Australian Government

Department of Health
Therapeutic Goods Administration

Advisory Committee on Complementary Medicines (ACCM)

Meeting statement

22 March 2018 – Meeting 19

Role of the ACCM in the TGA's regulatory decision making process

ACCM is a statutory advisory committee established by the *Therapeutic Goods Regulations 1990*. ACCM provides advice to the TGA on matters relating to the inclusion, variation or retention of complementary medicines on the Australian Register of Therapeutic Goods.

The advice provided by ACCM is an important element in the undertaking of the regulatory functions of the TGA. It forms part of the information that is available to a TGA delegate making a regulatory decision under the *Therapeutic Goods Act 1989*. Appropriate consideration will be given to such advice, although it is important to note that neither the TGA nor a TGA delegate is obliged to follow ACCM advice.

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 ACCM advice in finalising the permitted indications list. On 6 March 2018 the TGA implemented the list of permitted indications for listed medicines under Section 26A of the Act.

Overview of the safety reviews referred for advice

The committee's advice was sought on:

- The association between the use of *Camellia sinensis* and hepatotoxicity and whether risk mitigation strategies are warranted.
- The proposed course of action in relation to environmental contaminants in some listed medicines.
- The suitability of an excipient ingredient for use in topically applied listed medicines.

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:

- The clarity of the updated draft 'Assessed listed medicines evidence guidelines'.
- The implementation options proposed by the TGA in the draft public consultation paper for a 'claimer' for efficacy assessed non-prescription medicines.
- The TGA proposed approach and criteria for granting market exclusivity to new ingredients for use in listed medicines.

The advice was provided and was considered by the TGA in implementing the above reforms.

Further information

Meeting statements are made publicly available after each meeting.

For further information on the ACCM, please visit the ACCM web page.