Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Complementary Medicines (ACCM)

Meeting statement

28 March 2019 – Meeting 21

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 has considered ACCM advice on aligning the requirements of caffeine in oral listed medicines. The TGA has also considered ACCM advice in amending the requirements of boron-containing compounds in listed medicines.

Overview of the safety reviews referred for advice

The committee's advice was sought on:

- The suitability of a herbal ingredient in listed medicines indicated for use during conception, pregnancy and lactation.

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

Other matters considered

The committee's advice and comment was sought on:

- Establishing microorganism equivalence when evaluating probiotics.
- The standard of clinical study design for 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.