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

8 February 2013

Notice under subsections 42ZCZS and 42ZCZX of the Therapeutic Goods Regulations 1990 (the Regulations)

A delegate of the Secretary to the Department of Health and Ageing hereby gives notice of the delegates' final decisions for amending the Poisons Standard (commonly referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons* – SUSMP) under subsections 42ZCZS and 42ZCZX of the Therapeutic Goods Regulations 1990 (the Regulations). This notice also provides the reasons for each decision and the date of effect (implementation date) of the decision.

The delegates' final decisions and reasons relate to:

- scheduling proposals initially referred to the October 2012 meeting of the Advisory Committee on Chemicals Scheduling (ACCS#6);
- scheduling proposals initially referred to the October 2012 meeting of the Advisory Committee on Medicines Scheduling (ACMS#7);
- scheduling proposals initially referred to the October 2012 joint meeting of the ACCS and the ACMS (joint ACCS-ACMS#4);
- scheduling proposals considered as delegate-only matters, i.e. not referred to an expert advisory committee.

Scheduling proposals referred to the expert advisory committees

Pre-meeting public notice

A 'pre-meeting' public notice inviting submissions on the scheduling proposals referred to the expert advisory committees was published on 14 August 2012 at http://www.tga.gov.au/newsroom/consult-scheduling-acmcs-1210.htm.

Redacted versions of the public submissions received in response to this invitation were published on 10 January 2013 at http://www.tga.gov.au/industry/scheduling-submissions-1210.htm.

Interim decisions

The delegates' interim decisions on recommendations by the ACCS#6, ACMS#7 and joint ACCS-ACMS#4 were published on 7 January 2013 at http://www.tga.gov.au/industry/scheduling-decisions-1301-interim.htm. This public notice also invited further comment from the applicant and from those parties who made a valid submission in response to the original invitation for submissions.

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, may not be considered by the delegate.

Redacted versions of valid public submissions received in response to the interim decisions were published on 10 January 2013 at http://www.tga.gov.au/industry/scheduling-submissions-1210.htm.

Final decisions

In accordance with subsection 42ZCZR of the Regulations, if a delegate makes an interim decision on an application, the delegate may make a final decision either confirming, varying or setting aside the interim decision, but only after considering any valid submissions received in response to the interim decisions.

Matters not referred to an advisory committee

A delegate may decide not to refer a scheduling proposal to an expert advisory committee for advice and instead may make a delegate-only decision. When deciding not to refer a matter to a committee, the delegate considers the scheduling guidelines as set out in the *Scheduling Policy Framework* (SPF), available at http:www.tga.gov.au/industry/scheduling-spf.htm

Publishing of the amendments to the Poisons Standard

The amendments to the Schedules, Appendices or other parts of the Poisons Standard are published electronically on ComLaw and in a hardcopy Amendment to the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) prior to the date of effect (implementation date) of the final decisions. Further information, including links to the Poisons Standard on ComLaw, is available at http:www.tga.gov.au/industry/scheduling-poisons-standard.htm.

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Part A - Final decisions on matters referred to an expert advisory committee

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

1.1 Thymol

Scheduling proposal

The chemicals scheduling delegate (the delegate) considered a proposal from the Office of Chemical Safety (OCS) to include thymol in Schedule 6.

The OCS evaluated data that was provided in support of an application for the approval of thymol. The applicant was provided with a copy of the OCS evaluation report and supports the proposal for inclusion in Schedule 6.

The delegate referred the proposal to the October 2012 meeting of the Advisory Committee on Chemicals Scheduling (ACCS) for advice.

Scheduling status

Thymol is not specifically scheduled.

Thyme oil (a derivative of thymol) is included in Schedule 5 and Appendix E. It is also included in Part 2, Labels and Containers, subparagraph 25(1), as requiring a child-resistant closure when included in Schedule 5.

Scheduling history

In February 2000, the National Drugs and Poisons Schedule Committee (NDPSC) decided to include more than 50 per cent thyme oil in Schedule 5. The NDPSC also decided to exempt small pack sizes (25 mL or less) from scheduling, subject to specified packaging conditions.

In October 2005, the NDPSC decided to amend the Schedule 5 entry for thyme oil to include the 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*".

Pre-meeting public submissions

A pre-meeting public notice inviting submissions on the scheduling proposal was published on 14 August 2012 at http://www.tga.gov.au/newsroom/consult-scheduling-acmcs-1210.htm.

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 were published on 10 January 2013 at http://www.tga.gov.au/industry/scheduling-submissions-1210.htm.

ACCS advice to the delegate

In October 2012, the ACCS considered the referral from the delegate. The ACCS recommended that the toxicity profile of thymol met the requirements for a Schedule 6 entry without a cut-off.

Delegate's interim decision

The delegate made an interim decision to include thymol in Schedule 6 with the specific wording "THYMOL when packed and labelled for the control of *Varroa* mites in bee hives". The proposed implementation date for this decision was 1 May 2013.

The interim decision was published on 7 January 2013 at http://www.tga.gov.au/industry/scheduling-decisions-1301-interim.htm.

Interim decision public submissions

One public submission was received. This submission supported the interim decision.

The redacted public submission is published at http://www.tga.gov.au/industry/scheduling-submissions-1210.htm.

Delegate's consideration

The delegate considered the following in regards to this proposal.

- The scheduling proposal (not publicly available).
- The OCS evaluation report (not publicly available).
- The applicant's support for inclusion in Schedule 6.
- The advice of the ACCS (not publicly available).
- The pre-meeting and interim decision public submissions.
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.
- Other relevant information.

Delegate's final decision

The delegate has confirmed the interim decision as no evidence has been received to alter the interim decision.

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include thymol, when packed and labelled for the control of *Varroa* mite in bee hives, in Schedule 6.

The delegate has confirmed the implementation date of 1 May 2013.

The delegate has confirmed that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits; (b) purpose and the extent of use; (c) toxicity, and (d) dosage, formulation, labelling, packaging and presentation.

The delegate has confirmed that the reasons for the final decision are in keeping with those for the interim decision.

- The toxicity profile, including LD50 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 6 – New Entry

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

2. Scheduling proposals referred to the October 2012 meeting of the Advisory Committee on Medicines Scheduling (ACMS#7)

2.1 Chloramphenicol

Scheduling proposal

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

The delegate referred the proposal to the October 2012 meeting of the Advisory Committee on Medicines Scheduling (ACMS) for advice. The delegate did not refer the proposal for evaluation.

Scheduling status

Chloramphenicol is included in Schedule 4 and chloramphenicol for ophthalmic use only is included in Schedule 3.

Scheduling history

In 2009, the National Drugs and Poisons Schedule Committee (NDPSC) decided to include chloramphenicol for ophthalmic use in Schedule 3.

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

Pre-meeting public submissions

A pre-meeting public notice inviting submissions on the scheduling proposal was published on 14 August 2012 at http://www.tga.gov.au/newsroom/consult-scheduling-acmcs-1210.htm.

Eight pre-meeting 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.

The redacted public submissions were published on 10 January 2013 at http://www.tga.gov.au/industry/scheduling-submissions-1210.htm.

ACMS advice to the delegate

In October 2012, the ACMS considered the referral from the delegate. The ACMS did not recommend the rescheduling of chloramphenicol for ophthalmic use from Schedule 3 to Schedule 4.

Delegate's interim decision

The delegate made an interim decision that the current scheduling of chloramphenicol for ophthalmic use remained appropriate, i.e. no change to the current scheduling.

The interim decision was published on 7 January 2013 at http://www.tga.gov.au/industry/scheduling-decisions-1301-interim.htm.

Interim decision public submissions

No public submissions were received.

Delegate's consideration

The delegate considered the following in regards to this proposal.

- The rescheduling application (not publicly available).
- The advice of the ACMS (not publicly available).
- The pre-meeting public submissions.
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.
- Other relevant information.

Delegate's final decision

The delegate has confirmed the interim decision as no public submissions or other evidence has been received to alter the interim decision.

The delegate has made a final decision that the current scheduling of chloramphenicol for ophthalmic use remains appropriate, i.e. no change to the current scheduling.

The delegate has confirmed that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits, and (d) dosage, formulation, labelling, packaging and presentation.

The delegate has confirmed that the reasons for the final decision are in keeping with those for the interim decision:

- Quick and easy access to this substance is a vital issue for patients.
- Need to ensure labelling is appropriate regarding contraindication for use in contact lens wearers.

2.2 Diclofenac

Scheduling proposal

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

The delegate referred this proposal to the October 2012 meeting of the Advisory Committee on Medicines Scheduling (ACMS) for advice. The delegate also referred the proposal for independent external evaluation.

Scheduling status

Diclofenac is included in Schedules 2, 3 and 4, and Appendices F and H.

Scheduling history

In March 1981, the Drugs and Poisons Schedule Subcommittee (DPSSC) decided to include diclofenac in Schedule 4.

In February 1997, the National Drugs and Poisons Schedule Committee (NDPSC) decided to reschedule diclofenac dermal preparations (creams) containing 1 per cent or less of diclofenac from Schedule 4 to Schedule 2. This 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, the NDPSC decided to exempt dermal preparations of diclofenac from scheduling. This decision was based on additional safety data.

Pre-meeting public submissions

A pre-meeting public notice inviting submissions on the scheduling proposal was published on 14 August 2012 at http://www.tga.gov.au/newsroom/consult-scheduling-acmcs-1210.htm.

Three pre-meeting public submissions were received.

- One submission supported the proposal.
- One submission did not support the proposal.
- One submission was undecided.

The redacted public submissions were published on 10 January 2013 at http://www.tga.gov.au/industry/scheduling-submissions-1210.htm.

ACMS advice to the delegate

In October 2012, the ACMS considered the referral from the delegate. The ACMS recommended that the Schedule 2 entry for diclofenac be amended to include transdermal preparations for topical use containing 140 mg or less of diclofenac.

Delegate's interim decision

The delegate made an interim decision to amend the Schedule 2 entry for diclofenac to include transdermal preparations for topical use containing 140 mg or less of diclofenac. The proposed implementation date for this decision was 1 May 2013.

The interim decision was published on 7 January 2013 at http://www.tga.gov.au/industry/scheduling-decisions-1301-interim.htm.

Interim decision public submissions

No public submissions were received.

Delegate's consideration

The delegate considered the following in regards to this proposal.

- The rescheduling application (not publicly available).
- The independent evaluation report (not publicly available).
- The applicant's comments on the evaluation report (not publicly available).
- The advice of the ACMS (not publicly available).
- Pre-meeting public submissions.
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.
- Other relevant information.

Delegate's final decision

The delegate has confirmed the interim decision as no public submissions or other evidence has been received to alter the interim decision.

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include diclofenac in Schedule 2 when in transdermal preparations for topical use containing 140 mg or less of diclofenac.

The delegate has confirmed the implementation date of 1 May 2013.

The delegate has confirmed that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits; (b) purpose and the extent of use; (c) toxicity; (d) dosage, formulation, labelling, packaging and presentation, and (f) any other matters considered necessary to protect public health.

The delegate has confirmed that the reasons for the final decision are in keeping with those for the interim decision.

- Similar patches are already available overseas.
- Although dermal preparations of diclofenac are unscheduled, it is felt that a consumer should be able to seek advice from a pharmacist to ensure the new product formulation is used correctly and safely.
- Adverse effects are well known and previously managed at the over-the-counter level with packaging and labelling.
- No new information to justify higher scheduling.
- 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 preparations.

Schedule 2 – Amendment

DICLOFENAC – Amend entry to read:

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.

2.3 Mometasone

Scheduling proposal

The medicines scheduling delegate (the 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 October 2012 meeting of the Advisory Committee on Medicines Scheduling (ACMS) for advice. The delegate also referred the proposal for independent external evaluation.

Scheduling status

Mometasone is included in Schedules 2 and 4.

Scheduling history

In February 1993, the Drugs and Poisons Schedule Subcommittee (DPSSC) decided to include mometasone in Schedule 4. This decision was based on the Australian Drug Evaluation Committee's approval to register a new drug application for mometasone furoate.

In November 1999, the National Drugs and Poisons Schedule Committee (NDPSC) decided to reschedule mometasone 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. The NDPSC considered that this rescheduling was appropriate given mometasone's safety in use based on pharmacokinetic parameters, and that the treatment of seasonal allergic rhinitis has a place in Schedule 3.

In May 2000, the NDPSC decided to include mometasone in Appendix H.

In June 2003, the NDPSC decided to reschedule mometasone from Schedule 3 to Schedule 2 for the short-term prophylaxis or treatment of allergic rhinitis, with dose and age restrictions. The NDPSC considered that this rescheduling was appropriate given mometasone's 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 would no longer be a Schedule 3 entry, the NDPSC also decided to delete mometasone from Appendix H.

Pre-meeting submission

A pre-meeting public notice inviting submissions on the scheduling proposal was published on 14 August 2012 at http://www.tga.gov.au/newsroom/consult-scheduling-acmcs-1210.htm.

Seven public submissions were received.

- Four submissions supported the proposal to reschedule mometasone in preparations for topical use, from Schedule 4 to Schedule 3.
- Three submissions did not support the proposal.

The redacted public submissions were published on 10 January 2013 at http://www.tga.gov.au/industry/scheduling-submissions-1210.htm.

ACMS advice to the delegate

The October 2012 meeting of the ACMS considered the referral from the delegate. The ACMS recommended that the current scheduling of mometasone remained appropriate.

Delegate's interim decision

The delegate made an interim decision that the current scheduling of mometasone remained appropriate, i.e. no change to the current scheduling.

The interim decision was published on 7 January 2013 at http://www.tga.gov.au/industry/scheduling-decisions-1301-interim.htm.

Interim decision public submissions

No public submissions were received.

Delegate's consideration

The delegate considered the following in regards to this proposal.

- The rescheduling application (not publicly available).
- The independent evaluation report (not publicly available).
- The applicant's comments on the evaluation report (not publicly available).
- The advice of the ACMS (not publicly available).
- The pre-meeting public submissions.
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.
- Other relevant information.

Delegate's final decision

The delegate has confirmed the interim decision as no public submissions or other evidence has been received to alter the interim decision.

The delegate has made a final decision that the current scheduling of mometasone remains appropriate, i.e. no change to the current scheduling.

The delegate has confirmed that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits; (b) purpose and extent of use; (c) toxicity, and (e) potential for abuse.

The delegate has confirmed that the reasons for the final decision are in keeping with those for the interim decision.

- Adverse dermatological effects.
- Use of a potent corticosteroid.
- 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.

2.4 Ostarine (enobosarm)/Selective Androgen Receptor Modulators (SARM)

Scheduling proposal

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

The delegate referred the proposal to the October 2012 meeting of the Advisory Committee on Medicines Scheduling (ACMS) for advice. The delegate did not refer the proposal for evaluation.

Scheduling status

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

Pre-meeting public submissions

A pre-meeting public notice inviting submissions on the scheduling proposal was published on 14 August 2012 at http://www.tga.gov.au/newsroom/consult-scheduling-acmcs-1210.htm.

No public submissions were received.

ACMS advice to the delegate

In October 2012, the ACMS considered the referral from the delegate. The ACMS recommended the creation of:

- a new entry for enobosarm in Schedule 4;
- a new class entry for selective androgen receptor modulators (SARM) in Schedule 4; and
- a new entry for selective androgen receptor modulators (SARM) in Appendix D, paragraph 5.

Delegate's interim decision

The scheduling delegate made an interim decision to create:

- a new entry for enobosarm in Schedule 4;
- a new class entry for selective androgen receptor modulators (SARM) in Schedule 4; and
- a new entry for selective androgen receptor modulators (SARM)in Appendix D, paragraph 5.

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

The interim decision was published on 7 January 2013 at http://www.tga.gov.au/industry/scheduling-decisions-1301-interim.htm.

Interim decision public submissions

No public submissions were received.

Delegate's consideration

The delegate considered the following in regards to this proposal.

- The scheduling proposal (not publicly available).
- The advice of the ACMS (not publicly available).
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.
- Other relevant information.

The delegate noted that:

- Enobosarm was being imported into Australia and was being used by body builders seeking its anabolic effects on muscle. SARMs were not captured by the anabolic steroids group entry even though they appeared to have an anabolic effect on bone and muscle. The Australian Customs Service had indicated to South Australian Police in May 2012 that they had made over 30 seizures of ostarine (enobosarm). Customs were able to seize imports of ostarine as anabolic or androgenic substances (not limited to steroidal agents) are prohibited imports. The Australian Sports Anti-Doping Authorithy (ASADA) website indicated SARMs were banned for use, both in and out of competition.
- Sufficient data was not 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. scheduling factors for Schedule 4.
- Scheduling both enobosarm and SARMs would address the potential problem of misuse and abuse. 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. There is access to SARMs that are more toxic than enobosarm. If only one SARM was scheduled, consumers would be able to source another SARM.

Delegate's final decision

The delegate has confirmed the interim decision as no public submissions or other evidence has been received to alter the interim decision.

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include:

- enobosarm in Schedule 4;
- a class entry for selective androgen receptor modulators (SARM) in Schedule 4; and
- a class entry for selective androgen receptor modulators (SARM) in Appendix D, paragraph 5.

The delegate has confirmed the implementation date of 1 May 2013.

The delegate has confirmed that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits; (b) purpose and extent of use; (c) toxicity, and (e) potential for abuse.

The delegate has confirmed that the reasons for the final decision are in keeping with those for the interim decision.

- Risks associated with non-medical use are yet to be established.
- Conditions that it is to be used for require 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.

Schedule 4 – New Entries

ENOBOSARM.

SELECTIVE ANDROGEN RECEPTOR MODULATORS (SARM).

Appendix D, Paragraph 5 – New Entry

SELECTIVE ANDROGEN RECEPTOR MODULATORS (SARM), including those separately specified in Schedule 4.

2.5 Pantoprazole

Scheduling proposal

The medicines scheduling delegate (the 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 October 2012 meeting of the Advisory Committee on Medicines Scheduling (ACMS) for advice. The delegate did not refer the proposal for evaluation.

Scheduling status

Pantoprazole is included in Schedule 4. It is also 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 heart burn and other symptoms of GORD.

Scheduling history

In February 1995, the National Drugs and Poisons Schedule Committee (NDPSC) decided to include pantoprazole in Schedule 4. This decision was based on the Australian Drug Evaluation Committee's approval to register a new drug application for pantoprazole.

In June 2005, the NDPSC decided to reschedule pantoprazole 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. This decision was based on the available efficacy and safety data which supported a Schedule 3 entry.

Pre-meeting public submissions

A pre-meeting public notice inviting submissions on the scheduling proposal was published on 14 August 2012 at http://www.tga.gov.au/newsroom/consult-scheduling-acmcs-1210.htm.

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

The redacted public submissions were published on 10 January 2013 at http://www.tga.gov.au/industry/scheduling-submissions-1210.htm.

ACMS advice to the delegate

In October 2012, the ACMS considered the referral from the delegate. The ACMS recommended that the current scheduling of pantoprazole remained appropriate.

Delegate's interim decision

The delegate made an interim decision that the current scheduling of pantoprazole remained appropriate, i.e. no change to the current scheduling.

The interim decision was published on 7 January 2013 at http://www.tga.gov.au/industry/scheduling-decisions-1301-interim.htm.

Interim decision public submissions

No public submissions were received.

Delegate's consideration

The delegate considered the following in regards to this proposal.

- The rescheduling application (not publicly available).
- The advice of the ACMS (not publicly available).
- The pre-meeting public submissions.
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.
- Other relevant information.

The delegate noted that:

- The availability of a pack size of 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 seek further medical assessment.
- The availability of a pack size of 28 days' supply may result in an unnecessary extended time period before a medical consultation takes place.
- Proton pump inhibitors (PPIs) can mask serious underlying conditions and medical consultation with a consumer requesting an additional supply after 14 days of treatment was important.

Delegate's final decision

The delegate has confirmed the interim decision as no public submissions or other evidence has been received to alter the interim decision.

The delegate has made a final decision that the current scheduling of pantoprazole remains appropriate, i.e. no change to the current scheduling.

The delegate has confirmed that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits, and (d) dosage, formulation, labelling, packaging and presentation.

The delegate has confirmed that the reasons for the final decision are in keeping with those for the interim decision.

- Delay in patients seeking medical advice.
- Risk of masking a serious condition.
- Lack of clarity around quantity and duration of treatment.

2.6 Paracetamol in combination with ibuprofen

Scheduling proposal

The medicines scheduling delegate (the 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; and
- include Schedule 3 paracetamol when combined with ibuprofen in Appendix H.

The delegate referred the proposal to the October 2012 meeting of the Advisory Committee on Medicines Scheduling (ACMS) for advice. The delegate also referred the proposal for independent external evaluation.

Scheduling status

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

Scheduling history

In June 2010, the National Drugs and Poisons Schedule Committee (NDPSC) considered the scheduling of paracetamol in combination with ibuprofen. 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 were combined with another therapeutically active ingredient they became Schedule 2. The NDPSC considered that the Schedule 2 entry remained appropriate, but noted the possibility that more robust evidence of additional risk could come to light through any application for product approval with the Therapeutic Goods Administration. The delegate confirmed the NDPSC's decision and the reasons for the decision in August 2010.

In June 2011, the delegate decided to reschedule from Schedule 2 to Schedule 3, combination ibuprofen+paracetamol preparations (up to 200 mg of ibuprofen and 500 mg of paracetamol) when in packs of 30 dosage units or less. The delegate also decided that combination ibuprofen+paracetamol preparations in packs of more than 30 dosage units are to be captured by Schedule 4.

Pre-meeting public submissions

A pre-meeting public notice inviting submissions on the scheduling proposal was published on 14 August 2012 at http://www.tga.gov.au/newsroom/consult-scheduling-acmcs-1210.htm.

Three public submissions were received. Two submissions supported both proposals while one submission did not.

The redacted public submissions were published on 10 January 2013 at http://www.tga.gov.au/industry/scheduling-submissions-1210.htm.

ACMS advice to the delegate

In October 2012, the ACMS considered the referral from the delegate. The ACMS recommended that the current scheduling of paracetamol in combination with ibuprofen in Schedule 3 remained appropriate. The ACMS also recommended that paracetamol in combination with ibuprofen not be included in Appendix H.

Delegate's interim decision

The delegate made an interim decision that the current scheduling of paracetamol in combination with ibuprofen remained appropriate, i.e. no change to the current scheduling.

The interim decision was published on 7 January 2013 at http://www.tga.gov.au/industry/scheduling-decisions-1301-interim.htm.

Interim decision public submissions

No public submissions were received.

Delegate's consideration

The delegate considered the following in regards to this proposal.

- The rescheduling application (not publicly available).
- The independent evaluation report (not publicly available).
- The applicant's comments on the evaluation report (not publicly available).
- The advice of the ACMS (not publicly available).
- The pre-meeting public submissions.
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.
- Other relevant information.

Delegate's final decision

The delegate has confirmed the interim decision as no public submissions or other evidence has been received to alter the interim decision.

The delegate has made a final decision that the current scheduling of paracetamol in combination with ibuprofen remains appropriate, i.e. no change to the current scheduling.

The delegate has confirmed that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits; (b) purpose and extent of use; (c) toxicity; (d) dosage, formulation, labelling, packaging and presentation; (e) potential for abuse, and (f) any other matters considered necessary to protect public health.

The delegate has confirmed that the reasons for the final decision are in keeping with those for the interim decision.

- Safety concerns with this combination since 2009 and that there had not been enough data provided to disprove these concerns.
- Lack of evidence to support rescheduling to Schedule 2. The *Scheduling Policy Framework* scheduling factors for Schedule 2 had not been satisfied, especially in relation to the risk profile of the product.
- 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.
- 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.

2.7 Retigabine

Scheduling proposal

The delegate considered an application from the Therapeutic Goods Administration (TGA) to schedule retigabine, a new chemical entity for a human therapeutic medicine.

The delegate proposed that retigabine be included in Schedule 4 and Appendix K and referred the matter to the October 2012 meeting of the Advisory Committee on Medicines Scheduling (ACMS) for advice.

Scheduling status

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

Pre-meeting public submissions

A pre-meeting public notice inviting submissions on the scheduling proposal was published on 14 August 2012 at http://www.tga.gov.au/newsroom/consult-scheduling-acmcs-1210.htm.

No public submissions were received.

ACMS advice to the delegate

In October 2012, the ACMS considered the referral from the delegate. The ACMS recommended that new Schedule 4 and Appendix K entries be created for retigabine.

Delegate's interim decision

The delegate made an interim decision to create new Schedule 4 and Appendix K entries for retigabine. The proposed implementation date for this decision was 1 May 2013.

The interim decision was published on 7 January 2013 at http://www.tga.gov.au/industry/scheduling-decisions-1301-interim.htm.

Interim decision public submissions

No public submissions were received.

Delegate's consideration

The delegate considered the following in regards to this proposal.

- The advice of the TGA (not publicly available).
- The advice of the ACMS (not publicly available).
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.
- Other relevant information.

The delegate noted that:

- retigabine is a new chemical entity with no clinical or marketing experience in Australia; and
- the adverse side effects profile in the overseas product information included somnolence, dizziness, fatigue, psychosis, disorientation, vertigo and blurred vision.

Delegate's final decision

The delegate has confirmed the interim decision as no public submissions or other evidence has been received to alter the interim decision.

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include retigabine in Schedule 4 and Appendix K.

The delegate has confirmed the implementation date of 1 May 2013.

The delegate has confirmed that the relevant matters under subsection52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits; (b) purpose and extent of use; (c) toxicity; (d) dosage, formulation, labelling, packaging and presentation, and (e) potential for abuse.

The delegate has confirmed that the reasons for the decision to include retigabine in Schedule 4 are in keeping with those for the interim decision.

- It is a new chemical entity with no clinical or marketing experience in Australia.
- The indication to be treated requires medical diagnosis, treatment and monitoring.
- Requires medical supervision and warnings to the patient on possible side effects.

The delegate has confirmed that the reasons for the decision to include retigabine in Appendix K are in keeping with those for the interim decision.

- Potential for somnolence, dizziness and fatigue indicates a sedation warning is needed, via an Appendix K listing.
- Sedation label required at dispensing.

Schedule 4 – New Entry

RETIGABINE.

Appendix K – New Entry

RETIGABINE

2.8 Teriflunomide

Scheduling proposal

The delegate considered an application from the Therapeutic Goods Administration (TGA) to schedule teriflunomide, a new chemical entity for a human therapeutic medicine.

The delegate proposed that teriflunomide be included in Schedule 4, Appendix F and Appendix L and referred the matter to the October 2012 meeting of 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 included in Schedule 4, Appendix F and Appendix L.

Scheduling history

In August 1999, the National Drugs and Poisons Schedule Committee (NDSC) decided to include leflunomide in Schedule 4.

In February 2000, the NDPSC decided to include leflunomide in Appendix F, with a consequential amendment to include leflunomide in paragraph 45, Dispensed Medicines, in Part 3, Miscellaneous Regulations. This decision was based on the teratogenicity of leflunomide and the requirements for additional labelling.

In October 2007, the NDPSC decided that leflunomide did not warrant an Appendix D entry at that time. This followed a review of the Appendix D entries with regard to the Australian Pregnancy Category X medicines.

In August 2010, the delegate confirmed the decisions of the June 2010 meeting of the NDPSC to transfer leflunomide to Appendix L. Appendix L was a new appendix created to list all of the requirements for dispensing labels previously included in the body of the Poisons Standard (i.e. paragraph 45, Dispensed Medicines, of Part 3, Miscellaneous Regulations) as part of the transitional amendments required to change the *Standard for the Uniform Scheduling of Drugs and Poisons No. 24* into the *Standard for the Uniform Scheduling of Medicines and Poisons No. 1*, under the revised scheduling arrangements commencing 1 July 2010.

Pre-meeting public submissions

A pre-meeting public notice inviting submissions on the scheduling proposal was published on 14 August 2012 at http://www.tga.gov.au/newsroom/consult-scheduling-acmcs-1210.htm.

One submission was received. The submission supported new Schedule 4 and Appendix L entries for teriflunomide.

The redacted public submissions were published on 10 January 2013 at http://www.tga.gov.au/industry/scheduling-submissions-1210.htm.

ACMS advice to the delegate

In October 2012, the ACMS considered the referral from the delegate. The ACMS recommended that teriflunomide be included in Schedule 4, Appendix F and Appendix L.

Delegate's interim decision

The delegate made an interim decision to include teriflunomide in Schedule 4, Appendix F and Appendix L. The proposed implementation date for this decision was 1 May 2013.

Schedule 4 – Interim decision proposed new entry

TERIFLUNOMIDE.

Appendix F, Part 3 – Interim decision proposed new entry

Poison	Warning statements
Teriflunomide	7, 62, 87

Appendix L, Part 2 – Interim decision proposed new entry

Column 1 Substance	Column 2 Warning statement
Teriflunomide	77, 62 and 87

The interim decision was published on 7 January 2013 at http://www.tga.gov.au/industry/scheduling-decisions-1301-interim.htm.

Interim decision public submissions

No public submissions were received.

Delegate's consideration

The delegate considered the following in regards to this proposal.

- The advice of the TGA (not publicly available).
- The advice of the ACMS (not publicly available).
- The pre-meeting public submissions.
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.
- Other relevant information.

The delegate noted that teriflunomide:

- is a new chemical entity with no clinical or marketing experience in Australia; and
- is classified as a Category X medicine under the Australian categorisation of risk of drug use in pregnancy:

> ***Category X*** *– Drugs which have such a high risk of causing permanent damage to the fetus that they should not be used in pregnancy or when there is a possibility of pregnancy.*

In making the final decision, the delegate noted the inadvertent inclusion of warning statement '77' [WARNING – May causes birth defects] in the interim decision's proposed new Appendix L entry. The correct warning statement is '7' [WARNING – Causes birth defects].

Delegate's final decision

The delegate has confirmed the interim decision as no public submissions or other evidence has been received to alter the interim decision.

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to:

- include teriflunomide in Schedule 4
- include teriflunomide in Appendix F with warning statements:

  7. WARNING – Causes birth defects.

  62. Do not use if pregnancy.

  87. *(insert brand name)* remains in the body for many months after treatment has stopped. Do not become pregnant or father a child before consulting your doctor.

- include teriflunomide in Appendix L with warning statements 7, 62, 87 (noting that the inclusion of warning statement '77' in the interim decision was incorrect and should have read '7').

The delegate has confirmed the implementation date of 1 May 2013.

The delegate has confirmed that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits; (b) purpose and extent of use; (c) toxicity; (d) dosage, formulation, labelling, packaging and presentation, and (f) any other matters considered necessary to protect public health.

The delegate has confirmed that the reasons for the decision to include teriflunomide in Schedule 4 are in keeping with those for the interim decision.

- It is a new chemical entity with no clinical or marketing experience in Australia.
- Requires medical intervention, with the indication and toxicity profile supporting a Schedule 4 entry.
- Appropriate for a medical practitioner to continue therapy after initiation by a specialist.

The delegate has confirmed that the reasons for the decision to include teriflunomide in Appendix F and Appendix L are in keeping with those for the interim decision.

- It is a Pregnancy Category X medicine with a teratogenicity profile requiring Appendix L listing.
- Appendix L is not consistently adopted across the jurisdictions. An Appendix F listing ensures labelling requirements are consistent regardless of the source of the product, with the warning statements consistent with those for leflunomide.
- Appendix D entry was not considered appropriate.

Schedule 4 – New Entry

TERIFLUNOMIDE.

Appendix F, Part 3 – New Entry

Poison	Warning statements
Teriflunomide	7, 62, 87

Appendix L, Part 2 – New Entry

Column 1 Substance	Column 2 Warning statement
Teriflunomide	7, 62 and 87

2.9 Vitamin D

Scheduling proposal

The medicines scheduling delegate (the 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
- include vitamin D in Appendix H.

The delegate referred the proposal to the October 2012 meeting of the Advisory Committee on Medicines Scheduling (ACMS) for advice. The delegate also referred the proposal for independent external evaluation.

Scheduling status

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

Scheduling history

In March 1972, the Drugs and Poisons Schedule Subcommittee (DPSSC) decided to include vitamin D in Schedule 4 when the recommended daily dosage on the label exceeds 10 micrograms. This recommendation was based on a recommendation by the Nutrition Committee of the National Health & Medical Research Council that the attention of pharmaceutical firms be drawn to the dangers of vitamin A overdose.

In July 1972, the DPSSC decided to include vitamin D in Schedule 4 when the recommended daily dose exceeded 25 micrograms. This decision was based on the Canadian restrictions on vitamins A and D that drugs containing more than 10,000 international units of vitamin A in a recommended daily dose were prescription only and that the same restriction would apply to drugs containing more than 1,000 units of vitamin D in a recommended daily dose.

Pre-meeting public submissions

A pre-meeting public notice inviting submissions on the scheduling proposal was published on 14 August 2012 at http://www.tga.gov.au/newsroom/consult-scheduling-acmcs-1210.htm.

Three public submissions were received. Two submissions supported the proposal to reschedule vitamin D and one submission opposed the proposal.

The redacted public submissions were published on 10 January 2013 at http://www.tga.gov.au/industry/scheduling-submissions-1210.htm.

ACMS advice to the delegate

In October 2012, the ACMS considered the referral from the delegate. The ACMS recommended that a new Schedule 3 entry be created for vitamin D for a single weekly dose of vitamin D up to 175 micrograms (7000IU) per recommended dose. The ACMS also recommended that an Appendix H entry for vitamin D was not required.

Delegate's interim decision

The delegate made an interim decision to create a new Schedule 3 entry for vitamin D to include vitamin D as a single weekly dose of up to 175 micrograms (7000IU) per recommended dose. The delegate also made an interim decision to not include vitamin D in Appendix H. The proposed implementation date for this decision was 1 May 2013.

Schedule 3 – interim decision proposed 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 – interim decision proposed amendment

VITAMIN D for human internal therapeutic use **except:**

(a) in preparations containing 25 micrograms or less of less of vitamin D per recommended daily dose ; or

(b) when included in Schedule 3.

The interim decision was published on 7 January 2013 at http://www.tga.gov.au/industry/scheduling-decisions-1301-interim.htm.

Interim decision public submissions

One public submission was received. This submission did not support the delegate's decision to not include vitamin D in Appendix H.

The redacted public submission is published at http://www.tga.gov.au/industry/scheduling-submissions-1210.htm.

Delegate's consideration

The delegate considered the following in regards to this proposal.

- The rescheduling application (not publicly available).
- The independent evaluation report (not publicly available).
- The applicant's comments on the evaluation report (not publicly available).

- The advice of the ACMS (not publicly available).
- The pre-meeting and interim decision public submissions.
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.
- Other relevant information.

In making the final decision, the delegate noted that the word 'single' had been inadvertently omitted from the interim decision's proposed new Schedule 3 entry. The entry should have read, in part, 'per recommended single weekly dose'.

Delegate's final decision

The delegate has confirmed the interim decision as no evidence has been received to alter the interim decision.

The delegate has made a final decision:

- to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include vitamin D, as a single weekly dose of up to 175 micrograms (7000IU) per recommended dose, in Schedule 3 (noting that the wording "per recommended weekly dose" in the interim decision's proposed Schedule 3 entry should have read "per recommended single weekly dose"); and
- to not include vitamin D in Appendix H.

The delegate has confirmed the implementation date of 1 May 2013.

The delegate has confirmed that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits; (b) purpose and extent of use; (c) toxicity; (d) dosage, formulation, labelling, packaging and presentation, and (f) any other matters considered necessary to protect public health.

The delegate has confirmed that the reasons for the decision to include vitamin D in Schedule 3 are in keeping with those for the interim decision.

- Advice required from a pharmacist in relation to a single weekly dose.
- The potential for enhanced compliance with treatment with a once-weekly dose of a vitamin D preparation.
- Pharmacist intervention would assist with compliance.
- The benefits to a consumer outweighed any potential risks.
- Risk of toxicity with inadvertent daily dose is minimal.
- Unusual dosage regimen.

The delegate has confirmed that the reasons to not include vitamin D in Appendix H are in keeping with those for the interim decision.

- Off-label use could occur and could be inadvertently promoted through an Appendix H listing.
- Existing public health campaigns around vitamin D supplementation.

Schedule 3 – New Entry

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

Schedule 4 – Amendment

VITAMIN D – Amend entry to read:

VITAMIN D for human internal therapeutic use **except:**

(a) in preparations containing 25 micrograms or less of less of vitamin D per recommended daily dose ; or

(b) when included in Schedule 3.

3. Scheduling proposals referred to the October 2012 joint meeting of the Advisory Committee on Chemicals Scheduling and Advisory Committee on Medicines Scheduling (ACCS-ACMS#4)

3.1 Hydrogen peroxide and Carbamide peroxide

Scheduling proposal

The chemicals scheduling delegate and the medicines scheduling delegate (the delegates) considered the following scheduling proposals with regard to hydrogen peroxide and carbamide peroxide:

- to exempt teeth whitening products containing 3 per cent or less of hydrogen peroxide and 9 per cent or less of carbamide peroxide from scheduling;
- for teeth whitening products containing between 3 per cent to 6 per cent of hydrogen peroxide and between 9 per cent to 18 per cent 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 per cent hydrogen peroxide and more than 18 per cent carbamide peroxide to be legally accessed by registered health practitioners.

The delegates referred the proposals to the October 2012 joint meeting of the Advisory Committee on Chemicals Scheduling (ACCS) and the Advisory Committee on Medicines Scheduling (ACMS) for advice. The delegates also referred the proposal for independent external evaluation.

Scheduling status

Hydrogen peroxide and carbamide peroxide are included in Schedules 5 and 6.

Scheduling history

In August and November 1993, the National Drugs and Poisons Schedule Committee (NDPSC) decided to exempt from scheduling hydrogen peroxide at 3 per cent or less; to include 3 per cent up to 6 per cent of hydrogen peroxide in Schedule 5; and to include all other concentrations in Schedule 6.

In April and November 1994 and May 1995, the NDPSC decided to amend the scheduling of hydrogen peroxide to include exemptions for hair preparations: 6 per cent or less in the Schedule 5

entry because of the packaging and low exposure potential and 12 per cent or less in the Schedule 6 entry to capture hair dye preparations containing >6 per cent up to 12 per cent in Schedule 5. The NDPSC also decided that the hydrogen peroxide concentration would determine the appropriate warning statements.

In February 2005, the NDPSC decided to include carbamide peroxide in Schedules 5 and 6 and in Appendices E and F to align with the scheduling of hydrogen peroxide. 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 public submissions

A pre-meeting public notice inviting submissions on the scheduling proposal was published on 14 August 2012 at http://www.tga.gov.au/newsroom/consult-scheduling-acmcs-1210.htm.

Ten pre-meeting 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 Schedule 6 entries. One submission supported amending the Schedule 5 entry to capture all teeth whitening products of 3 per cent or more of hydrogen peroxide and 9 per cent or more of carbamide peroxide.
- Two submissions supported the proposal to exempt teeth whitening products containing 3 per cent or less of hydrogen peroxide and 9 per cent 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.

The redacted public submissions were published on 10 January 2013 at http://www.tga.gov.au/industry/scheduling-submissions-1210.htm.

ACCS-ACMS advice to the delegate

In October 2012, the ACCS- ACMS joint meeting considered the referral from the delegates. The joint meeting 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 final wording of the Appendix C entry to be confirmed by the states and territories with regard to the supply chain; and
- the current Schedule 5 and Schedule 6 entries for carbamide peroxide and hydrogen peroxide remained appropriate.

Delegate's interim decision

The delegates made an interim decision to include teeth whitening preparations containing more than 18 per cent of carbamide peroxide and more than 6 per cent (20 volume) of hydrogen peroxide in Appendix C. The delegates also decided to exempt from the proposed Appendix C entry teeth

whitening preparations containing 18 per cent or less of carbamide peroxide and 6 per cent or less of hydrogen peroxide manufactured and supplied solely for direct in-clinic use by registered dental practitioners as part of their dental practice. The proposed implementation date for this decision was 1 May 2013.

Appendix C – interim decision proposed new entries

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.

The interim decision was published on 7 January 2013 at http://www.tga.gov.au/industry/scheduling-decisions-1301-interim.htm.

Interim decision public submissions

Three submissions were received. Two submissions supported no change to the Schedule 5 and Schedule 6 entries, but sought clarification on the wording of the proposed Appendix C entries. The third submission supported the proposed Appendix C entries, but expressed concern that no decision was made to place stricter controls on access to teeth whitening preparations containing >3 per cent to 6 per cent of hydrogen peroxide and >9 per cent to 18 per cent of carbamide peroxide.

The redacted public submissions are published at http://www.tga.gov.au/industry/scheduling-submissions-1210.htm.

Delegate's consideration

The delegates considered the following in regards to this proposal:

- The scheduling application (not publicly available).
- The independent evaluation report (not publicly available).
- The applicant's comments on the evaluation report (not publicly available).
- The advice of the ACCS-ACMS joint meeting (not publicly available).
- The pre-meeting public submissions.
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- *Scheduling Policy Framework* scheduling factors.
- Other relevant information.
- The interim decision public submissions. In particular:
  - One submission argued that preparations currently included in Schedule 5 should also be limited to use by dental practitioners.

The delegates have decided to accept the advice of the expert advisory committees that the current scheduling of preparations in Schedules 5 and 6 remains appropriate. The delegates noted the decision to retain listing of teeth whitening preparations containing up to 6 per cent hydrogen peroxide or 18 per cent carbamide peroxide in Schedule 5, or exempt when below 3 per cent and 9 per cent respectively, is to some extent also consistent with the evaluation of such products by the European Commission Scientific Committee on Cosmetics and Non Food Products intended for Consumers (SCCNFP).

– One submission raised an issue about the legal status of teeth whitening being undertaken by other than qualified dental practitioners.

  The delegates considered this to be a matter for other jurisdictions and not an issue for the scheduling of teeth whitening preparations in the Poisons Standard.

Delegate's final decision

The delegates have decided to vary the interim decision.

The delegates have decided that the wording of the interim decision to list the highest strength teeth whitening preparations in Appendix C is to be amended to remove the restriction "for direct in-clinic use". The delegates considered this to be too restrictive to dental practitioners in the exercise of their professional practice* and it did not accurately reflect the advice of the expert advisory committees. This approach was supported by all but one submission received during the consultation on the interim decision, with the exception of a wording change to reflect that the intent was not to limit the way dental practitioners use such products in exercising their professional practice.

The delegates have made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to:

· include teeth whitening preparations containing more than 18 per cent of carbamide peroxide and more than 6 per cent (20 volume) of hydrogen peroxide in Appendix C; and

· exempt from the new Appendix C entries, teeth whitening preparations containing more than18 per cent of carbamide peroxide and more than 6 per cent of hydrogen peroxide manufactured for and supplied solely by registered dental practitioners as part of their dental practice.

The delegates have decided that the implementation date for this decision will be 1 May 2013.

*Post script note: The expression "too restrictive to dental practitioners in the exercise of their professional practice" is a comment on the scope of the SUSMP to place controls on the activities of professional practitioners. The location of use of a chemical substance, whether by a registered practitioner in-clinic or by an individual consumer at home, is not intended to be controlled through the SUSMP. Limitations on the location of use would be applied through the policies of professional practice boards (ie the Dental Board of Australia) or other relevant regulatory authorities (including the Australian Competition and Consumer Commission).

The delegates have confirmed that the current scheduling of preparations in Schedules 5 and 6 remains appropriate.

The delegates have decided that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (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 delegates' reasons for the final decision to include teeth whitening preparations containing more than 18 per cent of carbamide peroxide and more than 6 per cent of hydrogen peroxide in Appendix C comprise of the following.

- Since these products are intended for cosmetic, rather than therapeutic use, access restrictions available under Schedules 2, 3 or 4 were not considered suitable.
- Existing labelling and access controls for Schedule 5 and exempt products, including teeth whiteners, are considered adequate.
- The current Schedule 5 and 6 entries for hydrogen peroxide and carbamide peroxide include products available to the consumer other than teeth whiteners.
- Hydrogen peroxide and carbamide peroxide are strong oxidising agents, and have the potential to cause significant tissue damage, through ingestion or topical application.

The delegates' reasons for the final decision to exempt from the proposed Appendix C entries, teeth whitening preparations containing more than18 per cent of carbamide peroxide and more than 6 per cent of hydrogen peroxide manufactured for and supplied solely by registered dental practitioners as part of their dental practice, comprise of the following.

- 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.
- Preparations containing more than 6 per cent hydrogen peroxide or 18 per cent carbamide peroxide, when supplied to dentists under the Appendix C exemption, would still need to be labelled in accordance with the Schedule 6 entry, as currently applies to such products.

Appendix C – New entries

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

Part B - Final decisions on matters not referred to an expert advisory committee

4. New chemical entities – medicines for human therapeutic use

4.1 Alogliptin

Scheduling proposal

The delegate considered an application from the Therapeutic Goods Administration (TGA) to schedule alogliptin, a new chemical entity for a human therapeutic medicine.

Alogltiptin is an inhibitor of dipeptidylpeptidase-4 (anti-diabetic DPP-4 inhibitor) and is proposed for use in the treatment of Type 2 diabetes mellitus.

Scheduling status

Alogliptin is not specifically scheduled and is not captured by any entry in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).

Alogliptin is not classified in New Zealand.

Delegate's consideration

The delegate considered the following in regards to this application.

- The new drug application (not publicly available).
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.

The delegate noted that currently there are no issues of concern that require additional control other than by inclusion in Schedule 4.

The delegate decided to make a delegate-only decision. The Advisory Committee on Medicines Scheduling was not consulted.

Delegate's final decision

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include alogliptin in Schedule 4, with an implementation date of 1 May 2013.

The delegate decided that the relevant matter under subsection 52E(1) of the *Therapeutic Goods Act 1989* is (a) risks and benefits of the use of a substance.

The delegate's reason for the final decision is that alogliptin is a new chemical entity with no clinical or marketing experience in Australia.

Schedule 4 – New Entry

ALOGLIPTIN.

4.2 Canagliflozin

Scheduling proposal

The delegate considered an application from the Therapeutic Goods Administration (TGA) to schedule canagliflozin, a new chemical entity for a human therapeutic medicine.

Canagliflozin is an inhibitor of subtype 2 sodium-glucose transport protein (SGLT2), which is responsible for at least 90% of the glucose reabsorption in the kidney. Blocking this transporter causes blood glucose to be eliminated through the urine.

Canagliflozin is proposed for use in the treatment of type 2 diabetes mellitus.

Scheduling status

Canagliflozin is not specifically scheduled and is not captured by any entry in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).

Canagliflozin is not classified in New Zealand.

Delegate's consideration

The delegate considered the following in regards to this application.

· The new drug application (not publicly available).

· Subsection 52E(1) of the *Therapeutic Goods Act 1989*.

· The *Scheduling Policy Framework* scheduling factors.

The delegate noted that currently there are no issues of concern that require additional control other than by inclusion in Schedule 4.

The delegate decided to make a delegate-only decision. The Advisory Committee on Medicines Scheduling was not consulted.

Delegate's final decision

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include canagliflozin in Schedule 4, with an implementation date of 1 May 2013.

The delegate decided that the relevant matter under subsection 52E(1) of the *Therapeutic Goods Act 1989* is (a) risks and benefits of the use of a substance.

The delegate's reason for the final decision is that canagliflozin is a new chemical entity with no clinical or marketing experience in Australia.

Schedule 4 – New Entry

CANAGLIFLOZIN.

4.3 Crofelemer

Scheduling proposal

The delegate considered an application from the Therapeutic Goods Administration (TGA) to schedule crofelemer, a new chemical entity for a human therapeutic medicine.

Crofelemer is a proanthocyanidin from the bark latex of the tree Croton lechleri that acts locally on the intestinal lumen to normalise flow of chloride ions and water into the gastrointestinal tract.

Crofelemer is indicated for the control and symptomatic relief of diarrhoea in patients with HIV/AIDS.

Scheduling status

Crofelemer is not specifically scheduled and is not captured by any entry in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).

Crofelemer is not classified in New Zealand.

Delegate's consideration

The delegate considered the following in regards to this application.

· The new drug application (not publicly available).

- The TGA evaluation report (not publicly available).
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.

The delegate noted that:

- Limited safety information suggests low toxicity. Very little crofelemer is absorbed. Its purported mechanism in ameliorating the symptoms in HIV-associated diarrhoea is inhibition of chloride ion secretion. The inhibition blocks chloride secretion and accompanying high volume water loss in secretory diarrhoea, normalising the flow of chloride ions and water in the gastrointestinal tract.
- The recommended dose of crofelemer is one 125 mg tablet taken orally two times a day, with or without food. No dosage adjustment is required for renal or hepatic disease or for patients on dialysis.
- The potential for abuse is low.
- There are currently no issues of concern that require additional control other than by inclusion in Schedule 4.

The delegate decided to make a delegate-only decision. The Advisory Committee on Medicines Scheduling was not consulted.

Delegate's final decision

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include crofelemer in Schedule 4, with an implementation date of 1 May 2013.

The delegate decided that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits; (b) purpose and extent of use; and (f) any other matters considered necessary to protect public health.

The delegate's reasons for the final decision comprise of the following.

- It is a new chemical entity with no clinical or marketing experience in Australia.
- It is indicated for a specific population group taking multiple medications, but few drug interaction studies have been performed.
- No active control efficacy and safety studies were submitted and there is minimal pharmacokinetics.

Schedule 4 – New Entry

CROFELEMER.

4.4 Dimethyl fumarate

Scheduling proposal

The delegate considered an application from the Therapeutic Goods Administration (TGA) to schedule dimethyl fumarate, a new chemical entity for a human therapeutic medicine.

Dimethyl fumarate is indicated for patients with relapsing multiple sclerosis to reduce the frequency of relapses and to delay the progression of disability.

Scheduling status

Dimethyl fumarate is not specifically scheduled and is not captured by any entry in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).

Dimethyl fumarate is not classified in New Zealand.

Delegate's consideration

The delegate considered the following in regards to this application.

- The new drug application (not publicly available).
- The TGA evaluation report (not publicly available).
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.

The delegate noted that there are currently no issues of concern that require additional control other than by inclusion in Schedule 4. The pregnancy category is yet to be finalised, but it is not a pregnancy category D or X agent.

The delegate decided to make a delegate-only decision. The Advisory Committee on Medicines Scheduling was not consulted.

Delegate's final decision

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include dimethyl fumarate in Schedule 4, with an implementation date of 1 May 2013.

The delegate decided that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits; (b) purpose and extent of use; (c) toxicity and (f) dosage, formulation, labelling, packaging and presentation.

The delegate's reasons for the final decision comprise of the following.

- It is a new chemical entity with no clinical or marketing experience in Australia.
- It is an immunomodifying agent for use in the treatment of Multiple Sclerosis.
- As an immunomodifying agent, the product has considerable toxicity.
- It is an oral agent requiring instructions to healthcare professionals and consumers.

Schedule 4 – New Entry

DIMETHYL FUMARATE.

4.5 Ivacaftor

Scheduling proposal

The delegate considered an application from the Therapeutic Goods Administration (TGA) to schedule ivacaftor, a new chemical entity for a human therapeutic medicine.

Ivacaftor is a respiratory agent. It potentiates the cystic fibrosis transmembrane conductance protein (CFTR), specifically G551D-CFTR, resulting in increased chloride transport on the surface of epithelial cells in multiple organs.

Ivacaftor is proposed for the treatment of cystic fibrosis (CF) in patients 6 years of age and older who have a G551D mutation in the CFTR gene.

Scheduling status

Ivacaftor is not specifically scheduled and is not captured by any entry in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).

Ivacaftor is not classified in New Zealand.

Delegate's consideration

The delegate considered the following in regards to this application.

- The new drug application (not publicly available).
- The TGA evaluation report (not publicly available).
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.

The delegate noted that currently there are no issues of concern that require additional control other than by inclusion in Schedule 4.

The delegate decided to make a delegate-only decision. The Advisory Committee on Medicines Scheduling was not consulted.

Delegate's final decision

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include ivacaftor in Schedule 4, with an implementation date of 1 May 2013.

The delegate decided that the relevant matter under subsection 52E(1) of the *Therapeutic Goods Act 1989* is (a) risks and benefits of the use of a substance.

The delegate's reason for the final decision is that ivacaftor is a new chemical entity with no clinical or marketing experience in Australia.

Schedule 4 – New Entry

IVACAFTOR.

4.6 Micafungin

Scheduling proposal

The delegate considered an application from the Therapeutic Goods Administration (TGA) to schedule micafungin, a new chemical entity for a human therapeutic medicine.

Micafungin is an echinocandin class of antifungal agents. It is indicated for the treatment of invasive candidiasis, oesophageal candidiasis for whom IV therapy is appropriate; prophylaxis of Candida infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia for 10 or more days.

Scheduling status

Micafungin is not specifically scheduled and is not captured by any entry in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).

Micafungin is not classified in New Zealand.

Delegate's consideration

The delegate considered the following in regards to this application.

· The TGA evaluation reports (not publicly available).

· Subsection 52E(1) of the *Therapeutic Goods Act 1989*.

· The *Scheduling Policy Framework* scheduling factors.

The delegate noted that currently there are no issues of concern that require additional control other than by inclusion in Schedule 4.

The delegate decided to make a delegate-only decision. The Advisory Committee on Medicines Scheduling was not consulted.

Delegate's final decision

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include micafungin in Schedule 4, with an implementation date of 1 May 2013.

The delegate decided that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits; (b) purpose and extent of use; (c) toxicity; and (d) dosage, formulation, packaging and presentation.

The delegate's reasons for the final decision comprise of the following.

· It is a new chemical entity with no clinical or marketing experience in Australia.

· Other substances of the same class are included in Schedule 4.

· It is to be used in a patient population with very high morbidity and mortality.

· Intervention by a medical professional is required for diagnosis, management and monitoring of the conditions to be treated.

· Identified risks include allergic reactions, haemolytic reactions, Steven-Johnson's syndrome and damage to liver and kidneys.

Schedule 4 – New Entry

MICAFUNGIN.

4.7 Olodaterol

Scheduling proposal

The delegate considered an application from the Therapeutic Goods Administration (TGA) to schedule olodaterol, a new chemical entity for a human therapeutic medicine.

Olodaterol is a long-acting beta2-agonist and is proposed for use in the treatment of chronic obstructive pulmonary disease (COPD).

Scheduling status

Olodaterol is not specifically scheduled and is not captured by any entry in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).

Olodaterol is not classified in New Zealand.

Delegate's consideration

The delegate considered the following in regards to this application.

· Subsection 52E(1) of the *Therapeutic Goods Act 1989*.

· The *Scheduling Policy Framework* scheduling factors.

The delegate noted that currently there are no issues of concern that require additional control other than by inclusion in Schedule 4.

The delegate decided to make a delegate-only decision. The Advisory Committee on Medicines Scheduling was not consulted.

Delegate's final decision

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include olodaterol in Schedule 4, with an implementation date of 1 May 2013.

The delegate agreed that the relevant matter under subsection 52E(1) of the *Therapeutic Goods Act 1989* is (a) risks and benefits of the use of a substance.

The delegate's reason for the final decision is that olodaterol is a new chemical entity with no clinical or marketing experience in Australia.

Schedule 4 – New Entry

OLODATEROL.

4.8 Pasireotide diaspartate

Scheduling proposal

The delegate considered an application from the Therapeutic Goods Administration (TGA) to schedule pasireotide diaspartate, a new chemical entity for a human therapeutic medicine.

Pasireotide diaspartate is proposed for the treatment of patients with Cushing's disease for whom medical therapy is appropriate. It is a somatostatin analogue that binds to 4 of the 5 human somatostatin (hsst) receptors, especially hsst-5 which is expressed at high levels in corticotropin (ACTH)-producing adenomas. The resulting inhibition of ACTH secretion is used in the treatment of Cushing's disease, particularly when surgery is not an option or has failed. It is given as the diaspartate, but doses are expressed in terms of the base; 125 micrograms of pasireotide diaspartate is equivalent to about 100 micrograms of pasireotide.

Scheduling status

Pasireotide and pasireotide diaspartate are not specifically scheduled and are not captured by any entry in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).

Pasireotide and pasireotide diaspartate are not classified in New Zealand.

Delegate's consideration

The delegate considered the following in regards to this application.

· The new drug application (not publicly available).

- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.

The delegate noted that currently there are no issues of concern that require additional control other than by inclusion in Schedule 4.

The delegate decided to make a delegate-only decision. The Advisory Committee on Medicines Scheduling was not consulted.

Delegate's final decision

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include pasireotide and pasireotide diaspartate in Schedule 4, with an implementation date of 1 May 2013.

The delegate agreed that the relevant matter under subsection 52E(1) of the *Therapeutic Goods Act 1989* is (a) risks and benefits of the use of a substance.

The delegate's reason for the final decision is that pasireotide and pasireotide diaspartate are new chemical entities with no clinical or marketing experience in Australia.

Schedule 4 – New Entries

PASIREOTIDE.

PASIREOTIDE DIASPARTATE.

4.9 Retapamulin

Scheduling proposal

The delegate considered an application from the Therapeutic Goods Administration (TGA) to schedule retapamulin, a new chemical entity for a human therapeutic medicine.

Retapamulin is an antibiotic, indicated for the topical treatment of the following bacterial skin and skin structure infections (SSSI):

- primary impetigo;
- secondary infected traumatic lesions e.g. small lacerations, abrasions, sutured wounds; and
- secondary infected dermatoses including infected psoriasis, infected atopic dermatitis and infected contact dermatitis.

Scheduling status

Retapamulin is not specifically scheduled in Australia, but is captured by the Schedule 4 class entry for antibiotic substances.

Retapamulin is not classified in New Zealand.

Delegate's consideration

The delegate considered the following in regards to this application.

- The TGA evaluation report (not publicly available).
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.

· The *Scheduling Policy Framework* scheduling factors.

· Long-standing scheduling policy that antibiotics are specifically scheduled.

The delegate noted that there are no issues of concern that require additional control other than by inclusion in Schedule 4.

The delegate decided to make a delegate-only decision. The Advisory Committee on Medicines Scheduling was not consulted.

Delegate's final decision

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include retapamulin in Schedule 4, with an implementation date of 1 May 2013.

The delegate agreed that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (a) risks and benefits and (b) purpose and extent of use.

The delegate's reasons for the final decision comprise of the following.

· It is a new chemical entity with no clinical or marketing experience in Australia.

· It is to be prescribed by medical practitioners to treat specific bacterial skin and skin structure infections.

Schedule 4 – New Entry

RETAPAMULIN.

4.10 Vilanterol trifenatate

Scheduling proposal

The delegate considered an application from the Therapeutic Goods Administration (TGA) to schedule vilanterol trifenatate, a new chemical entity for a human therapeutic medicine.

Vilanterol trifenatate is a long-acting beta2 agonist and is proposed for use in the treatment of asthma in adults and adolescents aged 12 years and above.

Scheduling status

Vilanterol and vilanterol trifenate are not specifically scheduled and are not captured by any entry in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).

Vilanterol and vilanterol trifenatate are not classified in New Zealand.

Delegate's consideration

The delegate considered the following in regards to this application.

· Subsection 52E(1) of the *Therapeutic Goods Act 1989*.

· The *Scheduling Policy Framework* scheduling factors.

The delegate noted that currently there are no issues of concern that require additional control other than by inclusion in Schedule 4.

The delegate decided to make a delegate-only decision. The Advisory Committee on Medicines Scheduling was not consulted.

Delegate's final decision

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include vilanterol and vilanterol trifenatate in Schedule 4, with an implementation date of 1 May 2013.

The delegate agreed that the relevant matter under subsection 52E(1) of the *Therapeutic Goods Act 1989* is (a) risks and benefits of the use of a substance.

The delegate's reason for the final decision is that vilanterol and vilanterol trifenatate are new chemical entities with no clinical or marketing experience in Australia.

Schedule 4 – New Entries

VILANTEROL.

VILANTEROL TRIFENATATE.

5. New chemical entities - poisons

5.1 Cyantraniliprole

Scheduling proposal

The chemical scheduling delegate (delegate) considered a proposal from the Office of Chemical Safety (OCS) to include cyantraniliprole, a new insecticide, in Schedule 5 with no cut-off.

The OCS evaluated data that was provided in support of an application for approval of the new insecticide. The applicant was provided with a copy of the OCS evaluation report and supports the proposed Schedule 5 entry.

The delegate decided to make a delegate-only decision. The Advisory Committee on Chemicals Scheduling (ACCS) was not consulted.

Scheduling status

Cyantraniliprole is not specifically scheduled. Other similar substances, such as chlorantraniliprole and flubendiamide are listed in Appendix B and in Schedule 5 respectively.

Scheduling consideration

The delegate considered the following in regards to this application:

- The OCS evaluation report (not publicly available).
- The applicant's support for inclusion in Schedule 5.
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.

Delegate's final decision

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include cyantraniliprole in Schedule 5, with an implementation date of 1 May 2013.

The delegate decided that the relevant matter under section 52E (1) of the *Therapeutic Goods Act 1989* is (c) toxicity.

The delegate's reasons for the final decision comprise of the following.

- The toxicological profile of cyantraniliprole is well characterised. Based on the OCS evaluation report, this profile is consistent with either listing in Schedule 5 or exemption from scheduling.
- The primary reason for considering Schedule 5 to be more appropriate is the slight eye irritancy observed with technical cyantraniliprole, along with the skin and eye irritancy observed with the proposed products (possibly aggravated by other formulation constituents).
- The Schedule 5 listing is supported by the applicant.

Schedule 5 – New Entry

CYANTRANILIPROLE.

5.2 Tildipirosin

Scheduling proposal

The delegate considered a proposal from the Office of Chemical Safety (OCS) to include tildipirosin, a new chemical entity, in Schedule 4.

The OCS evaluated data that was provided in support of an application for approval of tildipirosin, a new chemical entity for a veterinary medicine. The applicant was provided with a copy of the OCS evaluation report and supports the Schedule 4 entry.

Scheduling status

Tildipirosin is not specifically scheduled.

Scheduling consideration

The delegate considered the following in regards to this application.

- The OCS evaluation report (not publicly available).
- The applicant's support for inclusion in Schedule 4.
- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.

The delegate decided to make a delegate-only decision. The Advisory Committee on Chemicals Scheduling (ACCS) was not consulted.

Delegate's final decision

The delegate has made a final decision to amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to include tildipirosin in Schedule 4, with an implementation date of 1 May 2013.

The delegate decided that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are (b) purpose and extent of use; (c) toxicity, and (f) any other matters considered necessary to protect public health.

The delegate's reasons for the final decision comprise of the following:

- Tildipirosin is a semisynthetic derivative of the macrolide antibiotic tylosin, intended for administration by a veterinarian for the control of respiratory infections.

- The toxicity of tildipirosin is consistent with that of an antibiotic substance related to tylosin, and requires the professional control of a veterinarian to minimise toxicity in the target species.
- There are no toxicological issues that would warrant control via any other Schedule. While the OCS report suggests that tildipirosin is inactivated by metabolism and gut actions and is unlikely to represent a significant risk for disseminating microbial resistance, this is not a scheduling issue when Schedule 4 controls put responsibility on the prescribing veterinarian for managing microbial resistance issues.

Schedule 4 – New Entry

TILDIPIROSIN.

6. Editorials and errata

6.1 Eformoterol fumarate dihydrate

Scheduling proposal

The delegate considered an application from the Therapeutic Goods Administration (TGA) to schedule eformoterol fumarate dihydrate in relation to a new fixed dose combination product of eformoterol fumarate dihydrate and mometasone.

The eformoterol fumarate dihydrate and mometasone combination product is proposed for use in maintenance treatment of asthma

The delegate has made a delegate-only decision. The Advisory Committee on Medicines Scheduling was not consulted.

Scheduling status

Eformoterol fumarate dihydrate is not specifically scheduled, but is captured by the Schedule 4 entry for formoterol.

Formoterol is classified as a prescription medicine in New Zealand.

Delegate's consideration

The delegate considered the following in regards to this application.

- Subsection 52E(1) of the *Therapeutic Goods Act 1989*.
- The *Scheduling Policy Framework* scheduling factors.
- Current scheduling policy for AANs (Australian Approved Names) to be included in the SUSMP, in line with:
  - paragraph 2 under Reading the Schedules in the Introduction to the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP); and
  - 'approved name' in Part 1, Interpretation of the SUSMP.
- Eformoterol (et al) is the AAN and formoterol (et al) is the INN (International Nonproprietary Name).
- Scheduling history

- In February 1997, the then National Drugs and Poisons Schedule Committee (NDPSC) included the new chemical entity 'eformoterol' in Schedule 4.
- In November 1999, the NDPSC amended the Schedule 4 entry to read 'eformoterol (formoterol)' to achieve partial harmonisation with New Zealand who had classified 'formoterol' as a prescription medicine.
- In October 2006, the NDPSC amended the Schedule 4 entry to read 'formoterol' in line with the then scheduling policy of including INNs in the Poisons Standard and to achieve full harmonisation with New Zealand.

· Currently, there are 10 products on the ARTG containing 'eformoterol' (et al), but no products containing 'formoterol' (et al).

Delegate's final decision

The delegate has decided that eformoterol fumarate dihydrate is appropriately captured by the Schedule 4 entry for formoterol.

However, in line with current scheduling policy that AANs (Australian Approved Names) are to be included in the *Standard for the Uniform Scheduling of Medicines and Poisons*, the delegate has made a final decision to editorially amend the current Schedule 4 entry for formoterol to read eformoterol, with an implementation date of 1 May 2013.

Schedule 4 – Amendment

FORMOTEROL – Amend entry to read:

EFORMOTEROL.

6.2 Thiamazole

Scheduling proposal

The chemicals scheduling delegate (the delegate) has initiated an editorial amendment to the thiamazone entry in the Index to the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).

Scheduling consideration

· In August 2012, the delegate considered a proposal to include carbimazole in Schedule 4 for the management of feline hyperthyroidism.

· The delegate noted that the data submitted in the application for carbimazole also consisted of methimazole (also known as thiamazole), which carbimazole is rapidly and completely metabolized to.

· The delegate noted that thiamazole was previously considered by the delegate and found that the cross-reference entry for thiamazone in the Index of SUSMP No. 3 was incorrectly spelt and should read thiamazole.

Delegate's final decision

The delegate has made a final decision to editorially amend the thiamazone cross-reference entry in the Index of the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) to read thiamazole, with the amended entry to be included in the next consolidation of the SUSMP, i.e. SUSMP No.4.

SUSMP Index – Amendment for SUSMP No.4 Consolidation

THIAMAZONE – Amend entry to read:

THIAMAZOLE

See METHIMAZOLE

6.3 Appendix L

Scheduling proposal

The medicines scheduling delegate (the delegate) has initiated an editorial amendment to Appendix L of the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).

Delegate's consideration

The delegate noted that:

- warning statement '77' [WARNING - May cause birth defects] is incorrectly listed in Appendix L:
  - for acitretin, adapalene, , bosentan, etretinate, isotretinoin, lenalidomide, thalidomide and tretinoin when 'for oral use'; and
  - for ambrisentan, bosentan, leflunomide and sitaxentan,
- the correct warning statement is '7' [WARNING - Causes birth defects];
- the correct warning statement '7' was listed against these substances in Appendix L in the previous edition of the *Standard for the Uniform Scheduling of Medicines and Poisons*, i.e. SUSMP2;
- Appendix L appears to have been corrupted during the consolidation of SUSMP3.

Delegate's final decision

The delegate has made a final decision to editorially amend the *Standard for the Uniform Scheduling of Medicines and Poisons* to replace warning statement '77' with warning statement '7' in Appendix L:

- for acitretin, adapalene, , bosentan, etretinate, isotretinoin, lenalidomide, thalidomide and tretinoin when 'for oral use'; and
- for ambrisentan, bosentan, leflunomide and sitaxentan.

The delegate has decided that the implementation date for this decision will be 1 May 2013.

Appendix L, Part 2 – Amendments

Column 1 Substance	Column 2 Warning statement
Acitretin – Amend entry to read: Acitretin:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
Adapalene – Amend entry to read: Adapalene:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
Ambrisentan – Amend entry to read:	
Ambrisentan.	7, 62 and 76
Bexarotene – Amend entry to read: Bexarotene:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
Bosentan – Amend entry to read:	
Bosentan.	7, 62 and 76
Etretinate – Amend entry to read: Etretinate:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77

Column 1 Substance	Column 2 Warning statement
Isotretinoin – Amend entry to read: Isotretinoin:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
Leflunomide – Amend entry to read:	
Leflunomide.	7, 62 and 87
Lenalidomide – Amend entry to read: Lenalidomide:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
Sitaxentan – Amend entry to read:	
Sitaxentan.	7, 62 and 76
Thalidomide – Amend entry to read: Thalidomide:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
Tretinoin – Amend entry to read: Tretinoin:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77