Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medical Devices (ACMD)

Meeting statement

Friday 23 February 2018 – meeting 39

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

The following updates for items considered by the committee at ACMD 33 were provided:

An application for a bone void filler was rejected.

A further three applications for bone fillers were approved.

The following updates for items considered by the committee at ACMD 34 were provided:

Applications for all components of the intracardiac pacemaker system were withdrawn by the sponsor.

Adverse events for continuous glucose monitoring systems and associated insulin pumps continue to be monitored and investigated accordingly.

The following updates for items considered by the committee at ACMD 36 were provided:

All applications associated with one of the knee joint replacement systems considered were approved.

All applications associated with one of the knee joint replacement systems considered were rejected.

An application for a specific component of a knee replacement system was withdrawn by the sponsor.

An application for a specific component of a knee replacement system was approved.

Applications for specific components of a hip system were withdrawn by the sponsor.

Applications for specific components from two different hip systems were approved.

A proposal to cancel the endovascular device used in the repair of abdominal aortic aneurysms was issued following the meeting and the sponsor subsequently cancelled the product.

The following updates for items considered by the committee at ACMD 37 were provided:

Investigations into an acetabular component used in a hip replacement system and two components used in knee replacement systems, as identified in the AOANJRR annual report, are now underway.

The following updates for items considered by the committee at ACMD 38 were provided:

The application for a synthetic surgical mesh considered by the committee was withdrawn at the request of the applicant.

The application for the animal-origin surgical mesh considered by the committee was withdrawn at the request of the applicant.

The critical care ventilator considered at ACMD 38 has been suspended for a further six months while the sponsor addresses issues.

Overview of the medical devices referred for advice

At the 39th ACMD meeting the committee considered the following devices:

- A pre-contoured cranial titanium mesh,
- A system for minimally invasive lung volume reduction to treat patients with emphysema,
- A knee replacement system,
- A hip replacement system,
- A transcatheter aortic heart valve system, and
- A balloon expandable stent graft.

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 39th ACMD meeting the committee considered the following post market issue:

- Safety and performance of a spinal stimulation system.

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