TGA THERAPEUTIC GOODS ADMINISTRATION

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Commonwealth Department of Health and Ageing

Child-Resistant Packaging – Stakeholder Consultation on a Proposed New Therapeutic Goods Order

The current Therapeutic Goods Orders (TGOs) relating to child-resistant packaging are Therapeutic Goods Order No. 20 *Child Resistant Containers* and Therapeutic Goods Order No. 33 *Amendment of Schedules to Therapeutic Goods Order No. 20 Child Resistant Containers*. These TGOs, made in 1985 and 1990 respectively, require revision to reflect current international standards for child-resistant packaging and those substances of concern in accidental childhood poisoning.

The Therapeutic Goods Committee (the statutory committee established under the *Therapeutic Goods Regulations 1990* to advise on standards for therapeutic goods, including requirements for labelling and packaging) consequently has undertaken a review of child-resistant packaging requirements and standards, with a view to developing a new TGO to supersede TGOs 20 and 33.

A draft of the new TGO is now released for broad stakeholder consultation. It is intended that stakeholder comment together with a final draft of the TGO will be considered by the Therapeutic Goods Committee at its next meeting in late November 2002.

Comments on the draft Order should be forwarded to:

The Secretary, Therapeutic Goods Committee
Conformity Assessment Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Or by facsimile to: (02) 6232 8687
Or email to: lyn.lewis@health.gov.au

Comments should be received by the close of business 13 November 2002.

If you require further advice or assistance, please contact Ms Lyn Lewis on (02) 6232 8661 or email to the above address.

Therapeutic Goods Act 1989

THERAPEUTIC GOODS ORDER NO. 65

Child-resistant packaging for therapeutic goods

I, Terry Slater, delegate of the Minister for Health and Ageing, for the purposes of the exercise of the Minister's powers under section 10 of the *Therapeutic Goods Act 1989* and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of that Act:

(a) REVOKE the following Orders:

(i) on and from {date of signing plus three years}, Therapeutic Goods Order No. 20 entitled 'Child Resistant Containers'; and

(ii) on and from {date of signing plus three years}, Therapeutic Goods Order No. 33 entitled 'Amendment of Schedules to Therapeutic Goods Order No. 20 Child Resistant Containers'; AND

(b) DETERMINE that, subject to subparagraphs (i), (ii), (iii) and (iv), therapeutic goods to which this Order applies must be packaged in accordance with the requirements of this Order:

(i) therapeutic goods that are included in an application lodged under section 23 of the Act, being an application lodged before {date of signing + 12 months}, must, until {date of signing + three years}, comply with either this Order or Therapeutic Goods Order No. 20 'Child Resistant Containers', as modified by Therapeutic Goods Order No. 33;

(ii) therapeutic goods that are included in an application lodged under section 23 of the Act, being an application lodged before {date of signing + 12 months}, must comply with this Order from {date of signing + three years};

(iii) therapeutic goods that are included in an application lodged under section 23 of the *Therapeutic Goods Act 1989* ("the Act"), being an application lodged on or after {date of signing + 12 months}, must comply with this Order; and

(iv) therapeutic goods that are subject to this Order but which are not included in an application made under section 23 of the Act must comply with this Order from (date of signing + three years}.

This Order includes the First Schedule and the Second Schedule to this Order.

This Order commences from the day it is gazetted in the Commonwealth Gazette.

1 Application and exemptions

1(1) This Order applies to:

(a) therapeutic goods which contain a substance specified in Schedule 1 to this Order or a salt or ester or other derivative of a substance specified in Schedule 1 to this Order, except goods:

(i) that are in a container holding 500 solid dosage units or more except goods packed and labelled for retail supply;

(ii) intended to be administered by injection;

(iii) that are solid or semi solid (excluding solid dosage forms) and are intended to be applied to the skin or mucous membrane;

(iv) that are liquid and are intended to be applied to the eye or mucous membrane and are supplied in a container which has a nominal capacity of 20 millilitre or less or is fitted with a restricted flow insert;

(v) that are individually wrapped powders;

(vi) that fall within the description of Item 9(a) of Schedule 5 of the Regulations;

(vii) that have not reached their final stage of manufacture;

(viii) supplied to a person whom the healthcare professional authorised under relevant State or Territory legislation to supply or prescribe believes would suffer undue hardship through difficulty in opening a container complying with the requirements of this Order;

(ix) to be used by, or administered to, a patient for treatment in a public hospital, private hospital or nursing home; or

(x) that are solely for export; and

(b) therapeutic goods to which subclause 1(1)(a) does not apply but, which through their packaging or labelling, state or imply that the goods, as presented, are child-resistant.

2 Interpretation

2(1) In this Order -

'**Act**' means the *Therapeutic Goods Act 1989*, as amended from time to time;

'**blister**' means a package in which one or more dosage units are enclosed between a pre-formed tray with individual pockets and a lidding material which may be flat or shaped. The dosage units can only be extracted singly. The material of the tray is usually different from that of the lid. It must be cut or torn in order to access the contents;

'**child-resistant packaging**' means packaging that is designed or constructed to be significantly difficult for a young child to open, or gain access to the contents of, within a

reasonable time but not unduly difficult for adults to use properly, but does not mean packaging which all such children cannot open, or obtain the contents of, within a reasonable time. Child-resistant is not synonymous with child-proof;

'**closure**' means the portion(s) of a package that keeps the package closed. A closure may be separately identifiable or an integral component of a package;

'**container**', in relation to therapeutic goods, means the vessel, bottle, tube, ampoule, syringe, vial, sachet, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the goods, but does not include an article intended for ingestion;

'**goods**' means a therapeutic good as defined in subsection 3(1) of the Act;

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

'**packaging**' means a package, including any closure system, being the sum of components that together immediately contain and protect the dosage form. It includes containers, closures and closure liners. Packaging may be either reclosable or non-reclosable, including packages to which access is not intended;

'**Poisons Standard**' has the same meaning as defined in regulation 2 of the Regulations and subsection 3(1) of the Act;

'**reclosable package**' means a package which, once opened, can be reclosed to re-form a child-resistant package;

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

'**Sponsor**' has the same meaning as in subsection 3(1) of the Act;

'**strip**' means a package in which 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 can only be extracted singly. Each layer may be of the same or different material. It must be cut or torn in order to access the contents; and

'**therapeutic goods**' has the same meaning as defined in subsection 3(1) of the Act.

3 General requirements

3(1) The requirements of this Order apply in addition to any other packaging requirements that may be applied under the Act or Regulations.

3(2) The packaging for goods to which this Order applies must be fit for purpose for the shelf-life of the goods;

3(3) The packaging for goods to which this Order applies must retain its child-resistant properties for the expected in-use life of the product;

3(4) Performance of the child-resistant feature must not be adversely affected by the contents of the package; and

3(5) Sight, unusual strength or unusual dexterity shall not be required to access the contents of the package or, in the case of reclosable packages, to re-engage the child-resistant feature.

4 Reclosable packages

4(1) Where goods to which this Order applies are in a reclosable package, the package must:

(a) comply with at least one of the following Standards:

(i) the International Organization for Standardization Standard ISO 8317:1989 entitled *Child-resistant packaging – Requirements and testing procedures for reclosable packages*;

(ii) the British Standards Institution Standard BS EN 28317:1993 entitled *Child-resistant packaging – Requirements and testing procedures for reclosable packages*;

(iii) the Canadian Standards Association Standard CSA Z76.1-99 entitled *Reclosable Child-Resistant Packages*;

(iv) the United States Code of Federal Regulations, Title 16, Section 1700.15, entitled *Poison prevention packaging standards* and Section 1700.20, entitled *Testing procedure for special packaging*, as in effect at the date of this Order;

(v) the Australian Standard AS 1928-2001 entitled *Child-resistant packages*; or

(b) be a container which is fitted with a closure that is specified and described in Schedule 2 to this Order.

4(2) Where goods to which this Order applies are in a reclosable package that complies with any one of the Standards listed in subclause 4(1)(a), the sponsor of the goods is to hold evidence that the package so complies. Such evidence may consist of:

(a) certification (or appropriately authorised copies of such certification) from a recognised testing authority, attesting that the package complies with a relevant Standard, expressed so as to make 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;

(b) where the package is not certified as above, information proving compliance with a relevant Standard, expressed so as to make 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.

4(3) In addition to the requirement referred to in subclause 4(2), where goods to which this Order applies are in a reclosable package, the sponsor of the goods is to hold evidence demonstrating that the package will remain fit for purpose for the shelf-life of the goods, will retain its child-resistant properties for the expected in-use life of the product, and that performance of the child-resistant feature will not be adversely affected by the contents of the package;

4(4) Where a change in specifications for a package occurs, the sponsor of the goods is to hold additional evidence demonstrating that the child-resistant properties of the package and operation of the closure have not been adversely affected.

4(5) In addition to the requirements referred to in subclauses 4(1), 4(2), 4(3), and 4(4), where goods to which this Order applies are in a reclosable package, the sponsor of the goods is to hold, and apply information, in relation to:

(a) the types and sizes of container to which a specified closure may be applied;

(b) the suitability of the package for the product type;

(c) instructions appropriate to the particular packaging system to ensure correct application of the closure to the container after filling and engagement of the child resistant mechanism; and

(d) the quality control tests applied to demonstrate that production lots of the package are of consistent and satisfactory quality and appropriate for use.

4(6) When goods to which this Order applies are in a reclosable package, adequate directions for opening and effectively reclosing the package shall be conspicuously marked or written on the package or on a label securely affixed or attached to the container.

4(7) Any directions on the container or label for goods to which this Order applies concerning the correct operation of the child-resistant mechanism must be written in the English language or clearly demonstrated in graphics.

4(8) All components forming the reclosable package shall be identifiable through appropriate manufacturer's markings.

4(9) Where goods to which this Order applies contain a substance specified in Schedule 1, and are packaged together with a separate dropper or applicator that is reasonably expected to replace the original closure on the product once the product is in use, then that configuration also must comply with the requirements of subclauses 4(1), 4(2), 4(3), 4(4), 4(5), 4(6), 4(7) and 4(8).

5 Non-Reclosable Packages

5(1) Subject to the qualification given in subclause 5(2), when goods to which this Order applies are in a package which is 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 in which a single dosage unit is enclosed, whether as part of a continuous series comprising a strip or sheet of like material or not.

5(2) A non-reclosable package referred to in subclause 5(1) shall not be formed from cellulose film or unlaminated paper.

Dated this day of 2002
Terry Slater
National Manager
Therapeutic Goods Administration
Delegate of the Minister for Health and Ageing

First schedule

ANTI-ARRHYTHMICS – All preparations containing one or more ANTI-ARRHYTHMIC ingredients including but not limited to the following:

Amiodarone	Disopyramide	Flecainide
Mexiletine	Procainamide	Quinidine
Sotalol	Verapamil	

ANTICONVULSANTS - All preparations containing one or more ANTICONVULSANT ingredients including but not limited to the following:

Carbamazepine	Clonazepam	Ethosuximide
Gabapentin	Lamotrigine	Levetiracetam
Methylpheno-barbitone	Oxcarbazepine	Phenytoin
Primidone	Sodium valproate	Sulthiame
Tiagabine	Topiramate	Vigabatrin

ANTIHISTAMINES - All preparations containing one or more ANTIHISTAMINE ingredients including but not limited to the following:

Antazoline	Astemizole	Azatadine
Brompheniramine	Cetirizine	Chlorpheniramine
Clemizole*	Cyproheptadine	Dexchlorpheniramine
Dimenhydrinate	Diphenhydramine	Doxylamine
Fexofenadine	Hydroxyzine	Loratadine
Mepyramine	Methdilazine	Pheniramine
Promethazine	Terfenadine	Trimeprazine

* in dosage forms other than ointment or suppository

ASPIRIN.

BETA BLOCKERS - All preparations containing one or more BETA BLOCKER ingredients including but not limited to the following:

Atenolol	Carvedilol	Esmolol
Metoprolol	Oxprenolol	Pindolol
Propranolol	Sotalol	Timolol

CALCIUM ANTAGONISTS - All preparations containing one or more CALCIUM ANTAGONIST ingredients including but not limited to the following:

Amlodipine	Diltiazem	Felodipine
Lercanidipine	Nifedipine	Nimodipine
Perhexiline	Verapamil	

CAMPHOR (including CAMPHORATED OIL) in liquid preparations when included in Schedule 4, 5 or 6 of the Poisons Standard.

CHLOROQUINE.

CINEOLE in a volume of 2 litres or less, when included in Schedule 6 of the Poisons Standard.

CLONIDINE.

CLOZAPINE.

COLCHICINE.

DEXAMPHETAMINE.

DEXTROPROPOXYPHENE.

DIGITALIS GLYCOSIDES.

DIPHENOXYLATE HYDROCHLORIDE WITH ATROPINE SULPHATE.

ESSENTIAL OILS in a volume of 200 millilitres or less, when included in Schedule 5 or 6 of the Poisons Standard, including but not limited to the following:

Anise oil	Basil oil	Bay oil
Cajuput oil	Cassia oil	Cinnamon bark oil
Cinnamon leaf oil	Clove oil	Marjoram oil
Nutmeg oil	Pennyroyal oil	Sage (Dalmatian) oil
Thyme oil		

EUCALYPTUS OIL in a volume of 2 litres or less, when included in Schedule 6 of the Poisons Standard.

FLUORIDE SALTS in packs containing the equivalent of more than 100 milligrams of elemental fluorine.

HYDROXYCHLOROQUINE.

IRON COMPOUNDS - All solid dosage forms except preparations containing the equivalent of 5 milligrams or less of elemental iron in each dosage unit; and in liquid preparations containing the equivalent of more than 250 mg of elemental iron in the total contents of the container.

LITHIUM CARBONATE.

MELALEUCA OIL (Tea-tree Oil) in a volume of 200 millilitres or less, when included in Schedule 6 of the Poisons Standard.

METHADONE.

METHYLPHENIDATE.

METHYL SALICYLATE in liquid preparations containing more than 50 per cent volume in volume of methyl salicylate, in a volume of 200 mL or less.

MINOXIDIL in liquid preparations or preparations for oral administration.

MONOAMINE OXIDASE INHIBITORS - All preparations containing one or more MONOAMINE OXIDASE INHIBITOR ingredients including but not limited to the following:

Phenelzine	Tranylcypromine

NARCOTIC ANALGESICS - All preparations containing one or more NARCOTIC ANALGESIC ingredients including but not limited to the following:

Buprenorphine	Codeine	Dextromoramide
Dihydrocodeine	Diphenoxylate	Fentanyl
Hydromorphone	Morphine	Oxycodone
Pentazocine	Pethidine	

NATEGLINIDE.

ORPHENADRINE.

PARACETAMOL - All solid dosage forms and liquid preparations.

PHENOTHIAZINES - All preparations containing one or more PHENOTHIAZINE ingredients including but not limited to the following:

Chlorpromazine	Fluphenazine	Pericyazine
Perphenazine	Prochlorperazine	Promazine*
Promethazine	Thioridazine	Trifluoperazine
Trimeprazine		

* other than liquid for injection

PIOGLITAZONE.

QUININE.

SULPHONYLUREAS - All preparations containing one or more SULPHONYLUREA ingredients including but not limited to the following:

Glibenclamide	Gliclazide	Glipizide
Tolazamide	Tolbutamide	

THEOPHYLLINE.

TRICYCLIC, TETRACYCLIC AND OTHER ANTIDEPRESSANTS - All preparations containing one or more TRICYCLIC, TETRACYCLIC AND/OR OTHER ANTIDEPRESSANT ingredients including but not limited to the following:

Amitriptyline	Clomipramine	Desipramine
Dothiepin	Doxepin	Fluoxetine
Fluvoxamine	Imipramine	Mianserin
Moclobemide	Nefazodone	Nortriptyline
Paroxetine	Reboxetine	Sertraline
Trimipramine	Venlafaxine	

ZIPRASIDONE.

Second schedule

Name of Closure	Approved Sizes	Known Australian Distributor	Manufacturer	Identifying Features and Markings	Date Approved	Standard Complied
ANCHOR CR	28 mm	Anchor Plastics Pty Ltd 5 Marshall Road KIRRAWEE NSW 2232 (02) 9521 3688	Anchor Plastics Pty Ltd	No trademark, no patent number	July 1992	Unspecified
ARGUS-LOC I	24, 28, 33, & 38 mm For use with plastic or glass containers with GPI or SPI 400/405 neck finish	ACI Plastics Packaging 4 Kingsway MOORABBIN VIC 3189 (03) 9555 0444	Owens-Illinois (USA)	Trademark but no patent number	Original approval pre-1985; Extended to include 24 mm July 2002	Unspecified US 16 CFR 1700
ARGUS-LOC TAMPERTEL	24, 28, & 38 mm with Tampertel T/E break band For use with glass or plastic containers with Tampertel neck finish	ACI Plastics Packaging 4 Kingsway MOORABBIN VIC 3189 (03) 9555 0444	ACI Plastics Packaging	Trademark but no patent number	July 2002	Approval based on equivalence of CR mechanism to previously approved Argus-Loc

Name of Closure	Approved Sizes	Known Australian Distributor	Manufacturer	Identifying Features and Markings	Date Approved	Standard Complied
BORMIOLI	18, 24, 28 & 35 mm with T/E feature For use with glass PFP finish or plastic BMP finish bottles	Unspecified	Bormioli Rocco E Figlio (Italy)	No trademark or patent number Bormiloi drawing A 3456	November 2000	ISO 8317:1989
CLIC-LOC II	24, 28 & 38 mm For use with standard thread glass or plastic containers	ACI Plastics Packaging 4 Kingsway MOORABBIN VIC 3190 (03) 9555 0444	ACI Plastics Packaging	Trademark, Australian patent number 477954	February 1991	Unspecified
CLIC-LOC III	33 mm For use with standard thread glass or plastic containers	ACI Plastics Packaging 4 Kingsway MOORABBIN VIC 3190 (03) 9555 0444	Owens-Illinois (USA)		Unknown	US 16CFR 1700 (limited evidence)

Name of Closure	Approved Sizes	Known Australian Distributor	Manufacturer	Identifying Features and Markings	Date Approved	Standard Complied
CORMACK/ KERR CRIII	Closures within size ranges 16-30 mm & 31-50 mm For use with glass or plastic containers with standard SP-400 neck finish	Cormack Packaging Pty Ltd 25 Garland Road KINGS PARK NSW 2148 (02) 9830 0000	Cormack Packaging Pty Ltd		December 1999	AS 1928-1982
DUMA Twist-Off 35	35 mm with T/E feature For use with Duma Twist-Off or Duma Twist-Off Q HDPE containers with standard neck finish	Unspecified	Superfos Pharma Pack (Denmark)		May 2002	ISO 8317:1989 plus US 16 CFR 1700 (Senior adult use)
EASY LOK	28 and 38 mm	Alto Plastics Ltd, Australia Level 1, 150 William Street EAST SYDNEY NSW (02) 9357 4288	Alto Plastics Ltd (New Zealand)	No trademark Australian patent number 467825	July 1983	Unspecified

Name of Closure	Approved Sizes	Known Australian Distributor	Manufacturer	Identifying Features and Markings	Date Approved	Standard Complied
GAPLAST	36 mm continuous thread closure For use with 60K or 30K polypropylene Gaplast round bottles	Unspecified	Gaplast GmbH (Germany)		February 1999	ISO 8317:1989 plus US 16 CFR 1700 (Senior resecuring effectiveness)
KERR CR-1	20, 22, 24, 28, 30, 33 & 38 mm	Cormack Packaging 25 Garland Road KINGS PARK NSW 2148 (02) 9830 0000	Cormack Packaging	Trademark but no patent number	Pre-1985	Unspecified
KERR TE CR-1	20, 24, 28, 33 & 38 mm with T/E feature	Cormack Packaging 25 Garland Road KINGS PARK NSW 2148 (02) 9830 0000	Kerr Group (USA)	Trademark but no patent number	October 1993	Approval based on equivalence to Kerr CR-1 (non-TE range)
PP28 CLIC-LOC	PP28 (28 mm) Clic-Loc closure with T/E feature For use with glass or plastic containers with standard PP28 mm neck finish	Unspecified	United Closures & Plastics Plc (UCP) (England)	Australian Patent Number 622583	September 2001	ISO 8317:1989

Name of Closure	Approved Sizes	Known Australian Distributor	Manufacturer	Identifying Features and Markings	Date Approved	Standard Complied
REXAM Series FG	33 & 38 mm For use glass or plastic bottles with 33-400 or 38-400 neck finishes	Unspecified	Rexam PLC (USA)		October 2000	US 16 CFR 1700
SAF-CAP I Dropper Closure	24 mm	Cormack Packaging 25 Garland Road KINGS PARK NSW 2149 (02) 9830 0000	Kerr Group (USA)		July 1992; Amended specifications December 1997	Unspecified
SAFE STOP	28 mm with T/E feature and Clic-Loc Technology For use on glass bottles with standard neck finish PP28S Pilfer Proof 28 mm standard	Vidchem Pty Ltd 1a/307 Wattletree Road MALVERN VIC 3144 (03) 9500 0005	Astra Plastique (France)	No trademark or patent number	May 2000	ISO 8317:1989

Name of Closure	Approved Sizes	Known Australian Distributor	Manufacturer	Identifying Features and Markings	Date Approved	Standard Complied
SAFE VISTOP	28 mm For use with plastic or glass bottles with neck finish PP28S Pilfer Proof 28 mm standard	Vidchem Pty Ltd 1a/307 Wattletree Road MALVERN VIC 3144 (03) 9500 0005	Astra Plastique (France)	Astra Plastique artwork No. 201944	May 1997	ISO 8317:1989
SAFE-CAP III	24, 28, 33, 38 & 45 mm For use with glass or plastic bottles with standard continuous thread	Plaspak Closures Pty Ltd 22 Yalgar Road KIRRAWEE NSW 2232 (02) 9521 8444	Van Blarcom Closures (USA)	No trademark or patent number	July 1997	US 16 CFR 1700 (limited evidence)
SECRO	• Secro 92 (18 mm) dropper closure with T/E feature • Secro PP24 (24 mm) with T/E feature • Secro PP28 (28 mm) with T/E feature For use with glass or plastic containers with	Cormack Packaging Pty Ltd 25 Garling Road Kings Park NSW 2148 (02) 9830 0000	Stella (Germany)		December 2000	ISO 8317:1989

Name of Closure	Approved Sizes	Known Australian Distributor	Manufacturer	Identifying Features and Markings	Date Approved	Standard Complied
	Secro 92, Secro PP24 or Secro PP28 neck finishes					
SUNBEAM FG	28 mm	Alto Plastics Ltd, Australia Level 1, 150 William Street EAST SYDNEY NSW (02) 9357 4288	Alto Plastics Ltd (New Zealand)	No trademark Australian patent number 542853	July 1984	Unspecified
TAMPERDISC	24, 28, 33 & 38 mm with T/E feature For use with glass or plastic bottles utilising BSI standard thread	Williamson Plastics Pty Ltd 99 Rookwood Road YAGOONA NSW 2199 (02) 9790 4026	Williamson MFG. Pty Ltd	Trademark but no patent number	August 1996	Approval based on equivalence to Willsafe closure.
WILLIAMSON 2000 SERIES	• 20 & 24 mm • 20 and 24 mm dropper closure For use with glass or plastic bottles utilising BSI standard thread	Williamson Plastics Pty Ltd 99 Rookwood Road YAGOONA NSW 2199 (02) 9790 4026	Williamson MFG. Pty Ltd	No trademark, Australian patent number 725139	February 2001	AS 1928 – 1982

Name of Closure	Approved Sizes	Known Australian Distributor	Manufacturer	Identifying Features and Markings	Date Approved	Standard Complied
WILLSAFE	20, 24, 28, 33 & 38 mm For use with glass or plastic bottles utilising BSI standard thread	Williamson Plastics Pty Ltd 99 Rookwood Road YAGOONA NSW 2199 (02) 9790 4026	Williamson MFG. Pty Ltd	Trademark, Australian patent number 550878	24, 33 & 38 mm – February 1988 28 mm – May 1989 20 mm – November 1993	AS 1928 – 1982

Supplementary notes

Child-resistant packaging for therapeutic goods

The following Supplementary Notes are intended to explain various parts of the Order and do not form part of the Order.

A Scope of the Order

The requirements of this Order apply to therapeutic goods that come within the operation of the *Therapeutic Goods Act 1989*, as provided in section 6 of the Act as follows:

6(1) This Act applies to:
- (a) things done by corporations; and
- (b) things done by natural persons or corporations in so far as those things are done:
  - (i) in the course of, or in preparation for, trade or commerce between Australia and a place outside Australia, among the States, between a State and a Territory or between 2 Territories; or
  - (ii) under a law of the Commonwealth relating to the provision of pharmaceutical or repatriation benefits; or
  - (iii) in relation to the Commonwealth or in relation to an authority of the Commonwealth.

6(2) Without limiting the effect of this Act apart from this subsection, this Act also has the effect it would have if the reference in paragraph (1)(a) to things done by corporations were confined to things done by trading corporations for the purposes of their trading activities.

As a standard determined in accordance with section 10 of the Act, the scope of this Order is limited to medicines, and other therapeutic goods that are not classified as medical devices. Hospital, household and commercial disinfectants regulated as therapeutic goods fall within this latter category.

This Order broadens the scope of application of standards for child-resistant packaging from only medicines containing certain specified substances, as given in Therapeutic Goods Orders No. 20 *Child Resistant Containers* (TGO 20) and No. 33 *Amendment of Schedules to Therapeutic Goods Order No. 20 Child Resistant Containers* (TGO 33). The scope now covers medicines and other therapeutic goods containing any of the revised list of substances specified in the First Schedule to the Order, as well as other therapeutic goods which, through their presentation, imply that the packaging is child-resistant.

This means that whilst the use of child-resistant packaging is not mandatory unless the product contains any of the specified substances, if the product is presented in such a way that could reasonably cause consumers to believe the packaging is child-resistant, then the same standards for child-resistance apply. Presentations considered to imply packaging is child-resistant include closures with the push-down and turn graphics typically used on child-resistant caps and label statements referring to the closure as being child-safe or preventing access by children.

B Provision for exemption for specific products

Subsection 14(1) of the Act requires therapeutic goods to comply with standards including standards for labelling and packaging as follows:

> Compliance with standards
>
> (1) Except with the consent in writing of the Secretary, a person must not:
> (a) import therapeutic goods into Australia; or
> (b) supply therapeutic goods for use in Australia;
> if the goods do not conform with a standard applicable to the goods.
>
> Maximum penalty: 240 penalty units.

In effect, this subsection provides a mechanism for seeking an exemption for individual products from compliance with standards such as any of the child-resistant packaging requirements specified in this Order.

Subsection 14(2) of the Act states:

> (2) Paragraph (1)(a) does not apply to goods that do not conform with a standard applicable to the goods by reason only of matters relating to labelling or packaging.

Subsection 14(2) of the Act therefore allows importation of therapeutic goods, the packaging of which does not comply with the requirements of this Order. However if imported goods, or goods manufactured in Australia, are intended for supply in Australia, the packaging must comply with the requirements of this Order, except when the consent of the Secretary is granted under subsection 14(1) of the Act.

Where exemption from any of the child-resistant packaging requirements in this Order is sought for goods intended for supply in Australia, the sponsor is required to apply in writing to the Therapeutic Goods Administration (TGA) for a formal exemption stating precisely the particular requirement against which the exemption is sought, and providing justification for the exemption.

However, as the requirements of this Order are intended to contribute to the protection of public health and safety through reducing the incidence of accidental poisoning, exemptions under section 14 would only be considered where it can be established that the exemption sought will not compromise public health and safety, or exceptional circumstances otherwise exist.

C General exemptions

Certain classes of therapeutic goods are exempt from compliance with the child-resistant packaging requirements specified in this Order and are referred to in clause 1 of this Order. In general, these classes of goods are those for which the risk of accidental ingestion by children is reduced, for example by the particular presentation [see subclauses 1(1)(a)(ii), (iii), (iv) and (v)], or where availability to children is minimal, for example, products not at

their final stage of manufacture, or products only for use in a public hospital, private hospital or nursing home. Subclause 1(1)(a)(x) also exempts goods that are solely for export.

Subclause 1(1)(a)(vi) of this Order exempts goods that fall within the description of Item 9(a) of Schedule 5 of the Regulations from the requirements of this Order. These goods are medicines used as starting materials used in the manufacture of therapeutic goods except when pre-packaged for supply for other therapeutic purposes or formulated as a dosage form. This means that active ingredients and excipients intended for use in the manufacture of medicines or other therapeutic goods are exempt. However, if the same ingredients are prepackaged ready for sale they are not exempt. For example, an ingredient such as eucalyptus oil can be used in manufacture of medicines, in which case it is exempt from these requirements; alternatively it can be pre-packaged for sale to the public, in which case it is not exempt. Similarly bulk finished tablets which are still to be packaged for supply are exempt from the requirements in this Order as they have not reached their final stage of manufacture [see subclause 1(1)(a)(vii)]. However, large pack sizes are only exempt if these packs are not for retail supply [subclause 1(1)(a)(i)].

The general exemptions also recognise that certain patients may be disadvantaged through the supply of medications in child-resistant packaging, which the patient may experience difficulty in opening. To remedy this, healthcare professionals authorised under relevant State or Territory legislation to supply or prescribe may determine in individual cases that the supply of goods in child-resistant packaging complying with this Order is not appropriate.

D Interpretation

Throughout this Order, the term ‘child-resistant packaging’ has been used in preference to the term ‘child-resistant containers’ used in the superseded Therapeutic Goods Orders, TGOs 20 and 33. This changed terminology reflects that currently used in the specified national and international Standards, and recognises that child-resistance is associated with a package as a whole rather than any individual component of the package such as a closure or a bottle. Testing protocols for child-resistance necessarily involve a complete package, and it is the complete package to which any certification relates.

The definition of ‘child-resistant packaging’ includes the term ‘young child’ and this should be taken to mean a child within the age group specified in the protocols given in the specified Standards for the testing of child-resistance. This age group is most commonly given as 42 to 51 months of age.

While packaging that complies with the requirements of any of the specified Standards can be expected to be difficult for children of other ages to open, the ability of children outside the given age range to open the package is not tested and thus cannot be assumed.

It should be noted also that ‘child-resistant’ is not synonymous with ‘child-proof’ and that compliance of a package with any of the specified Standards does not mean that all children included in the test group were unable to open the package or gain access to its contents.

E General requirements

Clause 3 of this Order specifies a number of general requirements for child-resistant packaging. Although these requirements are consistent with the requirements of the

Australian Standard AS 1928-2001, they are specified in this Order to ensure their applicability to child-resistant packaging complying with other specified Standards.

In this Order, fitness for purpose extends to include consideration of the child-resistant properties of the package rather than being limited to the more general concept of suitability of the package, including its material of construction, for use with therapeutic goods.

The Order makes a distinction between the shelf-life of the goods and their in-use life. Shelf-life relates to the expiry dating of the goods and, as for any packaging used for therapeutic goods, child-resistant packaging must retain its integrity and functionality for the duration of this period. In-use life refers to the number of times the container will be opened in order to fully use the contents of the container. The particular child-resistant package chosen for use must be able to withstand this number of openings and closings without any deterioration in the child-resistant characteristics or performance.

The requirement that performance of the child-resistant feature not be adversely affected by the contents of the package is based on the established incompatibility of some plastics with particular hydrocarbon solvents, and evidence that this incompatibility can cause failure of a child-resistant closure.

F Standards for reclosable packages

Clause 4 of this Order defines the required standards for child-resistant packaging. These requirements are based on the alternatives of:

- compliance with any of five specified national or international Standards for child-resistant packaging, and

- continued recognition of prior approvals of closures or container/closure systems.

Inclusion of a range of international Standards is intended to facilitate the use of packaging originating overseas, and to minimise the need for exposure of child panels to testing requirements. Notwithstanding slight differences among the five Standards, compliance with any of these Standards is considered to provide sufficient assurance that a package is of an acceptable standard. There is no order of precedence for the Standards, and if compliance is established against an overseas Standard, testing in accordance with the applicable Australian Standard is not required.

The responsibility for compliance with child-resistant packaging requirements rests with the sponsors of therapeutic goods to which this Order applies. Nevertheless it is in the interests of suppliers and manufacturers of packaging claimed to be child-resistant to ensure that their packaging has been certified as complying with one of the specified Standards and that it therefore can be recognised by the TGA as complying with that Standard.

Where this Order applies to a therapeutic good, the alternative to use of packaging complying with one of the specified Standards is the use of a packaging system described in the Second Schedule to this Order. This is largely a ‘grandfather’ provision to allow the continued use of current packaging on existing products, with the Schedule listing those closures and container/closure systems approved for use prior to the commencement of this Order. While no provisions for phasing out these forms of packaging have been included, it is expected that

for new products being introduced to the market, sponsors will preferentially select packaging that is compliant with one or more of the current Standards specified under subclause 4(1)(a).

G Evidence of compliance with Standards

Where a sponsor chooses to use a child-resistant package that complies with any of the specified Standards, the sponsor is required to hold, and be able to submit upon request, documentation establishing this. Depending on the level of product assessment, these data may or may not routinely be requested by TGA during the evaluation processes.

In most cases the required documentation will consist of authorised copies of certifications or test certificates from a recognised overseas testing authority[1], with sufficient information to establish that the package intended for use is the package tested. On occasions, particularly for packaging manufactured in Australia, sponsors may hold actual test data establishing compliance. This is acceptable but, as with certifications, it should be clearly demonstrable that the data do apply to the package intended for use.

Many of the specified Standards permit extrapolation of test results over a range of similar packages, for example over a range of closure or container sizes provided all other characteristics of the package remain the same. As an example, Australian Standard AS 1928-2001 groups closures sizes into the ranges of less than 18 mm in diameter, 18-38 mm in diameter and greater than 38 mm in diameter and allows extrapolation of results to cover the range. Extrapolation of results from one package to another as permitted by the specified Standards is acceptable for the purposes of compliance with this Order.

In circumstances where a particular package has been certified against a superseded version of one of the specified Standards, the performance of supplementary testing rather than a full test protocol may be sufficient to establish that the package complies with current requirements.

H Other evidence

For reclosable packages, subclause 4(3) requires that sponsors hold evidence to demonstrate that the general requirements of fitness for purpose, retention of child-resistant properties, and lack of adverse effect of the contents on the child-resistant properties, are met.

This requirement applies to both new and existing packaging and may necessitate sponsors of therapeutic goods to be pro-active in obtaining or generating such evidence. While it is not the intention of this requirement to necessitate further child panel testing, an absence of reported failures of the child-resistant feature is not adequate. Considerable information on compatibility is likely to be available from packaging manufacturers, and sponsors should be able to establish a simple test protocol specific to each product/package combination. This may involve a combination of pack opening and closing at intervals over the expected shelf-life of the product, plus confirmation of continuing compliance of component deliveries to quality control specifications in line with normal GMP requirements.

[1] Examples of recognised overseas testing authorities include the British Standards Institute (BSI) Supervisory Committee for Child Resistant Containers, Burford Research Consultants (UK), Perritt Laboratories (USA), Great Lakes Marketing (Toledo, USA), and Laboratoire National D'Essais (France)

I Directions for opening and closing

As failures of child-resistant packaging can result from closures not being adequately tightened or re-fastened, subclause 4(6) requires that any reclosable child-resistant package include on it adequate directions for both opening and closing. These instructions may appear in the form of words or graphics on the closure itself, or be conspicuously placed elsewhere on the label. Any written instructions must appear in the English language, but the inclusion of additional languages is not precluded.

J Identification of packaging components

As more than one packaging manufacturer may be licensed to manufacture a particular design closure or container, subclause 4(8) requires in relation to reclosable packages that all components forming the package be readily identifiable through appropriate manufacturers markings.

The specific components on which markings are required are the container and closure. Duplicative markings on the outer, inner and liner of the closure are not required, as a single set of markings on the closure should be sufficient to allow traceability.

K Dropper applicators

Subclause 4(9) relates to products that are supplied with a separate dropper or applicator that may be left in place on the container, in place of the original closure, once the product is in-use. Products commonly presented in this way include minoxidil lotions and paracetamol infant drops.

This requirement has been introduced to ensure that the convenience of leaving a dropper or applicator in the container of a product warranting child-resistant packaging does not compromise child-safety throughout the product's in-use life.

L The First Schedule

Products containing any of the substances listed in the First Schedule to this Order, or salts, esters or other derivatives of these substances, must have child-resistant packaging unless a general exemption exists under subclause 1(1)(a).

Substances are included in the First Schedule primarily on the basis of their toxicity and likelihood of adverse consequences if accidentally ingested in overdose by a child. Other factors taken into account include actual reports of accidental poisoning involving those substances, and availability and use of the substance in the community.

The First Schedule categorises a number of substances by therapeutic group. In such cases, this Order applies to all substances in the named therapeutic group, irrespective of whether the particular substance is mentioned individually or not. As a consequence, if a new substance is marketed that falls into any of the therapeutic groups listed, then products containing that substance will be required to have child-resistant packaging unless a general exemption exists under subclause 1(1)(a) for the particular dosage form.

It should be expected that the First Schedule will be subject to regular review and amendment from time to time as new information becomes available, or new substances receive marketing authorisation.

M The Second Schedule

As outlined under section F above, the Second Schedule provides for the ongoing use of closures and container/closure systems that were accepted under previous Therapeutic Goods Orders as being of an acceptable child-resistant standard *at the time*. The packaging listed in the Second Schedule would not necessarily comply with current Standards for child-resistance and/or senior friendliness.

To assist sponsors in making packaging choices, the details of each closure or container/closure system included in the Second Schedule have been expanded to include, wherever possible, reference to the original date of approval and the Standard to which the packaging complied.

It is anticipated that the number of these closures and container/closure systems remaining in the marketplace will diminish with time through natural attrition, and supersession by newer versions compliant with current Standards.

The Second Schedule does not include details of all child-resistant packaging meeting the requirements of this Order, as it intentionally omits that packaging established as complying with one or more of the Standards specified under subclause 4(1)(a). For the convenience of sponsors however, a reference list of such packaging will be maintained by the TGA.