EXPLANATORY STATEMENT

Therapeutic Goods Act 1989
Section 10

Therapeutic Goods Order No. 69D *Amendment to Therapeutic Goods Order No. 69 general requirements for labels for medicines*

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 (the TGA), a part of the Department of Health, is responsible for administering the Act.

Therapeutic Goods Order No. 69D *Amendment to Therapeutic Goods Order No. 69 General requirements for labels for medicines* (TGO 69D) is an Order made by the delegate of the Minister for Health under section 10 of the Act.

TGO 69D amends Therapeutic Goods Order No.69 *General requirements for labels for medicines* (TGO 69), principally to omit references in TGO 69 about labelling requirements under the TGA document titled '*Required Advisory Statements for Medicine Labels*' (the RASML) and replaced by references to the advisory statements required to be included on the medicine's label set out in a legislative instrument made by the Minister under subsection 3(5A) of the Act (as in force from time to time). The amendment is carried out by amending the definition of "warning statements". The legislative instrument is the *Medicines Advisory Statements Specification 2014*.

TGO 69D commenced on the day after it was registered on the Federal Register of Legislative Instruments.

BACKGROUND

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 consulting with a committee established under the *Therapeutic Goods Regulations 1990* (the Regulations) to advise the Minister on standards. The Therapeutic Goods Committee (TGC) is the committee established for this purpose under regulation 34 of the Regulations.

TGO 69 is a standard for medicines made under section 10 of the Act. Specifically, it requires certain information to be included on medicines labels, and sets out requirements in relation to where and how such information is to be presented.

Paragraph 3(2)(g) of TGO 69 requires that medicine labels must include warning statements, where these apply to the medicines. The definition of 'warning statements' in TGO 69 currently includes any labelling requirements specified in the September 2008 edition of the RASML (also known as 'Update 4').

TGO 69D replaces this reference to the September 2008 edition of the RASML in the definition of 'warning statements' in TGO 69 with a reference to the *Medicines Advisory Statements Specification 2014* made by the Minister under subsection 3(5A) of the Act (the Specification), as in force from time to time.

Replacing the reference to the RASML in TGO 69 with a reference to the Specification will support the streamlining of requirements relating to the inclusion of advisory statements on medicines labels.

In particular, this will permit TGO 69 to refer to the Specification as in force from time to time (because the Specification is a legislative instrument) rather than, as has been the case previously, having to update TGO 69 each time a new edition of the RASML is proposed to be adopted.

In addition, it is also important to note that medicines mentioned in Part 1 of Schedule 10 to the Regulations – which are comprised of prescription medicines and medicines such as medical gasses, radiopharmaceuticals and dialysis solutions – will not be required to comply with the Specification.

These are currently captured by the scope of TGO 69, however there are important reasons why this is not necessary.

In the case of prescription medicines, the exclusion of these medicines from the need to comply with the requirement to include advisory statements on the medicine's label (as set out in the Specification) under TGO 69 (as amended by TGO 69D) reflects the current regulatory arrangement that access to prescription medicines is controlled by registered medical practitioners, and that the transmission of information about the potential benefits and risks of a prescription medicine is intrinsic to the consultation between patient and prescriber. Further, the risk-benefit profile of such medicines may vary considerably from patient to patient.

In relation to radiopharmaceuticals and the like, these are not, in most cases, supplied directly to consumers, but rather are principally utilised in a treatment setting such as a hospital.

The Specification consists of two separate versions of the RASML. Version 1 as set out in Schedule 1 to that Specification reflects the current edition of the RASML that was published by the TGA in 2008 (incorporating amendments up to "Update 4" of the RASML). Version 2 as set out in Schedule 2 to that Specification incorporates two subsequent updates to the RASML between 2009-2011 ("Update 5" and "Update 6") and a number of other advisory statements such as specific warnings about the use of cough and cold medicines by children, which have been required as a condition of marketing approval to be included on the labels of such medicines since early 2012.

Schedule 1 of the Specification will apply under the Specification for the first 18 months after the commencement of that instrument, and Schedule 22 will apply after that time. This will give sponsors a period of time to adjust to any new advisory statements they need to include on their products' labels under Version 2. Sponsors, will, however, have the option of complying with Version 2 from the Specification's commencement if they wish to do so.

CONSULTATION

Updates 5 and 6 of the RASML (which are incorporated into Schedule 2 of the Specification) were published in draft form on the TGA's website (www.tga.gov.au), and comments from industry were invited (via direct contact with relevant peak industry bodies), in July-August 2009 (in relation to Update 5) and in February- May 2011 (in relation to Update 6). A total of 22 submissions were received.

Following that consultation, Update 6 was revised to incorporate some of the feedback received from industry in that regard. A response from the TGA to industry's comments was published on the TGA website in October 2011.

In February 2012, the TGA sought comments from interested parties on proposed advisory statements for cough and cold medicines for use in children (which are included in Schedule 2 of the Specification).

This followed reviews between 2007-2009 by regulatory authorities in the USA, Canada, the United Kingdom, New Zealand and Australia of the safety and efficacy of over-the-counter cough and cold medicines for children under two years of age. A large number of submissions were received in relation to that request for comment, and the TGA subsequently published a response summarising its consideration of each of the submissions.

In 2012 and 2013, the TGA published requests for submissions in relation to proposed advisory statements for loperamide, fexofenadine, famciclovir, loratadine, desloratadine, azelastine and *Kunzea ambigua* (these also form part of Schedule 2 of the Specification). The TGA considered the submissions and published its conclusions on the respective consultation web-pages.

These consultations were consistent with the level of consultation agreed between the TGA and industry for the updating of the RASML.

In addition, the Therapeutic Goods Committee (TGC) was consulted in relation to Update 5 at its October 2009 and in relation to Update 6 at its 6April 2011 meeting. The TGC was consulted in relation to the Specification (and the proposal to refer to it rather than to particular editions of the RASML in TGO 69) at its meeting in August 2013. At the latter meeting, the TGC was supportive of the new arrangements relating to the Specification and TGO 69.

In relation to compatibility with human rights, it is considered that the TGO 69D 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 attached.

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

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

Therapeutic Goods Order No.69D *Amendment to Therapeutic Goods Order No.69 General requirements for labels for medicines*

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

Therapeutic Goods Order No.69D *Amendment to Therapeutic Goods Order No.69 General requirements for labels for medicines* is made by the Minister under section 10 of the *Therapeutic Goods Act 1989* (the Act), and amends Therapeutic Goods Order No.69 *General requirements for labels for medicines* (TGO 69) to replace the current reference in TGO 69 to the September 2008 edition of the RASML in the definition of 'warning statements' in TGO 69 with a reference to the *Medicines Advisory Statements Specification 2014* made by the Minister under subsection 3(5A) of the Act (the Specification). In particular, this will permit TGO 69 to refer to the Specification as in force from time to time (because the Specification is a legislative instrument) rather than, as has been the case previously, having to update TGO 69 each time a new edition of the RASML is proposed to be adopted.

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.

Professor John Skerritt, delegate of the Minister for Health