Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Committee

Meeting Statement

27 August 2013 – Meeting 39

Role of the Therapeutic Goods Committee in the TGA's regulatory decision making process

The Therapeutic Goods Committee (TGC) 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 Therapeutic Goods Committee provides advice to the TGA on, among other things:

- the adoption of standards for therapeutic goods
- the requirements for labelling and packaging of therapeutic goods
- standards for the manufacture of therapeutic goods
- matters relating to medical device standards, conformity assessment standards and standards for biologicals.

The advice provided by the Therapeutic Goods Committee 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 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.

Information about committee advice may not become publicly available for some time. 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

Since the previous meeting, two Therapeutic Goods Orders (TGO) have been determined by a delegate of the Minister under subsection 10(4) of the *Therapeutic Goods Act 1989* in relation to which the TGC has previously provided advice:

- Therapeutic Goods Order No. 80A - Amendments to Therapeutic Goods Order No. 80 - Child-Resistant Packaging Requirements for Medicines, which commenced on 1 October 2013.
- Therapeutic Goods Order No. 88 - Standards for donor selection, testing, and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products, which commenced on 31 May 2013.

Overview of standards referred for advice

At this meeting, the committee's advice was sought in relation to 14 Therapeutic Goods Orders, including possible adoption, amendment and revocation.

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

Other matters considered

The committee was also provided with updates on:

- the TGA Labelling and Packaging Review
- the current 'default standards' under section 3 of the *Therapeutic Goods Act 1989*
- amendments to Regulation 34A of the Therapeutic Goods Regulations 1990 affecting the role of the committee.

Further information

Meeting Statements are made publicly available after each meeting.

For further information on the Therapeutic Goods Committee, please visit TGC or contact the TGC Secretary by phone on 02 6232 8623 or email: TGC@tga.gov.au