



Advisory Committee on Medical Devices (ACMD)

Meeting Statement

9 December 2021 – Meeting 64

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- An application for absorbable meshes for breast surgery, considered at ACMD 56, has been withdrawn by the sponsor.
- An application for a knee replacement system, considered at ACMD 56, has been approved.
- A marketed device to treat emphysema, considered at ACMD 57 was cancelled for non-compliance with the conditions of inclusion
- An application for a shoulder replacement system, considered at ACMD 48, has been withdrawn by the sponsor.
- An application for an implantable nerve stimulator for treatment sleep apnoea, considered at ACMD 55, has been approved.

- Applications for three total knee replacement systems, considered at ACMD 57, have been approved with restrictions to their use.
- An application for a surgical mesh device to treat stress urinary incontinence, considered at ACMD 57, has been approved.
- An application for an ophthalmic viscosurgical device, considered at ACMD 57, has been withdrawn by the sponsor.
- An application for a single use sterile medical device kit designed for the preparation and application of a coating for implants, considered at ACMD 58, has been withdrawn by the sponsor.
- An application for a non-invasive neural stimulation medical device to assist physical rehabilitation, considered at ACMD 58, has been approved with amended intended purpose.
- An application for intraocular lens implant, considered at ACMD 59, has been withdrawn by the sponsor.
- An application for an HIV blood test, considered at ACMD 60, has been withdrawn by the sponsor.
- An application for a non-surgical shunt device, considered at ACMD 62, has been by the sponsor.
- An application for a carbon dioxide injector used with X-rays, considered at ACMD 62, has been approved.
- An application for a spinal implant device, considered at ACMD 62, has been approved.
- An application for a modular knee replacement system, considered at ACMD 62, has been withdrawn by the sponsor.

Overview of the medical devices referred for advice

At the 64th ACMD meeting, the committee considered the following devices:

- an aortic pump designed for long-duration circulatory support;
- a femoral reconstruction system;
- a hip joint reconstruction system;
- a breast implant;
- a continuous glucose monitoring system;
- a drug coated balloon catheter to treat urethral strictures;
- a knee replacement system, and
- an atrial appendage occlusion device.

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