

NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

PRE-FEBRUARY 2004 SCHEDULING MEETING NOTICE

Notice under Regulations 42ZCU of the *Therapeutic Goods Regulations 1990*

The Chair of the National Drugs and Poisons Schedule Committee (NDPSC) hereby gives notice that the next scheduling meeting of the NDPSC will be held on 24-26 February 2004. Substances to be considered for scheduling by the NDPSC are open for public comment.

Accordingly, public submissions are invited on those substances mentioned below which are to be considered for scheduling at the February 2004 meeting. Public submissions must address a matter mentioned in section 52E of the Therapeutic Goods Act 1989 and received by the closing date. Public submissions must also include the name of the person making the submission and a contact address. Persons making a submission in regard to a substance where a Schedule 3 classification may be an outcome are invited to provide additional comment on inclusion of that substance in Appendix H - Schedule 3 Poisons Permitted to be Advertised. Inclusion in Appendix H may be a consequential consideration of the Committee following a decision to include a substance in Schedule 3.

Public submissions should be made to:

The Secretary
National Drugs and Poisons Schedule Committee
PO Box 100
WODEN ACT 2606
Facsimile 02-6270 4353

The closing date for submissions is **4 February 2004**.

The NDPSC, in making a decision in relation to the classification and scheduling of a substance, must consider all public submissions made by the closing date that address a matter mentioned in section 52E of the Act. Public submissions that reserve the right to comment on a scheduling proposal or are made after the closing date need not be considered by the NDPSC.

The post-February 2004 meeting notice will invite further public submissions on substances that are the subject of an amendment to the Schedules at the February 2004 meeting. However, the invitation will be restricted to those who make a valid public submission in relation to the substance in response to this pre-meeting notice.

Further information may be obtained from the NDPSC Secretariat on 02-6270 4400 during business hours or by e-mailing NDPSC@health.gov.au. To promote timely communications with stakeholders, the NDPSC has an e-mail subscription list. Subscribers will be notified by e-mail of new information on the NDPSC website including pre- and post-meeting gazette notices, Record of the Reasons, advice on the publication of the SUSDP and other information relating to NDPSC operations. For further information follow the "Subscribe by email:" link at: <http://www.tga.gov.au/ndpsc/>

SUBSTANCES TO BE CONSIDERED FOR SCHEDULING

1. FORESHADOWED DECISIONS FROM PREVIOUS MEETING(S) (See October 2004 Record of the Reasons for further information)

1.1 FLUORIDES – consideration of the following foreshadowed amendments.

Schedule 2 - Amendment

FLUORIDES for human therapeutic use (**except** in preparations containing 15 mg/kg or 15 mg/L or less of fluoride ion):

- (a) as sodium fluoride, in preparations for ingestion containing 2.2 mg or less of sodium fluoride per dosage unit; or
- (b) in preparations for topical use containing 2.5 per cent or less of fluoride ion **except**:
 - (i) pastes, powders or gels for the cleaning of teeth included in Schedule 3;
 - (ii) pastes, powders or gels for the cleaning of teeth containing 1000 mg/kg or less of fluoride ion; or
 - (iii) other dental hygiene products containing 100 mg/kg or 100 mg/L or less of fluoride ion.

Schedule 3 - Amendment

FLUORIDES in pastes, powders or gels for the cleaning of teeth containing more than 100 mg/kg of fluoride ion.

Schedule 4 - Amendment

FLUORIDES in preparations for human therapeutic use **except**:

- (a) when included in Schedule 2 or 3;
- (b) pastes, powders or gels for the cleaning of teeth containing 1000 mg/kg or less of fluoride ion;
- (c) other dental hygiene products containing 100 mg/kg or 100 mg/L or less of fluoride ion; or
- (d) in other substances containing 15 mg/kg or 15 mg/L or less of fluoride ion.

Schedule 5

FLUORIDES in preparations containing 3 per cent or less of fluoride ion **except**:

- (a) when included in Schedule 2, 3 or 4;
- (b) in pastes, powders or gels for the cleaning of teeth containing 1000 mg/kg or less of fluoride ion; or
- (c) in preparations containing 15 mg/kg or less of fluoride ion.

Schedule 6

FLUORIDES except:

- (a) when included in Schedule 2, 3, 4 or 5; or
- (b) when separately specified in this Schedule; or
- (c) in pastes, powders or gels for the cleaning of teeth containing 1000 mg/kg or less of fluoride ion; or
- (d) in preparations containing 15 mg/kg or less of fluoride ion.

1.2 PROMETHAZINE – consideration of the following foreshadowed amendment.

Schedule 2 - Amendment

PROMETHAZINE – amend entry to read:

PROMETHAZINE:

- (a) in preparations for the prevention or treatment of motion sickness not labelled for the treatment of children under two years of age **except** in primary packs containing 12 or less such tablets or capsules; or
- (b) in combination preparations for oral use when:
 - (i) compounded with a decongestant; or
 - (ii) in a pack containing promethazine in a night time dose; and
 - (iii) not labelled for the treatment of children under two years of age.

1.3 DIMENHYDRINATE – consideration of the following foreshadowed amendment.

Schedule 2 - Amendment

DIMENHYDRINATE:

- (b) in preparations for the prevention or treatment of motion sickness not labelled for the treatment of children under two years of age **except** in primary packs containing 12 or less such tablets or capsules; or
 - (b) in combination preparations for oral use when:
 - (i) compounded with a decongestant; or
 - (ii) in a pack containing dimenhydrinate in a night time dose; and
 - (iii) not labelled for the treatment of children under two years of age.
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1.4 METHYLCYCLOPENTADIENYL MANGANESE TRICARBONYL – consideration of the following foreshadowed amendments.

Schedule 7 – New Entry

METHYLCYCLOPENTADIENYL MANGANESE TRICARBONYL **except** when included in Schedule 6.

Schedule 6 – New Entry

METHYLCYCLOPENTADIENYL MANGANESE TRICARBONYL in fuel additive preparations containing 10 per cent or less of methylecyclopentadienyl manganese tricarbonyl when fitted with a child-resistant closure.

1.5 MITRAGYNA SPECIOSA – consideration of the following foreshadowed amendment.

Schedule 9 – New entry

MITRAGYNA SPECIOSA.

1.6 HYOSCYAMUS NIGER – consideration of the following foreshadowed amendments.

Schedule 2 – Amendment

HYOSCYAMUS NIGER for oral use:

- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (b) in divided preparations containing 0.03 mg of total solanaceous alkaloids or less per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids,

except in a pack containing 30 micrograms or less of total solanaceous alkaloids.

Schedule 4

HYOSCYAMUS NIGER **except**:

- (a) when included in Schedule 2; or
- (b) in a pack containing 30 micrograms or less of total solanaceous alkaloids.

1.7 PANCREATIC ENZYMES – consideration of the following foreshadowed amendment.

Schedule 4 - Amendment

PANCREATIC ENZYMES.

1.8 Sedating antihistamines– consideration of the following foreshadowed amendments.

Schedule 2 - Amendments

(sedating antihistamines for oral use - brompheniramine, chlorpheniramine, dexchlorpheniramine, diphenhydramine, diphenylpyraline, doxylamine, trimeprazine and triprolidine):

[SUBSTANCE] when combined with one or more other therapeutically active substances in preparations for oral use when:

- (i) compounded with a decongestant; or
- (ii) in a primary pack containing night-time doses of [substance],

except in preparations for the treatment of children under two years of age.

(sedating antihistamines with indications other than for oral use):

PHENIRAMINE – amend entry to read:

PHENIRAMINE:

- (a) in eye drops; or
- (b) when combined with one or more other therapeutically active substances in preparations for oral use when:
 - (i) compounded with a decongestant; or
 - (ii) in a primary pack containing night time doses of pheniramine,

except in preparations for the treatment of children under two years of age.

THENYLDIAMINE – amend entry to read:

THENYLDIAMINE:

- (a) in nasal preparations for topical use; or
- (b) when combined with one or more other therapeutically active substances in preparations for oral use when:
 - (i) compounded with a decongestant; or
 - (ii) in a primary pack containing night time doses of thenyldiamine,

except in preparations for the treatment of children under two years of age.

1.9 CODEINE – consideration of the following foreshadowed amendment.

Schedule 2 – Amendment

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:
 - (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.
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1.10 3,4-METHYLENEDIOXY-N, α -DIMETHYLPHENYLETHYLAMINE (MDMA) – consideration of the following foreshadowed amendment.

Schedule 9 – Amendment

(+/-)-N, α -DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE *(MDMA).

2. SUBSTANCES REFERRED BY THE NATIONAL REGISTRATION AUTHORITY FOR AGRICULTURAL AND VETERINARY CHEMICALS

- 2.1 Ethoxysulfuron – consideration of scheduling.
 - 2.2 Imidacloprid & moxidectin – consideration of scheduling.
 - 2.3 Ethyl formate – consideration of scheduling.
 - 2.4 Pyridalyl – consideration of scheduling.
 - 2.5 Procymidone – consideration of scheduling.
 - 2.6 *Helicoverpa armigera* – consideration of scheduling.
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3. OTHER AGRICULTURAL/VETERINARY, INDUSTRIAL AND DOMESTIC CHEMICALS

- 3.1 Star anise oil and Anise oil – consideration of scheduling.

- 3.2 Creosote including related compounds and fractions – consideration of scheduling.
- 3.3 Diethylene glycol butyl ether (DEGBE)– consideration of scheduling.
- 3.4 10, 10' - oxydiphenoxarcine (OBPA) – consideration of scheduling.
- 3.5 Isohexadecane and isododecane – consideration of scheduling.
- 3.6 Sodium dichloroisocyanurate – consideration of scheduling.
- 3.7 Pine oil – consideration of scheduling.
- 3.8 Naphthalene – consideration of scheduling and Appendix F warning statements.
- 3.9 Home garden pesticides – consideration of proposal to limit the pack size to 1 kg or 1 L.

4. ANTIBIOTICS FOR CONSIDERATION FOLLOWING RECOMMENDATION OF THE JOINT EXPERT ADVISORY COMMITTEE ON ANTIBIOTIC RESISTANCE (JETACAR)

- 4.1 Virginiamycin – consideration of scheduling of preparations for use in non-food producing animals.
- 4.2 Tiamulin – consideration of scheduling.
- 4.3 Diaverdien – consideration of scheduling.
- 4.4 Neomycin – consideration of scheduling.
- 4.5 Roxarsone – consideration of scheduling.

5. SUBSTANCES REFERRED BY THE AUSTRALIAN DRUG EVALUATION COMMITTEE

- 5.1 Adalimumab – consideration of scheduling.
- 5.2 Enfuvirtide – consideration of scheduling.
- 5.3 Escitalopram – consideration of scheduling.
- 5.4 Dukoral – consideration of scheduling.
- 5.5 Adefovir – consideration of scheduling.
- 5.6 Levosimendan – consideration of scheduling.

6. OTHER PHARMACEUTICALS

- 6.1 Nicotine – consideration of the proposal to exempt lozenges for use in smoking cessation for consistency with gums and transdermal patches.
- 6.2 Pseudoephedrine – consideration of scheduling of undivided, combination and slow release preparations in Schedule 2.
- 6.3 Fluorides – consideration of scheduling of mouthwash preparations.
- 6.4 Triamcinolone – consideration of scheduling of intranasal spray for AR.
- 6.5 *Melia azedarach* including its extracts or derivatives - consideration of scheduling.
- 6.6 Kava and kavalactones – consideration of scheduling.
- 6.7 Aripiprazole – consideration of inclusion in Appendix K.

7. SUBSTANCES REFERRED BY THE NEW ZEALAND MEDICINES CLASSIFICATION COMMITTEE

No items.

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

- 8.1 Meclozine – consideration of scheduling of preparations for the prevention of travel sickness.

- 8.2 Amphotericin - consideration of inclusion in Schedule 3 of topical preparations for the treatment of oral candidiasis.

9. PROPOSALS FROM OTHER NDPSC WORKING PARTIES

No items.

10. MATTERS EXPECTED TO LEAD TO AN AMENDMENT OF PARTS 1-3 OR PART 5 OF THE SUSDP, FOR WHICH THE NDPSC INVITE PUBLIC SUBMISSIONS.

10.1 FORESHADOWED DECISIONS FROM PREVIOUS MEETING(S).

- 10.1.1 PART 1 – INTERPRETATION – consideration of the following foreshadowed amendment.

PART 1 – INTERPRETATION – AMENDMENT

Sub-paragraph 1.(1) – Amend entry for “Child-resistant closure” and “Child-resistant packaging” to read:

Child-Resistant Packaging: means packaging that is designed or constructed to be significantly difficult for a young child to open, or gain access to the contents of, within a reasonable time but not unduly difficult for adults to use properly, but does not mean packaging which all such children cannot open, or obtain the content of, within reasonable time.

Packaging that:

- (1) is reclosable and complies with the requirements of at least one of the following standards:
 - (i) the International Organization for Standardization Standard ISO 8317:1989 entitled *Child-resistant packaging - requirements and testing procedures for reclosable packages*;
 - (ii) the British Standards Institution Standard BS EN 28317:1993 entitled *Child-resistant packaging - requirements and testing procedures for reclosable packages*;
 - (iii) the Canadian Standards Association Standard CSA Z76.1-99 entitled *Reclosable child-resistant packages*;
 - (iv) the United States Code of Federal Regulations, Title 16, Section 1700.15, entitled *Poison prevention packaging standards* and Section 1700.20, entitled *Testing procedure for special packaging*;
 - (v) the Australian Standard AS1928-2001 entitled *Child-resistant packages*; or

- (2) is approved as child-resistant by any order made under section 10(3) of the Commonwealth *Therapeutic Goods Act 1989*;
 - (3) in the case of a can fitted with a press-on lid, a lid of the design known as “double tight” or “triple tight”;
 - (4) is in the form of a blister and strip packaging; or
 - (5) is non-access access packaging that complies with the requirements of Australian Standard AS4710-2001 entitled *Packages for chemicals not intended for access or contact with their contents by humans*,
- is deemed to be child-resistant packaging for the purpose of the requirements of the SUSDP.

10.1.2 PART 2, LABELS AND CONTAINERS SUB-PARAGRAPH 7(1)(a)(iv) – consideration of the following foreshadowed amendment.

PART 2, LABELS AND CONTAINERS SUB-PARAGRAPH 7(1)(a)(iv)

- (iv) if the poison:
 - (A) is a Schedule 5 poison, with nothing, other than a Class label as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail* or a statement of the principal hazard of the poison, written on that line;
 - (B) is a Schedule 8 poison, with nothing, other than a designation as specified in the *New Zealand Misuse of Drugs Act (1975)* written on that line; or
 - (C) is not a Schedule 5 or a Schedule 8 poison, with nothing, other than a Class label as specified in the *Australian Code for the Transport of Dangerous Goods by Road and Rail*, written on that line;

10.1.3 MERCURY – consideration of the following foreshadowed amendment.

Appendix G – new entry

MERCURY

(concentration to be determined)