Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Advisory Committee on Biologicals

Meeting Statement

Meeting 16 – 12 November 2020

Role of the 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 seven 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 1989*. While appropriate consideration will be given to such advice, 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.

Overview of the therapeutic goods referred for advice

At this meeting, the committee's advice was sought on one issue:

- Updates to the tissue product-specific standards Therapeutic Goods Orders (TGO) 83, 84, 85, 86, the biologicals labelling standard TGO 87 and the infectious disease minimisation standard TGO 88.