Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Complementary Medicines (ACCM)

Meeting statement

10 November 2020 – Meeting 26

Role of the 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 seven 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 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.

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

The TGA considered previous ACCM advice regarding the relationship between taste disturbance/loss-of-taste adverse events reported for products that contain *Andrographis paniculata,* and whether listed medicines containing higher doses of various forms of magnesium should carry a label warning or have additional restrictions for potential laxative effects. The TGA publicly consulted on these matters on 25 August 2020 and final decisions on these matters were published on 1 December 2020.

Overview of the matters referred for advice

The Committee's advice and comment was sought on the TGA's pilot efficacy monographs for listed medicines containing vitamins B6 and B12.

The efficacy monographs are being developed by the TGA as part of a pilot in response to recommendation 46 of the Expert Review of Medicines and Medical Devices Regulation. The intention is that is that sponsors can use these monographs as evidence to support the efficacy of particular indications related to vitamins B6 or B12 in their listed medicine rather than having to retrieve and hold their own evidence.

Advice was sought on whether the overall evidence obtained for vitamins B6 and B12 is sufficiently robust to support the indications in the draft efficacy monographs.

This advice has now been provided for consideration.

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 by phone on (02) 6289 2305 or email: accm@health.gov.au.