



# Advisory Committee on Medical Devices

## Meeting statement

20 September 2013 - ACMD 13

### **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 sometime 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 13, the committee considered four medical devices, including three animal derived collagen-based devices used for various tissue repairs, and an ophthalmic stent.

The committee considered the risks of certain design features, the adequacy of clinical evidence, whether acceptable performance had been demonstrated, and whether the design and construction conforms to safety principles.

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

## **Other matters considered**

The committee received a report regarding the ongoing work of the Office of Devices Authorisation, and a report providing feedback from the Advisory Committee on the Safety of Medical Devices (ACSMD).

The TGA also provided feedback regarding a number of devices that the Committee had previously provided advice on.

## **Next meeting**

The next meeting of the ACMD is scheduled for 22 November 2013.

## **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 8514 or email: [acmd@tga.com.au](mailto:acmd@tga.com.au).