EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Order No.69 – General requirements for labels for medicines 2017

OUTLINE

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in or exported from Australia. The Therapeutic Goods Administration (TGA), which is part of the Department of Health, is responsible for administering the Act.

Under powers of the Act, the TGA is responsible for establishing and enforcing requirements for the way medicines are labelled for commercial supply in Australia. Under section 10 of the Act, the Minister may, by way of a legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods.

Therapeutic Goods Order No. 69 – General requirements for labels for medicines 2017 (TGO 69 (2017), this Order) is an Order made by the delegate of the Minister for Health under section 10 of the *Therapeutic Goods Act 1989* (the Act).

This Order repeals the existing Therapeutic Goods Order No. 69, entitled 'General requirements for labels for medicines', made on 27 August 2001 (TGO 69), as amended (Register ID: F2014C00926) which is due to 'sunset' under the *Legislation Act 2003* (the Legislation Act) soon. The sunsetting date for TGO 69 is 1 October 2017, as it was re-registered on Federal Register of Legislation (FRL) on 16 May 2007.

Labelling requirements for medicines have recently been reviewed, and two new labelling Orders have been implemented with a four year transition period. These new labelling Orders, Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines (TGO 91) and Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines (TGO 92), commenced on 31 August 2016. TGO 91 and TGO 92 are intended to replace TGO 69 at the end of the transition period provided for when those new instruments commenced (1 September 2020).

Although TGO 69 is now more than 16 years old and does not align with international best practice labelling standards, it is being remade to serve throughout this transition period for TGOs 91 and 92 to assist industry to adapt to the requirements in the new instruments. During this time, sponsors can choose between complying with either the requirements of TGO 69, or TGOs 91 or 92, as relevant to their medicine.

TGO 69 (2017) replaces TGO 69, principally to reflect the above transitional arrangements (previously these had been set out in TGOs 91 and 92, but not mentioned in TGO 69), remove from the scope of the Order medicines that are not required to be entered in the Australian Register of Therapeutic Goods because they are authorised for supply by health practitioner notification under subsection 19(7A) of the Act (introduced recently by the

Therapeutic Goods Amendment (2016 Measures No.1) Act 2017), and correct a small number of errors.

This Order commences on 1 July 2017 and, as with TGO 69, will cease to be in force once the four year transition period to TGO 91 and TGO 92 ends.

BACKGROUND

Standards made under section 10 of the Act may relate to any matter relevant to the quality, safety or efficacy of a medicine, and generally, a medicine must not be imported, exported or supplied if it does not conform to an applicable standard. Paragraph (c) of subsection 10(2) of the Act states that an Order establishing a standard for therapeutic goods may require that therapeutic goods, or a class of therapeutic goods identified in the Order, be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the Order.

TGO 69 (2017) mandates information that must be on labels and the format and placement in which it must be presented, to contribute to the quality use of medicines by Australian consumers and healthcare professionals. Examples of information required by TGO 69 (2017) include the name of the medicine, the name of the active ingredient and its strength or quantity, storage requirements, expiry date and the declaration of certain inert or inactive ingredients ('excipient' ingredients).

Compared to TGO 69, TGO 69 (2017):

- reflects the transition arrangement for the implementation of TGO 91 and TGO 92;
- notes that medicines that are authorised for supply by health practitioner notification under subsection 19(7A) of the Act (introduced recently by the *Therapeutic Goods Amendment (2016 Measures No.1) Act 2017*) are not required to comply with this Order;
- removes the references to goods intended solely for use in animals, and other references to animals or veterinary surgeons, that are no longer relevant as the definition of 'therapeutic goods' in the Act only relates to such goods that are for use in relation to humans; and
- makes a small number of minor fixes, including updating the definition 'warning statements' to replace the reference to the legislative instrument the 'Medicines Advisory Statements Specification 2014' (which has been repealed by the Medicines Advisory Statements Specification 2017) with a reference to the instrument made by the Minister under subsection 3(5A) of the Act, to ensure that the most current legislative instrument made under that provision must be complied with.

CONSULTATION

Other than the minor changes outlined above, TGO 69 (2017) does not represent a major change as compared with the legislative instrument it replaces, TGO 69. As such, the particular changes that would be made by TGO 69 (2017) have not been specifically consulted on, as they are minor and machinery in nature.

The Therapeutic Goods Committee (which no longer exists following amendments to regulations that took effect on 1 January 2017) was, however, consulted on some of these aspects.

At its 41st meeting, held on 4 September 2015, and its 42nd meeting on 13 May 2016, the Therapeutic Goods Committee (TGC) was asked to consider issues relating to the possible amendment of TGO 69. At its 41st meeting, the TGC noted the need to replicate TGO 69 to extend its operation beyond its sunsetting date of 1 October 2017. At its meeting on 13 May 2016, the TGC recommended that TGO 69 be varied by deleting the specific reference to '*Medicines Advisory Statements Specification 2014'* in consideration of the risks of not varying TGO 69, particularly the potential legal complexities that may arise if the Order did not refer to the current specification. The meeting reports and resolution of the TGC's 41st and 42nd meeting may be viewed and downloaded from the TGA's website (www.tga.gov.au), at no cost.

In addition, since 2011 extensive stakeholder consultations have been held with consumers, academics, healthcare professionals and industry in relation to the development of TGOs 91 and 92, which this Order has been amended (in part) to recognise.

In June 2017, targeted consultation was undertaken with the major industry sponsors that would supply unapproved therapeutic goods authorised for supply by health practitioner notification under subsection 19(7A) of the Act. In that consultation, in which the top 20 manufacturers and suppliers of unapproved goods via the Special Access Scheme and the relevant peak industry bodies, sponsors were made aware that Therapeutic Goods Orders Nos. 69, 91 and 92 will be amended to exempt goods supplied under subsection 19(7A) of the Act (the new Category C pathway) from the labelling requirements.

REGULATION IMPACT

The remaking of TGO 69 (as represented by this Order) to cover the transition period for the introduction of new labelling requirements in TGOs 91 and 92, was addressed in the Regulation Impact Statement - General requirements for labels for medicines - Version 3.0, July 2016 (http://ris.pmc.gov.au/2016/08/19/clearer-labels-medicines) that was prepared for these two orders.

REFERENCED DOCUMENTS

The following documents are referred to in TGO 69 (2017) and may be obtained from the following websites:

1. the industry code of practice entitled *Labelling Code of Practice: Designing usable non-prescription medicine labels for consumers,* published by the Communications Research Institute of Australia Inc. This code creates and modifies the labels that consumers can use effectively, and which are consistent with current regulations for those who write and design labelling for non-prescription products and may be obtained from ASMI's website (http://www.asmi.com.au/documents/Industry/labelling_code_of_practice.pdf), at no cost; and

2. the current edition of 'MIMS Annual' provides its comprehensive and trusted medicines information in a wide variety of formats that enable the busy healthcare professional to access the right information at the right time and in the most appropriate way and may be obtained from MIMS' website with an extra cost of $575 per year. Generally, most medicine sponsors are MIMS Annual subscribers and as such should not have any difficulties in accessing this information (http://www.mims.com.au/index.php/products/product-overview).

TGO 69 (2017) is a legislative instrument for the purposes of the Legislation Act.

In relation to compatibility with human rights, it is considered that TGO 69 (2017) 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 below.

SUPPLEMENTARY NOTE

Names of large volume injections [subsection 7(6)]

The naming of large volume injections is described at paragraph 7(6)(a) of this Order. This note provides further guidance to manufacturers in the naming of large volume injections. The 'non-proprietary name' should include the name or names of the active ingredient(s), together with a word(s) denoting the name of the dosage form.

The majority of large volume injections contain one, two or three active ingredients and the use of the non-proprietary name which specifies the identity and amount of each active ingredient together with the usual name of the dosage form should not present any difficulty.

However, it would be impractical to include the name of each individual active ingredient in the non-proprietary name for the medicine containing, for example, multiple amino acids. For such products the non-proprietary name can be a general name which categorises the types of active ingredient present.

For example:

'Amino Acid and Electrolyte Intravenous Infusion'

'Triglyceride, Phospholipid and Glycerol x% Intravenous Infusion'

The use of a general term such as 'electrolyte', 'carbohydrate', 'amino acid', etc. will be permitted where the product contains more than three active ingredients in one category.

SUPPLEMENTARY MATERIAL - STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS 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. 69 - General Requirements for Labels for Medicines 2017

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 Legislative Instrument

Although TGO 69 is now more than 16 years old and does not align with international best practice labelling standards, it is being re-made to serve throughout the transition period for the new Labelling Orders, Therapeutic Goods Order No. 91- Standard for labels of prescription and related medicines (TGO 91) and Therapeutic Goods Order No.92- Standard for labels of non-prescription medicines (TGO 92).

The re-made *Therapeutic Goods Order No. 69 - General Requirements for Labels for Medicines 2017* [TGO 69 (2017)] was drafted to repeal Therapeutic Goods Order No. 69, entitled 'General requirements for labels for medicines', made on 27 August 2001, as amended (Register ID: F2014C00926), which was due to 'sunset' under the *Legislation Act 2003* soon (1 October 2017).

TGO 69 (2017) does not represent a significant change as compared with the legislative instrument it replaces, TGO 69, except the following changes have been included:

1. reflection of the transition arrangement for the implementation of TGO 91 and TGO 92;
2. notes that medicines that are authorised for supply by health practitioner notification under subsection 19(7A) of the Act (introduced recently by the *Therapeutic Goods Amendment (2016 Measures No.1) Act 2017*) are not required to comply with this Order;
3. removal of the references to goods intended solely for use in animals, and other references to animals or veterinary surgeons; and
4. a small number of minor fixes, including updating the definition 'warning statements' to replace the reference to the legislative instrument the 'Medicines Advisory Statements Specification 2014' (which has been repealed by the Medicines Advisory Statements Specification 2017) with a reference to the instrument made by the Minister under subsection 3(5A) of the Act, to ensure that the most current legislative instrument made under that provision must be complied with.

TGO 69 (2017) is made by a delegate of the Minister under section 10 of the *Therapeutic Goods Act 1989*. TGO 69 (2017) sets out the general requirements for the labelling of listed and registered medicines in the Australian Register of Therapeutic Goods.

TGO 69 (2017) will commence on 1 July 2017 and will cease to be in force once the four year transition period to TGO 91 and TGO 92 ends (1 September 2020).

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.

Larry Kelly, delegate of the Minister for Health