Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Advisory Committee on Medical Devices

Meeting statement

15 March 2013 – ACMD 12

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 12, the committee considered in vitro diagnostic (IVD) point of care tests broadly, but no specific product application was discussed. Point of care testing is performed outside the laboratory environment, near to or at the side of the patient.

The committee considered acceptable levels of sensitivity and specificity of these types of IVD medical devices.

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 also discussed the changes to premarket assessment requirements for medical devices proposal paper the subject of public consultation between January 2013 and March 2013.

Members discussed the ongoing role of the ACMD in the context of the proposed changes, and noted the proposed changes to the publishing of committee outcomes, via the introduction of the meeting statements.

Next meeting

The next meeting of the ACMD is scheduled for 28 June 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