

NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

PRE-FEBRUARY 2005 SCHEDULING MEETING NOTICE

Notice under Regulation 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 22-24 February 2005. 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 2005 meeting. Public submissions must address a matter mentioned in section 52E of the *Therapeutic Goods Act 1989* and be 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 **26 January 2005**.

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 2005 meeting notice will invite further public submissions on substances that are the subject of an amendment to the Schedules at the February 2005 meeting. Regulation 42ZCY of the *Therapeutic Good Regulations 1990*, however, restricts this invitation to those persons who made 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.

SUBSTANCES TO BE CONSIDERED FOR SCHEDULING

1. **FORESHADOWED DECISIONS FROM THE PREVIOUS MEETING**
(Please refer to the October 2004 Record of the Reasons for further information and the proposed amendment to the SUSDP. The Record of Reasons can be accessed through <http://www.tga.gov.au/ndpsc>.)
 - 1.1 STRYCHNOS spp – consideration of a proposal to include an exemption for preparations containing 1 milligram or less per litre or kilogram of strychnine in the Schedule 4 entry.

Additionally, the removal of the entry for STRYCHNOS spp in Appendix G is also under consideration.

- 1.2 PHENYLENEDIAMINES – consideration of a proposal to amend the Appendix C entry to include use in eyelashes or eyebrows tinting.
- 1.3 TOLUENEDIAMINE – consideration of a proposal to include in Appendix C an entry for use in eyelashes or eyebrows tinting.
- 1.4 MELIA AZEDARACH – consideration of a proposal to include in Appendix C.
- 1.5 2,5-DIMETHOXY-4-ETHYLTHIOPHENETHYLAMINE (2C-T-2) – consideration of a proposal to include in Schedule 9.
- 1.6 2,5-DIMETHOXY-4-IODOPHENETHYLAMINE (2C-I) – consideration of a proposal to include in Schedule 9.
- 1.7 2,5-DIMETHOXY-4-(N)-PROPYLTHIOPHENETHYLAMINE (2C-T-7) – consideration of a proposal to include in Schedule 9.
- 1.8 5-METHOXY- α -METHTRYPTAMINE (5-Meo-AMT) – consideration of a proposal to include in Schedule 9.

2. SUBSTANCES REFERRED BY THE AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY

- 2.1 α -Amylase/ β -glucanase/cellulase/pectinase/phytase/fungal protease/xylanase – consideration of scheduling with possible exemption from scheduling requirements.
- 2.2 Fipronil/cure-lure [4-[4-(acetyloxy)phenyl]-2-butanone] – consideration of scheduling.
- 2.3 Potassium peroxomonsulfate/silver/copper/sodium persulfate – consideration of scheduling.
- 2.4 Thiabendazole – consideration of scheduling.
- 2.5 Deracoxib – consideration of scheduling.
- 2.6 Forchlorfenuron – consideration of scheduling.

3. OTHER AGRICULTURAL/VETERINARY, INDUSTRIAL AND DOMESTIC CHEMICALS

- 3.1 Glycolic acid – consideration of scheduling including a proposal to amend the current Schedule 6 entry to include agricultural use.
- 3.2 Pine oils (derived from *Pinus radiata*) – consideration of scheduling. (Please refer to the October 2004 Record of the Reasons for further information.)
- 3.3 Pyraflufen-ethyl – consideration of scheduling. (Please refer to the October 2004 Record of the Reasons for further information.)

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

No items.

5. SUBSTANCES REFERRED BY THE AUSTRALIAN DRUG EVALUATION COMMITTEE

- 5.1 Moxonidine – consideration of scheduling of a new medicine.
- 5.2 Efalizumab – consideration of scheduling of a new medicine.
- 5.3 Duloxetine hydrochloride – consideration of scheduling of a new medicine.
- 5.4 Emtricitabine – consideration of scheduling of a new medicine.

6. OTHER PHARMACEUTICALS

- 6.1 Ibuprofen – consideration of a proposal to amend the warning statements in Schedule 2 to remove duplication and maintain consistency with expiry provisions included in the S2 aspirin and paracetamol entries.

- 6.2 Oseltamivir – consideration of a proposal to include preparations for the treatment and prevention of influenza type A and B in Schedule 3 and Appendix H.
- 6.3 Diphenhydramine – consideration of the Schedule 2 entry.
- 6.4 Diclofenac – consideration of a proposal to reschedule divided preparations for oral use from Schedule 3 to Schedule 2.

7. SUBSTANCES REFERRED BY THE NEW ZEALAND MEDICINES CLASSIFICATION COMMITTEE

- 7.1 Zinc compounds – consideration of scheduling with regard to a proposal to increase the cut-off for unscheduled preparations for human internal use. (Please refer to the October 2004 Record of the Reasons for further information.)

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

No items.

9. PROPOSALS FROM OTHER NDPSC WORKING PARTIES

No items.

10. MATTERS EXPECTED TO LEAD TO AN AMENDMENT OF PARTS 1-3 OR PART 5 (except Appendices A, B and C) OF THE SUSDP, FOR WHICH THE NDPSC INVITE PUBLIC SUBMISSIONS.

- 10.1 Part 2, LABELS AND CONTAINERS subparagraph 7(1)(a)(iv) – consideration of the inclusion of the New Zealand MODA designation in the Schedule 8 signal heading. (Please refer to the October 2004 Record of the Reasons for further information.)
- 10.2 Sodium hydroxide – consideration of labelling and packaging requirements.
- 10.3 Orlistat – consideration of inclusion in Appendix H.
- 10.4 Part 2, LABELS AND CONTAINERS – consideration of container requirements for essential oils.
- 10.5 Aripiprazole – consideration of inclusion in Appendix K.
- 10.6 Part 1, INTERPRETATION and Appendix F – consideration of the inclusion of a reference to the Required Advisory Statements for Medicine Labels.