



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Advisory Committee on Medical Devices (ACMD)

Meeting Statement

11 August 2022 - Meeting 68

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

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

Overview of the medical devices referred for advice

At the 68 ACMD meeting the committee considered the following devices:

- Two knee replacement system components
- An implantable heart monitoring device
- A marketed laser used in eye treatment
- Marketed devices that used to monitor the heart rate of unborn babies

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.

Further 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 #68, two members indicated a potential conflict of interest:

One member indicated they worked in a state health system that had reported problems with the type of device being discussed, in the same area of health. The committee assessed this and did not deem it a conflict; the member participated fully in the meeting.

A second member declared a conflict of interest relating to work completed for a manufacturer of devices being discussed. The committee considered this a conflict of interest, however, the member was not present for the meeting or involved in the discussion and as such the committee considered there to be no risk.

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 email acmd.secretariat@health.gov.au.