Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Advisory Committee on Complementary Medicines

ACCM 11 meeting statement

7 September 2012

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, 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 to make this information available as soon as reasonably practical after the relevant meeting.

Overview of the therapeutic goods referred for advice

At ACCM 11, the committee's advice was sought on two applications before the TGA: the first being a new substance for use in listed medicines (specifically the suitability of the substance for use as an active ingredient); and the second, registration of a new medicine (specifically on quality aspects of the proposed medicine, the adequacy of the information appearing on the medicine's label and its package insert and aspects of the Consumer Medicines Information).

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

Other matters considered

Members were provided with an update on the complementary medicines regulatory reforms. In this context, members noted that the revised document entitled Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants) was publicly available on the TGA's website with a closing date for comment of 22 October 2012.

Members also noted with interest the work being done by the TGA in relation to standard indications for listed complementary medicines, which will include a public consultation process later in the year.

Stakeholder engagement

From time to time representatives from other statutory committees and international regulators are invited to attend a TGA statutory advisory committee meeting. In this context, members welcomed the attendance of Dr Antonov from Swissmedic at this meeting.

Next meeting

The next meeting of the ACCM is scheduled for 7 December 2012.

Further information

Meeting statements are made publicly available after each meeting.

For further information on the ACCM, please visit the ACCM web page or contact the ACCM Secretary: Jennifer Burnett by phone on 02 6232 8280 or email: accm@tga.gov.au