EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Order No. 91 - Standard for labels of prescription and related 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 (TGA), which is part of the Department of Health and Aged Care, 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. Further, under subsection 10(4) of the Act, the Minister must not make, vary or revoke an order unless consultation has taken place with a committee established by the regulations to advise the Minister on standards.

Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines (TGO 91) has been drafted in conjunction with Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines (TGO 92). The purpose of TGO 91 and TGO 92 is to replace, over time, the Therapeutic Goods Order No. 69 - General requirements for labels for medicines (TGO 69), the current labelling Order. TGO 69 is now more than 16 years old and does not align with labelling standards set by overseas regulators.

Separate Orders were drafted in recognition of the specific risks associated with prescription and non-prescription medicines and their different contexts of use (i.e. prescription by a medical practitioner versus self-selection by a consumer).

Both Orders will be implemented with a 4-year transition period. During this time, sponsors can choose between complying with the current requirements of TGO 69 or the new Order that is relevant to their medicine. At the end of the transition period, all medicines supplied in Australia must be labelled in accordance with TGO 91 or TGO 92, whichever applies.

The amendments to the requirements for labels of prescription and related medicines involve substantial policy changes to better align with current international best practice for medicine labelling. Key changes include:

- Increased prominence and consistent location of information on active ingredients to facilitate product identification and reduce the opportunity for error (noting the minimum text height for all other information is 1.5 millimetres). This includes:
    - introduction of new requirements for the name(s) and quantities of active ingredient(s):

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- a minimum text size of 3.0 millimetres on the main label, placed either directly under or adjacent to the trade name; or
- for a medicine containing four or more active ingredients, in a minimum text size of 2.5 millimetres on a side or rear panel; or
- for a medicine supplied in a small container (i.e. containers with a capacity up to or equal to 25 millilitres but greater than 3.0 millilitres), the name of the medicine and the name of all active ingredients in a minimum text size of 2.0 millimetres.

- New requirements for declarations of certain substances (e.g. crustacea, fish, eggs, soya, milk, tree nuts). The cut off for declaring gluten has also been modified and aligns with Food Standards Australia and New Zealand.
- Introduction of a new requirement such that Schedule 1 substances must be declared on the label or identified by a statement that directs consumers to the Consumer Medicine Information. The current TGO 69 requirements for declaration of Schedule 1 substances do not apply to prescription medicines.

  The purpose of these requirements is to improve public safety because these substances have the potential to cause severe allergic reactions or result in other serious adverse health consequences in some individuals.

- Introduction of a new requirement for a defined space to be made available for a dispensing label. The purpose of this is to ensure that other information is not covered up when a dispensing label is applied by a pharmacist.
- Introduction of a new requirement for inclusion of a machine-readable code. The purpose of this requirement is to more closely align with international requirements, noting that this will not preclude future convergence with the international serialisation requirements for prescription medicines.

TGO 91 will commence on 31 August 2016.

The intention is for TGO 69 to be re-made, thereby extending its period of operation beyond the current sun-setting date of 1 October 2017. Further, the intention is for TGO 69 to cease to be in force once the 4-year transition period for TGO 91 ends (from 1 September 2020).

BACKGROUND

TGO 69 provides a standard within the Act, setting out the requirements for the labelling of medicines. In addition to other state or territory legislation, it provides the core compliance standard underpinning the legislative framework regulating the labelling of prescription and non-prescription medicines to the public.

TGO 69 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 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).

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CONSULTATION

A broad range of stakeholder groups, including consumers, academics, healthcare professionals and industry, have assisted the TGA in the development of TGO 91. Since 2011, extensive stakeholder consultation has been conducted as part of a number of broader TGA reviews. Two public consultations on new draft labelling orders also took place, in 2012 and 2014.

The Therapeutic Goods Committee (TGC) has been consulted in the development of the new Orders, TGO 91 and 92, as required under subsection 10(4) of the Act. The TGC was established under regulation 34 of the Therapeutic Goods Regulations 1990 to provide advice and to make recommendations to the Minister on matters such as the adoption of standards for therapeutic goods and matters relating to the requirements for labelling and packaging of therapeutic goods.

The Office of Best Practice Regulation (OBPR) was consulted on a Regulation Impact Statement (RIS), including an analysis of options for labelling changes and the cost impacts of each option. OBPR assessed the RIS as compliant with the Government's RIS requirements and the RIS is best practice.

TGO 91 is a legislative instrument for the purposes of the *Legislation Act 2003*.

In relation to compatibility with human rights, it is considered that TGO 91 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.

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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. 91 - Standard for labels of prescription and related 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 Legislative Instrument

The *Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines* (TGO 91) is made by a delegate of the Minister under section 10 of the *Therapeutic Goods Act 1989*. TGO 91 sets out the requirements for the labelling of prescription and related medicines.

Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines (TGO 91) has been drafted in conjunction with Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines (TGO 92). The purpose of TGO 91 and TGO 92 is to replace, over time, the Therapeutic Goods Order No. 69 - General requirements for labels for medicines (TGO 69), the current labelling Order. TGO 69 is now more than 16 years old and does not align with labelling standards set by overseas regulators.

Separate Orders were drafted in recognition of the specific risks associated with prescription and non-prescription medicines and their different contexts of use (i.e. prescription by a medical practitioner versus self-selection by a consumer).

Both Orders will be implemented with a 4-year transition period. During this time, sponsors can choose between complying with the current requirements of TGO 69 or the new Order that is relevant to their medicine. At the end of the transition period, all medicines supplied in Australia must be labelled in accordance with TGO 91 or TGO 92, whichever applies.

The amendments to the requirements for labels of prescription and related medicines involve substantial policy changes to better align with current international best practice for medicine labelling. Key changes include:

- Increased prominence and consistent location of information on active ingredients to facilitate product identification and reduce the opportunity for error (noting the minimum text height for all other information is 1.5 millimetres). This includes:
    - introduction of new requirements for the name(s) and quantities of active ingredient(s):
        - a minimum text size of 3.0 millimetres on the main label, placed either directly under or adjacent to the trade name; or

- for a medicine containing four or more active ingredients, in a minimum text size of 2.5 millimetres on a side or rear panel; or
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  The purpose of these requirements is to improve public safety because these substances have the potential to cause severe allergic reactions or result in other serious adverse health consequences in some individuals.

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- Introduction of a new requirement for inclusion of a machine-readable code. The purpose of this requirement is to more closely align with international requirements, noting that this will not preclude future convergence with the international serialisation requirements for prescription medicines.

TGO 91 will commence on 31 August 2016.

The intention is for TGO 69 to be re-made, thereby extending its period of operation beyond the current sun-setting date of 1 October 2017. Further, the intention is for TGO 69 to cease to be in force once the 4-year transition period for 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.

Harry Rothenfluh, delegate of the Minister for Health and Aged Care