Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medical Devices (ACMD)

Meeting Statement

Thursday 15 April 2021 – Meeting 60

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 knee replacement, considered at ACMD 49, has had the application approved.

Spinal bone screws, considered at ACMD 50, has had its application lapsed and closed.

Multiple tissue extraction systems used in gynaecological surgery were considered at ACMD 54. Sponsors are updating instructions for use.

A skin cancer therapy device considered at ACMD 56, has had its application approved 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 60th ACMD meeting the committee considered the following devices:

- Two currently marketed orthopaedic devices;
- A marketed fracture fixation system;
- Components of a hip replacement system;
- A bone substitute material;
- A focused ultrasound system to treat tumours;
- A nerve stimulation device to treat many several conditions; and
- A HIV blood test.

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.