Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Advisory Committee on Complementary Medicines

Meeting statement

2 August 2013 - Meeting 14

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.

Update on matters where the Committee previously provided advice and a TGA decision has been made

The committee's advice was sought previously in relation to an application for a new registered complementary medicine. Members were informed of the delegate's decision to register the medicine and updated on the inclusion of NeuroTabs (AUST R 209079) on the Australian Register of Therapeutic Goods in May 2013.

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 new substances for use in listed medicines (specifically whether submitted data are sufficient to establish safety of the substances).

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

Other matters considered

Food and medicine interface regulatory issues

Members were provided with background information and a comparison between the current regulatory schemes for food and medicines in Australia, noting the particular relevance of these issues to the regulation of complementary medicines.

The committee noted the legislative complexity in determining whether certain products fall in the food or medicine category and the work that the TGA is conducting in consultation with other agencies such as the wider Department of Health and Ageing, Food Standards Australia New Zealand and various Australian State and Territory offices.

Updates on regulatory reforms affecting complementary medicines

Members were provided with an update on the complementary medicines regulatory reforms. In this context, members noted progress on the implementation of the recommendations made by the Auditor General in respect to complementary medicines.

Updates on the use of excipients that affect bioavailability of active ingredients

Members were provided with an update on a previously discussed item – 'Bioavailability enhancing effects of excipients' (see extracted ratified minutes of ACCM 10, ACCM extracted ratified minutes, Meeting 10, 1 June 2012).

At that time the committee considered that the natural variability in herbal ingredients would be of greater significance than the effect of such excipient ingredients and therefore no obvious safety concerns were identified. This was on the basis that the safety of the active herbal ingredient and the excipient ingredient had been separately established.

Members were informed of a recent internal TGA discussion which identified that, when evaluating use of betacyclodextrin in registered pharmaceutical medicines, consideration is given to the 1995 Joint FAO/WHO Expert Committee on Food Additives (JECFA) recommendation of an Acceptable Daily Intake (ADI) up to 5 mg/kg body weight. While the ADI is known to be conservative, it is TGA practice to seek additional safety data if significantly higher intakes are associated with proposed new medicine formulations.

Members noted that, in the absence of any other identified safety concerns, there is no current intention to review the use of betacyclodextrin in listed medicines.

In addition, the committee was provided with information on two recent TGA listing compliance reviews of medicines that included bioavailability enhancing excipients.

Next meeting

The next meeting of the ACCM is scheduled for 6 December 2013.

Further information

Meeting statements are made publicly available after each meeting.

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