Australian Government

Department of Health
Therapeutic Goods Administration

Advisory Committee on Complementary Medicines (ACCM)

Meeting statement

8 December 2017 – Meeting 18

Role of the ACCM in the TGA's regulatory decision making process

ACCM is a statutory advisory committee established by the *Therapeutic Goods Regulations 1990.* ACCM provides advice to the TGA on matters relating to the inclusion, variation or retention of complementary medicines on the Australian Register of Therapeutic Goods.

The advice provided by ACCM is an important element in the undertaking of the regulatory functions of the TGA. It forms part of the information that is available to a TGA delegate making a regulatory decision under the *Therapeutic Goods Act 1989*. Appropriate consideration will be given to such advice, although it is important to note that neither the TGA nor a TGA delegate is obliged to follow ACCM advice.

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 communicated the upcoming changes to the proposed maximum daily dose for cysteine, cysteine hydrochloride and cysteine hydrochloride monohydrate to sponsors of listed medicines that contain these ingredients on the Australian Register of Therapeutic Goods. Subject to the approval of the Delegate of the Minister of Health, the Therapeutic Goods (Permissible Ingredients) Determination will be updated to include the new listing requirements for these ingredients.

Overview of the therapeutic goods referred for advice

The committee's advice was sought on a number of issues that arose from consultation on the list of permitted indications for listed medicines. Specifically, advice was sought on Traditional Chinese Medicine (TCM) indications not being understood by general consumers, and the inclusion of indications in the permitted indications list referring to: vulnerable populations, cellular actions, cosmetic-like claims and biomarkers.

The committee's advice was also sought on the appropriateness of a registered complementary medicine application proposing a trade name that implied the medicine contains certain active ingredients.

Finally, the committee's advice was sought on the TGA proposal to discontinue pre-market evaluation of Herbal Component Names (HCNs).

The 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 forthcoming complementary medicines regulatory reforms.

Further information

Meeting statements are made publicly available after each meeting.

For further information on the ACCM, please visit the ACCM web page.