



Advisory Committee on Medical Devices (ACMD)

Meeting statement

Tuesday 2 May 2017 – meeting 32

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 committee ratified the minutes from the 31st meeting and received an update from items considered at both the 30th and 31st meeting.

Overview of the medical devices referred for advice

At the 32nd ACMD meeting the committee considered the following devices:

- A left ventricular assist system;
- A neurovascular embolization system;
- An aortic valve prosthesis;
- A range of implantable cardioverter-defibrillators;
- A range of implantable pacemakers; and
- An aortic annuloplasty ring.

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.

Overview of the post market issues referred for advice

At the 32nd ACMD meeting the committee considered the following post market issue:

- Delamination of the outer polyurethane layer in certain gel-filled breast implants.

The committee's advice has now been provided to the TGA for consideration as part of the TGA's regulatory decision-making processes.

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