



Advisory Committee on Medical Devices

Meeting statement

14 May 2015 – ACMD 20

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 TGA currently has ten statutory advisory committees from which it can obtain independent expert advice on specific scientific and technical matters to aid the TGA's regulatory decision making and other regulatory processes. The ACMD provides advice to the TGA on, amongst other things, matters relating to medical device applications.

The advice provided by the ACMD is an important element in the undertaking of the regulatory functions of the TGA. However, it forms only part of the information that is available to, for instance, a TGA delegate making a regulatory decision under the Therapeutic Goods Act. While appropriate consideration will be given to such advice, it is important to note that neither the TGA nor a TGA delegate is obliged to follow it.

It should also be noted that information about advice provided by the committee may not become publicly available for some time after a 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 received an update on the two therapeutic goods considered at the previous meeting held on 31 March 2015. The percutaneous guidewire was approved by the TGA delegate with conditions placed on its indications for use as recommended by the committee. The TGA has requested further information on the transcatheter heart valve system as per the ACMD's advice, to assist with the decision-making process.

Overview of the therapeutic goods referred for advice

At the ACMD 20th meeting the committee considered five medical devices submitted under the conformity assessment application process. The devices were:

- Two transcatheter aortic heart valve prostheses with animal-origin components,
- An implantable animal-origin patch for soft tissue repair,
- A surgical aortic heart valve prosthesis with animal-origin components, and;

- An orthopaedic bone cement with medicine.

The committee considered whether the benefits outweighed the risks for each device and whether enough supporting data had been provided to demonstrate safety and performance through compliance with the Essential Principles.

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 Secretary by phone on (02) 6232 8216 or email: acmd@tga.com.au