Australian Government

Department of Health
Therapeutic Goods Administration

Advisory Committee on Complementary Medicines (ACCM)

Meeting statement

16 July 2020 – Meeting 25

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.

Overview of the matters referred for advice

The Committee's advice and comment was sought on:

- Relevant aspects of microorganism characterisation for the purposes of establishing the quality and safety of applications relating to microorganisms for use in listed medicines and registered complementary medicines.
- The relationship between taste disturbance/loss-of-taste adverse events reported for products that contain *Andrographis paniculata*, and whether there is sufficient evidence to support restrictions to mitigate the risk of taste-related adverse events when used in listed medicines.

- The potential for *Valeriana officinalis* to cause herb-induced liver injury, and whether there is sufficient evidence to support restrictions to mitigate the risk of liver injury when used in listed medicines.

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

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.