EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Order No. 95 - Child-resistant packaging requirements 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.

Therapeutic Goods Order No. 95 - *Child-resistant packaging requirements for medicines 2017* (TGO 95, 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 is designed to succeed the existing Therapeutic Goods Order No. 80 (TGO 80), entitled '*Child-Resistant Packaging Requirements for Medicines*', gazetted on 27 August 2008 (Register ID: F2008L03428), because TGO 80 will sunset on 1 October 2018 under the provisions of the *Legislation Act 2003*.

This Order commences the day after it is registered on the Federal Register of Legislation (FRL). The implementation of this Order includes a transition period until 30 September 2018 for medicines to achieve compliance with the provisions of this Order. During this time, sponsors can choose between complying with the current requirements of TGO 80 or the new Order as relevant to their medicine. At the end of the transition period, all medicines supplied in Australia to which this Order applies, must comply with the requirements of this Order.

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.

The purpose of this Order (and of the current TGO 80) is to set particular requirements for the packaging of medicines that may present a significant risk of toxicity to children if accidentally ingested. These requirements relate to child-resistant packaging — that is, packaging that is designed to be resistant to opening by children, thereby reducing the incidence of accidental poisoning.

The need for this type of packaging is based on the inclusion of certain substances in a medicine and these substances are identified in Schedule 1 to both this Order and TGO 80. The Orders also include references to international standards with which child-resistant packaging must comply. Child-resistant packaging serves a critical public health purpose in relation to safety of therapeutic goods in Australia, for which there is a need that will continue after TGO 80 sunsets on 1 October 2018.

Compared to TGO 80, this Order:

- removes examples of substances in Part 1 and Part 3 of Schedule 1 to the Order, for the purpose of preventing the Order being misinterpreted as an exhaustive list of substances, and to promote the use of the World Health Organization Anatomical Therapeutic Chemical (WHO ATC) classification system to identify by class the substances to which this Order applies;
- includes additional substances, podophyllum/podophyllotoxin and alpha blockers, in Schedule 1 to the Order. These substances were included due to their toxicity, extent and pattern of availability in the community, and number of incidents of accidental poisonings. 'Alpha blockers' are not identified as a separate class under the WHO ATC classification system. Therefore, alpha blockers have been added to the Order under the classes 'alpha and beta blockers' and 'alpha-adrenoreceptor antagonists' in line with the WHO ATC. The alpha-adrenoreceptor antagonist 'phenoxybenzamine' has been specifically identified, as it is currently not classified in the WHO ATC;
- updates the international packaging standards referenced in the Order to reflect the current editions of the standards;
- makes minor editorial amendments in line with current legislation, including updates to reflect current Australian Approved Names for substances identified in the Order, and TGA's new statutory advisory committee structure.

CONSULTATION

The changes made by this Order to current child-resistant packaging requirements are minor and machinery in nature.

The inclusion of podophyllum/podophyllotoxin in this Order will affect one product registered on the Australian Register of Therapeutic Goods (ARTG) and currently in supply in Australia. There are two other products containing podophyllum/podophyllotoxin on the ARTG which will be unaffected by the change; one already has child-resistant packaging and the other is exempt from the Order as it is a semi-solid product intended for application to the skin.

The inclusion of alpha-blockers in this Order will potentially affect two products on the ARTG. According to TGA records, neither are currently marketed in Australia. There are 138 other alpha-blocker products on the ARTG. However, of these, 29 products already comply with this Order and nine products are exempt from the Order as they are for export only. The remaining products contain substances that are classified as both alpha- and beta-blockers and, as beta-blockers are already required by the Order to have child-resistant packaging, the addition of the alpha blockers to the Order will not affect these products.

In a targeted consultation, sponsors of products that may be affected by inclusion of the additional substances were contacted to comment on the addition of the proposed substances.

With consideration to replies received in the targeted consultation, the Advisory Committee on Medicines (ACM) endorsed the remaking of TGO 80, including incorporation of the proposed changes.

REGULATION IMPACT

The proposed changes have been reviewed by the Office of Best Practice Regulation (OBPR) within the Department of the Prime Minister and Cabinet who have determined that the changes will have minor regulatory impact on businesses, community organisations and individuals and a regulation impact statement is not required (OBPR ID 22051).

REFERENCED DOCUMENTS

The following documents are referred to in the Order and may be obtained from various sources including the International Organization for Standardisation (ISO) website, the SAI Global website or the Canadian Standards Association (CSA) website:

1. The International Standards Organisation Standard ISO 8317:2015 entitled *Child-resistant packaging — Requirements and testing procedures for reclosable packages* with a fee of $121.00 (pdf version).
2. The British Standards Institution Standard BS EN ISO 8317:2015 entitled *Child-resistant packaging. Requirements and testing procedures for reclosable packages* with a fee of $157.06 (hardcopy version). Its content is identical to ISO 8317:2015.
3. The Canadian Standards Association Standard CSA Z76.1-16 entitled *Reclosable child-resistant packages* from the CSA Canadian website with a fee of $110 Canadian dollars.
4. The United States Code of Federal Regulations, Title 16, Part 1700, Section [1700.]15, entitled *Poison prevention packaging standards,* and Title 16, Part 1700, Section [1700.]20 entitled *Testing procedure for special packaging*, as in effect at the date of this Order may be viewed and downloaded from the United States Government Publishing Office free of charge.
5. The Australian Standard AS 1928-2007 entitled *Child-resistant packaging - Requirements and testing procedures for reclosable packages* (ISO 8317:2003, MOD) with a fee of $130.23 (pdf version). The provisions of this standard are reproduced from ISO 8317:2003 and its technical corrigendum, with Australian variations based on Australia's smaller population size.

The referenced documents are available to the public from the sources, and for the fees, noted above. This reflects established practice for access to Australian and international standards, and it is expected that affected sponsors that are required to comply with this Order would be familiar with these documents and have access to them. The fees noted above are similar to those charged for previous versions of the above documents, and the amounts would not appear onerous. It is very important for public health and safety that standards made under section 10 of the Act are able to reflect the most up to date scientific knowledge and requirements, and these international and Australian standards are referred to in the Order for that purpose. The standards referenced in the United States Code of Federal Regulations are available to the public free of charge.

TGO 95 is a legislative instrument for the purposes of the *Legislation Act 2003*.

In relation to compatibility with human rights, it is considered that TGO 95 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 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. 95 - Child-resistant packaging requirements 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

The *Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017* (TGO 95, this Order) is designed to succeed the existing Therapeutic Goods Order No. 80, entitled '*Child-Resistant Packaging Requirements for Medicines*', gazetted on 27 August 2008 (Register ID: F2008L03428), because TGO 80 will sunset on 1 October 2018 under the provisions of the *Legislation Act 2003*.

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This Order commences on the day after registration on the Federal Register of Legislation.

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