

EXPLANATORY STATEMENT

Subject: THERAPEUTIC GOODS ORDER NO. 85 – STANDARDS FOR HUMAN OCULAR TISSUE

Section 10, Therapeutic Goods Act 1989

OUTLINE

Therapeutic Goods Order No. 85 *Standards for human ocular tissue* (TGO 85) is an Order made by the delegate of the Minister for Health and Ageing under section 10 of the *Therapeutic Goods Act 1989* (the Act).

TGO 85 determines that the matters specified in the instrument constitute the standards applying to biologicals that are human ocular tissue. TGO 85 specifies a number of general requirements relating to human ocular tissue, and determines that the standards for the examination and evaluation of human ocular tissue are based on relevant requirements set out in key reference document “EBAANZ Medical and Quality Standards for Eye Donation and Eye Tissue Banking”, Second Edition, dated April 2009, published by the Eye Bank Association of Australia and New Zealand (EBAANZ).

TGO 85 commences on 31 May 2012. This will allow a transition period for manufacturers to achieve compliance with the standards.

BACKGROUND

The Act provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods for use in humans. The Therapeutic Goods Administration (TGA) is responsible for administering the Act.

Section 10 of the Act authorises the Minister, or the Minister's delegate, to determine standards for therapeutic goods, or to amend or revoke existing standards, after consultation with the Therapeutic Goods Committee (TGC), a committee established under the Therapeutic Goods Regulations 1990 (the Regulations) to advise the Minister on matters relating to standards.

Unless consent is granted by the Secretary under sections 14 and 14A of the Act, therapeutic goods imported into Australia, supplied in Australia or exported from Australia must comply with applicable standards.

A number of new provisions have been added to the *Therapeutic Goods Act 1989* (the Act) and the Regulations to establish and implement a new regulatory framework for biologicals. The new regulatory scheme for biologicals commenced on 31 May 2011.

Human tissue products, including human ocular tissue, are biologicals and are covered by the new regulatory framework for biologicals. Prior to commencement of the biologicals regulatory framework, manufacturers of human tissue, including ocular tissue, were required to hold a manufacturing licence, but such products were exempt from the requirement to be included in the Australian Register of Therapeutic Goods (the Register).

Under the new regulatory framework, human tissue products are required to be included in the Register, as biologicals. For those human tissue products (including those that are human ocular tissue) that are classified under the Regulations as being class 2, 3 or 4 biologicals (the Regulations specify and define 4 classes of biologicals), compliance with applicable standards must be demonstrated as part of the evaluation process in relation to suitability for inclusion in the Register. Applicants for inclusion of class 1 biologicals in the Register must certify that the biological conforms to every standard (if any) applicable to it.

TGO 85 is a new standard made under section 10 of the Act, and applies to human ocular tissue such as eye globes, corneas or sclera collected from living and deceased human donors.

TGO 85 specifies the minimum technical requirements that are considered necessary in relation to the safety and quality of human ocular tissues. The technical requirements set out in TGO 85 include requirements relating to the collection, processing, storage conditions and sterility testing of such tissues, as well as requirements relating to the recording and reporting of certain information about human ocular tissues and requirements relating to the transport of human ocular tissues.

For example, TGO 85 requires that the collection of human ocular tissue from a deceased donor must commence within 48 hours after asystole (the reference time for cardiac death), and that human ocular tissue may be collected from such donors between 24 and 48 hours after asystole only if the tissue is evaluated for quality and suitability by the relevant medical director and transplanting surgeon before the tissue is released for use in a recipient.

In addition, TGO 85 requires that the examination and evaluation of human ocular tissue be in accordance with section 10 of the EBAANZ document referred to above. This document sets out a number of important requirements relating to the examination and evaluation of human ocular tissue, such as specifying matters for which corneal-scleral segments should be examined when retrieved from a donor (e.g. clarity and foreign objects) and specifying matters for which cornea should be examined prior to storage (e.g. scars, oedema and certain defects).

TGO 85 provides that the following products are exempt from the requirements of the Order, those being:

- human ocular cells and tissue samples collected solely for the purpose of in vitro diagnosis;
- human ocular tissue that is processed beyond minimal manipulation; and
- amniotic membrane that may be used for therapeutic ocular procedures.

Diagnostic ocular tissue samples have been exempted from the scope of TGO 85 as these samples are not for use in a recipient.

Human ocular tissue that is processed beyond minimal manipulation has been exempted from TGO 85 because this Order has been specifically developed for tissues that have been processed within the meaning of that term, as defined in regulation 2 of the Regulations. Human ocular tissues that are processed beyond minimal manipulation include limbal stem cells that are cultured to induce cell proliferation. While such products have been exempted from the requirements of TGO 85 they may be required to meet other regulatory requirements including, for example, the proposed Code of Good Manufacturing Practice for Human Blood and Blood Components, Human Tissues and Human Cellular Therapy Products.

Amniotic membrane has been exempted from TGO 85 because the requirements in this Order are specific to the manufacture of ocular tissue, and do not apply to amniotic membrane although this tissue type may be used to treat ocular defects.

CONSULTATION

A draft of TGO 85 was made available by the TGA for public consultation in December 2009. A substantially revised version, which took into account feedback received regarding the first draft, was published by the TGA in December 2010 for a second round of public consultation, at which time exclusive meetings were held with EBAANZ to discuss details of the proposed standard.

In addition, TGO 85 has been considered and endorsed by the Therapeutic Goods Committee (the TGC) subcommittee on biologicals, and has been adopted by the TGC.

REGULATION IMPACT STATEMENT

The Office of Best Practice Regulation has agreed that no Regulation Impact Statement is necessary for TGO 85 (ORR ID number 12194).

It is important to note that the 'Regulatory Impact Statement for the Regulation of Human Cellular and Tissue Therapy Products (biologicals)' (ORR ID 5066 February 2009) included the requirement for human tissue products, including ocular tissue, to comply with standards. In addition, the proposed new standards relating to biologicals (including human ocular tissue) have been discussed with the Australian eye banking sector, and the sector has indicated that the requirements of TGO 85 are not likely to have any significant additional direct or indirect impact on the eye banking sector.