



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Advisory Committee on Biologicals

Meeting statement

18 April 2013, Meeting No. 2

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

The ACB 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 ACB provides advice to the TGA on, amongst 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, 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 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

The ACB will usually be asked to provide advice on specific issues/questions. However, as the Biologicals framework is new, applications which are first in Class or unusual may be provided to the Committee for their information even when there is no specific request for advice.

At this meeting two biological applications, for one Class 2 and one Class 3 biological were provided to the Committee for information. The Committee was not requested to provide advice in regard to any specific issues in relation to these applications.

Other matters considered

Members were asked to provide advice about matters canvassed in a submission from an association of tissue banks relating to exemptions to donor testing for infectious diseases.

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

Next meeting

The next meeting of the ACB is scheduled for 20 June 2013.

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: Nagendram Nandapalan by phone on (02) 6232 8492 or email: acb@tga.gov.au