seeking a new generic medicine; three seeking extensions of indications; one application seeking extension of indications with a new strength; and one application for multiple major variations.

Sub-committee update (Pharmaceutical Subcommittee)

No updates

Update on matters where the Committee previously provided advice and a TGA decision has been made

An Australian Public Assessment Report for prescription medicines (AusPAR) provides information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application. For more information about AusPARs see: https://www.tga.gov.au/australian-public-assessment-reports-prescription-medicines-auspars

To browse all AusPARs see: https://www.tga.gov.au/browse-auspars-active-ingredient

The ACPM was advised the following applications, which were previously considered by the committee at meetings 299 through to 303, have resulted in the publication of an AusPAR.

Active	Application Type
Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed) [DTPa-hepB-IPV-Hib].	Type A - New chemical entity
Inactivated influenza virus vaccine (surface antigens)	Type A - New chemical entity
Anakinra	Type C - Extension of indications
Rituximab	Type F - Major variation (dosage)
Etanercept	Type C - Extension of indications
Sevelamer carbonate	Type A - New chemical entity
Regorafenib	Type C - Extension of indications
Ulipristal acetate	Type A - New chemical entity
Triptorelin acetate	Type A - New salt
Apremilast	Type A - New chemical entity
Rifaximin	Type C - Extension of indications
Sofosbuvir / Ledipasvir	Type A - New chemical entity
Daclatasvir (as dihydrochloride)	Type A - New chemical entity

Active	Application Type
Apixaban	Type C - Extension of indications
Adalimumab	Type C - Extension of indications

Further information

Meeting statements are made publicly available after each meeting.

For further information on the ACPM, please visit: https://www.tga.gov.au/committee/advisory-committee-prescription-medicines-acpm or contact the ACPM Secretary by phone on (02) 6232 8251 or email: ACPM.Secretariat@tga.gov.au