

NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

PRE-OCTOBER 2008 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 14-16 October 2008. 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 October 2008 meeting. Public submissions must address a matter mentioned in section 52E of the *Therapeutic Goods Act 1989* ("the Act") 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.

The NDPSC has moved to an E-agenda and is increasingly using electronic documents at its meetings. Persons making public submissions to the Committee are strongly encouraged to lodge submissions in electronic format (word or unsecured PDF is preferred) via the NDPSC email address. Accordingly, public submissions, **preferably in electronic format**, should be made to:

The Secretary
National Drugs and Poisons Schedule Committee
GPO Box 9848
CANBERRA ACT 2601
e-mail NDPSC@health.gov.au. Facsimile 02-6160 3299

The closing date for submissions is **10 September 2008**.

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 simply 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-October 2008 meeting notice will invite further public submissions on substances that are the subject of an amendment to the Schedules at the October 2008 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 02-6160 3200 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 June 2008 Record of the Reasons for further information and the proposed SUSDP amendment. The Record of Reasons can be accessed through <http://www.tga.gov.au/ndpsc>.)

- 1.1 Lead in paints and tinters (see item 2.4.1 of the June 2008 Record of Reasons).
- 1.2 Prothioconazole (see item 6.1 of the June 2008 Record of Reasons).
- 1.3 Atropine (see item 7.1 of the June 2008 Record of Reasons).

- 1.4 Codeine / ibuprofen combinations – consideration of scheduling including a proposal to amend the Schedule 2 and Schedule 3 pack size limits (see item 11.1 of the June 2008 Record of Reasons).
- 1.5 Hydroquinone (see item 14.1 of the June 2008 Record of Reasons).
- 1.6 Ethylhexanediol (see item 21.1.2 of the June 2008 Record of Reasons).
- 1.7 Basic Orange 31 (see item 21.1.2 of the June 2008 Record of Reasons).
- 1.8 Methyl methacrylate (see item 21.1.2 of the June 2008 Record of Reasons).
- 1.9 Formaldehyde (see item 21.1.2 of the June 2008 Record of Reasons).
- 1.10 Paraformaldehyde (see item 21.1.2 of the June 2008 Record of Reasons).

2 SUBSTANCES REFERRED BY THE AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY

- 2.1 Benomyl – consideration of scheduling including a proposal to upschedule from Schedule 6 to Schedule 7.
- 2.2 Didecyldimethylammonium chloride / carbonate / bicarbonate – consideration of scheduling including possible broadening of the existing didecyldimethylammonium chloride schedule entry to encompass all salts or, alternatively, specific schedule entries for the carbonate and bicarbonate salts.
- 2.3 Pergolide – consideration of scheduling for animal use.

3 OTHER AGRICULTURAL/VETERINARY, INDUSTRIAL AND DOMESTIC CHEMICALS

- 3.1 Pyrithione zinc – consideration of scheduling including a proposal to exempt 0.1% or less when in construction material such as jointing compounds and sealing materials.

4 SUBSTANCES REFERRED BY THE REGISTRATION PROCESSES FOR PRESCRIPTION MEDICATIONS

- 4.1 Anidulafungin - consideration of scheduling.
- 4.2 Dexvenlafaxine – consideration of scheduling including consideration of whether dexvenlafaxine is captured by the current venlafaxine Schedule 4 entry.
- 4.3 Romiplostim – consideration of scheduling.
- 4.4 Influenza virus haemagglutinin – consideration of scheduling.
- 4.5 Rabbit anti-human thymocyte immunoglobulin – consideration of scheduling including consideration of whether rabbit anti-human thymocyte immunoglobulin is captured by the current Schedule 4 entry for immunoglobulins.

5 OTHER PHARMACEUTICALS

- 5.1 Nicotine – consideration of a proposal to amend the scheduling of nicotine in relation to use in electronic cigarettes.
- 5.2 Isotretinoin – consideration of scheduling including a proposal to amend the Appendix D prescribing restrictions to allow prescribing by General Practitioners.
- 5.3 Lignocaine – consideration of scheduling including a proposal to broaden the current Schedule 2 exemption for dermal use ($\leq 2\%$) to also exempt use on gums.
- 5.4 Ketotifen – consideration of scheduling including a proposal to reschedule $\leq 0.025\%$ for ophthalmic use from Schedule 3 to Schedule 2.

6 SUBSTANCES REFERRED BY THE NEW ZEALAND MEDICINES CLASSIFICATION COMMITTEE (MCC).

Nil.
