



Advisory Committee on Medical Devices (ACMD)

Meeting Statement

10 February 2022 – Meeting 65

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

- Applications for synthetic ligaments for repair of: Achilles Tendon, Anterior Cruciate Ligament and Rotator Cuff injuries, considered at ACMD 53, had been withdrawn.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 65th ACMD meeting the committee considered the following devices:

- an application for a bone and soft tissue filler that can be used with infections
- an application for a revision knee replacement system.

The committee also considered the following for discussion:

- **Persosnalised Medical Devices**

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 #65, one member declared share ownership of a biotech company and fees received from a medical device company for services performed. These did not represent a real or perceived conflict for that member, as they were unrelated to items being considered; the member participated fully in the meeting.

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 (email: acmd.secretariat@health.gov.au)