



Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Prescription Medicines

Meeting Statement

Meeting 309, Friday 1 April 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 11 applications before the TGA, including: two for new chemical entities; two for new biological entities; six seeking extensions of indications; and one application seeking a change in dosage.

Sub-committee update Pharmaceutical Subcommittee (PSC)

Members noted the minutes from PSC meetings 165 held on 24 November 2015, 166 held on 25 January 2016 and 167 held on 9 February 2016.

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>>

There were no updates provided to the ACPM of applications, which were previously considered at previous meetings, which have resulted in the publication of an AusPAR.

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