Australian Government

Department of Health
Therapeutic Goods Administration

EXPLANATORY STATEMENT

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

Section 10, Therapeutic Goods Act, 1989

OUTLINE

Therapeutic Goods Order No. 70C *Standards for Export Only Medicine* (TGO 70C - Attachment 1) is an Order made by the delegate of the Minister for Health under section 10 of the *Therapeutic Goods Act 1989* (the Act).

TGO 70C revokes Therapeutic Goods Order No. 70B *Standards for Export Only Medicine* (TGO 70 B), and determines that the matters specified in the instrument constitute the standard applicable to medicines that are manufactured in Australia, or imported into Australia, solely for export (export only medicines).

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 (the TGC), a committee established by the Therapeutic Goods Regulations 1990 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.

Export only medicines are listed in the Australian Register of Therapeutic Goods, and it is a condition of the listing of such medicines that they are not permitted for supply in Australia, including via duty free outlets.

TGO 70B, which has been revoked and replaced by TGO 70C, specified that particular editions of international pharmacopoeia, being, the British Pharmacopoeia, the United States Pharmacopoeia, the European Pharmacopoeia and the Japanese Pharmacopoeia constitute alternative standards for export only medicines.

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.

At the time of the making of TGO 70B in February 2007, the British Pharmacopoeia was the only pharmacopoeia recognised in the Act as being the standard to which therapeutic goods for use in humans were required to conform if there was no Order in place under section 10 of the Act in relation to the goods.

The definition of the British Pharmacopoeia included in the Act at that time only included updates to that pharmacopoeia that were specified by the Minister in an order published in the *Gazette*.

In 2009, a number of amendments were made to the Act by the *Therapeutic Goods (Medical Devices and Other Measures) Act 2009* in relation to standards, with the effect that the United States Pharmacopoeia and the European Pharmacopoeia were added as additional 'default standards'. Definitions for each of these pharmacopoeia were introduced to the Act, and a new definition for the British Pharmacopoeia was also added (subsection 3(1) of the Act refers).

These new definitions include any additions and amendments made to the pharmacopoeia by the bodies responsible for their publication, from the effective date of such changes (i.e. without the need for the Minister to *Gazette* updates).

To reflect these developments, TG0 70C principally replaces the references to particular editions of each of the British, European and United States Pharmacopoeia in TGO 70B with references to those pharmacopoeia as they are defined in subsection 3(1) of the Act.

TGO 70C also updates the reference to the edition of the Japanese Pharmacopoeia mentioned in TGO 70B, from the 14th edition to the 16th edition, to reflect updates to that document since 2007 and because the Japanese Pharmacopoeia has not been added to the Act as a default standard.

TGO 70C determines that the British Pharmacopoeia, United States Pharmacopoeia, European Pharmacopoeia (as updated by the respective authorities responsible for those documents) and the 16th edition of the Japanese Pharmacopoeia constitute alternative standards for export only medicine. That is, it will be sufficient for the purposes of the Act in relation to compliance with applicable standards for an export only medicine to meet the relevant requirements set out in one of these pharmacopoeias.

TGO 70C will assist sponsors of export only medicines to comply with the requirements of the Act in relation to standards, and provide continued flexibility for sponsors of such products in relation to complying with applicable standards by specifying a number of different international pharmacopoeia with which to comply. TG0 70C continues the role of TGO 70B and relevant related previous s.10 Orders for export only medicines in supporting the quality and safety of export only medicines exported from Australia.

CONSULTATION
A draft of TGO 70C was made available to peak industry associations the Australian Self-Medication Industry, Medicines Australia, the Generic Medicines Industry Association and the Complementary Healthcare Council of Australia.

TGO 70C has also been considered and endorsed by the Therapeutic Goods Committee (the TGC) and has been adopted by the TGC.

In relation to compatibility with human rights, it is considered that TGO 70C is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*, and a Statement of Compatibility setting that out in further detail is set out below.

SUPPLEMENTARY MATERIAL - STATEMENT OF COMPATIBILITY FOR A LEGISLATIVE INSTRUMENT THAT DOES NOT RAISE ANY HUMAN RIGHTS ISSUES

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Therapeutic Goods Order No. 70C

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Bill/Legislative Instrument

TGO 70C is an Order made by the delegate of the Minister for Health under section 10 of the *Therapeutic Goods Act 1989* (the Act). The Order specifies pharmacopoeia (the British, European, United States and Japanese pharmacopoeias) that constitute alternative standards for medicines made in Australia, or imported into Australia, solely for export. These documents are comprehensive compilations of information about the preparation of medicines and the characterisation of their ingredients. Compliance with applicable standards is a requirement for marketing approval of export only medicines, and they may be cancelled if they do not so comply.

Human rights implications

This legislative instrument does not engage any of the applicable rights or freedoms.

Conclusion

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

Delegate of the Minister for Health