Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on the Safety of Medical Devices

Meeting statement

Meeting 6 – 21 February 2014

Role of the Advisory Committee on the Safety of Medical Devices (ACSMD) in the TGA's regulatory decision making process

The ACSMD 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 ACSMD provides advice to the TGA on, amongst other things, matters relating to the safety, risk assessment, risk management and performance of medical devices supplied in Australia.

The advice provided by the ACSMD 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 1989*. 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.

New members

Nine (9) new members have recently been appointed to the committee by the Assistant Minister for Health; Senator the Hon Fiona Nash, and eight of these new members attended this meeting for the first time. The new members provide additional expertise to the committee in the areas of plastic and reconstructive surgery, human factors analysis, orthopaedics, respiratory medicine, pathology, gynaecology, ophthalmology and ear, nose and throat surgery.

Update on matters where the Committee previously provided advice and a TGA decision has been made

Members were provided with an update on matters recently considered by the committee and the outcomes of recent TGA safety investigations.

Overview of the safety reviews and therapeutic goods referred for advice

The TGA continually monitors therapeutic goods supplied in Australia to ensure their ongoing safety, efficacy and quality. As part of this process, the TGA routinely undertakes safety reviews of therapeutic goods.

At this meeting, the committee's advice was sought on three (3) safety / post market surveillance reviews of a bone graft medical device used for specific spinal fusion procedures and two left ventricular assist devices which are used to provide haemodynamic support to patients with end-stage heart failure.

Specifically, the committee was asked to provide advice on the risks and benefits associated with the use of these devices, the need to update safety information contained in the Instructions for Use manuals, the need for the continued monitoring and provision of annual reports by the sponsors, areas where the TGA should focus its further investigation, advice in relation to the rates of adverse events being reported and whether the devices meet relevant Essential Principles for safety and performance.

The committee's advice will shortly be provided to the TGA for consideration as part of the TGA's regulatory decision making processes.

Other matters considered

Members were updated on the TGA's Adverse Event Reporting project, noted that the second edition of the Medical Devices Safety Update (MDSU) has recently been published on the TGA website and also noted the media releases, statements and safety alerts published by the TGA since the committee's last meeting.

Stakeholder engagement

From time to time representatives from other statutory committees and international regulators are invited to attend a TGA statutory advisory committee meeting.

In this context, it is a standing arrangement for a representative from MedSafe to participate in the ACSMD meetings. At this meeting, MedSafe was represented by Mr Robert Jelas, Senior Adviser (Product Safety – Medical Devices), Compliance Management.

Subcommittee update – Orthopaedic Subcommittee

The OSC's functions are to advise the ACSMD and the TGA on prostheses which have been identified in the Australian Orthopaedic Association's National Joint Replacement Registry (NJRR) annual report as having a higher than expected revision rate. This includes:

- assessment of clinical data and other relevant information and provision of advice on whether the revision rates associated with the joint replacement are acceptable;
- consideration of possible reasons for the higher than expected rates of early revision for the identified implants, including if there is a link between implant design or manufacture and the revision rates; and

- provide advice on the strength of the evidence to support the benefit of joint replacement compared with the higher risk of a possible early revision.

The OSC also provides the TGA with advice in relation to orthopaedic issues in general. For example, the advice of the OSC was sought on the matter of metal-on-metal hip replacement devices.

Since the second meeting of the OSC which was held on 25 November 2013, the subcommittee's advice has been provided to the TGA and is now being considered as part of the TGA's regulatory decision making processes.

The next meeting of the OSC is scheduled for 18 March 2014.

Further information

Meeting statements are made publicly available after each meeting.

For further information on the ACSMD, please visit the ACSMD webpage or contact the ACSMD Secretary by phone on 02 6232 8641 or email: acsmd.secretariat@tga.gov.au