Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Committee

Meeting statement

Meeting 42, 13 May 2016

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 ten 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, amongst other things, matters relating to:

- 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, 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 seek this advice in making a decision or to follow it.

It should also be noted that information about advice provided by the committees 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 make this available as soon as reasonably practical after the relevant meeting.

Overview of the standards referred for advice

At the 42nd meeting, the committee's advice was sought in relation to:

- a minor variation to Therapeutic Goods Order No. 69 *General Requirements for the Labelling of Medicines*;

- draft Therapeutic Goods Order No. 91 - *Standard for the labels of prescription and related medicines* and Therapeutic Goods Order No. 92 - *Standard for labels of non-prescription medicines*.

The committee was asked to note that Therapeutic Goods Order No. 75 *Standard for Haematopoietic Progenitor Cells Derived From Cord Blood* and Therapeutic Goods Order No. 81 *Standards for Blood and Blood Components* are due to 'sunset' in 2017 and are under review by the TGA.

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

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