Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Required advisory statements for medicine labels

Edition 1 including update 4

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TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. The TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

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Introduction

Background

The *Required Advisory Statements for Medicine Labels* (RASML) document was established to enable the transfer of all mandatory label advisory statements from the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) and the Therapeutic Goods Regulations 1990 (the Regulations) to a new document, separate from but linked to TGO 69 – *General requirements for labels for medicines* (the Labelling Order).

The Labelling Order makes it mandatory for medicine labels to include any label advisory statements specified in *Required Advisory Statements for Medicine Labels*. By physically separating the documents, the advisory statements can be updated at regular intervals without issuing an entirely new Labelling Order each time.

Source documents

The advisory statements included in RASML have been sourced from the following documents:

- SUSDP Appendix F;
- SUSDP schedules where a reverse scheduling situation applies (this means that a substance is placed in an SUSDP schedule **except** when it is labelled with a relevant statement);
- Schedule 4 of the Regulations (statements that are applicable to listed goods which contain certain herbal substances); and
- Schedule 2 Part 2 of the Regulations (required statements for vitamin and mineral preparations).

Where these source documents required statements that were more than one sentence long (eg. SUSDP Appendix F warnings 34 and 35), the warnings have been separated into single sentences in this document. At the commencement of operation of this document (1 July 2004), the requirements imposed by this document are identical to those previously required by the source documents.

Other label advisory statements currently included in guidelines (e.g. the *Australian Regulatory Guidelines for OTC Medicines*) and in the Electronic Lodgement Facility (ELF) will be reviewed at a later stage, in consultation with stakeholders, to determine whether they are suitable for transfer into *Required Advisory Statements for Medicine Labels*.

Signal headings and cautionary statements (required by Part 2 of the SUSDP) continue to be mandatory requirements for labels of medicines. Sponsors should refer to the most recent edition of the SUSDP for further information.

Application of advisory statements

Application to medicines

Advisory statements apply to all medicines for supply in Australia (i.e. registered prescription, non-prescription and complementary medicines, listed and exempt medicines) by virtue of the operation of the Labelling Order.

Unless otherwise specified in Column 2 of the table in Section 1, the requirements apply only if the substance is included in the medicine as an active ingredient.

Date of effect

The requirements of the original RASML came into effect on 1 July 2004.

In all other cases, unless otherwise specified in this document, the requirements apply:

- in relation to applications for new products, from the date of Gazettal shown in Column 4; and
- in relation to existing products, from a date 12 months from the date of Gazettal shown in Column 4 of the table (the Implementation Date).

The document

The RASML is divided into sections. These are:

Introduction

Preliminary and background information.

Glossary and interpretation

Explanation of acronyms and other terms.

How to use this document

This section provides detailed instructions on how the document works.

How statements are required to be included on the labels

This section explains in detail how required statements should be included on medicine labels.

Section 1 – Medicines to which advisory statements apply

This section specifies the advisory statements that are required on the labels of particular medicines. Details on how to use this section are provided in the section 'How to use this document'.

Section 2 –Advisory statements

This section gives the wording of the advisory statements to be included on the labels of medicines. Details are provided in the section 'How statements are required to be included on the labels'.

Section 3 –Additional requirements

This section gives details of additional requirements (such as font, letter height, capitalisation, position of statement etc) which are required in certain cases. Further details are provided in the section 'How statements are required to be included on the labels'.

Appendices

These sections provide information on:

- Procedural matters such as how to apply to have this document amended (Appendix 1).
- Archived entries (that is, entries that are no longer current) (Appendix 2)

This document is available electronically on the TGA's web site at www.tga.gov.au. The site will be updated to include changes to this document as they occur.

Glossary and interpretation

Term	Definition/Interpretation
Act	*Therapeutic Goods Act 1989*
ARTG	Australian Register of Therapeutic Goods
child-resistant closure	has the same meaning as in the SUSDP which states: ***'child-resistant closure'*** *means:* a. a closure which complies with the requirements for a child-resistant closure in the Australian Standard AS 1928-2001 entitled Child Resistant Packages as specified or amended from time to time; b. a closure approved by any order made under section 10(3) of the Commonwealth Therapeutic Goods Act 1989; or c. in the case of a can fitted with a press-on lid, a lid of the design known as "double tight" or "triple tight".
child-resistant packaging	has the same meaning as in the SUSDP which states: ***'child-resistant packaging'*** *means packaging that:* a. complies with the requirements of the Australian Standard AS 1928-2001 entitled Child Resistant Packages as specified or amended from time to time; or b. is reclosable and complies with the requirements of at least one of the following standards as specified or amended from time to time: 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*; or* c. is approved as child-resistant by any order made under section 10(3) of the Commonwealth Therapeutic Goods Act 1989; or

Term	Definition/Interpretation
	d. is in the form of a blister or strip packaging in which a unit of use is individually protected until the time of release and that complies with Section 3 (Requirements for non-Reclosable Packages) of Australian Standard AS 1928-2001 Child-resistant packages.
concentration, strength or quantity	Unless the contrary intention appears, where a concentration, strength or quantity is specified in Section 1 of this document in respect of a substance: a. if the substance is present as a salt, active principle or derivative (including an ester or ether), the concentration, strength or quantity is calculated as the equivalent amount of the substance that is listed in Section 1; and b. the expression "one per cent" means: i. in the case of a liquid preparation, 1 gram of the substance per 100 mL of the preparation; or ii. in the case of a solid or semi-solid preparation, 1 gram of the substance per 100 grams of the preparation; and iii. any expression of greater or lesser percentages shall have a corresponding meaning; and c. in the case of codeine, such concentration, strength or quantity is calculated as anhydrous codeine.
container	has the meaning as defined in subclause 2(1) of the Labelling Order, which states: ***'container'*** *means an article that immediately covers the goods, and includes an ampoule, blister pack, bottle, sachet, dial dispenser pack, strip pack, syringe, tube, vessel, vial, wrapper or other similar article, but does not include an article intended for ingestion.*
dermal use	means application to the skin primarily for localised effect.
divided preparation	means a preparation manufactured and packed as discrete pre-measured dosage units prior to sale or supply, and includes tablets, capsules, cachets, single dose powders or single dose sachets of powders or granules.

Term	Definition/Interpretation
essential oils	means products obtained from natural raw materials either by distillation with water or steam or from the epicarp of citrus fruits by a mechanical process, or by dry distillation. It also means: a. oils of equivalent composition derived through synthetic means; or b. compounded oils of equivalent composition comprising a mixture of synthetic and natural components.
existing products	products which were included in the ARTG as current products at the time of gazettal of an amendment to the RASML document.
external	in relation to the use of a medicine means application in the ears, eyes or nose or to a body surface other than in the mouth, rectum, vagina, urethra or other body orifice.
g	gram(s)
height	in relation to letters used for words, expressions or statements on labels means the height of capital letters or lower case letters having an ascender or descender.
Implementation Date	Unless otherwise specified in this document: · In relation to applications for new products, the Implementation Date is from the date of Gazettal shown in Column 4 of the table in Section 1; and · In relation to existing products, the Implementation Date is from a date 12 months from the date of Gazettal shown in Column 4 of the table in Section 1.
internal use	means administration: a. orally, except for topical effect in the mouth; or b. for absorption and the production of a systemic effect, i. by way of a body orifice other than the mouth; or ii. parenterally, other than by application to unbroken skin.
label	has the same meaning as defined in subclause 2(1) of the Labelling Order which states: ***'label'*** *means a display of printed information upon, or securely affixed to, the container and any primary pack containing the goods.*
Labelling Order	Therapeutic Goods Order (TGO) 69 – *General requirements for labels for medicines*. Also referred to as TGO 69.

Term	Definition/Interpretation
main label	has the same meaning as defined in subclause 2(1) of the Labelling Order which states: ***'main label'*** *means:* *a. where there are two or more labels or two or more portions of a single label – that label or portion of the label where the product name is more or most conspicuously shown; or* *b. where the product name is equally conspicuous on two or more panels or portions of a label – each such label or portion.*
mg	milligram(s)
mL	millilitre(s)
NDPSC	National Drugs and Poisons Schedule Committee
new products	products which were not included in the ARTG as current products at the time of gazettal of an amendment to the RASML document.
primary pack	has the same meaning as defined in subsection 3(1) of the Act, which states: ***'primary pack****, in relation to therapeutic goods, means the complete pack in which the goods, or the goods in their container, are to be supplied to consumers.*
Regulations	Therapeutic Goods Regulations 1990
restricted flow insert	means a restriction fitted, or moulded, in the neck of a container which: a. cannot be readily removed from the container by manual force; and b. limits the delivery of the contents to drops each of which is not more than 200 microlitres.

Term	Definition/Interpretation
signal heading	means the signal word or words relating to the Schedule of the SUSDP in which the substance is included and the purpose for which it is to be used, as shown in the following table:

Schedule	Purpose	Signal Words Required
2	for any purpose	PHARMACY MEDICINE
3	for any purpose	PHARMACIST ONLY MEDICINE
4	for human use	PRESCRIPTION ONLY MEDICINE
5	for any purpose	CAUTION
6	for any purpose	POISON
7	for any purpose	DANGEROUS POISON
8	for any purpose	CONTROLLED DRUG

Term	Definition/Interpretation
substance	Unless the contrary intention appears, a reference to a substance in Section 1 of this document includes: a. that substance prepared from natural sources or artificially; and b. where the substance is a plant (other than a plant referred to in Schedules 8 or 9 of the SUSDP), that plant or any part of that plant when packed or prepared for therapeutic use; and c. every salt, active principle or derivative of the substance, including esters and ethers and every salt of such an active principle or derivative; and d. every alkaloid of the substance and every salt of such an alkaloid; and e. except where the substance is levomethorphan or levorphanol, every stereoisomer of the substance and every salt of such a stereoisomer; and f. a preparation or admixture containing any proportion of the substance, but **does not include**: g. a preparation or product included in Appendix A of the SUSDP; or h. a substance included in Appendix G of the SUSDP at a concentration not exceeding the concentration specified in column 2 of that Appendix in respect of the substance; or i. any other substance included in Schedules 1 to 6 of the SUSDP, at a concentration not exceeding 10 mg per litre or 10 mg per kilogram, unless that substance is also included in Schedule 7 or 8 of the SUSDP.
supply	has the same meaning as defined in subsection 3(1) of the Act, which states: ***'supply'*** *includes:* *a. supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase; and* *b. supply, whether free of charge or otherwise, by way of sample or advertisement; and* *c. supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods in persons or animals; and* *d. supply by way of administration to, or application in the treatment of, a person or animal.*

Term	Definition/Interpretation
SUSDP	*Standard for the Uniform Scheduling of Drugs and Poisons*
TGA	Therapeutic Goods Administration
TGO 69	Therapeutic Goods Order 69 – *General requirements for labels for medicines*. Also referred to as the Labelling Order.
topical use	means application of a substance for the purpose of producing a localised effect on the surface of the organ or within the tissue to which it is applied.
mg	microgram(s)
mL	microlitre(s)

How to use this document

The following stepwise explanation and Flow Chart 1 provide guidance on how to use the information in Sections 1, 2 and 3 of this document.

Step 1

In Section 1, check Column 1 of the table headed "**Medicines Containing ...**"

Medicines are arranged alphabetically in this list by substance. Substances may be designated in a number of ways including:

- by use of its Australian Approved Name (AAN, ABN, AHN etc)
- by designation of its pharmaceutical class (eg antihistamines)

It is possible that a medicine may require advisory statements from any or all of these groups. It is the sponsor's responsibility to ensure that **all** relevant advisory statements are included on the label.

> *For example, a medicine containing paracetamol and an antihistamine would be required to include advisory statements for both "paracetamol" and "antihistamines".*

If the medicine includes a substance referred to in this column, go to Step 2. If not, no advisory statements are required by this document. However, sponsors should ensure that the label complies with all other regulatory requirements.

Step 2

For each relevant substance in Column 1, check the conditions stated in Column 2 "**Which Meet The Following Conditions ...**".

Unless otherwise specified in Column 2 of the table in Section 1, the requirements apply only if the substance is included in the medicine as an active ingredient.

If the condition for the relevant substance in Column 2 is "All", then the advisory statements referred to in Column 3 are required whenever the substance is included as an active ingredient in a medicine. If the condition is "All, including where present as an excipient.", the advisory statements referred to in Column 3 are required whenever the ingredient is included in a medicine. Go to Step 3.

If another condition is shown in Column 2 for the relevant substance, then the advisory statements referred to in Column 3 will only be required where the condition applies to the medicine – go to Step 3. If the condition is not met, the statements shown in Column 3 are not required.

> *For example, the entry for Alclometasone shows the condition "When included in Schedule 3 of the SUSDP" in Column 2. Medicines included in Schedule 3 of the SUSDP that contain this ingredient must include the advisory statements numbered 2, 80, 112, 117, 52 on the label and meet the additional requirement 'j' in relation to all of the required statements. However, if the medicine containing Alclometasone is included in another schedule of the SUSDP (eg. Schedule 4), these statements are not required.*

Step 3

Where the medicine contains a substance referred to in Column 1 and meets the condition(s) shown in Column 2, the advisory statements referred to in Column 3 "**Require Statement(s)**" must be included on the label. The numbers shown in Column 3 correspond to the statement texts included in Section 2 of this document, "**Advisory Statements**". If additional requirements apply to

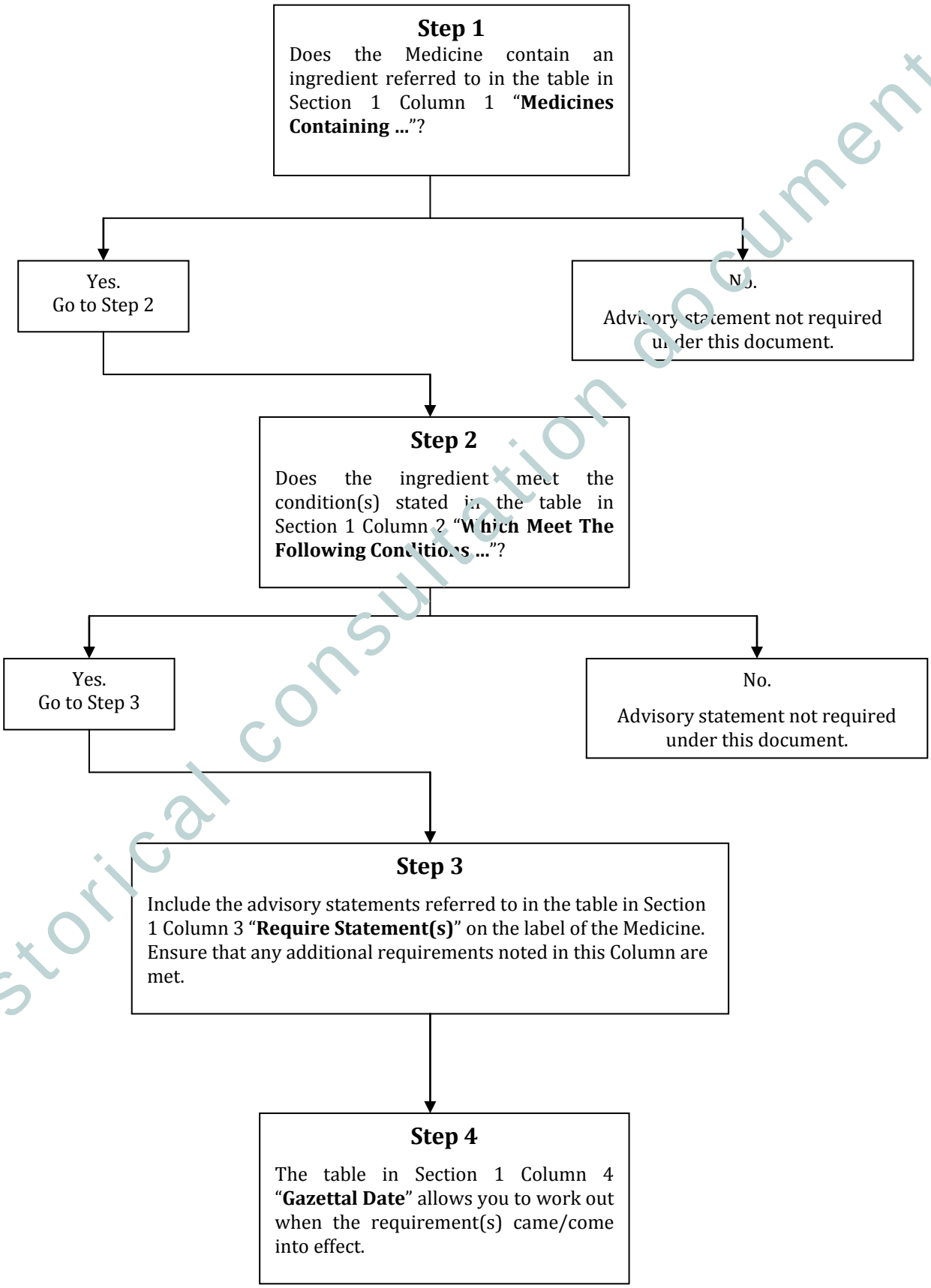
a particular statement, these are shown as superscripted letters in Column 3. These letters correspond to the additional requirements included in Section 3 of this document "**Additional Requirements**". Go to Step 4.

Step 4

Column 4 "**Gazettal Date**" shows the date on which the requirement for a label advisory statement was published in the Commonwealth Gazette. In relation to applications for new products, the statement is required to be included on relevant labels from the date of Gazettal. Unless otherwise indicated, a transition period of 12 months from the date of the gazettal notice will apply for existing products, after which the statement is required to be included on labels of relevant products.

If an entry has been amended, it is shown in duplicate for the duration of the transition period allowed for existing products. During this time, labels of existing products that comply with either set of criteria will be acceptable. Once the transition period expires for existing products, the criteria that were gazetted most recently will apply. The outdated entry will be removed and placed in the Archived Entries table (Appendix 2). In relation to applications for new products, the requirements of the amended entry are to be included on relevant labels from the date of Gazettal.

Flow Chart 1



How required statements are to be included on the labels

What needs to be included on the label

The Labelling Order requires the advisory statement(s) indicated in Section 1 of this document to be included on the labels of relevant medicines.

The wording shown in Section 2 is wording that will be acceptable in most cases. However, the wording of the statements may be varied provided that the intent is not changed.

When the statement needs to be included on the label

- Unless otherwise specified, the initial transition period for existing products as at 1 July 2004 will run until 30 June 2005, that is, **12 months from the date of effect** of the RASML (rather than from Gazettal). In all other cases, unless otherwise specified in this document, the requirements apply from the Implementation Date which:
  - in relation to applications for new products, is from the date of Gazettal shown in Column 4 of the table in Section 1; and
  - in relation to existing products, is from a date 12 months from the date of Gazettal shown in Column 4 of the table in Section 1.
- A shorter time frame may be imposed in the case of an immediate safety concern. In that situation, the relevant Regulator would contact all sponsors of existing products affected by the new advisory statement and advise them accordingly.
- Products supplied (see Glossary) by the sponsor on or after the Implementation Date will be required to include the relevant statements on the labels.
- Where necessary, overstickering of a newly required advisory statement will usually be permitted to cover short-term contingencies, provided that it is conducted under GMP conditions. Sponsors should contact the relevant Regulator directly in this regard, and provide a justification for the need to oversticker.

Additional requirements

In some cases, additional requirements apply to advisory statements, such as font, letter size etc. Where such additional requirements exist, they are indicated by a letter superscript to the advisory statement number shown in Column 3 of the table in Section 1. These letter superscripts are explained in the table in Section 3.

For example, an entry for aspirin when not scheduled is:

Medicines Containing ...	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Aspirin *(Entry 1 of 3)*	*For the purpose of exclusion from the Schedules to the SUSDP.*	*[53 or (60 and 61)], 10[a,c], 3[a,c]*	*23 Jun 2004*

The requirement is that medicines containing the imaginary ingredient that are not scheduled by the SUSDP include statements:

- *either of –*
- *53; or*
- *both 60 and 61; and*
- *10; and*
- *3.*

Additional requirements "a" (statement to be included in capital letters) and "c" (statement must be included in the directions for use) both apply to statements 10 and 3 but not to 53, 60 or 61.

If a letter superscript appears outside brackets that contain more than one advisory statement number, then the superscript requirement applies to all the advisory statements within the brackets.

For example, the entry for aromatic extract oils when scheduled is:

Medicines Containing ...	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Aromatic extract oils	When included in a Schedule to the SUSDP	(79, 87, 81, 89, 88)[h], (123 or 124)[f]	23 Jun 2004

The requirement is that for medicines containing aromatic extract oils that are scheduled by the SUSDP, the labels include statements 79, 87, 81, 89 and 88 grouped together as a distinct section of the label and prefaced by the heading "Safety Directions" which is to be written in bold sanserif characters. Either statement 123 or 124 must be included on a separate line or lines immediately below the cautionary statement "KEEP OUT OF REACH OF CHILDREN" in bold-face sanserif capital letters of uniform thickness at least four tenths the height of the letters used for the signal heading and with nothing written on the same line.

Multiple statements

In many cases more than one advisory statement is required. If required statements are shown separated by a comma, all the indicated statements are required. In some cases alternate statements are allowed. In this case, the alternate statements are separated by an "or" statement (eg. 123 or 124).

> *For example, in the case of aromatic extract oils (see example above), the sponsor may choose which of these statements (123 or 124) to include on the label. Statements 79, 87, 81, 89 and 88 are required in addition to 123 or 124.*

Combination of statements

Where more than one statement is required, they may be combined to form simple sentences where appropriate, provided that the intent of each of the statements is not changed and any additional requirements are also met.

Section 1: Medicines to which advisory statements apply

NOTES:

1. Further explanation of the operation of the various sections of this document is provided in the sections –

   – How to Use this Document; and
   – How Statements are Required to be Included on the Labels.

2. The Glossary and Interpretation section of this document includes the interpretation of the term "**substance**" and guidance on interpreting statements of **concentration, strength or quantity**.

Requirements

Where a medicine:

a. includes a substance described in Column 1 of the following table 'Medicines to Which Advisory Statements Apply'; and

b. meets the conditions described in Column 2 of the table;

the statement(s) denoted in Column 3 of the table (the text of which is included in Section 2 of this document) are to be included on the label of the container and the primary pack (if any). Such statements must meet any additional requirements denoted in Column 3 of the table (and specified in Section 3 of this document).

The required label statements are specified as a number in Column 3 (eg. "79"). Where an additional requirement applies, it is specified as a superscripted alphabetical character immediately following the number (eg. "122[g]"). A superscripted alphabetical character outside brackets applies to all the statements specified within the brackets (eg. "(79, 83)[f]").

The wording of the statements specified in this document may be varied provided that the intent is not changed. Where more than one statement is required, they may be combined to form simple sentences where appropriate, provided that the intent is not changed and that any additional requirements (see Section 3) are also met.

Date from which requirements apply

Unless otherwise specified, the initial transition period for existing products will run until 30 June 2005, that is, **12 months from the date of effect** of the RASML (rather than from Gazettal). In all other cases, unless otherwise specified in this document, the requirements apply from the Implementation Date, which:

· in relation to applications for new products, is from the date of Gazettal shown in Column 4; and

· in relation to existing products, is from a date 12 months from the date of Gazettal shown in Column 4 of the table (the Implementation Date).

Medicines to which advisory statements apply

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Acetone	In concentrations greater than 75 per cent.	(79, 87, 110)[h], 122[g], (123 or 124)[f]	23 Jun 2004
Acitretin	When included in a Schedule to the SUSDP.	(20, 13, 21)[j]	23 Jun 2004
Activated charcoal	When included in Schedule 4 Part 5 Division 3 Item 1 of the Regulations.	135, 136, 137	23 Jun 2004
Adapalene	For topical use.	(22, 43)[j]	23 Jun 2004
Ademetionine in the form of sulphate salts, tosylate salts or mixed sulphate and tosylate salts	When included in Schedule 4 Part 5 Division 3 Item 2 of the Regulations.	43	23 Jun 2004
(S)-S-Adenosylmethionine in the form of sulphate salts, tosylate salts or mixed sulphate and tosylate salts	When included in Schedule 4 Part 5 Division 3 Item 10 of the Regulations.	43	23 Jun 2004
Alclometasone	When included in SUSDP Schedule 3.	(2, 80, 112, 117, 52)[j]	23 Jun 2004
Anise oil	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations containing more than 50 per cent of anise oil; and b. packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert.	1[a]	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Antihistamines	When: a. included in a Schedule to the SUSDP; and b. not separately specified in this Table and they are NOT any one or more of: i. dermal, ocular, parenteral and paediatric preparations; or ii. oral preparations of astemizole, desloratidine, fexofenadine, loratadine or terfenadine ; or iii. nasal preparations of azelastine.	(46 and 49 and 47)[j] or (48 and 50)[j]	23 Jun 2004
Arginine	When included in Schedule 4 Part 1 Item 10A of the Regulations.	153	5 Apr 2006
Aspirin *(Entry 1 of 7)*	For the purpose of exclusion from the Schedules to the SUSDP, when: a. each dosage unit contains more than 100 mg of aspirin; and b. the preparation is NOT indicated for the inhibition of platelet aggregation.	126, 127, 128, 140, 130, 141, 10, 142, 176	10 Sep 2008
Aspirin *(Entry 2 of 7)*	For the purpose of exclusion from the Schedules to the SUSDP, when: a. each dosage unit contains more than 100 mg of aspirin; and b. the preparation is indicated for the inhibition of platelet aggregation.	126, 127, 128, 140, 130, 141, 10, 176	10 Sep 2008
Aspirin *(Entry 3 of 7)*	For the purpose of exclusion from the Schedules to the SUSDP, when: a. each dosage unit contains 100 mg or less of aspirin; and b. the preparation is indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation.	63	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Aspirin *(Entry 4 of 7)*	When included in a Schedule to the SUSDP and: a. the preparation is indicated for inhibition of platelet aggregation; or b. in sustained release preparations containing 650 mg or more of aspirin.	63[j]	23 Jun 2004
Aspirin *(Entry 5 of 7)*	When included in a Schedule to the SUSDP, and: a. the preparation is indicated exclusively for treatment of dysmenorrhoea; and b. NOT in sustained release preparations containing 650mg or more of aspirin; and c. NOT in combination with other therapeutically active substances (other than an effervescent agents)	126, 127, 128, 140 130, 141, 10, 142	10 Sep 2008
Aspirin *(Entry 6 of 7)*	When included in a Schedule to the SUSDP, and: a. in combination with other therapeutically active substances (other than an effervescent agents); and b. NOT in sustained release preparations containing 650mg or more of aspirin; and c. the preparation is NOT indicated: i. for inhibition of platelet aggregation; or ii. exclusively for treatment of dysmenorrhoea.	126, 127, 128, 140, 130, 141, 10, 176	10 Sep 2008

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Aspirin *(Entry 7 of 7)*	When included in a Schedule to the SUSDP, and: a. NOT in combination with other therapeutically active substances (other than an effervescent agents); and b. NOT in sustained release preparations containing 650mg or more of aspirin; and c. the preparation is NOT indicated: i. for inhibition of platelet aggregation; or ii. exclusively for treatment of dysmenorrhoea.	126, 127, 128, 140, 130, 141, 10, 142, 176	10 Sep 2008
Astemizole	When included in a Schedule to the SUSDP	(42, 64)[j]	23 Jun 2004
Azadirachta indica (neem) *(Entry 1 of 2)*	When: a. included in Schedule 4 Part 4 Item 5A of the Regulations; or b. for the purpose of exclusion from the Schedules to the SUSDP when: i. in preparations for human dermal therapeutic use; and ii. in a container fitted with a child resistant closure.	120, 1, 14	23 Jun 2004
Azadirachta indica including its extracts and derivatives *(Entry 2 of 2)*	When included in SUSDP Schedule 6.	14[j]	23 Jun 2004
Backhousia citriodora	When included in Schedule 4 Part 4 Division 2 Item 6 of the Regulations.	90, 4, 15	23 Jun 2004
Basil oil	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations or oils containing more than 5 per cent of methyl chavicol; and b. packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert. .	1[a]	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Bay oil	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations containing more than 25 per cent of bay oil; and b. packed in containers having: i. a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or ii. a nominal capacity of 25 mL or less, fitted with a restricted flow insert and child-resistant closure.	1[a], 120[a]	23 Jun 2004
Benzoyl peroxide	When included in SUSDP Schedule 2.	(91, 92, 69, 70)[j]	23 Jun 2004
Bergamot oil	a. For the purpose of exclusion from the Schedules to the SUSDP; or b. when included in a Schedule to the SUSDP.	93[j]	23 Jun 2004
Bexarotene *(Entry 1 of 2)*	For human use.	(20, 13, 21)[j]	23 Jun 2004
Bexarotene *(Entry 2 of 2)*	For topical use.	(22, 13)[j]	23 Jun 2004
Bosenatan	When included in a Schedule to the SUSDP.	20, 13, 21	23 Jun 2004
Bovine colostrum powder	When included in Schedule 4 Part 5 Division 3 Item 3 of the Regulations.	138, 139	23 Jun 2004
Bovine lactoferrin	When included in Schedule 4 Part 5 Division 3 Item 4 of the Regulations.	38	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Caffeine *(Entry 1 of 2)*	When included in a Listed medicine, except medicines containing less than 1 mg of caffeine in the maximum recommended daily dose: · for oral or sublingual administration, and · the maximum recommended daily dose of which contains 10 mg of caffeine or less. When the caffeine is from a herbal source	173	23 April 2008
Caffeine *(Entry 2 of 2)*	When included in a Listed medicine: · for oral or sublingual administration, and · the maximum recommended daily dose of which contains more than 10 mg of caffeine; and When the caffeine is from a herbal source	174	23 April 2008
Cajuput oil	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations or oils containing more than 25 per cent of cajuput oil; and b. packed in containers having: i. a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or ii. a nominal capacity of 25 mL or less, fitted with a restricted flow insert and child-resistant closure.	1[a], 120[a]	23 Jun 2004
Calcium sodium caseinate	When included in Schedule 4 Part 5 Division 3 Item 5 of the Regulations.	38	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Camphor *(Entry 1 of 3)*	For the purpose of exclusion from the Schedules to the SUSDP when: a. included as a natural component in essential oils containing greater than 2.5 per cent of camphor but 10 per cent or less of camphor; and b. packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert.	1[a], 120[a]	23 Jun 2004
Camphor *(Entry 2 of 3)*	For the purpose of exclusion from the Schedules to the SUSDP when: a. in essential oils when the camphor is present as a natural component of the oil; and b. packed in containers having i. a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or ii. a nominal capacity of 25 mL or less, fitted with a restricted flow insert and child-resistant closure.	1[a], 120[a]	23 Jun 2004
Camphor *(Entry 3 of 3)*	When a. included in a Schedule to the SUSDP; and b. NOT in block, ball, disc or pellet form, enclosed in a device which, in normal use, prevents removal or ingestion of its contents.	11[j], 79[h], (123 or 124)[f]	23 Jun 2004
Cannabis indicum L. var indicum	When included in a listed medicine (refer Listing Notice 2005 (No 1))	156	5 Apr 2006
Cassia oil	When included in a Schedule to the SUSDP	87[h], 122[g], (123 or 124)[f]	23 Jun 2004
Charcoal – activated	When included in Schedule 4 Part 5 Division 3 Item 1 of the Regulations.	135, 136, 137	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Chelidonium majus	When the preparation is for oral use, OTHER THAN homoeopathic preparations containing *Chelidonium majus* in concentrations more dilute than a 1000-fold dilution of the mother tincture.	157, 152	5 Apr 2006
Chromates (including dichromates) of alkali metals or ammonia	When included in a Schedule to the SUSDP.	(79, 87, 110)[h], (123 or 124)[f]	23 Jun 2004
Cimetidine	When included in SUSDP Schedule 3.	(65, 60, 72)[j]	23 Jun 2004
Cimicifuga racemosa	When included in a Listed medicine	153, 172	23 April 2008
Cineole	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations or oils containing more than 25 per cent of cineole (other than rosemary oil or camphor oil); and b. packed in containers having: i. a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or ii. a nominal capacity of 25 mL or less, fitted with a restricted flow insert and child-resistant closure.	1[a], 120[a]	23 Jun 2004
Cinnamon bark oil	When included in a Schedule to the SUSDP.	87[h], 122[g], (123 or 124)[f]	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Cinnamon leaf oil	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations containing more than 25 per cent of cinnamon leaf oil; and b. packed in containers having: i. a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or ii. a nominal capacity of 25 mL or less, fitted with a restricted flow insert and child-resistant closure.	1[a], 120[a]	23 Jun 2004
Clobetasone	When included in SUSDP Schedule 3.	(80, 112, 117, 52, 5)[j]	23 Jun 2004
Clotrimazole	In vaginal preparations when included in SUSDP Schedule 3.	(66, 16, 75, 74)[j]	23 Jun 2004
Clove oil *(Entry 1 of 2)*	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations containing more than 25 per cent of clove oil; and b. packed in containers having: i. a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or ii. a nominal capacity of 25 mL or less, fitted with a restricted flow insert and child-resistant closure.	1[a], 120[a]	23 Jun 2004
Clove oil *(Entry 2 of 2)*	When included in a Schedule to the SUSDP.	79[h], 122[g], (123 or 124)[f]	23 Jun 2004
Colostrum powder – bovine	When included in Schedule 4 Part 5 Division 3 Item 3 of the Regulations.	138, 139	23 Jun 2004
Creatine	When included in Schedule 4 Part 5 Division 3 Item 6 of the Regulations.	67	23 Jun 2004
Creatine monohydrate	When included in Schedule 4 Part 5 Division 3 Item 7 of the Regulations.	67	23 Jun 2004
Creatine phosphate	When included in Schedule 4 Part 5 Division 3 Item 8 of the Regulations.	67	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Diclofenac *(Entry 1 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160)[j]	23 April 2008
Diclofenac *(Entry 2 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160 176)[j]	10 Sep 2008
Diethyltoluamide (DEET)	All, including where present as an excipient.	94[j]	23 Jun 2004
Diphenoxylate	When included in SUSDP Schedule 3.	{[(46 and 49 and 47) or (48 and 50)], 6, 17}[j]	23 Jun 2004
Econazole	In vaginal preparations when included in SUSDP Schedule 3.	(66, 16, 75, 74)[j]	23 Jun 2004
Ephedrine	In nasal preparations for topical use.	76[j]	23 Jun 2004
Etretinate	When included in a Schedule to the SUSDP.	(20, 13, 21)[j]	23 Jun 2004
Eucalyptus oil	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations containing more than 25 per cent of eucalyptus oil; and b. packed in containers having: i. a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or ii. a nominal capacity of 25 mL or less, fitted with a restricted flow insert and child-resistant closure.	1[a], 120[a]	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Eugenol *(Entry 1 of 2)*	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations containing more than 25 per cent of eugenol; and b. packed in containers having: i. a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or ii. a nominal capacity of 25 mL or less, fitted with a restricted flow insert and child-resistant closure.	1[a], 120[a]	23 Jun 2004
Eugenol *(Entry 2 of 2)*	When included in a Schedule to the SUSDP.	79[a], 122[g], (123 or 124)[f]	23 Jun 2004
Famotidine	When included in SUSDP Schedule 2.	(60, 72)[j]	23 Jun 2004
Fenoterol	In metered aerosols.	45[j]	23 Jun 2004
Fluconazole	When included in a Schedule to the SUSDP.	75[j]	23 Jun 2004
Fluorides	For the purpose of exclusion from the Schedules to the SUSDP when: a. in dental hygiene products (other than pastes, powders or gels for the cleaning of teeth); b. the preparation contains 220 mg/kg or 220 mg/L or less of fluoride ion; and c. in packs containing not more than 120 mg total fluoride fitted with a child-resistant closure.	(122, 150)[j]	1 Jun 2005
Flurbiprofen	When included in a Schedule to the SUSDP.	(126, 127, 18, 149, 130, 133, 159, 160)[j]	23 April 2008
Glucosamine hydrochloride	When included in a Listed medicine and derived from a marine source	164	23 April 2008
Glucosamine sulphate	When included in a Listed medicine and derived from a marine source	164	23 April 2008

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Glucosamine sulfate potassium chloride complex *(Entry 1 of 2)*	When included in a Listed medicine and derived from a marine source	164	23 April 2008
Glucosamine sulfate potassium chloride complex *(Entry 2 of 2)*	When included in a Listed medicine for oral use	165, 166, 1	23 April 2008
Glucosamine sulfate sodium chloride complex	When included in a Listed medicine and derived from a marine source	164	23 April 2008
Hexachlorophane	In preparations for skin cleansing purposes containing 3 per cent or less of hexachlorophane.	(97, 98)[j]	23 Jun 2004
High selenium yeast	When included in Schedule 4 Part 5 Division 3 Item 11 of the Regulations.	27, 28	23 April 2008
Honey	When included in Schedule 4 Part 5 Division 3 Item 9 of the Regulations.	7	23 Jun 2004
Hydrocortisone *(Entry 1 of 2)*	For dermal use when included in SUSDP Schedule 2 or 3.	(2, 80, 112, 117, 52)[j]	23 Jun 2004
Hydrocortisone *(Entry 2 of 2)*	For topical rectal use when included in SUSDP Schedule 3.	(2, 52)[j]	23 Jun 2004
Hydrofluoric acid (including mixtures that generate hydrofluoric acid) *(Entry 1 of 2)*	When included in SUSDP Schedule 5.	95[j], (79, 87)[h], 122[g], (123 or 124)[f]	23 Jun 2004
Hydrofluoric acid (including mixtures that generate hydrofluoric acid) *(Entry 2 of 2)*	When included in SUSDP Schedule 6 or Schedule 7.	(99, 100, 101)[j], (79, 87, 89, 110, 102)[h], (123 or 124)[f]	23 Jun 2004
Hydrogen peroxide *(Entry 1 of 3)*	When included in concentrations of more than 3 per cent up to 10 per cent.	96[j], 79[h], 122[g], (123 or 124)[f]	23 Jun 2004
Hydrogen peroxide *(Entry 2 of 3)*	When included in concentrations of more than 10 per cent up to 20 per cent.	96[j], 82[h], (123 or 124)[f]	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Hydrogen peroxide *(Entry 3 of 3)*	When included in concentrations of more than 20 per cent.	95[j], (82, 87)[h], (123 or 124)[f]	23 Jun 2004
8-Hydroxyquinoline (including salts and derivatives)	When prepared for internal use.	51[j]	23 Jun 2004
Hydroquinone	When included in SUSDP Schedule 2.	(113, 9, 83, 114, 115)[j]	23 Jun 2004
Hypericum perforatum	When included in Schedule 4 Part 4 Division 2 Item 20 of the Regulations.	44, 68	23 Jun 2004
Ibuprofen *(Entry 1 of 4)*	For the purpose of exclusion from the Schedules to the SUSDP, when the preparation is for oral use and is indicated exclusively for the treatment of dysmenorrhoea.	126, 127, 151, 130, 131, 132, 159, 160	23 April 2008
Ibuprofen *(Entry 2 of 4)*	For the purpose of exclusion from the Schedules to the SUSDP, when the preparation is for oral use and is NOT indicated exclusively for the treatment of dysmenorrhoea.	126, 127,-151, 130, 131, 132, 159, 160, 176	10 Sep 2008
Ibuprofen *(Entry 3 of 4)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160)[j]	23 April 2008
Ibuprofen *(Entry 4 of 4)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160, 176)[j]	10 Sep 2008
Iodine	When: a. included in a Schedule to the SUSDP; and b. in preparations for human internal therapeutic use containing 300 micrograms or more of iodine per recommended daily dose.	(26, 25)[j]	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Ipratropium bromide	In metered aerosols.	45[j]	23 Jun 2004
Isoprenaline	In metered aerosols.	45[j]	23 Jun 2004
Isotretinoin *(Entry 1 of 2)*	For human oral use.	(20, 13, 21)[j]	23 Jun 2004
Isotretinoin *(Entry 2 of 2)*	For topical use.	(22, 13)[j]	23 Jun 2004
Ketoprofen *(Entry 1 of 2)*	When: a. (a) included in a Schedule to the SUSDP; and b. (b) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160)[j]	23 April 2008
Ketoprofen *(Entry 2 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160, 176)[j]	10 Sep 2008
Kunzea ambigua	When included in Schedule 4 Part 4 Division 2 Item 21 of the Regulations.	119, 1, 116	23 Jun 2004
Lactoferrin – bovine	When included in Schedule 4 Part 5 Division 3 Item 4 of the Regulations.	38	23 Jun 2004
Larrea tridentata	When included in a Listed medicine	161, 152	23 April 2008
Leflunomide	When included in a Schedule to the SUSDP.	(20, 13, 23, 24)[j]	23 Jun 2004
Lemon oil	a. For the purpose of exclusion from the Schedules to the SUSDP; or b. when included in a Schedule to the SUSDP.	93[j]	23 Jun 2004
Levocabastine *(Entry 1 of 2)*	In eye or nasal preparations containing 0.5 mg/mL or less of levocabastine.	13[j]	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Levocabastine *(Entry 2 of 2)*	In preparations OTHER THAN eye or nasal preparations containing 0.5 mg/mL or less of levocabastine.	{13, [(46 and 49 and 47) or (48 and 50)]}[j]	23 Jun 2004
Lime oil	a. For the purpose of exclusion from the Schedules to the SUSDP; or b. when included in a Schedule to the SUSDP.	93[j]	23 Jun 2004
Loperamide	When included in SUSDP Schedule 2.	(6, 17)[j]	23 Jun 2004
Marjoram oil	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations containing more than 50 per cent of marjoram oil; and b. packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert.	1[a]	23 Jun 2004
Mefenamic acid *(Entry 1 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160)[j]	23 April 2008
Mefenamic acid *(Entry 2 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160, 176)[j]	10 Sep 2008

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Melaleuca oil	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations containing more than 25 per cent of melaleuca oil; and b. when packed in containers having: i. a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or ii. a nominal capacity of 25 mL or less, fitted with a restricted flow insert and child-resistant closure.	1[a], 120[a]	23 Jun 2004
Methoxamine	In nasal preparations for topical use.	76[j]	23 Jun 2004
Miconazole	In vaginal preparations when included in Schedule 3.	(66, 16, 75, 74)[j]	23 Jun 2004
Misoprostol	When included in a Schedule to the SUSDP.	19[j]	23 Jun 2004
Naphazoline	In nasal preparations for topical use.	76[j]	23 Jun 2004
Naproxen *(Entry 1 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160)[j]	23 April 2008
Naproxen *(Entry 2 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160, 176)[j]	10 Sep 2008
Nizatidine	When included in SUSDP Schedule 2.	(60, 72)[j]	23 Jun 2004
Noradrenaline	In metered aerosols.	45[j]	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Nutmeg oil	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations containing more than 50 per cent of nutmeg oil; and b. packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert.	1[a]	23 Jun 2004
Nystatin	In vaginal preparations when included in SUSDP Schedule 3.	(66, 16, 75, 78, 74)[j]	23 Jun 2004
Orange oil (bitter)	a. For the purpose of exclusion from the Schedules to the SUSDP; or b. when included in a Schedule to the SUSDP.	93[j]	23 Jun 2004
Orciprenaline	In metered aerosols.	45[j]	23 Jun 2004
Oxymetazoline	In nasal preparations for topical use.	76[j]	23 Jun 2004
Paracetamol *(Entry 1 of 2)*	For the purpose of exclusion from the Schedules to the SUSDP.	(143 and 144), (145 and 146), 147, 148	23 Jun 2004
Paracetamol *(Entry 2 of 2)*	When included in a Schedule to the SUSDP.	{[(143 and 144) and/or (145 and 146)], 147, 148}[j]	23 Jun 2004
Paullinia cupana	When included in Schedule 4 Part 4 Division 2 Item 32 of the Regulations.	36, 37	23 Jun 2004
Pennyroyal oil	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations containing more than 4 per cent of d-pulegone; and b. when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and child-resistant closure.	1[a], 120[a]	23 Jun 2004
Permanganates	When included in a Schedule to the SUSDP.	95[j], 103[h], (123 or 124)[f]	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Phenol and any other homologue of phenol.	When included in a Schedule to the SUSDP.	(79, 87)[h], 122[g], (123 or 124)[f]	23 Jun 2004
Phenylalanine	When included in a Listed medicine for oral or sublingual administration, the maximum recommended daily dose of which contains more than 500 mg of phenylalanine	14	23 April 2008
Phenylephrine	In nasal preparations for topical use.	76[j]	23 Jun 2004
Phenylpropanolamine	When included in a Schedule to the SUSDP.	39[j]	23 Jun 2004
Piper methysticum *(Entry 1 of 2)*	When included in Schedule 4 Part 4 Division 2 Item 35 of the Regulations	55, 77, 15, 125	5 Apr 2006
Piper methysticum *(Entry 2 of 2)*	For the purpose of exclusion from the Schedules to the SUSDP.	55, 15, 125	5 Apr 2006
Podophyllin *(Entry 1 of 3)*	When: a. included in a Schedule to the SUSDP; and b. in preparations specifically for use on anal or genital area.	63[j]	23 Jun 2004
Podophyllin *(Entry 2 of 3)*	When: a. included in SUSDP Schedule 2 or Schedule 3; and b. in liquid preparations other than in preparations specifically for use on anal or genital area.	105[j]	23 Jun 2004
Podophyllin *(Entry 3 of 3)*	When: a. included in SUSDP Schedule 2; and b. in solid or semi-solid preparations other than in preparations specifically for use on anal or genital area.	104[j]	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Podophyllotoxin *(Entry 1 of 3)*	When: a. included in a Schedule to the SUSDP; and b. in preparations specifically for use on anal or genital area.	63[j]	23 Jun 2004
Podophyllotoxin *(Entry 2 of 3)*	When: a. included in SUSDP Schedule 2 or Schedule 3; and b. in liquid preparations other than in preparations specifically for use on anal or genital area.	105[j]	23 Jun 2004
Podophyllotoxin *(Entry 3 of 3)*	When: a. included in SUSDP Schedule 2; and b. in solid or semi-solid preparations other than in preparations specifically for use on anal or genital area.	104[j]	23 Jun 2004
Polygonum multiflorum	When included in a listed medicine	175, 154	23 April 2008
Potassium hydroxide *(Entry 1 of 3)*	When: a. included in a Schedule to the SUSDP; and b. in preparations containing 0.5 per cent or less of potassium hydroxide.	96[j], (79, 87, 88)[h], 122[g], (123 or 124)[f]	23 Jun 2004
Potassium hydroxide *(Entry 2 of 3)*	When: a. included in a Schedule to the SUSDP; and b. in solid preparations containing more than 0.5 per cent of potassium hydroxide.	(95, 108, 86)[j], (81, 89, 109)[h], (123 or 124)[f]	23 Jun 2004
Potassium hydroxide *(Entry 3 of 3)*	When: a. included in a Schedule to the SUSDP; and b. in liquid preparations containing more than 0.5 per cent of potassium hydroxide.	(95, 108, 86)[j], (81, 89)[h], (123 or 124)[f]	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Propolis *(Entry 1 of 2)*	When included in a Listed medicine for internal use	168	23 April 2008
Propolis *(Entry 2 of 2)*	When included in a Listed medicine for external use	169	23 April 2008
Pyridoxal *(see also Vitamins)*	For the purpose of exclusion from the Schedules to the SUSDP when in preparations for human use containing more than 50 mg of pyridoxal per recommended daily dose.	53 or 56	5 Apr 2006
Pyridoxamine *(see also Vitamins)*	For the purpose of exclusion from the Schedules to the SUSDP when in preparations for human use containing more than 50 mg of pyridoxamine per recommended daily dose.	53 or 57	5 Apr 2006
Pyridoxine *(see also Vitamins)*	For the purpose of exclusion from the Schedules to the SUSDP when for human use in preparations for human use containing more than 50 mg of pyridoxine per recommended daily dose.	53 or 58	5 Apr 2006
Pyrithione zinc	For the purpose of exclusion from the Schedules to the SUSDP when in shampoos for human therapeutic use containing 2 per cent or less of pyrithione zinc.	84 or 85	23 Jun 2004
Ranitidine	When included in SUSDP Schedule 2.	(60, 72)[j]	23 Jun 2004
Royal jelly	When included in a Listed medicine	170[k,l],171	23 April 2008
Safrole	When included in a Schedule to the SUSDP in preparations for therapeutic use.	79[h], (123 or 124)[f]	23 Jun 2004
Sage oil	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations containing more than 4 per cent of thujone; and b. packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert and child-resistant closure.	1[a], 120[a]	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Salbutamol	In metered aerosols or in dry powder formulations.	45[j]	23 Jun 2004
Salicylamide	When included in a Schedule to the SUSDP.	{54 or [(60 and 61) or (60 and 62)]}[j]	23 Jun 2004
Sassafras oil	When included in a Schedule to the SUSDP in preparations for therapeutic use.	79[h], (123 or 124)[f]	23 Jun 2004
Selenium yeast – high	When included in Schedule 4 Part 5 Division 3 Item 11 of the Regulations.	27, 28	23 April 2008
Selenocysteine	When included in Schedule 4 Part 5 Division 3 Item 12 of the Regulations.	27, 28	23 April 2008
Selenomethionine	When included in Schedule 4 Part 5 Division 3 Item 13 of the Regulations.	27, 28	23 April 2008
Shark cartilage	When included in a Listed medicine	167	23 April 2008
Silver *(see also Silver salts)*	For the purpose of exclusion from the Schedules to the SUSDP when for therapeutic use: a. in chewing gum containing 5 mg or less of silver per dosage unit; or b. in solutions for human oral use containing 0.3 per cent or less of silver.	106	23 Jun 2004
Silver salts *(see also Silver)*	In smoking deterrents.	107[j]	23 Jun 2004
Sodium fluoride	In preparations for human ingestion when in Schedule 2.	40[j]	23 Jun 2004
Sodium hydroxide *(Entry 1 of 3)*	When: a. included in a Schedule to the SUSDP; and b. in preparations containing 0.5 per cent or less of sodium hydroxide.	96[j], (79, 87, 88)[h], 122[g], (123 or 124)[f]	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Sodium hydroxide *(Entry 2 of 3)*	When: a. included in a Schedule to the SUSDP; and b. in solid preparations containing more than 0.5 per cent of sodium hydroxide.	(95, 108, 86)[j], (81, 89, 109)[h], (123 or 124)[f]	23 Jun 2004
Sodium hydroxide *(Entry 3 of 3)*	When: a. included in a Schedule to the SUSDP; and b. in liquid preparations containing more than 0.5 per cent of sodium hydroxide.	(95, 108, 86)[j], (81, 89,)[h], (123 or 124)[f]	23 Jun 2004
Sodium selenate	When included in Schedule 4 Part 5 Division 3 Item 14 of the Regulations.	27, 28	23 April 2008
Sodium selenite	When included in Schedule 4 Part 5 Division 3 Item 15 of the Regulations.	27, 28	23 April 2008
Sodium sulfate	When included in Schedule 4 Part 5 Division 3 Item 16 of the Regulations.	134	23 Jun 2004
(S)-S-Adenosylmethionine in the form of sulphate salts, tosylate salts or mixed sulphate and tosylate salts	When included in Schedule 4 Part 5 Division 3 Item 10 of the Regulations.	43	23 Jun 2004
Star anise oil	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations containing more than 50 per cent of star anise oil; and b. packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert.	1[a]	1 Jun 2005
Sugar cane wax alcohols	When included in Schedule 4 Part 5 Division 3 Item 17 of the Regulations.	15	23 Jun 2004
Symphytum spp.	When included in SUSDP Schedule 5.	(111, 118)[h], 122[g], (123 or 124)[f]	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Tazarotene	For topical use.	(22, 13)[j]	23 Jun 2004
Terbutaline	In metered aerosols.	45[j]	23 Jun 2004
Terfenadine	When included in a Schedule to the SUSDP.	(42, 64)[j]	23 Jun 2004
Tetrahydrozoline	In nasal preparations for topical use.	76[j]	23 Jun 2004
Thalidomide	When included in a Schedule to the SUSDP.	(20, 13, 21)[j]	23 Jun 2004
Thyme oil	For the purpose of exclusion from the Schedules to the SUSDP when: a. in preparations containing more than 50 per cent of thyme oil; and b. packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert.	1[a]	23 Jun 2004
Tramazoline	In nasal preparations for topical use.	76[j]	23 Jun 2004
Tranexamic acid	When included in SUSDP Schedule 3.	66[j]	23 Jun 2004
Tretinoin *(Entry 1 of 2)*	For human oral use.	(20, 13, 21)[j]	23 Jun 2004
Tretinoin *(Entry 2 of 2)*	For topical use.	(22, 13)[j]	23 Jun 2004
Triamcinolone	When in topical preparations for the treatment of mouth ulcers.	(75 or 73)[j]	23 Jun 2004
Triethanolamine	When included in a Schedule to the SUSDP.	96[j], (79, 87)[h], 122[g], (123 or 124)[f]	23 Jun 2004
Tymazoline	In nasal preparations for topical use.	76	23 Jun 2004
Ubidecarenone	When included in Schedule 4 Part 5 Division 3 Item 18 of the Regulations.	41	23 Jun 2004

Column 1 Medicines Containing ...	Column 2 Which Meet The Following Conditions ...	Column 3 Require Statement(s)	Column 4 Gazettal Date
Vitamin A (see also Vitamins)	In medicines for internal use containing 3 000 µg retinol equivalents or less of vitamin A other than those containing: a. 33 µg retinol equivalents or less of vitamin A per dosage unit of a divided preparation; or b. 33 µg retinol equivalents or less of vitamin A per gram of an undivided preparation.	31[d,e], 32[d,e,c] 33[d,e,c]	23 April 2008
Vitamins *(see also:* *Pyridoxal* *Pyridoxamine* *Pyridoxine* *Vitamin A)*	When included in Schedule 2 Part 2 Item 1 of the Regulations.	34 or 35	1 Jun 2005
Xylometazoline	In nasal preparations for topical use.	76[j]	23 Jun 2004
Yeast – high selenium	When included in Schedule 4 Part 5 Division 3 Item 11 of the Regulations.	27, 28	23 April 2008
Zinc chloride	When included in a Schedule to the SUSDP.	(79, 87)[h], (123 or 124)[f]	23 Jun 2004
Zinc compounds	For the purpose of exclusion from the Schedules to the SUSDP when for human internal use in preparations with a recommended daily dose of more than 25 mg but not more than 50 mg of zinc.	53 or 59	23 Jun 2004
Zinc sulfate	When included in SUSDP Schedule 6.	(79, 87)[h], (123 or 124)[f]	23 Jun 2004
Zingiber officinale	When included in a Listed medicine; AND when the extraction ratio is 25:1 or higher; AND when the equivalent dry weight per dosage unit is 2g or higher	162, 163	23 April 2008

Section 2: Advisory statements

The following table gives details of the text to be included on the labels of medicines specified in Section 1.

Advisory statements

No	Statement Text	Gazettal Date
1	Keep out of reach of children.	23 Jun 2004
2	CAUTION - Do not use for children under 2 years old unless a doctor has told you to.	23 Jun 2004
3	CAUTION - do not give to children under two years of age except on doctor's advice.	23 Jun 2004
4	Not recommended for use by children aged 12 years or under.	23 Jun 2004
5	CAUTION - Do not use for children under 12 years old unless a doctor has told you to.	23 Jun 2004
6	Do not give to children under 12 years of age.	23 Jun 2004
7	Not suitable for infants under 12 months.	23 Jun 2004
8	Not suitable for use by children under 15.	23 Jun 2004
9	Do not use on children.	23 Jun 2004
10	Unless a doctor has told you to, do not use [this product/*insert name of product*] in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever.	23 Jun 2004
11	Can be fatal to children if sucked or swallowed.	23 Jun 2004
12	WARNING - May be fatal to children.	23 Jun 2004
13	Do not use if pregnant.	23 Jun 2004
14	Do not use if pregnant or likely to become pregnant.	23 Jun 2004
15	Not recommended for use by pregnant or lactating women.	23 Jun 2004

No	Statement Text	Gazettal Date
16	See a doctor if you are pregnant or diabetic.	23 Jun 2004
17	Do not use beyond 48 hours or in pregnancy or lactation except on doctor's advice.	23 Jun 2004
18	Do not use during the last three months of pregnancy.	23 Jun 2004
19	CAUTION - (Name of substance) should not be used by pregnant women.	23 Jun 2004
20	WARNING - Causes Birth Defects.	23 Jun 2004
21	Do not become pregnant during use or within (Insert number of months as per approved product information) month(s) of stopping treatment.	23 Jun 2004
22	WARNING - May Cause Birth Defects.	23 Jun 2004
23	(Insert brand name) remains in the body for many months after treatment has stopped.	23 Jun 2004
24	Do not become pregnant or father a child before consulting your doctor.	23 Jun 2004
25	WARNING - Contains iodine - do not take when pregnant except on physician's advice.	23 Jun 2004
26	CAUTION - Total iodine intake may exceed recommended level when taking this preparation.	23 Jun 2004
27	This product contains selenium which is toxic in high doses.	23 April 2008
28	A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.	23 April 2008
29	Recommended daily dose is [*insert dose 100 mg or less*] of tryptophan.	23 Jun 2004
30	Removed and placed in 'Archived' - as is not used.	23 April 2008
31	The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.	23 April 2008

No	Statement Text	Gazettal Date
32	WARNING – When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.	23 April 2008
33	If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.	23 Jun 2004
34	Vitamins can only be of assistance if the dietary vitamin intake is inadequate.	23 Jun 2004
35	Vitamin supplements should not replace a balanced diet	23 Jun 2004
36	The goods contain caffeine.	23 Jun 2004
37	Each [insert name of dosage unit] contains [insert quantity] of caffeine.	23 Jun 2004
38	Derived from cows milk.	23 Jun 2004
39	WARNING - Can cause elevated blood pressure and interact adversely with other medication.	23 Jun 2004
40	Use of this product is not necessary in areas supplied with fluoridated water.	23 Jun 2004
41	Not to be taken, if on warfarin therapy, without medical advice.	23 Jun 2004
42	WARNING - Can react with other medicines.	23 Jun 2004
43	Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner.	23 Jun 2004
44	St John's Wort affects the way many prescription medicines work, including oral contraceptives.	5 Apr 2006
45	This preparation should be part of an overall treatment plan regularly assessed with your doctor.	23 Jun 2004
46	This medication may cause drowsiness.	23 Jun 2004
47	Avoid alcohol.	23 Jun 2004
48	This medication may cause drowsiness and may increase the effects of alcohol.	23 Jun 2004

No	Statement Text	Gazettal Date
49	If affected do not drive a vehicle or operate machinery.	23 Jun 2004
50	If affected do not drive a motor vehicle or operate machinery.	23 Jun 2004
51	Do not take for periods longer than four weeks except on medical advice.	23 Jun 2004
52	Do not use for more than 7 days unless a doctor has told you to.	23 Jun 2004
53	WARNING - This medication may be dangerous when used in large amounts or for a long period.	23 Jun 2004
54	WARNING - This medication may be dangerous when used in large amounts or for a long time (period).	23 Jun 2004
55	WARNING: Not for prolonged use.	5 Apr 2006
56	WARNING – this product contains pyridoxal which may be dangerous when used in large amounts or for a long time.	23 Jun 2004
57	WARNING – this product contains pyridoxamine which may be dangerous when used in large amounts or for a long time.	23 Jun 2004
58	WARNING – this product contains pyridoxine which may be dangerous when used in large amounts or for a long time.	23 Jun 2004
59	WARNING – Contains zinc, which may be dangerous when used in large amounts or for a long period.	23 Jun 2004
60	CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.	23 Jun 2004
61	Prolonged use without medical supervision could be harmful.	23 Jun 2004
62	Prolonged or excessive use without medical supervision could be harmful.	23 Jun 2004
63	For use under medical supervision only.	23 Jun 2004
64	Ask your doctor or pharmacist before taking.	23 Jun 2004
65	Use only under medical supervision if you are taking other medicines.	23 Jun 2004
66	Seek medical advice before first course of treatment.	23 Jun 2004

No	Statement Text	Gazettal Date
67	Seek professional advice before long term use.	23 Jun 2004
68	Consult your doctor.	23 Jun 2004
69	If these persist, consult a physician.	23 Jun 2004
70	Avoid excessive exposure to sunlight and other sources of ultra violet light.	23 Jun 2004
71	If symptoms recur within two weeks of completing the course, consult a doctor.	23 Jun 2004
72	If symptoms persist or recur within two weeks of completing the course, consult a doctor.	23 Jun 2004
73	If symptoms persist beyond 5 days consult a doctor (or) (dentist).	23 Jun 2004
74	See a doctor if problem returns.	23 Jun 2004
75	See a doctor (or) (dentist) if no better after (Insert number of days as per approved Product Information) days.	23 Jun 2004
76	If congestion persists, consult your doctor or pharmacist.	23 Jun 2004
77	If symptoms persist, seek advice from a health care practitioner.	23 Jun 2004
78	If getting better, keep using for (Insert number of days as per approved Product Information) days.	23 Jun 2004
79	Avoid contact with eyes.	23 Jun 2004
80	Do not use in the eyes.	23 Jun 2004
81	Wear eye protection when mixing or using.	23 Jun 2004
82	Attacks eyes - protect eyes when using.	23 Jun 2004
83	Do not use near the eyes.	23 Jun 2004
84	Keep out of eyes.	23 Jun 2004
85	If in eyes, rinse well with water.	23 Jun 2004

No	Statement Text	Gazettal Date
86	Attacks skin and eyes.	23 Jun 2004
87	Avoid contact with skin.	23 Jun 2004
88	Wash hands after use.	23 Jun 2004
89	Wear protective gloves when mixing or using.	23 Jun 2004
90	If skin irritation occurs, discontinue use.	23 Jun 2004
91	Keep from eyes, lips, mouth and sensitive areas of the neck.	23 Jun 2004
92	If excessive swelling, irritation, redness or peeling occurs, discontinue use.	23 Jun 2004
93	Application to skin may increase sensitivity to sunlight.	23 Jun 2004
94	WARNING - May be dangerous, particularly to children, if you use large amounts on the skin, clothes or bedding or on large areas of the body, especially if you keep using it for a long time.	23 Jun 2004
95	Corrosive.	23 Jun 2004
96	Irritant.	23 Jun 2004
97	For external washing only.	23 Jun 2004
98	Rinse skin thoroughly after use.	23 Jun 2004
99	Highly corrosive.	23 Jun 2004
100	Contact with eyes even for short periods can cause blindness.	23 Jun 2004
101	Causes severe burns, which are not likely to be immediately painful or visible.	23 Jun 2004
102	Obtain a supply of calcium gluconate gel.	23 Jun 2004
103	Avoid contact of the crystals or strong solutions with the eyes, mouth, nose and other mucous membranes.	23 Jun 2004
104	WARNING - Do not use on face or on anal or genital areas.	23 Jun 2004

No	Statement Text	Gazettal Date
105	WARNING - Do not use on face or on anal or genital areas except on doctor's advice.	23 Jun 2004
106	Overuse may stain skin or mouth.	23 Jun 2004
107	WARNING - Overuse may stain the skin or mouth.	23 Jun 2004
108	May produce severe burns.	23 Jun 2004
109	Do not mix with hot water.	23 Jun 2004
110	Avoid breathing dust (or) vapour (or) spray mist.	23 Jun 2004
111	Do not use on broken skin.	23 Jun 2004
112	Do not use for acne.	23 Jun 2004
113	WARNING - If a pigmented spot or mole has recently become darker, changed colour, become enlarged, itchy, or bleeds, do not use this product, see your doctor immediately.	23 Jun 2004
114	Mild irritation may occur; stop use if it becomes severe.	23 Jun 2004
115	If fading is not evident in three months, seek doctor's advice.	23 Jun 2004
116	Not to be applied undiluted to the skin except on the advice of a health care practitioner.	23 Jun 2004
117	Do not use under waterproof bandages unless a doctor has told you to.	23 Jun 2004
118	Do not use under occlusive dressing.	23 Jun 2004
119	For external use only.	23 Jun 2004
120	Not to be taken.	23 Jun 2004
121	Recommended daily dose is [*insert dose 1 g or less*] of acetylcysteine.	23 Jun 2004
122	Do not swallow.	23 Jun 2004
123	Read safety directions.	23 Jun 2004
124	Read safety directions before opening and using.	23 Jun 2004

No	Statement Text	Gazettal Date
125	May harm the liver.	23 Jun 2004
126	Do not use [this product/*insert name of product*] if you have a stomach ulcer.	23 Jun 2004
127	Do not use [this product/*insert name of product*] if you are allergic to [*insert name substance*] or other anti-inflammatory medicines.	23 Jun 2004
128	Unless a doctor has told you to, do not use [this product/*insert name of product*] for more than a few days at a time.	23 Jun 2004
129	Unless a doctor has told you to, do not use [this product/*insert name of product*] with other medicines containing aspirin or other anti-inflammatory medicines or other medicines that you are taking regularly.	23 Jun 2004
130	Unless a doctor has told you to, do not use [this product/*insert name of product*] if you have asthma.	23 Jun 2004
131	Unless a doctor has told you to, do not use [this product/*insert name of product*] in children 6 years of age or less.	23 Jun 2004
132	Unless a doctor has told you to, do not use [this product/*insert name of product*] if you are aged 65 years or over.	23 Jun 2004
133	Unless a doctor has told you to, do not use [this product/*insert name of product*] if you are pregnant.	23 Jun 2004
134	This preparation may have a laxative effect.	23 Jun 2004
135	Products containing activated charcoal should be used with caution in children since it may interfere with absorption of nutrients.	23 Jun 2004
136	This substance may interact with other medicines.	23 Jun 2004
137	Activated charcoal is not recommended for long-term use.	23 Jun 2004
138	Products containing bovine colostrum powder contain lactose and cow's milk proteins.	23 Jun 2004

No	Statement Text	Gazettal Date
139	This product is not suitable for use in children under the age of 12 months except on professional health advice.	23 Jun 2004
140	Unless a doctor has told you to, do not use [this product/*insert name of product*] with other medicines containing aspirin or other anti-inflammatory medicines	23 Jun 2004
141	Unless a doctor has told you to, do not use [this product/*insert name of product*] in children under 12 years of age	23 Jun 2004
142	See a doctor before taking [this product/*insert name of product*] for thinning the blood or for your heart.	23 Jun 2004
143	*Adults*: Keep to the recommended dose.	23 Jun 2004
144	Do not take this medicine for longer than a few days at a time unless advised to by a doctor.	23 Jun 2004
145	*Children and adolescents*: Keep to the recommended dose.	23 Jun 2004
146	Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor.	23 Jun 2004
147	If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage.	23 Jun 2004
148	Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.	23 Jun 2004
149	Unless a doctor has told you to, do not use [this product/*insert name of product*] with other medicines containing [*insert name of substance*] or other anti-inflammatory medicines.	23 Jun 2004
150	Do not use [this product / *insert name of product*] in children 6 years of age or less	1 Jun 2005
151	Unless a doctor has told you to, do not use [this product/*insert name of product*] with other medicines containing ibuprofen, aspirin or other anti-inflammatory medicines or other medicines that you are taking regularly.	1 Jun 2005
152	Use only under the supervision of a healthcare professional.	5 Apr 2006

No	Statement Text	Gazettal Date
153	Warning: In very rare cases, Black cohosh has been associated with liver failure	23 April 2008
154	Use under the supervision of a healthcare professional.	5 Apr 2006
155	This medicine contains arginine and is intended to be applied to the skin only and not to the mucosa, vagina or rectum.	5 Apr 2006
156	This product contains material derived from nuts.	5 Apr 2006
157	Warning: Greater Celandine may harm the liver in some people.	5 Apr 2006
158	Use only under the supervision of a healthcare professional.	5 Apr 2006
159	If you get an allergic reaction stop taking and see your doctor immediately.	23 April 2008
160	Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful	23 April 2008
161	Warning: Chaparral may harm the liver in some people.	23 April 2008
162	Individuals taking anticoagulants should seek medical advice before taking this product.	23 April 2008
163	Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this product	23 April 2008
164	Derived from seafood.	23 April 2008
165	Contains [amount of potassium] potassium.	23 April 2008
166	If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use.	23 April 2008
167	Children, pregnant or breastfeeding women, and those who have recently had a heart attack, surgery or a major accident should not consume this product without medical advice	23 April 2008

No	Statement Text	Gazettal Date
168	WARNING: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs - discontinue use.	23 April 2008
169	WARNING: Propolis may cause skin irritation. Test before use.	23 April 2008
170	Not to be taken by asthma and allergy sufferers	23 April 2008
171	This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities - especially in asthma and allergy suffers	23 April 2008
172	If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor	23 April 2008
173	The recommended dose of this medicine provides small amounts of caffeine	23 April 2008
174	Contains [amount of caffeine in milligrams] mg of caffeine	23 April 2008
175	Warning: *Polygonum multiflorum* may harm the liver in some people	23 April 2008
176	Do not use [this product/insert the name of the product] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.	10 Sep 2008

Section 3: Additional requirements

The following table gives details of additional requirements prescribed for certain advisory statements, as specified in Section 1.

Additional requirements

	Additional requirement	Gazettal Date
a	Statement(s) must be included on the label in capital letters.	23 Jun 2004
b	[Item left intentionally blank.]	23 Jun 2004
c	Statement(s) must be included in the directions for use on the label.	23 Jun 2004
d	Statement(s) must be included on the label where the preparation is labelled for adult use.	23 Jun 2004
e	Statement(s) must be included on the label in bold face letters.	23 Jun 2004
f	Statement(s) must be included on the label written: i. on a separate line or lines immediately below the cautionary statement "KEEP OUT OF REACH OF CHILDREN"; and ii. in bold-face sanserif capital letters of uniform thickness; and iii. in letters as least four tenths the height of the letters used for the signal heading; and iv. with nothing written on the same line.	23 Jun 2004
g	Statement(s) written in sanserif capital letters, must be included on the main label or as part of the directions for use.	23 Jun 2004
h	The heading "SAFETY DIRECTIONS", written in bold-face capital letters, must preface this/these statements, which are to be grouped together as a distinct section of the label.	23 Jun 2004

	Additional requirement	Gazettal Date
j	Statement(s) must: i. be grouped with any other statements marked with this additional requirement; and ii. if the heading "SAFETY DIRECTIONS" is required on the label, be included immediately after that heading; or iii. if the heading "SAFETY DIRECTIONS" is not required on the label, be included immediately preceding the directions for use.	23 Jun 2004
k	Statement(s) must be printed in type of 3 mm height or larger	23 April 2008
l	Statement(s) must be printed on the front of the goods	23 April 2008

Appendices

List of appendices

Appendix 1	**Updating the RASML – Procedural Matters**
Proposal Form	Ammendment of the *Required Advisory Statements for Medicine Labels*
Appendix 2	**Archived Entries**
Appendix 2.1	Archived Entries – Section 1
Appendix 2.2	Archived Entries – Section 2
Appendix 2.3	Archived Entries – Section 3

Appendix 1: Updating the RASML - Procedural matters

Overview

The statements in the RASML and their application to particular medicines will need to be updated at regular intervals. Changes could include:

- addition of a new label statement;
- amendment to the wording of an existing label statement;
- deletion of a label statement;
- application of an existing statement to a new substance or class of substances;
- application of a new label statement to a substance or a class of substances;
- removal of the requirement for an advisory statement for a substance or class of substances.

Updating the RASML

Proposals are to be dealt with by the relevant TGA Delegate within the TGA areas of responsibility as follows:

	TGA Area of Responsibility	Advisory Committee
Prescription medicines	Drug Safety and Evaluation Branch	ADEC
OTC medicines	OTC Medicines Section	MEC
Complementary medicines	Office of Complementary Medicines	CMEC
Rescheduling issues	Office of Chemical Safety (NDPSC Secretariat)	NDPSC

TGA delegates may request the advice of the relevant advisory committee (and other advisory committees where appropriate). Where rescheduling issues affect the advisory statements required on medicine labels in certain circumstances, the NDPSC is the primary source of expert advice. It may consult with the other advisory committees as required.

Existing Substances

Rescheduling of a Substance

The TGA uses the existing NDPSC consultation processes where advisory statements are required for the purpose of rescheduling a substance. Interested parties have the opportunity to comment on proposed statements and their application to particular substances through the NDPSC's Pre-Meeting/Gazettal process. Therefore, the consultation phase referred to below is not required in these cases. Changes recommended by the NDPSC and decided by the relevant TGA Delegate will be gazetted and published on the TGA's web site and implemented as outlined below.

Where Rescheduling of a Substance is Not Proposed

The process for change where rescheduling of a substance is not proposed is as follows:

- Proposal to Amend
- Proposals for change to RASML will be accepted from any interested person.
  - The form "*Proposal to Amend the Required Advisory Statements for Medicine Labels*" should be completed and forwarded to the RASML Document Manager.

- A copy of the form is at the end of this Appendix and it is also available on the TGA's web site.
- Applicants should note that all information provided with this form will be made available to the public.

· Consultation:

- Proposals are published on the TGA web site and peak bodies are contacted directly and invited to comment;
- The period for comments is 4 weeks from the date of publication on the TGA web site, unless otherwise specified in the web site information;
- the TGA Regulator may seek advice from the appropriate expert committee (e.g. the Medicines Evaluation Committee for OTC medicines or the Complementary Medicines Evaluation Committee for complementary medicines);

· Decision

  The decision is made by the relevant TGA Regulator after taking into account advice from the expert committee and all comments. All decisions to change the RASML document are gazetted (including text of the change). All decisions (including a decision not to change) and reasons for them are published on the TGA web site;

· Implementation

  Each new or amended label advisory statement will be identified with a date of gazettal. The statement will be required immediately on products where the application to register / list is pending the date of gazettal or received after the date of gazettal, and within 12 months on existing products. The 12 month transition period may be shortened in some circumstances (see section 'How Required Statements are to be Included on the Labels' for further details).

A flow chart of the process (Flow Chart 2) is shown on page 58.

New Substances

An abbreviated process (excluding the consultation phase) applies where an advisory statement is required in respect of a new substance (i.e. where there are no goods containing the substance included in the ARTG). This is appropriate:

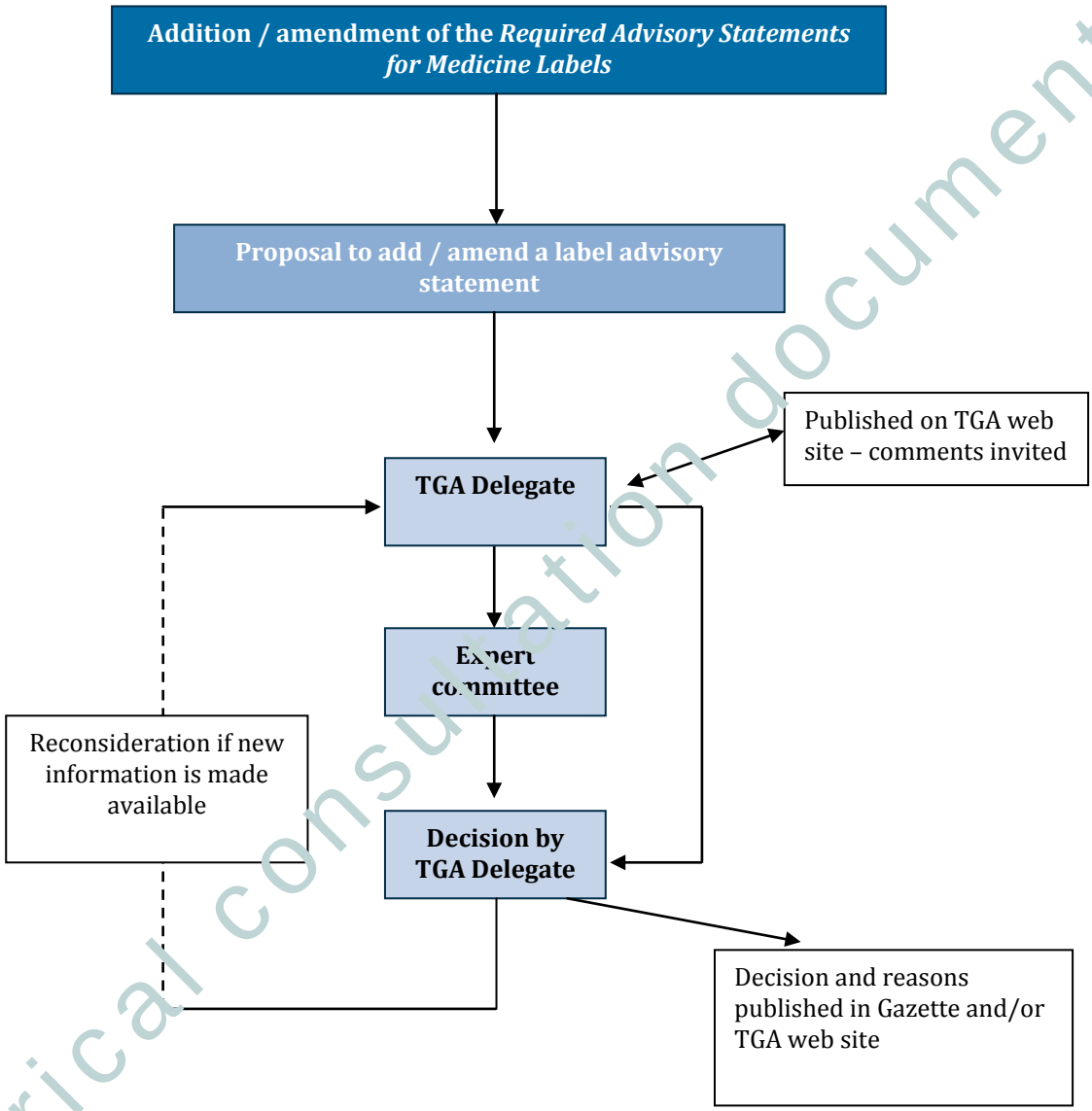
· because there are no existing products that will be affected;

· to avoid delays in the approval process for new substances;

· because the sponsor of the new substance application will be involved in the approval process and therefore aware of the requirement for the advisory statement

The need for advisory statements will be considered as part of the evaluation of the product.

Flow Chart 2



Updating the Required Advisory Statements for Medicine Labels - Questions and Answers

When does the process amend the Required Advisory Statements for Medicine Labels (RASML) apply?

Here are some circumstances in which this process applies:

- A new advisory statement is considered necessary to ensure the safe use of existing goods;
- A new advisory statement is required as a consequence of rescheduling existing goods (e.g. S4 to S3);
- An existing advisory statement is to be applied to existing goods where it has not been required in the past;
- An amendment to the wording of an existing advisory statement is proposed.

Who can initiate the process to amend the *RASML* requirements?

Any interested party (e.g. NDPSC, TGA, expert committee, sponsor, consumer) can initiate the process by making a submission to the TGA. The submission needs to specify the proposed label advisory statement, the circumstances in which it applies or is proposed to apply and the reasons for the proposal. The submission should be forwarded to the RASML Document Manager who will refer it to the appropriate TGA Area of Responsibility. It is preferred that submissions are made electronically to otc.medicines@health.gov.au.

Who provides the advice and who makes the decision to change the *RASML* requirements?

Each of the expert medicine advisory committees (ADEC, MEC and CMEC) may provide advice and make recommendations in their area of expertise. The NDPSC provides advice in relation to advisory statements required for the purpose of rescheduling substances. The decision is made by the relevant TGA Delegate. Where a proposed change affects goods from more than one category of medicines, a coordinated approach is adopted within the TGA to ensure the needs of all parties are taken into account.

What if I have existing products that are affected by a change to the *RASML* requirements?

The transition phase for application of new or amended advisory statements to existing products is 12 months from the date of gazettal, unless otherwise specified. If there is an immediate safety requirement, a shorter transition may be required. In this instance, the reasons for the decision are published on the TGA web site and sponsors of affected products are notified directly by the relevant TGA Area of Responsibility.

How long does it take to amend the *RASML* requirements?

The process takes approximately 6 months from receipt of a submission to gazettal of a decision and publication on the TGA's web site.

How will I know if an amendment to the *RASML* is being proposed?

The TGA publishes details of all proposals to change the RASML on the TGA web site and provides written consultation information to peak bodies. Comments are accepted from any source.

Who will be consulted regarding a proposal to amend the *RASML* requirements?

Peak bodies representing consumers, industry, the professions and related TGA expert committees are specifically invited to comment. All proposals are published on the TGA web site and any interested person can provide comment.

What information will be provided for consultation?

The information package includes:

- The proposed label advisory statement;
- The substance/s or class/es of substance/s to which it is proposed to apply;
- The conditions under which the statement is proposed to apply (e.g. SUSDP schedule, above/below a cut off concentration, for a particular indication);
- The reason why the advisory statement is considered necessary;
- The proposed transition period for existing products;
- Contact details for responses and/or further information;
- Cut off date for responses to be submitted; and
- Any other relevant information.

How long will the consultation period on a proposal to amend the RASML requirements be?

The time frame for consultation is 4 weeks from the date of publication on the TGA's web site, unless otherwise specified in the web site information. In exceptional circumstances where there is an overriding safety concern, consultation may be omitted or limited to peak bodies.

What if I disagree with a proposed amendment to the *RASML* requirements?

If you disagree with a proposed statement you can make a submission within the consultation timeframe stating your reasons for concern. This will be taken into consideration before any decision is made.

Will I be notified of the decision to amend the *RASML* requirements?

The decision to change the RASML (including the text of the change) is published in the Gazette. This information is also published on the TGA web site together with reasons for the decision. A decision **not** to change the RASML is published on the TGA web site together with reasons for the decision, but is not published in the Gazette. Amendments of the RASML will occur at the time of the Gazettal of the decision to amend.

What if I disagree with the decision to amend a *RASML* requirement?

If you have new information that has not been considered in the original proposal you can provide a further submission for consideration. This goes through the same process as a new submission. Because existing products are not required to change labelling for 12 months, there is sufficient time for reconsideration of the decision and confirming or amending it without affecting these products.

What if the decision to amend a requirement is not appropriate for my product?

If you can establish that a label advisory statement is not appropriate for a particular product, you can apply for an exemption under the Labelling Order. Requests for exemption should be directed to the appropriate TGA Regulator and should include a justification for the request.

Proposal Form

Amendment of the Required Advisory Statements for Medicine Labels

Applicants should note that **ALL** information submitted with this proposal **will be made available to the public.**

Applicants should:

- complete the relevant section(s) of the form as shown below. Note that more than one section may be completed if appropriate;
  - Proposed changes to section 1 (Medicines to which Advisory Statements Apply)
  - Proposed changes to section 2 (Advisory Statements)
  - Proposed changes to section 3 (Additional Requirements)
- complete the BACKGROUND, IMPLEMENTATION and APPLICANT DETAILS sections at the end of the form
- forward the amendment proposal and supporting documentation as shown below (under CONTACT DETAILS).

If insufficient space has been provided applicants may copy section/s of the form and/or attach further information as required.

Contact details

Submissions may be sent by post, fax or e-mail. Note that where the submission (including its attachments) is more than 20 A4 pages long when printed, the applicant is to send two hard copies of the submission to the postal address shown below, regardless of whether the submission has also been made by e-mail or fax.

RASML Document Manager
Non-Prescription Medicines Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Telephone: 02 6232 8652
Fax: [redacted]
E-mail: otc.medicines@health.gov.au

Proposed changes to Section 1

Proposed change type

I/We propose to amend Section 1 of the *Required Advisory Statements for Medicine Labels* by (more than one item may be selected):

- ☐ applying existing label advisory statement(s) to a new substance or class of substances
- ☐ applying new label advisory statement(s) to a substance or class of substances
- ☐ removing the requirement for label advisory statement(s) in relation to a substance or a class of substances
- ☐ adding an additional requirement (from Section 3) to an advisory statement that applies to a substance or class of substances
- ☐ removing an additional requirement (from Section 3) to an advisory statement that applies to a substance or class of substances
- ☐ other (specify) ……
  ……
  ……

Existing details

The substances currently included in Section 1 of the *Required Advisory Statements for Medicine Labels* that will be affected by the proposed change are:

☐ None ☐ Details are shown in the following table

State the existing information in columns 1 and 2 of Section 1. More than one substance may be included (expand space provided as required)

Column 1 Medicines Containing …	Column 2 Which Meet the Following Requirements
……	……
……	……
……	……
……	……

Details of proposed change

It is proposed to amend Section 1 by:

☐ applying the statement(s) shown to the following substance(s) or class of substances under the conditions shown in the following table.

Statements to be applied are: ☐ New (see Section 2 below)

☐ Existing (insert numbers): ……., ……., …….

Copy/expand table as required if more items

Substance	Conditions under which the statement(s) will apply (include details dosage form, route(s) of administration, strength (upper and/or lower cut off), indications, pack size, Poisons schedule, other as required. If proposal applies under all circumstances, state "All".)
……	……
……	……
……	……
……	……

AND/OR

☐ removing the requirement that the existing statements (insert numbers) ……,

……., ……., ……. apply to the following substances

Copy/expand table as required if more items

Substance	Conditions under which the statement(s) will NO LONGER apply (include details dosage form, route(s) of administration, strength (upper and/or lower cut off), indications, pack size, Poisons schedule, other as required. If proposal applies under all circumstances, state "All".)
……	……
……	……
……	……
……	……

AND/OR

☐ applying the additional requirement(s) shown to the following statements in relation to the substance(s) or class of substances under the conditions shown in the following table.

Additional requirements: ☐ New (see Section 3 below)

☐ Existing (insert letters) ……, ……, ……

are to be applied to the following statement(s):

☐ New (see Section 2 below)

☐ Existing (insert numbers): ……, ……, ……

in relation to the following substances under the conditions shown.

Copy/expand table as required if more items

Substance	**Conditions under which the statement(s) will apply** (include details dosage form, route(s) of administration, strength (upper and/or lower cut off), indications, pack size, Poisons schedule, other as required. If proposal applies under all circumstances, state "All".)
……	……
……	……
……	……
……	……

AND/OR

☐ removing the requirement that the existing additional requirements (insert letters): ……, ……, …… are applied to the existing statements (insert numbers) ……, ……, ……, …… in relation to the following substances under the conditions shown below.

Copy/expand table as required if more items

Substance	**Conditions under which the statement(s) will NO LONGER apply** (include details dosage form, route(s) of administration, strength (upper and/or lower cut off), indications, pack size, Poisons schedule, other as required. If proposal applies under all circumstances, state "All".)
……	……
……	……
……	……
……	……

Proposed changes to Section 2

Existing details

The label advisory statement/s currently included in Section 2 of the *Required Advisory Statements for Medicine Labels* that will be affected by the proposed change are:

☐ None ☐ Details are shown in the following table

State the existing information in Section 2. More than one statement may be included (Expand space provided as required)

No	Existing Statement Text

Details of proposed change

It is proposed to amend Section 2 by:

☐ adding the new statement(s) shown below

☐ amending existing statement(s) (Insert numbers). ……, …….., ……. as shown below

☐ deleting statement number (insert number) ……., …….

The text of the proposed new/amended statements is shown below (Expand space provided as required).

……

……

……

……

……

Proposed changes to Section 3

Existing details

The additional requirements currently included in Section 3 of the *Required Advisory Statements for Medicine Labels* that are affected by the proposed change are:

☐ None ☐ Details are included in the following table

State the existing information in Section 3. More than additional requirement may be included (expand space provided as required)

Requirement	Existing Text of Requirement

Details of proposed change

It is proposed to amend Section 3 by:

☐ adding new additional requirement(s) as shown below

☐ amending the existing additional requirement(s) as shown below (insert letters)

……., ……., …….

☐ deleting additional requirement(s) (insert letters) ……., ……., ……..

The text of the proposed new/amended additional requirements is shown below (Expand space provided as required)

……

……

……

……

……

Background

Why is the proposal being made? (expand space provided as required)

……

……

……

……

……

……

……

How will the safety of the relevant medicines be affected by the proposed change?

The safety of the affected medicines will be **increased / decreased / unaffected**

The following evidence is provided in support of the proposed change:
(Expand space provided or attach relevant documents as required. Include safety data, risk analysis etc where appropriate)

……

……

……

……

……

……

……

……

Other options that have been considered are (Expand space provided or attach relevant documents s required)**:**

……

……

……

……

……

……

The costs and benefits of the proposed change are (Expand space provided or attach relevant documents as required)**:**

……

……

……

……

……

……

……

……

……

The costs and benefits of the other options are (Expand space provided or attach relevant documents as required):

……

……

……

……

……

……

……

Other relevant information is (Expand space provided or attach relevant documents as required):

……

……

……
……
……
……
……
……
……

Implementation

It is proposed that a transition period for the introduction of the changes to relevant labels of existing products will be:

☐ 12 months from the date of Gazettal

☐ Other (specify, giving reasons for longer/shorter time proposed)

……
……
……
……

Applicant details

Organisation Name:			
TGA Client ID No (if any):			
Contact person:			
Address (postal):			
Telephone:		**Fax:**	
E-mail:			

Consultation

Office Use Only

Date Commences		**Date Closes**	

Appendix 2: Archived Entries

Appendix 2.1 - Archived Entries - Section 1 Medicines to Which Advisory Statements Apply

The following entries show requirements for labels of medicines that no longer apply. The date on which the entry ceased to be a requirement is shown in the "Date Ceased" column.

Medicines Containing ...	Which Meet The Following Conditions ...	Require Statement(s)	Gazettal Date	Date Ceased
Acetylcysteine	For the purpose of exclusion from the Schedules to the SUSDP when in preparations for oral use.	121	23 June 2004	1 Jun 2005
Aspirin *(Entry 1 of 9)* permitted until 30 April 2005````	For the purpose of exclusion from the Schedules to the SUSDP.	[53 or (60 and 61)], 10[a,c], 3[a,c]	23 Jun 2004	1 May 2005
Aspirin *(Entry 6 of 9)* permitted until 30 April 2005	When included in a Schedule to the SUSDP, except when: a. the preparation is indicated for inhibition of platelet aggregation; or b. in sustained release preparations containing 650mg or more of aspirin	{10, 2, [53 or (60 and 61) or (60 and 62 or 63]}[j]	23 Jun 2004	1 May 2005
Aspirin *(Entry 1 of 7)*	For the purpose of exclusion from the Schedules to the SUSDP, when: a. each dosage unit contains more than 100 mg of aspirin; and b. the preparation is NOT indicated for the inhibition of platelet aggregation.	126, 18, 127, 128, 140, 130, 141, 133, 142, 10[a,c], 3[a,c]	23 Jun 2004	5 Apr 2006

Medicines Containing ...	Which Meet The Following Conditions ...	Require Statement(s)	Gazettal Date	Date Ceased
Aspirin *(Entry 2 of 7)*	For the purpose of exclusion from the Schedules to the SUSDP, when: a. each dosage unit contains more than 100 mg of aspirin; and b. the preparation is indicated for the inhibition of platelet aggregation.	126, 18, 127, 128, 140, 130, 141, 133, 10[a,c], 3[a,c]	23 Jun 2004	5 Apr 2006
Aspirin *(Entry 5 of 7)*	When included in a Schedule to the SUSDP, and: a. the preparation is indicated exclusively for treatment of dysmenorrhoea; and b. NOT in sustained release preparations containing 650mg or more of aspirin; and c. NOT in combination with other therapeutically active substances (other than an effervescent agents)	10, 126, 127, 128, 140, 130, 141, 133, 142	23 Jun 2004	5 Apr 2006

Medicines Containing ...	Which Meet The Following Conditions ...	Require Statement(s)	Gazettal Date	Date Ceased
Aspirin *(Entry 6 of 7)*	When included in a Schedule to the SUSDP, and: a. in combination with other therapeutically active substances (other than an effervescent agents); and b. NOT in sustained release preparations containing 650mg or more of aspirin; and c. the preparation is NOT indicated: i. for inhibition of platelet aggregation; or ii. exclusively for treatment of dysmenorrhoea.	10, 126, 18, 127, 128, 140, 130, 141, 133	23 Jun 2004	5 Apr 2006
Aspirin *(Entry 7 of 7)*	When included in a Schedule to the SUSDP, and: a. NOT in combination with other therapeutically active substances (other than an effervescent agents); and b. NOT in sustained release preparations containing 650mg or more of aspirin; and c. the preparation is NOT indicated: (i) for inhibition of platelet aggregation; or (ii) exclusively for treatment of dysmenorrhoea.	10, 126, 18, 127, 128, 140, 130, 141, 133, 142	23 Jun2004	5 Apr 2006

Medicines Containing ...	Which Meet The Following Conditions ...	Require Statement(s)	Gazettal Date	Date Ceased
Aspirin *(Entry 1 of 7)*	For the purpose of exclusion from the Schedules to the SUSDP, when: a. each dosage unit contains more than 100 mg of aspirin; and b. the preparation is NOT indicated for the inhibition of platelet aggregation.	126, 18, 127, 128, 140, 130, 141, 10, 133, 142	5 Apr 2006	10 Sep 2008
Aspirin *(Entry 2 of 7)*	For the purpose of exclusion from the Schedules to the SUSDP, when: a. each dosage unit contains more than 100 mg of aspirin; and b. the preparation is indicated for the inhibition of platelet aggregation.	126, 18, 127, 128, 140, 130, 141, 10, 133	5 Apr 2006	10 Sep 2008
Aspirin *(Entry 5 of 7)*	a. When included in a Schedule to the SUSDP, and: b. the preparation is indicated exclusively for treatment of dysmenorrhoea; and c. NOT in sustained release preparations containing 650mg or more of aspirin; and d. NOT in combination with other therapeutically active substances (other than an effervescent agents)	126, 127, 128, 140, 130, 141, 10, 133, 142	5 Apr 2006	10 Sep 2008

Medicines Containing ...	Which Meet The Following Conditions ...	Require Statement(s)	Gazettal Date	Date Ceased
Aspirin *(Entry 6 of 7)*	When included in a Schedule to the SUSDP, and: a. in combination with other therapeutically active substances (other than an effervescent agents); and b. NOT in sustained release preparations containing 650mg or more of aspirin; and c. the preparation is NOT indicated: (i) for inhibition of platelet aggregation; or (ii) exclusively for treatment of dysmenorrhoea.	126, 18, 127, 128, 140, 130, 141, 10, 133	5 Apr 2006	10 Sep 2008
Aspirin *(Entry 7 of 7)*	When included in a Schedule to the SUSDP, and: a. NOT in combination with other therapeutically active substances (other than an effervescent agents); and b. NOT in sustained release preparations containing 650mg or more of aspirin; and c. the preparation is NOT indicated: (i) for inhibition of platelet aggregation; or (ii) exclusively for treatment of dysmenorrhoea	126, 18, 127, 128, 140, 130, 141, 10, 133, 142	5 Apr 2006	10 Sep 2008
Cimicifuga racemosa	When included in a Listed medicine	153,154	5 Apr2006	23 Apr 2008

Medicines Containing ...	Which Meet The Following Conditions ...	Require Statement(s)	Gazettal Date	Date Ceased
Diclofenac *(Entry 1 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 128, 149, 130)[j]	5 Apr 2006	23 Apr 2008
Diclofenac *(Entry 2 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, 128, 149, 130, 133)[j]	5 Apr 2006	23 Apr 2008
Diclofenac *(Entry 2 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, 149, 130, 133, 159, 160)[j]	23 Apr 2008	10 Sep 2008
High selenium yeast	When included in Schedule 4 Part 5 Division 3 Item 11 of the Regulations.	27, 28, 8	23 Jun 2004	23 Apr 2008
Ibuprofen *(Entry 1 of 5)*	For the purpose of exclusion from the Schedules to the SUSDP, when the preparation is indicated exclusively for the treatment of dysmenorrhoea.	{[54 or (60 and 61) or (60 and 62)], 126, 127, 128, 129, 130, 131, 132}[j]	23 Jun 2004	1 Jun 2005
Ibuprofen *(Entry 2 of 5)*	For the purpose of exclusion from the Schedules to the SUSDP, when the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	{[54 or (60 and 61) or (60 and 62)], 126, 18, 127, 128, 129, 130, 131, 132, 133}[j]	23 Jun 2004	1 Jun 2005

Medicines Containing ...	Which Meet The Following Conditions ...	Require Statement(s)	Gazettal Date	Date Ceased
Ibuprofen *(Entry 3 of 5)* permitted until 30 April 2005	When included in a Schedule to the SUSDP.	{[54 or (60 and 61) or (60 and 62)], 18}[j]	23 Jun 2004	1 May 2005
Ibuprofen *(Entry 1 of 4)*	For the purpose of exclusion from the Schedules to the SUSDP, when the preparation is for oral use and is indicated exclusively for the treatment of dysmenorrhoea.	{[54 or (60 and 61) or (60 and 62)], 126, 127, 128, 151, 130, 131, 132}[j]	1 Jun 2005	5 Apr 2006
Ibuprofen *(Entry 2 of 4)*	For the purpose of exclusion from the Schedules to the SUSDP, when the preparation is for oral use and is NOT indicated exclusively for the treatment of dysmenorrhoea.	{[54 or (60 and 61) or (60 and 62)], 126, 18, 127, 128, 151, 130, 131, 132, 133}[j]	1 Jun 2005	5 Apr 2006
Ibuprofen *(Entry 1 of 4)*	For the purpose of exclusion from the Schedules to the SUSDP, when the preparation is for oral use and is indicated exclusively for the treatment of dysmenorrhoea.	126, 127, 128, 151, 130, 131, 132	5 Apr 2006	23 Apr 2008
Ibuprofen *(Entry 2 of 4)*	For the purpose of exclusion from the Schedules to the SUSDP, when the preparation is for oral use and is NOT indicated exclusively for the treatment of dysmenorrhoea.	126, 18, 127, 128, 151, 130, 131, 132, 133	5 Apr 2006	23 Apr 2008
Ibuprofen *(Entry 3 of 4)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 128, 149, 130)[j]	23 Jun 2004	23 Apr 2008

Medicines Containing ...	Which Meet The Following Conditions ...	Require Statement(s)	Gazettal Date	Date Ceased
Ibuprofen *(Entry 4 of 4)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, 128, 149, 130, 133)[j]	23 Jun 2004	23 Apr 2008
Ibuprofen *(Entry 2 of 4)*	For the purpose of exclusion from the Schedules to the SUSDP, when the preparation is for oral use and is NOT indicated exclusively for the treatment of dysmenorrhoea.	126, 18, 127, 151, 130, 131, 132, 133, 159, 160	23 Apr 2008	10 Sep 2008
Ibuprofen *(Entry 4 of 4)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, 149, 130, 133, 159, 160)[j]	23 Apr 2008	10 Sep 2008
Ketoprofen *(Entry 2 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 18 130, 133, 159, 160)[j]	23 Apr 2008	10 Sep 2008
Mefenamic acid *(Entry 1 of 3)* permitted until 30 Apr 2005	When included in a Schedule to the SUSDP.	{54 or [(60 and 61) or (60 and 62)]}[j]	23 Jun 2004	1 May 2005
Mefenamic acid *(Entry 1 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126,127, 128, 149, 130)[j]	23 Jun 2004	23 Apr 2008

Medicines Containing ...	Which Meet The Following Conditions ...	Require Statement(s)	Gazettal Date	Date Ceased
Mefenamic acid *(Entry 2 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, 128, 149, 130, 133)[j]	23 Jun 2004	23 Apr 2008
Mefenamic acid *(Entry 2 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, 149, 130, 133, 159, 160)[j]	23 Apr 2008	10 Sep 2008
Naproxen *(Entry 1 of 4)* permitted until 30 April 2005	When: a. included in a Schedule to the SUSDP; and b. the preparations are indicated for the treatment of dysmenorrhoea	{54 or [(60 and 61) or (60 and 62)]}[j]	23 Jun 2004	1 May 2005
Naproxen *(Entry 3 of 4)* permitted until 30 Apr 2005	When: a. included in a Schedule to the SUSDP; and b. the preparations are NOT indicated for the treatment of dysmenorrhoea.	{54 or [(60 and 61) or (60 and 62)], 18}[j]	23 Jun 2004	1 May 2005
Naproxen *(Entry 1 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 128, 149, 130)[j]	23 Jun 2004	23 Apr 2008

Medicines Containing ...	Which Meet The Following Conditions ...	Require Statement(s)	Gazettal Date	Date Ceased
Naproxen *(Entry 2 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, 128, 149, 130, 133)[j]	23 Jun 2004	23 Apr 2008
Naproxen *(Entry 2 of 2)*	When: a. included in a Schedule to the SUSDP; and b. the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, 149, 130, 133, 159, 160)[j]	23 Apr 2008	10 Sep 2008
Paracetamol *(Entry 1 of 4)* permitted until 30 Apr 2005	For the purpose of exclusion from the Schedules to the SUSDP.	53 or [(60 and 61)	23 Jun 2004	1 May 2005
Paracetamol *(Entry 2 of 4)* required from 1 May 2005	For the purpose of exclusion from the Schedules to the SUSDP.	(143 and 144), (145 and 146), 147, 148	23 Jun 2004	1 May 2005
Paracetamol *(Entry 2 of 2)* permitted until 30 April 2005	When included in a Schedule to the SUSDP.	{54 or [(60 and 61) or (60 and 62)]}[j]	23 Jun 2004	1 May 2005
Piper methysticum	When included in Schedule 4 Part 4 Division 2 Item 35 of the Regulations.	55, 77, 15	23 Jun 2004	1 Jun 2005
Piper methysticum	When included in Schedule 4 Part 4 Division 2 Item 35 of the Regulations; or For the purpose of exclusion from the Schedules to the SUSDP.	55, 77, 15, 125	1 Jun 2005	5 Apr 2006

Medicines Containing ...	Which Meet The Following Conditions ...	Require Statement(s)	Gazettal Date	Date Ceased
Pyridoxal *(see also Vitamins)*	For the purpose of exclusion from the Schedules to the SUSDP when in preparations for human use containing more than the equivalent of 50 mg of pyridoxine per recommended daily dose.	53 or 56	23 Jun 2004	5 Apr 2006
Pyridoxamine *(see also Vitamins)*	For the purpose of exclusion from the Schedules to the SUSDP when in preparations for human use containing more than the equivalent of 50 mg of pyridoxine per recommended daily dose.	53 or 57	23 Jun 2004	5 Apr 2006
Pyridoxine *(see also Vitamins)*	For the purpose of exclusion from the Schedules to the SUSDP when for human use in preparations for human use containing more than the equivalent of 50 mg of pyridoxine per recommended daily dose.	53 or 58	23 Jun 2004	5 Apr 2006
Quinine	When included in a Schedule to the SUSDP.	12	23 Jun 2004	1 Jun 2005
Selenium yeast - high	When included in Schedule 4 Part 5 Division 3 Item 11 of the Regulations.	27, 28, 8	23 Jun 2004	23 Apr 2008
Selenocysteine	When included in Schedule 4 Part 5 Division 3 Item 13 of the Regulations.	27, 28, 8	23 Jun 2004	23 Apr 2008
Selenomethionine	When included in Schedule 4 Part 5 Division 3 Item 12 of the Regulations.	27, 28, 8	23 Jun 2004	23 Apr 2008
Sodium selenate	When included in Schedule 4 Part 5 Division 3 Item 14 of the Regulations.	27, 28, 8	23 Jun 2004	23 Apr 2008
Sodium selenite	When included in Schedule 4 Part 5 Division 3 Item 15 of the Regulations.	27, 28, 8	23 Jun 2004	23 Apr 2008
Yeast – high selenium	When included in Schedule 4 Part 5 Division 3 Item 11 of the Regulations.	27, 28, 8	23 Jun 2004	23 Apr 2008

Medicines Containing ...	Which Meet The Following Conditions ...	Require Statement(s)	Gazettal Date	Date Ceased
Tryptophan	For the purpose of exclusion from the Schedules to the SUSDP when for human therapeutic use in preparations labelled with a recommended daily dose of 100 mg or less of tryptophan.	29	23 Jun 2004	1 Jun 2005
Vitamin A *(see also Vitamins)*	For the purpose of exclusion from the Schedules to the SUSDP when for human therapeutic use in preparations for internal use OTHER THAN those: a. containing 100 International Units or less of vitamin A per dosage unit of a divided preparation; or b. 100 International Units or less of vitamin A per gram of an undivided preparation.	30, 31[d,e], 32[d,e,c], 33[d,e,c]	23 Jun 2004	1 Jun 2005
Vitamin A (see also Vitamins)	For the purpose of exclusion from the Schedules to the SUSDP when for human therapeutic use in preparations for internal use OTHER THAN those: a. containing 100 International Units or less of vitamin A per dosage unit of a divided preparation; or b. 100 International Units or less of vitamin A per gram of an undivided preparation.	31[d,e], 32[d,e,c] 33[d,e,c]	1 Jun 2005	23 Apr 2008

Medicines Containing ...	Which Meet The Following Conditions ...	Require Statement(s)	Gazettal Date	Date Ceased
Vitamins *(see also:* *Pyridoxal* *Pyridoxamine* *Pyridoxine* *Vitamin A)*	When: a. in preparations for oral ingestion; and b. required by Schedule 2 Part 2 Item 1 of the Regulations to be labelled in accordance with this document.	34 or 35	23 Jun 2004	1 Jun 2005

Appendix 2.2 - Archived Entries - Section 2 Advisory Statements

The following entries show label statements that no longer apply. The date on which the entry ceased to be a requirement is shown in the "Date Ceased" column.

No	Statement Text	Gazettal Date	Date Ceased
10	Consult a doctor before giving this medication to children or teenagers with chicken pox, influenza or fever.	23 Jun 2004	5 Apr 2006
27	Selenium is toxic in high doses.	23 Jun 2004	23 Apr 2008
28	Selenium in dietary supplements should not exceed a daily dose of 100 mg.	23 Jun 2004	23 Apr 2008
30	Recommended daily amount is 5000 International Units or less of Vitamin A.	23 Jun 2004	23 Apr 2008
31	The recommended adult daily amount of vitamin A from all sources is 2 500 International Units.	23 Jun 2004	23 Apr 2008
32	WARNING – When taken in excess of 8 000 IU vitamin A can cause birth defects.	23 Jun 2004	23 Apr 2008
44	St John's Wort affects the way some prescription medicines work.	23 Jun 2004	5 Apr 2006
55	Not for prolonged use.	23 Jun 2004	5 Apr 2006
153	WARNING: Black cohosh may harm the liver in some individuals.	5 Apr 2006	23 Apr 2008

Appendix 2.3 - Archived Entries - Section 3 Additional Requirements

The following entries show additional requirements that no longer apply. The date on which the entry ceased to be a requirement is shown in the "Date Ceased" column.

No	Statement Text	Gazettal Date	Date Ceased

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 02 6232 8444 Fax: 02 6232 8605
www.tga.gov.au