



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Advisory Committee on Medical Devices (ACMD)

Meeting statement

Thursday 21 February 2019 – Meeting 46

## **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 pre-contoured cranial titanium mesh, considered at ACMD 39, was included in the ARTG. Additional conditions were imposed.

A radio frequency ablation device, considered at ACMD 42, was included in the ARTG. Some additional conditions were imposed on the entry.

An acetabular cup, liner and femoral head system, considered at ACMD 43, was included in the ARTG.

A cardiac ablation catheter, considered at ACMD 43, was included in the ARTG.

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

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

At the 46<sup>th</sup> ACMD meeting the committee considered the following devices:

- An application for a glucose monitoring system;
- A system for manufacturing products for intra-articular injection;
- An abdominal hernia mesh;
- A spinal interbody fusion system; and
- A surgical sealant for bleeding.

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@tga.com.au](mailto:acmd@tga.com.au).