EXPLANATORY STATEMENT

Subject: THERAPEUTIC GOODS ORDER NO. 87 – *GENERAL REQUIREMENTS FOR THE LABELLING OF BIOLOGICALS*

Section 10, Therapeutic Goods Act 1989

OUTLINE

Therapeutic Goods Order No. 87 General requirements for the labelling of biologicals (TGO 87) 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 87 determines that the matters specified in the instrument constitute the standards applying to biologicals in relation to labelling.

TGO 87 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 any applicable standard.

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.

Biologicals are defined in subsection 32A(1) of the Act as either things that comprise, contain or are derived of, human cells or tissues, or things specified by the Secretary in a legislative instrument under subsection 32A(2) of the Act as being biologicals. Prior to the commencement of the new regulatory framework for biologicals, manufacturers of human tissues and cellular therapy products 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, biologicals are required to be included in the Register. For biologicals 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 87 is a new standard made under section 10 of the Act, and applies to all biologicals, including for example human ocular tissue (e.g. corneas) and musculoskeletal tissue (e.g. bone) collected from living or deceased human donors and released for supply. The requirements of the labelling Order recognise the unique circumstances in which biologicals, as distinct from other therapeutic goods, are collected, transported, processed, supplied and used including, for example, that biologicals are typically used in a clinical setting and not supplied directly to public consumers.

TGO 87 specifies the minimum labeling requirements that are considered necessary in relation to the safety and traceability of biologicals, including requirements regarding the information to be included on the label of a biological at the time of both collection and release of a biological.

In some instances, biologicals may be collected or supplied in several layers of packaging, such as in the case of femoral head (bone) donations, and the labeling of a layer may compromise the sterility of the biological. In addressing such circumstances, TGO 87 requires that the non-sterile layer must be labelled. TGO 87 also permits biological products with small labels that can not fit all the required information to set out a minimum amount of specified kinds of information on the label, with all other required information able to be provided with the product as accompanying documentation.

The requirements of TGO 87 do not apply to a transparent covering that wraps a container or primary pack containing a biological where a compliant label is clearly visible through that transparent covering.

CONSULTATION

A draft of TGO 87 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.

In addition, TGO 87 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 87 (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 labelling requirements, to comply with standards. In addition, the proposed new standards relating to biologicals (including labelling standards) have been discussed with the Australian tissue banking sector and the sector has indicated that the requirements of TGO 87 are not likely to have any significant additional direct or indirect impact on the tissue sector.