



Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Biologicals

Meeting statement

Meeting 6, Thursday 28 May 2015

Role of the Advisory Committee on Biologicals (ACB) in the TGA's regulatory decision making process

The Advisory Committee on Biologicals (ACB) 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 regulatory decision making and other regulatory processes. The ACB provides advice to the TGA on, among other things, matters relating to the inclusion, variation, removal or continued inclusion of biologicals (cell and tissue therapy products) on the Australian Register of Therapeutic Goods.

The advice provided by the ACB 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.

It should also be noted that information about advice provided by the committee 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 for it to be available as soon as reasonably practical after the relevant meeting.

Overview of therapeutic goods referred for advice

At this meeting, the committee's advice was sought on two applications before the TGA including one Class 3 biological and one CTX application. General comments were also sought from the Committee on the feedback from the TGA consultation on the regulation of autologous stem cell therapies.

The committee's advice will be provided to TGA delegates 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 ACB, please visit the [ACB web page](#) or contact the ACB Secretary: Dr Glenn Smith on 02 6232 8291 or email: acb@tga.gov.au