



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

# Advisory Committee on Medical Devices (ACMD)

## Meeting Statement

Friday 16 October 2020 – Meeting 57

### **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**

A bone substitute, considered at ACMD 47, was included in the ARTG with conditions.

A total knee replacement system, considered at ACMD 50, has had all components except a tibial component, included in the ARTG.

An emergency airway suction system, considered at ACMD 50, has had the application withdrawn by the Sponsor.

Spinal fixation screws, considered at ACMD 51, was included in the ARTG.

A humeral stem for hip replacements, considered at ACMD 51, was rejected.

A nerve stimulation system, considered at ACMD 51, has had the application included in the ARTG.

A Left Atrial Appendage (LAA) closure device, considered at ACMD 53, was included in the ARTG with conditions.

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

### **Overview of the medical devices referred for advice**

At the 57<sup>th</sup> ACMD meeting the committee considered the following devices:

- Three total knee replacement systems;
- A transcatheter system to treat atrial fibrillation;
- A surgical mesh device to treat stress urinary incontinence;
- An endovascular system for arteries in the legs;
- An ophthalmic viscosurgical device; and
- A device to treat emphysema.

The committee also considered the following for discussion:

- The definition of “central circulatory system” used by the TGA; and
- A new guidance document the TGA is writing on clinical evidence requirements for medical devices

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](mailto:acmd.secretariat@health.gov.au).