

NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE**MEETING 27 (16-18 May 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 28 June 2000 as decisions arising from the 27th NDPSC Meeting held on 16-18 May 2000.

These amendments were made in respect of substances mentioned in the Gazette of 5 April 2000 as substances to be considered for scheduling at the May 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 13 July 2000 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 December 2000, unless otherwise indicated.

PART B – advises of other outcomes from the 27th Meeting in relation to substances notified in the Gazette of 5 April 2000 as substances to be considered for scheduling at the February 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 A – RECORD OF REASONS

1. RESCHEDULING SUBMISSIONS

- (a) **Glutaraldehyde** – consideration of proposal to introduce a concentration cut-off to exempt into the Schedule 5 entry for glutaraldehyde.

Outcome - The Committee considered preparations containing glutaraldehyde should be exempt from scheduling in concentrations of 0.5 per cent or less of glutaraldehyde, conditional upon label warnings regarding eye irritancy.

Amendment and reasons

The scheduling decision was based on the conclusion that the main hazard associated with low concentrations of glutaraldehyde is eye irritancy, and this can be adequately addressed through appropriate label warnings.

Schedule 6 - Amendment

GLUTARALDEHYDE – amend entry to read:

GLUTARALDEHYDE **except:**

- (a) when included in Schedule 2 or 5; or
- (b) in preparations containing 0.5 per cent or less of glutaraldehyde when labelled with the statements:

IRRITANT; and

Avoid contact with eyes.

Schedule 5 – Amendment

GLUTARALDEHYDE – amend entry to read:

GLUTARALDEHYDE in preparations containing 5 per cent or less of glutaraldehyde **except:**

- (a) when included in Schedule 2; or
- (b) in preparations containing 0.5 per cent or less of glutaraldehyde when labelled with the statements:

IRRITANT; and

Avoid contact with eyes.

- (b) **Polyethylene glycol (Macrogol 3350)** – consideration of proposal for poisons scheduling when for therapeutic use.

Outcome - The Committee considered a Schedule 3 classification was appropriate for polyethylene glycol when in oral preparations for use for bowel cleansing purposes.

Amendment and reasons

The scheduling decision was based on:

- consistency in scheduling this preparation and sodium phosphate for bowel cleansing; and
- the available data on the toxicity profile of macrogol 3350 in bowel cleansing preparations being comparable to that on sodium phosphate.

Schedule 3 – New entry

MACROGOL 3350 in preparations for oral use for bowel cleansing purposes.

- (c) **Piroxicam** – consideration of a proposal for exemption from scheduling when in dermal preparations.

Outcome - The Committee supported the above proposal.

Amendment and reasons

The scheduling decision was based on the conclusion that:

- the safety profile of gel justifies exemption from scheduling; and
- the indication is appropriate for self-selection without access to professional advice.

Schedule 4 – Amendment

PIROXICAM – amend entry to read:

PIROXICAM **except** in preparations for dermal use.

Schedule 2 – Amendment

PIROXICAM – delete entry

- (d) **Ibuprofen** – consideration of a proposal for amendment of that part of the Schedule 2 entry which relates to liquid preparations to include liquid preparations for oral use with a specified maximum daily dose.

Outcome - The proposal was supported. The following amendment allows for a maximum daily dose of 1200 mg of ibuprofen in liquid preparations of 1200 mg and retains the current restriction

for liquid preparations of a maximum quantity of 4 g of ibuprofen per original pack.

Amendment and reasons

The scheduling decision was based on:

- the safety profile of ibuprofen and that Schedule 2 is appropriate when used in analgesic dose for minor and temporary ailments for short periods; and
- consistency with divided dose formulations.

Schedule 2 – Amendment

IBUPROFEN- amend entry to read:

IBUPROFEN

- (a) in preparations for oral use when labelled with a recommended daily dose of not more than 1200 mg of ibuprofen:
 - (i) in divided preparations in packs of 100 or less dosage units each containing 200 mg or less of ibuprofen; or
 - (ii) in liquid preparations when sold in the manufacturer's original pack each containing 4 grams or less of ibuprofen; or
- (b) in preparations for external use.
- (e) **Diphenoxylate** – consideration of proposals that diphenoxylate when in combination with atropine be included in Schedule 2 or Appendix H (Schedule 3 poisons permitted to be advertised).

Outcome - The Committee supported the proposal that combination preparations containing diphenoxylate and atropine should be permitted to be advertised. It was considered appropriate that the Schedule 3 classification be retained.

Amendment and reasons

The decision to allow advertising was based on:

- Public health benefits associated with advertising of this substance for its approved indications; and
- The need to ensure professional advice at point of sale for safety in use and to warn of dangers with accidental poisoning.

APPENDIX H – New entry

Diphenoxylate

- (f) **Mometasone** – consideration of a proposal that mometasone be included in Appendix H (Schedule 3 poisons permitted to be advertised).

Outcome - The Committee supported the proposal.

Amendment and reasons

The decision to allow advertising was based on:

- consistency with approach for other nasal sprays containing corticosteroids which are in Schedule 3; and
- no reason to differentiate in regard to mometasone.

APPENDIX H – New entry

Mometasone

- (g) **Flurbiprofen** - consideration of a proposal that flurbiprofen be included in Appendix H (Schedule 3 poisons permitted to be advertised).

Outcome - The Committee supported the proposal.

Amendment and reasons

The decision to allow advertising was based on:

- Public health benefits associated with public being more aware a new product is available for the treatment of common condition; and
- Indications appropriate for advertising.

APPENDIX H – New entry

Flurbiprofen

- (h) **Phenolphthalein** – consideration of the scheduling of phenolphthalein for human therapeutic use, including the options of inclusion in Schedule 4 or Appendix C.

Outcome - The Committee supported inclusion of phenolphthalein in Schedule 4.

Amendment and reasons

The scheduling decision below was based on:

- Safety concerns including potential carcinogenicity;
- The availability of safer laxatives; and
- Allowing patient access under medical supervision.

Schedule 4 – New entry

PHENOLPHTHALEIN for human therapeutic use.

- (i) **Codeine** – Consideration of a proposal to amend the Schedule 2 and 3 entries for codeine in relation to dosage restrictions for combination products.

Outcome - The Committee supported amendment of the Schedule 2 and 3 entries for codeine to include preparations containing *a recommended daily dose of 60 mg or less of codeine* rather than limit the schedule entries to preparations containing *a recommended dose of 15 mg or less of codeine*. The amendment also clarified the long-standing view of the Committee that combination analgesic preparations containing codeine should contain not more than one other non-opioid analgesic when available without prescription.

An amendment was made to paragraph 1(3) to clarify that the calculation of codeine content for scheduling purposes is based on anhydrous codeine content.

Amendment and reasons

The scheduling decision below was based on :

- no safety concerns associated with a change to allow a recommended daily dose of 60 mg or less of codeine rather than a recommended dose of 15 mg or less of codeine in Schedule 2 and 3 preparations; and
- a need for consistency in the availability of codeine and all non-opioid analgesic combination preparations.

Schedule 2 - Amendment

CODEINE – amend entry to read:

CODEINE when:

- (a) compounded:
- (i) with a single non-opiate analgesic substance in tablets or capsules each containing 10 mg or less of codeine when:
 - (A) packed in blister or strip packaging or in a container with a child-resistant closure; and
 - (B) in a primary pack containing 25 or less dosage units; or
 - (ii) with a single non-opiate analgesic substance in individually wrapped powders each containing 10 mg or less of codeine when in a primary pack containing 25 or less dosage units; or
 - (iii) with one or more other therapeutically active substances other than an antihistamine:
 - (A) in divided preparations each containing 10 mg or less of codeine; or

- (B) in undivided preparations containing 0.25 per cent or less of codeine; and
- (b) labelled with a recommended daily dose not exceeding 60 mg of codeine.

Schedule 3 – Amendment

CODEINE – amend entry to read:

CODEINE when compounded with a single non-opiate analgesic substance in divided preparations containing 10 mg or less of codeine per dosage unit and with a recommended daily dose not exceeding 60 mg of codeine, **except** when included in Schedule 2.

PART 1, INTERPRETATION – Amendment

Paragraph 1, sub-paragraph (3) – amend entry to read:

- (3) Unless the contrary intention appears where a concentration, strength or quantity is specified in a schedule or an appendix to this Standard in respect of a substance:
 - (a) if the substance is present as a salt, active principle or derivative (including an ester or ether), the concentration, strength or quantity is calculated as the equivalent amount of the substance that is listed in the schedule or appendix; and
 - (b) the expression “one per cent” means:
 - (i) in the case of a liquid preparation, 1 gram of the substance per 100 millilitres of the preparation; or
 - (ii) in the case of a solid or semi-solid preparation, 1 gram of the substance per 100 grams of the preparation; and
 - (iii) any expression of greater or lesser percentages has a corresponding meaning; and
 - (c) in the case of codeine such concentration strength or quantity is calculated as anhydrous codeine.

- (1) **Trans-4-[(3,5-dibromo-2-hydroxybenzyl)-amino]cyclohexanol hydrochloride monohydrate (sputolysin)** – consideration of a proposal for re-scheduling oral preparations for the treatment of animals from Schedule 6 to Schedule 5.

Outcome - The Committee supported rescheduling to Schedule 5 of oral preparations for veterinary use containing trans-4-[(3,5-dibromo-2-hydroxybenzyl)-amino]cyclohexanol

hydrochloride monohydrate (Sputolysin)

Amendment and reasons

The scheduling decision was based on the low toxicological hazard associated with the substance when formulated as an oral preparation for the treatment of animals.

Schedule 4 - Amendment

TRANS-4-[(3,5-DIBROMO-2-HYDROXYBENZYL)-AMINO]CYCLOHEXANOL
HYDROCHLORIDE MONOHYDRATE (Sputolysin) – amend entry to read:

TRANS-4-[(3,5-DIBROMO-2-HYDROXYBENZYL)-AMINO]CYCLOHEXANOL
HYDROCHLORIDE MONOHYDRATE (Sputolysin) **except** when included in Schedule 5.

Schedule 6 – Amendment

TRANS-4-[(3,5-DIBROMO-2-HYDROXYBENZYL)-AMINO]CYCLOHEXANOL
HYDROCHLORIDE MONOHYDRATE (Sputolysin) – delete entry.

Schedule 5 – New entry

TRANS-4-[(3,5-DIBROMO-2-HYDROXYBENZYL)-AMINO]CYCLOHEXANOL
HYDROCHLORIDE MONOHYDRATE (Sputolysin) in oral preparations for the treatment
of animals.

**2. MATTERS REFERRED BY THE AUSTRALIAN DRUG EVALUATION
COMMITTEE**

(a) **Aldesleukin** - New drug – Schedule required.

Outcome - The above drug was allocated a Schedule 4 classification.

Amendment and reasons

The scheduling decision was based on:

- aldesleukin being a new therapeutic substance and its use requires medical management.

Schedule 4 – New entry

ALDESLEUKIN.

(b) **Azelastine** - New drug – Schedule required.

Outcome - The above drug was allocated a Schedule 4 classification. In addition a Schedule 2 entry was made for azelastine when in preparations for nasal use.

Amendment and reasons

The scheduling decision was based on:

- Schedule 2 being appropriate for topical azelastine preparations; and
- On the grounds of harmonisation.

Schedule 4 – New entry

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

Schedule 2 – New entry

AZELASTINE in preparations for nasal use.

(c) **Fomivirsen** - New drug – Schedule required.

Outcome - The above drug was allocated a Schedule 4 classification.

Amendment and reasons

The scheduling decision was based on fomivirsen being a new therapeutic substance, the use of which requires medical management.

Schedule 4 – New entry

FOMIVIRSEN.

(d) **Fosphenytoin** - New drug – Schedule required.

Outcome - The above drug was allocated a Schedule 4 classification.

Amendment and reasons

The scheduling decision was based on fosphenytoin sodium being a new chemical substance, the use of which requires medical management.

Schedule 4 – New entry

FOSPHENYTOIN SODIUM.

(e) **Lepirudin** - New drug – Schedule required.

Outcome - The above drug was allocated a Schedule 4 classification.

Amendment and reasons

The scheduling decision was based on lepirudin being a new chemical substance the use of which requires medical management.

Schedule 4 – New entry

LEPIRUDIN.

- (f) **Rosiglitazone** - New drug – Schedule required.

Outcome - The above drug was allocated a Schedule 4 classification.

Amendment and reasons

The scheduling decision was based on rosiglitazone being a new chemical substance, the use of which requires medical management.

Schedule 4 – New entry

ROSIGLITAZONE.

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

- (a) **Dodine** – consideration of more restrictive scheduling.

Outcome - The Committee supported the rescheduling of dodine to Schedule 6.

Amendment and reasons

The scheduling decision was based on the toxicological profile of dodine, which was found to be consistent with the criteria for Schedule 6 classification - in particular the acute oral and inhalational toxicity and severe eye and skin irritancy.

Schedule 5 - Amendment

DODINE – delete entry

Schedule 6 – New entry

DODINE.

- (b) **Indoxacarb** – new chemical – consideration of poisons scheduling.

Outcome - The Committee supported a Schedule 6 entry for indoxacarb.

Amendment and reasons

The scheduling decision was based primarily on the acute oral toxicity profile of indoxacarb and the referred product being consistent with Schedule 6 criteria, and the findings of moderate eye irritancy and strong skin sensitisation potential.

Schedule 6 – New entry

INDOXACARB.

(c) **Quizalofop-p-ethyl** – review of poisons scheduling.

Outcome - The NDPSC supported the rescheduling from Schedule 6 to Schedule 5 of aqueous preparations containing 40% or less of quizalofop-p-ethyl.

Amendment and reasons

The scheduling decision was based on the finding that the acute toxicological profile of aqueous formulations of quizalofop-p-ethyl in concentration up to 40% is consistent with a Schedule 5 classification, while Schedule 6 remains appropriate for higher concentrations and other formulations.

Schedule 6 - Amendment

QUIZALOFOP ETHYL (D+ ISOMER) – amend entry to read:

QUIZALOFOP-P-ETHYL **except** when included in Schedule 5.

Schedule 5 – New entry

QUIZALOFOP-P-ETHYL in aqueous preparations containing 40 per cent or less of quizalofop-p-ethyl.

(d) **Nimesulide** – new veterinary active – consideration of poisons scheduling.

Outcome - The Committee supported a Schedule 4 entry for nimesulide.

Amendment and reasons

The scheduling decision was based on the toxicological profile of nimesulide and the need for veterinarian advice to ensure accurate diagnosis before, and appropriate management of, the use of this drug in dogs.

Schedule 4 – New entry

NIMESULIDE.

4. OTHER MATTERS FOR CONSIDERATION

(a) **ortho-Phthalaldehyde** – new chemical – consideration of poisons scheduling.

Outcome - The Committee supported a Schedule 6 classification for ortho-phthalaldehyde with a cut-off to Schedule 5 at 1 percent. The Committee considered it appropriate that preparations carry first aid instructions, and warning statements and safety directions.

Amendment and reasons

The scheduling decision was based on the toxicological profile of ortho-phthalaldehyde being consistent with the criteria for classification as Schedule 6. A Schedule 5 classification was considered necessary for concentrations below 1% because of eye irritancy even in low concentrations and demonstrated skin and respiratory sensitisation.

Schedule 6 – New entry

ORTHO-PHTHALALDEHYDE **except** when included in Schedule 5.

Schedule 5 – New entry

ORTHO-PHTHALALDEHYDE in preparations containing 1 per cent or less of ortho-phthalaldehyde.

APPENDIX E, Part 2 – New entry

ortho-Phthalaldehyde

- when included in Schedule 6 a,c,f,s
- when included in Schedule 5 a,s

APPENDIX F, Part 3 – New entry

ortho-Phthalaldehyde

- when included in Schedule 6
 - Warning statements 51, 59, 52
 - Safety directions 2, 4, 5, 8, 10
- when included in Schedule 5
 - Warning statements 51, 59, 52

Safety directions 1, 4, 5, 8, 10

- (b) **ortho-Dichlorobenzene** – review of first aid instructions.

Outcome - The Committee considered preparations containing o-dichlorobenzene should carry the first aid instructions detailed below.

Amendment and reasons

The decision to amend first aid instructions was taken to reflect current clinical practice with regard to gastric decontamination for ortho-dichlorobenzene.

APPENDIX E, Part 2 – Amendment

o-Dichlorobenzene – amend entry to read:

o-Dichlorobenzene a,c,e,f,s

- (c) **Copper oxide** – consideration of poisons scheduling of agricultural fungicides containing copper oxide.

Outcome - The Committee considered copper oxides should be included in Schedule 6 with a cut-off to Schedule 5 at 25 per cent, and exemption from scheduling when in preparations for internal use, marine paints or in other preparations at 5 per cent or less.

Amendment and reasons

The scheduling decision was based on the acute toxicological profile of copper oxide, in particular its oral toxicity and corrosive and irritant properties; exemption for internal use preparations was based on appropriate controls on doses being exercised through registration systems; exemption for marine paints based on the industrial nature of their use.

Schedule 6 – New entry

COPPER OXIDES except:

- (a) when included in Schedule 5;
- (b) in preparations for internal use;
- (c) in marine paints; or
- (d) in other preparations containing 5 per cent or less of copper oxides.

Schedule 5 – New entry

COPPER OXIDES in preparations containing 25 per cent or less of copper oxides **except**:

- (a) in preparations for internal use;
 - (b) in marine paints; or
 - (c) in other preparations containing 5 per cent or less of copper oxides.
- (d) Consideration of extension of **labelling requirements of paragraph 10 of SUSDP 15** (currently paragraph 8 & 9 of SUSDP 14) to apply to containers having a nominal capacity of 5 mL or less.

Outcome - The Committee supported the proposal and agreed the labelling requirements of paragraph 10 should apply to containers having a nominal capacity of 10 mL or less.

Amendment and reasons

The decision for exemption from certain labelling requirements was based on the practical difficulties of labelling small capacity injection vials with signal headings and the requirement for such selected containers to be packaged in primary packs which are labelled accordingly.

SUSDP, PART 2, LABELS AND CONTAINERS – Amendment

Paragraph 10 – amend lead before sub-paragraph 10 (1) to read:

- 10.** The requirements of paragraph 7 do not apply to a selected container, or an ampoule (other than an ampoule to which paragraph 11 applies) when:

- (e) Minor correction to entry in SUSDP for **benzoylmetronidazole**.

Outcome - The following amendment reflects the Australian Approved Name and the International Non-Proprietary Name for the substance.

Amendment and reasons

The amendment to the Schedule entry was made in order to reflect the Australian Approved Name and the International Non-Proprietary Name for the substance.

Schedule 4 – Amendment

BENZOYLMETRONIDAZOLE – amend entry to read:

METRONIDAZOLE BENZOATE (benzoyl metronidazole).

5. PROPOSALS ARISING FROM TRANS-TASMAN WORKING PARTY ON

THE HARMONISATION OF THE SCHEDULING OF DRUGS AND POISONS.

- (a) Consider deletion of the Appendix C entries for the certain substances, while ensuring that consequential amendments are made either to related entries or through new entries, to retain the controls of Appendix C.

Outcome - The NDPSC supported the following amendments to the SUSDP to achieve this outcome.

Amendment and reasons

The following scheduling decisions were based on the grounds of harmonisation and simplification, and that there would be no changed to the current level of control for the substances.

APPENDIX C – New entry

CINCHOPHEN and its derivatives for therapeutic use.

APPENDIX C – Amendments

CYNOGLOSSUM OFFICINALE – delete entry

CYNOGLOSSUM spp. – amend entry to read:
CYNOGLOSSUM spp. for therapeutic use.

HELIOTROPIUM RAMOSISSIMUM – delete entry

HELIOTROPIUM spp. – amend entry to read:
HELIOTROPIUM spp. for therapeutic use.

HELIOTROPIUM SUPINUM – delete entry

METHYLCINCHOPHEN – delete entry

PETASITES JAPONICUM – delete entry

PETASITES spp. – amend entry to read:
PETASITES spp. for therapeutic use.

PTERIDIUM AQUILINUM – delete entry

PTERIDIUM spp. – amend entry to read:
PTERIDIUM spp. for therapeutic use.

SENECIO CANNABIFOLIUS – delete entry

SENECIO JACOBAEA – delete entry

SENECIO LONGILOBUS – delete entry

SENECIO NUMORENSIS FUSCHII – delete entry

SENECIO spp. – amend entry to read:

SENECIO spp. for therapeutic use.

- (b) Consider a minor amendment to Appendix C entries for the **aminophenazone** to harmonise wording for entries in NZ and Australia.

Outcome - The NDPSC supported the following amendment to achieve this outcome.

Amendment and reasons

The following decision was based on the grounds of harmonisation.

APPENDIX C – Amendment

AMINOPHENAZONE – amend entry to read:

AMINOPHENAZONE (amidopyrine) and its derivatives for human therapeutic use.

- (c) Consider the scheduling of the anthelmintics: **piperazine**, for both human therapeutic and animal use; and **bephenium, dichlorophen, tetrachloroethylene** and **thiabendazole** for human therapeutic use. Consideration of the scheduling of piperazine for animal use arose from toxicity concerns identified by the Working Party, and is not directly related to harmonisation of scheduling.

Outcome - The Committee considered the anthelmintics piperazine, bephenium (as the salts), dichlorophen, tetrachloroethylene and thiabendazole when for human therapeutic use should be included in Schedule 2. It considered piperazine for animal use should be classified Schedule 5. Several consequential amendments to the related entries in the SUSDP were required.

Amendment and reasons

The scheduling decision on piperazine was based on the public health and safety associated with human and veterinary use.

The remaining scheduling decisions were based on the grounds public health and safety.

Schedule 2 – New entries

BEPHENIUM SALTS.

DICHLOROPHEN for internal human therapeutic use.

PIPERAZINE for human therapeutic use.

TETRACHLOROETHYLENE for human therapeutic use.

THIABENDAZOLE for human therapeutic use.

Schedule 5 – New entry

PIPERAZINE for animal use.

Schedule 5 – Amendment

TETRACHLOROETHYLENE – amend entry to read:

TETRACHLOROETHYLENE in preparations containing 5 per cent or less tetrachloroethylene **except**:

- (a) when included in Schedule 2;
- (b) in preparations for the treatment of animals; or
- (c) when absorbed into an inert solid.

Schedule 6 – Amendments

DICHLOROPHEN – amend entry to read:

DICHLOROPHEN **except**:

- (a) when included in Schedule 2 or 5; or
- (b) in fabrics other than when:
 - (i) for human therapeutic use; or
 - (ii) as part of a registered pesticidal product.

TETRACHLOROETHYLENE – amend entry to read:

TETRACHLOROETHYLENE **except**:

- (a) when included in Schedule 2 or 5;
- (b) in preparations containing 6 per cent or less of tetrachloroethylene when absorbed into an inert solid; or

- (c) in preparations for the treatment of animals.

Appendix F, Part 3 – Amendment

Tetrachloroethylene – amend entry to read:

Tetrachloroethylene when in Schedule 5 or 6

Warning statements	12,16
Safety directions	1,4,8,11

- (d) Consider the scheduling of the following substances on the grounds of harmonisation: **indanazoline and tuaminoheptane; chlophedianol; methylene blue; felbinac and etofenamate; diamthazole and sulconazole; deoxyribonuclease; and nicofuranose.**

Outcome - The Committee supported the following amendments to the SUSDP on the grounds of harmonisation.

Amendment and reasons

The following scheduling decisions were based on the grounds of harmonisation.

Schedule 2 – New entries

CHLOPHEDIANOL.

ETOFENAMATE in preparations for external use.

FELBINAC in preparations for external use.

INDANAZOLINE.

SULCONAZOLE in preparations for dermal use.

TUAMINOHEPTANE.

Schedule 4 – New entries

DEOXYRIBONUCLEASE **except:**

- (a) when separately specified in this schedule; or
- (b) for external use.

DIAMTHAZOLE.

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

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

METHYLENE BLUE in preparations for injection.

NICOFURANOSE.

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

- (e) Consider a Schedule 2 entry for **oral vaccines**, other than when specified in Schedule 4.

Outcome - The Committee supported a specific entry in Schedule 4 for cholera vaccine, which is currently covered under the generic Schedule 4 entry for vaccines. The matter of a Schedule 2 entry for oral vaccines was referred back to the Working Party.

Amendment and reasons

The decision to make a separate entry was made for the purposes of clarification, recognising that there is no scheduling amendment.

Schedule 4 – New entry

CHOLERA VACCINE.

- (f) Consider a Schedule 2 entry for **squill** **except** when in preparations containing 1 per cent or less of squill.

Outcome - The Committee supported the proposal.

Amendment and reasons

The scheduling decision below was made on the basis of:

- Harmonisation and public health concerns associated with high doses.

Schedule 2 – New entry

SQUILL **except** in preparations containing 1 per cent or less of squill.

- (g) Consider amendment to the Schedule 2 entry for **creosote** to allow a cut-off to exempt at 10 per cent or less of creosote.

Outcome - The Committee supported the proposal.

Amendment and reasons

The scheduling decision was made on the basis of harmonisation.

Schedule 2 – Amendment

CREOSOTE – amend entry to read:

CREOSOTE for human therapeutic use **except** in preparations containing 10 per cent or less of creosote.

- (h) Consider the scheduling of **paraformaldehyde** and **formaldehyde** in preparations for human therapeutic use.

Outcome - The Committee supported the inclusion of paraformaldehyde and formaldehyde in Schedule 2 when in preparations for human therapeutic use containing more than 5% of formaldehyde.

Amendment and reasons

The scheduling decision was based on the grounds of harmonisation.

Schedule 2 – New entries

FORMALDEHYDE (excluding its derivatives) for human therapeutic use **except** in preparations containing 5 per cent or less of formaldehyde.

PARAFORMALDEHYDE (excluding its derivatives) for human therapeutic use **except** in preparations containing 5 per cent or less of formaldehyde.

Schedule 6 – Amendments

FORMALDEHYDE – amend entry to read:

FORMALDEHYDE (excluding its derivatives) **except**:

- (a) when included in Schedule 2; or
- (b) in preparations containing 5 per cent or less of formaldehyde.

PARAFORMALDEHYDE – amend entry to read:

PARAFORMALDEHYDE (excluding its derivatives) **except**:

- (a) when included in Schedule 2; or

- (b) in preparations containing 5 per cent or less of formaldehyde.
- (i) Consider inclusion of **zinc chloride** in Schedule 2 when in preparations for dermal use with a cut-off to exemption at 5%.

Outcome - The Committee supported the proposal.

Amendment and reasons

The scheduling decision was based on the grounds of harmonisation.

Schedule 2 – New entry

ZINC CHLORIDE for human dermal use **except** in preparations containing 5 per cent or less of zinc chloride.

Schedule 6 – Amendment

ZINC CHLORIDE – amend entry to read:

ZINC CHLORIDE **except**:

- (a) when included in Schedule 2; or
- (b) in preparations containing 5 per cent or less of zinc chloride.

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

- (a) **Melaleuca oil** – clarification of species of melaleuca to which melaleuca oil Schedule entry applies.

Outcome – The Committee agreed that the melaleuca oil entry applies to tea-tree oil and does not apply to other oils obtained from melaleuca species.

Amendment and reasons

The amendment to the Schedule entry was made to rectify the unintentional omission of the words ‘tea tree oil’ and to indicate that it was not the Committee’s intention that all oils derived from *Melaleuca* species be scheduled through this entry.

Schedule 6 – Amendment

MELALEUCA OIL – amend entry to read:

MELALEUCA OIL (TEA-TREE OIL) **except**:

- (a) when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert, and labelled with the warnings:
 “KEEP OUT OF REACH OF CHILDREN”; and
 “NOT TO BE TAKEN”;
- (b) when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and child-resistant closure, and labelled with the warnings:
 “KEEP OUT OF REACH OF CHILDREN”; and
 “NOT TO BE TAKEN”; or
- (c) in preparations containing 25 per cent or less of melaleuca oil.

- (b) **Rosemary oil / cineole** – consideration of exemption of rosemary oil from the provisions of the cineole Schedule entry.

Outcome – The Committee agreed that rosemary oil should be specifically exempted from the provisions of the Schedule 6 cineole entry.

Amendment and reasons

The amendment to the cineole Schedule entry was made to clarify the Committee’s intention that rosemary oil, which can contain up to 55% cineole, not be considered as being scheduled by virtue of its cineole content.

Schedule 6 – Amendment

CINEOLE – amend entry to read:

CINEOLE **except**:

- (a) when packed in containers having a nominal capacity of 15 mL or less fitted with a restricted flow insert, and labelled with the warnings:
 “KEEP OUT OF REACH OF CHILDREN”; and
 “NOT TO BE TAKEN”;
- (b) when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and child-resistant closure, and labelled with the warnings:
 “KEEP OUT OF REACH OF CHILDREN”; and

“NOT TO BE TAKEN”;

- (c) in preparations containing 25 per cent or less of cineole;
- (d) in oils containing 25 per cent or less of cineole; or
- (e) in rosemary oil.

7. NEW SCHEDULING DECISIONS ARISING FROM FURTHER PUBLIC SUBMISSIONS RECEIVED IN RESPONSE TO THE POST-FEBRUARY 2000 GAZETTE NOTICE AND CONSIDERED AT THE MAY 2000 MEETING.

(a) Anise oil

Outcome – The Committee agreed to increase the nominal capacity of containers of anise oil eligible for exemption from scheduling from 25 mL (as indicated in the post-February 2000 Gazette Notice) to 50 mL. Other conditions of exemption from scheduling remain as given previously. The requirement for child-resistant closures will be introduced with the same effective date as the Schedule 5 entry.

Amendment and reasons

The decision below is a variation to the decision taken at the February 2000 meeting, agreed by the NDPSC following consideration of public submissions. That the exemption level is now set at 50 mL rather than 25 mL reflects the information received that 50 mL is a common pack size for flavourings.

Schedule 5 – New entry

ANISE OIL except:

- (a) when packed in containers having a nominal capacity of 50 mL or less fitted with a restricted flow insert, and labelled with the warning:

“KEEP OUT OF REACH OF CHILDREN”; or
- (b) in preparations containing 50 per cent or less of anise oil.

PART 2 –LABELS AND CONTAINERS – CONTAINERS – New entry

Child-resistant Closures – Paragraph 25

Amend Table by adding:

Anise oil when included in Schedule 5	200 millilitres or less
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PART B – OTHER OUTCOMES

Outcome of: (i) proposals in relation to other substances mentioned in the Gazette of 5 April 2000 as being considered for scheduling at the May 2000 meeting; and (ii) other general matters considered by the Committee.

Proposals in relation to other substances mentioned in the Gazette of 5 April 2000 as being considered for scheduling at the May 2000 meeting

- (a) **Diphenhydramine** – consideration of a proposal that diphenhydramine when combined with paracetamol be included in Appendix H (Schedule 3 poisons permitted to be advertised).

Outcome – The Committee did not support the proposal. It considered that advertising to the consumer of diphenhydramine for sedative effect when associated with pain is not appropriate.

- (b) **Pseudoephedrine** – consideration of the scheduling of pseudoephedrine in preparations, when it is the only active ingredient, and in pack sizes of 30 dosage units or less.

Outcome – The Committee did not support the rescheduling of pseudoephedrine in preparations when it is the only active ingredient, in pack sizes of 30 dosage units or less and the preparation is not a sustained release preparation. The amendment proposed at the February 2000 meeting was amended as detailed below to reflect this view retaining that part of the amendment relevant to the rescheduling of pack sizes of more than 30 dosage units. The amendment is not subject to further public comment

Schedule 4 - Amendment

PSEUDOEPHEDRINE – amend entry to read:

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

Schedule 2 – Amendment

PSEUDOEPHEDRINE – amend entry to read:

PSEUDOEPHEDRINE in preparations (other than preparations for stimulant, appetite suppression or weight-control purposes), with a recommended daily dose of 240 mg or less of pseudoephedrine:

- (a) in undivided preparations containing 60 mg or less of pseudoephedrine per recommended dose;
- (b) when the only therapeutically active substances in divided preparations containing 60

mg or less of pseudoephedrine per recommended dose in a pack containing 30 or less dosage units;

(c) when compounded with other therapeutically active substances; or

(d) in slow release preparations.

(c) **Danthron** – consideration of the rescheduling of danthron for human therapeutic use from Schedule 4 to Appendix C.

Outcome – The Committee did not support the proposal.

(d) **Butafenacil-allyl** – new chemical – consideration of poisons scheduling.

Outcome – On the basis of the low acute toxicological hazard of the compound, the NDPSC agreed that butafenacil-allyl should be exempt from poisons scheduling.

(e) **Copper oxine** – consideration of poisons scheduling.

Outcome – On the basis of the limited (industrial) use proposed for copper oxine at the present time, and the ability to adequately address skin and eye irritancy through label statements applied during product registration, the NDPSC agreed that copper oxine need not be scheduled at this time.

(f) **Azafenidin** – new chemical – consideration of poisons scheduling.

Outcome - The consideration of azafenidin was deferred, pending evaluation of additional data.

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

Outcome – On the basis of the low acute toxicological hazard of picolinafen, the NDPSC agreed that picolinafen should be exempt from poisons scheduling.

(h) **Methiocarb** – consideration of more restrictive scheduling.

Outcome – On the basis of the Existing Chemicals Review Program review of toxicological data for methiocarb, which indicated that the acute oral and inhalational toxicity of methiocarb meet Schedule 7 criteria, the Committee proposed that methiocarb be rescheduled from Schedule 6 to Schedule 7. The proposal that preparations containing 20 per cent or less should remain in Schedule 6, and pelleted preparations remain in Schedule 5 was based on extrapolation of acute

oral toxicity findings and data held on various product formulations. Comments will be sought on this proposal in the August pre-meeting gazette notice.

- (i) **Glycolic acid** – consideration of poisons scheduling.

Outcome – On the basis of the toxicological profile of glycolic acid, in particular its corrosivity or irritation potential when applied to the skin or inadvertent contact with the eyes occurs, the NDPSC proposed the inclusion of glycolic acid in cosmetic preparations in Schedule 6 of the SUSDP, with exemption from scheduling for preparations containing 20 per cent or less of glycolic acid and a pH of 3.5 or greater. The NDPSC will investigate exemptions for other preparations labelled in accordance with NOHSC requirements for the labelling of workplace hazardous substances; and preparations containing low concentrations of glycolic acid irrespective of pH. Comments will be sought on the proposal in the August pre-meeting gazette notice.

- (j) **Chlorinating compounds** – further consideration of the foreshadowed decisions arising from the omnibus review of chlorinating compounds.

Outcome - Consideration deferred to August 2000 meeting, pending further consultation.

- (k) **Proposals arising from Trans-Tasman Working Party on Harmonisation of Scheduling of Drugs and Poisons.**

Outcomes

Carboxymethylcysteine – deferred until the August 2000 meeting.

Mannityl hexanitrate – deferred until the August 2000 meeting

Loperamide – deferred until the August 2000 meeting.

Fluorides – referred back to the Working Party

Local anaesthetics – referred back to the Working Party

- (l) **Matters arising from The Essential Oils Working Party and Subsequent Deliberations**

Outcomes

Marjoram oil – deferred until the August 2000 meeting.

Oregano and savory oils – the Committee agreed that in view of the low usage of these oils,

scheduling was not warranted at this time.

Orange oil (bitter) - deferred until the August 2000 meeting.

Other **citrus oils (bergamot, lemon, lime and sweet orange)** - deferred until the August 2000 meeting.

Camphor oil (Shui) - deferred until the August 2000 meeting.

Camphor oil (white) / cineole - deferred until the August 2000 meeting.

Essential oils containing camphor not otherwise exempted from scheduling – consideration of requirements for child-resistant closures - deferred until the August 2000 meeting .

Definition of essential oils - deferred until the August 2000 meeting.

Other general matters considered by the Committee.

(a) Advertising submissions

The Committee supported a proposal that:

When consideration of a rescheduling proposal results in a substance being included in Schedule 3 the Committee will, at that time, consider whether inclusion in Appendix H is appropriate.

The Committee considered that, irrespective of whether a substance is included in Schedule 3 as a result of a specific submission requesting such scheduling, or as the result of rejection of an application for listing in Schedule 2, the information available to the Committee (company submission, public comments etc) would probably be sufficient for the Committee to also make a decision relating to listing in Appendix H.

The Committee directed this policy should be disseminated as widely as possible to allow the matter to be addressed by applicants, if they so wish, when making a scheduling submission to the NDPSC where a Schedule 3 classification may be an outcome. Also, to allow those parties providing comment in regard to scheduling proposals to address advertising issues if they so wish, knowing that this may be an outcome if a Schedule 3 classification is applied.

(b) First Aid Instructions Working Party Final Report and Recommendations for Amendment to the Appendix E First Aid Instruction Requirements

The Committee gave preliminary consideration to the Final Report of the First Aid Instructions Working Party, which makes a number of recommendations for change to the first aid instructions contained in Appendix E of the SUSDP. All recommendations in the Report were accepted in

principle.

As implementation of the recommended amendments would be complex and impact widely, the Committee wishes to undertake extensive consultation in order for the recommendations to be reviewed in relation to:

- Overall regulatory impact;
- The application of the revised requirements to specific substances and products;
- Possible implementation strategies for progressing changes to Appendix E and the consequential label changes; and
- Necessary implementation timeframes.

The NDPSC is considering a staged approach for the implementation of the changes to Appendix E, with the highest priority being accorded to removal of all instructions relating to induction of vomiting. The Committee is therefore seeking comment on mechanisms by which that action could be implemented with urgency.

The Final Report of the Working Party and a Proposal for Staged Implementation can be accessed through: <http://www.health.gov.au/tga/docs/html/ndpsc/ndpsc.htm> . Public submissions are invited on the recommendations of the Final Report and the Proposals for Staged Implementation of the Appendix E changes. These submissions will be considered by the NDPSC at its 28th Meeting to be held on 15-17 August 2000.