Interim decisions and reasons for decisions by delegates of the Secretary to the Department of Health and Ageing

January 2013 invitation for further submissions

Notice under subsections 42ZCZP of the Therapeutic Goods Regulations 1990 (the Regulations)

A delegate of the Secretary to the Department of Health and Ageing hereby gives notice of delegates’ interim decisions under subsection 42ZCZP of the Therapeutic Goods Regulations 1990 (the Regulations).

This notice provides the interim decisions of delegates, the reasons for those decisions and invites further submissions from the applicant and parties who made a valid submission in response to the original invitation for submissions (published on 14 August 2012 at http://www.tga.gov.au/newsroom/consult-scheduling-acmcs-1210.htm). Edited versions of these submissions are available at www.tga.gov.au/industry/scheduling-submissions.htm.

Further submissions must be relevant to the proposed amendment, must address a matter mentioned in section 52E of the Therapeutic Goods Act 1989 and be received by the closing date (21 January 2013).

Further submissions from parties other than those who made a valid submission in response to the original invitation or the applicant, or those received after the closing date, need not be considered by the delegate.

Please note that all valid submissions received on or before the closing date will be published following removal of confidential information. It is up to the person making the submission to highlight any information which they wish to be considered as confidential. Material claimed to be commercial-in-confidence will be considered against the guidelines for the use and release of confidential information set out in Chapter 6 of the Scheduling Policy Framework (SPF), issued by the National Coordinating Committee on Therapeutic Goods. The SPF is accessible at www.tga.gov.au/industry/scheduling-spf.htm.

Persons making submissions are strongly encouraged to lodge submissions in electronic format (word or unsecured PDF preferred) via the email address provided below. Submissions, preferably in electronic format, should be made to:

Medicines and Poisons Scheduling Secretariat (MDP88)
GPO Box 9848
CANBERRA ACT 2601
e-mail SMP@health.gov.au
Facsimile 02-6289 2650

The closing date for further submissions is 21 January 2013.

Delegates’ reasons for interim decision
January 2013
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## Glossary

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<th>Name</th>
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<tbody>
<tr>
<td>AAN</td>
<td>Australian Approved Name</td>
</tr>
<tr>
<td>AC</td>
<td>Active constituent</td>
</tr>
<tr>
<td>ACCC</td>
<td>Australian Competition and Consumer Commission</td>
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<tr>
<td>ACCM</td>
<td>Advisory Committee on Complementary Medicines (formerly Complementary Medicine Evaluation Committee [CMEC])</td>
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<tr>
<td>ACNM</td>
<td>Advisory Committee on Non-prescription Medicines (formerly Medicines Evaluation Committee [MEC])</td>
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<tr>
<td>ACPM</td>
<td>Advisory Committee on Prescription Medicines (formerly Australian Drug Evaluation Committee [ADEC])</td>
</tr>
<tr>
<td>ACSOM</td>
<td>Advisory Committee on the Safety of Medicines (formerly Adverse Drug Reactions Advisory Committee [ADRAC])</td>
</tr>
<tr>
<td>ADEC</td>
<td>Australian Drug Evaluation Committee (now Advisory Committee on Prescription Medicines [ACPM])</td>
</tr>
<tr>
<td>ADI</td>
<td>Acceptable daily intake</td>
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<tr>
<td>ADRAC</td>
<td>Adverse Drug Reactions Advisory Committee (now Advisory Committee on the Safety of Medicines [ACSOM])</td>
</tr>
<tr>
<td>AHMAC</td>
<td>Australian Health Ministers' Advisory Council</td>
</tr>
<tr>
<td>APVMA</td>
<td>Australian Pesticides and Veterinary Medicines Authority</td>
</tr>
<tr>
<td>AQIS</td>
<td>Australian Quarantine and Inspection Service</td>
</tr>
<tr>
<td>ARfD</td>
<td>Acute reference dose</td>
</tr>
<tr>
<td>ASCC</td>
<td>Australian Safety and Compensation Council</td>
</tr>
<tr>
<td>ASMI</td>
<td>Australian Self-Medication Industry</td>
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<tr>
<td>ARTG</td>
<td>Australian Register of Therapeutic Goods</td>
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<tr>
<td>Abbreviation</td>
<td>Name</td>
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<td>--------------</td>
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<tr>
<td>CAS</td>
<td>Chemical Abstract Service</td>
</tr>
<tr>
<td>CHC</td>
<td>Complementary Healthcare Council of Australia</td>
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<tr>
<td>CMEC</td>
<td>Complementary Medicine Evaluation Committee (now Advisory Committee on Complementary Medicines [ACCM])</td>
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<td>CMI</td>
<td>Consumer Medicine Information</td>
</tr>
<tr>
<td>COAG</td>
<td>Councils of Australian Governments</td>
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<tr>
<td>CRC</td>
<td>Child-resistant closure</td>
</tr>
<tr>
<td>CTFAA</td>
<td>Cosmetic, Toiletry &amp; Fragrance Association of Australia</td>
</tr>
<tr>
<td>CWP</td>
<td>Codeine Working Party</td>
</tr>
<tr>
<td>DAP</td>
<td>Drafting Advisory Panel</td>
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<tr>
<td>ECRP</td>
<td>Existing Chemicals Review Program</td>
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<tr>
<td>EPA</td>
<td>Environmental Protection Authority</td>
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<tr>
<td>ERMA</td>
<td>Environmental Risk Management Authority (New Zealand)</td>
</tr>
<tr>
<td>FAISD</td>
<td>First Aid Instructions and Safety Directions</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration (United States)</td>
</tr>
<tr>
<td>FOI</td>
<td><em>Freedom of Information Act 1982</em></td>
</tr>
<tr>
<td>FSANZ</td>
<td>Food Standards Australia New Zealand</td>
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<tr>
<td>GHS</td>
<td>Globally Harmonised System for Classification and Labelling of Chemicals</td>
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<tr>
<td>GIT</td>
<td>Gastro-intestinal tract</td>
</tr>
<tr>
<td>GP</td>
<td>General practitioner</td>
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<tr>
<td>HCN</td>
<td>Health Communication Network</td>
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<tr>
<td>Abbreviation</td>
<td>Name</td>
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<td>--------------</td>
<td>----------------------------------------------------------------------</td>
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<tr>
<td>INN</td>
<td>International Non-proprietary Name</td>
</tr>
<tr>
<td>ISO</td>
<td>International Standards Organization</td>
</tr>
<tr>
<td>LC50</td>
<td>The concentration of a substance that produces death in 50% of a population of experimental organisms. Usually expressed as mg per litre (mg/L) as a concentration in air.</td>
</tr>
<tr>
<td>LD50</td>
<td>The concentration of a substance that produces death in 50% of a population of experimental organisms. Usually expressed as milligrams per kilogram (mg/kg) of body weight.</td>
</tr>
<tr>
<td>LOAEL</td>
<td>Lowest observed adverse effect level</td>
</tr>
<tr>
<td>LOEL</td>
<td>Lowest observed effect level</td>
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<tr>
<td>MCC</td>
<td>Medicines Classification Committee (New Zealand)</td>
</tr>
<tr>
<td>MEC</td>
<td>Medicines Evaluation Committee (now Advisory Committee on Non-prescription Medicines [ACNM])</td>
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<tr>
<td>MOH</td>
<td>Ministry of Health (New Zealand)</td>
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<tr>
<td>NCCTG</td>
<td>National Coordinating Committee on Therapeutic Goods</td>
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<tr>
<td>NDPSC</td>
<td>National Drugs and Poisons Schedule Committee</td>
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<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<tr>
<td>NICNAS</td>
<td>National Industrial Chemicals Notification &amp; Assessment Scheme</td>
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<tr>
<td>NOAEL</td>
<td>No observed adverse effect level</td>
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<tr>
<td>NOEL</td>
<td>No observable effect level</td>
</tr>
<tr>
<td>NOHSC</td>
<td>National Occupational Health &amp; Safety Commission</td>
</tr>
<tr>
<td>OCM</td>
<td>Office of Complementary Medicines</td>
</tr>
<tr>
<td>OCSEH</td>
<td>Office of Chemical Safety and Environmental Health (now Office of Chemical Safety [OCS])</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Name</td>
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<tr>
<td>--------------</td>
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</tr>
<tr>
<td>OCS</td>
<td>Office of Chemical Safety (formerly Office of Chemical Safety and Environmental Health [OCSEH])</td>
</tr>
<tr>
<td>ODA</td>
<td>Office of Devices Authorisation</td>
</tr>
<tr>
<td>OMA</td>
<td>Office of Medicines Authorisation (formerly Office of Prescription and Non-prescription Medicines)</td>
</tr>
<tr>
<td>OOS</td>
<td>Out of session</td>
</tr>
<tr>
<td>OTC</td>
<td>Over-the-counter</td>
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<tr>
<td>PACIA</td>
<td>Plastics and Chemicals Industries Association</td>
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<tr>
<td>PAR</td>
<td>Prescription animal remedy</td>
</tr>
<tr>
<td>PBAC</td>
<td>Pharmaceutical Benefits Advisory Committee</td>
</tr>
<tr>
<td>PEC</td>
<td>Priority existing chemical</td>
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<tr>
<td>PGA</td>
<td>Pharmaceutical Guild of Australia</td>
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<tr>
<td>PHARM</td>
<td>Pharmaceutical Health and Rational Use of Medicines</td>
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<tr>
<td>PI</td>
<td>Product Information</td>
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<td>PIC</td>
<td>Poisons Information Centre</td>
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<td>PSA</td>
<td>Pharmaceutical Society of Australia</td>
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<tr>
<td>QCPP</td>
<td>Quality Care Pharmacy Program</td>
</tr>
<tr>
<td>QUM</td>
<td>Quality Use of Medicines</td>
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<tr>
<td>RFI</td>
<td>Restricted flow insert</td>
</tr>
<tr>
<td>SCCNFP</td>
<td>Scientific Committee on Cosmetic and Non-Food Products</td>
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<tr>
<td>SCCP</td>
<td>Scientific Committee on Consumer Products</td>
</tr>
<tr>
<td>STANZHA</td>
<td>States and Territories and New Zealand Health Authorities</td>
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<tr>
<td>Abbreviation</td>
<td>Name</td>
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<td>-------------</td>
<td>-------------------------------------------------------------</td>
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<tr>
<td>SUSDP</td>
<td>Standard for the Uniform Scheduling of Drugs and Poisons</td>
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<tr>
<td>SUSMP</td>
<td>Standard for the Uniform Scheduling of Medicines and Poisons</td>
</tr>
<tr>
<td>SVT</td>
<td>First aid for the solvent prevails</td>
</tr>
<tr>
<td>TCM</td>
<td>Traditional chinese medicine</td>
</tr>
<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
</tr>
<tr>
<td>TGC</td>
<td>Therapeutic Goods Committee</td>
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<tr>
<td>TGO</td>
<td>Therapeutic Goods Order</td>
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<tr>
<td>TTHWP</td>
<td>Trans-Tasman Harmonisation Working Party</td>
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<tr>
<td>TTMRA</td>
<td>Trans-Tasman Mutual Recognition Agreement</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WP</td>
<td>Working party</td>
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<tr>
<td>WS</td>
<td>Warning statement</td>
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Interim decisions on proposal referred to an advisory committee

1. October 2012 meeting of the Advisory Committee on Chemicals Scheduling (ACCS) - ACCS # 6

1.1 Thymol

Scheduling proposal

The chemicals scheduling delegate considered a proposal to include thymol in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons.

The delegate referred the proposal to the Advisory Committee on Chemicals Scheduling (ACCS) for advice.

Scheduling status

Thymol is not specifically scheduled. Thyme oil (a derivative of thymol) is listed in Part 2, Schedule 5 and Appendix E.

Scheduling history

In February 2000, a decision was made to include more than 50 per cent thyme oil in Schedule 5. It was also decided to exempt from scheduling for small pack sizes (25 mL or less) subject to specified packaging conditions.

In October 2005, the following wording “in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and when the label on the primary pack complies with the requirements of the Required Advisory Statements for Medicine Labels” was added to the thyme oil Schedule 5 entry.

Pre-meeting submissions

Six public submissions were received.

All submissions indicated that therapeutic and/or cosmetic and/or household preparations containing thymol should be exempt from scheduling.

The redacted public submissions are available at Public submissions on scheduling matters.

Advisory Committee on Chemicals Scheduling (ACCS) advice to the delegate

The ACCS considered the referral from the chemicals scheduling delegate to include thymol in Schedule 6 of the SUSMP. The Committee recommended that the toxicity profile of thymol met the requirements for a Schedule 6 entry without a cut-off.

Delegate's consideration

The delegate considered the following in regards to this proposal:

• the evaluation report (not publically available);
• scheduling application;
• ACCS advice;
Delegate’s interim decision

The scheduling delegate has made an interim decision to include thymol in Schedule 6 of the SUSMP with the specific wording of “THYMOL when packed and labelled for the control of *Varroa* mites in bee hives”.

The proposed implementation date for this decision is 1 May 2013.

The relevant matters considered by the delegate under section 52E (1) of the *Therapeutic Goods Act 1989* include (a) the risks and benefits (b) the purpose and the extent of use (c) the toxicity and (d) the dosage, formulation, labelling, packaging and presentation.

The decision to include thymol in Schedule 6 incorporated the following reasons:

- The toxicity profile, including LD$_{50}$ and severe eye irritancy/corrosivity potential are consistent with the Schedule 6 listing.
- There are potential risks to applicators through inadvertent exposure to this product, although exposure risks to the general public are considered low.
- The wording of the Schedule 6 entry includes the specific use pattern on bee hives so that there are no inadvertent consequences or regulatory impact on thyme oil or other health and consumer products containing thymol, for which there are no safety concerns based on current and previous uses.

Schedule entry

*Schedule 6 - New entry*

THYMOL when packed and labelled for the control of *Varroa* mites in bee hives.

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2. October 2012 meeting of the joint Advisory Committee on Chemicals Scheduling (ACCS) and the Advisory Committee on Medicines Scheduling - ACCS & ACMS #4

2.1 Hydrogen peroxide and carbamide peroxide

Scheduling proposal

The chemicals scheduling delegate and the medicines scheduling delegate considered a proposal regarding hydrogen peroxide and carbamide peroxide. The following was requested:

- to exempt teeth whitening products containing 3% or less of hydrogen peroxide and 9% or less of carbamide peroxide from scheduling;

- for teeth whitening products containing between 3% - 6% of hydrogen peroxide and between 9% - 18% of carbamide peroxide to be only legally accessible from a registered health practitioner. Patients to be permitted to use these products 'at home' only after consultation with their registered health practitioner; and

- for teeth whitening products containing more than 6% hydrogen peroxide and more than 18% carbamide peroxide to be legally accessed by registered health practitioners.

The delegates referred the proposal to the joint Advisory Committee on Chemicals Scheduling (ACCS) and the Advisory Committee on Medicines Scheduling (ACMS) for advice.

Scheduling status

Hydrogen peroxide and carbamide peroxide are currently listed in Schedules 5 and 6 of the Standard for the Uniform Scheduling of Medicines and Poisons.

Scheduling history

In August and November 1993, it was decided that hydrogen peroxide be exempt from scheduling at 3% or less, classified as Schedule 5 from 3% up to 6% and all other concentrations placed in Schedule 6.

In April and November 1994 and May 1995, it was decided to amend the scheduling of hydrogen peroxide through inclusion of exemptions for hair preparations: 6% or less for the Schedule 5 entry because of the packaging and low exposure potential; and 12% or less for Schedule 6 allowing capture of hair dye preparations containing > 6% up to 12% of hydrogen peroxide in Schedule 5. It was also agreed that the hydrogen peroxide concentration would determine the appropriate warning statements.

In February 2005, it was agreed to include carbamide peroxide in Schedules 5 and 6 and Appendices E and F to align it with the hydrogen peroxide scheduling. It was also decided to use a ratio of 3:1 for the conversion from hydrogen peroxide values to carbamide peroxide values on the basis of simplicity and clarity.

Pre-meeting submission

Ten public submissions were received.

Four submissions suggested an Appendix C entry for hydrogen peroxide and carbamide peroxide with various cut off values. Three of these submissions supported the current Schedule 5 and 6 entries. One submission supported amending the Schedule 5 entry to capture all teeth whitening products of \( \geq 3 \) per cent hydrogen peroxide and \( \geq 9 \) per cent carbamide peroxide.
Two submissions supported the proposal to exempt teeth whitening products containing 3% or less of hydrogen peroxide and 9% or less of carbamide peroxide from scheduling.

One submission supported the scheduling proposal.

One submission supported the proposal in-principle, but would require more information regarding implementation.

One submission supported the proposal for the lower and higher concentration cut-offs, however raised concerns regarding the ambiguous wording of the mid-range concentration.

One submission did not support the proposal.


**Advisory Committee on Chemicals Scheduling (ACCS) and Advisory Committee on Medicines Scheduling (ACMS) advice to the delegate**

The joint ACCS & ACMS considered the referral from the chemicals scheduling and the medicines scheduling delegate proposal to exempt teeth whitening products containing 3% or less of hydrogen peroxide and 9% or less of carbamide peroxide from scheduling:

- for teeth whitening products containing between 3% - 6% of hydrogen peroxide and between 9% - 18% of carbamide peroxide to be only legally accessible from a registered health practitioner. Patients to be permitted to use these products 'at home' only after consultation with their registered health practitioner.

- for teeth whitening products containing more than 6% hydrogen peroxide and more than 18% carbamide peroxide to be legally accessed by registered health practitioners.

The Committees recommended that a new Appendix C entry be created for hydrogen peroxide greater than 6 per cent and carbamide peroxide greater than 18 per cent.

The Committees also recommended that the final wording of the Appendix C entry be confirmed by the states and territories with regard to the supply chain.

- The Committees recommended that the current Schedule 5 and Schedule 6 entries for carbamide peroxide and hydrogen peroxide remained appropriate.

**Delegates consideration**

The delegate considered the following in regards to this proposal:

- public submissions;
- scheduling proposal;
- the evaluation report (not publically available);
- ACCS & ACMS advice;
- section 52E of the *Therapeutic Goods Act 1989*;
- scheduling factors\(^2\);

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• other relevant information.

**Delegates interim decision**

The scheduling delegates have made an interim decision to include teeth whitening preparations containing more than 18 per cent carbamide peroxide and more than 6 per cent (20 volume) hydrogen peroxide in Appendix C. The scheduling delegates also decided to exempt from this entry for teeth whitening preparations containing 18 per cent or less carbamide peroxide and 6 per cent or less hydrogen peroxide manufacture and supplied solely for direct in-clinic use by registered dental practitioners as part of their dental practice from this entry.

The proposed implementation date for this decision is 1 May 2013.

The relevant matters considered by the delegates under section 52E (1) of the *Therapeutic Goods Act 1989* include (a) the risks and benefits (b) the purpose for and the extent of use (c) the toxicity (d) the dosage, formulation, labelling, packaging and presentation (e) the potential for abuse and (f) any other matters considers necessary to protect public health.

The decision to include teeth whitening preparations containing more than 18 per cent carbamide peroxide and more than 6 per cent hydrogen peroxide in Appendix C incorporated the following reasons:

- The risks of soft tissue damage associated with the highest strength products are such that self-treatment is inappropriate and that such products require the professional supervision of a registered dental practitioner.
- The products to be controlled under the Appendix C listing are used for cosmetic, not for therapeutic purposes.
- Hydrogen peroxide and carbamide peroxide are strong oxidising agents, and have the potential to cause significant tissue damage, through ingestion or topical application. Existing labelling and access controls for Schedule 5 and exempt products, including teeth whiteners, are considered adequate.
- The potential for misuse of the highest strength teeth whitening products by individuals or non-professionals who may be unaware of the risks is such that restriction to use of such products under supervision of a registered dental practitioner is warranted.
- Since these products are intended for cosmetic, rather than therapeutic use, access restrictions available under medicines Schedules 2, 3 or 4 were not considered suitable.

**Schedule entry**

*Appendix C - New entry*

CARBAMIDE PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 18 per cent of carbamide peroxide except in preparations manufactured and supplied solely for direct in-clinic use by registered dental practitioners as part of their dental practice.

HYDROGEN PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide except in preparations manufactured and supplied solely for direct in-clinic use by registered dental practitioners as part of their dental practice.
3. October 2012 meeting of the Advisory Committee on Medicines Scheduling - ACMS #7

3.1 Chlormphenicol

Scheduling proposal

The medicines scheduling delegate considered a proposal to reschedule chloramphenicol from Schedule 3 to Schedule 4 for ophthalmic use.

The delegate referred the proposal to the Advisory Committee on Medicines Scheduling (ACMS) for advice.

Scheduling status

Chloramphenicol is currently included in Schedule 4 except when included in Schedule 3 for ophthalmic use only.

Scheduling history

In 2009, chloramphenicol for ophthalmic use was included in Schedule 3.

In June 2011, the medicines scheduling delegate considered a request to restrict the use of chloramphenicol (Schedule 3) to ophthalmic use for the treatment of bacterial conjunctivitis only. The medicine scheduling delegate decided that a more restricted wording of the Schedule 3 chloramphenicol entry would not result in further benefits concerning its ophthalmic use, therefore the wording remained unchanged.

Pre-meeting submission

Eight public submissions were received.

Two submissions supported the proposal.

Five submissions did not support the proposal and recommended that the current scheduling remained appropriate.

One submission stated that labelling and training should be addressed if chloramphenicol was to remain in Schedule 3.


Advisory Committee on Medicines Scheduling (ACMS) advice to the delegate

The ACMS considered the referral from the medicines scheduling delegate’s proposal to reschedule chloramphenicol from Schedule 3 to Schedule 4 for ophthalmic use. The Committee did not recommend the rescheduling of chloramphenicol for ophthalmic use from Schedule 3 to Schedule 4.

Delegates consideration

The delegate considered the following in regards to this proposal:

- public submissions;
- scheduling proposal;
- ACMS advice;
• section 52E of the *Therapeutic Goods Act 1989*;
• scheduling factors;
• other relevant information.

**Delegates interim decision**

The Scheduling delegate has made an interim decision that the current chloramphenicol for ophthalmic use remains appropriate, i.e. no changes to the current scheduling.

The relevant matters considered by the delegates under section 52E (1) of *the Therapeutic Goods Act 1989* include (a) the risks and benefits and (d) the dosage, formulation, labelling, packaging and presentation.

The decision not to reschedule chloramphenicol from Schedule 3 to Schedule 4 for ophthalmic use incorporated the following reasons:

• quick and easy access to this substance is a vital issue for patients.
• need to ensure labelling is appropriate regarding contradiction to use in contact lens wearers.

3.2 Diclofenac

**Scheduling proposal**

The medicines scheduling delegate considered a proposal to amend the Schedule 2 entry for diclofenac when presented in a transdermal drug delivery system for topical use (containing 140 mg or less).

The delegate referred this proposal to the Advisory Committee on Medicines Scheduling (ACMS) for advice.

**Scheduling status**

Diclofenac is included in Schedules 2, 3 and 4, and Appendices F and H of the Standard for Uniform Scheduling of Medicines and Poisons.

**Scheduling history**

In March 1981, diclofenac was included in Schedule 4.

In February 1997, diclofenac dermal preparations (creams) containing 1 per cent or less of diclofenac was rescheduled from Schedule 4 to Schedule 2. The decision was based on the safety profile of a 1 per cent formulation and the then approved indications for use in readily recognised conditions (minor pain relief), which did not include treatment of solar keratosis.

In February 2000, based on additional safety data, dermal preparations of diclofenac were exempted from scheduling.

**Pre-meeting submission**

Three public submissions were received.

One submission supported the proposal.

One submission did not support the proposal.

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One submission was undecided.


**Advisory Committee on Medicines Scheduling (ACMS) advice to the delegate**

The ACMS considered the referral from the medicines scheduling delegate to amend the Schedule 2 entry for diclofenac when presented in a transdermal drug delivery system for topical use (containing 140 mg or less).

The Committee recommended that the Schedule 2 entry for diclofenac be amended to include transdermal preparations for topical use containing 140 mg or less of diclofenac.

**Delegates consideration**

The delegate considered the following in regards to this proposal:

- public submissions;
- scheduling proposal;
- ACMS advice;
- section 52E of the *Therapeutic Goods Act 1989*;
- scheduling factors⁴;
- other relevant information.

**Delegates interim decision**

The scheduling delegate has decided to amend the Schedule 2 diclofenac entry to include transdermal preparations for topical use containing 140 mg or less of diclofenac.

The proposed implementation date for this decision is 1 May 2013.

The relevant matters considered by the delegates under section 52E (1) of the *Therapeutic Goods Act 1989* include (a) the risks and benefits (b) the purpose for and the extent of use (c) the toxicity (d) the dosage, formulation, labelling, packaging and presentation and (f) any other matters considers necessary to protect public health.

The decision to include diclofenac transdermal preparations for topical use containing 140 mg or less diclofenac in Schedule 2 incorporated the following reasons:

- similar products were already available in the United Kingdom and the United States of America.
- although dermal preparations of diclofenac were unscheduled it is felt that a consumer should be able to seek advice from a pharmacist to ensure the new product formulation was correctly and safely used.
- adverse effects are well known and managed previously at over the counter level with packaging and labelling.
- no new information to justify higher scheduling.

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• consumers are able to self-diagnose strains and sprains.

• data presented has not indicated that the new dosage form would result in a different level or range of adverse effects to other previously scheduled diclofenac products.

**Schedule entry**

**Schedule 2 – Amendment**

DICLOFENAC when:

(a) in divided preparations for oral use containing 12.5 mg or less of diclofenac per dosage unit in a pack containing 20 or less dosage units and labelled with a recommended daily dose of 75 mg or less of diclofenac;

(b) in preparations for dermal use containing 4 per cent of diclofenac except in preparations for dermal use containing 1 per cent or less of diclofenac or for the treatment of solar keratosis; or

(c) in transdermal preparations for topical use containing 140 mg or less of diclofenac.

### 3.3 Mometasone

**Scheduling proposal**

The medicines scheduling delegate considered a proposal to reschedule mometasone from Schedule 4 to Schedule 3 when in preparations for topical use containing 0.1 per cent or less of mometasone in packs containing 30 g or less of the preparation when labelled for the treatment of adults and children 12 years and over.

The delegate referred the proposal to the Advisory Committee on Medicines Scheduling (ACMS) for advice.

**Scheduling status**

Mometasone is currently included in Schedules 2 and 4 in the Standard for the Uniform Scheduling of Medicines and Poisons.

**Scheduling history**

In February 1993, mometasone was included in Schedule 4 based on the Australian Drug Evaluation Committee’s approval to register mometasone furoate.

In November 1999, mometasone was rescheduled from Schedule 4 to Schedule 3 for use in aqueous nasal sprays for the treatment of seasonal allergic rhinitis, with certain dose and age conditions.

This rescheduling was considered appropriate given the safety in use, safety based on mometasone’s pharmacokinetic parameters and that the treatment of seasonal allergic rhinitis has a place in Schedule 3.

In May 2000, mometasone was included in Appendix H.

In June 2003, mometasone was rescheduled from Schedule 3 to Schedule 2 for the short-term prophylaxis or treatment of allergic rhinitis, with dose and age restrictions. This rescheduling was considered appropriate given extensive local and overseas experience, demonstrated effectiveness in the treatment of allergic rhinitis and that allergic rhinitis is readily diagnosed and self-monitored by the consumer with pharmacist advice or counselling available if necessary. As there was no longer a Schedule 3 entry, mometasone was also deleted from Appendix H.
Pre-meeting submission

Seven public submissions were received.

Four submissions supported the proposal to reschedule mometasone from Schedule 4 to Schedule 3 in preparations for topical use.

Three submissions did not support the proposal.


Advisory Committee on Medicines Scheduling (ACMS) advice to the delegate

The ACMS considered the referral from the medicines scheduling delegate to reschedule mometasone from Schedule 4 to Schedule 3 when in preparations for topical use containing 0.1 per cent or less of mometasone in packs containing 30 g or less of the preparation when labelled for the treatment of adults and children 12 years and over.

The Committee recommended that the current scheduling of mometasone remains appropriate.

Delegates consideration

The delegate considered the following in regards to this proposal:

- public submissions;
- the scheduling proposal;
- evaluation report (not publically available);
- ACMS advice;
- section 52E of the *Therapeutic Goods Act 1989*;
- scheduling factors⁵;
- other relevant information.

Delegates interim decision

The scheduling delegate has decided that the current scheduling of mometasone remains appropriate, i.e. no changes.

The relevant matters considered by the delegates under section 52E (1) of the *Therapeutic Goods Act 1989* include (a) the risks and benefits (b) the purpose for and the extent of use (c) the toxicity and (e) potential for abuse.

The decision not to reschedule mometasone from Schedule 4 to Schedule 3 when in preparations for topical use containing 0.1 per cent or less of mometasone in packs containing 30 g or less of the preparation when labelled for the treatment of adults and children 12 years and over incorporated the following reasons:

- adverse dermatological effects.
- inappropriate diagnosis of potentially severe skin conditions.

- use of mometasone should be limited to the treatment of severe skin conditions requiring diagnosis and monitoring by a medical practitioner.
- increased risk of toxicity due to potency.
- potential for misuse by consumers where lower potency corticosteroid would be more appropriate.

3.4 Ostarine (Enobosarm) / Selective Antrogen Receptor Modulators (SARM)

**Scheduling proposal**

The medicines scheduling delegate considered a proposal to create a new Schedule 4 entry for ostarine (enobosarm) and a new Schedule 4 class entry for selective androgen receptor modulators (SARMs).

The delegate referred the proposal to the Advisory Committee on Medicines Scheduling (ACMS) for advice.

**Scheduling status**

Ostarine and SARMs are not currently scheduled in Australia or in New Zealand.

**Pre-meeting submission**

No public submissions were received.

**Advisory Committee on Medicines Scheduling (ACMS) advice to the delegate**

The ACMS considered the referral from the medicines scheduling delegate to create a new Schedule 4 entry for ostarine (enobosarm) and a new Schedule 4 class entry for selective androgen receptor modulators (SARMs). The Committee recommended the creation of:

- a new entry for enobosarm in Schedule 4;
- a new class entry for SARMs in Schedule 4; and
- a new entry for SARMS in Appendix D, paragraph 5.

**Delegates consideration**

The delegate considered the following in regards to this proposal:

- scheduling application;
- ACMS advice;
- section 52E of the *Therapeutic Goods Act 1989*;
- scheduling factors6;
- other relevant information.

**Delegates interim decision**

The scheduling delegate has made an interim decision to create:

- a new entry for enobosarm in Schedule 4;

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• a new class entry for SARMs in Schedule 4; and
• a new entry for SARMs in Appendix D, Paragraph 5.

The proposed implementation date for this decision is 1 May 2013.

The relevant matters considered by the delegate under section 52E (1) of the Therapeutic Goods Act 1989 include (a) the risks and benefits (b) the purpose and the extent of use (c) the toxicity and (e) potential for abuse.

The decision to include enobosarm in Schedule 4, a class entry for SARMs in Schedule 4 and SARMs in Appendix D, Paragraph 5 incorporated the following reasons:

• risks associated with non-medical use are yet to be established.
• conditions that it is to be used for require medical diagnosis and monitoring by a medical practitioner.
• toxicity is yet to be established as there has been no marketing experience in Australia.
• evidence of misuse.
• enobosarm was being imported into Australia and was being used by body builders seeking its anabolic effects on muscle. Further, SARMs were not captured by the anabolic steroids group entry even though they appeared to have an anabolic steroids group entry even though they appeared to have an anabolic effect on bone and muscle. Customs indicated to South Australian Police in May 2012 that they had made over 30 seizures of ostarine. Customs were able to seize imports of ostarine as anabolic or androgenic substances (not limited to steroidal agents) are prohibited imports. Further, the Australian Sports Anti-Doping Authorithy (ASADA) website indicated SARMs were banned for use, both in and out of competition.
• Not sufficient data available on the therapeutic use of non-steroidal SARMs. No SARMs were currently marketed, however, enobosarm was undergoing clinical trials in a range of medical conditions such as cachexia, sarcopenia, osteoporosis and frailty. These conditions require medical diagnosis, monitoring and management i.e. Schedule 4.
• listing both enobosarm and SARMs would address the potential problem of misuse and abuse. Further, the class entry for SARMs was recommended as there are other SARMs being developed. Patients being treated with these drugs would require medical diagnosis, monitoring and management. Also, there is access to SARMs that are more toxic than enobosarm. If only one SARM were scheduled, consumers would be able to source another SARM.

Schedule entry

Schedule 4 - New entry
ENOBOSARM.

Schedule 4 - New entry
SELECTIVE ANDROGEN RECEPTOR MODULATORS (SARM).

Appendix D, Paragraph 5 - New entry
SELECTIVE ANDROGEN RECEPTOR MODULATORS (SARM), including those separately specified in Schedule 4.
3.5 Pantoprazole

**Scheduling proposal**

The medicines scheduling delegate considered a proposal to amend the Schedule 3 entry for pantoprazole 20 mg to increase the maximum allowable pack size from 14 to 28 dosage units.

The delegate referred the proposal to the Advisory Committee on Medicines Scheduling (ACMS) for advice.

**Scheduling status**

Pantoprazole is currently included Schedule 3 and Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons. It is included in Schedule 3 when in oral preparations containing 20 mg or less per dosage unit in packs containing not more than 14 days’ supply for the relief of heartburn and other symptoms of GORD.

**Scheduling history**

In February 1995, pantoprazole was included in Schedule 4 in light of the Australian Drug Evaluation Committee’s approval to register pantoprazole.

In June 2005, pantoprazole was rescheduled from Schedule 4 to Schedule 3 when in oral preparations containing 20 mg or less of pantoprazole for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease (GORD), in packs containing not more than 14 days’ supply. The available efficacy and safety data supported a Schedule 3 entry.

**Pre-meeting submission**

Three public submissions were received. These submissions did not support the proposal and recommended that the current scheduling remained appropriate.


**Advisory Committee on Medicines Scheduling (ACMS) advice to the delegate**

The ACMS considered the referral from the medicines scheduling delegate to amend the Schedule 3 entry for pantoprazole 20 mg to increase the maximum allowable pack size from 14 to 28 dosage units.

The Committee recommended that the current scheduling of pantoprazole remains appropriate.

**Delegates consideration**

The delegate considered the following in regards to this proposal:

- public submissions;
- scheduling application;
- ACMS advice;
- section 52E of the *Therapeutic Goods Act 1989*;
- scheduling factors.

Delegates’ reasons for interim decision

Delegates interim decision

The scheduling delegate has made an interim decision not to amend the current scheduling of pantoprazole, i.e. current pantoprazole scheduling remains appropriate.

The relevant matters considered by the delegates under section 52E (1) of the Therapeutic Goods Act 1989 include (a) the risks and benefits and (d) the dosage, formulation, labelling, packaging and presentation.

The decision not to amend the Schedule 3 entry for pantoprazole 20 mg to increase the maximum allowable pack size from 14 to 28 dosage units incorporated the following reasons:

- the request for an increased pack size to 28 days’ supply may result in the whole pack being used regardless of the pack being labelled with “14 day treatment”. Consumers who initiate this treatment in a pharmacy setting may not see a medical practitioner for a month. If a consumer has not responded to treatment after 14 days, it is a flag for them to see further medical assessment.
- the availability of a 28 day pack may result in an unnecessary extended time period before such a consultation may take place.
- Proton pump inhibitors (PPI) can make serious underlying conditions and consultation with a consumer requesting an additional supply after 14 days’ of treatment was important.

3.6 Paracetamol in combination with ibuprofen

Scheduling proposal

The medicines scheduling delegate considered a proposal to:

- reschedule paracetamol 500 mg when combined with ibuprofen 200 mg from Schedule 3 to Schedule 2 for pack sizes of 12 units or less;
- include Schedule 3 paracetamol when combined with ibuprofen in Appendix H.

The delegate referred the proposal to the Advisory Committee on Medicines Scheduling (ACMS) for advice.

Scheduling status

Paracetamol in combination with ibuprofen in a primary pack containing 30 dosage units or less is included in Schedule 3. The combination in packs containing greater than 30 dosage units is included in Schedule 4.

Scheduling history

In June 2010, the scheduling of paracetamol in combination with ibuprofen was considered. Paracetamol preparations containing 500 mg or less of paracetamol as the only therapeutically active constituent (other than phenylephrine, effervescent agents or guaiphenesin) in packs of 25 or less were exempt from scheduling. However, when these preparations are combined with another therapeutically active ingredient they become Schedule 2.

The Schedule 2 entry remained appropriate but noted the possibility of more robust evidence of additional risk could come to light through any application for ibuprofen paracetamol combination product approval.
In June 2011, the medicine scheduling delegate considered the scheduling of paracetamol in combination with ibuprofen and sought advice from the ACMS. The delegate made a final decision to include paracetamol in combination with ibuprofen in preparations up to 500 mg of paracetamol and 200 mg of ibuprofen when in pack sizes of up to 30 dosage units in Schedule 3. Larger pack sizes would be included in Schedule 4.

**Pre-meeting submission**

Three public submissions were received.

Two submissions supported both proposals while one submission did not.


**Advisory Committee on Medicines Scheduling (ACMS) advice to the delegate**

The ACMS considered the referral from the medicines scheduling delegates to:

- reschedule paracetamol 500 mg when combined with ibuprofen 200 mg from Schedule 3 to Schedule 2 for pack sizes of 12 units or less;
- include Schedule 3 paracetamol when combined with ibuprofen in Appendix H.

The Committee recommended that the current scheduling of paracetamol in combination with ibuprofen in Schedule 3 remains appropriate. The Committee also recommended that paracetamol in combination with ibuprofen not be included in Appendix H.

**Delegates consideration**

The delegate considered the following in regards to this proposal:

- public submissions;
- the evaluation report (not publically available);
- scheduling proposal;
- ACMS advice;
- section 52E of the *Therapeutic Goods Act 1989*;
- scheduling factors[^8];
- other relevant information.

**Delegates interim decision**

The scheduling delegate has made an interim decision not to amend the current scheduling of paracetamol in combination with ibuprofen.

The relevant matters considered by the delegates under section 52E (1) of the *Therapeutic Goods Act 1989* include (a) the risks and benefits (b) the purpose for and the extent of use (c) the toxicity (d) the dosage, formulation, labelling, packaging and presentation (e) the potential for abuse and (f) any other matters considers necessary to protect public health.

The decision not to reschedule paracetamol 500 mg when combined with ibuprofen 200 mg from Schedule 3 to Schedule 2 for pack sizes of 12 units or less and not to include Schedule 3 paracetamol when combined with ibuprofen in Appendix H incorporated the following reasons:

- safety concerns with this combination since 2009 and that there had not been enough data provided to disprove these concerns.
- the factors for a Schedule 2 entry, as listed in Scheduling Policy Framework (SPF), especially in relation to the risk profile of the product, had not been satisfied.
- lack of evidence to support rescheduling to Schedule 2.
- inclusion of paracetamol in combination with ibuprofen in Appendix H did not have any public health benefit resulting from any promotional activities that could be quantified and that advertising of the product could potentially lead to inappropriate medication use.
- additive gastro-intestinal side effects.
- concern about lack of professional intervention for this combination product to ensure safe and effective use.
- concern with the lack of long-term evidence.
- therapeutically sub-optimal combination.
- potential for inadvertent misuse.
- no public benefit.
- no experience with the use of the product in Australia.

3.7 Retigabine

**Scheduling proposal**

The medicines scheduling delegate considered a proposal to include a new Schedule 4 and Appendix K entry for retigabine.

The delegate referred the proposal to the Advisory Committee on Medicines Scheduling (ACMS) for advice.

**Scheduling status**

Retigabine is not specifically scheduled in Australia nor classified in New Zealand.

**Pre-meeting submission**

No public submissions were received.

**Advisory Committee on Medicines Scheduling (ACMS) advice to the delegate**

The ACMS considered the referral from the medicines scheduling delegate to include a Schedule 4 and Appendix K entry for retigabine. The Committee recommended that a new Schedule 4 and Appendix K entry be created for retigabine.

**Delegates consideration**

The delegate considered the following in regards to this proposal:

- scheduling application;
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• ACMS advice;
• section 52E of the Therapeutic Goods Act 1989;
• scheduling factors⁹;
• other relevant information.

Delegates interim decision

The scheduling delegate has made an interim decision to create a new Schedule 4 and Appendix K entry for retigabine.

The proposed implementation date for this decision is 1 May 2013.

The relevant matters considered by the delegate under section 52E (1) of the Therapeutic Goods Act 1989 include (a) the risks and benefits (b) the purpose and the extent of use (c) the toxicity (d) and (d) the dosage, formulation, labelling, packaging and presentation and (e) potential for abuse.

The decision to include retigabine in Schedule 4 and Appendix K incorporated the following reasons:

• the indication of the product. Indication requires medical diagnosis, treatment and monitoring.
• the adverse side effects profile in the overseas product information included somnolence, dizziness, fatigue, psychosis, disorientation, vertigo and blurred vision.
• potential for somnolence, dizziness and fatigue indicates a sedation warning is needed, via Appendix K listing.
• requires medical supervision and warnings to the patient on possible side effects.
• sedation label required at dispensing.

Schedule entry

Schedule 4 - New entry
RETIGABINE.

Appendix K - New entry
RETIGABINE

3.8 Teriflunomide

Scheduling proposal

The medicines scheduling delegate considered a proposal to include a new Schedule 4, Appendix L and Appendix F entries for teriflunomide.

The delegate referred the proposal to the Advisory Committee on Medicines Scheduling (ACMS) for advice.

Scheduling status

Teriflunomide is not specifically scheduled in Australia.

Leflunomide, the parent compound of teriflunomide, is listed in Schedule 4 and Appendix F Part 3 of the Standard for the Uniform Scheduling of Medicines and Poisons.

**Scheduling history**

In August 1999, leflunomide was included leflunomide in Schedule 4.

In February 2000, additional requirements for labelling and/or availability of leflunomide based on the teratogenicity was considered and was decided to include leflunomide in Appendix F and Part 3 ‘Miscellaneous Regulations Dispensed Medicines’.

In October 2007, a review of the Appendix D entries with regard to the ADEC pregnancy category X medicines was undertaken and was decided that leflunomide did not warrant an Appendix D entry at that time.

**Pre-meeting submission**

One submission from the sponsor was received. The submission supported a new Schedule 4 and Appendix L entry for teriflunomide.


**Advisory Committee on Medicines Scheduling (ACMS) advice to the delegate**

The ACMS considered the referral from the medicines scheduling delegate to include a Schedule 4, Appendix F and Appendix L entries for teriflunomide.

The Committee recommended that teriflunomide be included in Schedule 4, Appendix F and Appendix L.

**Delegates consideration**

The delegate considered the following in regards to this proposal:

- public submissions;
- scheduling proposal;
- ACMS advice;
- section 52E of the *Therapeutic Goods Act 1989*;
- scheduling factors\(^1\);
- other relevant information.

**Delegates interim decision**

The scheduling delegate has made an interim decision to include teriflunomide in Schedule 4, Appendix F and Appendix L.

The proposed implementation date for this decision is 1 May 2013.

The relevant matters considered by the delegate under section 52E (1) of the *Therapeutic Goods Act 1989* include (a) the risks and benefits (b) the purpose and the extent of use (c) the toxicity (d) and (f) other matters.

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The decision to include teriflunomide in Schedule 4 and Appendix F and Appendix L incorporated the following reasons:

- teratogenicity potential.
- indication supports a Schedule 4 entry.
- requires medical intervention.
- the side effects and requirement for monitoring.
- appropriate for Appendix L entry based on TGA’s Pregnancy Category X listing.
- appropriate for a medical practitioner to continue therapy after initiation by a specialist.
- appendix D entry was not considered appropriate.
- appendix L is not consistently adopted across the jurisdictions and using Appendix F means labeling requirements are consistent regardless of the source of the product.

**Schedule entry**

*Schedule 4 - New entry*

TERIFLUNOMIDE.

*Appendix F, Part 3 - New entry*

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*Appendix L, Part 2 - New entry*

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<td>Substance</td>
<td>Warning statement</td>
</tr>
<tr>
<td>Teriflunomide</td>
<td>77, 62 and 87</td>
</tr>
</tbody>
</table>

**3.9 Vitamin D**

**Scheduling proposal**

The medicines scheduling delegate considered a proposal to:

- create a new Schedule 3 entry to allow a weekly dose of vitamin D up to 175 micrograms (7000IU) per recommended dose; and

- to include vitamin D in Appendix H.

The delegate referred the proposal to the Advisory Committee on Medicines Scheduling (ACMS) for advice.
**Scheduling status**

Preparations containing more than 25 micrograms vitamin D per recommended daily dose for human therapeutic use are included in Schedule 4.

**Scheduling history**

In March 1972, it was decided that products containing more than 1000 units (25 micrograms) of vitamin D in a recommended daily dose (RDD) be classified as prescription only.

In July 1972, vitamin D was rescheduled to Schedule 4 when the RDD exceeded 25 micrograms.

**Pre-meeting submission**

Three public submissions were received.

Two submissions supported the proposal to reschedule vitamin D and one submission opposed the proposal.


**Advisory Committee on Medicines Scheduling (ACMS) advice to the delegate**

The Committee agreed that a new Schedule 3 entry be created for vitamin D to include as a single weekly dose of vitamin D up to 175 micrograms (7000IU) per recommended dose. The Committee also agreed that an Appendix H entry for vitamin D was not required.

**Delegates consideration**

The delegate considered the following in regards to this proposal:

- public submissions;
- scheduling proposal;
- the evaluation report (not publically available);
- ACMS advice;
- section 52E of the *Therapeutic Goods Act 1989*;
- scheduling factors\(^{11}\);
- other relevant information.

**Delegates interim decision**

The scheduling delegate has made an interim decision to create a new Schedule 3 entry for vitamin D to include as a single weekly dose of vitamin D up to 175 micrograms (7000IU) per recommended dose. The delegate also decided not to include vitamin D in Appendix H listing.

The proposed implementation date for this decision is 1 May 2013.

The relevant matters considered by the delegate under section 52E (1) of the *Therapeutic Goods Act 1989* include (a) the risks and benefits (b) the purpose and the extent of use (c) the toxicity (d) the dosage, formulation, labelling, packaging and presentation and (f) other matters.

The decision to include vitamin D in Schedule 3 incorporated the following reasons:

- advice required from a pharmacist in relation to a single weekly dose.
- the potential for enhanced compliance with treatment with a once-weekly dose vitamin D preparation.
- pharmacists intervention would assist with compliance.
- the benefits to a consumer outweighed any potential risks.
- off label use could occur and could be inadvertently promoted through an Appendix H listing.
- Risk of toxicity with inadvertent daily dose is minimal.
- Unusual dosage regimen.
- Existing public health campaigns around vitamin D supplementation.

**Schedule entry**

**Schedule 3 - New entry**

VITAMIN D for human internal therapeutic use in preparations containing 175 micrograms or less of vitamin D per recommended weekly dose except in preparations containing 25 micrograms or less of vitamin D per recommended daily dose.

**Schedule 4 - Amendment**

VITAMIN D for human internal therapeutic use except:

(a) in preparations containing 25 micrograms or less of vitamin D per recommended daily dose; or
(b) when included in Schedule 3.