Australian Government

Department of Health

Therapeutic Goods Administration

Advisory Committee on Medical Devices (ACMD)

Meeting statement

Friday 12 November 2015 – meeting 24

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 sometime 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 bare-metal coronary artery stent considered at the previous meeting. The committee's advice was that the clinical evidence was insufficient. The manufacturer has been given the opportunity to address the deficiency.

The dura mater biomatrix implant considered at the previous meeting was issued a conformity assessment certificate after the provision of further clinical evidence.

Overview of the therapeutic goods referred for advice

At the ACMD 24th meeting the committee considered a Class III medical device application. The device was:

- A wearable subcutaneous glucose sensor

The committee considered whether the benefits outweighed the risk for the device 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