



# Advisory Committee on Medical Devices (ACMD)

## Meeting Statement

Friday 16 August 2019 – Meeting 49

### **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**

An acetabular shell and liner, considered at ACMD 42, has had the application withdrawn by the Sponsor.

A manual nasal aspirator, considered at ACMD 43, was included on the ARTG with conditions.

An intravascular lithotripsy device, considered at ACMD 44, was included on the ARTG with conditions.

A breast examination system, considered at ACMD 44, has had the application withdrawn by the sponsor.

A glucose bolus calculator, considered at ACMD 46, was included on the ARTG.

A porous bone substitute, considered at ACMD 47, was included on 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 49th ACMD meeting the committee considered the following devices:

- A cemented and cementless stem neck femoral components of a hip replacement system;
- Total knee replacement systems;
- A partial shoulder replacement system; and
- A haemofilter/dialyser.

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) 6232 8665 or email: [ACMD.secretariat@health.gov.au](mailto:ACMD.secretariat@health.gov.au)