EXPLANATORY STATEMENT

Subject: THERAPEUTIC GOODS ORDER (TGO) NO.70B - STANDARDS FOR EXPORT ONLY MEDICINES

Section 10, Therapeutic Goods Act, 1989

OUTLINE

Therapeutic Goods Order No. 70B Standards for Export Only Medicine (TGO 70B - Attachment 1) 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).

This Order revokes Therapeutic Goods Order No. 70 - Standards for Export Only Medicine (TGO 70) and Therapeutic Goods Order No. 70A – Amendments to Therapeutic Goods Order No. 70 (TGO 70A), and updates relevant pharmacopoeial standards that apply to medicines which are subject to the operation of the Act for export only.

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. The Therapeutic Goods Administration (TGA) is responsible for administering the Act.

Section 10 of the Act provides the Minister, or the Minister's delegate, with the power 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 to advise the Minister on a range of matters relating to standards for therapeutic goods.

Therapeutic goods must not be imported into, supplied in or exported from Australia unless they comply with any applicable standards determined under section 10 of the Act, other than standards relating to the labelling of the goods for supply in Australia.

TGO 70 came into effect on 29 May 2002, and specified relevant pharmacopoeial standards as applying to medicines which are subject to the operation of the Act for export only. TGO 70 required sponsors of export only medicines to meet standards set out either in the British Pharmacopeia, United States Pharmacopeia, Japanese Pharmacopeia or the European Pharmacopeia, and included references to the then current editions of those pharmacopoeias.

TGO 70A came into effect on 17 December 2003, and amended TGO 70 by updating the references to the British Pharmacopeia and the United States Pharmacopeia in TGO 70 to the then most current editions of those pharmacopoeias.

A pharmacopoeia is a comprehensive compilation of information regarding the preparation of medicines and characterisation of their ingredients by suitable monographs. A monograph contained in a pharmacopeia may be adopted as a standard by a health authority. Pharmacopoeias are published by the authority of a government or a medical or a pharmaceutical society.

As new editions of each of the pharmacopoeias referred to in TGO 70 have been published recently (since both TGO 70 and TGO 70A), the TGC recommended at its meeting on 7 September 2006 (by its resolution No. 29/07) that TGO 70 and TGO 70A both be revoked, and replaced with a new therapeutic goods order (TGO 70B) including updated editions of relevant pharmacopoeial standards.

The pharmacopoeias referred to in TGO 70 and/or TGO 70A, and the editions of those pharmacopoeias that the TGC in its Resolution No. 29/07 recommended be set out in a new Order (TGO 70B) are:

1. British Pharmacopoeia 2002 (set out in TGO 70A) to British Pharmacopoeia 2005;

2. United States Pharmacopoeia 26th edition (set out in TGO 70A) to United States Pharmacopoeia National Formulary USP 29-NF 24;

3. Japanese Pharmacopoeia 14th edition (set out in TGO 70) to Japanese Pharmacopoeia 14th edition, including Supplement 1 and Supplement 2; and

4. European Pharmacopoeia 4th edition (set out in TGO 70) to European Pharmacopoeia 5thedition, including Supplements 5.1 to 5.6.

TGO 70B will assist sponsors of export only medicines to comply with the requirements of the act, and provide continued flexibility for those sponsors in relation to the standards they must meet regarding export only medicines.

REGULATION IMPACT STATEMENT

The Office of Best Practice Regulation (OBPR) were consulted in relation to this matter, and advised that a Regulation Impact Statement (RIS) was not required (RIS ID 8823). Further, the adoption of TGO 70B has been supported by the TGC. However, the following relevant peak industry associations were consulted in relation to this matter, and indicated their acceptance of the proposed amendments: Australian Self-Medication Industry (ASMI), Medicines Australia (MED AU), Generic Medicines Industry Association (GMIA) and the Complementary Healthcare Council of Australia (CHC).

ATTACHMENTS

1. Therapeutic Goods Order no.70B – standards for export only medicine (TGO 70B).
2. Therapeutic goods order no. 70 - standards for export only medicine (TGO 70).
3. Therapeutic goods order no. 70A - amendment to therapeutic goods order no. 70 (TGO 70A).

COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1989

THERAPEUTIC GOODS ORDER NO. 70

STANDARDS FOR EXPORT ONLY MEDICINE

I, Terry Slater, delegate of the Minister for Health and Ageing for the purposes of section 10 of the Therapeutic Goods Act 1989 and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of the said Act, hereby

DETERMINE that the matters specified in a relevant monograph of each of the publications listed in column 1 below constitute alternative standards for medicine manufactured in Australia, or imported into Australia, for export only subject to the limitations (if any) set out in column 2:

Column 1	**Column 2**
British Pharmacopoeia (2001 edition)	(i) the medicine is not to be supplied in Australia, (ii) the exporter must hold evidence that a relevant authority of the country to which the medicine is to be exported has confirmed its willingness to accept the medicine which complies with this order, except in a country where the medicine is regulated other than as a medicine, and (iii) the medicine is not human blood and does not contain human blood components
United States Pharmacopoeia (25th edition)	"
Japanese Pharmacopoeia (14th edition)	"
European Pharmacopoeia (4th edition)	"

This Order shall commence to operate on the date it is gazetted in the Commonwealth Gazette.

Dated this 20th day of May 2002

Terry Slater
Delegate of the Minister for Health and Ageing

THERAPEUTIC GOODS ADMINISTRATION

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Commonwealth Department of Health and Ageing

Commonwealth of Australia Gazette No. GN 50, 17 December 2003

COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1989

Therapeutic Goods Order No. 70 A

Amendment to Therapeutic Goods Order No. 70 – Standards for Export Only Medicine

I, Terry Slater, delegate of the Minister for Health and Ageing for the purposes of section 10 of the *Therapeutic Goods Act 1989* and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of the said Act, hereby

AMEND Therapeutic Goods Order (TGO) No. 70 "Standards for Export Only Medicine" made on 20 May 2002 in the manner set out below.

Under the Column 1 in the TGO 70 where pharmaceutical standards are referenced:

1) (a) delete British Pharmacopoeia (2001 edition); and
(b) replace with British Pharmacopoeia (2002 edition)

2) (a) delete United States Pharmacopoeia (25th edition); and
(b) replace with United States Pharmacopoeia (26th edition)

This Order shall commence to operate on the date it is gazetted in the *Commonwealth Gazette.*

Dated this 5th day of December 2003

Terry Slater
Delegate of the Minister for Health and Ageing