



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

# Advisory Committee on Medical Devices

## Meeting statement

13 June 2014 - ACMD 15

### **Role of the Advisory Committee on Medical Devices (ACMD) in the TGA's regulatory decision making process**

The ACMD is a statutory advisory committee established by the Therapeutic Goods Regulations 1990.

The TGA currently has nine 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 premarket conformity assessment and post market monitoring.

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.

### **Overview of the therapeutic goods referred for advice**

At ACMD 15, the committee considered five medical devices, being:

- One coronary sinus cannula
- One animal derived cardiac valve graft
- One mobile extracorporeal gas exchange system
- One lubricated latex condom
- One balloon dilation angioplasty catheter

The committee considered whether the risk outweighed the benefit for each device and whether enough supporting data had been provided to demonstrate safety and efficacy.

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 8715 or email: [acmd@tga.com.au](mailto:acmd@tga.com.au).