



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**



## ***DRAFT MANAGING DIRECTOR'S ORDER***

### ***CHILD-RESISTANT PACKAGING OF THERAPEUTIC PRODUCTS***

### ***AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AUTHORITY***

Consultation Draft – April 2006

*Notes:*

- This draft Order makes reference in some parts to aspects of the proposed regulatory scheme that have still to be finalised. These areas are marked in the text in <<grey highlight>>.*



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**DRAFT**



<<Name of Act/Rules>>

Managing Director's Order No. <<XX>>

## CHILD-RESISTANT PACKAGING OF THERAPEUTIC PRODUCTS

### Commencement

<<Appropriate legal statement regarding making of the Order by the Managing Director in accordance with provisions of the Act and/or Rules>>

This Order includes the First Schedule (Parts 1 and 2) to this Order.

This Order commences from the day it is published in the Gazette <<or other date as specified>>.

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## 1 Introduction

The objective of this Order is to set particular requirements for the packaging of therapeutic products that may present a significant risk of toxicity to children if accidentally ingested. These particular requirements relate to child-resistant packaging – that is, packaging that is designed to be resistant to opening by children.

Child-resistant packaging has an important role, alongside other measures, in reducing the incidence and public health burden of accidental poisoning in children and the associated morbidity and mortality. While child-resistant packaging is not child-proof, it delays the time taken by a child to open a package, thereby increasing the probability of adult intervention before the contents are fully accessible and can be ingested.

The mandatory requirements for child-resistant packaging that are specified in this Order are confined to those products identified as being potentially hazardous.

The criteria used in the determination of a requirement for child-resistant packaging are:

- (1) the toxicity of the substance, and risk of harm if it is accidentally ingested by a young child;
- (2) the extent and patterns of availability of the substance in the community;
- (3) the number and type of incidents reported to Poisons Information Centres and other relevant organisations involving accidental ingestion of the substance;
- (4) the consequences of these incidents (hospital admission or other treatment, serious injury, or death);
- (5) any special needs of patients who regularly need access to the substances, such as elderly persons or those with disabilities; and
- (6) the technical feasibility and practicality of child-resistant packaging for the substance, taking into account its usual dosage form and presentation.

As a guideline, a substance will be considered to be sufficiently toxic to warrant child-resistant packaging if a maximum prescription quantity (for example under the Australian Pharmaceutical Benefits Scheme or the New Zealand Pharmaceutical Schedule) or the largest retail pack quantity, is likely to produce significant harm (i.e. requirement for hospital treatment, or death) in a child of 15 kg (i.e. the average size for an 18 month old child).

While the above criteria and guideline relate only to toxicity from ingestion, if a product presents a hazard in terms of potential to cause serious harm to a young child through contact with the eyes, the skin or mucous membranes, then these products will also be considered for child-resistant packaging.

The above criteria are not intended to be considered in isolation and recommendations for child-resistant packaging are made on balance. Consideration of these criteria permits the objective assessment of the risk/benefit balance although emphasis will be given to public health and safety matters.

Product licence holders may elect to use child-resistant packaging for a wider range of products than identified in this Order. In such cases, when the package is promoted (either directly or through implication) as being child-resistant, then this packaging must comply with the same requirements as apply when child-resistant packaging is mandatory.

The forms of child-resistant 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.

At this time, requirements for non-reclosable child-resistant packages such as blister or foil strips do not involve performance testing, but instead are based on specified materials of construction. While this form of packaging has been regarded to date as inherently child-resistant, and there is historical evidence that this is so, there is also mounting evidence that the robustness and effectiveness of blister or foil strip packaging as a child-barrier needs to be increased in order to further reduce instances of accidental childhood poisoning. Product licence holders are therefore encouraged to consider voluntary compliance with the performance requirements of available Standards<sup>1</sup> for non-reclosable child-resistant packages in the selection of such packaging components.

The mandatory aspects of this Order are contained in clauses 2-8 inclusive and the First Schedule to the Order.

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<sup>1</sup> British Standards Institution Standard BS EN 14375:2003 entitled *Child-resistant non-reclosable packaging for pharmaceutical products. Requirements and testing*; Canadian Standards Association Standard CAN/CSA-Z76.2-00 (R2005) *Nonreclosable Child-Resistant Packages*

## 2 Application

2(1) The requirements set out in this Order apply to those therapeutic products that come within the operation of the <<name of the Act and Rules>>, and:

- (a) contain a substance that is specified in the First Schedule to this Order or a salt, ester or other derivative of a substance specified in the First Schedule to this Order; or
- (b) contain a substance, or a salt, ester or other derivative of a substance that can be classified as belonging to a class of substance that is specified in the First Schedule to this Order; or
- (c) are therapeutic products to which subclause 2(1)(a) or subclause 2(1)(b) does not apply but which, through their labelling or packaging, state or imply that the products, as presented, are child-resistant,

unless specifically exempted under clause 3 or unless an exemption from compliance with this Order has been granted by the Managing Director of the Australia New Zealand Therapeutic Products Authority in accordance with <<reference to the provisions in the Rules allowing exemption from standards>>.

### 3 General Exemptions

3(1) The requirements of this Order do not apply to therapeutic products that are:

- (a) in a container holding 500 solid dosage units or more (excluding goods packed and labelled for retail supply);
- (b) liquid preparations in a container having a nominal volume of one litre or more (excluding products packed and labelled for retail supply);
- (c) intended to be administered by injection;
- (d) solid or semi-solid (excluding solid dosage forms) intended for application to the skin or mucous membrane, including transdermal patches;
- (e) liquid or semi-solid intended for application to the eye or mucous membrane, and supplied in a container that has a nominal capacity of not more than 20 millilitres or is fitted with a restricted flow insert;
- (f) individually wrapped powders;
- (g) homoeopathic medicines;
- (h) liquid preparations in spray presentations where:
  - (i) the delivery device is engaged into the container in such a manner that prevents it from being readily removed;
  - (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 children to accomplish;
- (i) starting materials used in the manufacture of therapeutic products except when pre-packaged for supply for other therapeutic purposes or formulated as a dosage form;
- (j) not at their final stage of manufacture;
- (k) supplied to a person whom a healthcare professional, authorised under relevant Australian or New Zealand legislation to supply or prescribe the goods, believes would suffer undue hardship through difficulty in opening packaging complying with the requirements of this Order;
- (l) to be used by, or administered to, a patient for treatment in a public hospital, private hospital or nursing home; or
- (m) export-only medicines.

## 4 Interpretation

4(1) In this Order:

**'Act'** means the <<name of Act>>, 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 from one pocket at a time. 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 young children 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 young 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 reclosable package that keeps the package closed. A closure may be separately identifiable or an integral component of a package;

**'Gazette'** has the same meaning as in <<reference to Rules>>;

[NOTE: the definition as at the date of this Order is as follows: <<definition from Rules to be inserted>>;

**'homoeopathic medicine'** has the same meaning as in <<reference to Rules>>;

[NOTE: the definition as at the date of this Order is as follows: <<definition from Rules to be inserted>>;

**'product'** means a therapeutic product;

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

**'packaging'** means packaging, 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;

**'product licence holder'** has the same meaning as in <<reference to Rules>>.

[NOTE: the definition as at the date of this Order is as follows: <<definition from Rules to be inserted>>;

**'reclosable package'** means a package which, once opened, can be reclosed to its original child-resistant state;

**'Rules'** means the <<title of the Rules>>, as amended from time to time;

**'Standard'** means any of the national or international Standards referred to in clause 6;

**'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 from one pocket at a time. Each layer may be of the same or different material. It must be cut or torn in order to access the contents;

**'therapeutic product'** has the same meaning as in Article 1 of the Agreement Between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products dated 9 Sep 2003

[NOTE: the definition as at the date of this Order is as follows:

**therapeutic product:**

(a) means:

- (i) a product that is represented in any way to be, or that is, whether because of the way in which the product is presented or for any other reason, likely to be taken to be for therapeutic use;
- (ii) an ingredient or component in the manufacture of a product referred to in subparagraph (i);
- (iii) a container or part of a container for a product, ingredient or component referred to in subparagraphs (i) or (ii); or
- (iv) a product falling within a class of products the sole or principal use of which is, or ordinarily is, a therapeutic use; and

(b) includes:

- (i) a product which the Rules provide shall be treated as a therapeutic product for the purposes of this Agreement; and
- (ii) a product which is declared to be a therapeutic product in an Order made under paragraph 2 of Article 10; but

(c) does not include:

- (i) a product which the Rules provide shall not be treated as a therapeutic product for the purposes of this Agreement; or
- (ii) a product which is declared not to be a therapeutic product in an Order made under paragraph 2 of Article 10.]

**'young children'** means children within the age groups specified in the protocols given in the Standards referred to in clause 6 for the testing of child-resistance.

## 5 General requirements

- 5(1) The requirements of this Order apply in addition to any other packaging requirements that may be applied under the Act or Rules.
- 5(2) The packaging for products to which this Order applies must be fit for purpose for the shelf-life of the products.
- 5(3) The packaging for products to which this Order applies must retain its child-resistant properties for the expected in-use life of the products.
- 5(4) Performance of the child-resistant feature must not be adversely affected by the contents of the package.
- 5(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.

## 6 Reclosable packages

6(1) Where a product 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 8317:2003 entitled *Child-resistant packaging – Requirements and testing procedures for reclosable packages* (as amended by *Technical corrigendum issued January 2005: ISO 8317:2003/Cor 1:2005 : Child-resistant packaging - Requirements and testing procedures for reclosable packages - Technical Corrigendum 1*);
- (b) The British Standards Institution Standard BS EN ISO 8317:2004 entitled *Child-resistant packaging. Requirements and testing procedures for reclosable packages*;
- (c) The Canadian Standards Association Standard CSA Z76.1-99 entitled *Reclosable Child-Resistant Packages*;
- (d) 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; or
- (e) The Australian Standard AS 1928-2001 entitled *Child-resistant packages*.

6(2) Where a product to which this Order applies is in a reclosable package that complies with any one of the Standards listed in subclause 6(1), the product licence holder 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 product licence holder, together with a statement of the protocol used to demonstrate child-resistance; or
- (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 product licence holder, together with a statement of the protocol used to demonstrate child-resistance; or
- (c) information demonstrating that the package as specified by the product licence holder has been established previously as complying with a relevant Standard.

- 6(3) In addition to the requirements referred to in subclauses 6(1) and 6(2), where a product to which this Order applies is in a reclosable package, the product licence holder 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 goods, and that performance of the child-resistant feature will not be adversely affected by the contents of the package.
- 6(4) Where a change in specifications for a reclosable package occurs, the product licence holder is to hold additional evidence demonstrating that the child-resistant properties of the package and operation of the closure have not been adversely affected.
- 6(5) In addition to the requirements referred to in subclauses 6(1), 6(2), 6(3), and 6(4), where a product to which this Order applies is in a reclosable package, the product licence holder is to hold information on:
- (a) the types and sizes of container to which a specified closure may be applied;
  - (b) the suitability of the package for the type of goods;
  - (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(6) When a product to which this Order applies is in a reclosable package, adequate directions for opening and effectively reclosing the package shall be:
- (a) conspicuously marked or written on the package or on a label securely affixed or attached to the package; and
  - (b) written in the English language or clearly demonstrated in graphics.
- 6(7) Where a product 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 product once the product is in use, then that configuration also must comply with the requirements of this Order.

## 7 Non-reclosable packages

- 7(1) Subject to subclause 7(2), when a product 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 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.
- 7(2) A non-reclosable package referred to in subclause 7(1) shall not be formed from cellulose film or unlaminated paper.

Dated this                      day of                      2007

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XXXX  
Managing Director  
Australia New Zealand Therapeutic Products Agency

## First Schedule

### Part 1 CLASS ENTRIES<sup>2</sup>

Column 1 <b>CLASS</b>	Column 2 <b>CLASS CONSIDERED TO INCLUDE, BUT NOT LIMITED TO, THE FOLLOWING SUBSTANCES</b>	
<b>ACE INHIBITORS</b> - All preparations containing one or more ACE INHIBITOR ingredient.	Captopril Enalapril Fosinopril Lisinopril	Perindopril Quinapril Ramipril Trandolapril
<b>ANAESTHETICS, LOCAL</b> - All preparations containing one or more LOCAL ANAESTHETIC ingredient.	Amethocaine (INN tetracaine) Articaine Benzocaine Bupivacaine Cinchocaine Levobupivacaine	Lignocaine (INN lidocaine) Mepivacaine Oxybuprocaine Procaine Ropivacaine
<b>ANGIOTENSIN II ANTAGONISTS</b> - All preparations containing one or more ANGIOTENSIN II ANTAGONIST ingredient.	Candesartan Eprosartan Irbesartan Losartan	Olmesartan medoxomil Telmisartan Valsartan
<b>ANTIARRHYTHMICS</b> – All preparations containing one or more ANTIARRHYTHMIC ingredient.	Amiodarone Bretylium tosylate Disopyramide Dofetilide Esmolol Flecainide Ibutilide	Lignocaine (INN lidocaine) Mexiletine Procainamide Quinidine Sotalol Verapamil
<b>ANTICHOLINERGICS</b> - All preparations containing one or more ANTICHOLINERGIC ingredient.	Atropine Benzhexol (INN trihexyphenidyl) Benztropine (INN benztropine) Bethanechol Biperiden Carbachol Cyclopentolate Glycopyrrolate Homatropine	Neostigmine Orphenadrine Oxybutamine Pilocarpine Procyclidine Pyridostigmine Tolterodine Tropicamide

<sup>2</sup> Inclusion of class entries imposes an automatic requirement for child-resistant packaging on any new substance falling within any of those classes. However although substances are listed under classes, requirements for child-resistant packaging are independent of indication. Therefore, any substance named in Column 2 is required to be packaged in child-resistant packaging (unless a general exception exists for the particular presentation or circumstances) even if licensed for an indication not consistent with the class under which the substance has been named.

<p><b>Column 1</b></p> <p><b>CLASS</b></p>	<p><b>Column 2</b></p> <p><b>CLASS CONSIDERED TO INCLUDE, BUT NOT LIMITED TO, THE FOLLOWING SUBSTANCES</b></p>	
<p><b>ANTI-DEMENTIA DRUGS</b> - All preparations containing one or more ANTI-DEMENTIA DRUG ingredient.</p>	<p>Donepezil Galantamine</p>	<p>Memantine Rivastigmine</p>
<p><b>ANTIDEPRESSANTS</b> - All preparations containing one or more ANTIDEPRESSANT ingredient.</p>	<p>Amitriptyline Citalopram Clomipramine Desipramine Dothiepin (INN dosulepin) Doxepin Escitalopram Fluoxetine Fluvoxamine Imipramine Mianserin</p>	<p>Mirtazapine Moclobemide Nefazodone Nortriptyline Paroxetine Protriptyline Reboxetine Sertraline Trazodone Trimipramine Venlafaxine</p>
<p><b>ANTIEMETICS AND ANTINAUSEANTS</b> - All preparations containing one or more ANTIEMETIC OR ANTINAUSEANT ingredient.</p>	<p>Aprepitant Dimenhydrinate Dolasetron Domperidone Granisetron</p>	<p>Hyoscine hydrobromide Metoclopropamide Ondansetron Tropisetron</p>
<p><b>ANTIEPILEPTICS</b> - All preparations containing one or more ANTIEPILEPTIC ingredient.</p>	<p>Carbamazepine Clonazepam Ethosuximide Gabapentin Lamotrigine Levetiracetam Methylphenobarbitone Oxcarbazepine Phenobarbitone</p>	<p>Phenytoin Pregabalin Primidone Sodium valproate Sulthiame Tiagabine Topiramate Vigabatrin</p>
<p><b>ANTIHISTAMINES</b> - All preparations containing one or more ANTIHISTAMINE ingredient.</p>	<p>Antazoline Astemizole Azatadine Azelastine Brompheniramine Cetirizine Chlorpheniramine Clemizole Cyproheptadine Desloratidine Dexchlorpheniramine Dimenhydrinate Diphenhydramine Doxylamine Fexofenadine</p>	<p>Hydroxyzine Ketotifen Levocabastine Loratadine Meclozine Mepyramine Mequitazine Methdilazine Pheniramine Promethazine Terfenadine Thiethylperazine Trimeprazine (INN alimemazine) Triprolidine</p>

<p>Column 1</p> <p><b>CLASS</b></p>	<p>Column 2</p> <p><b>CLASS CONSIDERED TO INCLUDE, BUT NOT LIMITED TO, THE FOLLOWING SUBSTANCES</b></p>	
<p><b>ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS</b> - All preparations containing one or more NON-STERIODAL ANTIINFLAMMATORY OR ANTIRHEUMATIC ingredient.</p>	<p>Benzydamine Bufexamac Celecoxib, Diclofenac Etoricoxib Flurbiprofen Ibuprofen Indomethacin (INN indometacin) Ketoprofen Ketorolac Lumiracoxib</p>	<p>Mefenamic acid Meloxicam Nabumetone Naproxen Parecoxib Phenylbutazone Piroxicam Sulindac Tiaprofenic acid Valdecoxib</p>
<p><b>ANTIMALARIALS</b> - All preparations containing one or more ANTIMALARIAL ingredient, <b>except</b> doxycycline.</p>	<p>Artemether Atovaquone Chloroquine Hydroxychloroquine Lumefantrine Mefloquine</p>	<p>Primaquine Proguanil Pyrimethamine Quinine Sulfadoxine</p>
<p><b>ANTINEOPLASTIC AGENTS</b> - All preparations containing one or more ANTINEOPLASTIC AGENT ingredient.</p>	<p>Altretamine Arsenic trioxide Bevacizumab Bleomycin Busulfan Capecitabine Carboplatin Carmustine Cetuximab Chlorambucil Cisplatin Cladribine Cyclophosphamide Cytarabine Dacarbazine Dactinomycin Daunorubicin Docetaxel Doxorubicin Epirubicin Estramustine Etoposide Fludarabine Fluorouracil Fotemustine Gefitinib Gemcitabine Hydroxyurea Idarubicin</p>	<p>Ifosfamide Imatinib Irinotecan Levamisole Lomustine Melphalan Mercaptopurine Methotrexate Methyl aminolevulinate Mitomycin Mitotane Mitoxantrone Paclitaxel Pemetrexed Procarbazine Raltitrexed Rituximab Tegafur Temozolomide Teniposide Thioguanine (INN tioguanine) Thiotepa Topotecan Trastuzumab Tretinoin Verteporfin Vinblastine Vincristine Vindesine Vinorelbine</p>

<p><b>Column 1</b></p> <p><b>CLASS</b></p>	<p><b>Column 2</b></p> <p><b>CLASS CONSIDERED TO INCLUDE, BUT NOT LIMITED TO, THE FOLLOWING SUBSTANCES</b></p>	
<p><b>ANTI-PARKINSON DRUGS</b> - All preparations containing one or more ANTI-PARKINSON DRUG ingredient.</p>	<p>Amantadine Apomorphine Benzhexol Benztropine Biperiden Bromocriptine Cabergoline Entacapone</p>	<p>Levodopa Orphenadrine Pergolide Pramipexole Procyclidine Ropinirole Selegiline</p>
<p><b>ANTIPSYCHOTICS</b> - All preparations containing one or more ANTIPSYCHOTIC ingredient.</p>	<p>Amisulpride Aripiprazole Chlorpromazine Clozapine Droperidol Flupenthixol (INN flupentixol) Fluphenazine Haloperidol Lithium carbonate Methyltrimeprazine Olanzapine Pericyazine (INN periciazine) Perphenazine</p>	<p>Pimozide Prochlorperazine Promazine Promethazine Quetiapine Risperidone Sulpiride Tetrabenazine Thioridazine Trifluoperazine Trimeprazine (INN alimemazine) Ziprasidone Zuclopenthixol</p>
<p><b>BENZODIAZEPINE DERIVATIVES</b> - All preparations containing one or more BENZODIAZEPINE DERIVATIVE ingredient.</p>	<p>Alprazolam Bromazepam Clobazam Clonazepam Diazepam Flunitrazepam Lorazepam</p>	<p>Lormetazepam Midazolam Nitrazepam Oxazepam Potassium clorazepate Temazepam Triazolam</p>
<p><b>BETA BLOCKING AGENTS</b> - All preparations containing one or more BETA BLOCKING AGENT ingredient.</p>	<p>Acebutolol Atenolol Betaxolol Betaxolol Bisoprolol fumarate Carvedilol Celiprolol Esmolol Labetalol</p>	<p>Levobunolol Metoprolol Nadolol Oxprenolol Pindolol Propranolol Sotalol Timolol</p>
<p><b>CALCIUM CHANNEL BLOCKERS</b> - All preparations containing one or more CALCIUM CHANNEL BLOCKER ingredient.</p>	<p>Amlodipine Diltiazem Felodipine Isradipine Lercanidipine</p>	<p>Nifedipine Nimodipine Perhexiline Verapamil</p>

Column 1 <b>CLASS</b>	Column 2 <b>CLASS CONSIDERED TO INCLUDE, BUT NOT LIMITED TO, THE FOLLOWING SUBSTANCES</b>	
<b>CARDIAC GLYCOSIDES</b> - All preparations containing one or more CARDIAC GLYCOSIDE ingredient.	Digoxin Digitalis purpurea	Digitalis lanata
<b>CENTRALLY ACTING SYMPATHOMIMETICS</b> - All preparations containing one or more CENTRALLY ACTING SYMPATHOMIMETIC ingredient.	Atomoxetine Dexamphetamine (INN dexamfetamine)	Methylphenidate Modafinil
<b>DIURETICS</b> - All preparations containing one or more DIURETIC ingredient.	Amiloride Bendrothiazide Chlorothiazide Chlorthalidone (INN chlortalidone) Ethacrynic acid (INN etacrynic acid) Frusemide	Hydrochlorothiazide Hydroflumethiazide Indapamide Spironolactone Triamterene
<b>ERGOT ALKALOIDS</b> - All preparations containing one or more ERGOT ALKALOID ingredient.	Dihydroergotamine Ergotamine	Methysergide
<b>ESSENTIAL OILS, PURE, except</b> when: (a) separately specified in Part 2 to this Schedule; or (b) packed in containers fitted with a restricted flow insert.		
<b>MONOAMINE OXIDASE INHIBITORS</b> - All preparations containing one or more MONOAMINE OXIDASE INHIBITOR ingredient.	Moclobemide Phenelzine	Tranylcypromine
<b>OPIOIDS</b> - All preparations containing one or more OPIOID ingredient <b>except</b> pholcodine.	Alfentanil Buprenorphine Butorphanol Codeine Dextromoramide Dextropropoxyphene Dihydrocodeine Diphenoxylate Fentanyl Hydromorphone	Loperamide Methadone Morphine Opium Oxycodone Pentazocine Pethidine Remifentanyl Tramadol

<p style="text-align: center;"><b>Column 1</b></p> <p style="text-align: center;"><b>CLASS</b></p>	<p style="text-align: center;"><b>Column 2</b></p> <p style="text-align: center;"><b>CLASS CONSIDERED TO INCLUDE, BUT NOT LIMITED TO, THE FOLLOWING SUBSTANCES</b></p>	
<p><b>ORAL BLOOD GLUCOSE LOWERING AGENTS</b> - All preparations containing one or more ORAL BLOOD GLUCOSE LOWERING AGENT ingredient.</p>	<p>Acarbose Chlorpropamide Glibenclamide Gliclazide Glimepiride Glipizide Metformin</p>	<p>Miglitol Nateglinide Pioglitazone Repaglinide Rosiglitazone Tolazamide Tolbutamide</p>

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## First Schedule

### Part 2 – Individual substance entries

#### ANISE OIL **except:**

- (a) when packed in containers having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 50 per cent or less of anise oil.

#### ASPIRIN.

#### BASIL OIL **except:**

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

#### BAY OIL **except:**

- (a) when packed in containers having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 25 per cent or less of bay oil.

#### CAJUPUT OIL **except:**

- (a) when packed in containers having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 25 per cent or less of cajuput oil.

#### CAMPHORATED OIL.

#### CAMPHOR **except:**

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

CASSIA OIL **except** in preparations containing 2 per cent or less of cassia oil.

CINNAMON BARK OIL **except** in preparations containing 2 per cent or less of cinnamon bark oil.

#### CINNAMON LEAF OIL **except:**

- (a) when packed in containers having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 25 per cent or less of cinnamon leaf oil.

#### CINEOLE in a volume of 2 litres or less **except:**

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

#### CLONIDINE.

**CLOVE OIL except:**

- (a) when packed in containers having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert;
- (b) in preparations containing 25 per cent or less of clove oil.

**COLCHICINE.**

**ETHANOL**, in mouthwash preparations containing more than 5 grams of ethanol in a single pack.

**EUCALYPTUS OIL** in a volume of 2 litres or less **except:**

- (a) when packed in containers having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 25 per cent or less of eucalyptus oil.

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

**IRON COMPOUNDS** in packs containing a total of more than 250 milligrams of elemental iron, **except** for divided preparations in which the iron is compounded with one or more other active ingredients and the amount of elemental iron per dosage unit is 5 milligrams or less. (Note - Iron oxides when present as an excipient, in either divided preparations containing 10 milligrams or less of total iron oxides per dosage unit or undivided preparations containing 1 per cent or less of total iron oxides, are excluded from the calculation of elemental iron content.)

**MARJORAM OIL except:**

- (a) when packed in containers having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert, or
- (b) in preparations containing 50 per cent or less of marjoram.

**MELALEUCA OIL (Tea-tree Oil)** in a volume of 200 millilitres or less **except:**

- (a) when packed in containers having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 25 per cent or less of melaleuca oil.

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

**MINOXIDIL** in liquid preparations or preparations for oral administration.

**MOUTHWASH** preparations – see **ETHANOL**.

**NICOTINE.**

**NUTMEG OIL except:**

- (a) when packed in containers having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 50 per cent or less of nutmeg oil.

**PARACETAMOL** All solid dosage forms and liquid preparations.

**PENNYROYAL OIL except** in preparations containing 4 per cent or less of d-pulegone.

POTASSIUM SALTS, in packs containing a total of more than 4000 milligrams of elemental potassium, **except** for divided preparations in which the amount of elemental potassium per dosage unit is 40 milligrams or less.

PSEUDOEPHEDRINE.

SAGE (DALMATIAN) OIL **except** in preparations containing 4 per cent or less of thujone.

SALBUTAMOL.

SASSAFRAS OIL **except** in preparations containing 1 per cent or less of safrole.

STAR ANISE OIL **except:**

- (a) when packed in containers having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 50 per cent or less of star anise oil.

THEOPHYLLINE.

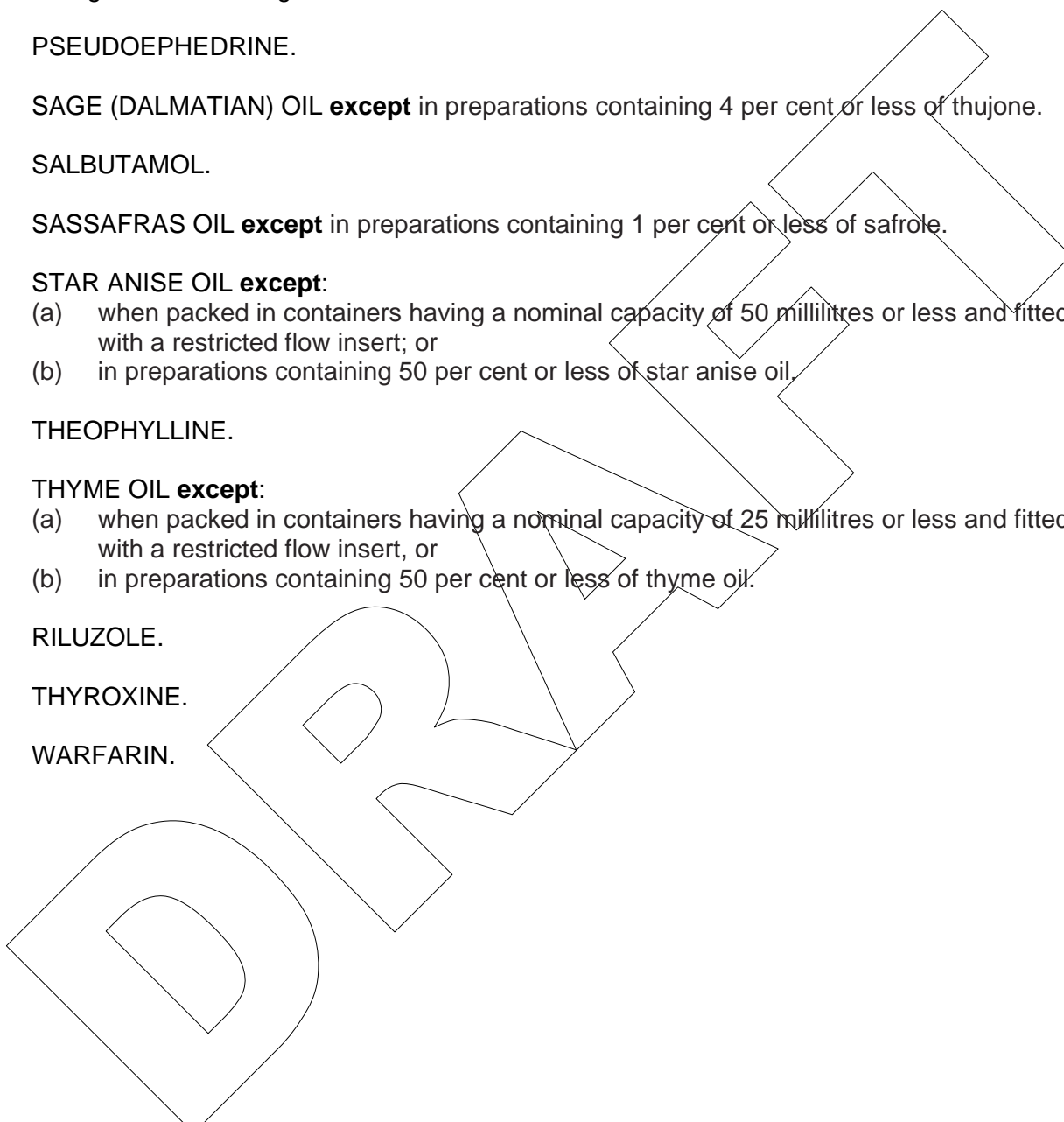
THYME OIL **except:**

- (a) when packed in containers having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert, or
- (b) in preparations containing 50 per cent or less of thyme oil.

RILUZOLE.

THYROXINE.

WARFARIN.



## Alphabetical Listing of First Schedule entries

Acarbose (Oral Blood Glucose Lowering Agents).

ACE INHIBITORS - All preparations containing one or more ACE INHIBITOR ingredient.

Acebutolol (Beta Blocking Agents).

Alfentanil (Opioids).

Alprazolam (Benzodiazepine Derivatives).

Altretamine (Antineoplastic Agents).

Amantadine (Anti-Parkinson Drugs).

Amethocaine (INN tetracaine) (Local Anaesthetics).

Amiloride (Diuretics).

Amiodarone (Antiarrhythmics).

Amisulpride (Antipsychotics).

Amitriptyline (Antidepressants).

Amlodipine (Calcium Channel Blockers).

ANAESTHETICS, LOCAL - All preparations containing one or more LOCAL ANAESTHETIC ingredient.

ANGIOTENSIN II ANTAGONISTS - All preparations containing one or more ANGIOTENSIN II ANTAGONIST ingredient.

Anise oil **except:**

(a) when packed in containers having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert; or

(b) in preparations containing 50 per cent or less of anise oil.

Antazoline (Antihistamines).

ANTIARRHYTHMICS – All preparations containing one or more ANTIARRHYTHMIC ingredient.

ANTICHOLINERGICS - All preparations containing one or more ANTICHOLINERGIC ingredient.

ANTI-DEMENTIA DRUGS - All preparations containing one or more ANTI-DEMENTIA DRUG ingredient.

ANTIDEPRESSANTS - All preparations containing one or more ANTIDEPRESSANT ingredient.

ANTIEMETICS AND ANTINAUSEANTS - All preparations containing one or more ANTIEMETIC OR ANTINAUSEANT ingredient.

ANTIEPILEPTICS - All preparations containing one or more ANTIEPILEPTIC ingredient.

ANTIHISTAMINES - All preparations containing one or more ANTIHISTAMINE ingredient.

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS - All preparations containing one or more NON-STEROIDAL ANTIINFLAMMATORY OR ANTIRHEUMATIC ingredient.

ANTIMALARIALS - All preparations containing one or more ANTIMALARIAL ingredient, **except** doxycycline.

ANTINEOPLASTIC AGENTS - All preparations containing one or more ANTINEOPLASTIC AGENT ingredient.

ANTI-PARKINSON DRUGS - All preparations containing one or more ANTI-PARKINSON DRUG ingredient.

ANTIPSYCHOTICS - All preparations containing one or more ANTIPSYCHOTIC ingredient.

Apomorphine (Anti-Parkinson Drugs).

Aprepitant (Antiemetics and Antinauseants).

Aripiprazole (Antipsychotics).

Arsenic Trioxide (Antineoplastic Agents).

Artemether (Antimalarials).

Articaine (Anaesthetics, Local).

Aspirin.

Astemizole (Antihistamines).

Atenolol (Beta Blocking Agents).

Atomoxetine (Centrally Acting Sympathomimetics).

Atovaquone (Antimalarials).

Atropine (Anticholinergics).

Azatadine (Antihistamines).

Azelastine (Antihistamines).

Basil oil **except**:

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

Bay oil **except**:

- (a) when packed in containers having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 25 per cent or less of bay oil.

Bendrothiazide (Diuretics).

Benzhexol (Anti-Parkinson Drugs).

Benzhexol (INN Trihexyphenidyl) (Anticholinergics).

Benzocaine (Anaesthetics, Local).

**BENZODIAZEPINE DERIVATIVES** - All preparations containing one or more  
BENZODIAZEPINE DERIVATIVE ingredient.

Benztropine (Anti-Parkinson Drugs).

Benztropine (INN benztropine) (Anticholinergics).

Benzzydamine (Antiinflammatory and Antirheumatic Products, Non-Steroids).

**BETA BLOCKING AGENTS** - All preparations containing one or more BETA BLOCKING  
AGENT ingredient.

Betaxolol (Beta Blocking Agents).

Betaxolol (Beta Blocking Agents).

Bethanechol (Anticholinergics).

Bevacizumab (Antineoplastic Agents).

Biperiden (Anticholinergics).

Biperiden (Anti-Parkinson Drugs).

Bisoprolol Fumarate (Beta Blocking Agents).

Bleomycin (Antineoplastic Agents).

Bretylium Tosilate (Antiarrhythmics).

Bromazepam (Benzodiazepine Derivatives).

Bromocriptine (Anti-Parkinson Drugs).

Brompheniramine (Antihistamines).

Bufexamac (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Bupivacine (Anaesthetics, Local).

Buprenorphine (Opioids).

Busulfan (Antineoplastic Agents).

Butorphanol (Opioids).

Cabergoline (Anti-Parkinson Drugs).

Cajuput oil **except:**

- (a) when packed in containers having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 25 per cent or less of cajuput oil.

**CALCIUM CHANNEL BLOCKERS** - All preparations containing one or more CALCIUM  
CHANNEL BLOCKER ingredient.

Camphor **except:**

- (a) in liquid preparations containing 2.5 per cent or less of camphor;
- (b) in essential oils containing 10 per cent or less of camphor, packed in containers having a nominal capacity of 25 millilitres or less fitted with a restricted flow insert;

- (c) in essential oils packed in containers having a nominal capacity of 15 millilitres or less fitted with a restricted flow insert; or
- (d) in rosemary oil, sage oil (Spanish), or lavandin oil as such.

Camphorated oil.

Candesartan (Angiotensin II Antagonists).

Capecitabine (Antineoplastic Agents).

Captopril (ACE Inhibitors).

Carbachol (Anticholinergics).

Carbamazepine (Antiepileptics).

Carboplatin (Antineoplastic Agents).

CARDIAC GLYCOSIDES - All preparations containing one or more CARDIAC GLYCOSIDE ingredient.

Carmustine (Antineoplastic Agents).

Carvedilol (Beta Blocking Agents).

Cassia oil **except** in preparations containing 2 per cent or less of cassia oil.

Celecoxib (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Celiprolol (Beta Blocking Agents).

CENTRALLY ACTING SYMPATHOMIMETICS - All preparations containing one or more CENTRALLY ACTING SYMPATHOMIMETIC ingredient.

Cetirizine (Antihistamines).

Cetuximab (Antineoplastic Agents).

Chlorambucil (Antineoplastic Agents).

Chloroquine (Antimalarials).

Chlorothiazide (Diuretics).

Chlorpheniramine (Antihistamines).

Chlorpromazine (Antipsychotics).

Chlorpropamide (Oral Blood Glucose Lowering Agents).

Chlorthalidone (Diuretics).

Cinchocaine (Anaesthetics, Local).

Cineole in a volume of 2 litres or less **except**:

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

Cinnamon bark oil **except** in preparations containing 2 per cent or less of cinnamon bark oil.

Cinnamon leaf oil **except**:

- (a) when packed in containers having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 25 per cent or less of cinnamon leaf oil.

Cisplatin (Antineoplastic Agents).

Citalopram (Antidepressants).

Cladribine (Antineoplastic Agents).

Clemizole (Antihistamines).

Clobazam (Benzodiazepine Derivatives).

Clomipramine (Antidepressants).

Clonazepam (Antiepileptics).

Clonazepam (Benzodiazepine Derivatives).

Clonidine.

Clove oil **except:**

- (a) when packed in containers having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert;
- (b) in preparations containing 25 per cent or less of clove oil.

Clozapine (Antipsychotics).

Codeine (Opioids).

Colchicine.

Cyclopentolate (Anticholinergics).

Cyclophosphamide (Antineoplastic Agents).

Cyproheptadine (Antihistamines).

Cytarabine (Antineoplastic Agents).

Dacarbazine (Antineoplastic Agents).

Dactinomycin (Antineoplastic Agents).

Daunorubicin (Antineoplastic Agents).

Desipramine (Antidepressants).

Desloratidine (Antihistamines).

Dexamphetamine (INN dexamfetamine) (Centrally Acting Sympathomimetics).

Dexchlorpheniramine (Antihistamines).

Dextromoramide (Opioids).

Dextropropoxyphene (Opioids).

Diazepam (Benzodiazepine Derivatives).

Diclofenac (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Digitalis Lanata (Cardiac Glycosides).

Digitalis Purpurea (Cardiac Glycosides).

Digoxin (Cardiac Glycosides).

Dihydrocodeine (Opioids).  
Dihydroergotamine (Ergot Alkaloids).  
Diltiazem (Calcium Channel Blockers).  
Dimenhydrinate (Antiemetics and Antinauseants).  
Dimenhydrinate (Antihistamines).  
Diphenhydramine (Antihistamines).  
Diphenoxylate (Opioids).  
Disopyramide (Antiarrhythmics).  
DIURETICS - All preparations containing one or more DIURETIC ingredient.  
Docetaxel (Antineoplastic Agents).  
Dofetilide (Antiarrhythmics).  
Dolasetron (Antiemetics and Antinauseants).  
Domperidone (Antiemetics and Antinauseants).  
Donepezil (Anti-Dementia Drugs).  
Dothiepin (INN Dosulepin) (Antidepressants).  
Doxepin (Antidepressants).  
Doxorubicin (Antineoplastic Agents).  
Doxylamine (Antihistamines).  
Droperidol (Antipsychotics).  
Enalapril (ACE Inhibitors).  
Entacapone (Anti-Parkinson Drugs).  
Epirubicin (Antineoplastic Agents).  
Eprosartan (Angiotensin II Antagonists).  
ERGOT ALKALOIDS - All preparations containing one or more ERGOT ALKALOID ingredient.  
Ergotamine (Ergot Alkaloids).  
Escitalopram (Antidepressants).  
Esmolol (Antiarrhythmics).  
Esmolol (Beta Blocking Agents).  
ESSENTIAL OILS, PURE, except when:  
    (a) separately specified in Part 2 to this Schedule; or  
    (b) packed in containers fitted with a restricted flow insert.  
Estramustine (Antineoplastic Agents).  
Ethacrynic Acid (INN Etacrynic Acid) (Diuretics).  
Ethanol, in mouthwash preparations containing more than 5 grams of ethanol in a single pack.  
Ethosuximide (Antiepileptics).

Etoposide (Antineoplastic Agents).

Etoricoxib (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Eucalyptus oil in a volume of 2 litres or less **except:**

- (a) when packed in containers having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 25 per cent or less of eucalyptus oil.

Felodipine (Calcium Channel Blockers).

Fentanyl (Opioids).

Fexofenadine (Antihistamines).

Flecainide (Antiarrhythmics).

Fludarabine (Antineoplastic Agents).

Flunitrazepam (Benzodiazepine Derivatives).

Fluoride salts in packs containing the equivalent of more than 100 milligrams of elemental fluorine.

Fluorouracil (Antineoplastic Agents).

Fluoxetine (Antidepressants).

Flupenthixol (INN Flupentixol) (Antipsychotics).

Fluphenazine (Antipsychotics).

Flurbiprofen (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Fluvoxamine (Antidepressants).

Fosinopril (ACE Inhibitors).

Fotemustine (Antineoplastic Agents).

Frusemide (Diuretics).

Gabapentin (Antiepileptics).

Galantamine (Anti-Dementia Drugs).

Gefitinib (Antineoplastic Agents).

Gemcitabine (Antineoplastic Agents).

Glibenclamide (Oral Blood Glucose Lowering Agents).

Gliclazide (Oral Blood Glucose Lowering Agents).

Glimepiride (Oral Blood Glucose Lowering Agents).

Glipizide (Oral Blood Glucose Lowering Agents).

Glycopyrrolate (Anticholinergics).

Granisetron (Antiemetics and Antinauseants).

Haloperidol (Antipsychotics).

Homatropine (Anticholinergics).

Hydrochlorothiazide (Diuretics).

Hydroflumethiazide (Diuretics).

Hydromorphone (Opioids).

Hydroxychloroquine (Antimalarials).

Hydroxyurea (Antineoplastic Agents).

Hydroxyzine (Antihistamines).

Hyoscine Hydrobromide (Antiemetics and Antinauseants).

Ibuprofen (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Ibutilide (Antiarrhythmics).

Idarubicin (Antineoplastic Agents).

Idarubicin (Antineoplastic Agents).

Imipramine (Antidepressants).

Indapamide (Diuretics).

Indomethacin (INN Indometacin) (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Irbesartan (Angiotensin II Antagonists).

Iron compounds in packs containing a total of more than 250 milligrams of elemental iron, **except** for divided preparations in which the iron is compounded with one or more other active ingredients and the amount of elemental iron per dosage unit is 5 milligrams or less. (Note - Iron oxides when present as an excipient, in either divided preparations containing 10 milligrams or less of total iron oxides per dosage unit or undivided preparations containing 1 per cent or less of total iron oxides, are excluded from the calculation of elemental iron content.)

Isradipine (Calcium Channel Blockers).

Ketoprofen (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Ketorolac (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Ketotifen (Antihistamines).

Labetalol (Beta Blocking Agents).

Lamotrigine (Antiepileptics).

Lercanidipine (Calcium Channel Blockers).

Levetiracetam (Antiepileptics).

Levobunolol (Beta Blocking Agents).

Levobupivacaine (Anaesthetics, Local).

Levocabastine (Antihistamines).

Levodopa (Anti-Parkinson Drugs).

Lignocaine (INN Lidocaine) (Antiarrhythmics; Anaesthetics, Local).

Lisinopril (ACE Inhibitors).

Lithium Carbonate (Antipsychotics).

Lomustine (Antineoplastic Agents).

Loperamide (Opioids).

Loratadine (Antihistamines).

Lorazepam (Benzodiazepine Derivatives).

Lormetazepam (Benzodiazepine Derivatives).

Losartan (Angiotensin II Antagonists).

Lumefantrine (Antimalarials).

Lumiracoxib (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Marjoram oil **except:**

- (a) when packed in containers having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert, or
- (b) in preparations containing 50 per cent or less of marjoram.

Meclozine (Antihistamines).

Mefanamic Acid (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Mefloquine (Antimalarials).

Melaleuca oil (Tea-tree Oil) in a volume of 200 millilitres or less **except:**

- (a) when packed in containers having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 25 per cent or less of melaleuca oil.

Meloxicam (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Melphalan (Antineoplastic Agents).

Memantine (Anti-Dementia Drugs).

Mepivacaine (Anaesthetics, Local).

Mepyramine (Antihistamines).

Mequitazine (Antihistamines).

Mercaptopurine (Antineoplastic Agents).

Metformin (Oral Blood Glucose Lowering Agents).

Methadone (Opioids).

Methdilazine (Antihistamines).

Methotrexate (Antineoplastic Agents).

Methyl Aminolevulinate (Antineoplastic Agents).

Methyl salicylate in liquid preparations containing more than 50 per cent volume in volume of methyl salicylate, in a volume of 200 millilitres or less

Methylphenidate (Centrally Acting Sympathomimetics).

Methylphenobarbitone (Antiepileptics).

Methyltrimeprazine (Antipsychotics).

Methysergide (Ergot Alkaloids).

Metoclopramide (Antiemetics and Antinauseants).

Metoprolol (Beta Blocking Agents).

Mexiletine (Antiarrhythmics).

Mianserin (Antidepressants).

Midazolam (Benzodiazepine Derivatives).

Miglitol (Oral Blood Glucose Lowering Agents).

Minoxidil in liquid preparations or preparations for oral administration.

Mirtazapine (Antidepressants).

Mitomycin (Antineoplastic Agents).

Mitotane (Antineoplastic Agents).

Mitoxantrone (Antineoplastic Agents).

Moclobemide (Antidepressants).

Moclobemide (Monoamine Oxidase Inhibitors).

Modafinil (Centrally Acting Sympathomimetics).

MONOAMINE OXIDASE INHIBITORS - All preparations containing one or more  
MONOAMINE OXIDASE INHIBITOR ingredient.

Morphine (Opioids).

Mouthwash preparations – see Ethanol.

Nabumetone (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Nadolol (Beta Blocking Agents).

Naproxen (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Nateglinide (Oral Blood Glucose Lowering Agents).

Nefazodone (Antidepressants).

Neostigmine (Anticholinergics)

Nicotine.

Nifedipine (Calcium Channel Blockers).

Nimodipine (Calcium Channel Blockers).

Nitrazepam (Benzodiazepine Derivatives).

Nortriptyline (Antidepressants).

Nutmeg oil **except:**

- (a) when packed in containers having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 50 per cent or less of nutmeg oil.

Olanzapine (Antipsychotics).

Olmesartan Medoxomil (Angiotensin II Antagonists).

Ondansetron (Antiemetics and Antinauseants).

OPIOIDS - All preparations containing one or more OPIOID ingredient **except** pholcodine.

Opium (Opioids).

ORAL BLOOD GLUCOSE LOWERING AGENTS - All preparations containing one or more  
ORAL BLOOD GLUCOSE LOWERING AGENT ingredient.

Orphenadrine (Anticholinergics).  
Orphenadrine (Anti-Parkinson Drugs).  
Oxazepam (Benzodiazepine Derivatives).  
Oxcarbazepine (Antiepileptics).  
Oxprenolol (Beta Blocking Agents).  
Oxybuprocaine (Anaesthetics, Local).  
Oxybutamine (Anticholinergics).  
Oxycodone (Opioids).  
Paclitaxel (Antineoplastic Agents).  
Paracetamol - All solid dosage forms and liquid preparations.  
Parecoxib (Antiinflammatory and Antirheumatic Products, Non-Steroids).  
Paroxetine (Antidepressants).  
Pemetrexed (Antineoplastic Agents).  
Pennyroyal oil **except** in preparations containing 4 per cent or less of d-pulegone.  
Pentazocine (Opioids).  
Pergolide (Anti-Parkinson Drugs).  
Perhexiline (Calcium Channel Blockers).  
Pericyazine (Antipsychotics).  
Pericyazine (INN Periciazine) (Antipsychotics).  
Perindopril (ACE Inhibitors).  
Perphenazine (Antipsychotics).  
Pethidine (Opioids).  
Phenelzine (Monoamine Oxidase Inhibitors).  
Pheniramine (Antihistamines).  
Phenobarbitone (Antiepileptics).  
Phenylbutazone (Antiinflammatory and Antirheumatic Products, Non-Steroids).  
Phenytoin (Antiepileptics).  
Pilocarpine (Anticholinergics).  
Pimozide (Antipsychotics).  
Pindolol (Beta Blocking Agents).  
Pioglitazone (Oral Blood Glucose Lowering Agents).  
Piroxicam (Antiinflammatory and Antirheumatic Products, Non-Steroids).  
Potassium Clorazepate (Benzodiazepine Derivatives).

Potassium salts, in packs containing a total of more than 4000 milligrams of elemental potassium, **except** for divided preparations in which the amount of elemental potassium per dosage unit is 40 milligrams or less.

Pramipexole (Anti-Parkinson Drugs).

Pregabalin (Antiepileptics).

Primaquine (Antimalarials).

Primidone (Antiepileptics).

Procainamide (Antiarrhythmics).

Procaine (Anaesthetics, Local).

Procarbazine (Antineoplastic Agents).

Prochlorperazine (Antipsychotics).

Procyclidine (Anticholinergics).

Procyclidine (Anti-Parkinson Drugs).

Proguanil (Antimalarials).

Promazine (Antipsychotics).

Promethazine (Antihistamines).

Promethazine (Antipsychotics).

Propranolol (Beta Blocking Agents).

Protriptyline (Antidepressants).

Pseudoephedrine.

Pyridostigmine (Anticholinergics).

Pyrimethamine (Antimalarials).

Quetiapine (Antipsychotics).

Quinapril (ACE Inhibitors).

Quinidine (Antiarrhythmics).

Quinine (Antimalarials).

Raltitrexed (Antineoplastic Agents).

Ramipril (ACE Inhibitors).

Reboxetine (Antidepressants).

Remifentanyl (Opioids).

Repaglinide (Oral Blood Glucose Lowering Agents).

Riluzole.

Risperidone (Antipsychotics).

Rituximab (Antineoplastic Agents).

Rivastigmine (Anti-Dementia Drugs).

Ropinirole (Anti-Parkinson Drugs).

Ropivacaine (Anaesthetics, Local).

Rosiglitazone (Oral Blood Glucose Lowering Agents).

Sage (Dalmatian) oil **except** in preparations containing 4 per cent or less of thujone.

Salbutamol.

Sassafras oil **except** in preparations containing 1 per cent or less of safrole.

Selegilene (Anti-Parkinson Drugs).

Sertraline (Antidepressants).

Sodium Valproate (Antiepileptics).

Sotalol (Antiarrhythmics).

Sotalol (Beta Blocking Agents).

Spironolactone (Diuretics).

Star anise oil **except**:

- (a) when packed in containers having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert; or
- (b) in preparations containing 50 per cent or less of star anise oil.

Sulfadoxine (Antimalarials).

Sulindac (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Sulpiride (Antipsychotics).

Sulthiame (Antiepileptics).

Tegafur (Antineoplastic Agents).

Telmisartan (Angiotensin II Antagonists).

Temazepam (Benzodiazepine Derivatives).

Temozolomide (Antineoplastic Agents).

Teniposide (Antineoplastic Agents).

Terfenadine (Antihistamines).

Tetrabenazine (Antipsychotics).

Theophylline.

Thiethylperazine (Antihistamines).

Thioguanine (INN Tioguanine) (Antineoplastic Agents).

Thioridazine (Antipsychotics).

Thiotepa (Antineoplastic Agents).

Thyme oil **except**:

- (a) when packed in containers having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert, or
- (b) in preparations containing 50 per cent or less of thyme oil.

Thyroxine.

Tiagabine (Antiepileptics).

Tiaprofenic Acid (Antiinflammatory and Antirheumatic Products, Non-Steroids).

Timolol (Beta Blocking Agents).  
Tolazamide (Oral Blood Glucose Lowering Agents).  
Tolbutamide (Oral Blood Glucose Lowering Agents).  
Topiramate (Antiepileptics).  
Topotecan (Antineoplastic Agents).  
Tolterodine (Anticholinergics).  
Tramadol (Opioids).  
Trandolapril (ACE Inhibitors).  
Tranylcypromine (Monoamine Oxidase Inhibitors).  
Trastuzumab (Antineoplastic Agents).  
Trazodone (Antidepressants).  
Tretinoin (Antineoplastic Agents).  
Triamterene (Diuretics).  
Triazolam (Benzodiazepine Derivatives).  
Trifluoperazine (Antipsychotics).  
Trimeprazine (INN Alimemazine) (Antihistamines; Antipsychotics).  
Trimipramine (Antidepressants).  
Triprolidine (Antihistamines).  
Tropicamide (Anticholinergics).  
Tropisetron (Antiemetics and Antinauseants).  
Valdecoxib (Antiinflammatory and Antirheumatic Products, Non-Steroids).  
Valsartan (Angiotensin II Antagonists).  
Venlafaxine (Antidepressants).  
Verapamil (Antiarrhythmics).  
Verapamil (Calcium Channel Blockers).  
Verteporfin (Antineoplastic Agents).  
Vigabatrin (Antiepileptics).  
Vinblastine (Antineoplastic Agents).  
Vincristine (Antineoplastic Agents).  
Vindesine (Antineoplastic Agents).  
Vinorelbine (Antineoplastic Agents).  
Warfarin.  
Ziprasidone (Antipsychotics).  
Zuclopenthixol (Antipsychotics).