



Australian Government

Department of Health
Therapeutic Goods Administration

Advisory Committee on Complementary Medicines (ACCM)

Meeting statement

18 March 2021 – Meeting 27

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 the matters referred for advice

Given the association of vitamin B6 (pyridoxine) with peripheral neuropathy and TGA's review of [adverse event reports of peripheral neuropathy associated with pyridoxine](#), the Committee's advice and comment was sought on whether:

- risk mitigation strategies are warranted for listed medicines that provide less than 50 mg equivalent (eqv.) pyridoxine per day;
- the current maximum daily dose for listed medicines (200 mg eqv. pyroxidine) is appropriate; and
- there should be any specific requirements relating to vitamin B6 for paediatric populations.

This advice has now been provided for consideration.

Further information

Meeting statements are made publicly available after each meeting.

For further information on the ACCM, please visit the [ACCM web page](#) or contact the ACCM Secretary by phone on (02) 6289 2305 or email: accm@health.gov.au.