EXPLANATORY STATEMENT

Subject: THERAPEUTIC GOODS ORDER NO. 86 – *STANDARDS FOR HUMAN SKIN*

Section 10, Therapeutic Goods Act 1989

OUTLINE

Therapeutic Goods Order No. 86 *Standards for human skin and* (TGO 86) 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 86 determines that the matters specified in the instrument constitute the standards applying to biologicals that are human skin. TGO 86 specifies a number of important requirements relating to human.

TGO 86 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 section 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 skin, 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 skin, 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 skin) 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 86 is a new standard made under section 10 of the Act, and applies to human skin collected from living and deceased human donors.

TGO 86 specifies the minimum technical requirements that are considered necessary in relation to the safety and quality of human skin. The technical requirements set out in TGO 86 include requirements relating to the collection, microbial testing, processing, packaging and storage conditions of such tissues. TGO 86 specifies that if microbial growth of clinically significant organisms is detected on the tissue, the skin must not be used for transplantation.

TGO 86 provides that the following products are exempt from the requirements of the Order, those being:

- human skin collected solely for the purpose of in vitro diagnosis; and
- human skin that is processed beyond minimal manipulation.

Diagnostic human skin samples have been exempted from the scope of TGO 86 as these samples are not for use in a recipient.

Human skin that is processed beyond minimal manipulation has been exempted from TGO 86 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 skin tissues that are processed beyond minimal manipulation include keratinocytes or dermal substitutes, which are made from skin that is dissociated into individual cells and subsequently grown in culture. While such products have been exempted from the requirements of TGO 86, 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.

CONSULTATION

A draft of TGO 86 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 the Australasian Tissue and Biotherapeutics Forum (ATBF) to discuss details of the proposed standard.

In addition, TGO 86 has been considered and endorsed by the Therapeutic Goods Committee (the TGC) expert 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 86 (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 human skin, to comply with standards. In addition, the proposed new standards relating to biologicals (including human skin) have been discussed with the Australian tissue banking sector and the sector has indicated that the

requirements of TGO 86 are not likely to have any significant additional direct or indirect impact on the skin banking sector.