

Therapeutic Goods Administration

Advisory Committee on Complementary Medicines (ACCM)

Meeting statement

27 November 2019 - Meeting 23

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 matters referred for advice

The committee's advice and comment was sought on:

- The sufficiency and reliability of the evidence to support the registration of a probiotic complementary medicine, as well as whether the product is suitable to be a self-selected medicine without healthcare professional involvement.
- What constitutes adequate control of the composition, strength, stability and performance characteristics of a multi-strain probiotic product.

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>.