

NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

MEETING 29 (14-16 November 2000)

RECORD OF REASONS FOR AMENDMENT TO THE STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS and ADVICE OF OTHER OUTCOMES

PART A – contains the Record of Reasons for amendments to the Standard for the Uniform Scheduling of Drugs and Poisons notified in Commonwealth of Australia Gazette of 10 January 2001 as decisions arising from the 29th NDPSC Meeting held on 14-16 November 2000.

These amendments were made in respect of substances mentioned in the Gazette of 4 October 2000 as substances to be considered for scheduling at the November 2000 Meeting.

These amendments are **subject to the receipt of further public submissions**.

Persons who made a public submission in relation to the substances listed in this Part A are invited to make a further submission to the Secretary NDPSC. Submissions must be made by 24 January 2001 and address a matter mentioned in section 52E of the Act and be relevant to the reasons for the making of the decision.

If a submission is made to the Committee in respect of a substance set out below, the Committee must consider the submission and: confirm the amendment; or vary the amendment; or set aside the amendment, replace it with a new scheduling decision and publish notice of the decisions under section 52D of the Act. (If a new scheduling decision is made and notice of it published under section 52D, the public consultation process commences again). Subject to the matters set out above, the amendments in Part A come into effect on 1 June 2001, unless otherwise indicated.

PART B – advises of other outcomes from the 29th Meeting in relation to substances notified in the Gazette of 4 October 2000 as substances to be considered for scheduling at the November 2000 Meeting, and other general matters considered by the Committee.

These outcomes include proposals not supported, decisions to exempt substances from scheduling, deferral of matters to future meetings, and requests for further information.

PART C – List of substances for which amendments will be included in Amendment 3 to SUSDP 15 (decisions of the August 2000 meeting) and related matters.

PART A – RECORD OF REASONS

1. RESCHEDULING SUBMISSIONS

- (a) **Dialkoyl quaternary ammonium compounds** – consideration of a proposal for exemption from scheduling.

Outcome – The Committee supported exemption from scheduling of dialkoyl quaternary ammonium compounds. The decision to exempt was based on the consideration that the toxicity profile of dialkoyl quaternary ammonium compounds was similar to that of dialkyl quaternary ammonium compounds which have been considered exempt from scheduling.

Schedule 6 – Amendment

QUATERNARY AMMONIUM COMPOUNDS – amend entry to read:

QUATERNARY AMMONIUM COMPOUNDS **except:**

- (a) when separately specified in these Schedules;
- (b) when included in Schedule 5;
- (c) dialkyl or dialkoyl quaternary ammonium compounds where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16/C18) sources; or
- (d) in preparations containing 5 per cent or less of such quaternary ammonium compounds.

Schedule 5 – Amendment

QUATERNARY AMMONIUM COMPOUNDS – amend entry to read:

QUATERNARY AMMONIUM COMPOUNDS in preparations containing 20 per cent or less of quaternary ammonium compounds **except:**

- (a) when separately specified in these Schedules;
- (b) dialkyl or dialkoyl quaternary ammonium compounds where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16/C18) sources; or
- (c) in preparations containing 5 per cent or less of such quaternary ammonium compounds.

- (b) **Tetanus antitoxin** – consideration of poisons scheduling when for use in animals.

Outcome – The Committee considered it appropriate to exempt from scheduling tetanus antitoxin when used for short-term protection or treatment of tetanus in animals on the grounds that it was formerly exempt from scheduling and that it has been in routine use for many years in animal health management in Australia with no adverse effects.

Schedule 4 – Amendment

TETANUS ANTITOXIN – amend entry to read:

TETANUS ANTITOXIN **except** when used for short-term protection or treatment of tetanus in animals.

- (c) **Dimethyl sulfoxide** – consideration of poisons scheduling when for the treatment of animals.

Outcome – The Committee considered a Schedule 6 classification appropriate for dimethyl sulfoxide in animal treatments containing 1 per cent or less of methyl salicylate. The Committee based its decision on:

- The toxicological profile of a formulated product meeting the Schedule 6 criteria.
- The product has been available for many years without prescription.
- There is no requirement for professional diagnosis or management to safely use the product.

Schedule 6 – Amendment

DIMETHYL SULFOXIDE – amend entry to read:

DIMETHYL SULFOXIDE

- (a) when not for therapeutic use; or
- (b) for the treatment of animals:
 - (i) when combined with no other therapeutic substance(s);
 - (ii) in liquid preparations containing copper salicylate and 1 per cent or less of methyl salicylate as the only other therapeutic substance; or
 - (iii) in clay poultices containing 2 per cent or less of dimethyl sulfoxide.

- (d) **Ranitidine** – consideration of rescheduling from Schedule 3 to Schedule 2.

Outcome – The proposal was supported. The decision was based on the grounds that:

- The safety data justifies a Schedule 2 classification
- The indications meet the Schedule 2 classification criteria

Schedule 4 – Amendment

RANITIDINE – amend entry to read:

RANITIDINE **except** when included in Schedule 2.

Schedule 3 – Amendment

RANITIDINE – delete entry

Schedule 2 – New entry

RANITIDINE for the relief of symptoms of gastro-oesophageal reflux, in packs containing not more than 14 days supply.

Appendix F, Part 3 – Amendment

Ranitidine – amend entry to read:

Ranitidine when included in Schedule 2	
Warning statements	35,68,69,70

Appendix H – Amendment

Ranitidine – delete entry

- (e) **Fluticasone** – consideration of rescheduling of aqueous nasal spray preparations from Schedule 4 to Schedule 3 and inclusion in Appendix H

Outcome – The Committee supported the proposal. The Committee considered the data showed fluticasone nasal spray formulation is comparable in safety to other Schedule 3 nasal corticosteroids and should be available under similar conditions.

Schedule 4 – Amendment

FLUTICASONE – amend entry to read:
FLUTICASONE **except** when included in Schedule 3.

Schedule 3 - New entry

FLUTICASONE in aqueous nasal sprays delivering 50 micrograms or less of fluticasone per actuation when the maximum recommended daily dose is no greater than 200 micrograms and when packed in a primary pack containing 200 actuations or less, for the short-term prophylaxis or treatment of seasonal allergic rhinitis in adults and children 12 years and over.

Appendix H – New entry

Fluticasone

- (f) **Trometamol** – consideration of poisons scheduling.

Outcome – The Committee supported a Schedule 4 classification for trometamol when in injectable formulations. The decision below was based on the need for medical management in the use of such preparations.

Schedule 4 – New entry

TROMETAMOL in preparations for injection.

- (g) **Lithium** – consideration of exemption from scheduling of low dose formulations.

Outcome – The Committee supported exemption from scheduling of preparations containing 0.01 per cent or less of lithium. The decision was made to rectify the inadvertent scheduling of low dose therapeutic formulations.

Schedule 4 - Amendment

LITHIUM – amend entry to read:

LITHIUM for therapeutic use, **except**:

- (a) when included in Schedule 2; or
- (b) in preparations containing 0.01 per cent or less of lithium.

Schedule 2 - Amendment

LITHIUM – amend entry to read:

LITHIUM for dermal use in preparations containing 1 per cent or less of lithium **except** in preparations containing 0.01 per cent or less of lithium.

- (h) **Methoxyflurane** – consideration of the scheduling of analgesic preparations.

Outcome – The Committee considered such preparations should be included in Schedule 4. The decision was based on the need to rectify the inadvertent exemption from scheduling of analgesic preparations the use of which requires appropriate medical supervision.

Schedule 4 - Amendment

METHOXYFLURANE – amend entry to read:

METHOXYFLURANE.

- (i) **Acetylcysteine** - consideration of scheduling

Outcome - The decision was based on the grounds of harmonisation and in consideration that it is appropriate to include oral formulations in Schedule 2.

Schedule 4 – Amendment

ACETYLCYSTEINE – amend entry to read:

ACETYLCYSTEINE **except** when included in Schedule 2.

Schedule 2 - New entry

ACETYLCYSTEINE in preparations for oral use.

- (j) **Erythryl tetranitrate, glyceryl trinitrate, isosorbide dinitrate, and mannityl hexanitrate** – Consideration of the scheduling of these substances when in short-acting formulations for the treatment of angina pectoris and in topical preparations for local effect.

Outcome – The decision was based on the view that short acting treatments for acute angina should be available without prescription and with the benefit of professional advice to assist in appropriate management of the condition. Rescheduling of topical preparations was not supported.

Schedule 2 - Amendment

GLYCERYL TRINITRATE – amend entry to read:
GLYCERYL TRINITRATE **except** when included in Schedule 3 or 4.

ISOSORBIDE DINITRATE – delete entry

Schedule 3 – New entries

GLYCERYL TRINITRATE in oral preparations.

ISOSORBIDE DINITRATE in oral preparations containing 10 mg or less of isosorbide dinitrate per dosage unit.

Schedule 4 – Amendment

ISOSORBIDE DINITRATE – amend entry to read:
ISOSORBIDE DINITRATE **except** when included in Schedule 3.

(k) Aminophylline, theophylline and acepifylline –Consideration of a recommendation arising from Trans-Tasman Harmonisation Working Party to re-schedule from Schedule 3 to Schedule 4.

Outcome – The Committee agreed liquid oral preparations containing 2 per cent or less of aminophylline or theophylline should remain in Schedule 3, and that entries for the obsolete drug, acepifylline be deleted. The decision was based on the grounds of harmonisation, and that use of the aminophylline and theophylline in asthma management should be under medical supervision.

Schedule 3 - Amendments

ACEPIFYLLINE – delete entry

AMINOPHYLLINE – amend entry to read:
AMINOPHYLLINE in liquid oral preparations containing 2 per cent or less of aminophylline.

THEOPHYLLINE – amend entry to read:
THEOPHYLLINE in liquid oral preparations containing 2 per cent or less of theophylline.

Schedule 4 - Amendment

ACEPIFYLLINE – delete entry

2. MATTERS REFERRED BY THE AUSTRALIAN DRUG EVALUATION COMMITTEE

New drugs – Schedule required

Brinzolamide	Bupropion hydrochloride
Cetorelix	Eletriptan
Exemestane	Oseltamivir
Oxcarbazepine	Rabeprazole
Salcatonin	Tasonermin
Trastuzumab	Verteporfin

Outcome – The Committee supported a Schedule 4 classification for all of the above drugs.

Brinzolamide

The decision was based on:

- brinzolamide is a new substance and the condition being treated requires medical management; and
- on the grounds of harmonisation.

Schedule 4 – New entry

BRINZOLAMIDE.

Bupropion hydrochloride

The decision below was based on:

- bupropion is a new substance and the condition being treated requires medical management; and
- on the grounds of harmonisation.

Schedule 4 – New entry

BUPROPION.

Cetorelix

The decision below was based on:

- cetorelix is a new substance and the condition being treated requires medical management; and
- on the grounds of harmonisation.

Schedule 4 – New entry

CETRORELIX.

Eletriptan

The decision below was based on:

- eletriptan is a new substance and the condition being treated requires medical management; and
- on the grounds of harmonisation.

Schedule 4 – New entry

ELETRIPTAN.

Exemestane

The decision below was based on:

- exemestane is a new substance and the condition being treated requires medical management; and
- on the grounds of harmonisation.

Schedule 4 – New entry

EXEMESTANE.

Oseltamivir

The decision below was based on:

- oseltamivir is a new substance and the condition being treated requires medical management; and
- on the grounds of harmonisation.

Schedule 4 – New entry

OSELTAMIVIR.

Oxcarbazepine

The decision below was based on:

- oxcarbazepine is a new substance and the condition being treated requires medical management; and
- on the grounds of harmonisation.

Schedule 4 – New entry

OXCARBAZEPINE.

Rabeprazole

The decision below was based on:

- rabeprazole is a new substance and the condition being treated requires medical management; and
- on the grounds of harmonisation.

Schedule 4 – New entry

RABEPRAZOLE.

Salcatonin

The decision clarifies that all forms of calcitonin as well as salcatonin are classified as Schedule 4.

Schedule 4 – New entry

SALCATONIN.

Tasonermin

The decision below was based on tasonermin is a new substance and the condition being treated requires medical management.

Schedule 4 – New entry

TASONERMIN.

Trastuzumab

The decision below was based on:

- trastuzumab is a new substance and the condition being treated requires medical management; and
- on the grounds of harmonisation.

Schedule 4 – New entry

TRASTUZUMAB.

Verteporfin

The decision below was based on verteporfin is a new substance and the condition being

treated requires medical management

Schedule 4 – New entry

VERTEPORFIN.

3. MATTERS REFERRED BY THE NATIONAL REGISTRATION AUTHORITY FOR AGRICULTURAL AND VETERINARY CHEMICALS

(a) Mecoprop-p – new chemical – consideration of poisons scheduling.

Outcome – The Committee considered a Schedule 6 classification appropriate for mecoprop-p. The decision was based on:

- Similar toxicity profile to mecoprop, appropriate for inclusion in Schedule 6; and
- Consistency with the labelling requirements of the National Registration Authority.

Schedule 6 – New entry

MECOPROP-P.

(b) **Bifenthrin** – consideration of poisons scheduling of granular formulations.

Outcome – The Committee considered preparations containing 0.5 per cent or less of bifenthrin should be exempt from scheduling. The decision was based on:

- the toxicology profile of bifenthrin and formulation toxicology was consistent with an exemption at or about the level of the formulations tested; and
- For continuity with the existing exemption in the SUSDP.

Schedule 7 – Amendment

BIFENTHRIN – amend entry to read:

BIFENTHRIN **except**:

- (a) when included in Schedule 6; or
- (b) in preparations containing 0.5 per cent or less of bifenthrin.

Schedule 6 – Amendment

BIFENTHRIN – amend entry to read:

BIFENTHRIN in preparations containing 10 per cent or less of bifenthrin **except** in preparations containing 0.5 per cent or less of bifenthrin.

(c) **Florfenicol** – new chemical – consideration of poisons scheduling.

Outcome – The Committee supported a Schedule 4 classification for florfenicol. The decision was based on:

- The prerequisites of veterinary diagnosis and prescription for the diseases controlled by this product; and
- The requirement for professional management of the use of broad spectrum antibiotics in food producing animals including the control of potential residues; and
- The need for professional supervision of the use of injectable antibiotics and intervention where issues of safety, or adverse effects arise.

Schedule 4 – New entry

FLORFENICOL.

- (d) **Alpha-cypermethrin** – consideration of poisons scheduling cut-offs.

Outcome – The Committee supported a cut-off at 25 per cent from Schedule 7 to Schedule 6 for alpha-cypermethrin when in aqueous preparations. The decision was based on an acute toxicity profile for a product, consistent with entry in Schedule 6.

Schedule 6 – Amendment

ALPHA-CYPERMETHRIN – amend entry to read:

ALPHA-CYPERMETHRIN

- (a) in aqueous preparations containing 25 per cent or less of alpha-cypermethrin except when included in Schedule 5; or
- (b) in other preparations containing 10 per cent or less of alpha-cypermethrin except when included in Schedule 5.

4. OTHER MATTERS FOR CONSIDERATION

- (a) **Review of Schedule entries using chemical names** with a view to replacing with approved names:

- 2-[1-(Ethoxyimino)propyl]-3-hydroxy-5-(3-butrylmesityl)-cyclohex-2-enone (Butroxydim)
- 3-Iodo-2-propynyl butyl carbamate (Iodocarb)
- 2-methylthio-4-(2-methylprop-2-yl) amino-6-cyclopropylamino-5- triazine (Irgarol)
- Poly (hexamethylene biguanide)
- 2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one (Pyridaben)
- 5-Benzylfur-3-ylmethyl (1'R,3'S.E)-2',2'-dimethyl-3'-(2-oxo-2,3,4,5-tetrahydro-3-thienylidenemethyl)-cyclopropane carboxylate
- N-[5-chloro-4-[(4-chlorophenyl)-cyanomethyl]-2 methylphenyl]-2-hydroxy-3,5-diiodobenzamide (Closantel)
- N-(2,6-dichloro-3-methylphenyl)-5,7-dimethoxy-[1,2,4]-triazolo[1,5a]pyrimidine-2-sulfonamide (Metosulam)
- 4,5-dichloro-2-N-octyl-3(2H)-isothiazolone
- (RS)-2-methyl-4-oxo-3-prop-2-ynylcyclopent-2-enyl-(1RS,3RS;1RS,3S R)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate (Prallethrin)
- 2-octyl-4-isothiazolin-3-one (Octhilnone)
- 2,2',6,6'-Tetraisopropyl-diphenyl-carbodiimide

Outcome – The Committee supported the following amendments to schedule entries for clarity, to reflect the approved chemical name, to remove references to tradenames and duplication of entries.

2-[1-(Ethoxyimino)propyl]-3-hydroxy-5-(3-butyrylmesityl)-cyclohex-2-enone (Butroxydim)

The Committee based its decision on the rationale that it would be appropriate to apply the provisional ISO for this chemical which is butroxydim.

Schedule 5 – Amendment

2-[1-(ETHOXYIMINO)PROPYL]-3-HYDROXY-5-(3-BUTYRYLMESITYL)-
CYCLOHEX-2-ENONE (Butroxydim) – amend entry to read:

BUTROXYDIM.

3-Iodo-2-propynyl butyl carbamate (Iodocarb)

The Committee agreed that the SUSDP entry for 3-iodo-2-propynyl butyl carbamate (Iodocarb) required no amendment at this time.

2-methylthio-4-(2-methylprop-2-yl) amino-6-cyclopropylamino-5- triazine (Irgarol)

The Committee based its decision on the rationale that irgarol is not an approved common name therefore it would be appropriate to apply its chemical name.

Schedule 5 – Amendment

2-METHYLTHIO-4-(2-METHYLPROP-2-YL) AMINO-6-CYCLOPROPYLAMINO-5-
TRIAZINE (Irgarol) – amend entry to read:

2-METHYLTHIO-4-(2-METHYLPROP-2-YL) AMINO-6-CYCLOPROPYLAMINO-5-
TRIAZINE.

Poly (hexamethylene biguanide)

The Committee based its decision on the rationale that polihexanide is a WHO rINN and therefore an approved name specified in the SUSDP.

Schedule 5 – Amendment

POLY (HEXAMETHYLENE BIGUANIDE) – amend entry to read:

POLIHEXANIDE **except** in preparations containing 5 per cent or less of polihexanide.

Appendix F, Part 3 - Amendment

Poly (hexamethylene biguanide) hydrochloride - amend entry to read:

Polihexanide.....

Safety directions 1, 4, 8

2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one (Pyridaben)

The Committee based its decision on the rationale that pyridaben is an approved name.

Schedule 5 – Amendment

2-TERT-BUTYL-5-(4-TERT-BUTYLBENZYLTHIO)-4-CHLOROPYRIDAZIN-3(2H)-ONE (Pyridaben) – amend entry to read:

PYRIDABEN in preparations containing 25 per cent or less of pyridaben.

Schedule 6 – Amendment

2-TERT-BUTYL-5-(4-TERT-BUTYLBENZYLTHIO)-4-CHLOROPYRIDAZIN-3(2H)-ONE (Pyridaben) – amend entry to read:

PYRIDABEN **except** when included in Schedule 5.

5-Benzylfur-3-ylmethyl (1'R,3'S.E)-2',2'-dimethyl-3'-(2-oxo-2,3,4,5-tetrahydro-3-thienylidenemethyl)-cyclopropane carboxylate

The Committee based its decision on the rationale that the approved name for the substance listed below is resmethrin, for which there are entries in the SUSDP.

Schedule 6 – Amendment

5-BENZYL-FUR-3-YLMETHYL (1'R,3'S.E)-2',2'-DIMETHYL-3'-(2-OXO-2,3,4,5-TETRAHYDRO-3-THIENYLIDENEMETHYL)-CYCLOPROPANE CARBOXYLATE – delete entry

N-[5-chloro-4-[(4-chlorophenyl)-cyanomethyl]-2-methylphenyl]-2-hydroxy-3,5-diiodobenzamide (Closantel)

The Committee based its decision on the rationale that closantel is a WHO rINN and therefore an approved name specified for use in the SUSDP.

Schedule 6 – Amendment

N-[5-CHLORO-4-[(4-CHLOROPHENYL)-CYANOMETHYL]-2-METHYLPHENYL] -2-HYDROXY-3,5-DIODOBENZAMIDE (Closantel) – amend to read:

CLOSANTEL.

N-(2,6-dichloro-3-methylphenyl)-5,7-dimethoxy-[1,2,4]-triazolo[1,5a]pyrimidine-2-sulfonamide (Metosulam)

The Committee based its decision on the rationale that metosulam is an approved name.

Schedule 6 – Amendment

N-(2,6-DICHLORO-3-METHYLPHENYL)-5,7-DIMETHOXY-[1,2,4]-TRIAZOLO-[1,5a]PYRIMIDINE-2-SULFONAMIDE (Metosulam) – amend entry to read:

METOSULAM.

4,5-dichloro-2-N-octyl-3(2H)-isothiazolone

The Committee supported retention of the current SUSDP entry for this chemical to reflect only its chemical name on the basis that there was no approved common name.

(RS)-2-methyl-4-oxo-3-prop-2-ynylcyclopent-2-enyl-(1RS,3RS;1RS,3S R)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate (Prallethrin)

The Committee based its decision on the rationale that prallethrin is an approved name.

Schedule 6 – Amendment

(RS)-2-METHYL-4-OXO-3-PROP-2-YNYLCYCLOPENT-2-ENYL-(1RS,3RS;1RS,3S R)-2,2-DIMETHYL-3-(2-METHYLPROP-1-ENYL)-YCLOPROPANECARBOXYLATE (Prallethrin) (cis:trans=20:80) – amend entry to read:

PRALLETHRIN (cis:trans=20:80).

2-octyl-4-isothiazolin-3-one (Octhilinone)

The Committee based its decision on the rationale that octhilinone is an approved name.

Schedule 6 – Amendment

2-OCTYL-4-ISOTHIAZOLIN-3-ONE (octhilinone) – amend entry to read:

OCTHILINONE **except** in paints containing 1 per cent or less of octhilinone calculated on the non-volatile content of the paint.

Appendix E, Part 2 – Amendment

2-Octyl-4-isothiazolin-3-one (Octhilinone) - amend entry to read:

Octhilinone..... a, c, f, s

2,2',6,6'-Tetraisopropyl-diphenyl-carbodiimide

The Committee supported the retention of the current SUSDP entry for this chemical to reflect only its chemical name on the basis that there was no approved common name.

- (b) **Ivermectin, moxidectin, selamectin, abamectin, milbemycin and diethylcarbamazine** – consideration of poisons scheduling when used for the prevention of heartworm in cats and dogs.

Outcome – The Committee supported the rescheduling from Schedule 4 to Schedule 5 of ivermectin in preparations for heartworm in cats and dogs. The decision was based on:

- No apparent difference in the risk to animals between those macrolides that are in Schedule 4 and those that are open sale.
- Evidence that all of the macrolides are safe and effective for prophylaxis of heartworm when used without professional intervention.
- Positive evidence for some of the macrolides that inadvertent treatment of infected dogs did not significantly increase the risk of additional morbidity.
- Consistency of scheduling decisions across the therapeutic class.

Schedule 4 – Amendment

IVERMECTIN – amend entry to read:

IVERMECTIN for human use.

Schedule 5 – Amendment

IVERMECTIN – amend entry to read:

IVERMECTIN for the treatment of animals

- (a) in preparations containing 2% or less of ivermectin; or
 - (b) in intraruminal implants containing 160mg or less of ivermectin.
- (c) **Pyrithione zinc** – consideration of the foreshadowed decision to require pyrithione zinc shampoos for animal use to be labelled with either "Keep out of eyes" or "If in eyes rinse well with water" as a condition of exemption from the Schedule 6 entry for pyrithione zinc.

Outcome – The Committee agreed the above proposal should proceed. The decision was based on:

- Consistency with shampoos for human therapeutic use;
- Risk management of specific toxicity in a product otherwise exempt.

Schedule 6 – Amendment

PYRITHIONE ZINC – amend entry to read:

PYRITHIONE ZINC **except:**

- (a) when included in Schedule 2;
- (b) in semi-solid hair preparations; or
- (c) in shampoos containing 2 per cent or less of pyrithione zinc when labelled with the statement, “Keep out of eyes” or “If in eyes, rinse well with water”.

5. MATTERS REFERRED BY THE NEW ZEALAND MEDICINES CLASSIFICATION COMMITTEE

- (a) **Famotidine** – consideration of rescheduling from Schedule 3 to Schedule 2.

Outcome – The Committee supported the proposal. The following decision was made on the basis of:

- A safety record comparable with ranitidine and therefore a Schedule 2 classification was justified
- The indications meet the Schedule 2 criteria
- On the grounds of harmonisation.

Schedule 4 - Amendment

FAMOTIDINE – amend entry to read:

FAMOTIDINE **except** when included in Schedule 2.

Schedule 3 – Amendment

FAMOTIDINE – delete entry

Schedule 2 – New entry

FAMOTIDINE for the relief of symptoms of gastro-oesophageal reflux, in packs containing not more than 14 days supply.

Appendix F, Part 3 – Amendment

Famotidine – amend entry to read:

Famotidine when included in Schedule 2

Warning statements	35,68,69,70
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Appendix H- Amendment

Famotidine – delete entry

(b) New drugs - recently scheduled in New Zealand – consideration of scheduling

Alosetron Hydrochloride	Amisulpride
Amprenavir	Artemether
Aviptadil	Balsalazide disodium
Bivalirudin	Dexmedetomidine
Esomeprazole	Ganirelix
Gatifloxacin	Icodextrin
Interleukins	Lercanidipine hydrochloride
Levobupivacaine hydrochloride	Linezolid
Lumefantrine	Mangafodipir
Moxifloxacin hydrochloride	Nateglinide
Oxaliplatin	Palivizumab
Pioglitazone hydrochloride	Rapacuronium bromide
Sertindole	Sialoepoetin
Sirolimus	Tegafur
Tegaserod	Tenecteplase
Unoprostone isopropyl	Uracil
Zaleplon	Ziprasidone

Outcome – The Committee supported a Schedule 4 classification as detailed below on the grounds they were new substances and the conditions being treated required medical management; and on the grounds of harmonisation.

Schedule 4 – New entries

ALOSETRON.
 AMISULPRIDE.
 AMPRENAVIR.
 ARTEMETHER.
 LUMEFANTRINE.
 AVIPTADIL.
 BALSALAZIDE.
 BIVALIRUDIN.
 DEXMEDETOMIDINE.
 ESOMEPRAZOLE.
 GANIRELIX.
 GATIFLOXACIN.
 INTERLEUKINS **except** when separately specified in these Schedules.
 LERCANIDIPINE.
 LEVOBUPIVACAINE.
 LINEZOLID.
 MOXIFLOXACIN.
 NATEGLINIDE.
 OXALIPLATIN.
 PIOGLITAZONE.
 RAPACURONIUM BROMIDE.
 SERTINDOLE.

SIALOPOETIN.
 SIROLIMUS.
 TEGAFUR.
 URACIL.
 TEGASEROD.
 TENECTEPLASE.
 UNOPROSTONE.
 ZALEPLON.
 ZIPRASIDONE.

Substances included in pre-meeting gazette notice and not scheduled.

Mangofodipir is a magnetic resonance agent and is exempt from scheduling under the Appendix A entry for ENHANCING AGENTS.

The scheduling of icodextrin, a dialysis solution, was not supported.

Palivizumab was included in Schedule 4 at the May 1999 NDPSC meeting.

(c) **Anabolic agents** – consideration of scheduling

androstanolone	androstenediol
androstenedione	dehydrochloromethyltestosterone
metandienone	metenolone
19-norandrostenediol	19-norandrostenedione

Outcome – The Committee supported a Schedule 4 classification for the above anabolic agents on the basis inclusion of these substances in Schedule 4 was consistent with past practice, and would maintain harmonisation.

Schedule 4 - New entries

ANDROSTANOLONE.
 # ANDROSTENEDIOL.
 # ANDROSTENEDIONE.
 # METENOLONE.
 # 19-NORANDROSTENEDIOL.
 # 19-NORANDROSTENEDIONE.

Schedule 4 – Amendment

CHLOROXYMESTERONE – amend entry to read:
 # DEHYDROCHLOROMETHYLTESTOSTERONE.

METHANDIENONE – amend entry to read:
 # METHANDIENONE (metandienone).

6. PROPOSALS ARISING FROM TRANS-TASMAN WORKING PARTY ON THE HARMONISATION OF THE SCHEDULING OF DRUGS AND POISONS.

Outcome - All matters relating to proposals arising from the sixth meeting of the Working Party were deferred to the February 2001 meeting with the exception of those substances listed under the heading 'Proposals for amendment to the Standard for the Uniform Scheduling of Drugs and Poisons ' in the pre-meeting gazette notice (nicotine, salbutamol and terbutaline, and aminophylline, theophylline and acepyfylline), and those relating to bambuterol and isoetharine.

The following entries were supported on the grounds of harmonisation.

Schedule 4 - New entry

BAMBUTEROL.

Schedule 4 - Amendment

ISOETHARINE – amend entry to read:

ISOETARINE.

7. MATTERS ARISING FROM THE ESSENTIAL OILS WORKING PARTY AND SUBSEQUENT DELIBERATIONS

(a) Essential oil definition for inclusion in SUSDP. The August 2000 Meeting of the NDPSC proposed a definition for essential oils be included in the Interpretation section of the SUSDP.

Outcome – The Committee supported inclusion of the following definition in the SUSDP. The decision was based on :

- Establishment of the meaning of the term '*essential oils*' when used in regard to poisons scheduling; and
- to reflect the intention of the SUSDP that the Schedule entries for the various essential oils cover all oils with equivalent composition irrespective of source.

PART 1, INTERPRETATION – Amendment

Amend paragraph 1 (1) to include:

"Essential oils" means products obtained from natural raw materials either by distillation with water or steam or from the epicarp of citrus fruits by a mechanical process, or by dry distillation. For scheduling purposes it also means:

- (a) oils of equivalent composition derived through synthetic means; or
- (b) compounded oils of equivalent composition comprising a mixture of synthetic and natural components.

PART B – OTHER OUTCOMES

Outcome of: (i) proposals in relation to other substances mentioned in the Gazette of 4 October 2000 as being considered for scheduling at the November 2000 meeting; and (ii) other general matters considered by the Committee.

(i) Proposals in relation to other substances mentioned in the Gazette of 4 October 2000 as being considered for scheduling at the November 2000 meeting

- (a) Olaquinox** – review of scheduling on basis of reports of photo-allergic contact dermatitis.

Outcome – The Committee did not support a change to the scheduling of olaquinox. The Committee considered the recommended Instructions and Safety Directions advised to the National Registration Authority in 1996 in relation to olaquinox which were concurred by the Veterinary Chemicals Consultative Committee to be sufficient as a first step in addressing the health issue raised.

- (b) Nicotine** – Consideration of the relaxation of the scheduling of nicotine replacement therapies to also allow sale from smoking cessation clinics, and exemption from scheduling for chewing gum and transdermal patches. The consideration has followed from changes in availability of such products in NZ

Outcome – The Committee did not support changes to the scheduling of nicotine replacement therapies. The proposal as it related to exemption from scheduling of nicotine when in transdermal patches and chewing gum to assist in smoking cessation did not receive the required support of the Committee. There was support for the Commonwealth Department of Health and Aged Care's policy position that the research under the National Tobacco Strategy be carried out to allow the Committee to make a more informed decision on the availability of the therapies. When this data was available it would be brought back to the NDPSC for its consideration.

The Committee supported the view that the nicotine cessation therapies of chewing gums and transdermal patches be available from smoking cessation clinics. The Committee agreed that to facilitate a uniform approach the National Co-Ordinating Committee on Therapeutic Goods be advised:

The NDPSC has retained the scheduling of nicotine cessation therapies but sees some merit in supply through smoking cessation clinics. The NDPSC is seeking the advice of NCCTG in regard to mechanisms available across Australia, to allow nicotine chewing gum and transdermal patches to be uniformly made more available via smoking cessation clinics.

- (c) Salbutamol and terbutaline** – Review of scheduling of inhaled and oral formulations

Outcome – The Committee did not support amendments to the scheduling of salbutamol and terbutaline at this meeting and oral liquid and tablet formulations will remain in Schedule 4.

However, the Committee foreshadowed that at the February 2001 meeting it would consider the aligning the scheduling of metered dose aerosols and dry powder formulations, and that there may be sufficient justification to reschedule some formulations to Schedule 3. The Committee considered rotocaps®, rotodisks® and turbohalers® to be dry powder formulations for the purposes of this consideration.

- (d) **Ethametsulfuron-methyl** – new chemical – consideration of poisons scheduling.

Outcome – The Committee considered ethametsulfuron-methyl should be exempt from poisons scheduling. The decision was based on the low acute toxicity and generally unremarkable toxicological end points for ethametsulfuron-methyl.

- (e) **Methoxyfenozide** – new chemical – consideration of poisons scheduling;

Outcome – The Committee considered methoxyfenozide should be exempt from poisons scheduling. The decision was based on the low acute toxicity and generally unremarkable toxicological end points for methoxyfenozide.

- (f) **1,3 – Dichloropropene** – consideration of poisons scheduling with a cut-off to a lower schedule.

Outcome – The Committee did not support a change to the SUSDP entries for 1,3-dichloropropene.

- (g) **Novaluron** – new chemical – consideration of poisons scheduling.

Outcome - The Committee considered novaluron should be exempt from poisons scheduling. The decision was based on the low acute toxicity and generally unremarkable toxicological end points for novaluron.

- (h) **Hydrofluoric acid** – consideration of labelling and packaging requirements including child-resistant closures

Outcome – The matter was deferred to the May 2001 meeting pending the availability of the Priority Existing Chemicals report on hydrofluoric acid.

- (i) **Dimethyl phthalate** – consideration of the foreshadowed decision to include dimethyl phthalate in either Schedule 7 or Appendix C because of concerns over developmental effects.

Outcome – The matter was deferred to a future meeting pending the receipt of further information.

- (j) **Chlorinating compounds – trichloroisocyanuric acid, bromochlorodimethylhydantoin, calcium hypochlorite, chlorinated lime, dichloroisocyanurates, sodium hypochlorite, chlorine dioxide and similar oxidising compounds capable of releasing chlorine** – further consideration of the scheduling of chlorinating compounds, with the possibility of some chlorinating compounds being re-scheduled to Schedule 6.

Outcome – The matter was deferred to a future meeting pending the receipt of further information.

- (k) **Precursor Chemicals** – Consideration of inclusion of model regulations (in SUSDP Part 3) and a new Appendix listing precursor chemicals to facilitate the imposition of mandatory controls on monitoring the use and distribution of precursor chemicals in Australia.

Outcome – The matter was deferred to a future meeting pending the receipt of further information.

- (l) **Diphenhydramine** – Consideration of requiring Appendix F Warning Statement 90 on diphenhydramine preparations indicated for the relief of insomnia.

Warning Statement 90 - This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.

Outcome – The Committee did not support requiring the above warning statement on diphenhydramine preparations via the SUSDP. However, it will advise the Medicines Evaluation Committee that it considers it appropriate that a similar labelling requirement be applied via the Australian Guidelines for the Registration of Drugs.

- (m) **Matters arising from the First Aid Instructions Working Party and subsequent Deliberations**

- (a) Revised Introduction to Appendix E incorporating details of new first aid instructions and the transitional period; and
- (b) Review of first aid instructions and corresponding safety directions and warning statements.

Outcome – For further consideration at the February 2001 meeting. See February 2001 pre-meeting gazette notice.

- (ii) **General Matters**

- (a) **Resolutions of the National Co-Ordinating Committee on Therapeutic Goods concerning Trans-Tasman Harmonisation of Scheduling.**

The NDPSC will advise the NCCTG of the public comment received, and supported the forwarding of the resolutions to the New Zealand Ministry of Health for its consideration.

PART C – OUTCOMES RELATING TO AUGUST 2000 DECISIONS

PART C

The public consultation process in respect of the substances set out in this Part C(1) has been concluded. The amendments relating to substances set out in Part C (1) are therefore final amendments and as notified in the Gazette of 27 September 2000, come into effect on 1 March 2001. The amendments will be published in Amendment 3 to SUSDP 15.

The amendments relating to substances set out in Part C(2) will not proceed as an outcome of the August 2000 meeting.

PART C (1)

AMINOETHOXYVINYLGLYCINE
 ANTIMONY COMPOUNDS
 BARIUM SALTS
 BECLOMETHASONE
 BUDESONIDE.
 CADMIUM COMPOUNDS
 CAJUPUT OIL
 CARBOCISTEINE.
 CHROMATES
 DIDECYLDIMETHYLAMMONIUM CHLORIDE
 DIFLOXACIN.
 ETANERCEPT
 FLUNISOLIDE
 GLYCERYL TRINITRATE
 GLYCOLIC ACID
 HYPOTHALAMIC RELEASING FACTORS
 INFLIXIMAB.
 IODOSULFURON-METHYL-SODIUM.
 ISOSORBIDE DINITRATE
 ISOSORBIDE MONONITRATE
 LEAD COMPOUNDS
 LOPERAMIDE
 MARJORAM OIL
 METHIOCARB
 N,N-BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,5-DIMETHANAMINE
 N,N-BIS(PHENYLMETHYLENE)-BICYCLO-(2.2.1)HEPTANE-2,6-DIMETHANAMINE
 PARAGRAPH 25 - AMENDMENT
 PARAGRAPH 45 – AMENDMENT
 PHENYAPIN
 PIPENZOLATE
 POLY(OXY-1,2-ETHANEDIYL), a-[2-[(2-HYDROXYETHYL)AMINO]-2-OXOETHYL]-
 ? -HYDROXY-, MONO-C13-15-ALKYL ETHERS.
 PYRITHIONE ZINC
 RISEDRONIC ACID.

SELENIUM
 TRIAMCINOLONE
 TRIFLUPERIDOL

PART C(2)

- (a) BERGAMOT OIL
 LEMON OIL
 LIME OIL
 ORANGE OIL (BITTER)

Outcome

The Committee did not confirm its decisions in regard to the above essential oils. The Committee is seeking additional information and further consideration will be subject to the NDPSC pre- and post meeting consultation process. Therefore, the scheduling status of the oils remains unscheduled at this time.

- (b) AMMONIUM PERSULFATE
 POTASSIUM PERSULFATE
 SODIUM PERSULFATE

Outcome

The Committee did not confirm its decisions in regard to the above substances. The substances will be subject to further consideration at the February 2001 meeting. See February 2001 pre-meeting gazette notice.

- (c) VITAMIN A

Outcome

The August 2000 decision relating to Vitamin A was the subject of public comment. The Committee supported a variation to the wording of the warning statement as detailed below. This variation is subject to further comment as detailed under Part A of record, and those who made submissions prior to the meeting on this matter are invited to comment.

The Committee agreed the effective date of the amendment would be 1 June 2001 and that the warning statement, 'WARNING – Taking more than 2 500IU a day during pregnancy may cause birth defects' would be deleted from the SUSDP in Amendment 4 to SUSDP 16 effective date 1 June 2002.

The decision was based on:

- Consideration of comments received post-meeting;
- Consideration that the epidemiological data supported the conclusion that a daily intake of vitamin A of 8000 IU or less is not associated with birth defects;
- The conclusion that on balance, a greater benefit would result to the consumer from inclusion of a limit in the warning statement for guidance to consumers, doctors and

- pharmacists; and
- Implementation to be effected by 1 June 2002.

Schedule 4 - Amendment

VITAMIN A – amend entry to read:

VITAMIN A for human therapeutic or cosmetic use, **except:**

- (a) in preparations for topical use containing 1 per cent or less of vitamin A; or
- (b) in preparations for internal use, containing 100 IU or less of vitamin A per dosage unit of a divided preparation, or 100 IU or less of vitamin A per gram of an undivided preparation; or
- (c) in other preparations for internal use labelled:
 - (i) with a recommended daily amount of 5 000 IU or less of vitamin A; and
 - (ii) where the preparation is labelled for adult use, in bold face letters not less than 1.5 mm high:

(A) with a statement to the following effect:

The recommended adult daily amount of vitamin A from all sources is 2 500 IU.

(B) and, at the beginning of the directions for use, with a warning statement to the following effect:

WARNING – When taken in excess of 8 000 IU vitamin A can cause birth defects. If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

or

WARNING – Taking more than 2 500IU a day during pregnancy may cause birth defects.