Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medical Devices

Meeting statement

28 November 2014 – ACMD 17

Role of the Advisory Committee on Medical Devices (ACMD) in the TGA's regulatory decision making process

The Advisory Committee on Medical Devices (ACMD) is a statutory advisory committee established by the Therapeutic Goods Regulations 1990.

The TGA currently has nine 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 ACMD provides advice to the TGA on, amongst other things, matters relating to premarket conformity assessment.

The advice provided by the ACMD 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. 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 committee received an update on several of the therapeutic goods considered at the previous meeting held on 26 September 2014. It was noted that of three applications considered at the 16th meeting, one of them was approved with limitations suggested by the ACMD and two of the other applications are still in progress.

Overview of the therapeutic goods referred for advice

At the ACMD 17th meeting the committee considered two devices submitted under the conformity assessment application process, and one device submitted under the ARTG inclusion application process. The devices were:

- An anaesthesia depth patient monitoring system

- An aortic transcatheter heart valve bioprosthesis
- An implantable sleep apnoea treatment system

The committee considered whether the benefits outweighed the risks for each device and whether enough supporting data had been provided to demonstrate safety and performance through compliance with the Essential Principles.

The committee's advice has now been provided to the TGA for consideration as part of the TGA's regulatory decision making processes.

Other matters considered

The committee was presented with a paper on "Update of joint implant definition" relating to the reclassification of these implants. The paper was circulated among all the committee members and they were requested to provide their feedback and comments.

The committee was also presented with a paper on "Increased utilisation of Committee expertise". They were informed about the TGA proposal in regards to the referral criteria for applications to the ACMD and the number of applications per meeting, along with the proposed meeting dates for the year 2015. The paper was circulated among all the committee members and they were requested to provide their feedback and comments.

Further information

Meeting statements are made publicly available after each meeting.

For further information on the ACMD, please visit the ACMD web page or contact the ACMD Secretary by phone on 02 6232 8216 or email: acmd@tga.com.au.