

Therapeutic Goods Administration

Advisory Committee on Complementary Medicines

Meeting statement

6 June 2014 - Meeting 16

Role of the Advisory Committee on Complementary Medicines (ACCM) in the TGA's regulatory decision making process

The ACCM 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 ACCM provides advice to the TGA on, amongst other things, matters relating to the inclusion, variation or retention of complementary medicines on the Australian Register of Therapeutic Goods.

The advice provided by the ACCM 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 1989*. 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 two applications before the TGA, both being applications for new registered complementary medicines. The first application related to determining whether the submitted data were sufficient to establish safety of the medicine, while the second application sought advice on the appropriateness and clarity of information included in the proposed Product Information.

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



Other matters considered

Updates on regulatory reforms affecting complementary medicines

Members were provided with an update on the complementary medicines regulatory reforms.

Next meeting

The next meeting of the ACCM is scheduled for September 2014.

Further information

Meeting statements are made publicly available after each meeting.

For further information on the ACCM, please visit: <u>ACCM web page</u> or contact the ACCM Secretary: Dr Kaylene Raynes by phone on 02 6232 8229 or email: <u>accm@tga.gov.au</u>