

## EXPLANATORY STATEMENT

**Subject: THERAPEUTIC GOODS ORDER NO. 90 – Standard for human albumin**

*Section 10, Therapeutic Goods Act 1989*

### OUTLINE

Therapeutic Goods Order No. 90 Standard for human albumin (TGO 90) 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 90 determines that the matters specified in the instrument constitute the standard for human albumin.

TGO 90 commenced on the day after the day it was registered on the Federal Register of Legislative Instruments.

### 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 by 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 or 14A of the Act, therapeutic goods imported into Australia, supplied in Australia or exported from Australia must comply with any applicable standard.

TGO 90 is a new standard made under section 10 of the Act, and applies to human albumin used as a therapeutic good or as an ingredient in a therapeutic good.

TGO 90 specifies that human albumin complies with the monographs of the British Pharmacopoeia or the European Pharmacopoeia for human albumin. There is no difference between the requirements of the British and European pharmacopoeias.

### CONSULTATION

A draft TGO was made available by the TGA for public consultation in September 2009. It was published on the TGA Internet site and key stakeholders were informed. There were three responses.

At its 36<sup>th</sup> meeting in August 2010, the Therapeutic Goods Committee (TGC) advised the Minister and the TGA that the draft Order should be amended to reflect that personal importation of medicines containing human albumin should be subject to the Order, and that

the Order should be finalised and should take effect from its date of entry onto the Federal Register of Legislative Instruments.

The registered version of TGO 90 is not materially different to the consultation draft.

## **REGULATION IMPACT STATEMENT**

The Office of Best Practice Regulation has agreed that no Regulation Impact Statement is necessary for TGO 90 (OBPR reference number 11770).

## **REFERENCED DOCUMENTS**

Information on the documents referred to in TGO 90 or this Explanatory Statement follows.

- The current definition of the ***British Pharmacopoeia*** under subsection 3(1) of the Act is the British Pharmacopoeia 2011, as amended by online updates. The British Pharmacopoeia 2011 is a collection of approximately 3375 monographs for pharmaceutical substances and medicinal products for human use. The monograph for human albumin specifies requirements for the plasma (including the use of nucleic acid amplification techniques), protein composition, molecular size distribution, bacterial endotoxins and sterility, amongst other things. Associated test methods are also included in the British Pharmacopoeia. The British Pharmacopoeia is published by The Stationery Office, on behalf of the Medicines and Healthcare products Regulatory Agency of the UK. It is available for purchase in hard copy or soft copy (compact disc or online edition). The British Pharmacopoeia reproduces all monographs and requirements of the European Pharmacopoeia.
- The current definition of the ***European Pharmacopoeia*** under subsection 3(1) of the Act is the European Pharmacopoeia 7<sup>th</sup> edition, including supplements 7.1 and 7.2. It includes more than 2000 specific and general monographs. The monograph for human albumin specifies requirements for the plasma (including the use of nucleic acid amplification techniques), protein composition, molecular size distribution, bacterial endotoxins and sterility, amongst other things. Associated test methods are also included in the European Pharmacopoeia. The European Pharmacopoeia is published by the Directorate for the Quality of Medicines & HealthCare of the Council of Europe. It is available for purchase in three formats – print, online and USB stick.
- The meeting reports and resolution of the TGC's 36<sup>th</sup> meeting referred to in this Explanatory Statement may be viewed and downloaded from the TGA Internet site.