



Advisory Committee on Complementary Medicines (ACCM)

Meeting statement

23 May 2017 – Meeting 17

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.

Overview of the therapeutic goods referred for advice

At this meeting, the committee's advice was sought on a proposed maximum daily dose for cysteine, cysteine hydrochloride and cysteine hydrochloride monohydrate. The TGA proposed a maximum daily dose of 450 mg L-cysteine. This equates to 585 mg cysteine hydrochloride and 652 mg cysteine hydrochloride monohydrate.

The committee noted the European Chemicals Agency (ECHA) Derived No Effect Level (DNEL) for L-cysteine, data from the Norwegian Scientific Committee for Food Safety (VKM) evaluation and the Australia-New Zealand Food Standard 2.9.4. The committee considered that a dose restriction of 750mg cysteine for adults and 500mg cysteine for children could be appropriate. The advice has now been provided for consideration as part of the TGA's regulatory decision making process.

Other matters considered

Updates on regulatory reforms affecting complementary medicines

Members were provided with an update on the forthcoming complementary medicines regulatory reforms.

Next meeting

The next meeting of ACCM is scheduled for December 2017.

Further information

Meeting statements are made publicly available after each meeting.

For further information on the ACCM, please visit the [ACCM web page](#).