Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medical Devices

Meeting statement

26 September 2014 – ACMD 16

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 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 several of the therapeutic goods considered at the previous meeting. It was noted that one previous application has been withdrawn from conformity assessment since the last meeting. A decision has been made to not issue a conformity assessment certificate for another application previously considered. Two other applications are still undergoing conformity assessment and another was to be considered by the committee again in light of additional clinical evidence.

Overview of the therapeutic goods referred for advice

At ACMD 16, the committee considered three medical devices, being:

- A non-biodegradable polymeric mesh

- An internal cardiac valve prosthesis
- A mobile extracorporeal gas exchange system

The committee considered whether the risk outweighed the benefit for each device and whether enough supporting data had been provided to demonstrate safety and efficacy.

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 discussed the data and evidence requirements for Magnetic Resonance Imaging safety for pacemaker and defibrillator leads. The committee believes that clinical data addressing MRI safety is required and that pre-clinical/engineering data (i.e. bench testing) alone is not sufficient to establish safety.

The TGA is currently reviewing the definition of hip, knee and shoulder joint replacement implants, which are currently being reclassified from Class IIb to Class III medical devices, the committee provided comment.

The committee considered the performance requirements for IVDs intended to be used for the detection of human immunodeficiency virus (HIV).

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.