



**Australian Government**

---

**Department of Health**  
Therapeutic Goods Administration

# **Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017**

*Therapeutic Goods Act 1989*

---

I, Larry Kelly, delegate of the Minister for Health for the purposes of section 10 of the *Therapeutic Goods Act 1989* and acting under that section, determine that the matters specified in this Order constitute a standard for therapeutic goods of the kind described in section 6 of this Order.

Dated 29 November 2017

(Signed by)

**LARRY KELLY**  
Delegate of the Minister for Health

---

---

## Contents

<b>1</b>	<b>Name of Order</b>	<b>3</b>
<b>2</b>	<b>Commencement</b>	<b>3</b>
<b>3</b>	<b>Transition</b>	<b>3</b>
<b>4</b>	<b>Introduction</b>	<b>3</b>
<b>5</b>	<b>Interpretation</b>	<b>5</b>
<b>6</b>	<b>Application</b>	<b>6</b>
<b>7</b>	<b>Medicines to which this Order does not apply</b>	<b>7</b>
<b>8</b>	<b>General requirements</b>	<b>7</b>
<b>9</b>	<b>Reclosable packages</b>	<b>8</b>
<b>10</b>	<b>Non-reclosable packages</b>	<b>9</b>
<b>Schedule 1</b>	<b>Medicines to which this Order applies</b>	<b>10</b>
<b>Part 1</b>	<b>Classes of substance</b>	<b>10</b>
<b>Part 2</b>	<b>Individual substances</b>	<b>11</b>

---

## 1 Name of Order

This Order is the *Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017* (TGO 95).

## 2 Commencement

This Order commences on the day after it is registered.

## 3 Transition

- (1) From the commencement of this Order up to and including 30 September 2018, each medicine to which this Order applies must comply with either this Order or Therapeutic Goods Order No. 80 - *Child-Resistant Packaging Requirements for Medicines*.
- (2) On and from 1 October 2018, each medicine to which this Order applies must comply with this Order.

*Note* Under the provisions of the *Legislation Act 2003*, Therapeutic Goods Order No. 80 will sunset on 1 October 2018.

## 4 Introduction

- (1) The objective of this Order 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 young children.
- (2) Child-resistant packaging is not child-proof. While it has an important role in reducing the incidence and public health burden of accidental poisoning in children and the associated morbidity and mortality, it provides only one safeguard in that it delays the time taken by a child to open a package and access multiple units, thereby increasing the probability of adult intervention before the contents are fully accessible and can be ingested.
- (3) Compliance of packaging with the national or international Standards for child-resistance referred to in this Order only establishes a packaging system as child-resistant, not child-proof.
- (4) The criteria used to determine whether a substance should be included in Schedule 1 are:
  - (a) the toxicity of the substance contained in the medicine, and risk of harm if it is accidentally ingested by a young child;
  - (b) the extent and patterns of availability in the community of medicines containing the substance;
  - (c) the number and type of incidents reported to Poisons Information Centres and other relevant organisations involving accidental ingestion of medicines containing the substance;
  - (d) the consequences of these incidents (hospital admission or other treatment, serious injury, or death), including the difficulty or complexity of treatment;

- 
- (e) any special needs of patients who regularly need access to medicines containing the substances, such as older persons or people with a disability; and
  - (f) the technical feasibility and practicality of child-resistant packaging for medicines containing the substance, taking into account the usual dosage form and presentation.
- (5) A substance will, in general, be considered to be sufficiently toxic to warrant child-resistant packaging if the amount contained in a maximum prescription quantity (for example under the Pharmaceutical Benefits Scheme) or the largest retail pack quantity, is likely to produce significant harm (i.e. a requirement for hospital treatment, or death) in a child of 11 kg (i.e. a typical weight of an 18 month old child, representative of the age group in which accidental poisoning is most common).
  - (6) While subsections 4(4) and 4(5) relate to toxicity only from ingestion, if medicines present a hazard in terms of potential to cause serious harm to young children through inadvertent contact with the eyes, skin or mucous membranes, then these medicines will also be considered for child-resistant packaging.
  - (7) None of the criteria set out in subsection 4(4) are intended to be considered in isolation and recommendations for child-resistant packaging are made on balance. Consideration of all of the criteria permits the objective assessment of the risk/benefit balance although emphasis will be given to public health and safety.
  - (8) The criteria do recognise that child-resistant packaging can present difficulties for older persons and those with a disability. This also is recognised in each of the Standards for child-resistance referred to in this Order, which include protocols for testing not only with young children but also with adults who are between 50 and 70 years of age.
  - (9) The forms of packaging permitted by this Order may be either reclosable or non-reclosable. Requirements for reclosable child-resistant packages are performance-based and rely on compliance with at least one of a range of specified national or international Standards, together with a small number of other requirements.
  - (10) At this time, requirements of this Order for non-reclosable packages such as blister or foil strips do not involve performance testing, but instead are based on design and specified materials of construction. These requirements reflect the general requirements of Australian Standard AS 1928-2001 *Child-resistant packages*.
  - (11) While non-reclosable packaging has been accepted to date as providing a child-barrier, it is intended that a best practice guideline on this form of packaging will be developed in order to help sponsors improve the robustness and effectiveness of blister or foil strip packaging in order to further reduce the potential for accidental childhood poisoning from medicines packaged in this way.

---

## 5 Interpretation

(1) In this Order:

**Act** means the *Therapeutic Goods Act 1989*.

**blister** means a package in which:

- (a) one or more dosage units are enclosed in pockets between a pre-formed tray with individual pockets and a lidding material which may be flat or shaped;
- (b) the dosage units can only be extracted from one pocket at a time;
- (c) the material of the tray is usually different from that of the lid; and
- (d) the material of the tray or lid must be cut, torn or peeled open in order to access the contents of individual pockets.

**bulk medicine pack** means a pack intended to be broken down and repackaged by a pharmacist to allow individual courses of treatment to be dispensed to a patient.

**child-resistant packaging** means packaging that is designed or constructed to be difficult for young children to open, or gain access to the contents, within a reasonable time but is not unduly difficult for adults to use properly.

*Note* Child-resistant packaging does not mean packaging that is impossible for young children to open, or obtain the contents of, within a reasonable time. Child-resistant is not synonymous with child-proof.

**closure** means the part of a reclosable package that keeps the package closed.

*Note* A closure may be separately identifiable or an integral component of a package.

**container** has the same meaning as in the Act.

**export only medicine** has the same meaning as in the Act.

**homoeopathic preparation** has the meaning as in the Regulations.

**indications** has the meaning as in the Act.

**label** means a display of printed information on, or securely affixed to, the container, any intermediate packaging and any primary pack containing the medicine.

**listed medicine** means a medicine that is included in the Part of the Register for goods known as listed goods.

**medicine** has the same meaning as in the Act.

**non-reclosable package** means a package that, having been opened, is not capable of being reclosed to its original state.

**packaging** means the components that together immediately contain and protect the dosage form of a medicine.

*Note* The components that immediately contain and protect the dosage form include containers, closures and closure systems, and closure liners. Packaging may be either reclosable or non-reclosable.

**primary pack** has the same meaning as in the Act.

**reclosable package** means a package that, once opened, can be reclosed to its original state.

**Register** has the same meaning as in the Act.

---

**registered medicine** means a medicine that is included in the part of the Register for goods known as registered goods.

**Regulations** means the *Therapeutic Goods Regulations 1990*, as amended from time to time.

**restricted flow insert** means a restriction that:

- (a) is fitted or moulded into the neck of a container;
- (b) cannot readily be removed from the container by manual force; and
- (c) limits the delivery of the contents to drops each of which is not more than 200 microlitres.

**Secretary** has the same meaning as in the Act.

**sponsor** means the person in relation to whom the medicine is registered or listed in the Register, or in relation to whom a medicine is exempt or the subject of an approval or authority in relation to that requirement.

**Standard** means any of the national or international Standards referred to in section 9 of this Order.

**strip** means packaging in which:

- (a) one or more dosage units are enclosed individually in a continuous strip made by bonding two layers of material together so that the dosage units are separated and protected; and
- (b) the dosage units can only be extracted from one pocket at a time; and
- (c) each layer of material may be similar or different; and
- (d) the material must be cut or torn in order to access the contents.

**young children** means children within the age groups specified in the protocols given in the Standards referred to in section 9 for the testing of child-resistance.

*Note* The age range specified in the protocols given in the Standards referred to in section 9 for the testing of child-resistance is 42 to 51 months inclusive.

## 6 Application

- (1) This Order applies to each medicine for human use that is supplied by a sponsor and that is:
  - (a) a registered medicine that contains a substance, or a salt, ester or other derivative of a substance, that belongs to a class of substance specified in Part 1 of Schedule 1; or
  - (b) a listed or registered medicine that contains a substance, or a salt, ester or other derivative of a substance, specified in Part 2 of Schedule 1 in the strength or pack size specified in Part 2 to Schedule 1; or
  - (c) any other medicine that is labelled or packaged in a way that states or implies to a consumer or purchaser that the product, as presented, is child-resistant.
- (2) However, this Order does not apply to a medicine that is mentioned in section 7 of this Order.

---

## 7 Medicines to which this Order does not apply

This Order does not apply to a medicine that is:

- (a) in a container intended only as a bulk medicine pack and that is clearly labelled 'For dispensing only' and 'This pack not to be supplied to a patient' or words to that effect; or
- (b) intended to be administered by injection; or
- (c) a solid or semi-solid (excluding solid dosage forms) preparation intended for application to the skin or mucous membrane, including transdermal patches; or
- (d) a liquid or semi-solid preparation intended for application to the eye, ear or mucous membrane, and supplied in a container that:
  - (i) has a nominal capacity of not more than 20 millilitres; or
  - (ii) is fitted with a restricted flow insert; or
- (e) an individually wrapped powder; or
- (f) a medicine containing only homoeopathic preparations; or
- (g) a liquid preparation in spray presentation if:
  - (i) the delivery device is engaged into the container in such a way that prevents it from being readily removed; and
  - (ii) direct suction through the delivery device results in delivery of no more than one dosage unit; and
  - (iii) actuation of the spray device is ergonomically difficult for young children to accomplish; or
- (h) a paste, powder or gel for the cleaning of teeth; or
- (i) a starting material used in the manufacture of medicines except when pre-packaged for supply for other therapeutic purposes or formulated as a dosage form; or
- (j) not at its final stage of manufacture; or
- (k) to be used by, or administered to, a patient for treatment in a public hospital, private hospital, nursing home, dental hospital or dental surgery; or
- (l) an export-only medicine.

## 8 General requirements

- (1) The requirements of this Order apply in addition to any other packaging requirements that may be applied to medicines under the Act or Regulations.
- (2) The packaging for a medicine to which this Order applies must:
  - (a) remain fit for its purpose until the expiry date of the medicine; and
  - (b) retain its child-resistant properties for the expected number of openings and closings necessary to fully use the contents.
- (3) Performance of the child-resistant feature must not be adversely affected by the contents of the package.
- (4) Sight, unusual strength or unusual dexterity must not be required to access the contents of the package or, in the case of a reclosable package, to re-engage the child-resistant feature.

---

## 9 Reclosable packages

- (1) If a medicine to which this Order applies is in a reclosable package, the package must comply with at least one of the following Standards:
  - (a) The International Standards Organisation Standard ISO 8317:2015 entitled *Child-resistant packaging -- Requirements and testing procedures for reclosable packages*;
  - (b) The British Standards Institution Standard BS EN ISO 8317:2015 entitled *Child-resistant packaging. Requirements and testing procedures for reclosable packages*;
  - (c) The Canadian Standards Association Standard CSA Z76.1-16 entitled *Reclosable Child-Resistant Packages*;
  - (d) 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;
  - (e) The Australian Standard AS 1928-2007 entitled *Child-resistant packaging- Requirements and testing procedures for reclosable packages* (ISO 8317:2003, MOD).
- (2) If a medicine to which this Order applies is in a reclosable package that complies with a Standard mentioned in subsection 9(1), the sponsor of the medicine must hold evidence of the compliance. The evidence may consist of:
  - (a) a certificate (or an appropriately authorised copy of a certificate) from a test agency, attesting that the package complies with a relevant Standard, expressed in a way that makes it beyond doubt that the certification in fact refers to the package specified by the sponsor, together with a statement of the protocol used to demonstrate child-resistance and, if requested, evidence of the test agency's standing; or
  - (b) if the package is not certified as mentioned in paragraph (a), information proving compliance with a relevant Standard, expressed in a way that makes it beyond doubt that the information in fact refers to the package specified by the sponsor, together with a statement of the protocol used to demonstrate child-resistance; or
  - (c) information demonstrating that the package as specified by the sponsor has been established previously as complying with a relevant Standard.
- (3) In addition to the requirements mentioned in subsections 9(1) and 9(2), if a medicine to which this Order applies is in a reclosable package, the sponsor must hold evidence demonstrating that the requirements of subsections 8(2) and 8(3) are met.
- (4) If a change in specifications for a reclosable package occurs, the sponsor must hold additional evidence demonstrating that the child-resistant properties of the package and operation of the closure have not been adversely affected.
- (5) In addition to the requirements mentioned in subsections 9(1), 9(2), 9(3), and 9(4), if a medicine to which this Order applies is in a reclosable package, the sponsor must hold information on:
  - (a) the types and sizes of container of immediate relevance to the sponsor's range of medicines to which a specified closure may be applied;
  - (b) the suitability of the package for the type of medicine;



- 
- (c) the correct application of the closure to the container after filling and engagement of the child-resistant mechanism, as appropriate to the particular packaging system; and
  - (d) the quality control tests applied to demonstrate that production lots of the package components are of consistent and satisfactory quality and appropriate for use.
- (6) If a medicine to which this Order applies is in a reclosable package, adequate directions for opening and effectively reclosing the package must be:
- (a) conspicuously marked or written on the package or on a label securely affixed or attached to the package; and
  - (b) written in English or clearly demonstrated in graphics.
- (7) If a medicine to which this Order applies is packaged together with a separate dropper or applicator that is reasonably expected to replace the original closure on the medicine once the product is in use, then that configuration also must comply with the requirements of this Order.

## **10 Non-reclosable packages**

- (1) Subject to subsection 10(2), if a medicine to which this Order applies is in a non-reclosable package, the package must be in the form of a blister or other sealed unit formed from paper, film, plastic material, metal foil or other sheet or strip material, or a combination of these materials in which a single dosage unit is enclosed, whether as part of a continuous series comprising a strip or sheet of the same material or not.
- (2) A non-reclosable package referred to in subsection 10(1) must not be formed from cellulose film or unlaminated paper.

---

# Schedule 1 Medicines to which this Order applies

(section 6)

## Part 1 Classes of substance

*Note 1* Class names reflect the Anatomical Therapeutic Chemical (ATC) classification system of the World Health Organization *Collaborating Centre for Drug Statistics Methodology* (<http://www.whocc.no/atcddd/>). Classes shown include any substance included under the given ATC classification, unless the substance is specifically exempted from this Order.

Item	Class
1	ACE INHIBITORS
2	ALPHA AND BETA BLOCKING AGENTS
3	ALPHA-ADRENORECEPTOR ANTAGONISTS including phenoxybenzamine
4	ANESTHETICS, LOCAL
5	ANGIOTENSIN II ANTAGONISTS
6	ANTIARRHYTHMICS
7	ANTICHOLINERGICS
8	ANTI-DEMENTIA DRUGS
9	ANTIDEPRESSANTS
10	ANTIEMETICS AND ANTINAUSEANTS
11	ANTIEPILEPTICS
12	ANTIHISTAMINES
13	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS
14	ANTIMALARIALS, except doxycycline
15	ANTINEOPLASTIC AGENTS
16	ANTI-PARKINSON DRUGS
17	ANTIPSYCHOTICS
18	ANTITHROMBOTIC AGENTS
19	BENZODIAZEPINE DERIVATIVES and BENZODIAZEPINE RELATED DRUGS
20	BETA BLOCKING AGENTS
21	CALCIUM CHANNEL BLOCKERS
22	CARDIAC GLYCOSIDES
23	CENTRALLY ACTING SYMPATHOMIMETICS
24	DIURETICS
25	ERGOT ALKALOIDS
26	MONOAMINE OXIDASE INHIBITORS
27	OPIOIDS
28	ORAL BLOOD GLUCOSE LOWERING DRUGS

---

## **Part 2 Individual substances**

ALISKIREN.

AMBRISENTAN.

ANISE OIL, except:

- (a) when packed in a container having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert; or
- (b) in a preparation containing 50 per cent or less of anise oil, or a combination of anise oil and any other essential oil named in this Part.

ASPIRIN.

*AZADIRACHTA INDICA* (NEEM), in a preparation for human dermal use containing more than 1 per cent of cold pressed neem seed oil.

BASIL OIL, except:

- (a) when packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert; or
- (b) in a preparation or oil containing 5 per cent or less of methyl chavicol.

BAY OIL, except:

- (a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in a preparation containing 25 per cent or less of bay oil, or a combination of bay oil and any other essential oil named in this Part.

BOSENTAN.

BROMHEXINE.

CAJUPUT OIL, except:

- (a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in a preparation containing 25 per cent or less of cajuput oil, or a combination of cajuput oil and any other essential oil named in this Part.

CAMPHORATED OIL.

CAMPHOR, except:

- (a) in a liquid preparation containing 2.5 per cent or less of camphor;
- (b) in an essential oil containing 10 per cent or less of camphor, packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert;
- (c) in an essential oil packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (d) in rosemary oil, sage oil (Spanish), or lavandin oil as such.

*CARAPICHEA IPECACUANHA* (IPECACUANHA).

CASSIA OIL, except in a preparation containing 2 per cent or less of cassia oil.

---

CHLORAL HYDRATE.

CILOSTAZOL.

CINEOLE, except:

- (a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert;
- (b) in a preparation or oil containing 25 per cent or less of cineole; or
- (c) in rosemary oil or camphor oil (white).

CINNAMON BARK OIL, except in a preparation containing 2 per cent or less of cinnamon bark oil.

CINNAMON LEAF OIL, except:

- (a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in a preparation containing 25 per cent or less of cinnamon leaf oil, or a combination of cinnamon leaf oil and any other essential oil named in this Part.

CLONIDINE.

CLOVE OIL, except:

- (a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in a preparation containing 25 per cent or less of clove oil, or a combination of clove oil and any other essential oil named in this Part.

COLCHICINE.

DEFERASIROX.

DEXTROMETHORPHAN.

ETHANOL, in a mouthwash preparation containing more than 3 grams of ethanol in a single pack.

EUCALYPTUS OIL, except:

- (a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in a preparation containing 25 per cent or less of eucalyptus oil, or a combination of eucalyptus oil and any other essential oil named in this Part.

FLUORIDE SALTS, in a pack containing the equivalent of more than 100 milligrams of elemental fluorine.

GUAIFENESIN.

IRON COMPOUNDS, in a pack containing a total of more than 250 milligrams of elemental iron, except for divided preparations in which:

- (a) the iron is compounded with one or more other active ingredients; and
- (b) the amount of elemental iron per dosage unit is 5 milligrams or less.

---

However iron oxides that are present as an excipient, in either a divided preparation containing 10 milligrams or less of total iron oxides per dosage unit or an undivided preparation containing 1 per cent or less of total iron oxides, may be excluded from the calculation of elemental iron content.

IVABRADINE.

LANTHANUM.

LENALIDOMIDE.

MARJORAM OIL, except:

- (a) when packed in a container having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert, or
- (b) in a preparation containing 50 per cent or less of marjoram oil, or a combination of marjoram oil and any other essential oil named in this Part.

MELALEUCA OIL, except:

- (a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in a preparation containing 25 per cent or less of melaleuca oil, or a combination of melaleuca oil and any other essential oil named in this Part.

METHYL SALICYLATE, in a liquid preparation containing 5 per cent or more of methyl salicylate.

MINOXIDIL, in a liquid preparation or a preparation for oral administration.

MOUTHWASH preparations — *see* ETHANOL.

NICOTINE.

NUTMEG OIL, except:

- (a) when packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert; or
- (b) in a preparation containing 50 per cent or less of nutmeg oil, or a combination of nutmeg oil and any other essential oil named in this Part.

OXYMETAZOLINE.

PARACETAMOL - all solid dosage forms and liquid preparations.

PENNYROYAL OIL, except in a preparation containing 4 per cent or less of d-pulegone.

PENTOXYVERINE.

PHENYLEPHRINE.

PHOLCODINE.

---

PODOPHYLLUM/PODOPHYLLOTOXIN.

*POLYGALA SENEGA* (SENEGA).

POTASSIUM SALTS, in a pack containing a total of more than 4000 milligrams of elemental potassium, except:

- (a) in a divided preparation in which the amount of elemental potassium per dosage unit is 40 milligrams or less; or
- (b) when the potassium is present in the form of glucosamine sulfate potassium chloride complex.

PSEUDOEPHEDRINE.

RILUZOLE.

SAGE OIL DALMATIAN, except in a preparation containing 4 per cent or less of thujone.

SALBUTAMOL.

SASSAFRAS OIL, except in a preparation containing 1 per cent or less of safrole.

STAR ANISE OIL, except:

- (a) when packed in a container having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert; or
- (b) in a preparation containing 50 per cent or less of star anise oil, or a combination of star anise oil and any other essential oil named in this Part.

THEOPHYLLINE.

THYME OIL, except:

- (a) when packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert; or
- (b) in a preparation containing 50 per cent or less of thyme oil, or a combination of thyme oil and any other essential oil named in this Part.

THYROXINE.

VARENICLINE.

WINTERGREEN OIL — *see* METHYL SALICYLATE.

XYLOMETAZOLINE.