



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration



Consultation Paper

Proposed Medicine Label Statements

July 2007

HOW TO MAKE A SUBMISSION

You are invited to provide written comment on this consultation paper. Submissions can be sent by post or e-mail and, where possible, should be cross-referenced to the specific sections set out in this consultation paper.

Please also refer to the 'Stakeholder Comment' section on page 5 for further information in this regard.

Content of submissions

Your submission should include:

- your name and full contact details including: address, telephone number, and if applicable, facsimile and e-mail address;
- the particular issue being addressed;
- relevant evidence and/or examples to support the views expressed; and
- in the case of organisations, the level at which the submission was authorised.

Confidentiality of submissions

If you wish any information contained in your submission to be treated as confidential, please clearly identify that information and outline the reasons why you consider it to be confidential. Note that general disclaimers in covering emails will not be taken to be sufficient reason for submissions to be treated confidentially.

Address for submissions

Electronic submissions should be e-mailed to: RASML@anztpa.org with "Submission for the RASML Project Officer" in the subject heading.

Hardcopy submissions should be addressed to either of the addresses below:

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Questions relating to submissions

Any questions relating to submissions should be directed to the RASML Project Officer, by e-mail at: RASML@anztpa.org

Deadline for submissions

The deadline for receipt of submissions is **18 August 2007**.

Consultation Document:

Proposed Medicine Label Statements for ANZTPA

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Preface

The ANZTPA regulatory scheme will require certain advisory statements to be placed on medicine labels, when appropriate.

In anticipation of the scheme's commencement, Medsafe (New Zealand) and the Therapeutic Goods Administration – TGA (Australia) have rationalised the current statements used in their respective countries into a single set of label advisory statements.

This document has been produced to:

1. explain the approach behind the rationalisation of the Required Advisory Statements on Medicine Labels (RASML) dataset;
2. provide the wording of the proposed rationalised advisory statements;
3. describe a possible internet ANZTPA RASML database that will readily inform users of advisory statements;
4. detail the circumstances of when the advisory statements are required to be included on medicine labels; and
5. ask stakeholders to provide relevant comments.

The requirements for medicine labels under the ANZTPA Scheme will be detailed in the Order titled *General Requirements for the Labelling of Medicines Australia New Zealand Therapeutic Products Authority* (see previous consultation document at <http://www.anztpa.org/label/dr-labelorder.htm>). This Order will require labels to contain warning and advisory statements which will be captured in the ANZTPA RASML.

It has been proposed that the mandatory 'signal heading' of "Caution" and "Poison" labelling for therapeutic products containing substances currently scheduled in Schedule 5 or 6 of the Standard for the Uniform Scheduling of Drugs and Poisons (current Scheduling Standard in Australia), be transferred to the ANZTPA RASML to allow these requirements to be recognised in both Australia and New Zealand. The regulatory mechanism currently under consideration to implement this proposal is to exclude all licensed or exempt (from licensing) therapeutic products from Schedules 5 and 6 of the ANZTPA Scheduling Standard. Licence holders should refer to the draft ANZTPA Scheduling Standard which was recently released for public consultation on the ANZTPA project website at <http://www.anztpa.org/> for further information.

At the time of this consultation, the legal framework for the proposed ANZTPA RASML has not been finalised and cannot be detailed in this document. Therefore, this document has no legal basis of its own, and is not intended to replace either the current edition of the RASML in Australia or the medicine label statements in Volume 1 of the New Zealand Regulatory Guidelines for Medicines in New Zealand. It is intended only to form the basis for:

- Consultation and discussion on whether all the requirements relating to advisory statements are captured;
- Creation of a finalised ANZTPA RASML set; and
- To inform the working party of a direction forward, and to form a basis for a work-plan.

Some of the information and terminology used in the proposed ANZTPA RASML cannot be finalised until related documents, such as the ANZTPA Labelling Order and the ANZTPA Medicines Rule, are finalised. Therefore, parts of the ANZTPA RASML document may need to be amended to be consistent with related documents. However, it is anticipated that neither the specific wording of any of the proposed advisory statements, nor, particularly, the circumstances in which these statements will need to be included on labels, should need to be changed as a result of the finalisation of related ANZTPA documents.

Stakeholder comment

Specifically, stakeholder comment is sought on:

1. The principle that statements which previously applied to some ingredients or medicines in one country only will now apply to these ingredients or medicines in both countries when the joint regulatory scheme commences.
2. The approach taken to craft the ANZTPA RASML dataset, specifically improvements on the coding system.
3. The proposed ANZTPA RASML statements, specifically:
 - a. whether the intent and meaning of the advisory statements in the ANZTPA RASML have been retained for each relevant ingredient/indication following the rationalisation of advisory statements currently required in New Zealand and Australia;
 - b. whether the ANZTPA RASML (Part 2 of this document) makes it clear when an advisory statement needs to be included on a medicine intended for supply and, if not, how could this be made clearer;
 - c. whether the process around maintaining or changing the ANZTPA RASML are adequately described.
4. The structure of the internet ANZTPA RASML database.

Important:

Stakeholder comment is not sought on whether a statement should or should not apply to an ingredient or indication. This has already been decided by existing relevant committees at Medsafe and TGA.

This document is divided into the following parts:

Part 1 - Approach to constructing the ANZTPA RASML dataset
describes the approach taken to rationalise the various statements.

Part 2 - ANZTPA's *Required Advisory Statements for Medicine Labels* (ANZTPA RASML)
contains the 186 proposed rationalised statements, and the existing Consolidated Advisory Statements Required on Medicine Labels (CASRML) statement number the proposed rationalised statement replaces.

Part 3 - The electronic ANZTPA RASML database and search facility
describes the structure of the database and how it is used.

- Part 4 - Medicines to which advisory statements will apply**
contains the glossary and interpretation of terms used in Part 3 (based on the current TGA RASML) and shows how the ANZTPA RASML matches to ingredients or products currently requiring advisory statements in Australia and New Zealand.
- Part 5 - Changes or updates to the RASML**
Contains information about the processes involved in updating or changing the statements and their application to particular medicines.

Part 1 – Approach to constructing the ANZTPA RASML dataset

Currently, certain advisory statements have been required to be placed on medicine labels as a condition of approval in both Australia and New Zealand. There are significant overlaps in many label statements from various sources, giving considerable scope for rationalisation. This part describes the approach used to review the several hundred existing statements for incorporation into the ANZTPA RASML set, with the aim of creating a single dataset that can be easily and appropriately managed, such that overlaps in the intended message to be conveyed, from various sources, no longer occur.

1.1 Rationalising existing similar statements

Existing similar statements (from both the New Zealand and Australian sets of required advisory statements) have been rationalised and replaced by a single statement, for example:

<i>Existing statements</i>	<i>Rationalised statement</i>
Application to skin may increase sensitivity to sunlight. This product may make your skin more sensitive to sunlight.	This product may make your skin more sensitive to sunlight.

1.2 Standardising the structure of statements

The structure of the statements has been standardised to ensure that a uniform approach can be taken to the construction of future statements (such as by a future expert committee or advisory group), for example:

<i>Existing statements</i>	<i>Standardised structure</i>
See a doctor before taking [this product/ <i>insert name of product</i>] for thinning the blood or for your heart.	Consult a doctor before use for thinning the blood or for the heart.
If symptoms persist for more than a few days or recur, consult a doctor. Consult a doctor if the problem returns. Consult a doctor [or dentist if appropriate] if symptoms/condition persist(s).	Consult a doctor if symptoms/condition persist(s), or the problem returns.

1.3 Deconstructing Compound statements

Most existing compound statements have been separated to increase the utility of the statements. This enables the separated statements to be utilised (where necessary or appropriate) for more than one product or ingredient, for example:

<i>Existing compound statements</i>	<i>Separated statements</i>
Consult a doctor before use for thinning the blood or for the heart.	Consult a doctor before use for thinning the blood. Consult a doctor before use for your heart.
See your doctor before taking this product if you have high blood pressure or heart problems or are taking antidepressant medication.	Consult a doctor before use if you have high blood pressure. Consult a doctor before use if you have heart problems. Consult a doctor before use if you are taking antidepressant medication.

1.4 Prefix-Situation-Suffix format

Many of the statements exist in a 'Prefix-Situation-Suffix' format. A suffix can modify a statement from an absolute position to a relative position, such as making an absolute contraindication into a relative contraindication, for example:

<i>Rationalised statement</i>	<i>Prefix</i>	<i>Situation(s)</i>	<i>Suffix</i>
Consult a doctor before use for thinning the blood or for the heart.	Consult a doctor before use	For thinning the blood For the heart	—
Do not use in children under 6 months old.	Do not use in children	Under 6 months old	—
Do not use in children under 6 months old except on doctor's advice.	Do not use in children	Under 6 months old	Except on doctor's advice
Do not use in children under 6 months old except on doctor's or pharmacist's advice.	Do not use in children	Under 6 months old	Except on doctor's or pharmacist's advice

Adopting this approach to all statements allows a future expert committee or advisory group that is deliberating a new advisory statement to consider a number of options, in order to derive an appropriate statement for the situation, for example:

<i>Situation</i>	<i>Possibilities</i>	<i>Type of statement</i>
Asthma e.g.	Do not use if you have asthma.	Absolute contraindication
...if you have asthma	Do not use if you have asthma	Relative contraindication
...with asthma	<i>except on doctor's or pharmacist's advice.</i>	
...for asthma	Consult a doctor before use if you have asthma.	Precaution
etc.	Consult a doctor or pharmacist before use if you have asthma.	Precaution

	Do not use in children with asthma.	Absolute contraindication
	Do not use in children for asthma <i>except on doctor's or pharmacist's advice.</i>	Relative contraindication / Precaution
	etc.	

The following Prefixes and Suffixes are proposed in order to cover the existing range of situations:

PREFIX	
1	Do not use...
2	Do not use in children (with/who have/for) [delete as appropriate]...
3	Consult a doctor before use...
4	Consult a doctor or pharmacist before use...
5	Consult a healthcare professional before use...
6	Consult a doctor if...
7	Consult a doctor or pharmacist if...
8	Consult a healthcare professional if...

SUFFIX	
a	...except on doctor's advice.
b	...except on doctor's or pharmacist's advice.
c	...except on the advice of a healthcare professional.

1.5 Statement Categories and Coding

The rationalised statements have been grouped into categories (and have been coded and numbered). The coding allows their nature to be easily recognised and managed by ANZTPA, for example:

<i>Nature of the statement</i>	<i>2-letter Code</i>
Age-related usage advice	AG
Contents advice	CO
Contraindications and Precautions	CP
Directions for use	DR
Dosage advice	DS
Duration of use advice	DU
General and miscellaneous advice	GM
Interactions	IN
Overdose	OD
Pregnancy and breastfeeding advice	PB
Side effects	SE

Finally, a Prefix-Situation-Suffix coding system has been derived to manage the proposed set of required advisory statements. The proposed coding system is a basic Number-Letter-Letter-Number-letter code, corresponding to:

<i>Prefix</i>	<i>Situation (i.e. nature and number of statement)</i>	<i>Suffix</i>
Number	Letter-Letter-Number	letter
2	CP18	a

The proposed approach permits a minimal number of statements to be applied to many situations, i.e. provides maximum flexibility, without the number or type of root situations growing unreasonably:

<i>Root Situation</i>	<i>Root Code</i>		<i>Required advisory statement</i>	<i>Resulting Code</i>	<i>Effect of statement</i>
...if you have asthma...	CP18	allows	Do not use if you have asthma.	1 CP18	Contraindication
			Consult a doctor or pharmacist before use if you have asthma.	4 CP18	Precaution
			Do not use in children with asthma / who have asthma except on doctor's or pharmacist's advice.	2 CP18b	Relative contraindication
			Consult a healthcare professional if you have asthma.	8 CP18	Side-effect / Symptom

The sole purpose of the coding system is for management of the ANZTPA RASML dataset. It is anticipated that future expert committees or advisory groups deliberating on an advisory statement to be applied to an ingredient or product can mix and match prefixes and suffixes with the root situations as necessary, and apply the resultant new code to the ingredient, indication, or product. It should be noted that at this stage the suggested coding system is the preferred approach for ANZTPA, but is being released to stakeholders for consultation. It is anticipated that stakeholders may suggest improvements or refinements to this approach.

Part 2 - ANZTPA's Required Advisory Statements for Medicine Labels (ANZTPA RASML)

2.1 The Rationalised Statements

This part contains the rationalised statements that are proposed to be used for medicine labels at the commencement of the ANZTPA regulatory scheme. The first column provides the code for the statement, the second column provides the actual statement and the third column shows the equivalent statement(s) contained in the TGA's CASMRL document that has/have been replaced by the rationalised statement. A statement required in New Zealand (and which does not have a CASRML equivalent) is marked 'NZ'.

The main use of the code is as an identifier for ANZTPA to use when managing the RASML dataset. It is not anticipated that sponsors will need to use or refer to this code. For convenience, prefixes are in a bold font, suffixes are in an italic font. Comments and explanatory notes are in square brackets.

CODE 'AG' AGE-RELATED USE		
		<i>replaces CASRML number</i>
<i>subcategory: Children</i>		
2 AG01	Do not use in children or infants	535, 580, 592, 9,
2 AG01 <i>a</i>	Do not use in children or infants <i>except on doctor's advice.</i>	612
2 AG02	Do not use in children under 6 months old.	509, 630, 721,
2 AG02 <i>a</i>	Do not use in children under 6 months old <i>except on doctor's advice.</i>	722, 652, 527,
2 AG02 <i>b</i>	Do not use in children under 6 months old <i>except on doctor's or pharmacist's advice.</i>	643, 723, 724
2 AG03	Do not use in children under 12 months old.	7, 646, 721, 722,
2 AG03 <i>a</i>	Do not use in children under 12 months old <i>except on doctor's advice.</i>	139, 607, 723,
		724
2 AG04	Do not use in children under 2 years old.	508, 721, 722, 2,
2 AG04 <i>a</i>	Do not use in children under 2 years old <i>except on doctor's advice.</i>	3, 540, 609, 647,
		723, 724
2 AG05	Do not use in children aged 6 months to 2 years.	644
2 AG05 <i>b</i>	Do not use in children aged 6 months to 2 years <i>except on doctor's or pharmacist's advice.</i>	
2 AG06	Do not use in children under 6 years old	131, 723, 724,
2 AG06 <i>a</i>	Do not use in children under 6 years old <i>except on doctor's advice.</i>	150, 721, 722
2 AG07	Do not use in children under 12 years old	5, 141, 645, 656,
2 AG07 <i>a</i>	Do not use in children under 12 years old <i>except on doctor's advice.</i>	723, 724, 4, 6,
2 AG07 <i>b</i>	Do not use in children under 12 years old <i>except on doctor's or pharmacist's advice.</i>	536, 721, 722

2 AG08	Do not use in children under 15 years old	8, 721, 722
2 AG09	Do not use in children under [<i>insert lowest age for which a dose is stated on the label</i>].	721, 722, 723, 724
2 AG09a	Do not use in children under [<i>insert lowest age for which a dose is stated on the label</i>] <i>except on doctor's advice</i> .	
2 AG10 a	Do not use in children 12 to 16 years old, with or recovering from chicken pox, influenza or fever <i>except on doctor's advice</i> .	10
2 AG11	Do not use in children weighing less than 7 kg.	NZ
subcategory: Adults		
3 AG21	Consult a doctor before use if you are 40 years of age and over.	NZ
3 AG22	Consult a doctor before use if you are aged 65 years or over.	132

CODE 'CO' PRODUCT CONTENTS		
		<i>replaces CASRML number</i>
CO01	Contains [<i>insert name of ingredient or label-AAN for Grouping Name if two or more ingredients from the same ingredient Group are included in the medicine</i>].	533, 601, 649, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 689, 691, 692, 693, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 716
CO02	Contains [<i>insert name of component or contaminant shown in entry in Part 4</i>].	36, 138, 555
CO03	[This product / <i>insert name of product</i>] contains [<i>insert quantity and units</i>] of [<i>insert name of ingredient or component shown in Part 4 entry</i>] per dose/g/mL (<i>delete as appropriate</i>).	37
CO04	[This product / <i>insert name of product</i>] contains [<i>insert quantity in mg and mmol</i>] of [sodium/potassium] [<i>select substance</i>] per [<i>select dose/g/mL as appropriate</i>] which provides [<i>insert quantity and units</i>] of [sodium/potassium] per maximum recommended daily dose. This should be taken into account by those on a low [sodium/potassium] diet.	567, 513
CO05	[This product/ <i>insert name of product</i>] contains [<i>insert quantity and units</i>] of [<i>insert name of sugar alcohol</i>] per maximum recommended daily dose.	574, 523
CO06	Derived from [<i>insert source shown in entry in Part 4</i>].	38, 156, 579,

CODE 'CP' CONTRAINDICATIONS AND PRECAUTIONS
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<i>subcategory: Purpose-related</i>		
1 CP01	Do not use for acne.	112
1 CP02	Do not use to treat iron deficiency conditions.	524
1 CP03	Do not use unless under the supervision of a healthcare professional.	152, 154, 534
1 CP04 <i>a</i>	Do not use for any purpose other than that specified on the label <i>except on doctor's advice</i> .	NZ
<i>subcategory: Pre-existing conditions</i>		
1 CP11	Do not use if you are allergic to <i>[insert name substance]</i> .	127
1 CP12	Do not use if you are allergic to anti-inflammatory medicines.	127
1 CP13	Do not use if you suffer from allergies.	127, 575
1 CP14	Do not use if you have diarrhoea or develop diarrhoea.	557, 633
1 CP15	Do not use if you have abdominal pain.	557, 633
1 CP16	Do not use if you have nausea.	557, 633
1 CP17	Do not use if you are vomiting.	557, 633
1 CP18	Do not use if you have asthma.	130, 575
1 CP18 <i>a</i>	Do not use if you have asthma <i>except on doctor's advice</i> .	
1 CP19	Do not use if you have diabetes	16, 611
1 CP19 <i>a</i>	Do not use if you have diabetes <i>except on doctor's advice</i> .	
1 CP20	Do not use if you have impaired circulation.	611
1 CP21	Do not use if you have glaucoma or other serious eye conditions.	627
1 CP22 <i>a</i>	Do not use if you have recently had a heart attack <i>except on doctor's advice</i> .	580
1 CP23 <i>a</i>	Do not use if you have recently had surgery or a major accident <i>except on doctor's advice</i> .	580
1 CP24 <i>c</i>	Do not use if you suffer from bipolar depression <i>except on the advice of a healthcare practitioner</i> .	43
1 CP25	Do not use if you have a stomach ulcer.	126
3 CP26	Consult a doctor before use for the first time.	63, 64, 66, 68, 559, 660
3 CP27	Consult a doctor before use if you are at risk of bleeding problems.	554
3 CP28	Consult a doctor before use in cases of ear perforation (or where this is likely) or where grommets (ventilation tubes) are present.	624
3 CP29	Consult a doctor before use if you have had a baby with spina bifida or neural tube defect.	566
4 CP30	Consult a doctor or pharmacist before use if you have high blood pressure.	619, 657

4 CP31	Consult a doctor or pharmacist before use if you have heart problems.	619, 657
4 CP32	Consult a doctor or pharmacist before use if you have kidney problems or impaired renal function.	657
4 CP33	Consult a doctor or pharmacist before use if you have a nasal or sinus infection.	666, 667, 668
4 CP34	Consult a doctor or pharmacist before use if you have recently had an injury or surgery to your nose.	666, 667, 668
4 CP35	Consult a doctor or pharmacist before use if you have ulceration in your nose.	666, 667, 668
Subcategory: Children with pre-existing conditions		
2 CP51 a	Do not use in children suffering from urticaria <i>except on doctor's advice.</i>	NZ
2 CP52 a	Do not use in children suffering from rhinitis <i>except on doctor's advice.</i>	NZ
2 CP53 a	Do not use in children who have shown hypersensitivity to aspirin, ibuprofen or other NSAIDs <i>except on doctor's advice.</i>	NZ
2 CP54 a	Do not use in children who are suffering from dehydration through diarrhoea or vomiting <i>except on doctor's advice.</i>	NZ
2 CP55 a	Do not use in children suffering from asthma <i>except on doctor's advice.</i>	NZ
2 CP56 a	Do not use in children with abdominal pain <i>except on doctor's advice.</i>	NZ
2 CP57 a	Do not use in children with kidney problems or impaired renal function <i>except on doctor's advice.</i>	NZ
subcategory: Concomitant medication		
1 CP101 a	Do not use with other medicines containing [name of active ingredient] <i>except on doctor's advice.</i> [147, 148 = paracetamol]	129, 140, 147, 148, 149, 151
1 CP102 a	Do not use with aspirin or other anti-inflammatory medicine <i>except on doctor's advice.</i>	129, 140, 149, 151
1 CP103 a	Do not use with other medicines you are taking regularly <i>except on doctor's advice.</i>	129, 140, 149, 151,
4 CP103	Consult a doctor or pharmacist before use with other medicines you are taking-regularly.	65, 619, 657, 719
1 CP104 a	Do not use if you are on warfarin therapy <i>except on doctor's advice.</i>	41
1 CP105 c	Do not use with anti-depressant medication <i>except on the advice of a healthcare practitioner.</i>	43, 619,
3 CP106	Consult a doctor before use if you are using other eye products.	626
3 CP107	Consult a doctor before use if you are taking anticoagulants.	553

3 CP108	Consult a doctor before use if you are already taking another steroid product eg tablets, asthma or nasal inhaler or eye/nose drops.	NZ
3 CP109	Consult a doctor before use if taking [this product/insert name of product] for thinning the blood.	142
3 CP110	Consult a doctor before use if taking [this product/insert name of product] for your heart.	142
3 CP111	Consult a doctor before use if taking warfarin, phenytoin or theophylline.	NZ
subcategory: Children on concomitant medication		
2 CP151 a	Do not use in children who are taking other medicines <i>except on doctor's advice</i> .	NZ
subcategory: General symptoms		
6 CP201	Consult a doctor if the problem returns.	74
6 CP202	Consult a doctor if new or additional symptoms occur.	NZ
6 CP203	Consult a doctor if symptoms/condition persist(s) or worsens.	69, 506, 550, 596, 616, 617, 628, 631
8 CP203	Consult a healthcare professional if symptoms/condition persist(s) or worsens.	76, 77, 541, 551, 577
subcategory: General symptoms - time related		
6 CP210	Consult a doctor if symptoms/condition persist(s) for more than 6 hours.	544, 620
6 CP211	Consult a doctor if symptoms/condition persist(s) for more than 12 hours.	545, 621
6 CP212	Consult a doctor if symptoms/condition persist(s) for more than 24 hours.	546, 622
6 CP213	Consult a doctor if symptoms/condition persist(s) for more than 48 hours.	542, 543, 547, 623, 654
6 CP214	Consult a doctor if symptoms/condition persist(s) for more than 3 days.	NZ
7 CP215	Consult a doctor or pharmacist if symptoms/condition persist(s) for more than 7 days.	669
6 CP216	Consult a doctor if symptoms/condition persist(s) for more than a few days or recur.	71, 72, 73, 75
6 CP217	Consult a doctor if symptoms/condition persist(s) for more than x days. [x = number of days in approved Product Information (PI) document].	75

6 CP218	Consult a doctor if symptoms/condition persist(s) for more than 3 months.	115
<i>subcategory: Specific symptoms</i>		
6 CP251	Consult a doctor if you notice blood in your urine. The presence of blood in the urine warrants immediate medical attention.	654, 543
6 CP252	Consult a doctor if irritation occurs.	594
8 CP253	Consult a healthcare professional if your nose bleeds.	670, 671, 672
8 CP254	Consult a healthcare professional if you develop signs/symptoms of nasal infection such as fever, facial pain or swelling, or discoloured nasal discharge.	670, 671, 672
8 CP255	Consult a healthcare professional if you have eye pain or visual disturbances.	670, 671, 672
6 CP256	Consult a doctor if sleeplessness (or anxiety) persists.	NZ

CODE 'DR' DIRECTIONS		
<i>replaces CASRML number</i>		
<i>subcategory: General</i>		
DR00	Read [directions/enclosed Consumer Medicine Information (<i>delete as appropriate</i>)] before using this product.	123, 124, 516
<i>subcategory: Internal use</i>		
DR01	Do not take powder alone. Mix with food or fluid.	538, 539
DR02	This product should be taken at least one hour after any other medication as it may reduce the effect of other medication.	537
<i>subcategory: External use</i>		
DR51	If you have sensitive skin, test this product on a small area of skin before applying it to a large area.	589
1 DR52	Do not use on broken skin.	111, 155, 548, 635
1 DR53 c	Do not use undiluted on the skin <i>except on the advice of a healthcare professional.</i>	116
1 DR54	Do not use on burnt or damaged skin.	NZ
1 DR55	Do not use rectally.	639
1 DR56 1 DR56a	WARNING - Do not use on face or on anal or genital areas. WARNING - Do not use on face or on anal or genital areas <i>except on doctor's advice.</i>	104, 105
1 DR57	Do not use on the mucosa, vagina or rectum.	155

1 DR58	Do not use on or near eyes, lips, mouth, sensitive areas of the neck, nose and other mucous membranes.	91, 103
1 DR59 1 DR59 a	Do not use under waterproof dressings. Do not use under waterproof dressings <i>except on doctor's advice</i> .	117, 118, 608
DR60	Use only on common warts. Do not use on moles, birthmarks or unusual skin growths. Do not treat warts over large areas at one time.	658, 663, 664

CODE 'DS' DOSAGE STATEMENTS		
		<i>replaces CASRML number</i>
DS01	Keep to the recommended dose.	143, 145
DS02	The maximum recommended daily dose of <i>[insert approved name of ingredient]</i> is <i>[insert maximum daily dose]</i> .	28, 29, 30, 121
DS03 DS03 a	Do not exceed the maximum stated dose Do not exceed the maximum stated dose <i>except on doctor's advice</i> .	565, 614

CODE 'DU' DURATION OF USE		
		<i>replaces CASRML number</i>
<i>subcategory: Time specific</i>		
1 DU01 a	Do not use for longer than 48 hours <i>except on doctor's advice</i> .	17, 146
1 DU02 a	Do not use for longer than a few days at a time <i>except on doctor's advice</i> .	128, 144
1 DU03 a	Do not use for longer than 5 days <i>except on doctor's advice</i> .	655
1 DU04 a	Do not use for longer than 7 days <i>except on doctor's advice</i> .	52
1 DU05 a	Do not use for longer than 4 weeks <i>except on doctor's advice</i> .	51
1 DU06 a 1 DU06 b	Do not use for longer than 6 months <i>except on doctor's advice</i> . Do not use for longer than 6 months <i>except on doctor's or pharmacist's advice</i> .	613
5 DU07	Consult a healthcare professional before use for prolonged periods.	67
1 DU07 a	Do not use for prolonged periods <i>except on doctor's advice</i> .	NZ
<i>subcategory: General</i>		
DU11	The product should be used for 14 days after symptoms disappear.	600
DU12	If getting better, keep using for <i>[insert number of days as per approved Product Information (PI) document]</i> days.	78

DU13	This product is for temporary use only. <i>[or]</i> Not for prolonged use.	55, 137, 504
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CODE ‘GM’ GENERAL AND MISCELLANEOUS		
		<i>replaces CASRML number</i>
<i>subcategory: General</i>		
GM01	Keep out of reach of children.	1
GM02	Test before use.	570
GM03	CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed.	60
<i>subcategory: External</i>		
GM11	For external use only.	119, 548, 155, 97
GM12	For vaginal use only.	638
GM13	This medicine may affect the rubber used in condoms or other contraceptive devices.	NZ
GM21	Do not swallow.	122, 120
GM22	Can be fatal to children if sucked or swallowed.	11
GM23	Avoid breathing dust/vapour/spray mist <i>[delete as appropriate]</i> .	110
<i>subcategory: Skin/Eyes</i>		
GM31	Corrosive.	95
GM32	Irritant.	96
GM33	Avoid skin contact.	87
GM34	Keep out of eyes.	79, 80, 83, 84
GM35	May be irritant to the eyes/skin <i>[delete as appropriate]</i> .	549, 569
GM36	Wear protective eyewear/gloves <i>[delete as appropriate]</i> when mixing or using.	81, 82, 89
<i>subcategory: Internal</i>		
GM41	Do not take hot food or drink soon after using this product because it may burn your mouth.	593
GM42	Avoid alcohol.	47
<i>subcategory: Sun</i>		
GM44	Avoid [prolonged/excessive (delete as appropriate)] exposure to sunlight and other sources of ultra violet light.	70, 525

GM45	Wear protective clothing, hats and eyewear and use sunscreen when exposed to the sun.	582, 588
subcategory: First aid		
GM50	Contact the Poisons Information Centre (Phone eg Australia 13 1126; New Zealand 0800 764 766) or a doctor.	604, 648, 706, 707
GM51	If swallowed, do NOT induce vomiting.	708
GM52	Immediately give a glass of water.	529
GM53	Avoid giving milk or oils.	530
GM54	If in eyes, wash out immediately with water.	85, 561, 585, 709
GM55	Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.	690
GM56	Wash hands/skin/gloves [<i>delete as appropriate</i>] after use.	88, 98, 586
GM57	If irritation, rash or swelling occurs or persists, discontinue use.	90, 92, 114, 572, 591, 594, 653
MISCELLANEOUS		
subcategory: Asthma medication		
GM101	This product should be part of an overall treatment plan regularly assessed with a doctor.	45
subcategory: Spermicides		
GM102	Sexually transmitted diseases (STDs) alert: This product does not protect against the AIDS virus (HIV) or other sexually transmitted diseases (STD's). Consult a doctor before use if you have a new sex partner, multiple sex partners or unprotected sex. Frequent use (more than once a day) of this product may increase vaginal irritation, which may increase the risk of becoming infected with the AIDS virus (HIV) or other STDs from infected partners. Ask a doctor or other health professional for your best birth control method. Stop use and ask a doctor if you or your partner get burning, itching, a rash, or other irritation of the vagina or penis.	637, 640, 641, 661, 662, 642
subcategory: Bath oils		
GM103	CAUTION: Use of this product may cause the body and bathroom surfaces to become slippery. Particular care should be exercised when handling a baby.	602, 603
subcategory: Sleeping aid		

GM104	<p>Go to bed and arise at the same time daily.</p> <p>Engage in relaxing activities before bedtime.</p> <p>Exercise regularly but not in the late evening.</p> <p>Avoid eating meals or large snacks just before bedtime.</p> <p>Eliminate daytime naps.</p> <p>Avoid caffeine-containing drinks after midday.</p> <p>Avoid alcohol or the use of nicotine late in the evening.</p> <p>Minimise external disruption (eg light and noise).</p> <p>If you are unable to sleep, do not become anxious; leave the bedroom and participate in relaxing activities such as reading or listening to music until you are tired.</p>	711, 712, 713, 714, 715, 705, 687, 584, 583
subcategory: Vitamins		
GM105	<p>Vitamins can only be of assistance if the dietary vitamin intake is inadequate. [or] Vitamin supplements should not replace a balanced diet.</p>	34, 35
subcategory: Fluoride		
GM106	<p>Use of this product is not necessary in areas supplied with fluoridated water.</p> <p>Contact your dental professional or local water authority for information on the fluoride content of your water supply.</p>	40, 505
subcategory: Threadworm		
GM107	<p>A common symptom of threadworm infestation is itching around the anus and vagina, which may result in restless sleep and irritability.</p> <p>Evidence of infestation should be present before treating for threadworm.</p> <p>If a family member has threadworms, then each member of the family should be treated.</p>	597, 598, 599
subcategory: Diarrhoea		
GM108	<p>Drink plenty of water.</p> <p>Increase fibre in diet except in cases of medication induced constipation.</p>	563, 632,
subcategory: Head lice		

GM109	<p>Use enough to thoroughly cover the scalp, including the back of the neck and behind the ears.</p> <p>Remove all the eggs (nits) you can find after treatment (this is easier with a fine tooth comb and hair conditioner on wet or dry hair).</p> <p>Repeat the treatment after 7-10 days to kill lice that have hatched from any remaining eggs that were not killed by the first treatment.</p> <p>If you find live lice or more eggs appear after the second treatment, seek advice from a health care professional.</p> <p>Only use the product when you can see live lice or their eggs. Don't use regularly or to prevent head lice.</p> <p>Check other people in the household and treat if necessary.</p> <p>Lice can quickly spread back to people who have already been treated.</p>	573, 560, 552, 531, 526, 581, 562
subcategory: Minor burns		
GM110	<p>The product is for the first-aid treatment of minor burns only. Consult a doctor before use for treatment of more serious burns. Immediate treatment should consist of the rapid application of cold water or cold packs for at least 20 minutes and that the product should only be applied later.</p> <p>Ice should not be applied directly to the burnt area.</p>	532, 665, 605, 606

CODE 'IN' INTERACTIONS		
		<i>replaces CASRML number</i>
IN01	WARNING – Can interact with other medicines.	42, 136
IN02	St John's Wort can interact with many prescription medicines, including oral contraceptives.	44
IN03	Products containing activated charcoal should be used with caution in children since it may interfere with absorption of nutrients.	135
IN04	Cimetidine can interact with warfarin, phenytoin and theophylline.	NZ

CODE 'OD' OVERDOSE / OVERUSE		
		<i>replaces CASRML number</i>

subcategory: General		
OD01	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.	147, 148
OD02	Prolonged or excessive use may be harmful.	61, 62, 556, 625, 629
OD03	Prolonged use is undesirable and may lead to dependence.	634
OD04	[Insert approved ingredient name] is toxic in high doses.	27
OD05	WARNING – This product contains [insert approved ingredient name] which may be dangerous when used in large amounts or for a long time.	53, 54, 56, 57, 58, 59
OD06	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.	94
subcategory: Product specific / Specific substances		
OD11	CAUTION – Total iodine intake may exceed recommended level when taking this preparation.	26
OD12	WARNING – Vitamin A can cause birth defects when more than 8,000 IU is taken per day.	32

CODE ‘PB’ PREGNANCY / BREASTFEEDING		
<i>replaces CASRML number</i>		
subcategory: Birth defects		
PB01	WARNING – Causes Birth Defects.	20
PB02	WARNING – May Cause Birth Defects.	22
PB03	Do not become pregnant during use or within [insert number of months as per approved Product Information (PI) document] month(s) of stopping treatment.	21
PB04	[This product/insert name of product] remains in the body for many months after treatment has stopped. Consult your doctor before becoming pregnant or fathering a child.	23, 24
subcategory: Pregnancy		
1 PB11 1 PB11 a 1 PB11 b	Do not use if you are pregnant. Do not use if you are pregnant <i>except on doctor’s advice.</i> Do not use if you are pregnant <i>except on doctor’s or pharmacist’s advice.</i>	13, 14, 15, 16, 17, 19, 25 133, 135, 580, 610
1 PB12 1 PB12 b	Do not use if you are likely to become pregnant. Do not use if you are likely to become pregnant <i>except on doctor’s or pharmacist’s advice.</i>	720, 14

1 PB13 <i>b</i>	Do not use if you are considering becoming pregnant <i>except on doctor's or pharmacist's advice.</i>	33
1 PB14	Do not use in the last 3 months of pregnancy.	18
subcategory: Breastfeeding		
1 PB51	Do not use if you are breastfeeding.	15, 610
1 PB51 <i>a</i>	Do not use if you are breastfeeding <i>except on doctor's advice.</i>	17, 558, 580, 659

CODE 'SE' SIDE EFFECTS		
<i>replaces CASRML number</i>		
subcategory: Allergic reaction		
SE01	WARNING – [This product/ <i>insert name of product</i>] can cause severe allergic reactions.	568, 571
SE02	This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers.	576
subcategory: Skin		
SE10	This product may make your skin more sensitive to sunlight.	93, 587
SE11	Overuse may stain skin or mouth.	106, 107
SE12	Transient stinging or irritation may occur when using this product.	590
SE13	Darkening of the skin may occur.	629
SE14	WARNING – If a pigmented spot or mole has recently become darker, changed colour, become enlarged or itchy, or bleeds, do not use this product, see your doctor immediately.	113
subcategory: Sedation		
SE21	This product may cause drowsiness and may increase the effects of alcohol.	46, 48
SE22	Although the medicine is unlikely to affect your ability to drive or operate machinery, a few people may be impaired and care should be taken.	158
SE23	If affected do not drive a vehicle or operate machinery.	49, 50, 503
SE24	This preparation is an aid to sleep. Drowsiness may continue the following day.	501, 502
SE25	Be cautious about driving a vehicle or operating machinery within 8 hours of taking this medicine.	NZ

<i>subcategory: Miscellaneous</i>		
SE101	WARNING – Can cause elevated blood pressure.	39
SE102	WARNING: <i>[insert approved ingredient name]</i> may harm the liver.	125, 153, 157, 534
SE103	This product may have a laxative effect or cause diarrhoea.	134, 564, 574, 523
SE104	<i>[Insert approved ingredient name]</i> may cause sleeplessness if it is taken up to several hours before going to bed.	618

2.2 *Statements proposed to be removed*

It is proposed that the statements shown in the table below are not necessary and can be removed. The circumstances for requiring many of these do not fit into a medicines environment. Other statements are not directed to the end user, or are redundant.

STATEMENTS PROPOSED TO BE REMOVED	<i>CASRML number</i>
A lower maintenance dose should be used once full effect is obtained.	615
Adults only.	522
Application to skin may increase sensitivity to sunlight.	93
Attacks skin and eyes.	86
Causes severe burns, which are not likely to be immediately painful or visible.	101, 108
Consult a doctor/pharmacist before use if you are taking any other medication for osteoporosis.	717
Contact with eyes even for short periods can cause blindness.	100
Do not mix with hot water.	109
Do not use in conjunction with heat pads.	510
Even if you feel well there is a risk of delayed, serious liver damage.	147
For temporary relief of symptoms only.	512
High fibre products may interact with other medicines by altering their absorption.	718
Highly corrosive.	99
If inhaled, remove from contaminated area.	520
If skin or hair contact occurs, immediately remove contaminated clothing and wash with running water.	514, 515, 518, 521, 710
If sprayed in mouth, rinse with water.	517
If swallowed or inhaled, remove from contaminated area. Apply artificial respiration if not breathing. Do not give direct mouth-to-mouth resuscitation. To protect rescuer, use air-viva, oxy-viva or one way mask. Resuscitate in a well-ventilated area.	519, 650, 651, 673, 688
If swallowed, give activated charcoal if instructed.	528
Obtain a supply of calcium gluconate gel.	102
The dose should be reduced if tea, coffee or other products containing caffeine are taken.	595
The presence of the antibacterial/antimicrobial/antiseptic agent in this product has not been shown to have a beneficial effect on the severity or duration of a sore throat.	511
Then apply calcium gluconate gel.	507
This product should be used with caution on infants, small children, pregnant or breastfeeding women.	636
Urgent hospital treatment is likely to be needed.	578
WARNING - May be fatal to children.	12

Part 3 - How the electronic ANZTPA RASML database works

It is intended that the statements will exist as an electronic database. In the longer term, it may be possible to link this database to the various registries, such as the ANZTPA Electronic Licensing Facility (ELF) for Class 1 medicines, and the Class 2 OTC and Prescription medicines licensing systems, so that just one central repository of statements needs to be managed. For example in ANZTPA ELF, the required advisory statements could appear on-screen as the validation of a lodgement proceeds. There will not be a “paper” RASML document, however it is anticipated that a print facility will be available from the database.

It is intended that users will key an ingredient or indication into an internet based search facility on the ANZTPA website, and, after selecting the applicable condition, the screen will readily display the actual required advisory statement(s) for the chosen ingredient/indication, and its date of effect.

The coding system is not intended to be used by sponsors, though there will be the occasional reference to a ‘code’ in the “condition” applying to a particular ingredient. The database and search facility are intended to eliminate the requirement to look up various codes, such as the statement numbers in the current RASML or CASRML documents. However, it will still be possible to look up a code for its associated statement.

3.1 Example of the electronic ANZTPA RASML database

When a user enters the name of an ingredient into the database search facility, the required advisory statement for that ingredient will appear on the screen in the following format:

Enter ingredient
name(s):

Ingredient Name

Screen returns:

Ingredient Name	
Conditions that apply	
Code	Required advisory statement.

3.2 Examples

1. Arachis Oil

Enter ingredient name(s):

Arachis oil

Screen returns:

Arachis oil	
All medicines. Note: statement should include the word “peanut”.	
CO01	Contains [insert name of ingredient or label-AAN for Grouping Name if two or more ingredients from the same ingredient Group are included in the medicine].

2. Clobetasone

Enter ingredient name(s):

Clobetasone

Screen returns

Clobetasone	
In medicines for dermal use: <ul style="list-style-type: none"> • as a single active ingredient; and • containing less than 0.05 per cent of clobetasone; and • in packs containing 30 g or less of the preparation. 	
CO01	Contains [insert name of ingredient or label-AAN for Grouping Name if two or more ingredients from the same ingredient Group are included in the medicine].

3. Clotrimazole

Enter ingredient name(s):

Clotrimazole

Screen returns:

Clotrimazole	
(a) In preparations for vaginal use. (b) Unless (a) above applies, in OTC medicines for topical use.	
(a) 1CP19a, CP26, CP201, CP217, PB11a	(a) Do not use if you have diabetes except on doctor's advice. Consult a doctor before use for the first time. Consult a doctor if the problem returns. Consult your doctor if symptoms/condition persist(s) for more than x days. [x = number of days in approved Product Information (PI) document]. Do not use if you are pregnant, unless a doctor has told you to.
(b) DU11	(b) The product should be used for 14 days after symptoms disappear.

Note that the user can select the appropriate condition [either (a) or (b)] and the screen will only show the advisory statements that apply to that condition for this ingredient.

4. Laxative, use as a

Enter ingredient name(s):

Laxative, use as a

Screen returns:

Laxative, use as a	
When included in an OTC medicine. <ul style="list-style-type: none"> • OD03 is not required when the medicine is a bulk forming laxative. • 1CP14, 1CP15, 1CP16, 1CP17, 1PB11a and 1PB51a are not required unless the medicine includes aloe, senna or cascara as an active ingredient. 	
1CP14 1CP15 1CP16 1CP17	Do not use if you have diarrhoea or develop diarrhoea Do not use if you have abdominal pain Do not use if you have nausea Do not use if you are vomiting

8CP203	Consult a doctor/pharmacist/healthcare professional if symptoms/condition persist(s).
GM108	Drink plenty of water. Increase fibre in diet except in cases of medication induced constipation.
OD03	Prolonged use is undesirable and may lead to dependence.
1PB11a	Do not use if you are pregnant except on doctor's advice.
1PB51a	Do not use if you are breastfeeding except on doctor's advice.

An example of the model screen is shown below. Please note that this example is to illustrate the format concept only.

Find Ingredient: Laxative, use as a

Conditions: 4

- When included in an OTC medicine

When included in an OTC medicine

Required advisory statements:

1CP14	Do not use if you have diarrhoea or develop diarrhoea
1CP15	Do not use if you have abdominal pain
1CP16	Do not use if you have nausea
1CP17	Do not use if you are vomiting
8CP203	Consult a healthcare professional if symptoms/condition persist(s) or worsens
GM108	Drink plenty of water.
OD03	Prolonged use is undesirable and may lead to dependence.
1PB11a	Do not use if you are pregnant except on doctor's advice
1PB51a	Do not use if you are breastfeeding except on doctor's advice

3.3 Searching by Code

Users will also be able to enter a code, and discover its associated required advisory statement:

Enter code: Prefix Statement Suffix

1 CP25 c

returns:

Code	Required advisory statement(s)
1CP25c	Do not use if you have a stomach ulcer except on the advice of a healthcare professional.

However, it is envisaged that the codes will mainly be used as a management tool by ANZTPA expert advisory committees.

3.4 Statements and codes that do not exist

If a user enters an ingredient which does not have an associated advisory statement, or a code which does not yet exist, the database will return a null result, for example: the code does not exist / a statement has not been required:

Code	Required advisory statement(s)
9XX25z	An advisory statement does not exist for this code.

OR

Code	Required advisory statement(s)
28ZZ66y	This code does not exist.

OR

Ingredient name	Required advisory statement(s)
Sodium cromoglycate	An advisory statement has not (yet) been considered necessary for this ingredient.

OR

Ingredient name	Required advisory statement(s)
Bisalton	This ingredient does not exist / An ingredient was not found under this name.

Part 4 - Medicines to which advisory statements apply

Glossary and Interpretation

4.1 Explanation of acronyms and other terms

Pink indicates definition and/or acronym that will require revision when other documents become available

Term	Definition/Interpretation
Act	
ANZTPA	Australia New Zealand Therapeutic Products Authority.
child-resistant closure	Will align with ANZTPA packaging order
child-resistant packaging	Will align with ANZTPA packaging order
Class 1 medicine	Will align with the Medicine Rule
Class 2 medicine	Will align with the Medicine Rule
complementary medicine	Will align with the Medicines Rule
concentration, strength or quantity	<p>Unless the contrary intention appears, where a concentration, strength or quantity is specified in Part 4 of this document in respect of a substance:</p> <p>(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 Part 4; and</p> <p>(b) the expression “one per cent” means:</p> <p>(i) in the case of a liquid preparation, 1 gram of the substance per 100 mL of the preparation; or</p> <p>(ii) in the case of a solid or semi-solid preparation, 1 gram of the substance per 100 grams of the preparation; and</p> <p>(iii) any expression of greater or lesser percentages shall have a corresponding meaning; and</p> <p>(c) in the case of codeine, such concentration, strength or quantity is calculated as anhydrous codeine.</p>
container	<p>Note: will align with the definition in the Administration and Interpretation Rule:</p> <p><i>container, in relation to a therapeutic product, means an article that immediately covers the product, 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.</i></p>

Term	Definition/Interpretation
dermal use	means application to the skin primarily for localised effect. <i>Will need to align with the SUSMP.</i>
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.
existing products	<i>Will refer to products on the ANZTPA register (which will hold products previously on ARTG and on SMARTI)</i>
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).
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	<i>Note - will align with the definition used in the Administration and Interpretation Rule: label, in relation to a therapeutic product, means a display of printed information about the product: (a) on, or attached to, the product; or (b) on, or attached to, a container or primary pack in which the product is supplied; or (c) otherwise intended to be supplied to consumers with such a container or pack.</i>
Labelling Order	<i>Will align with name of ANZTPA order.</i>
Medicine Rule	<i>Will align with the Act or Medicine Rule</i>
mg	milligram(s).
mL	millilitre(s).
MSC	<i>Medicine Scheduling Committee. Note – will align with Administration and Interpretation Rule.</i>
non-prescription medicine	means a medicine regulated by either the Office Of OTC Medicines or the Office of Complementary Medicines of the ANZTPA (i.e. an OTC medicine, or a complementary medicine).
OTC	means ‘Over the Counter’.
OTC medicine	means a medicine regulated by the Office of OTC Medicines of the ANZTPA.
PLR	<i>Product Licence Register – meaning the ANZTPA register of licensed therapeutic products.</i>
ppm	means parts per million.

Term	Definition/Interpretation															
primary pack	<p>Note - Will align with the Administration and Interpretation Rule:</p> <p><i>primary pack, in relation to a therapeutic product, means the complete pack in which the product is, or the product and its container are, to be supplied to consumers.</i></p>															
RASML	<p><i>Required Advisory Statements for Medicine Labels</i> edition 1 as amended from time to time.</p>															
restricted flow insert	<p>means a restriction fitted, or moulded, in the neck of a container which:</p> <p>(a) cannot be readily removed from the container by manual force; and</p> <p>(b) limits the delivery of the contents to drops each of which is not more than 200 microlitres.</p> <p>Note – needs to align with ANZTPA packaging order</p>															
signal heading	<p>means the signal word or words relating to the Schedule to the SUSMP in which the substance is included and the purpose for which it is to be used, as shown in the following table:</p> <table border="0" data-bbox="391 862 1380 1108"> <thead> <tr> <th data-bbox="391 862 518 896">Schedule</th> <th data-bbox="518 862 821 896">Purpose</th> <th data-bbox="821 862 1380 896">Signal Words Required</th> </tr> </thead> <tbody> <tr> <td data-bbox="391 907 518 940">2</td> <td data-bbox="518 907 821 940">for any purpose</td> <td data-bbox="821 907 1380 940">PHARMACY MEDICINE</td> </tr> <tr> <td data-bbox="391 952 518 985">3</td> <td data-bbox="518 952 821 985">for any purpose</td> <td data-bbox="821 952 1380 985">PHARMACIST ONLY MEDICINE</td> </tr> <tr> <td data-bbox="391 996 518 1030">4</td> <td data-bbox="518 996 821 1030">for human use</td> <td data-bbox="821 996 1380 1030">PRESCRIPTION ONLY MEDICINE</td> </tr> <tr> <td data-bbox="391 1041 518 1075">8</td> <td data-bbox="518 1041 821 1075">for any purpose</td> <td data-bbox="821 1041 1380 1075">CONTROLLED DRUG.</td> </tr> </tbody> </table> <p>2,3,4,8 Note – will align with SUSMP. KEEP OUT OF REACH OF CHILDREN</p>	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	8	for any purpose	CONTROLLED DRUG.
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														
8	for any purpose	CONTROLLED DRUG.														

Term	Definition/Interpretation
substance	<p>Unless the contrary intention appears, a reference to a substance in Part 4 of this document includes:</p> <ul style="list-style-type: none"> (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 SUSMP), 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; (f) every recombinant form of the substance; and (g) a preparation or admixture containing any proportion of the substance, <p>but does not include:</p> <ul style="list-style-type: none"> (h) a preparation or product included in Appendix A of the SUSMP, or a substance and the reason for its entry in Appendix B of the SUSMP; or (i) any other substance included in Schedules 1 to 4 of the SUSMP, 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 SUSMP. <p>Note – It is anticipated that the wording will align with the SUSMP and be applicable to both AUS and NZ.</p>
supply	<p>Will align with the Medicine Rule</p> <p><i>‘supply’ includes:</i></p> <ul style="list-style-type: none"> (a) <i>supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase; and</i> (b) <i>supply, whether free of charge or otherwise, by way of sample or advertisement; and</i> (c) <i>supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods in persons or animals; and</i> (d) <i>supply by way of administration to, or application in the treatment of, a person or animal.</i>
SUSMP	<p><i>Standard for the Uniform Scheduling of Medicines and Poisons.</i></p>
topical use	<p>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.</p> <p>Will align with SUSMP.</p>
µg	<p>microgram(s).</p>
µL	<p>microlitre(s).</p>

Guidance

4.2 *Application to Medicines*

Advisory statements apply to all medicines for supply in Australia and New Zealand (i.e. Class 1, Class 2 and exempt medicines).

These statements apply IN ADDITION to the requirements of the << insert name of ANZTPA Medicine Labelling Order when finalised >>.

The specific legislation requiring labels to have Signal headings is still under review, but it is expected that there will be mandatory requirements for labels of scheduled medicines in Australia and New Zealand. Licence holders should refer to the most recent edition of the SUSMP for further information.

4.3 *Date of Effect*

Unless otherwise specified in this document, the requirements apply:

- in relation to products moving from a transitional licence to a full ANZTPA licence, from the date of commencement of the full ANZTPA licence;
- in relation to applications for new products during the transitional period, from the commencement of the joint regulatory scheme;
- in relation to applications for new products after the end of the transitional period, from the Date of effect (shown in the date column next to the relevant entry);
- in relation to a newly crafted statement required after the end of the transitional period, from a date 12 months from the Date of effect (shown in the date column next to the relevant entry).

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.

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. Licence holders should contact the relevant Regulator directly in this regard, and provide a justification for the need to overstick.

4.4 *Looking up a code*

The required advisory statements have been categorised and are presented in the following sequence:

Code	Category
AG	Age Related Use
CO	Product Contents
CP	Contraindications and Precautions
DR	Directions
DS	Dosage Statements
DU	Duration of Use

GM	General and Miscellaneous
IN	Interactions
OD	Overdose/Overuse
PB	Pregnancy/Breastfeeding
SE	Side Effects

When looking up a code for a statement in Part 2, use the category code first (e.g. CP). The codes within the category will be in numerical order (e.g. CP01, CP02, CP03 etc). The prefix and suffix (e.g. **1CP04a**, as bolded) do not influence the order of the codes.

4.5 What Needs to be Included on the Label

The advisory statement(s) indicated by the code in the requirements column of the table need(s) to be included on the labels of relevant medicines.

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

4.6 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.

4.7 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.

4.8 General requirements

These requirements apply in addition to any other requirements imposed by this document. In the event of a conflict between requirements, the more restrictive requirement prevails to the extent of the inconsistency.

Category of medicine	Requirements	Date
All Class 2 medicines.	GM01	
Vitamins - all medicines that contain vitamins for oral use.	GM105	
<p>All non-prescription medicines that:</p> <p>(a) have indications relating to symptoms of diseases, disorders or conditions, either directly or by implication;</p> <p>(b) are Class 1 medicines where any coded indication includes any one or more of the words or phrases:</p> <ul style="list-style-type: none"> • Aid(s); • Assist(s); • Help(s); • Symptomatic relief; • Symptomatic treatment; • relieves [symptom(s) or nominated symptom(s)]; • relief of [symptom(s) or nominated symptom(s)]; • temporary relief; • symptom(s) or nominated symptom(s); • May reduce; • May aid; • May assist; <p>(c) are Class 1 medicines where any non-coded indication directly or indirectly uses or implies any of the terms shown in (b) above;</p> <p>(d) are OTC medicines indicated for:</p> <ul style="list-style-type: none"> • Treatment of haemorrhoids; • Mouth ulcer relief; • Use as nasal decongestants; <p>Use as nasal decongestants.</p>	8CP203	
Where the medicine is known to interact with rubber.	GM13	
All corticosteroids intended for nasal inhalation.	4CP33, 4CP34, 4CP35, 3CP108, 7CP215, 8CP253, 8CP254, 8CP255, 1DU06b,	

Category of medicine	Requirements	Date
	DS03a	
All medicines that are antihistamines.	SE25	
All medicines that are non-sedating antihistamines (except cetirizine, in which case SE25 is required).	SE22	
When a claim is made that the medicine is an anxiolytic or anti-insomnia medicine.	2AG07, DU13, DS03, 6CP256, SE25, SE22	
Class 2 OTC medicines containing an active ingredient that is included in a pregnancy category other than category A (refer to the ADEC publication Prescribing medicines in pregnancy, available at www.tga.gov.au/docs/pdf/medpreg/pdf)	1PB11b, 1PB12b	
Class 2 OTC medicines where the label only includes doses for adults and/or children over a specified age.	2AG09, or if the product has an approved Product Information (PI) document, 2AG09a	

4.9 Requirements for Class 1 medicines by Indication.

In addition to any applicable general requirements (above) and any applicable ingredient-specific requirements (below), Class 1 medicines must meet the following requirements if applicable. In the event of a conflict between requirements, the more restrictive requirement prevails to the extent of the inconsistency.

Indication	Class 1 Medicine Standard Indication(s)	Requirements	Date
Bronchitis, relief of symptoms of	<ul style="list-style-type: none"> • Temporary relief of the cough of bronchitis. (or) Temporary relief of bronchial cough. [BRCH1] • Relief of the cough of bronchitis. (or) Relief of bronchial cough. [BRCH2] • Temporary relief of cough due to bronchial congestion. [BRCH3] • Temporary relief of cough due to bronchial irritation. [BRCH4] • Temporary relief of bronchial cough by soothing bronchial airways. [BRCH5] 	2AG04a or GM02	
Colds (upper respiratory tract infections), <i>See also:</i> <ul style="list-style-type: none"> • Coughs; • Influenza; 	<ul style="list-style-type: none"> • Relief of the symptoms of colds. [COLD1] • May help reduce the severity of the symptoms of colds. [COLD2] • May reduce the severity of colds. [COLD4] • May reduce the duration of colds. [COLD5] • May reduce the severity and duration of colds. [COLD6] • For relief of mucous congestion.[COLD7] • For the symptomatic relief of upper respiratory tract infections. [COLD9] • May assist in the management of upper respiratory tract infections. [COLD10] • Relief of mucous congestion. [MUC] • Relief of symptoms of mild upper respiratory infections. [RESP1] • Helps fight mild upper respiratory complaints. [RESP2] • Treatment of upper respiratory tract infections. [RESP3] • Treatment of symptoms of mild infections of upper respiratory tract. [RESP4] • For the symptomatic relief of recurrent upper respiratory tract infections. [RESP5] • May assist in the management of recurrent upper respiratory tract infections. [RESP6] 	2AG04a or GM02	

Indication	Class 1 Medicine Standard Indication(s)	Requirements	Date
Constipation	<ul style="list-style-type: none"> • Aids or assists in the relief of constipation. [CONST1] • Aids or assists in the treatment of constipation. [CONST2] • For the symptomatic relief of constipation. [GAST7] • May assist in the management of constipation. [GAST12] • Laxative. Aids or assists in the prevention of constipation. [LAX1] • A bulk producing laxative (fibre supplement) for the maintenance of regularity. [LAX5] 	GM108 Note: OD02 is also required if the formulation does not contain a bulk forming agent.	
Coughs <i>See also:</i> <ul style="list-style-type: none"> • Colds(<i>upper respiratory tract infections</i>) • Influenza 	<ul style="list-style-type: none"> • Temporary relief of coughs. [COU1] • Relief of coughs. [COU2] • Temporary relief of cough and sore throat. Sedating action on the coughing reflex. [COU3] 	2AG04a or GM02	
Cystitis, relief of symptoms of	<ul style="list-style-type: none"> • Relief of the pain and burning sensation associated with cystitis. [CYST] 	6CP213, 6CP251	
Diarrhoea	<ul style="list-style-type: none"> • Relief or treatment of diarrhoea. [DIAR2] 	6CP210, 6CP211, 6CP212, 6CP213	
Fluid retention	<ul style="list-style-type: none"> • Aids or assists in the treatment of fluid retention. [FLRET1] • Diuretic. Aids or assists in the treatment of fluid retention. [FLRET2] 	8CP203	
Haemorrhoids	<ul style="list-style-type: none"> • Relief of the discomfort of haemorrhoids by local application. [HAEM1] • Bulk laxative of indirect benefit to people suffering from haemorrhoids. [HAEM2] 	GM108	
Influenza <i>See also:</i> <ul style="list-style-type: none"> • Coughs; • Colds(<i>upper respiratory tract infections</i>) 	<ul style="list-style-type: none"> • Relief of the symptoms of influenza/flu. [FLU1] • Can assist in the treatment of flu by reducing the severity and duration of symptoms. [FLU2] • Relief of the pain of influenza/flu. [FLU3] • Relief of the fever of influenza/flu. [FLU4] • Treatment of colds/flu. [FLU5] 	2AG04a or GM02	

Indication	Class 1 Medicine Standard Indication(s)	Requirements	Date
Neural tube defect, prevention of	<ul style="list-style-type: none"> • Provides a daily dose of 400-500mcg of folic acid or folate. Contains folic acid which, if taken daily for one month before conception and during pregnancy, may reduce the risk of women having a child with birth defects of the brain and/or spinal chord such as the neural tube defects known as spina bifida and anencephaly. [NEUR1] • Provides a daily dose of 400-500mcg of folic acid or folate. Contains folic acid which, if taken daily for one month before conception and during pregnancy, may reduce the risk of having a child with spina bifida/neural tube defects. [NEUR2] 	3CP29, DS03	
Sunscreen, use as a	<ul style="list-style-type: none"> • A broad spectrum suncreening preparation of SPF30+. May assist in preventing some skin cancers. [SUNSC1] • A broad spectrum suncreening preparation of SPF30+. May reduce the risk of some skin cancers. [SUNSC2] • A broad spectrum suncreening preparation of SPF30+. Can aid in the prevention of solar keratoses. [SUNSC3] • A broad spectrum suncreening preparation of SPF30+. Can aid in the prevention of sunspots. [SUNSC4] 	GM44, GM45	

4.10 Requirements for OTC medicines by Indication.

In addition to any applicable general requirements (above) and any applicable ingredient-specific requirements (below), OTC medicines must meet the following requirements if applicable. In the event of a conflict between requirements, the more restrictive requirement prevails to the extent of the inconsistency.

Indication	Condition	Requirements	Date
Bath oil, use as a	All OTC medicines for use as bath oils.	GM103	
Burn treatments	All OTC medicines indicated for treatment of burns.	GM110	
Corns, treatment of	All OTC medicines indicated for treatment of corns	1CP19, 1CP20, 2AG01a	
Decongestant, oral	Refer – Oral decongestant, use as an		
Diarrhoea, treatment of	All OTC medicines indicated for treatment of diarrhoea, labelled for use in: (a) infants aged 0-6 months; and/or (b) infants and children aged 6 months to 3 years; and/or (c) children aged 3 to 6 years; and/or (d) persons over 6 years of age.	(a) 6CP211 (b) 6CP211 (c) 6CP212 (d) 6CP213	
Ear drops, use as	All OTC medicines intended for use as ear drops	3CP28	
Eye drops, use as	When the eye drops include a vasoconstrictor	1CP21, 3CP106, OD02	
Head lice, treatment of	All OTC medicines indicated for the treatment of head lice.	2AG02a, GM54, GM109	
Laxative, use as a	When included in an OTC medicine. <ul style="list-style-type: none"> OO03 is not required when the medicine is a bulk forming laxative. 1CP14, CP15, 1CP16, 1CP17 and 1PB11a, 1PB51a are not required unless the medicine includes aloe, senna or cascara as an active ingredient. 	1CP14, CP15, 1CP16, 1CP17, GM108, OD03, 1PB11a, 1PB51a	
Oral decongestant, use as an	For oral use; and <ul style="list-style-type: none"> the active ingredient is a sympathomimetic amine other than pseudoephedrine 	4CP30, 4CP31, 4CP103, 1CP105c	
Paediatric use	In medicines labelled for use in infants aged 0-6 months: (a) if the medicine is not absorbed and the condition is self-limiting; (b) in any other case.	(a) 2AG02b (b) 2AG02a	

Indication	Condition	Requirements	Date
Paediatric use containing cough suppressants	In OTC medicines containing a cough suppressant and: (a) labelled for use in infants aged 0-12 months; and/or (b) labelled for use in infants aged 12-24 months; or (c) where there is no dose for children less than 2 years of age on either the label or the ANZTPA approved published Product Information (PI) document.	(a) 2AG03 (b) 2AG04a (c) 2AG04	
Paediatric use for cold & flu relief	In OTC medicines for cold and flu relief and: (a) labelled for use in infants aged under 2 years; and (b)(i) if labelled for use in infants aged 0-6 months; or (b)(ii) where there is no dose for children less than 6 months of age on either the label or the ANZTPA approved published Product Information (PI) document.	(a) 2AG05 (b)(i) 2AG04a (b)(ii) 2AG02	
Urinary Alkalinisers	In OTC medicines.	4CP30, 4CP31, 2CP52, 8CP203, 6CP213, 6CP251, 2AG07a, 1DU03a	
Warts, treatment of	All OTC medicines intended for use as wart treatments	1CP19, 1CP20, DR60	

4.11 Ingredient-Specific Requirements

In addition to any applicable general requirements or requirements dependant upon particular indications (above), medicines must meet the following ingredient-specific requirements if applicable. In the event of a conflict between requirements, the more restrictive requirement prevails to the extent of the inconsistency.

Ingredient	Conditions	Requirements	Date
Acetone	(a) In a medicine (other than for internal use) in a concentration greater than 25 per cent; and (b) In addition to the requirements of (a) above, if the concentration of acetone is greater than 75 per cent.	(a) GM21, GM50, GM51 (b) GM23, GM34, GM33, DR00	
Acitretin	In concentrations greater than 10 mg/kg or 10 mg/L.	1PB11, PB03, PB01	
Activated charcoal	All Class 1 medicines.	DU13, IN01, IN03	
Adapalene	In concentrations greater than 10 mg/kg or 10 mg/L.	1PB11, PB02	
Ademetionine in the form of sulfate salts, tosylate salts or mixed sulfate and tosylate salts	All Class 1 medicines.	1CP24c, 1CP105c, 1CP105c	
(S)-S-Adenosylmethionine in the form of sulfate salts, tosylate salts or mixed sulfate and tosylate salts	All Class 1 medicines.	1CP24c, 1CP105c, 1CP105c	
Alclometasone	In medicines for dermal use: <ul style="list-style-type: none"> • as a single active ingredient; and • containing less than 0.05 per cent of clobetasone; and • in packs containing 30 g or less of the preparation. 	1CP01, 2AG04a, GM34, 1DR59, 1DU04a	
Almond oil	All medicines when included as an excipient. For CO01, the declaration is “Tree nuts” or “Tree nuts products”.	CO01	

Ingredient	Conditions	Requirements	Date
<i>Aloe barbadensis</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
<i>Aloe ferox</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
<i>Aloe peryi</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	

Ingredient	Conditions	Requirements	Date
<i>Aloes barbados</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
<i>Aloes cape</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
Alpha hydroxy acids	In OTC medicines for topical use.	1DR51, GM45, 2AG01, GM57, SE10, SE12	
Ammonia	<p>(a) In medicines:</p> <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 0.5 per cent of free ammonia. <p>(b) Regardless of whether (a) above applies, in addition to those requirements (if any) in products containing more than 20 per cent of ammonia.</p>	<p>(a) GM50, GM51, GM54</p> <p>(b) GM23, GM34, GM33</p>	

Ingredient	Conditions	Requirements	Date
<p>Anaesthetics, local <i>See also</i></p> <ul style="list-style-type: none"> • <i>Individual ingredient entries</i> 	<p>(a) In OTC medicines for dermal use.</p> <p>(b) In OTC medicines that are sore throat lozenges.</p>	<p>(a) 6CP252, GM57</p> <p>(b) GM41</p>	
Anise oil	<p>(a) In medicines containing more than 50 per cent anise oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 50 mL and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM01</p> <p>(b) GM50, GM51</p>	
Anthelmintics	In OTC medicines	8CP203, GM107	
Antifungals	In OTC medicines for topical use	DU11	

Ingredient	Conditions	Requirements	Date
Antihistamines, unless separately specified	<p>(a) If the antihistamine is included in a Schedule to the SUSMP; and</p> <ul style="list-style-type: none"> • The medicine is <ul style="list-style-type: none"> • Not for dermal, ocular, parenteral or paediatric use; and • Is not an oral preparation of astemizole, desloratadine, fexofenadine, loratadine or terfenadine or a nasal preparation of azelastine. <p>(b) Regardless of whether (a) above applies, if an OTC medicine is indicated for short term use to relieve occasional insomnia.</p> <p>(c) If the medicine is a paediatric preparation: <ul style="list-style-type: none"> (i) labelled for use in infants 0-6 months; or (ii) labelled for use in infants 6-24 months; or (iii) labelled for use in children aged 2-11 years and indicated for sedation; or (iv) where there is no dose for children less than 2 years of age on either the label or the ANZTPA approved published Product Information (PI) document. </p> <p>(d) If the medicine is a non-sedating antihistamine (except cetirizine):</p>	<p>(a) SE21, SE25, GM42</p> <p>(b) <ul style="list-style-type: none"> • 3CP26, DU13, 1PB11, 1PB51, SE25, SE24, GM42; and • GM104 unless this information is provided in a package insert supplied with the product, </p> <p>(c)(i) 2AG02a</p> <p>(c)(ii) 2AG02, 2AG05</p> <p>(c)(iii) 2AG07b</p> <p>(c)(iv) 2AG04</p> <p>(d) SE22</p>	
Antimony compounds	<p>Inorganic antimony compounds:</p> <ul style="list-style-type: none"> • in concentrations greater than 10 mg/kg or 10 mg/L; and • in medicines other than: <ul style="list-style-type: none"> • those for internal use ;or • those included in Schedule 3, 4 or 8 of the SUSMP: 	GM50	
<i>Arachis hypogaea</i>	All medicines when included as an excipient. For CO01, the declaration is “Peanut” or “Peanut products”	CO01	
Arachis (peanut) oil	All medicines when included as an excipient. For CO01, the declaration is “Peanut” or “Peanut products”	CO01	
Arginine	In Class 1 medicines for application to the skin	1DR52, 1DR57, GM11	
Aspartame	In medicines for oral use when included as an excipient.	CO01	

Ingredient	Conditions	Requirements	Date
Aspirin	<p>(a) In medicines:</p> <ul style="list-style-type: none"> • indicated only for the prevention of cardiovascular disease or for inhibition of platelet aggregation; or • in sustained release preparations containing 650 mg or more of aspirin. <p>(b) In medicines to which (a) above does not apply, except:</p> <ul style="list-style-type: none"> • 3CP109 and 3CP110 are not required if: <ul style="list-style-type: none"> • the preparation is indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation; or • aspirin is in combination with other therapeutically active substances (other than an effervescent agents); • 1PB14 and 1PB11a are not required when the medicine is indicated exclusively for treatment of dysmenorrhoea. 	<p>(a) 3CP26</p> <p>(b) 1CP25, 1CP11, 1CP18a, 1CP101a, 1CP102a, 1CP103a, 3CP109, 3CP110, 2AG07a, 2AG10a, 1DU02a, 1PB14, 1PB11a</p>	
<i>Avena fatua</i>	In medicines for internal use when included as an excipient, except if the medicine contains no detectable gluten and contains no oats or malt.	CO01	
<i>Avena sativa</i>	In medicines for internal use when included as an excipient, except if the medicine contains no detectable gluten and contains no oats or malt.	CO01	
<i>Azadirachta indica</i>	<p>(a) In Class 1 medicines.</p> <p>(b) In Class 2 medicines, other than:</p> <ul style="list-style-type: none"> • for internal use; • when the medicine is included in Schedules 3, 4 or 8 of the SUSMP; • in preparations containing 1 per cent or less of cold pressed neem seed oil. 	<p>(a) GM21, GM01, 1PB11, 1PB12</p> <p>(b) GM54, GM50, 1PB11, 1PB12</p>	
<i>Backhousia citriodora</i>	All Class 1 medicines.	2AG07, GM57, 1PB11, 1PB51	

Ingredient	Conditions	Requirements	Date
Basil oil	<p>(a) In medicines containing more than 5 per cent methyl chavicol.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 25 mL and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM01</p> <p>(b) GM50, GM51</p>	
Bay oil	<p>(a) In medicines containing more than 25 per cent of bay oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
Beclomethasone	In OTC medicines for use as a nasal spray, unless this information is provided in a package insert supplied with the product in which case US00 is required.	4CP33, 4CP34, 4CP35, 8CP253, 8CP254, 8CP255, 7CP215, DS03, 1DU06a	
Benzalkonium chloride	<p>In medicines:</p> <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 5 per cent of benzalkonium chloride 	GM50, GM51, GM54, GM55,	
Benzoates	All medicines when included as an excipient.	CO01	

Ingredient	Conditions	Requirements	Date
Benzoic acid	All medicines when included as an excipient.	CO01	
Benzoyl peroxide	In medicines for external use containing not more than 10 per cent of benzoyl peroxide.	8CP203, GM23, 1DR58, GM50, GM57	
Bergamot oil	All medicines	SE10	
Bexarotene	(a) In medicines for topical use. (b) In medicines other than for topical use.	(a) 1PB11, PB03, PB01 (b) 1PB11, PB02	
Bifonazole	In OTC medicines for topical use.	DU11	
Borax	In medicines: <ul style="list-style-type: none"> other than for internal use where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and containing more than 10 mg/kg or 10 mg/L of borax. 	GM50	
Boric acid	In medicines: <ul style="list-style-type: none"> other than for internal use where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and containing more than 10 mg/kg or 10 mg/L of boric acid 	GM50	
Bosenatan	In concentrations greater than 10 mg/kg or 10 mg/L	1PB11, PB03, PB01	
Bovine colostrum powder	All Class 1 medicines. Note: For CO02 the components to declared are lactose and cow's milk protein.	CO02, 2AG03a	
Bovine lactoferrin	All Class 1 medicines. Note: Source to be declared is cow's milk.	CO06	
Budesonide	In OTC medicines for use as a nasal spray, unless this information is provided in a package insert supplied with the product in which case US00 is required.	4CP33, 4CP34, 4CP35, 8CP253, 8CP254, 8CP255, 6CP216, DS03, 1DU06a	
Butyl esters of PVM/MA copolymer	All Class 1 medicines.	GM34, GM35	
Butyl hydroxybenzoate	All medicines when included as an excipient.	CO01	
Caffeine	In Class 1 medicines for oral and sublingual use as a component of <i>Paullinia cupana</i> .	CO01	

Ingredient	Conditions	Requirements	Date
Cajuput oil	<p>(a) In medicines containing more than 25 per cent of cajuput oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50</p>	
Calcium benzoate	All medicines when included as an excipient.	CO01	
Calcium sodium caseinate	All Class 1 medicines Note: Source to be declared is cow's milk.	CO06	

Ingredient	Conditions	Requirements	Date
Camphor	<p>(a) In medicines containing more than 2.5 per cent of camphor.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and if either of the following apply:</p> <ul style="list-style-type: none"> • the camphor is present as a natural component of an essential oil containing more than 2.5 per cent of camphor and: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 25 mL or • the container is not fitted with a restricted flow insert.; or • if the concentration of camphor is greater than 10 per cent and: <ul style="list-style-type: none"> • the nominal capacity of the container is greater than 15 mL; and • the container is not fitted with a child-resistant closure. <p>OR</p> <ul style="list-style-type: none"> • The camphor is not present as a natural component of an essential oil and the concentration of camphor is: <ul style="list-style-type: none"> • greater than 2.5 per cent in liquid preparations; or • greater than 12.5 per cent in solid or semi-solid preparations <p>unless the medicine:</p> <ul style="list-style-type: none"> • is enclosed in an inhaler device that prevents ingestion of its contents; or • the camphor is present as a natural component of an essential oil other than rosemary oil, sage oil Spanish. <p>(c) In addition to the requirements of (a) and (b) above, if (b) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the OTC. 	<p>(a) GM21, GM01</p> <p>(b) GM34, DR00, GM22</p> <p>(c) GM50, GM51, GM53</p>	
<i>Canarium indicum L. var indicum</i>	All Class 1 medicines. Note: Source to be declared is nuts.	CO06	

Ingredient	Conditions	Requirements	Date
Cascara Dry	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
Cascara Powder	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
<i>Cassia angustifolia</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	

Ingredient	Conditions	Requirements	Date
<i>Cassia fistula</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
<i>Cassia occidentalis</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
Cassia oil	<p>(a) In medicines:</p> <ul style="list-style-type: none"> • for dermal use as rubefacients containing more than 5 per cent of cassia oil; or • other preparations containing more than 2 per cent of cassia oil. <p>(b) In addition to (a) above, if (a) above applies and the medicine:</p> <ul style="list-style-type: none"> • is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM21, GM33</p> <p>(b) DR00, GM50, GM51,</p>	

Ingredient	Conditions	Requirements	Date
<i>Cassia senna</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
<i>Cassia tora</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
Cetirizine		SE25	
Charcoal – activated	All Class 1 medicines	DU13, IN01, IN03	
<i>Chelidonium majus</i>	In medicines for oral use, OTHER THAN homoeopathic preparations containing <i>Chelidonium majus</i> in concentrations more dilute than a 1000-fold dilution of the mother tincture.	1CP03, SE102	
Chitosan	All Class 1 medicines. Note: Source to be declared is seafood.	CO06, DR01, DR02	

Ingredient	Conditions	Requirements	Date
Chlorocresol	In medicines: <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 3 per cent of chlorocresol. 	GM50, GM51, GM54, GM55	
Chromates (including dichromates) of alkali metals or ammonia	(a) In concentrations greater than 10 mg/kg or 10 mg/L (b) In addition to the requirements of (a) above, if (a) above applies and <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	(a) GM23, GM34, GM33, DR00 (b) GM50, GM51, GM54, GM55	
Cimetidine	In pack sizes containing not more than 14 days supply of the medicine.	1CP103a, 6CP216, GM03 1CP102a, 6CP202, 3AG21, IN04, 3CP111	
<i>Cimicifuga racemosa</i>	All Class 1 medicines.	1CP03, SE102	
Cineole	(a) In medicines containing more than 25 per cent of cineole (other than rosemary oil or camphor oil). (b) In addition to the requirements of (a) above, if (a) above applies and <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	(a) GM21, GM01 (b) GM50, GM51	

Ingredient	Conditions	Requirements	Date
<i>Cinnamomum zeylanicum</i>	<p>(a) In medicines containing more than 25 per cent of cinnamon leaf oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
Cinnamon bark oil	<p>(a) In medicines containing more than 2 per cent of cinnamon bark oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM21, GM33, DR00, GM01</p> <p>(b) GM50, GM51</p>	

Ingredient	Conditions	Requirements	Date
Cinnamon leaf oil	<p>(a) In medicines containing more than 25 per cent of cinnamon leaf oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
Citronella oil	In medicines for topical use when included as an excipient.	CO01	
Clobetasone	<p>In medicines for dermal use:</p> <ul style="list-style-type: none"> • as a single active ingredient; and • containing less than 0.05 per cent of clobetasone; and • in packs containing 30 g or less of the preparation. 	1CP01, 2AG07a, GM34, 1DR59, 1DU04a	
Clotrimazole	<p>(a) In preparations for vaginal use.</p> <p>(b) Unless (a) above applies, in OTC medicines for topical use.</p>	<p>(a) 1CP19a, 3CP26, 6CP201, 6CP217, 1PB11a</p> <p>(b) DU11</p>	

Ingredient	Conditions	Requirements	Date
Clove bud oil	<p>(a) In medicines containing more than 25 per cent of clove oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and where any one or more of the following apply:</p> <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. <p>(c) In addition to the requirements of (a) and (b) above, if (b) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM21, GM01</p> <p>(b) GM34, DR00</p> <p>(c) GM50, GM51, GM54, GM55</p>	
Clove leaf oil	<p>(a) In medicines containing more than 25 per cent of clove oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and where any one or more of the following apply:</p> <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. <p>(c) In addition to the requirements of (a) and (b) above, if (b) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM21, GM01</p> <p>(b) GM34, DR00</p> <p>(c) GM50, GM51, GM54, GM55</p>	

Ingredient	Conditions	Requirements	Date
Clove oil	<p>(a) In medicines containing more than 25 per cent of clove oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and where any one or more of the following apply:</p> <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. <p>(c) In addition to the requirements of (a) and (b) above, if (b) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM21, GM01</p> <p>(b) GM34, DR00</p> <p>(c) GM50, GM51, GM54, GM55</p>	
Clove stem oil	<p>(a) In medicines containing more than 25 per cent of clove oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and where any one or more of the following apply:</p> <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. <p>(c) In addition to the requirements of (a) and (b) above, if (b) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM21, GM01</p> <p>(b) GM34, DR00</p> <p>(c) GM50, GM51, GM54, GM55</p>	
Coal tar	<p>In OTC medicines for topical use, except:</p> <ul style="list-style-type: none"> • 1US59 is not required when the medicine is a shampoo or is designed to be washed off after application. 	<p>2AG04a, 1DR59, 1PB11, 1PB51</p>	

Ingredient	Conditions	Requirements	Date
Cod	All medicines when included as an excipient. For CO01, the declaration is “Fish” or “Fish products”	CO01	
Cod – liver oil	All medicines when included as an excipient. For CO01, the declaration is “Fish” or “Fish products”	CO01	
Corticosteroids, unless separately specified	In OTC medicines for use as a nasal spray, unless this information is provided in a package insert supplied with the product in which case US00 is required.	4CP33, 4CP34, 4CP35, 8CP253, 8CP254, 8CP255, 6CP216, DS03, 1DU06a	
Crab	All medicines when included as an excipient. For CO01, the declaration is “Crustacean” or “Crustacean products”	CO01	
Creatine	All Class 1 medicines.	5DU07	
Creatine monohydrate	All Class 1 medicines.	5DU07	
Creatine phosphate	All Class 1 medicines.	5DU07	
Cresols	In medicines: <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 3 per cent in total of phenols, including cresols, xylenols or other phenol homologues with a boiling point below 220°C 	GM50, GM51, GM54, GM55	
Crustacea and Crustacean products	All medicines when included as an excipient. For CO01, the declaration is “Crustacean” or “Crustacean products”	CO01	
DEA-oleth-3 phosphate	All Class 1 medicines.	GM34, GM35	
ortho-Dichlorobenzene	(a) In medicines containing more than 10 mg/kg or 10 mg/L of ortho-dichlorobenzene. (b) In addition to the requirements of (a) above, if (a) above applies and <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	(a) GM23, GM34, GM33 (b) GM50, GM51, GM54	

Ingredient	Conditions	Requirements	Date
para-Dichlorobenzene	<p>(a) In medicines containing more than 10 mg/kg or 10 mg/L of para-dichlorobenzene.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> the medicine is not for internal use; and is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM34, GM33</p> <p>(b) GM50</p>	
Dichloromethane	<p>(a) In medicines containing more than 10 mg/kg or 10 mg/L of dichloromethane.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> the medicine is not for internal use; and is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM23, GM34, GM33</p> <p>(b) GM50, GM51, GM53, GM54</p>	
Diclofenac	<p>In medicines other than:</p> <ul style="list-style-type: none"> medicines for dermal use; or containing less than 10 mg/kg or 10 mg/L of diclofenac; <p>except:</p> <ul style="list-style-type: none"> 1PB14 and 1PB11a are not required when the medicine is indicated exclusively for treatment of dysmenorrhoea 	1CP25, 1CP11, 1CP18a, 1CP101a, 1CP102a, 1CP103a, 1DU02a, 1PB14, 1PB11a	
Diethanolamine	<p>(a) In medicines:</p> <p>(i) containing more than 5 per cent and 20 per cent or less of diethanolamine; and</p> <p>(ii) if the medicine is:</p> <ul style="list-style-type: none"> other than for internal use; and where the product is not included in Schedule 3, 4 or 8 of the SUSMP. <p>(b) In medicines:</p> <p>(i) containing more than 20 per cent of diethanolamine; and</p> <p>(ii) if the medicine is:</p> <ul style="list-style-type: none"> other than for internal use; and where the product is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a)(i) GM34, GM33, GM32</p> <p>(a)(ii) GM50, GM51</p> <p>(b)(i) GM23, GM34, GM33, GM31</p> <p>(b)(ii) GM50, GM51, GM54, GM55</p>	
Diethyltoluamide (DEET)	In concentrations greater than 10 mg/kg or 10 mg/L.	OD06	

Ingredient	Conditions	Requirements	Date
Diethylhexyl-2-6-naphthalate	All Class 1 medicines.	GM35	
Diphenoxylate	In medicines where: <ul style="list-style-type: none"> the pack size is 8 dosage units or less; and each dosage unit contains 2,5 mg or less of diphenoxylate and a quantity of atropine sulfate equivalent to at least 1 per cent of the dose of diphenoxylate. 	2AG07, 1DU01a, 1PB11a, 1PB51a, SE21, SE23, GM42	
d-Pulegone	(a) In medicines containing more than 4% d-pulegone. (b) In addition to the requirements of (a) above, if (a) above applies and <ul style="list-style-type: none"> the medicine is not for internal use; and is not included in Schedule 3, 4 or 8 of the SUSMP. 	(a) GM21, GM01 (b) GM50, GM51	
Econazole	(a) In preparations for vaginal use. (b) Unless (a) above applies, in OTC medicines for topical use.	(a) 1CP19a, 3CP26, 6CP201, 6CP217, 1PB11a (b) DU11	
Egg and egg products	All medicines when included as an excipient. For CO01, the declaration is “Egg” or “Egg products”	CO01	
Egg – whole	All medicines when included as an excipient. For CO01, the declaration is “Egg” or “Egg products”.	CO01	
Egg yolk – dried	All medicines when included as an excipient. For CO01, the declaration is “Egg” or “Egg products”.	CO01	
Ephedrine	In nasal preparations for topical use.	8CP203	
Erythrose	In Class 1 medicines for topical use.	GM34	
Ethanol	In concentrations of 3 per cent or more when included as an excipient.	CO01	
Ethanol – absolute	In concentrations of 3 per cent or more when included as an excipient.	CO01	

Ingredient	Conditions	Requirements	Date
Ethanolamine	(a) In medicines: <ul style="list-style-type: none"> (i) containing more than 5 per cent and 20 per cent or less of ethanolamine; and (ii) if the medicine is: <ul style="list-style-type: none"> • other than for internal use; and • where the product is not included in Schedule 3, 4 or 8 of the SUSMP. (b) In medicines: <ul style="list-style-type: none"> (i) containing more than 20 per cent of ethanolamine; and (ii) if the medicine is: <ul style="list-style-type: none"> • other than for internal use; and • where the product is not included in Schedule 3, 4 or 8 of the SUSMP.. 	(a)(i) GM34, GM33, GM32 (a)(ii) GM50, GM51 (b)(i) GM23, GM34, GM33, GM31 (b)(ii) GM50, GM51, GM54, GM55	
Ether	In medicines: <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 10 per cent of ether. 	GM50, GM51, GM54	
Ethohexadiol	In medicines for topical use when included as an excipient.	CO01	
Ethylene glycol	In medicines: <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 2.5 per cent of ethylene glycol. 	GM50	
Ethyl butylacetyl amino propionate	In Class 1 medicines for topical use.	GM35	
Ethyl hydroxybenzoate	All medicines when included as an excipient.	CO01	
Etretinate	In concentrations greater than 10 mg/kg or 10 mg/L.	1PB11, PB03, PB01	

Ingredient	Conditions	Requirements	Date
<i>Eucalyptus citriodora</i>	<p>(a) In medicines containing more than 25 per cent of eucalyptus oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
<i>Eucalyptus dives</i>	<p>(a) In medicines containing more than 25 per cent of eucalyptus oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	

Ingredient	Conditions	Requirements	Date
<i>Eucalyptus ficifolia</i>	<p>(a) In medicines containing more than 25 per cent of eucalyptus oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
<i>Eucalyptus fruticetorum</i>	<p>(a) In medicines containing more than 25 per cent of eucalyptus oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	

Ingredient	Conditions	Requirements	Date
<i>Eucalyptus globulus</i>	<p>(a) In medicines containing more than 25 per cent of eucalyptus oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
<i>Eucalyptus macrorhyncha</i>	<p>(a) In medicines containing more than 25 per cent of eucalyptus oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	

Ingredient	Conditions	Requirements	Date
Eucalyptus oil	<p>(a) In medicines containing more than 25 per cent of eucalyptus oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
<i>Eucalyptus radiata</i>	<p>(a) In medicines containing more than 25 per cent of eucalyptus oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	

Ingredient	Conditions	Requirements	Date
<i>Eucalyptus rostrata</i>	<p>(a) In medicines containing more than 25 per cent of eucalyptus oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
<i>Eucalyptus tereticortis</i>	<p>(a) In medicines containing more than 25 per cent of eucalyptus oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	

Ingredient	Conditions	Requirements	Date
Eugenol	<p>(a) In medicines containing more than 25 per cent of eugenol.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and where any one or more of the following apply:</p> <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. <p>(c) In addition to the requirements of (a) and (b) above, if (b) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM21, GM01</p> <p>(b) GM34, DR00</p> <p>(c) GM21, GM50, GM51, GM54, GM55</p>	
Famotidine	In pack sizes containing not more than 14 days supply of the medicine.	6CP216, GM03, 1CP102a, 6CP202, 3AG21	
Fenoterol	In metered aerosols.	GM101	
Fish and fish products	All medicines when included as an excipient. For CO01, the declaration is 'Fish' or 'Fish Products'	CO01	
Fluconazole	In concentrations greater than 10 mg/kg or 10 mg/L.	6CP217	
Fluorides <i>See also</i> <ul style="list-style-type: none"> • <i>Sodium fluoride</i> 	In dental hygiene products for topical use unless one or more of the following apply: <ul style="list-style-type: none"> • The product is a paste, powder or gel for the cleaning of teeth; • The product contains 220mg/kg or 220 mg/L or less of fluoride ion; • the pack contains not more than 120 mg total fluoride and is fitted with a child-resistant closure. 	2AG06, GM21	
Fluticasone	In OTC medicines for use as a nasal spray, unless this information is provided in a package insert supplied with the product in which case US00 is required.	4CP33, 4CP34, 4CP35, 8CP253, 8CP254, 8CP255, 6CP216, DS03, 1DU06a	

Ingredient	Conditions	Requirements	Date
Formaldehyde	<p>(a) In medicines containing more than 5 per cent of formaldehyde.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> the medicine is not for internal use; and is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM23, GM34, GM33</p> <p>(b) GM50, GM51, GM54, GM55</p>	
Formic acid	<p>(a) In medicines containing more than 0.5 per cent of formic acid.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> the medicine is not for internal use; and is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM23, GM34, GM33</p> <p>(b) GM23, GM50, GM51, GM54, GM55</p>	
Galactose	All medicines when included as an excipient.	CO01	
Glucofrangulins calculated as glucofrangulin A	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
Glucosamine hydrochloride	All Class 1 medicines. Note: Source to be declared is seafood.	CO06	
Glucosamine sulfate	All Class 1 medicines. Note: Source to be declared is seafood.	CO06	
Glucosamine sulfate - potassium chloride complex	All Class 1 medicines. Note: Source to be declared is seafood.	CO06	
Glucosamine sulfate - sodium chloride complex	All Class 1 medicines. Note: Source to be declared is seafood.	CO06	

Ingredient	Conditions	Requirements	Date
Glucose	Included as an excipient in medicines for oral use or for sublingual use; and <ul style="list-style-type: none"> • the total sugar content (including lactose) exceeds 100mg per maximum recommended daily dose; and • when the presence of sugars may have a significant glycaemic effect. For CO01, the declaration is “Sugars”	CO01	
Glucose - anhydrous	Included as an excipient in medicines for oral use or for sublingual use; and <ul style="list-style-type: none"> • the total sugar content (including lactose) exceeds 100mg per maximum recommended daily dose; and • when the presence of sugars may have a significant glycaemic effect. For CO01, the declaration is “Sugars”	CO01	
Glucose - liquid	Included as an excipient in medicines for oral use or for sublingual use; and <ul style="list-style-type: none"> • the total sugar content (including lactose) exceeds 100mg per maximum recommended daily dose; and • when the presence of sugars may have a significant glycaemic effect. For CO01, the declaration is “Sugars”	CO01	
Gluten or, excipients derived from gluten-containing grains	All medicines other than skin and mucous membrane applications; <ul style="list-style-type: none"> • where gluten or an excipient derived from gluten-containing grains is present 	CO01	
Gluteraldehyde	In medicines: <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and containing more than 10 mg/kg or 10 mg/L of gluteraldehyde.	GM50, GM51, GM54, GM55,	
<i>Glycine max</i>	All medicines when included as an excipient. For CO01 the declaration is “Soya beans” or “Soya bean products”.	CO01	
Halibut	All medicines when included as an excipient. For CO01, the declaration is ‘Fish’ or ‘Fish products’	CO01	
Hexachlorophane	In medicines for skin cleansing	GM11, GM56, 2AG03a, 1DR54	

Ingredient	Conditions	Requirements	Date
Honey	<p>(a) Included as an excipient in medicines for oral use or for sublingual use; and</p> <ul style="list-style-type: none"> • the total sugar content (including lactose) exceeds 100mg per maximum recommended daily dose; and • when the presence of sugars may have a significant glycaemic effect. <p>For CO01, the declaration is “Sugars”</p> <p>(b) Regardless of whether (a) above applies, all Class 1 medicines.</p>	<p>(a) CO01</p> <p>(b) 2AG03</p>	
Honey – purified	<p>(a) Included as an excipient in medicines for oral use or for sublingual use; and</p> <ul style="list-style-type: none"> • the total sugar content (including lactose) exceeds 100mg per maximum recommended daily dose; and • when the presence of sugars may have a significant glycaemic effect. <p>For CO01, the declaration is “Sugars”</p> <p>(b) Regardless of whether (a) above applies, all Class 1 medicines.</p>	<p>(a) CO01</p> <p>(b) 2AG03</p>	
Hydrocortisone (excluding salts and derivatives)	<p>(a) All non-prescription medicines.</p> <p>(b) When the medicine is for external use.</p>	<p>(a) 2AG04a, 1DU04a</p> <p>(b) 1CP01, GM34, 1DR59a, 1DU04a, 2AG04a</p>	
Hydrocortisone acetate	<p>(a) All non-prescription medicines.</p> <p>(b) When the medicine is for external use.</p>	<p>(a) 2AG04a, 1DU04a</p> <p>(b) 1CP01, GM34, 1DR59a, 1DU04a, 2AG04a</p>	

Ingredient	Conditions	Requirements	Date
Hydrogen peroxide (excluding salts and derivatives)	<p>(a) In medicines:</p> <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 3 per cent of hydrogen peroxide. <p>(b) Regardless of whether (a) above applies, if the medicine contains more than 3 per cent of hydrogen peroxide and:</p> <p>(i) 10 per cent or less of hydrogen peroxide; or</p> <p>(ii) more than 10 per cent but less than 20 per cent of hydrogen peroxide</p> <p>(iii) more than 20 per cent of hydrogen peroxide.</p>	<p>(a) DR00, GM50, GM51, GM54, GM55</p> <p>(b)(i) GM34, GM21, GM32</p> <p>(b)(ii) GM36, GM32</p> <p>(b)(iii) GM36, GM33, GM31, GM52</p>	
8-Hydroxyquinoline (including salts and derivatives)	In concentrations greater than 10 mg/kg or 10 mg/L in medicines for internal use.	1DU05a	
Hydroquinone	In medicines for external use containing 2 per cent or less of hydroquinone.	6CP218, 2AG01, GM34, OD02, SE13, GM50, GM51, GM57, SE14	
Hydroxyanthracene derivatives	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	

Ingredient	Conditions	Requirements	Date
Hydroxyanthracene derivatives calculated as anhydrous barbaloin	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
Hydroxyanthracene derivatives calculated as cascaroside A	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
Hydroxyanthracene derivatives calculated as cascaroside B	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	

Ingredient	Conditions	Requirements	Date
Hydroxyanthracene derivatives calculated as rhein	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
Hydroxyanthracene glycosides calculated as sennoside B	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
Hydroxybenzoic acid esters	All medicines when included as an excipient.	CO01	
<i>Hypericum perforatum</i>	All Class 1 medicines.	3CP26, IN02	

Ingredient	Conditions	Requirements	Date
Ibuprofen	<p>(a) In medicines other than:</p> <ul style="list-style-type: none"> • medicines for dermal use; or • containing less than 10 mg/kg or 10 mg/L of ibuprofen; <p>except:</p> <ul style="list-style-type: none"> • 1PB14 and 1PB11a are not required when the medicine is indicated exclusively for treatment of dysmenorrhoea. <p>(b) In addition to the requirements of (a) above, for the purpose of exclusion from scheduling in the SUSMP, when:</p> <ul style="list-style-type: none"> • in divided preparations in pack sizes containing not more than 25 dosage units; and • each dosage unit contains 200 mg or less of ibuprofen as the only therapeutically active ingredient (other than an effervescent agent); and • packed in a blister or strip pack or a container with a child-resistant closure. <p>(c) In liquid dosage forms intended for children:</p> <p>(d) In liquid dosage forms for both adults and children:</p>	<p>(a) 1CP25, 1CP11, 1CP18a, 1CP101a, 1CP102a, 1CP103a, 4CP32 1DU02a, 1PB14, 1PB11a</p> <p>(b) 2AG06a, 2CP51a</p> <p>(c) 2CP51a, 2CP52a, 2CP53a, 2CP54a, 2CP55a, 2CP56a, 2CP57a, 2CP151a, 6CP214, 2AG02, 2AG03a, 2AG11.</p> <p>(d) 1CP25, 1CP11, 1CP18a, 1CP101a, 1CP102a, 1CP103a, 4CP32, 1DU02a, 1PB14, 1PB11a, 2AG06a, 2CP51a, 2CP52a, 2CP53a, 2CP54a, 2CP55a, 2CP56a, 2CP57a, 2CP151a, 6CP214, 2AG02, 2AG03a, 2AG11</p>	

Ingredient	Conditions	Requirements	Date
<i>Illicium verum</i>	<p>(a) In medicines containing more than 50 per cent anise oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 50 mL and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM01</p> <p>(b) GM50, GM51</p>	
Invert Sugar	<p>Included as an excipient in medicines for oral use or for sublingual use; and</p> <ul style="list-style-type: none"> • the total sugar content (including lactose) exceeds 100mg per maximum recommended daily dose; and • when the presence of sugars may have a significant glycaemic effect. • For CO01, the declaration is “Sugars” 	CO01	
Iodine	<p>(a) In medicines for internal use.</p> <p>(b) In medicines for external use containing more than 2.5 per cent of available iodine (excluding salts, derivatives or iodophors); and</p> <ul style="list-style-type: none"> • where the product is not included in Schedule 3, 4 or 8 of the SUSMP. <p>(c) In medicines where the concentration of iodine exceeds 20%.</p>	<p>(a) OD11, 1PB11a</p> <p>(b) GM50, GM57</p> <p>(c) GM50, GM57, GM23, GM34, GM33</p>	
Ipratropium bromide	In metered aerosols.	GM105	
Iron	<p>In Class 1 medicines for oral use, except in multivitamin/mineral products that:</p> <ul style="list-style-type: none"> • are indicated for general nutritional support; and • which do not make claims related specifically to iron deficiency. 	1CP02	
Isobutyl hydroxybenzoate	All medicines when included as an excipient.	CO01	

Ingredient	Conditions	Requirements	Date
Isoconazole	(a) In preparations for vaginal use. (b) Unless (a) above applies, in OTC medicines for topical use.	(a) 1CP19a, 3CP26, 6CP201, 6CP217, 1PB11a (b) DU11	
Isomalt	In medicines when included as an excipient: <ul style="list-style-type: none"> for oral use or for sublingual use; and the total sugar alcohol content of the preparation exceeds 2g per maximum recommended daily dose. For CO01, the declaration is “Sugar alcohols”.	CO01, CO05, SE103	
Isoprenaline	In metered aerosols.	GM105	
Isopropyl hydroxybenzoate	All medicines when included as an excipient.	CO01	
Isobutyl hydroxybenzoate	All medicines when included as an excipient.	CO01	
Isotretinoin	(a) In concentrations greater than 10 mg/kg or 10 mg/L for oral use. (b) In concentrations greater than 10 mg/kg or 10 mg/L for topical use.	(a) 1PB11, PB03, PB01 (b) 1PB11, PB02	
Ispaghula husk dry	All Class 1 medicines labelled with a dose for children.	3CP26	
Ispaghula husk powder	All Class 1 medicines labelled with a dose for children.	3CP26	
<i>Juglans nigra</i>	All medicines when included as an excipient. For CO01, the declaration is “Tree nuts” or “Tree nuts products”.	CO01	
Kavalactones (<i>of Piper methysticum</i>)	All Class 1 medicines.	DU13, 1PB11, 1PB51, SE102	
<i>Kunzea ambigua</i>	All Class 1 medicines.	1DR53c, GM01, GM11	
Lactoferrin – bovine	All Class 1 medicines. Note: Source to be declared is cow’s milk.	CO06	
Lactose	All medicines for oral use, when included as an excipient.	CO01	
Lactitol	In medicines when included as an excipient: <ul style="list-style-type: none"> for oral use or for sublingual use; and the total sugar alcohol content of the preparation exceeds 2g per maximum recommended daily dose. For CO01, the declaration is “Sugar alcohols”.	CO01, CO05, SE103	

Ingredient	Conditions	Requirements	Date
<i>Larrea tridentata</i>	All Class 1 medicines.	1CP03, SE102	
Lecithin - egg	All medicines when included as an excipient.	CO01	
Leflunomide	In concentrations greater than 10 mg/kg or 10 mg/L.	1PB11, PB04, PB01	
Lemon oil	In medicines unless any one or more of the following apply: <ul style="list-style-type: none"> • for internal use; • in soaps, bath and shower gels that are washed off the skin; • when the lemon oil is steam distilled or rectified; • where the product is included in Schedule 3, 4 or 8 of the SUSMP; and • the medicine contains 0.05 per cent or less of lemon oil. 	GM50, GM51, SE10	
Levocabastine	(a) In an eye preparation, at any concentration. (b) In addition to the requirements of (a) above, in preparations other than eye or nasal preparations containing 0.5 mg/mL or less of levocabastine.	(a) 1PB11 SE22 (b) SE21, SE25, GM42	
Lignocaine	In OTC medicines for dermal use.	6CP201, GM57	
Lime oil	In medicines unless any one or more of the following apply: <ul style="list-style-type: none"> • for internal use; • in soaps, bath and shower gels that are washed off the skin; • when the lemon oil is steam distilled or rectified; • where the product is included in Schedule 3, 4 or 8 of the SUSMP; and • the medicine contains 0.5 per cent or less of lime oil. 	GM50, GM51, SE10	
Lobster	All medicines when included as an excipient.	CO01	
Local anaesthetics <i>See also</i> <ul style="list-style-type: none"> • <i>Individual ingredient entries</i> 	(a) In OTC medicines for dermal use. (b) In OTC medicines that are sore throat lozenges.	(a) 6CP201, GM57 (b) GM41	
Loperamide	For oral use in packs of 20 dosage units or less.	2AG07, 1DU01a, 1PB11a, 1PB51a	

Ingredient	Conditions	Requirements	Date
Macadamia nut oil	All medicines when included as an excipient. For CO01, the declaration is “Tree nuts” or “Tree nuts products”.	CO01	
<i>Macadamia ternifolia</i>	All medicines when included as an excipient. For CO01, the declaration is “Tree nuts” or “Tree nuts products”.	CO01	
Mace Oil	(a) In medicines containing more than 50 per cent of nutmeg oil. (b) In addition to the requirements of (a) above, if (a) above applies and <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 25 mL and/or • the container is not fitted with a restricted flow insert. 	(a) GM01 (b) GM50, GM51	
Maltitol	In medicines: <ul style="list-style-type: none"> • for oral use or for sublingual use when included as an excipient; and • the total sugar alcohol content of the preparation exceeds 2g per maximum recommended daily dose. 	CO01, CO05, SE103	
Maltitol solution	In medicines: <ul style="list-style-type: none"> • for oral use or for sublingual use when included as an excipient; and • the total sugar alcohol content of the preparation exceeds 2g per maximum recommended daily dose. 	CO01, CO05, SE103	
Maltose	Included as an excipient in medicines for oral use or for sublingual use; and <ul style="list-style-type: none"> • the total sugar content (including lactose) exceeds 100mg per maximum recommended daily dose; and • when the presence of sugars may have a significant glycaemic effect. 	CO01	
Mannitol	In medicines: <ul style="list-style-type: none"> • for oral use or for sublingual use when included as an excipient; and • the total sugar alcohol content of the preparation exceeds 2g per maximum recommended daily dose. 	CO01, CO05, SE103	

Ingredient	Conditions	Requirements	Date
Marjoram oil	<p>(a) In medicines containing more than 50 per cent of marjoram oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 50 mL and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM01</p> <p>(b) GM50, GM51</p>	
Marjoram Oil Spanish	<p>(a) In medicines containing more than 50 per cent of marjoram oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 50 mL and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM01</p> <p>(b) GM50, GM51</p>	
Marjoram Oil Sweet	<p>(a) In medicines containing more than 50 per cent of marjoram oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 50 mL and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM01</p> <p>(b) GM50, GM51</p>	
Mebendazole	In OTC medicines.	8CP203, GM107	

Ingredient	Conditions	Requirements	Date
Mefenamic acid	<ul style="list-style-type: none"> • In medicines containing more than 10 mg/kg or 10 mg/L of mefenamic acid; except: • 1PB14 and 1PB11a are not required when the medicine is indicated exclusively for treatment of dysmenorrhoea 	1CP25, 1CP11, 1CP18a, 1CP101a, 1CP102a, 1CP103a, 1DU02a, 1PB14, 1PB11a	
<i>Melaleuca alternifolia</i>	<p>(a) In medicines containing more than 25 per cent of melaleuca oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
<i>Melaleuca cajuputi</i>	<p>(a) In medicines containing more than 25 per cent of melaleuca oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	

Ingredient	Conditions	Requirements	Date
<i>Melaleuca dissitiflora</i>	<p>(a) In medicines containing more than 25 per cent of melaleuca oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
<i>Melaleuca ericifolia</i>	<p>(a) In medicines containing more than 25 per cent of melaleuca oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	

Ingredient	Conditions	Requirements	Date
<i>Melaleuca linariifolia</i>	<p>(a) In medicines containing more than 25 per cent of melaleuca oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
Melaleuca oil	<p>(a) In medicines containing more than 25 per cent of melaleuca oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	

Ingredient	Conditions	Requirements	Date
<i>Melaleuca quinquenervia</i>	<p>(a) In medicines containing more than 25 per cent of melaleuca oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
<i>Mentha pulegium</i>	<p>(a) In medicines containing more than 4% d-pulegone.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
Methanol	<p>(a) In medicines containing more than 2 per cent of methanol (except in industrial methylated spirits).</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM23, GM34, GM33</p> <p>(b) GM50, GM51</p>	
Methylated spirit – industrial	<p>In medicines:</p> <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 10 mg/kg or 10 mg/L of methanol. 	GM50, GM51	
Methyl hydroxybenzoate	All medicines when included as an excipient.	CO01	

Ingredient	Conditions	Requirements	Date
Methyl salicylate	In medicines: <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • in liquid preparations containing more than 25 per cent of methyl salicylate. 	GM50, GM51, GM54	
Miconazole	(a) In preparations for vaginal use. (b) Unless (a) above applies, in OTC medicines for topical use.	(a) 1CP19a, 3CP26, 6CP201, 6CP217, 1PB11a (b) DU11	
Milk and milk products	All medicines when included as an excipient. For CO01, the declaration is “Milk” or “Milk products”	CO01	
Milk – nonfat dry	All medicines when included as an excipient. For CO01, the declaration is “Milk” or “Milk products”	CO01	
Milk - whole dry	All medicines when included as an excipient. For CO01, the declaration is “Milk” or “Milk products”	CO01	
Milk protein - hydrolysed	All medicines when included as an excipient. For CO01, the declaration is “Milk” or “Milk products”	CO01	
Misoprostol	In concentrations greater than 10 mg/kg or 10 mg/L of misoprostol.	1PB11	
<i>Myristica fragrans</i>	(a) In medicines containing more than 50 per cent of nutmeg oil. (b) In addition to the requirements of (a) above, if (a) above applies and <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 25 mL and/or • the container is not fitted with a restricted flow insert. 	(a) GM01 (b) GM50, GM51	

Ingredient	Conditions	Requirements	Date
Naproxen	<ul style="list-style-type: none"> In medicines containing more than 10 mg/kg or 10 mg/L of naproxen; except: <ul style="list-style-type: none"> 1PB14 and 1PB11a are not required when the medicine is indicated exclusively for treatment of dysmenorrhoea 	1CP25, 1CP11, 1CP18a, 1CP101a, 1CP102a, 1CP103a, 1DU02a, 1PB14, 1PB11a	
Nitric acid (excluding its salts and derivatives)	In medicines: <ul style="list-style-type: none"> other than for internal use where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and containing more than 0.5 per cent of nitric acid. 	GM50, GM51, GM54, GM55	
Nitroprussides	In medicines: <ul style="list-style-type: none"> other than for internal use where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and containing more than 2.5 per cent of nitroprussides.	GM50, GM51	
Nizatidine	In pack sizes containing not more than 14 days supply of the medicine.	6CP216, GM03, 1CP102a, 6CP202, 3AG21	
Nonoxinol 9	In OTC medicines used as vaginal contraceptives.	1DR55, GM12, GM102	
Noradrenaline	In metered aerosols.	GM105	
Nutmeg oil	(a) In medicines containing more than 50 per cent of nutmeg oil. (b) In addition to the requirements of (a) above, if (a) above applies and <ul style="list-style-type: none"> the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and where either or both of the following apply: <ul style="list-style-type: none"> the nominal capacity of the container is more than 25 mL and/or the container is not fitted with a restricted flow insert. 	(a) GM01 (b) GM50, GM51	
Nystatin	In preparations for topical vaginal use.	1CP19a, 3CP26, 6CP201, 6CP217, DU12, 1PB11a	

Ingredient	Conditions	Requirements	Date
<p><i>Ocimum kilimandscharicum</i></p>	<p>(a) In medicines containing more than 2.5 per cent of camphor.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and if either of the following apply:</p> <ul style="list-style-type: none"> • the camphor is present as a natural component of an essential oil containing more than 2.5 per cent of camphor and: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 25 mL or • the container is not fitted with a restricted flow insert.; or • if the concentration of camphor is greater than 10 per cent and: <ul style="list-style-type: none"> • the nominal capacity of the container is greater than 15 mL; and • the container is not fitted with a child-resistant closure. <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • The camphor is not present as a natural component of an essential oil and the concentration of camphor is: <ul style="list-style-type: none"> • greater than 2.5 per cent in liquid preparations; or • greater than 12.5 per cent in solid or semi-solid preparations <p>unless the medicine:</p> <ul style="list-style-type: none"> • is enclosed in an inhaler device that prevents ingestion of its contents; or • the camphor is present as a natural component of an essential oil other than rosemary oil, sage oil Spanish. <p>(c) In addition to the requirements of (a) and (b) above, if (b) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the OTC. 	<p>(a) GM21, GM01</p> <p>(b) GM34, DR00, GM51</p> <p>(c) GM50, GM51, GM53</p>	
<p>Octyl bicycloheptene dicarboximide</p>	<p>In medicines for topical use when included as an excipient.</p>	<p>CO01</p>	

Ingredient	Conditions	Requirements	Date
Orange oil (bitter)	<p>In medicines unless any one or more of the following apply:</p> <ul style="list-style-type: none"> • for internal use; • in soaps, bath and shower gels that are washed off the skin; • when the lemon oil is steam distilled or rectified; • where the product is included in Schedule 3, 4 or 8 of the SUSMP; and • the medicine contains 1.4 per cent or less of orange oil (bitter) 	GM50, GM51, SE10	
Orciprenaline	In metered aerosols.	GM105	
Paracetamol	<p>In concentrations greater than 10 mg/kg or 10 mg/L of paracetamol.</p> <p>Note:</p> <ul style="list-style-type: none"> • For 1CP101a the active ingredient is paracetamol. 	OD01, 1CP101a, [1DU01a and/or 1DU02a], DS01, 2AG04a.	
<i>Paullinia cupana</i>	<p>All Class 1 medicines.</p> <p>Note: For CO02 and CO03, the component required to be stated and quantified is caffeine.</p>	CO02, CO03	
Peanut and peanut products	<p>All medicines when included as an excipient.</p> <p>For CO01, the declaration is “Peanuts” or “Peanut products”</p>	CO01	
Pennyroyal oil	<p>(a) In medicines containing more than 4% d-pulegone.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 15 mL; and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	

Ingredient	Conditions	Requirements	Date
Permanganates	<p>(a) In medicines containing more than 10 mg/kg or 10 mg/L of permanganates, except potassium permanganate in aqueous solutions containing 1 per cent or less of potassium permanganate.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) 1DR58, DR00, GM31</p> <p>(b) GM50, GM51, GM54, GM55</p>	
Phenol and any other homologue of phenol.	<p>In medicines:</p> <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and <p>containing more than 3 per cent in total of phenols, including cresols, xlenols or other phenol homologues with a boiling point below 220°C</p>	CO01, GM34, GM21, GM33, DR00, GM50, GM51, GM54, GM55	
Phenylalanine	<p>(a) All medicines other than skin and mucous membrane applications, when included as an excipient.</p> <p>(b) In addition, in Class 1 medicines where the maximum recommended daily dose contains more than 500 mg or phenylalanine.</p>	<p>(a) CO01</p> <p>(b) 1PB11, 1PB12</p>	
Phenylpropanolamine	In concentrations greater than 10 mg/kg or 10 mg/L of phenylpropanolamine.	IN01, SE101	
Phosphoric acid	<p>In medicines:</p> <ul style="list-style-type: none"> • other than for internal use; • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 15 per cent of phosphoric acid. 	GM50, GM51, GM54, GM55	

Ingredient	Conditions	Requirements	Date
<i>Pimenta racemosa</i>	<p>(a) In medicines containing more than 25 per cent of bay oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
<i>Pimpinella anisum</i>	<p>(a) In medicines containing more than 50 per cent anise oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 50 mL and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM01</p> <p>(b) GM50, GM51</p>	
Piperonyl butoxide	In medicines for topical use when included as an excipient.	CO01	
<i>Piper methysticum</i>	All Class 1 medicines	DU13, 1PB11, 1PB51, SE102,	
<i>Plantago afra</i>	All Class 1 medicines labelled with a dose for children.	3CP26	
<i>Plantago indica</i>	All Class 1 medicines labelled with a dose for children.	3CP26	
<i>Plantago ovata</i>	All Class 1 medicines labelled with a dose for children.	3CP26	
Plantago seed dry	All Class 1 medicines labelled with a dose for children.	3CP26	

Ingredient	Conditions	Requirements	Date
Podophyllin	<p>(a) In preparations specifically for use on anal or genital areas.</p> <p>(b) In liquid preparations:</p> <ul style="list-style-type: none"> • for the treatments of warts other than anogenital warts; and • containing 20 per cent or less of podophyllin. <p>(c) In solid or semi-solid preparations:</p> <ul style="list-style-type: none"> • for the treatments of warts other than anogenital warts; and • containing 10 per cent or less of podophyllin.. 	<p>(a) 3CP26</p> <p>(b) 1DR56a</p> <p>(c) 1DR56</p>	
Podophyllotoxin	<p>(a) In preparations specifically for use on anal or genital areas.</p> <p>(b) In liquid preparations:</p> <ul style="list-style-type: none"> • for the treatments of warts other than anogenital warts; and • containing 1 per cent or less of podophyllotoxin. <p>(c) In solid or semi-solid preparations:</p> <ul style="list-style-type: none"> • for the treatments of warts other than anogenital warts; and • containing 0.5 per cent or less of podophyllotoxin. 	<p>(a) 3CP26</p> <p>(b) 1DR56a</p> <p>(c) 1DR56</p>	
Pollen (including both pollen collected by bees or by mechanical means)	In medicines for oral use when included as an excipient. For CO01, the declaration is “Pollen” or “Pollen - Bee” (as applicable)	CO01 SE01	
Potassium benzoate	All medicines when included as an excipient.	CO01	
Potassium bicarbonate	All medicines for oral use, when included as an excipient.	CO04	
Potassium chloride	All medicines for oral use, when included as an excipient.	CO04	
Potassium clavulanate	All medicines for oral use, when included as an excipient.	CO04	

Ingredient	Conditions	Requirements	Date
Potassium hydroxide	<p>(a) In medicines containing potassium hydroxide where:</p> <ul style="list-style-type: none"> • the concentration of potassium hydroxide is more than 5 per cent; and/or • the pH of the preparation (or an aqueous solution of 10 g/L of a solid preparation) is more than 11.5. <p>then</p> <p>(i) if the preparation contains 0.5 per cent or less of potassium hydroxide; or</p> <p>(ii) if the preparation contains more than 0.5 per cent of potassium hydroxide</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a)(i) GM34, GM21, GM33, DR00, GM32, GM56</p> <p>(a)(ii) GM36, DR00, GM31</p> <p>(b) GM50, GM51, GM54, GM55,</p>	
Potassium metabisulfite	<p>(a) All medicines when included as an excipient. For CO01, the declaration is ‘Sulfites’.</p> <p>(b) In addition to the requirements of (a) above, in medicines:</p> <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 10 per cent of potassium metabisulfite. 	<p>(a) CO01</p> <p>(b) GM50</p>	
Potassium sorbate	All medicines when included as an excipient. For CO01, the declaration is ‘Sorbates’.	CO01	
Povidone-iodine	In OTC medicines for dermal use.	GM57	
Promethazine	<p>(a) In OTC medicines labelled for use in infants aged 0-12 months.</p> <p>(b) In OTC medicines labelled for use in infants aged 12-24 months.</p> <p>(c) In medicines for adult use.</p>	<p>(a) 2AG03</p> <p>(b) 2AG04a</p> <p>(c) SE25</p>	

Ingredient	Conditions	Requirements	Date
Propolis	(a) In Class 1 medicines for oral or sublingual use.	(a) CO01, GM57, SE01	
	(b) In Class 1 medicines for topical use.	(b) GM04, GM35	
Propolis balsam	(a) In Class 1 medicines for oral or sublingual use.	(a) CO01, GM57, SE01	
	(b) In Class 1 medicines for topical use.	(b) GM04, GM35	
Propolis dry extract	(a) In Class 1 medicines for oral or sublingual use.	(a) CO01, GM57, SE01	
	(b) In Class 1 medicines for topical use.	(b) GM04, GM35	
Propolis liquid extract	(a) In Class 1 medicines for oral or sublingual use.	(a) CO01, GM57, SE01	
	(b) In Class 1 medicines for topical use.	(b) GM04, GM35	
Propolis resin	(a) In Class 1 medicines for oral or sublingual use.	(a) CO01, GM57, SE01	
	(b) In Class 1 medicines for topical use.	(b) GM04, GM35	
Propolis tincture	(a) In Class 1 medicines for oral or sublingual use.	(a) CO01, GM57, SE01	
	(b) In Class 1 medicines for topical use.	(b) GM04, GM35	
Propyl hydroxybenzoate	All medicines when included as an excipient.	CO01	
<i>Prunus dulcis</i>	All medicines when included as an excipient. For CO01, the declaration is “Tree nuts” or “Tree nuts products”.	CO01	
Pseudoephedrine	In OTC medicines for oral use.	4CP30, 4CP31, 4CP33, 1CP105c, SE104	
Psyllium husk dry	All Class 1 medicines labelled with a dose for children.	3CP26	
Psyllium husk powder	All Class 1 medicines labelled with a dose for children.	3CP26	

Ingredient	Conditions	Requirements	Date
Psyllium hydrophilic mucilloid	All Class 1 medicines labelled with a dose for children.	3CP26	
Psyllium seed dry	All Class 1 medicines labelled with a dose for children.	3CP26	
Pyrantel embonate	All OTC medicines.	8CP203, GM107	
Pyrethrins	In medicines for topical use when included as an excipient.	CO01	
Pyridoxal <i>(see also Part 4.8 - 'General Requirements' for all Vitamins)</i>	In medicines containing 200 mg or less but more than 50 mg of pyridoxal per recommended daily dose.	OD05	
Pyridoxal 5-phosphate	In medicines containing 200 mg or less but more than 50 mg of pyridoxal per recommended daily dose.	OD05	
Pyridoxamine <i>(see also Part 4.8 - 'General Requirements' for all Vitamins)</i>	In medicines containing 200 mg or less but more than 50 mg of pyridoxal per recommended daily dose.	OD05	
Pyridoxine <i>(see also Part 4.8 - 'General Requirements' for all Vitamins)</i>	In medicines containing 200 mg or less but more than 50 mg of pyridoxal per recommended daily dose.	OD05	
Pyridoxine hydrochloride	In medicines containing 200 mg or less but more than 50 mg of pyridoxal per recommended daily dose.	OD05	
Pyrithione zinc	(a) In shampoos containing 2 per cent or less of pyrithione zinc. (b) In medicines: <ul style="list-style-type: none"> • other than: <ul style="list-style-type: none"> • where (a) above applies; or • for internal use; or • the medicine is a semi-solid hair preparation; or • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 10 mg/kg or 10 mg/L of pyrithione zinc. 	(a) GM34 or GM54 (b) GM50, GM54	

Ingredient	Conditions	Requirements	Date
Quaternary ammonium compounds <i>See also individual entries for active and excipient ingredients</i>	<p>(a) In medicines:</p> <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 5 per cent of quaternary ammonium compounds; except <ul style="list-style-type: none"> • if the ingredient is separately specified in this document; and/or • the ingredient is a dialkyl or dialkoyl quaternary ammonium compound where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16-C18) sources. <p>(b) In addition to the requirements of (a) above, if (a) above applies and the preparation contains more than 20 per cent of quaternary ammonium compounds.</p>	<p>(a) GM50, GM54, GM55</p> <p>(b) GM51</p>	
Ranitidine	In pack sizes containing not more than 14 days supply of the medicine.	6CP216, GM03, 1CP102a, 6CP202, 3AG21	
<i>Rhamnus catharticus</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	

Ingredient	Conditions	Requirements	Date
<i>Rhamnus frangula</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
<i>Rhamnus purshianus</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	

Ingredient	Conditions	Requirements	Date
<i>Rheum officinale</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
<i>Rheum palmatum</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	

Ingredient	Conditions	Requirements	Date
<i>Rheum rhaponticum</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
<i>Rheum tanguticum</i>	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	

Ingredient	Conditions	Requirements	Date
Rhubarb root dry	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	
Rhubarb root powder	<p>(a) In all Class 1 medicines for oral use; and</p> <p>(b) If the medicine has a maximum daily dose of 10 mg or more of hydroxyanthracene derivatives, in addition to (a) above; and</p> <p>(c) If the medicine is indicated for use a laxative, in addition to (a) and (b) (if applicable) above; or</p> <p>(d) If the medicine is not indicated for use a laxative, in addition to (a) and (b) (if applicable) above.</p> <p>Note: For CO02, the component to be declared is either “hydroxyanthracene derivatives” or the name(s) of the specific hydroxyanthracene derivatives contained in the product.</p>	<p>(a) 2AG07, OD02</p> <p>(b) 1CP14, CP15, 1CP16, 1CP17, 1PB11a, 1PB51a</p> <p>(c) GM108</p> <p>(d) CO02, SE103</p>	

Ingredient	Conditions	Requirements	Date
<i>Rosmarinus officinalis</i>	<p>(a) In medicines containing more than 25 per cent of cineole (other than rosemary oil or camphor oil).</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where any one or more of the following apply: <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	
Royal jelly	<p>(a) All medicines for oral or sublingual use when included as an excipient.</p> <p>(b) Regardless of (a) above applies, all Class 1 medicines.</p>	<p>(a) CO01 1CP13, 1CP18, SE02</p> <p>(b) 1CP13, 1CP18, 2AG01, SE02</p>	
Royal jelly fresh	<p>(a) All medicines for oral or sublingual use when included as an excipient.</p> <p>(b) Regardless of (a) above applies, all Class 1 medicines.</p>	<p>(a) CO01 1CP13, 1CP18, SE02</p> <p>(b) 2AG01, 1CP13, 1CP18, SE02</p>	
Royal jelly lyophilised	<p>(a) All medicines for oral or sublingual use when included as an excipient.</p> <p>(b) Regardless of (a) above applies, all Class 1 medicines.</p>	<p>(a) CO01 1CP13, 1CP18, SE02</p> <p>(b) 1CP13, 1CP18, 2AG01, SE02</p>	

Ingredient	Conditions	Requirements	Date
(S)-S-Adenosylmethionine in the form of sulfate salts, tosylate salts or mixed sulfate and tosylate salts	All Class 1 medicines.	1CP24c, 1CP105cc, 1CP105c	
Saccharin	All medicines for oral or sublingual use when included as an excipient. For CO01, the declaration is “Saccharin”.	CO01	
Saccharin calcium	All medicines for oral or sublingual use when included as an excipient. For CO01, the declaration is “Saccharin”.	CO01	
Saccharin sodium	All medicines for oral or sublingual use when included as an excipient. For CO01, the declaration is “Saccharin”.	CO01	
Safrole	(a) In medicines: <ul style="list-style-type: none"> other than for internal use; containing more than 1 per cent of safrole. (b) In addition to the requirements of (a) above, if (a) above applies and the medicines is not included in Schedule 3, 4 or 8 of the SUSMP.	(a) GM34, DR00 (b) GM50, GM51	
Sage oil	(a) In medicines containing more than 4% thujone. (b) In addition to the requirements of (a) above, if (a) above applies and <ul style="list-style-type: none"> the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and where either or both of the following apply: <ul style="list-style-type: none"> the nominal capacity of the container is more than 15 mL; and/or the container is not fitted with a restricted flow insert. 	(a) GM21, GM01 (b) GM50, GM51	
Salbutamol	In metered aerosols or in dry powder formulations.	GM105	
Salicylamide	In concentrations greater than 10 mg/kg or 10 mg/L of salicylamide.	OD05, 2AG07a, or OD02 and GM03 and 2AG07a	

Ingredient	Conditions	Requirements	Date
<i>Salicylates</i>	In medicines containing salicylates	OD05, 2AG07a, or OD02 and GM03 and 2AG07a	
<i>Salvia officinalis</i>	(a) In medicines containing more than 4% thujone. (b) In addition to the requirements of (a) above, if (a) above applies and <ul style="list-style-type: none"> the medicine is not for internal use; and is not included in Schedule 3, 4 or 8 of the SUSMP. 	(a) GM21, GM01 (b) GM50, GM51	
Sassafras oil	(a) In medicines: <ul style="list-style-type: none"> other than for internal use; containing more than 1 per cent of safrole. (b) In addition to the requirements of (a) above, if (a) above applies and the medicines is not included in Schedule 3, 4 or 8 of the SUSMP.	(a) GM34, DR00 (b) GM50, GM51	
<i>Secale cereale</i>	In medicines for internal use when included as an excipient, except if the medicine contains no detectable gluten and contains no oats or malt.	CO01	
Selenium	All Class 1 medicines. Note: For DS02, the maximum daily dose must be not more than 150 micrograms of selenium. Note - Agreement has been reached that the limit for both Australia and New Zealand will be 150 micrograms.	2AG08, DS02, OD04	
Selenium compounds <i>See also:</i> <ul style="list-style-type: none"> <i>Selenium yeast – high</i> <i>Selenocysteine</i> <i>Selenomethionine</i> <i>Sodium selenate</i> <i>Sodium selenite</i> 	(a) All Class 1 medicines. (b) In medicines: <ul style="list-style-type: none"> for topical use; where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and containing more than 3.5 per cent of selenium sulfide. 	(a) 2AG08, DS02, OD04 (b) GM50, GM54	
Selenium yeast – high <i>(see also – Selenium compounds)</i>	All Class 1 medicines.	2AG08, DS02, OD04	

Ingredient	Conditions	Requirements	Date
Selenocysteine (see also – Selenium compounds)	All Class 1 medicines.	2AG08, DS02, OD04	
Selenomethionine (see also – Selenium compounds)	All Class 1 medicines.	2AG08, DS02, OD04	
Sesame seeds and sesame seed products	All medicines when included as an excipient. For CO01, the declaration is ‘Sesame seeds or ‘Sesame seed products’	CO01	
Sesame oil	All medicines when included as an excipient. For CO01, the declaration is ‘Sesame seeds or ‘Sesame seed products’	CO01	
<i>Sesamum indicum</i>	All medicines when included as an excipient. For CO01, the declaration is ‘Sesame seeds or ‘Sesame seed products’	CO01	
Shark cartilage	All Class 1 medicines.	1CP22a, 2AG01a, PB01, 1PB51a, 1CP23a	
Shrimp - white	All medicines when included as an excipient. For CO01, the declaration is ‘Crustacea’ or ‘Crustacean products’	CO01	
Silver (see also Silver salts)	In medicines that are: <ul style="list-style-type: none"> • chewing gum containing 5 mg or less of silver per dosage unit; or • solutions for oral use containing 0.3 per cent or less of silver; or • for use as smoking deterrents, containing more than 1 per cent of silver. 	SE11	
Silver salts (see also Silver)	In medicines: <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 1 per cent of silver. 	GM50, GM54, GM55	
Sodium benzoate	All medicines when included as an excipient.	CO01	
Sodium bicarbonate	In medicines for oral use when: <ul style="list-style-type: none"> • included as an excipient, and • the total sodium content is more than 120mg per maximum recommended daily dose. 	CO01, CO04	
Sodium bisulfite	All medicines when included as an excipient. For CO01, the declaration is “Sulfites”.	CO01	
Sodium butyl hydroxybenzoate	All medicines when included as an excipient.	CO01	

Ingredient	Conditions	Requirements	Date
Sodium chloride	In medicines for oral use when: <ul style="list-style-type: none"> • included as an excipient, and • the total sodium content is more than 120mg per maximum recommended daily dose. 	CO01, CO04	
Sodium dichloro isocyanurate	In medicines: <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 10 mg/kg or 10 mg/L of sodium dichloroisocyanurate. 	GM50, GM51, GM54	
Sodium dodecylbenzene sulfonate	In medicines: <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 30 per cent of sodium dodecylbenzene sulfonate. 	GM50, GM51, GM54	
Sodium ethyl hydroxybenzoate	All medicines when included as an excipient.	CO01	
Sodium fluoride <i>See also – Fluorides</i>	In products for oral ingestion containing more than 2.2 mg of sodium fluoride.	GM106	
Sodium hydroxide	(a) In medicines containing sodium hydroxide where: <ul style="list-style-type: none"> • the concentration of sodium hydroxide is more than 5 per cent; and/or • the pH of the preparation (or an aqueous solution of 10 g/L of a solid preparation) is more than 11.5. then <ul style="list-style-type: none"> (i) if the preparation contains 0.5 per cent or less of sodium hydroxide; or (ii) if the preparation contains more than 0.5 per cent of sodium hydroxide (b) In addition to the requirements of (a) above, if (a) above applies and <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	(a)(i) GM34, GM21, GM33, DR00, GM32, GM56 (a)(ii) GM36, DR00, GM31 (b) GM50, GM51, GM54, GM55	

Ingredient	Conditions	Requirements	Date
Sodium metabisulfite	All medicines when included as an excipient. For CO01, the declaration is “Sulfites”.	CO01	
Sodium methyl hydroxybenzoate	All medicines when included as an excipient.	CO01	
Sodium propyl hydroxybenzoate	All medicines when included as an excipient.	CO01	
Sodium salts <i>See also individual entries for active and excipient ingredients</i>	In medicines for oral use when: <ul style="list-style-type: none"> included as an excipient, and the total sodium content is more than 120mg per maximum recommended daily dose. 	CO01, CO04	
Sodium selenate <i>(see also – Selenium compounds)</i>	All Class 1 medicines.	2AG08, DS02, OD04	
Sodium selenite <i>(see also – Selenium compounds)</i>	All Class 1 medicines.	2AG08, DS02, OD04	
Sodium sulfate	All Class 1 medicines.	2AG08, DS02, OD04	
Sodium sulfite	All medicines when included as an excipient. For CO01, the declaration is “Sulfites”. <ul style="list-style-type: none"> Sodium content must be included in calculations under <i>Sodium salts</i> entry above. 	CO01	
Sodium sulfite anhydrous	All medicines when included as an excipient. For CO01, the declaration is “Sulfites”. <ul style="list-style-type: none"> Sodium content must be included in calculations under <i>Sodium salts</i> entry above. 	CO01	
Sodium sulfite heptahydrate	All medicines when included as an excipient. For CO01, the declaration is “Sulfites”. <ul style="list-style-type: none"> Sodium content must be included in calculations under <i>Sodium salts</i> entry above. 	CO01	
Sorbates	All medicines when included as an excipient. For CO01, the declaration is “Sorbates”.	CO01	
Sorbic acid	All medicines when included as an excipient. For CO01, the declaration is “Sorbates”.	CO01	

Ingredient	Conditions	Requirements	Date
Sorbitol	In medicines when included as an excipient: <ul style="list-style-type: none"> for oral use or for sublingual use; and the total sugar alcohol content of the preparation exceeds 2g per maximum recommended daily dose. For CO01, the declaration is “Sugar alcohols”.	CO01, CO05, SE103	
Soya bean and soya bean products	All medicines when included as an excipient. For CO01 the declaration is “Soya beans” or “Soya bean products”.	CO01	
Soyabean oil	All medicines when included as an excipient. For CO01 the declaration is “Soya beans” or “Soya bean products”.	CO01	
Soya oil	All medicines when included as an excipient. For CO01 the declaration is “Soya beans” or “Soya bean products”.	CO01	
St John's wort herb dry	All Class 1 medicines.	3CP26, IN02	
St John's wort herb powder	All Class 1 medicines.	3CP26, IN02	
Star anise oil	(a) In medicines containing more than 50 per cent star anise oil. (b) In addition to the requirements of (a) above, if (a) above applies and <ul style="list-style-type: none"> the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and where either or both of the following apply: <ul style="list-style-type: none"> the nominal capacity of the container is more than 50 mL and/or the container is not fitted with a restricted flow insert. 	(a) GM01 (b) GM50, GM51	
Stearamidopropyl PG-dimonium chloride phosphate	All Class 1 medicines.	GM35	
Stearyl dimethicone	All Class 1 medicines.	GM34, GM35	
Sucrose	Included as an excipient in medicines for oral use or for sublingual use; and <ul style="list-style-type: none"> the total sugar content (including lactose) exceeds 100mg per maximum recommended daily dose; and when the presence of sugars may have a significant glycaemic effect. 	CO01	

Ingredient	Conditions	Requirements	Date
Sucrose polycottonseedate	All Class 1 medicines.	GM34, GM35	
Sugar alcohols	In medicines when included as an excipient: <ul style="list-style-type: none"> • for oral use or for sublingual use; and • the total sugar alcohol content of the preparation exceeds 2g per maximum recommended daily dose. For CO01, the declaration is “Sugar alcohols”.	CO01, CO05, SE103	
Sugar cane wax alcohols	All Class 1 medicines.	1PB11, 1PB51	
Sugars (monosaccharide and disaccharides)	Included as an excipient in medicines for oral use or for sublingual use; and <ul style="list-style-type: none"> • the total sugar content (including lactose) exceeds 100mg per maximum recommended daily dose; and • when the presence of sugars may have a significant glycaemic effect. 	CO01	
Sulfite, metabisulfite and bisulfite salts	All medicines when included as an excipient. For CO01, the declaration is “Sulfites”.	CO01	
Sulfur dioxide	All medicines when included as an excipient. For CO01, the declaration is “Sulfites”.	CO01	
Sulfuric acid	In medicines: <ul style="list-style-type: none"> • other than for internal use; • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 0.5 per cent of sulfuric acid. 	GM50, GM51, GM54, GM55	
<i>Symphytum</i> spp.	For dermal use in medicines containing more than 10 mg/kg or 10 mg/L of <i>Symphytum</i> spp.	GM21, 1DR52, 1DR59, DR00	

Ingredient	Conditions	Requirements	Date
<i>Syzygium aromaticum</i>	<p>(a) In medicines containing more than 25 per cent of clove oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and where any one or more of the following apply:</p> <ul style="list-style-type: none"> • the container is not fitted with a restricted flow insert; or • the nominal capacity of the container is more than 15 mL and the container is not fitted with a child-resistant closure; or • the nominal capacity of the container is more than 25 mL. <p>(c) In addition to the requirements of (a) and (b) above, if (b) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM21, GM01</p> <p>(b) GM34, DR00</p> <p>(c) GM50, GM51, GM54, GM55</p>	
Tazarotene	For topical use.	1PB11, PB02	
Terbutaline	In metered aerosols.	GM105	
Terfenadine	In concentrations greater than 10 mg/kg or 10 mg/L of terfenadine.	3CP26, IN01	
Thalidomide	In concentrations greater than 10 mg/kg or 10 mg/L of thalidomide.	1PB11, PB03, PB01	
Tartrazine CI 19140	<p>All medicines when included as an excipient. For CO01, the declaration is ‘Tartrazine CI 19140’.</p> <p>Note – Tartrazine is permitted in oral medicines only if supplied in Australia before 15 February 1991, and before 5 June 1986 in New Zealand.</p>	CO01	
Thujone	<p>(a) In medicines containing more than 4% thujone.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM21, GM01</p> <p>(b) GM50, GM51</p>	

Ingredient	Conditions	Requirements	Date
Thyme oil	<p>(a) In medicines containing more than 50 per cent thyme oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 25 mL and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM01</p> <p>(b) GM50, GM51</p>	
<i>Thymus capitatus</i>	<p>(a) In medicines containing more than 50 per cent thyme oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 25 mL and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM01</p> <p>(b) GM50, GM51</p>	
<i>Thymus mastichina</i>	<p>(a) In medicines containing more than 50 per cent thyme oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 25 mL and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM01</p> <p>(b) GM50, GM51</p>	

Ingredient	Conditions	Requirements	Date
<i>Thymus serpyllum</i>	<p>(a) In medicines containing more than 50 per cent thyme oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 25 mL and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM01</p> <p>(b) GM50, GM51</p>	
<i>Thymus vulgaris</i>	<p>(a) In medicines containing more than 50 per cent thyme oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 25 mL and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM01</p> <p>(b) GM50, GM51</p>	
<i>Thymus vulgaris</i> MIS	<p>(a) In medicines containing more than 50 per cent thyme oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 25 mL and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM01</p> <p>(b) GM50, GM51</p>	

Ingredient	Conditions	Requirements	Date
<i>Thymus zygis</i>	<p>(a) In medicines containing more than 50 per cent thyme oil.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use and is not included in Schedule 3, 4 or 8 of the SUSMP; and • where either or both of the following apply: <ul style="list-style-type: none"> • the nominal capacity of the container is more than 25 mL and/or • the container is not fitted with a restricted flow insert. 	<p>(a) GM01</p> <p>(b) GM50, GM51</p>	
Tioconazole	<p>(a) In preparations for vaginal use.</p> <p>(b) Unless (a) above applies, in OTC medicines for topical use.</p>	<p>(a) 1CP19a, 3CP26, 6CP201, 6CP217, 1PB11a</p> <p>(b) DU11</p>	
Tramazoline	In nasal preparations for topical use.	8CP203	
Tranexamic acid	For the treatment of menorrhagia.	3CP26	
Tree nuts and tree nut products (not including coconut)	All medicines when included as an excipient. For CO01, the declaration is “Tree nuts” or “Tree nuts products”.	CO01	
Tretinoin	<p>(a) In concentrations greater than 10 mg/kg or 10 mg/L for oral use.</p> <p>(b) In concentrations greater than 10 mg/kg or 10 mg/L for topical use.</p>	<p>(a) 1PB11, PB03, PB01</p> <p>(b) 1PB11, PB02</p>	
Triamcinolone	In topical preparations for the treatment of mouth ulcers.	6CP216 or 6CP217	
Triethanolamine	<p>(a) In medicines containing more than 5 per cent of triethanolamine.</p> <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	<p>(a) GM34, GM21, GM33, DR00, GM32</p> <p>(b) GM50, GM51, GM54</p>	
<i>Triticum aestivum</i>	In medicines for internal use, except if the medicine contains no detectable gluten and contains no oats or malt.	CO01	

Ingredient	Conditions	Requirements	Date
<i>Triticum durum</i>	In medicines for internal use, except if the medicine contains no detectable gluten and contains no oats or malt.	CO01	
Tuna	All medicines when included as an excipient.	CO01	
Turpentine Oil	In medicines: <ul style="list-style-type: none"> • other than for internal use • where the product is not included in Schedule 3, 4 or 8 of the SUSMP; and • containing more than 25 per cent of turpentine oil. except GM54 and GM55 are only required if the turpentine oil is derived from a vegetable source.	GM50, GM51, GM54, GM55	
Ubidecarenone	All Class 1 medicines.	1CP104a	
Vitamin A <i>(see also Part 4.8 - 'General Requirements' for all Vitamins)</i>	In medicines for internal use: <ul style="list-style-type: none"> • labelled with a recommended daily dose of 5000 IU or less of vitamin A; • other than medicines containing 100 IU per dosage unit (divided preparations) or 100 mg/g (undivided preparations) or less of vitamin A . 	OD12, 1PB11b, 1PB13b	
Walnut	All medicines when included as an excipient. For CO01, the declaration is “Tree nuts” or “Tree nuts products”.	CO01	
Xylitol	In medicines when included as an excipient: <ul style="list-style-type: none"> • for oral use or for sublingual use; and • the total sugar alcohol content of the preparation exceeds 2g per maximum recommended daily dose. For CO01, the declaration is “Sugar alcohols”.	CO01, CO05, SE103	
Xylometazoline	In nasal preparations for topical use.	8CP203	
Zinc	In medicines for internal use with a recommended daily dose of 50 mg or less but more than 25 mg of zinc.	OD05	
Zinc chloride	(a) In medicines containing more than 5 per cent of zinc chloride. (b) In addition to the requirements of (a) above, if (a) above applies and <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, 4 or 8 of the SUSMP. 	GM34, GM33, DR00 (b) GM50, GM51, GM54	

Ingredient	Conditions	Requirements	Date
<p>Zinc compounds</p> <p><i>See also individual entries for active and excipient ingredients</i></p>	<p>In medicines for internal use with a recommended daily dose of 50 mg or less but more than 25 mg of zinc.</p>	<p>OD05</p>	
<p>Zinc sulfate</p>	<p>(a) In medicines other than:</p> <ul style="list-style-type: none"> • when included in Schedule 4 to the SUSMP; or • for internal use with a recommended daily dose of 50 mg or less but more than 25 mg of zinc; or • containing 5 per cent or less of zinc sulfate. <p>(b) In addition to the requirements of (a) above, if (a) above applies and</p> <ul style="list-style-type: none"> • the medicine is not for internal use; and • is not included in Schedule 3, or 8 of the SUSMP. 	<p>(a) GM34, GM33, DR00</p> <p>(b) GM50, GM51, GM54</p>	
<p><i>Zingiber officinale</i></p>	<p>In Class 1 medicines for oral use and:</p> <ul style="list-style-type: none"> • the extraction ratio of <i>Zingiber officinale</i> is 25:1 or higher; and • the equivalent dry weight per dosage unit is 2 g or more. 	<p>3CP27, 3CP107</p>	

Part 5 - Changes or updates to the RASML

5.1 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.

5.2 Updating the RASML

Proposals are to be dealt with by the relevant Delegate within ANZTPA areas of responsibility. Delegates may request the advice of any relevant advisory committee where appropriate. Where rescheduling issues affect the advisory statements required on medicine labels in certain circumstances, the Medicines Scheduling Committee (MSC) is the primary source of expert advice. It may consult with the other advisory committees as required.

Existing Substances

Rescheduling of a Substance

This process is yet to be finalised.

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 available on the ANZTPA 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 ANZTPA 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 ANZTPA web site, unless otherwise specified in the web site information;

- the ANZTPA 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 ANZTPA Delegate after taking into account advice from the expert committee (where required) and all comments. All decisions (including a decision not to change) and reasons for them are published on the ANZTPA web site;
- **Implementation**
Each new or amended label advisory statement will be identified with an Implementation Date. The statement will be required immediately on products where the application to licence the product is pending on the Implementation Date or received after the Implementation Date, and within 12 months on existing products. The 12 month transition period may be shortened in some circumstances (see Guidance, Date of Effect, above).

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 prospective licence holder 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.

5.3 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. MSC, ANZTPA, expert committee, licence holder, consumer) can initiate the process by making a submission to ANZTPA. 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 ANZTPA Area of Responsibility. It is preferred that submissions are made electronically to RASML@anztpa.org.

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

Each of the expert medicine advisory committees may provide advice and make recommendations in their area of expertise. The MSC may provide advice in relation to advisory statements required for the purpose of rescheduling substances. The decision is made by the relevant ANZTPA Delegate. Where a proposed change affects goods from more than one category of medicines, a coordinated approach is adopted within ANZTPA 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 length of time allowed for existing products to change to the new or amended advisory statements is 12 months from the Implementation Date, 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 ANZTPA web site and sponsors of affected products are notified directly by the relevant ANZTPA 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 ANZTPA web site.

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

ANZTPA publishes details of all proposals to change the RASML on the ANZTPA 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 ANZTPA expert committees are specifically invited to comment. All proposals are published on the ANZTPA 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. SUSMP 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 6 weeks from the date of publication on the ANZTPA 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 on the ANZTPA web site together with reasons for the decision. A decision **not** to change the RASML is published on the ANZTPA web site together with reasons for the decision. Amendments to the RASML will be published at this time also.

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. Requests for exemption should be directed to the appropriate ANZTPA Regulator and should include a justification for the request.