Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medical Devices (ACMD)

Meeting statement

Friday 21 October 2016 – meeting 29

Role of the 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 eleven 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 medical devices.

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 the two orthopaedic implant applications that were considered at the meeting held on 26 August 2016.

The committee received an update on the coated knee femur prosthesis considered at the previous ACMD meeting. In accordance with the committee's advice the decision was made to not include the device on the Australian Register of Therapeutic Goods (ARTG) at this time.

The committee was advised at the time of the 28th meeting, the knee tibial stem and plateau considered at the previous ACMD meeting was still under consideration by the TGA.

Overview of the therapeutic goods referred for advice

At the ACMD 29th meeting the committee considered three Class III medical device applications for inclusion in the ARTG and once Class III medical device seeking conformity assessment certification. The devices were:

- An intracranial cannula,
- An implantable spinal cord electrical stimulation system,
- A neurovascular embolization coil, and;
- An intracardiac pacemaker.

The committee considered whether the benefits outweighed the risk for the devices and whether adequate evidence has 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.

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.