



Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Medical Devices (ACMD)

Meeting statement

Thursday 12 April 2018 – meeting 40

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

The following updates for items considered by the committee at ACMD 36 were provided:

An application for a specific component from an implantable hip joint replacement system was rejected.

The following updates for items considered by the committee at ACMD 37 were provided:

Two applications for femoral stems were rejected.

A component of an implantable shoulder system was approved for inclusion in the Australian Register of Therapeutic Goods with additional conditions.

Overview of the medical devices referred for advice

At the 40th ACMD meeting the committee considered the following devices:

- An aortic valve prosthesis, with animal-origin components, for surgical valve replacement,
- A cobalt chromium femoral head for use in a hip replacement system,
- A vascular stent graft system for aortic arch repair,
- A humeral resurfacing arthroplasty system, and
- An IVD device for screening blood and tissue donor samples for HIV and Hepatitis.

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 8734 or email: acmd@tga.com.au.