

Australian Government

Department of Health Therapeutic Goods Administration

Advisory Committee on Complementary Medicines (ACCM)

Meeting statement

26 July 2019 - Meeting 22

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 the suitability of an herbal ingredient in listed medicines indicated for use during conception, pregnancy and lactation. The TGA has also considered ACCM advice on establishing microorganism equivalence when evaluating probiotics.



Overview of matters referred for advice

The committee's advice and comment was sought on:

- A clinical trial paper on the effects of a listed complementary medicine, on the common cold.
- The evaluation of a new registered complementary medicine indicated for treating and preventing diarrhoea.

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 <u>ACCM web page</u>.