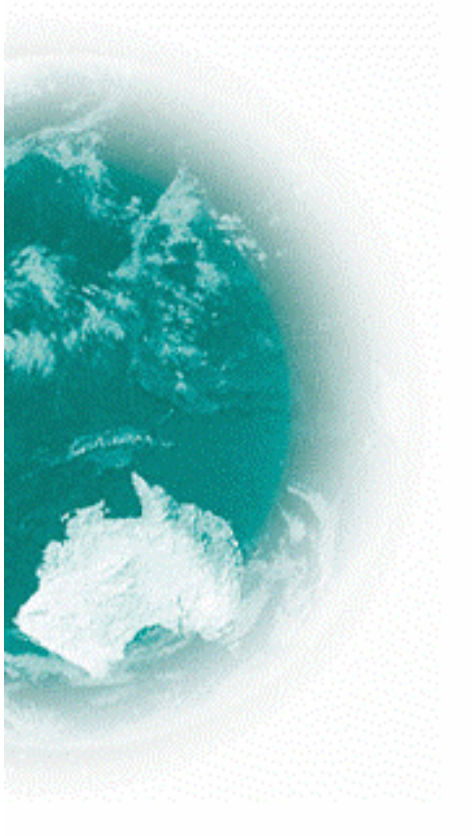
Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

Required Advisory Statements for Medicine Labels



Proposed Update 3.1

Consultation Document

November 2007

Required Advisory Statements for Medicine Labels – Proposed Update 3.1

NB. This version of the proposed updates to the Required Advisory Statements for Medicine Labels (RASML) is designated **3.1**.

In accordance with the procedural matters for amendments to the document that are specified as part of the RASML process, the proposal for the previous update (No. 3.0 dated 10 March 2006) was **not accepted** following TGA's consideration of responses from key stakeholders at the conclusion of the consultation period.

PURPOSE

This document is to advise stakeholders of proposed changes to the *Required Advisory Statements for Medicine Labels (edition 1, including update 2)* dated April 2006 (RASML).

REQUEST TO STAKEHOLDERS

Stakeholders are requested to review and comment on the proposed changes. Responses should include:

- Whether or not you support the proposed changes. If you do not support a change, you may make suggestions for an alternative acceptable to you;

- An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.

Responses should be sent to the TGA **no later than 6 weeks from the date this consultation paper is posted on the TGA website (19 December 2007).**

Please head all responses "RASML Update 3.1 – Response to Consultation"

Responses may be sent by mail, fax or e-mail as shown below.

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

Fax: 02 6232 8659

E-mail:otc.medicines@tga.gov.au

If you wish to discuss the proposed amendments, please call 02 6232 8652.

The TGA has specifically invited comment on the proposed amendments from the following organisations. You may wish to consider submitting your response to one of these organisations, for incorporation in its overall response, rather than submission direct to the TGA.

- Australian Self-Medication Industry Inc. (ASMI)
- Complementary Healthcare Council of Australia (CHC)
- Consumers' Health Forum
- Medicines Australia
- Pharmaceutical Society of Australia
- Pharmacy Guild of Australia

BACKGROUND INFORMATION

1. Revised warning statements on the labels of over the counter (OTC) non-selective non-steroidal anti-inflammatory drugs (NSAIDs).

The proposed changes pertaining to revised warning statements on the labels of over the counter (OTC) non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in this latest RASML amendment were initiated as a result of:

- The outcomes of the TGA's Review Report of cardiovascular, gastrointestinal and cutaneous safety of OTC non-selective non-steroidal anti-inflammatory drugs (NSAIDs): Ibuprofen, diclofenac, naproxen, flurbiprofen, ketoprofen and mefenamic acid (*TGA Review of NSAIDs)*;
  and,
- Recommendations by the Medicines Evaluation Committee (MEC), who discussed the *TGA Review of NSAIDs* at its meeting on 7 December 2006. The MEC considered a proposal by the TGA to expand the warning statements currently required for OTC products containing specified non-selective NSAIDs. The MEC supported the intent of revised warnings that addressed allergic reactions and the concept of 'the lowest effective dose used for the shortest possible duration', but recommended that a working group propose appropriate wording. Subsequently, a working group that included consumer, industry and TGA representation was established. This group provided the following suggested statements to the MEC for consideration at their meeting held on 7 June 2007:
  1. *"Do not use for more than a few days at a time unless a doctor has told you to. Keep to the recommended dose. Excessive use can be harmful"*.
  2. *"If you get an allergic or skin reaction, stop taking and see your doctor immediately"*.

  While the MEC recommended that the warning statements proposed by the working group were appropriate, the committee agreed with a suggestion from some members of the working group that it was not necessary to include the specific reference to 'skin' reactions in statement '2', above. Therefore, this statement was adjusted to read:
  - *"If you get an allergic reaction, stop taking and see your doctor immediately"*.

  Further to MEC's considerations, the TGA considered that in statement '1', above, the wording '*Keep to the recommended dose'* was not consistent with use of the 'lowest effective dose'. Therefore, this statement was adjusted to read:
  - *"Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful"*.

2. Vitamin A

Vitamin A is a fat-soluble vitamin which helps maintain normal reproduction, vision and immune function. Following the change to the scheduling of Vitamin A in Amendment No. 1 of the *Standard for the Uniform Scheduling of Drugs and Poisons* No. 22, the TGA has examined the adequacy and relevance of the existing label advisory statements for vitamin A, which are:

1. *The recommended adult daily amount of vitamin A from all sources is 2 500 International Units.*
2. *WARNING – When taken in excess of 8 000 IU vitamin A can cause birth defects.*
3. *If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist*

The TGA sought the advice of CMEC in relation to the label advisory statements for vitamin A. In accordance with the advice of CMEC, the TGA is proposing the revision of two of the label advisory statements for products containing 3 000 μg Retinol Equivalents or less, and the continued inclusion of the third. The revised statements are:

1. *The recommended adult daily intake of vitamin A from all sources is 700 μg retinol equivalents for women, and 900 μg retinol equivalents for men.*
2. *WARNING – When taken in excess of 3 000 μg retinol equivalents, vitamin A may cause birth defects.*
3. *If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist."*

Products containing 33 μg retinol equivalents or less of vitamin A per dosage unit of a divided preparation, or 33 μg retinol equivalents or less of vitamin A per gram of an undivided preparation, will not be required to be labelled with the advisory statements, in line with previous practice.

At present, *Therapeutic Goods Order 69* requires that the content of vitamin A in medicines be expressed on medicine labels in International Units. The TGA is investigating changing the labelling units for vitamin A to micrograms retinol equivalents. However, until such a change is mandated through an amendment to TGO69, sponsors should continue to use International Units as the units for expressing vitamin A content. Conversions to International Units (rounded) result in the following label advisory statements:

1. *The recommended adult daily intake of vitamin A from all sources is 2330 IU for women, and 3000 IU for men.*
2. *WARNING – When taken in excess of 10 000 IU, vitamin A may cause birth defects.*
3. *If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist."*

3. Selenium

Selenium is an antioxidant mineral commonly used in multivitamin/minerals and cardiovascular and prostate health products. Following the changes to the scheduling of selenium in Amendment No. 1 of the *Standard for the Uniform Scheduling of Drugs and Poisons* No. 22, the TGA has examined the adequacy and relevance of the current required label advisory statements for selenium. The existing statements are:

- *Selenium in dietary supplements should not exceed a daily dose of 100 μg.* (Statement 27)
- *Selenium is toxic in high doses.* (Statement 28)
- *Not suitable for use by children under 15.* (Statement 8)

The TGA sought the advice of the CMEC in relation to this matter. In accordance with the advice of CMEC, the TGA is proposing the revision of two of the label advisory statements, and the removal of the third. The proposed revised statements are:

- *This product contains selenium which is toxic in high doses.*
- *A daily dose of 150 microgram for adults of selenium from dietary supplements should not be exceeded.*

Of note, the statement in relation to use in children under 15 (statement 8) has been replaced with reference to adults in statement 28. Statement 8 is currently used only for selenium-containing products, however whilst is will no longer be required for selenium-containing products, it will not be removed from the RASML list of advisory statements as it may be of use in the future for other ingredients.

Advisory statements are to be applied to selenium containing Listed medicines. The selenium-containing ingredients currently approved for use in Listed medicines are high selenium yeast, selenocysteine, selenomethionine, sodium selenate, and sodium selenite. The proposed changes are to be applied to each ingredient entry.

4. *Cimicifuga racemosa* (Black cohosh)

Cimicifuga racemosa (Black cohosh) is a herb commonly used in menopause formulations. The Therapeutic Goods Administration (TGA) first reviewed the safety of Black cohosh in 2005 following reports of possible liver problems internationally and in Australia. Following the safety review, the TGA decided that medicines containing Black cohosh must carry the following label statement:

> "*Warning: Black cohosh may harm the liver in some individuals. Use under the supervision of a healthcare professional*"

This statement was included as advisory statements 153 and 154 in the April 2006 edition of *Required Advisory Statements for Medicine Labels*.

Since the initial safety review, some additional cases of liver reactions in association with the use of medicines containing Black cohosh have been reported in Australia. In order to determine whether additional regulatory controls for Black cohosh medicines might be necessary, the TGA convened a group of experts from Australia and New Zealand to provide advice on this matter.

Following consideration of all available information, the expert advisory group concluded that there appears to be an association between the use of Black cohosh and liver damage, but that it is very rare. It was not possible to identify, with any certainty, the strength of the association, or any particular vulnerable group, type of preparation, dose, duration of use or specific products.

The expert advisory group considered that Black cohosh is still suitable for use in complementary medicines, but recommended a revised advisory statement on the medicine label. The revised statement should aim to ensure that consumers are appropriately informed about the risk, provide sufficient information to assist them in the early detection of the more critical signs and symptoms of liver reactions and, if detected, to seek medical attention.

The TGA accepted the recommendations of the expert advisory group. Following consideration of stakeholder input, and confirmation of accordance with other international regulatory approaches, the wording of the black cohosh label warning will now be:

"*Warning: In very rare cases, Black cohosh has been associated with liver failure. If you experience yellowing of the skin or eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, stop using this product and see your doctor*"

5. *Larrea tridentata* (Chaparral)

Larrea tridentata (Chaparral) is a herb that is commonly used in preparations for inflammatory conditions.

In 1992, following publication of case reports of hepatotoxicity associated with Chaparral and a subsequent warning issued by the US FDA that consumption of this herb should be ceased, the TGA determined, that products containing chaparral could remain on the market providing they carried a warning to consumers to use the product under the supervision of a healthcare professional. As such, Listed medicines containing Chaparral have been included with the following warning on their label:

"*Warning: Chaparral may harm the liver in some people. Use only under the supervision of a healthcare professional.*"

The TGA undertook a full safety review of chaparral in 2002, and in April 2007, the Complementary Medicines Evaluation Committee (CMEC) was again requested to comment on the regulatory arrangements currently in place for products containing chaparral, and the adequacy of the current advisory statement. CMEC recommended to the TGA that existing regulatory arrangements, including the advisory statement, for Listed medicines that contain *Larrea tridentata* are appropriate.

As this statement has not previously been included in the *Required Advisory Statements for Medicine Labels*, the inclusion of this statement in the proposed update will formalise this requirement.

6. *Zingiber officinale*

Zingiber officinale (Ginger) is a herb commonly used for a large variety of conditions such as relief of nausea and mild anxiety through to weight management and the maintenance of health digestive function.

The TGA first considered the safety of ginger in 1997. Ginger rhizome has been used in traditional herbal medicine for thousands of years. Whilst 'adverse effects' are not identified in the traditional literature, there is an acknowledgement amongst practitioners that untoward effects can occur with 'inappropriate use'. At the time, the TGA had received reports of arthralgia, headache and diarrhoea in people taking a particular concentrated ginger product. Recent development of public interest in herbal medicine has spawned a modern approach to the preparation of the traditional ginger products. New methods of extraction and higher concentrations of the preparations are now available. These may be sold without advice from a healthcare practitioner and without warning of the potential side effects.

Given the possibility of adverse events associated with high concentration ginger products or those extracted using non-traditional methods, the TGA has proposed an advisory statement based around known potential adverse events for such products. The TGA considers that such products are still suitable for use in Listed medicines when labelled with an advisory statement. Since 1999, the TGA has advised sponsors to include the following advisory statement:

"*Individuals taking anticoagulants should seek medical advice before taking this product. Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this product*"

As this statement has not previously been included in the *Required Advisory Statements for Medicine Labels*, the inclusion of this statement in the proposed update will formalise this requirement.

7. Labelling for seafood-derived glucosamine products

Glucosamine is commonly used in joint formulations and was approved for use in Listed medicines in 1999. During deliberation of the use of glucosamine in Listed medicines, CMEC considered that an advisory statement was warranted for glucosamine products that are extracted from marine sources. CMEC's rationale for requiring a warning statement was that, if a person is allergic to seafood, minute quantities of allergen can produce a potentially fatal reaction.

Since 1999, the TGA has advised sponsors to include the following advisory statement on seafood-derived glucosamine products:

"*Derived from seafood*"

As this statement has not previously been included in the *Required Advisory Statements for Medicine Labels*, the inclusion of this statement in the proposed update will formalise this requirement.

8. Potassium content of Glucosamine sulfate potassium chloride complex

In addition to the advisory statement proposed above for seafood-derived glucosamine products, the TGA is proposing an advisory statement for the active ingredient *glucosamine sulfate potassium chloride complex* to draw the attention of potentially vulnerable consumers to the potassium content of this ingredient.

In late 2006, the National Drugs and Poisons Scheduling Committee revised the scheduling for potassium chloride. Through the consultation process, it became clear that there is a general lack of awareness, by both consumers and health care practitioners, about the potassium content in certain glucosamine products. Consequently, these products may have the potential to cause hyperkalemia in certain patient groups (e.g. the elderly, those with renal impairment, those on potassium-sparing diuretics, and those already taking potassium supplements).

The TGA requested that CMEC consider whether a label advisory statement is appropriate for products containing glucosamine sulfate potassium chloride complex, and if so, to provide advice on the wording of such a statement. CMEC advised that the proposed label advisory statement should be mandated, and the TGA has accepted this advice following consideration of stakeholder comment on the issue. The statement is:

"*Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use. Keep out of reach of children*"

9. Royal jelly

Royal jelly is a secretion of the salivary glands of the worker hive bee. It is a complex mixture of proteins, amino acids, lipids, carbohydrates, fatty acids and vitamins. Royal jelly has been used in therapeutic goods since the early 1990's.

Attention was first drawn to the allergic potential of royal jelly in Australia with the publication in 1993 of case studies of five people who developed asthma and anaphylaxis after ingestion of royal jelly. In 1994, following a further six reports of adverse events, including deaths, related to the ingestion of royal jelly, a requirement for a warning label on all therapeutic goods and foods containing royal jelly was introduced.

In 2001, following the receipt of adverse reaction reports, the TGA, in consultation with CMEC, reviewed a report entitled the *Bee Product Warning Scientific Review Working Group Report*. In light of the information in this review, and in line with the recommendation of CMEC, the TGA advised that a revised advisory statement should be placed on Listed medicines containing royal jelly.

The TGA has long advised sponsors to include on Listed medicines that contain royal jelly the following advisory statements:

> "*Not to be taken by asthma and allergy sufferers. This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities - especially in asthma and allergy suffers*".

The first sentence is to be printed on the front panel in 3mm type.

As this statement has not previously been included in the *Required Advisory Statements for Medicine Labels*, the inclusion of this statement in the proposed update will formalise this requirement.

10. Propolis

Propolis is a resinous substance used by bees as a structural element in hive repair. Propolis has a history of therapeutic use, and has been approved for use in Listed complementary medicines in Australia for over a decade.

As a bee product, propolis has the potential to cause severe allergic reactions in susceptible people. For this reason, the TGA has advised sponsors of propolis-containing medicines to include the following warning statement for products intended for external use:

> "*WARNING: Propolis may cause skin irritation. Test before use*"

Products intended for internal use should use the following statement:

> "*WARNING: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs - discontinue use*".

The warning statement above is consistent with the statements required for foods containing propolis.

As this statement has not previously been included in the *Required Advisory Statements for Medicine Labels*, the inclusion of this statement in the proposed update will formalise this requirement.

11. Shark Cartilage

Shark cartilage is commonly used in joint formulations. On 14 April 1999, the National Manager of the Therapeutic Goods Administration declared, under Section 7 of the *Therapeutic Goods Act*

1989, that shark cartilage, when presented in the form of capsules, pills, tablets or powder, other than as a wholesale product in powdered form for use as an ingredient in food, is a therapeutic good

To temper the impact of this declaration on industry, prior to the Section 7 declaration coming into effect, Schedule 4 of the *Therapeutic Goods Regulations 1990* was changed to allow shark cartilage to be used as an active ingredient in Listed medicines.

At the time of the addition of shark cartilage to Schedule 4 of the *Therapeutic Goods Regulations 1990*, CMEC recommended the addition of a warning statement to shark cartilage products. Since that time, the TGA has advised sponsors of the need to label shark cartilage products with the warning statement:

"*Children, pregnant or breastfeeding women, and those who have recently had a heart attack, surgery or a major accident should not consume this product without medical advice*"

As this statement has not previously been included in the *Required Advisory Statements for Medicine Labels*, the inclusion of this statement in the proposed update will formalise this requirement.

12. Phenylalanine

Phenylalanine is an amino acid that is used in many general nutritional supplement products for general wellbeing, as well as for mood improvement, weight loss and other purposes.

In August 2000, CMEC recommended to the TGA that all medicines containing L-phenylalanine as an active ingredient should carry the proposed warning statement when the recommended daily dose of L-phenylalanine exceeds 500 mg.

The label warning was recommended to reduce the likelihood of damage to the foetuses of women who are heterozygous for phenylketonuria. These women may be susceptible to elevated blood phenylalanine levels if a substantial amount of supplemental phenylalanine is consumed.

The TGA consulted with stakeholders at the time, and no substantial opposition to the warning was raised.

The proposed warning statement for oral or sublingual phenylalanine products the maximum recommended daily dose of which contains more than 500 mg of phenylalanine is:

"*Do not use if pregnant or likely to become pregnant*"

As this statement has not previously been included in the *Required Advisory Statements for Medicine Labels*, the inclusion of this statement in the proposed update will formalise this requirement.

13. Caffeine-containing herbs

Caffeine-containing herbs are commonly found in products indicated for weight management. In 2002, following consideration of reported adverse events relating to caffeine-containing medicines, CMEC advised the TGA that, for safety reasons, it was important that consumers be aware of the caffeine contained in the medicines they consume.

Based on the recommendations of CMEC, and in consultation with industry, the TGA has proposed a two-tiered warning statement in which products containing more than 10 mg of caffeine per maximum recommended daily dose (MRDD) are required to state the amount of caffeine per

MRDD. Products with 10 mg or less of caffeine per MRDD would not be required to quantify the amount of caffeine, but would be required to indicate its presence in the product.

The advisory statement for products containing more than 10 mg of caffeine per maximum recommended daily dose (MRDD) is:

"*Contains* [amount of caffeine in milligrams] *mg of caffeine*"

The advisory statement for products with 10 mg or less of caffeine per MRDD is:

"*The recommended dose of this medicine provides small amounts of caffeine*"

14. *Polygonum multiflorum*

Polygonum multiflorum is used in Traditional Chinese Medicine for a variety of purposes, including toning up the vital essence and blood, and fortifying the muscles, tendons and bones. It is used in dizziness with tinnitus, premature greying of the hair, soreness and weakness of low-back and knee, and numbness of limbs.

The medical literature contains ten cases of adverse reactions linking *P. multiflorum* use and hepatotoxicity. Seven cases have been reported by the European Medicines and Healthcare products Regulatory Agency (MHRA) in a media release. The TGA Adverse Drug Reactions Database includes one report to the TGA regarding hepatotoxicity following ingestion of *P. multiflorum*. However, the above numbers of cases cannot be added as it is likely that there is some overlap in the above sets of reports.

The reported cases of hepatotoxicity associated with *P. multiflorum* use suggest that symptoms of hepatotoxicity may develop within one to six months of use, with only one case reporting symptom development within two weeks. In all reported cases (involving 8 females and 2 males) hepatic symptoms resolved on cessation of the product. A report by the UK Medicines and Healthcare Products Regulatory Agency included an additional seven cases. In all cases there was no history of liver disease and an idiosyncratic reaction was suggested in 6 cases. In two cases, a positive re-challenge was noted. It is unclear how many reports included *P. multiflorum* as a single ingredient only, and in one case the product included *C. racemosa* (Black Cohosh), a herb that has been associated with hepatotoxicity. Details on preparation types were not complete.

At its 295th meeting (September 2006), ADRAC considered there to be sound evidence linking the use of *P. multiflorum* with the development of hepatic toxicity. Members determined that there is insufficient information available (eg. on possible relationships to dose or duration of treatment) to allow comment on the extent of the risk, but noted that the risk is unlikely to be high.

At its 61st meeting, CMEC recommended to the TGA that *Polygonum multiflorum* remains suitable for use in Listed medicines, but that the following advisory statement should be mandated for Listed medicines:

> "*Warning: Polygonum multiflorum may harm the liver in some people. Use under the supervision of a healthcare professional*"

PROPOSED AMENDMENTS

Introductory Sections

No changes proposed in this update.

Section 1 – Medicines to Which Advisory Statements Apply

Summary of Proposed Changes

Changes are proposed as follows:

Substance	Change Type
Diclofenac (Entry 1 of 2)	Amendment
Diclofenac (Entry 2 of 2)	Amendment
Flurbiprofen	New Entry
Ibuprofen (Entry 1 of 4)	Amendment
Ibuprofen (Entry 2 of 4)	Amendment
Ibuprofen (Entry 3 of 4)	Amendment
Ibuprofen (Entry 4 of 4)	Amendment
Ketoprofen (Entry 1 of 2)	New Entry
Ketoprofen (Entry 2 of 2)	New Entry
Mefenamic acid (Entry 1 of 2)	Amendment
Mefenamic acid (Entry 2 of 2)	Amendment
Naproxen (Entry 1 of 2)	Amendment
Naproxen (Entry 2 of 2)	Amendment
Vitamin A	Amendment
Selenium	Amendment
Cimicifuga racemosa	Amendment
Larrea tridentata	New Entry
Zingiber officinale	New Entry
Glucosamine hydrochloride	New Entry
Glucosamine sulfate potassium chloride complex	New Entry
Glucosamine sulfate potassium chloride complex	New Entry
Glucosamine sulfate sodium chloride complex	New Entry
Glucosamine sulphate	New Entry
Propolis	New Entry
Royal jelly	New Entry
Shark cartilage	New Entry
Phenylalanine	New Entry
Caffeine	New Entry
Polygonum multiflorum	New Entry

Details of the proposed changes are shown in the tables below. These tables show:

- the existing entry which requires amendment (showing proposed deletions ~~in blue strikethrough~~)
- the proposed new entry (inserted details in red and underlined)
- an explanation for why the change is being proposed
- proposed transitional arrangements

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing (Page 29)	Diclofenac *(Entry 1 of 2)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 128, 149, 130)[j]	5 April 2006
Proposed	Diclofenac *(Entry 1 of 2)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, ~~128~~, 149, 130, 159, 160)[j]	[date to be inserted]
Existing (Page 29)	Diclofenac *(Entry 2 of 2)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, 128, 149, 130, 133)[j]	5 April 2006
Proposed	Diclofenac *(Entry 2 of 2)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, ~~128~~, 149, 130, 133, 159, 160)[j]	[date to be inserted]
Comment	Inclusion as a result of the *TGA Review of NSAIDs* and MEC recommendations.			
Transition	The normal RASML transition period would apply, that is, the new requirement would apply to all new products approved after the date of gazettal, and to existing products one year from the date of gazettal.			

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing	No existing entry			
Proposed	Flurbiprofen	When included in a Schedule to the SUSDP.	(126, 127, 18, 149, 130, 133, 159, 160)[j]	[date to be inserted]
Comment	Statements 18, 126, 130, 133 and 149 - inclusion as a result of harmonisation with requirements for similar non-selective NSAIDs. Statements 159 and 160 - inclusion as a result of the *TGA Review of NSAIDs* and MEC recommendations.			
Transition	The normal RASML transition period would apply, that is, the new requirement would apply to all new products approved after the date of gazettal, and to existing products one year from the date of gazettal.			

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing (Page 32)	Ibuprofen *(Entry 1 of 4)*	For the purpose of exclusion from the Schedules to the SUSDP, when the preparation is for oral use and is indicated exclusively for the treatment of dysmenorrhoea.	126, 127, 128, 151, 130, 131, 132	5 Apr 2006
Proposed	Ibuprofen *(Entry 1 of 4)*	For the purpose of exclusion from the Schedules to the SUSDP, when the preparation is for oral use and is indicated exclusively for the treatment of dysmenorrhoea.	126, 127, ~~128~~, 151, 130, 131, 132, 159, 160	[date to be inserted]
Existing (Page 32)	Ibuprofen *(Entry 2 of 4)*	For the purpose of exclusion from the Schedules to the SUSDP, when the preparation is for oral use and is NOT indicated exclusively for the treatment of dysmenorrhoea.	126, 18, 127, 128, 151, 130, 131, 132, 133	5 Apr 2006
Proposed	Ibuprofen *(Entry 2 of 4)*	For the purpose of exclusion from the Schedules to the SUSDP, when the preparation is for oral use and is NOT indicated exclusively for the treatment of dysmenorrhoea.	126, 18, 127, ~~128~~, 151, 130, 131, 132, 133, 159, 160	[date to be inserted]
Existing (Page 32)	Ibuprofen *(Entry 3 of 4)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 128, 149, 130)[j]	23 Jun 2004
Proposed	Ibuprofen *(Entry 3 of 4)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, ~~128~~, 149, 130, 159, 160)[j]	[date to be inserted]
Existing (Page 32)	Ibuprofen *(Entry 4 of 4)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, 128, 149, 130, 133)[j]	23 Jun 2004

Proposed	Ibuprofen *(Entry 4 of 4)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, ~~128~~, 149, 130, 133, 159, 160)[j]	[date to be inserted]
Comment	Inclusion as a result of the *TGA Review of NSAIDs* and MEC recommendations.			
Transition	The normal RASML transition period would apply, that is, the new requirement would apply to all new products approved after the date of gazettal, and to existing products one year from the date of gazettal.			

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing	No existing entry			
Proposed	Ketoprofen *(Entry 1 of 2)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 130, 159, 160)[j]	[date to be inserted]
	Ketoprofen *(Entry 2 of 2)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 149, 18 130, 133, 159, 160)[j]	[date to be inserted]
Comment	Statements 18, 126, 130, 133 and 149 - inclusion as a result of harmonisation with requirements for similar non-selective NSAIDs. Statements 159 and 160 - inclusion as a result of the *TGA Review of NSAIDs* and MEC recommendations.			
Transition	The normal RASML transition period would apply, that is, the new requirement would apply to all new products approved after the date of gazettal, and to existing products one year from the date of gazettal.			

	Medicines Containing .	***Which Meet The Following Conditions..***	***Require Statement(s)***	***Gazettal Date***
Existing (Page 34)	Mefenamic acid *(Entry 1 of 2)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126,127, 128, 149, 130)[j]	23 Jun 2004
Proposed	Mefenamic acid *(Entry 1 of 2)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, ~~128~~, 149, 130, 159, 160)[j]	[date to be inserted]
Existing (Page 34)	Mefenamic acid *(Entry 2 of 2)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, 128, 149, 130, 133)[j]	23 Jun 2004
	Mefenamic acid *(Entry 2 of 2)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, ~~128~~, 149, 130, 133, 159, 160)[j]	[date to be inserted]
Comment	Inclusion as a result of the *TGA Review of NSAIDs* and MEC recommendations.			
Transition	The normal RASML transition period would apply, that is, the new requirement would apply to all new products approved after the date of gazettal, and to existing products one year from the date of gazettal.			

	Medicines Containing .	***Which Meet The Following Conditions..***	***Require Statement(s)***	***Gazettal Date***
Existing (Page 35)	Naproxen *(Entry 1 of 2)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, 128, 149, 130)[j]	23 Jun 2004
Proposed	Naproxen *(Entry 1 of 2)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is indicated exclusively for the treatment of dysmenorrhoea.	(126, 127, ~~128~~, 149, 130, 159, 160)[j]	[date to be inserted]
Existing (Page 35)	Naproxen *(Entry 2 of 2)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, 128, 149, 130, 133)[j]	23 Jun 2004
Proposed	Naproxen *(Entry 2 of 2)*	When: (a) included in a Schedule to the SUSDP; and (b) the preparation is NOT indicated exclusively for the treatment of dysmenorrhoea.	(126, 18, 127, ~~128~~, 149, 130, 133, 159, 160)[j]	[date to be inserted]
Comment	Inclusion as a result of the *TGA Review of NSAIDs* and MEC recommendations.			
Transition	The normal RASML transition period would apply, that is, the new requirement would apply to all new products approved after the date of gazettal, and to existing products one year from the date of gazettal.			

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing (Page 31)	High selenium yeast	When included in Schedule 4 Part 5 Division 3 Item 11 of the Regulations.	27, 28, ~~8~~	23 Jun 2004
Proposed	High selenium yeast	When included in Schedule 4 Part 5 Division 3 Item 11 of the Regulations.	27, 28	***[date to be inserted]***
Comment	Statement 8 is to be removed from this entry and its effect incorporated in statement 28. Stakeholders should note that changes to statements 27 and 28 are proposed below.			
Transition	For existing products, a one-year transition period is proposed. However, new products will be required to comply immediately.			

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing (Page 39)	Selenium yeast – high	When included in Schedule 4 Part 5 Division 3 Item 11 of the Regulations.	27, 28, ~~8~~	23 Jun 2004
Proposed	Selenium yeast – high	When included in Schedule 4 Part 5 Division 3 Item 11 of the Regulations.	27, 28	***[date to be inserted]***
Comment	Statement 8 is to be removed from this entry and its effect incorporated in statement 28. Stakeholders should note that changes to statements 27 and 28 are proposed below.			
Transition	For existing products, a one-year transition period is proposed. However, new products will be required to comply immediately.			

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing (Page 39)	Selenocysteine	When included in Schedule 4 Part 5 Division 3 Item 13 of the Regulations.	27, 28, ~~8~~	23 Jun 2004
Proposed	Selenocysteine	When included in Schedule 4 Part 5 Division 3 Item 13 of the Regulations.	27, 28	***[date to be inserted]***
Comment	Statement 8 is to be removed from this entry and its effect incorporated in statement 28. Stakeholders should note that changes to statements 27 and 28 are proposed below.			
Transition	For existing products, a one-year transition period is proposed. However, new products will be required to comply immediately.			

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing (Page 40)	Selenomethionine	When included in Schedule 4 Part 5 Division 3 Item 12 of the Regulations.	27, 28, ~~8~~	23 Jun 2004
Proposed	Selenomethionine	When included in Schedule 4 Part 5 Division 3 Item 12 of the Regulations.	27, 28	***[date to be inserted]***
Comment	Statement 8 is to be removed from this entry and its effect incorporated in statement 28. Stakeholders should note that changes to statements 27 and 28 are proposed below.			
Transition	For existing products, a one-year transition period is proposed. However, new products will be required to comply immediately.			

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing (Page 40)	Sodium selenate	When included in Schedule 4 Part 5 Division 3 Item 14 of the Regulations.	27, 28, ~~8~~	23 Jun 2004
Proposed	Sodium selenate	When included in Schedule 4 Part 5 Division 3 Item 14 of the Regulations.	27, 28	***[date to be inserted]***
Comment	Statement 8 is to be removed from this entry and its effect incorporated in statement 28. Stakeholders should note that changes to statements 27 and 28 are proposed below.			
Transition	For existing products, a one-year transition period is proposed. However, new products will be required to comply immediately.			

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing (Page 41)	Sodium selenite	When included in Schedule 4 Part 5 Division 3 Item 15 of the Regulations.	27, 28, ~~8~~	23 Jun 2004
Proposed	Sodium selenite	When included in Schedule 4 Part 5 Division 3 Item 15 of the Regulations.	27, 28	***[date to be inserted]***
Comment	Statement 8 is to be removed from this entry and its effect incorporated in statement 28. Stakeholders should note that changes to statements 27 and 28 are proposed below.			
Transition	For existing products, a one-year transition period is proposed. However, new products will be required to comply immediately.			

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing (Page 43)	Yeast – high selenium	When included in Schedule 4 Part 5 Division 3 Item 11 of the Regulations.	27, 28, ~~8~~	23 Jun 2004
Proposed	Yeast – high selenium	When included in Schedule 4 Part 5 Division 3 Item 11 of the Regulations.	27, 28	***[date to be inserted]***
Comment	Statement 8 is to be removed from this entry and its effect incorporated in statement 28. Stakeholders should note that changes to statements 27 and 28 are proposed below.			
Transition	For existing products, a one-year transition period is proposed. However, new products will be required to comply immediately.			

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing (Page 40)	Vitamin A (see also Vitamins)	~~For the purpose of exclusion from the Schedules to the SUSDP when for human therapeutic use in preparations for internal use OTHER THAN those:~~ ~~(a) containing 100 International Units or less of vitamin A per dosage unit of a divided preparation; or~~ ~~(b) 100 International Units or less of vitamin A per gram of an undivided preparation.~~	$31^{d,e}$, $32^{d,e,c}$ $33^{d,e,c}$	1 June 2005
Proposed	Vitamin A (see also Vitamins)	In medicines for internal use containing 3 000 µg retinol equivalents or less of vitamin A other than those containing: (a) 33 µg retinol equivalents or less of vitamin A per dosage unit of a divided preparation; or (b) 33 µg retinol equivalents or less of vitamin A per gram of an undivided preparation.	$31^{d,e}$, $32^{d,e,c}$ $33^{d,e,c}$	[date to be inserted]
Comment	The above change is proposed to align RASML with the SUSDP for vitamin A, and is in line with current evidence.			
Transition	For existing products, a one-year transition period is proposed. However, new products will be required to comply immediately.			

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing (Page 27)	*Cimicifuga racemosa*	When included in a Listed medicine	153,154	5 April 2006
Proposed	*Cimicifuga racemosa*	When included in a Listed medicine	(153,172)	[date to be inserted]
Comment	Following the receipt of additional adverse event reports associated with black cohosh, an expert advisory group reviewed the available data and recommended that although black cohosh remains suitable for use in Listed medicines, a revised warning statement is required.			
Transition	The normal RASML transition period would apply, that is, the new requirement would apply to all new products approved after the date of gazettal, and to existing products one year from the date of gazettal.			

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing	No existing entry			
Proposed	*Larrea tridentata*	When included in a Listed medicine	(161, 152)	[date to be inserted]
Comment	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to.			
Transition	It is proposed that its implementation be immediate.			
Existing	No existing entry			
Proposed	*Zingiber officinale*	When included in a Listed medicine; AND when the extraction ratio is 25:1 or higher; AND when the equivalent dry weight per dosage unit is 2g or higher	(162, 163)	[date to be inserted]
Comment	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to.			
Transition	It is proposed that its implementation be immediate.			

	Medicines Containing .	*Which Meet The Following Conditions ...*	*Require Statement(s)*	*Gazettal Date*
Existing	No existing entry			
Proposed	Glucosamine hydrochloride	When included in a Listed medicine and derived from a marine source	(164)	[date to be inserted]
Comment	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to.			
Transition	It is proposed that its implementation be immediate.			
Existing	No existing entry			
Proposed	Glucosamine sulfate potassium chloride complex	When included in a Listed medicine and derived from a marine source	(164)	[date to be inserted]
Comment	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to.			
Transition	It is proposed that its implementation be immediate.			
Existing	No existing entry			
Proposed	Glucosamine sulfate potassium chloride complex	When included in a Listed medicine	(165, 166, 1)	[date to be inserted]
Comment	See *Background* above			
Transition	The normal RASML transition period would apply, that is, the new requirement would apply to all new products approved after the date of gazettal, and to existing products one year from the date of gazettal.			
Existing	No existing entry			
Proposed	Glucosamine sulfate sodium chloride complex	When included in a Listed medicine and derived from a marine source	(164)	[date to be inserted]
Comment	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to.			
Transition	It is proposed that its implementation be immediate.			

	Medicines Containing .	*Which Meet The Following Conditions ...*	*Require Statement(s)*	*Gazettal Date*
Existing	No existing entry			
Proposed	Glucosamine sulphate	When included in a Listed medicine and derived from a marine source	(164)	[date to be inserted]
Comment	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to.			
Transition	It is proposed that its implementation be immediate.			
Existing	No existing entry			
Proposed	Propolis	When included in a Listed medicine for internal use	(168)	[date to be inserted]
Comment	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to.			
Transition	It is proposed that its implementation be immediate.			
Existing	No existing entry			
Proposed	Propolis	When included in a Listed medicine for external use	(169)	[date to be inserted]
Comment	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to.			
Transition	It is proposed that its implementation be immediate.			
Existing	No existing entry			
Proposed	Royal jelly	When included in a Listed medicine	(170[k,l],171)	[date to be inserted]
Comment	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to.			
Transition	It is proposed that its implementation be immediate.			
Existing	No existing entry			
Proposed	Shark cartilage	When included in a Listed medicine	(167)	[date to be inserted]
Comment	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to.			
Transition	It is proposed that its implementation be immediate.			

	Medicines Containing .	*Which Meet The Following Conditions ...*	*Require Statement(s)*	*Gazettal Date*
Existing	No existing entry			
Proposed	Phenylalanine	When included in a Listed medicine for oral or sublingual administration, the maximum recommended daily dose of which contains more than 500 mg of phenylalanine	(14)	[date to be inserted]
Comment	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to.			
Transition	It is proposed that its implementation be immediate.			
Existing	No existing entry			
Proposed	Caffeine (1 of 2)	When included in a Listed medicine: • for oral or sublingual administration, and • the maximum recommended daily dose of which contains more than 10 mg of caffeine; and When the caffeine is from a herbal source	(173)	[date to be inserted]
Comment	The statement proposed was recommended by CMEC. Industry consultation has been undertaken.			
Transition	The normal RASML transition period would apply, that is, the new requirement would apply to all new products approved after the date of gazettal, and to existing products one year from the date of gazettal.			
Existing	No existing entry			
Proposed	Caffeine (2 of 2)	When included in a Listed medicine: • for oral or sublingual administration, and • the maximum recommended daily dose of which contains 10 mg of caffeine or less; and When the caffeine is from a herbal source	(174)	[date to be inserted]
Comment	The statement proposed was recommended by CMEC. Industry consultation has been undertaken.			
Transition	The normal RASML transition period would apply, that is, the new requirement would apply to all new products approved after the date of gazettal, and to existing products one year from the date of gazettal.			

	Medicines Containing .	***Which Meet The Following Conditions ...***	***Require Statement(s)***	***Gazettal Date***
Existing	No existing entry			
Proposed	*Polygonum multiflorum*	When included in a Listed medicine	(175, 154)	[date to be inserted]
Comment	The statement proposed was recommended by CMEC. Consultation with ADRAC has been undertaken.			
Transition	The normal RASML transition period would apply, that is, the new requirement would apply to all new products approved after the date of gazettal, and to existing products one year from the date of gazettal.			

Section 2 – Advisory Statements

Summary of Proposed Changes

The advisory statements proposed below are required to give effect to the changes described under Section 1 above.

No changes to statements 1, 8, 14, 33, 152 and 154 are proposed. They are included for reference as it is proposed that new entries will refer to these statements.

	No	Statement Text	Gazettal Date
Existing	1	Keep out of reach of children.	23 Jun 2004
Existing	8	Not suitable for use by children under 15	23 Jun 2004
Existing	14	Do not use if pregnant or likely to become pregnant	23 Jun 2004
Existing	33	If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist	23 Jun 2004
Existing	152	Use only under the supervision of a healthcare professional.	5 Apr 2006
Existing	154	Use under the supervision of a healthcare professional.	5 Apr 2006

It is proposed to:

- amend statements 30 - 32 and 153.
- add statements 159 – 173 inclusive.
- archive original statement 30.

Statement 31 is to be amended as shown below in line with updated SUSDP entry and NHMRC recommendations.

	No	Statement Text	Gazettal Date
Existing Page 46	31	~~The recommended adult daily amount of vitamin A from all sources is 2 500 International Units.~~	23 Jun 2004
Proposed	31	The recommended adult daily intake of vitamin A from all sources is [700 µg retinol equivalents/2 330 IU as required by TGO69] for women, and [900 µg retinol equivalents/3 000 IU as required by TGO69] for men.	[date to be inserted]
	Note	Products that are clearly only for consumers of one sex may omit the RDI for the other sex. Examples may include products for conditions that are generally understood to be sex-specific such as period pain and prostate health, and products explicitly labeled as being for men or women (eg women's multivitamins)	

	No	Statement Text	Gazettal Date
Comment	The change aligns the label advisory statement to the National Health and Medical Research Council's Nutrient Reference Values. At present, sponsors are required by TGO 69 to use International Units on medicine labels to express vitamin A content.		
Transition	For existing products, a one-year transition period is proposed. However, new products will be required to comply immediately.		

Statement 32 is to be amended as shown below in line with current evidence.

	No	Statement Text	Gazettal Date
Existing Page 46	32	~~WARNING – When taken in excess of 8 000 IU vitamin A can cause birth defects.~~	23 Jun 2004
Proposed	32	WARNING - When taken in excess of [3 000 µg retinol equivalents/10 000 IU as required by TGO69], vitamin A may cause birth defects.	[date to be inserted]
Comment	In line with current evidence, the change above is proposed to the teratogenicity advisory statement for products containing Vitamin A.		
Transition	For existing products, a one-year transition period is proposed. However, new products will be required to comply immediately.		

Statement 153 is to be amended as shown below in line with the recommendations of the Comeplementary Medicines Advisory Committee and the Black Cohosh Expert Advisory Group.

	No	Statement Text	Gazettal Date
Existing Page 51	153	~~Warning: Black cohosh may harm the liver in some individuals.~~	~~5 April 2006~~
Proposed	153	Warning: In very rare cases, Black cohosh has been associated with liver failure	[date to be inserted]
Comment	Following consultation with expert advisory committees, the mandatory warning for products containing black cohosh (*Cimicifuga racemosa*) is being strengthened.		
Transition	A one-year phase-in period is to be provided		

Statement 127 and 128 are here for reference only.

	No	*Statement Text*	*Gazettal Date*
Existing	*127*	*Don't use [this product/insert name of product] if you are allergic to [insert name substance] or other anti-inflammatory medicines.*	*23 Jun 2004*
	128	*Unless a doctor has told you to, don't use [this product/insert name of product] for more than a few days at a time.*	*23 Jun 2004*

Statement **159** - to be added as a new statement

	No	**Statement Text**	**Gazettal Date**
Proposed new statement	159	"If you get an allergic reaction stop taking and see your doctor immediately."	[date to be inserted]
Comment	To be included as a separate new statement as a result of the *TGA Review of NSAIDs* and MEC recommendations to which the TGA made a slight amendment.		
Transition	Agreed transition period for this statement no later than [date to be inserted] for existing products (ie. entry applies to all new products approved after date of gazettal, and to existing products from no later than [date to be inserted].		

Statement **160** – to be added as a new statement

	No	**Statement Text**	**Gazettal Date**
Proposed new statement	160	"Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful"	[date to be inserted]
Comment	To be included as a separate new statement as a result of the *TGA Review of NSAIDs* and MEC recommendations.		
Transition	Agreed transition period for this statement no later than [date to be inserted] for existing products (ie. entry applies to all new products approved after date of gazettal, and to existing products from no later than [date to be inserted].		

Statement **161** – to be added as a new statement

	No	**Statement Text**	**Gazettal Date**
Proposed new statement	161	Warning: Chaparral may harm the liver in some people.	[date to be inserted]
Comment	Included in line with CMEC recommendations and current practice		
Transition	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to. It is proposed that its implementation be immediate.		

Statement **162** – to be added as a new statement

	No	**Statement Text**	**Gazettal Date**
Proposed new statement	162	Individuals taking anticoagulants should seek medical advice before taking this product.	[date to be inserted]
Comment	Included in line with CMEC recommendations and current practice		
Transition	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to. It is proposed that its implementation be immediate.		

Statement **163** – to be added as a new statement

	No	**Statement Text**	**Gazettal Date**
Proposed new statement	163	Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this product	[date to be inserted]
Comment	Included in line with CMEC recommendations and current practice		
Transition	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to. It is proposed that its implementation be immediate.		

Statement **164** – to be added as a new statement

	No	**Statement Text**	**Gazettal Date**
Proposed new statement	164	Derived from seafood.	[date to be inserted]
Comment	Included in line with CMEC recommendations and current practice		
Transition	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to. It is proposed that its implementation be immediate.		

Statement **165** – to be added as a new statement

	No	Statement Text	Gazettal Date
Proposed new statement	165	Contains potassium.	[date to be inserted]
Comment	Included in line with CMEC recommendations following NDPSC scheduling process		
Transition	A one-year phase-in period is to be provided		

Statement **166** – to be added as a new statement

	No	Statement Text	Gazettal Date
Proposed new statement	166	If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use.	[date to be inserted]
Comment	Included in line with CMEC recommendations following NDPSC scheduling process		
Transition	A one-year phase-in period is to be provided		

Statement **167** – to be added as a new statement

	No	Statement Text	Gazettal Date
Proposed new statement	167	Children, pregnant or breastfeeding women, and those who have recently had a heart attack, surgery or a major accident should not consume this product without medical advice	[date to be inserted]
Comment	Included in line with CMEC recommendations and current practice		
Transition	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to. It is proposed that its implementation be immediate.		

Statement **168** – to be added as a new statement

	No	Statement Text	Gazettal Date
Proposed new statement	168	WARNING: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs - discontinue use.	[date to be inserted]
Comment	Included in line with CMEC recommendations and current practice		
Transition	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to. It is proposed that its implementation be immediate.		

Statement **169** – to be added as a new statement

	No	**Statement Text**	**Gazettal Date**
Proposed new statement	169	WARNING: Propolis may cause skin irritation. Test before use.	[date to be inserted]
Comment	Included in line with CMEC recommendations and current practice		
Transition	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to. It is proposed that its implementation be immediate.		

Statement **170** – to be added as a new statement

	No	**Statement Text**	**Gazettal Date**
Proposed new statement	170	Not to be taken by asthma and allergy sufferers	[date to be inserted]
Comment	Included in line with CMEC recommendations and current practice		
Transition	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to. It is proposed that its implementation be immediate.		

Statement **171** – to be added as a new statement

	No	**Statement Text**	**Gazettal Date**
Proposed new statement	171	This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities - especially in asthma and allergy suffers	[date to be inserted]
Comment	Included in line with CMEC recommendations and current practice		
Transition	The addition of this statement to RASML is the formalisation of a statement that the TGA and Industry have long agreed to. It is proposed that its implementation be immediate.		

Statement **172** – to be added as a new statement

	No	Statement Text	Gazettal Date
Proposed new statement	172	If you experience yellowing of the skin or eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, stop using this product and see your doctor	[date to be inserted]
Comment	Included as a result of a review by an expert advisory of the regulatory status of black cohosh following the receipt of adverse reaction reports.		
Transition	A one-year phase-in period is to be provided		

Statement **173** – to be added as a new statement

	No	Statement Text	Gazettal Date
Proposed new statement	173	The recommended dose of this medicine provides small amounts of caffeine	[date to be inserted]
Comment	This statement to apply to Listed medicines containing 10 mg or less of caffeine in the MRDD		
Transition	A one-year phase-in period is to be provided		

Statement **174** – to be added as a new statement

	No	Statement Text	Gazettal Date
Proposed new statement	174	Contains [amount of caffeine in milligrams] mg of caffeine	[date to be inserted]
Comment	This statement to apply to Listed medicines more than 10 mg of caffeine in the MRDD		
Transition	A one-year phase-in period is to be provided		

Statement **175** – to be added as a new statement

	No	Statement Text	Gazettal Date
Proposed new statement	175	Warning: *Polygonum multiflorum* may harm the liver in some people	[date to be inserted]
Comment	The statement proposed was recommended by CMEC. Consultation with ADRAC has been undertaken.		
Transition	A one-year phase-in period is to be provided		

Summary of new RASML statements

No	Statement Text	Gazettal Date
31	The recommended adult daily amount of vitamin A from all sources is 750 micrograms retinol equivalents (RE).	[date to be inserted]
32	WARNING – When taken in excess of 2400 micrograms retinol equivalents (RE), vitamin A can cause birth defects.	[date to be inserted]
159	If you get an allergic reaction stop taking and see your doctor immediately.	[date to be inserted]
160	Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful	[date to be inserted]
161	Warning: Chaparral may harm the liver in some people.	[date to be inserted]
162	Individuals taking anticoagulants should seek medical advice before taking this product.	[date to be inserted]
163	Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this product	[date to be inserted]
164	Derived from seafood.	[date to be inserted]
165	Contains potassium.	[date to be inserted]
166	If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use.	[date to be inserted]
167	Children, pregnant or breastfeeding women, and those who have recently had a heart attack, surgery or a major accident should not consume this product without medical advice	[date to be inserted]
168	WARNING: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs - discontinue use.	[date to be inserted]
169	WARNING: Propolis may cause skin irritation. Test before use.	[date to be inserted]

No	Statement Text	Gazettal Date
170	Not to be taken by asthma and allergy sufferers	[date to be inserted]
171	This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities - especially in asthma and allergy suffers	[date to be inserted]
172	If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor	[date to be inserted]
173	The recommended dose of this medicine provides small amounts of caffeine	[date to be inserted]
174	Contains [amount of caffeine in milligrams] mg of caffeine	[date to be inserted]
175	Warning: *Polygonum multiflorum* may harm the liver in some people	[date to be inserted]

The following advisory statements are no longer in use and will be archived.

No	Statement Text	Gazettal Date
30	Recommended daily amount is 5000 International Units or less of Vitamin A.	23 Jun 2004

Section 3 and Appendices

k. Statement(s) must be printed in type of 3 mm height or larger
l. Statement(s) must be printed on the front of the goods

No other changes proposed except for consequential archive entries in appendices 2.1 and 2.2.