Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medical Devices (ACMD)

Meeting statement

Tuesday 5 December 2017 – meeting 38

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 committee provides independent expert advice on specific scientific and technical matters in order to aid the TGA's decision making and other regulatory processes.

While the advice provided by the ACMD is an important element in the undertaking of the TGA's regulatory functions it forms only part of the information that is available to delegates when they make a regulatory decision under the *Therapeutic Goods Act 1989*. It is important to note that while appropriate consideration will always be given to such advice, the TGA is not obliged to follow the specific recommendations and advice given by the committee.

It should also be noted that information about advice provided by the committee may not become publicly available for some time after the 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

Applications for knee implant system components considered at the last meeting have been withdrawn by the Sponsor.

An application for a femoral head considered at the last meeting has been approved.

An application for an implantable shoulder system component considered at the last meeting is being approved with conditions for additional post market monitoring.

A knee implant system identified by the AOANJRR and considered at the last ACMD meeting was cancelled from the ARTG and a hazard alert was issued.

Overview of the medical devices referred for advice

At the 38th ACMD meeting the committee considered the following devices:

- A synthetic surgical mesh;
- An animal-origin surgical mesh;
- A resorbable cardiovascular stent;
- An implantable spinal stimulation system;
- An in vitro diagnostic device for detecting HIV; and
- A surgical aortic valve.

The committee considered whether the benefits outweighed the risks for the devices and whether adequate evidence has been provided to demonstrate safety and performance through compliance with the Essential Principles.

Overview of the post market issues referred for advice

At the 38th ACMD meeting the committee considered the following post market issue:

- Safety and performance of a critical care ventilator.

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 Secretariat by phone on (02) 6232 8734 or email: acmd@tga.com.au