Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medical Devices (ACMD)

Meeting Statement

Thursday 10 December 2020 – Meeting 58

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 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 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 TGA advised:

- an implant to help fix screws into bone, considered at ACMD 48, had been rejected;
- a total knee replacement system considered at ACMD 48, had been rejected;
- a total hip replacement system considered at ACMD 54, had been approved;
- an application for artificial mesh ligaments and supporting devices considered at ACMD 53, had been withdrawn;
- a device to support heart valve function considered at ACMD 54, had been approved;
- a neurostimulator system for pain considered at ACMD 54, had been withdrawn;

- a neurostimulator system for obstructive sleep apnoea considered at ACMD 55, had been withdrawn;
- a device to treatment of mild to moderate stress urinary incontinence considered at ACMD 56, had been withdrawn; and
- four mesh devices for treatment of stress urinary incontinence considered at ACMD 57, had been approved with additional conditions.

Overview of the medical devices referred for advice

Devices considered at the 58th ACMD meeting included:

- a single use sterile medical device kit designed for the preparation and application of a coating for implants,
- a non-invasive neural-stimulation medical device to assist physical rehabilitation,
- a vaginal mesh positioning kit,
- a cardiac pacing lead,
- a pumping system to recirculate intestinal contents;
- a knee replacement system.

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

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) 6289 6880 or email: acmd.secretariat@health.gov.au.