



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Advisory Committee on Biologicals

## Meeting statement

24 July 2014, Meeting No. 4

### **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**

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 three Class 2 biological applications were provided to the Committee for information and general comments were sought from the Committee. The Committee was not requested to provide specific advice in regard to these applications.

## **Other matters considered**

Members were asked to provide advice on three matters: The regulation of autologous stem cell treatments, Biovigilance Guidance for Biologicals and Preclinical data requirements for pre-market evaluation of Biologicals.

The committee's advice was provided for consideration as part of the TGA's regulatory processes.

## **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](mailto:acb@tga.gov.au)