

## **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 Organization for Standardization Standard [ISO 8317:2015](#) entitled *Child-resistant packaging — Requirements and testing procedures for reclosable packages*, which is available from the ISO website (<https://www.iso.org>) for a fee of \$121.00 (pdf version) – this document is intended to be incorporated as published by the International Organization for Standardization on 5 November 2015;
2. The British Standards Institution Standard [BS EN ISO 8317:2015](#) entitled *Child-resistant packaging. Requirements and testing procedures for reclosable packages*, which is available from the website of SAI Global Limited (<https://infostore.saiglobal.com/>) for a fee of \$157.06 (hardcopy version) or \$309.79 (pdf) – this document is intended to be incorporated as published by the British Standards Institution on 31 December 2015 (its content is identical to ISO 8317:2015);
3. The Canadian Standards Association (CSA) Standard [CSA Z76.1-16](#) entitled *Reclosable child-resistant packages* which is available from the CSA Canadian website (<http://www.csagroup.org/>) for a fee of CAD \$110.00 (pdf) – this document is intended to be incorporated as published by the Canadian Standards Association on 1 December 2016;
4. The United States Code of Federal Regulations, [Title 16, Part 1700, Section \[1700.115\]](#), entitled *Poison prevention packaging standards*, and [Title 16, Part 1700, Section \[1700.120\]](#) 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; and
5. The Australian Standard [AS 1928-2007](#) entitled *Child-resistant packaging - Requirements and testing procedures for reclosable packages* (ISO 8317:2003, MOD), which is available from the website of SAI Global Limited (<https://infostore.saiglobal.com/>) for a fee of \$130.23 (pdf version) – this document is intended to be incorporated as published by Standards Australia on 31 October 2007 (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 above documents are adopted because they represent critical Australian or international benchmarks of safety and quality in relation to the safety of child-resistant packaging for medicines. It would not be feasible from a regulatory perspective to not adopt such benchmarks because they are not available for free.

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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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 continues after TGO 80 sunsets on 1 October 2018.

Compared to TGO 80, this Order:

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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;
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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**