

NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

PRE-JUNE 2006 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 20-22 June 2006. 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 June 2006 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.

The NDPSC is moving 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 via the NDPSC email address. Accordingly, public submissions, **preferably in electronic format**, should be made to:

The Secretary
National Drugs and Poisons Schedule Committee
PO Box 100
WODEN ACT 2606
e-mail NDPSC@health.gov.au. Facsimile 02-62893299

The closing date for submissions is **24 May 2006**.

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-June 2006 meeting notice will invite further public submissions on substances that are the subject of an amendment to the Schedules at the June 2006 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 02-6289 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 February 2006 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 Recombinant medicines - Consideration of the inclusion of a provision in Part 1 of the SUSDP which would cover all recombinant variants of parent molecules listed in the Schedules. (Refer Item 1.8.2.1.2).
- 1.2 Child resistant closures – Consideration of an amendment to Part 1, Paragraph 25(1) of the SUSDP so that food additives captured by the alkaline salts entries are to be required to have a child resistant closure where the volume is 2.5 litres or less. (Refer Item 4.2.1).
- 1.3 Ibuprofen - Consideration of an amendment to the Schedule 2 entry for ibuprofen to remove the exemption for solid-dose products labelled for use in children aged 6 years or under.

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

- 2.1 *Cydia pomonella* Granulosis virus – Consideration of scheduling.
- 2.2 Sulfuryl fluoride – Consideration of scheduling.
- 2.3 Prosulfocarb – Consideration of scheduling.
- 2.4 Tylosin tartrate – Consideration of scheduling.
- 2.5 Acetyl isovaleryltylosin tartrate – Consideration of scheduling.
- 2.6 Acetamiprid – Consideration of scheduling.
- 2.7 Metaflumizone – Consideration of scheduling.
- 2.8 Tulathromycin – Consideration of scheduling.
- 2.9 Indoxicarb – Consideration of scheduling.
- 2.10 Sulfentrazone – Consideration of scheduling.

3. OTHER AGRICULTURAL/VETERINARY, INDUSTRIAL AND DOMESTIC CHEMICALS

- 3.1 N-oleyl-1,3 diaminopropane – Consideration of scheduling.
- 3.2 Azelaic acid/Potassium azeloyl diglycinate for cosmetic use – Consideration of scheduling.
- 3.3 Phenylenediamines and toluenediamine (eyelash and eyebrow tints) – Consideration of scheduling.

4. SUBSTANCES REFERRED BY THE AUSTRALIAN DRUG EVALUATION COMMITTEE

- 4.1 Human plasma derived Protein C – Consideration of scheduling and/or possible exemption.
- 4.2 Octocog alfa – Consideration of scheduling and/or possible exemption.

(For the above items, please refer to the February 2006 Record of the Reasons – Items 11.4.1 and 11.4.2 – for further information. The Record of Reasons can be accessed through <http://www.tga.gov.au/ndpsc>.)

- 4.3 Plasma-derived Factor VIII - Consideration of scheduling and/or possible exemption.
- 4.4 Bortezomib - Consideration of scheduling.
- 4.5 Azacitidine - Consideration of scheduling.

5. OTHER PHARMACEUTICALS

- 5.1 Blood products – Consideration of the scheduling and/or inclusion in Appendix A of those products derived from the fractionation of plasma and comparable recombinant products.
- 5.2 Aconitium spp – Consideration of scheduling, particularly in relation to use in children.
- 5.3 *Schoenocaulon Officinale* (Sabadilla) - Consideration of scheduling.
- 5.4 Caffeine – Consideration of scheduling for therapeutic use.
- 5.5 Mometasone furoate – Consideration of a proposal to reschedule topical mometasone furoate 0.1% from Schedule 4 to Schedule 3 and inclusion in Appendix H.
- 5.6 Hydrocortisone and Hydrocortisone acetate – consideration of a proposal to reschedule hydrocortisone for rectal use from Schedule 3 to Schedule 2 when combined with a local anaesthetic.
- 5.7 Sumatriptan – Consideration of a proposal to include oral preparations containing 50 mg or less of sumatriptan in packs containing 2 dosage units or less for the treatment of migraine attacks in Schedule 3 and Appendix H.
- 5.8 Clotrimazole – Clarifying scheduling entry in relation to application to nails.
- 5.9 Ciclopirox - Clarifying scheduling entry in relation to application to nails.
- 5.10 Amorolfine - Clarifying scheduling entry in relation to application to nails.

6. SUBSTANCES REFERRED BY THE NEW ZEALAND MEDICINES CLASSIFICATION COMMITTEE

Nil

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

Nil

8. 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.

- 8.1 Cetirizine – Review of proposal to remove cetirizine for oral use from Appendix K.
- 8.2 Consideration of inclusion of a paragraph in Part 3 relating to the requirements for retail storage of Schedule 5 and 6 poisons.
- 8.3 Flupenthixol – Consideration of inclusion in Appendix K.