Australian Government
Department of Health
Therapeutic Goods Administration

Child-resistant packaging requirements for medicines

Guidance on TGO 95

Version 1.0, May 2018

TGA Health Safety Regulation

Contents

Introduction

This guidance assists medicine sponsors to meet the Australian requirements for child-resistant packaging (CRP). The requirements are outlined in Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017 (TGO 95). These requirements apply to prescription, over-the-counter (OTC) and listed medicines.

This guidance replaces the previous Guidance on Therapeutic Goods Order No. 80 (TGO 80) Child-resistant packaging requirements for medicines.

How to use this guidance

This guidance is not provided as a legal interpretation of TGO 95. It includes clarification on, and information relating to, the mandatory requirements.

Note

Following this guidance is not a guarantee that your CRP is fully compliant.

About child-resistant packaging

The purpose of TGO 95 is to set particular requirements for the packaging of medicines that present a significant risk of toxicity to children if accidentally ingested. These requirements describe packaging that is designed to be resistant to opening by children, thereby reducing the incidence of accidental poisoning.

CRP is not child proof – it should be difficult for young children to open, but should not be difficult for adults to use properly. It is intended to provide a delay in the time taken by a child to open a package, thereby increasing the probability of adult intervention before the contents are fully accessible.

Child-resistance is associated with a package as a whole, rather than an individual component such as a bottle closure.

Which medicines need child-resistant packaging?

Medicines that contain a substance that is listed in Part 1 (a list of substance classes) or Part 2 (a list of individual substances) of Schedule 1 to TGO 95 require CRP, unless a specific exemption applies. The requirements apply regardless of whether the medicine is available only on prescription or can be self-selected as an OTC or listed medicine.

Part 1 of Schedule 1 uses the Anatomical Therapeutic Chemical (ATC) classification system, an index of active ingredients by the World Health Organization Collaborating Centre for Drug Statistics Methodology. This index classifies drugs according to the organ or system on which they act, their therapeutic intent and the drug's chemical characteristics.

Part 2 of Schedule 1 lists specific substances rather than classes. A medicine containing a substance listed in Part 2 requires CRP unless an exemption applies (see *Medicines to which TGO 95 does not apply*).

Note

Compared to the previous Order for CRP (Therapeutic Goods Order No. 80 - Child-Resistant Packaging Requirements for Medicines), Part 1 of Schedule 1 to the Order no longer includes examples of substances. This change was made to:

- prevent Part 1 of Schedule 1 being misinterpreted as an exhaustive list of substances
- promote the use of the ATC index to identify by class the substances to which this Order applies

The criteria used to determine whether a substance should have CRP are outlined in Section 4 of the Order, and include:

- the toxicity of the substance and risk of harm if accidentally ingested by a child;
- the extent and patterns of availability in the community;
- the number and type of incidents reported to the Poisons Information Centres;
- the consequences of incidents (e.g. hospital admission, serious injury, or death);
- any special needs of patients who regularly need access to medicines (e.g. older persons or people with a disability); and
- the technical feasibility and practicality of CRP for medicines containing the substance.

A substance will generally require CRP if the amount contained in a maximum prescription quantity or the largest retail pack size is likely to produce significant harm in a typical 18 month old child. The requirement for CRP is not restricted to medicines that are ingested; CRP may also apply to medicines that may cause serious harm through inadvertent contact with the eyes, skin or mucous membranes (e.g. mouth or tongue).

Note

Compared to TGO 80, TGO 95 includes two additional substances in Schedule 1:

- podophyllum/podophyllotoxin
- alpha blockers.

These were included due to their toxicity, extent and pattern of availability in the community, and the number of incidents of accidental poisonings that have occurred in Australia.

'Alpha blockers' are not identified as a separate class in the ATC Index. Therefore, alpha blockers have been added to the Order under the classes 'alpha and beta blockers' and 'alpha-adrenoreceptor antagonists' in line with the ATC index. The alpha-adrenoreceptor antagonist 'phenoxybenzamine' has been specifically identified, as it is currently not classified in the ATC index.

Medicines to which TGO 95 does not apply

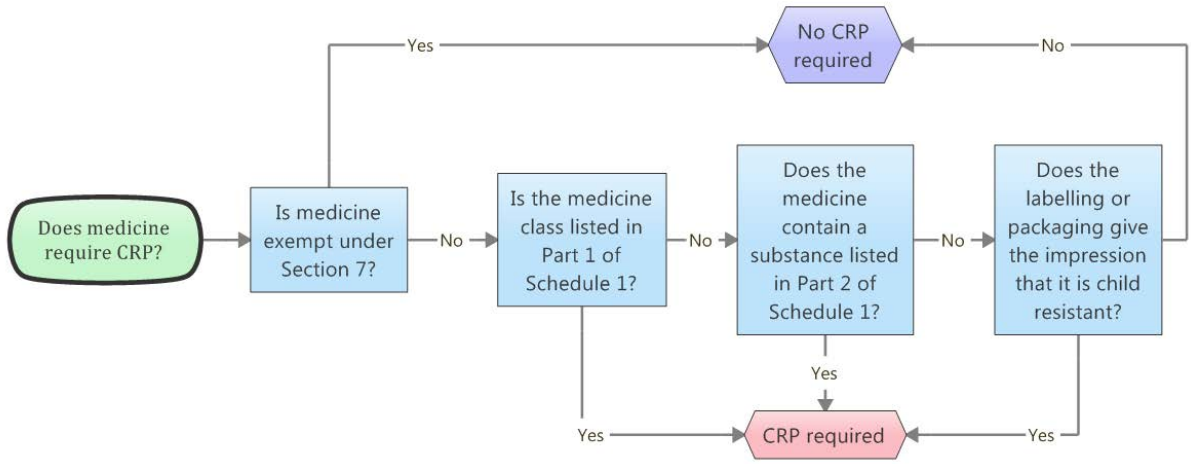
Section 7 of TGO 95 provides a list of pack types, dosage forms, intermediates and goods that do not require CRP. In general, medicines do not require CRP where the risk of accidental ingestion by children is low. These are goods that are difficult to open and gain access to the contents, e.g. medicines in small containers with restricted flow inserts.

Some exemptions are specific to the dosage form and intended application. For example, solids or semi-solids intended for application to the skin or mucous membranes, such as creams, ointments, sticks and dusting powders for external application.

Other exemptions are based on there being minimal chance of the medicine being available to children. Examples include bulk tablets not at their final stage of manufacture because they are still to be packaged; medicines only for use in a hospital setting; or bulk medicine packs that are only supplied to pharmacies.

To determine if a medicine requires CRP, sponsors should follow the flowchart in Figure 1.

Figure 1: Flowchart to determine if a medicine requires CRP.



Example

A sponsor is seeking to register a tablet containing diazepam in a reclosable bottle. The sponsor is not sure if the packaging requires CRP. The sponsor searches the ATC Index for 'diazepam'. The results show that diazepam is classified as:

N NERVOUS SYSTEM

N05 PSYCHOLEPTICS

N05B ANXIOLYTICS

N05BA Benzodiazepine derivatives

The sponsor then compares the results to Part 1 of Schedule 1 to the Order. 'Benzodiazepine derivatives' is listed in Part 1 of Schedule 1. If no exemptions apply then CRP must be used for the bottle of diazepam tablets.

My medicine requires CRP – what next?

The requirements for CRP are set out in Sections 8, 9 and 10 of TGO 95.

Generally, CRP must remain fit for purpose until the expiry date of the medicine. CRP must be able to withstand at least the number of openings and closings (if a reclosable container) needed for removal of all individual doses - no deterioration in the child-resistant characteristics or performance should occur.

Example

A tablet is packaged in a bottle with a child-resistant closure. The pack size is 100 tablets. The recommended dosage is one tablet daily. The child-resistant closure must be demonstrated to withstand at least 100 openings and closings without any deterioration.

There is a requirement that performance of the CRP must not be adversely affected by the contents of the package. In some cases, e.g. liquid formulations, medicine components may be incompatible with particular plastics and may cause failure of the CRP. In other cases, the performance of a closure can be compromised by liquid contents which are sugary because crystals or a layer of the liquid may be deposited around the mouth of the bottle with repeated use.

Reclosable packages

A reclosable package is a container closure which is capable of being reclosed with a similar degree of security after it has been initially opened.

Subsection 9(1) of the Order specifies international and Australian Standards with which child-resistant reclosable packages must comply. Compliance with any one of the five Standards is considered to provide equal assurance that a package, when tested according to the Standards, meets an acceptable level of child-resistance and ease of use for adults. There is no order of precedence for the Standards: all are accepted with equal standing.

The Standards referenced in the Order are available to the public for a fee, as is established practice for access to Australian and international Standards. The referenced United States Code of Federal Regulations Standards is available to the public free of charge.

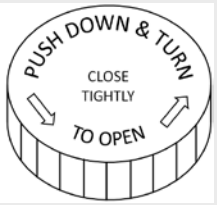
Note

Compared to TGO 80, the Standards referenced in TGO 95 have been updated to reflect the current editions.

In addition to compliance with Standards, the reclosable package must include adequate directions for opening and effectively reclosing the package. These directions must be clearly written in English or demonstrated in graphics.

Example

Illustrated example of directions on a reclosable bottle cap with CRP:



Evidence of compliance with Standards

Sponsors are required to hold, and be able to submit upon request, evidence that the CRP complies with at least one of the nominated Standards. This evidence may be requested during the TGA evaluation process or post-market review. For listed medicines, at the time that an application for listing is submitted, sponsors must certify that the medicine conforms to every applicable Standard which includes those relating to CRP.

In most cases, certification issued by an agency accredited to test packaging for child-resistance is sufficient evidence of compliance with Standards.

Other evidence requirements

Sponsors must also hold evidence to demonstrate that the CRP:

- is fit for purpose during the shelf-life of the medicine
- retains child-resistant properties throughout the in-use life of the medicine
- is not adversely affected by the contents
- is not adversely affected by any change in specifications of the package.

Additionally sponsors should hold information ensuring that the expected child-resistant performance of the package is achieved and maintained during the packaging processes.

Extrapolation of test results

Many of the nominated Standards permit extrapolation of test results over a range of similar packages, such as a range of closure (neck diameter) or container sizes, provided all other characteristics of the package remain the same.

Example

If a series of containers differ only in capacity and the closures are identical, the International Standards Organization Standard ISO 8317:2015 requires testing only on the largest and smallest container sizes.

Extrapolation of results from one package to another in a series to the extent permitted by the nominated Standard chosen for test is acceptable for the purposes of compliance with this Order.

Non-reclosable packages

Unlike the requirements for reclosable forms of CRP, requirements for non-reclosable packaging do not involve performance testing. Instead the requirements are based on design and materials of construction as outlined in Section 10 of the Order. Blister packaging is generally considered to be compliant with requirements for CRP.

Transition period

Prior to TGO 95, the requirements for CRP were outlined in Therapeutic Goods Order No. 80 - *Child-Resistant Packaging Requirements for Medicines* (TGO 80), which will cease to exist (sunset) on 1 October 2018.

TGO 95 commenced on 5 December 2017, the day after registration on the Federal Register of Legislation (FRL). Sponsors have **until 30 September 2018** to achieve compliance with the provisions of TGO 95. During this time, sponsors can choose between complying with the requirements of TGO 80 or TGO 95 as relevant to their medicine. At the end of the transition period, all medicines supplied in Australia to which TGO 95 applies, must comply with the requirements of TGO 95.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Scientific Operations Management Section	8/05/2018

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Reference/Publication #