



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

# Advisory Committee on Prescription Medicines

## Meeting statement

Meeting 297 Friday 4 April 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 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 twelve applications before the TGA, including: seven applications for new chemical entities; one application for a new combination of active ingredients and four applications seeking extensions of indications.

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**

The TGA proposes to amend its Note for Guidance on the Investigations of Drug Interactions so as to align with recent changes to the European version of the document. It has been updated in line with rapidly advancing knowledge and gives a clearer description on which studies are needed in which situation, and how these should be performed and interpreted. It outlines a comprehensive, systematic and mechanistic approach to the evaluation of the interaction potential of **a drug during its development**.

Revising the TGA Note for Guidance will align Australia internationally and help ensure that the prescriber receives clear information on the interaction potential as well as practical recommendations on how the interactions should be managed during clinical use.

Members were asked to provide advice on the proposed amendments, which has now been provided to the TGA for consideration.

## **Sub-committee update Pharmaceutical Subcommittee (PSC)**

No PSC meeting was held in January 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](mailto:ACPM.Secretariat@tga.gov.au).