



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Advisory Committee on Prescription Medicines

Meeting statement

Meeting 290 - Friday 5 April 2013

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 13 applications before the TGA, including: four applications for new chemical entities; five applications for extensions of indications; two applications for new combinations of active ingredients; one application for a new dose form; and one application for changes to an approved Product Information document.

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

Other matters considered

Members were also asked to provide advice on an application containing a different form of a currently approved active ingredient, due to possible safety concerns. This advice has now been provided to the TGA for consideration as part of the TGA's regulatory decision making process.

Stakeholder engagement

From time to time members of other statutory committees attend a meeting of a TGA statutory advisory committee. In this context, members welcomed the attendance of Pharmaceutical Subcommittee member, Associate Professor Juleen Cavanaugh, for the morning session.

Pharmaceutical Subcommittee (PSC) update

Members noted the Minutes from the 149 Meeting of the PSC, held 21 January 2013, and the advice from the 150 Meeting of the PSC, held Monday 25 March 2013.

Next meeting

The next meeting of the ACPM is scheduled for 7 June 2013.

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 8080 or email: acpm@tga.gov.au