



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Advisory Committee on Medical Devices

The 78th meeting of the Advisory Committee on Medical Devices (ACMD), 18 April 2024.

Role of the ACMD

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 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:

- a pulmonary heart valve replacement device considered at ACMD 75, has been approved.
- a device system used to treat heart attacks considered at ACMD 76, has been withdrawn.

There were no other decisions made for items previously considered by the committee.

Overview of the medical devices referred for advice

At the 78th ACMD meeting the committee considered the following devices:

- an artificial intelligence device to interpret brain scans
- a spinal cord stimulator
- a blood purification device
- a defibrillator
- a nasal sinus implant
- a knee replacement system
- a liver transplant transport system
- tests for infections

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

More information

Consideration and management of declarations of actual or potential conflicts of interest by committee members occurs by the Chair, committee members and the Department prior to and during the meeting (as appropriate).

For meeting #78, one member indicated a potential conflict of interest. The committee carefully discussed the potential conflict and concluded no conflict existed.

Meeting statements are made publicly available after each meeting.

For further information visit the [Advisory Committee on Medical Devices \(ACMD\)](#) webpage or contact the ACMD Secretariat by email TGAMedicalDevices@health.gov.au.