Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medical Devices (ACMD)

Meeting Statement

Thursday 7 October 2021 – Meeting 63

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

An iris diaphragm, considered at ACMD 56, has had the application withdrawn by the sponsor.

Breast implants, considered at ACMD 50, were approved with conditions.

A device to treat pancreatic cancers, considered at ACMD 59, has had the application withdrawn by the sponsor.

Components of a hip replacement system, considered at ACMD 60, has had the application withdrawn by the sponsor.

A bone substitute material, considered at ACMD 60, has had the application withdrawn by the sponsor.

A focused ultrasound system to treat tumours, considered at ACMD 60, has had the application withdrawn by the sponsor.

A nerve stimulation device to treat several conditions, considered at ACMD 60, has had the application withdrawn by the sponsor.

A valve repair system, considered at ACMD 61, has had the application approved.

A balloon catheter system for coronary arteries, considered at ACMD 61, has had the application withdrawn by the sponsor.

A tissue anchoring system, Considered at ACMD 61, has had the application withdrawn by the sponsor.

Overview of the medical devices referred for advice

At the 63rd ACMD meeting the committee considered the following devices:

- A tissue mesh device intended for use in breast reconstruction surgery;
- a femoral reconstruction system;
- a mesh tape used in orthopaedic surgery and
- a hip replacement system.

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.

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.