

Australian Government

Department of Health and Aged Care Therapeutic Goods Administration

## Advisory Committee on Complementary Medicines (ACCM)

#### **Meeting statement**

#### 3 November 2022- Meeting 30

#### 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 considered previous ACCM advice on whether products that must be administered under supervision of a healthcare professional are suitable to be regulated under the listed medicines framework. The advice was requested within the context of warnings statements that are required for certain ingredients used in listed medicines that are included in the Therapeutic Goods (Permissible Ingredients) Determination. The TGA held a <u>public consultation</u> on these matters on 4 August 2022 and <u>final decisions</u> were published on 1 December 2022.



## Overview of the matters referred for advice

The committee's advice and comment was sought to consider the potential for *Curcuma longa*, curcumin, and *Withania somnifera* to cause herb-induced liver injury, and the potential for probiotics to cause pre-eclampsia. The committee was asked to advise if risk mitigation was warranted and possible risk mitigation strategies for when these ingredients are 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 <u>ACCM web page</u> or contact the ACCM Secretary by phone on (02) 6289 2305 or email: <u>accm@health.gov.au</u>.