Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Prescription Medicines

Meeting statement

Meeting 300 Friday 3 October 2014

Role of the Advisory Committee on Prescription Medicines (ACPM) 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 nine 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 the TGA nor a TGA delegate is obliged to follow it.

It should also be noted that information about advice provided by the committee may not become publicly available for sometime 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 12 applications before the TGA, including: five applications for new chemical entities; one application for a new biological entity; one application for a new biosimilar medicine; one application seeking a new combination of active ingredients; two seeking extensions of indications; one application seeking a new dose form, and one application seeking changes to Product Information document (PI) requiring evaluation.

The committee's advice has now been provided to TGA delegates for consideration as part of the TGA's regulatory decision making process.

Sub-committee update Pharmaceutical Subcommittee (PSC)

Members noted the minutes from PSC meeting 158 held on 22 September 2014

Further information

Meeting statements are made publicly available after each meeting.

For further information on the ACPM, please visit the ACPM web page or contact the ACPM Secretary by phone on (02) 6232 8252 or email: ACPM.Secretariat@tga.gov.au.