ACMD meeting #79, 27 June 2024

The 79th meeting of the Advisory Committee on Medical Devices (ACMD), 27 June 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

No decisions have recently been made for items previously considered by the committee.

Overview of the medical devices referred for advice

At the 79th ACMD meeting the committee considered the following devices:

- a heart ablation catheter
- an artificial intelligence tool for interpreting x-rays
- a knee replacement system
- a knee replacement component that transmits data
- a hip resurfacing system
- a heart valve system

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 #79, one Committee Member declared a conflict of interest, having held, in the last five years, a commercial consulting agreement with the Sponsor of a device that the committee had been asked for advice on. This represented a real or perceived conflict for this member, and the member was excluded from the discussion on that item.

One Committee Member indicated a potential conflict of interest in relation to potential future academic research collaboration with one of the manufacturers of a device that the committee had been asked for advice on. This represented a real or perceived conflict for this member, and the member was excluded from the discussion on that item.

One invited expert advisor disclosed that they held a position on the board of an organisation that had interacted with the Sponsor of the device under review. The committee carefully discussed the potential conflict and chose to proceed with the advisor given the organisation has not received any funding from the Sponsor.

At the meeting, one Committee Member recognised that they had had past interactions as a client of one of the Sponsor companies when an item was introduced. The member promptly left the meeting for the duration of the discussion for that item, without having contributed.

Meeting statements are made publicly available after each meeting.

For more information see Advisory Committee on Medical Devices (ACMD) or contact the ACMD Secretariat by email TGAMedicalDevices@health.gov.au.