



Advisory Committee on Biologicals

Meeting statement

19 September 2013, Meeting No. 3

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 nine 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, 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

There were no products referred to the committee at this meeting.

Other matters considered

Infectious disease risk minimisation

Members were asked to provide advice on two matters relating to infectious disease risk minimisation approaches.

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

Update on matters the Committee previously provided advice on

The committee's advice was previously sought on a submission by an association of tissue banks, relating to exemptions to donor testing for infectious diseases. Members were informed TGA has considered the committee's advice and made a decision on the request.

Classification of biologicals

The committee was informed of the approach for classifying biologicals and advised their recommendations may be sought on this topic in the future.

Next meeting

The next meeting of the ACB is scheduled for 14 November 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: Dr Glenn Smith on 02 6232 8291 or email: acb@tga.gov.au.