

NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

PRE-FEBRUARY 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 21-23 February 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 February 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 submissions to the Committee are 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 **25 January 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-February 2006 meeting notice will invite further public submissions on substances that are the subject of an amendment to the Schedules at the February 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 October 2005 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 Chlorhexidine – Consideration of scheduling. (Refer item 6.4)
- 1.2 Potassium chloride – Consideration of scheduling in relation to a proposal to schedule oral potassium chloride for therapeutic use in Schedule 4. (Refer item 16.4)
- 1.3 Sedating Antihistamines (brompheniramine, chlorpheniramine, dexchlorpheniramine, diphenhydramine, diphenylpyraline, doxylamine, pheniramine, promethazine, thenyldiamine, trimeprazine, triprolozone) – Review of clarity of the Schedule 2 entry. (Refer item 16.3)

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

- 2.1 Amicarbazone – Consideration of scheduling.
- 2.2 Florasulam - Consideration of scheduling.
- 2.3 Prohexadione-calcium - Consideration of scheduling.

3. OTHER AGRICULTURAL/VETERINARY, INDUSTRIAL AND DOMESTIC CHEMICALS

- 3.1 Paraquat – Further consideration of scheduling of a new formulation.
- 3.2 Alkaline salts – Consideration of more restrictive scheduling for dishwasher products with pH > 12.5 including the possibility of placing these products in Schedule 7.
- 3.3 Cysteamine hydrochloride – Consideration of scheduling in relation to a proposal to reschedule cysteamine hydrochloride for cosmetic use.
- 3.4 Sodium polystyrene sulphonate – Consideration of scheduling in relation to a proposal to reschedule sodium polystyrene sulphonate for cosmetic use.
- 3.5 N-tallow alkyl-1,3-propanediamine acetate and tallow alkylamine acetates – Consideration of scheduling and/or possible exemption.
- 3.6 Industrial biocides – Consideration of inclusion in Appendix A.
- 3.7 Benzylpiperazine and Trifluoromethylphenylpiperazine – Consideration of scheduling in relation to a proposal to include these substance in Schedule 9.

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 October 2005 Record of the Reasons – Items 13.6.1 and 15.1.1 – for further information. The Record of Reasons can be accessed through <http://www.tga.gov.au/ndpsc>.)

- 4.3 Lanthanum – Consideration of scheduling of a new medicine.
- 4.4 Olmesartan – Consideration of scheduling of a new medicine.

- 4.5 Palifermin – Consideration of scheduling of a new medicine.
- 4.6 Pegvisomant – Consideration of scheduling of a new medicine.
- 4.7 Rasagiline – Consideration of scheduling of a new medicine.

5. OTHER PHARMACEUTICALS

- 5.1 Azelastine hydrochloride – Consideration of scheduling in relation to a proposal to reschedule azelastine in topical eye preparations containing 0.05% or less of azelastine from Schedule 4 to Schedule 2.
- 5.2 Clotrimazole – Consideration of scheduling in relation to a proposal to reschedule clotrimazole in preparations for vaginal use, from Schedule 3 to Schedule 2.
- 5.3 Codeine – Consideration of scheduling in relation to the scheduling status of liquid preparations containing codeine as a single active ingredient.
- 5.4 Ibuprofen – Consideration of scheduling in relation to a proposal to reschedule ibuprofen in divided doses, each containing 400mg, in packs of 50 or less dosage units, with a maximum daily dose of 1200mg, from Schedule 4 to Schedule 2.
- 5.5 Ketotifen – Consideration of scheduling in relation to a proposal to reschedule ketotifen in topical eye preparations containing 0.025% or less of ketotifen from Schedule 4 to either Schedule 3 (with Appendix H listing) or Schedule 2.
- 5.6 Metoclopramide and Essential Oils – Consideration of the appropriateness of the term ‘compounded’ in current schedule entries.
- 5.7 Levonorgestrel – Consideration of a proposal to amend the Schedule 3 entry to accommodate a single 1.5 mg tablet.
- 5.8 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 that are currently not scheduled.

6. SUBSTANCES REFERRED BY THE NEW ZEALAND MEDICINES CLASSIFICATION COMMITTEE

(Please refer to the October 2005 Record of the Reasons – Item 18.1.1 – for further information. The Record of Reasons can be accessed through <http://www.tga.gov.au/ndpsc>.)

- 6.1 Alemtuzumab - Consideration of scheduling.
- 6.2 Anecortave - Consideration of scheduling.
- 6.3 Cyclizine – Consideration of scheduling.
- 6.4 Dimenhydrinate - Consideration of scheduling.
- 6.5 Entecavir - Consideration of scheduling.
- 6.6 Erlotinib - Consideration of scheduling.
- 6.7 Fluticasone - Consideration of scheduling.
- 6.8 Fulvestrant - Consideration of scheduling.
- 6.9 Meclozine – Consideration of scheduling.
- 6.10 Mepyramine – Consideration of scheduling.
- 6.11 Mometasone - Consideration of scheduling.
- 6.12 Muraglitazar - Consideration of scheduling.
- 6.13 Nesiritide - Consideration of scheduling.
- 6.14 Oxiconazole - Consideration of scheduling.
- 6.15 Palonosetron - Consideration of scheduling.
- 6.16 Pegaptanib - Consideration of scheduling.
- 6.17 Posaconazole - Consideration of scheduling.
- 6.18 *Schoenocaulon Officinale* (sabadilla) – Consideration of scheduling.
- 6.19 Solifenacin - Consideration of scheduling.
- 6.20 Terlipressin - Consideration of scheduling.
- 6.21 Triamcinolone - Consideration of scheduling.

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

(Please refer to the October 2005 Record of the Reasons – Item 1.8.1.1 – for further information. The Record of Reasons can be accessed through <http://www.tga.gov.au/ndpsc>.)

- 7.1 *Aconitum* spp. - Consideration of scheduling.
- 7.2 Acrivastine - Consideration of scheduling.
- 7.3 Amidopyrine - Consideration of scheduling.
- 7.4 Amorolfine - Consideration of scheduling.
- 7.5 Antimony - Consideration of scheduling.
- 7.6 Aspirin - Consideration of scheduling.
- 7.7 Atosiban - Consideration of scheduling.
- 7.8 *Atropa belladonna* (belladonna) - Consideration of Appendix G.
- 7.9 Beclomethasone - Consideration of scheduling.
- 7.10 Budesonide - Consideration of scheduling.
- 7.11 Camphorated oil - Consideration of scheduling.
- 7.12 Cathine - Consideration of scheduling.
- 7.13 Propamidine/dibromopropamidine - Consideration of scheduling.
- 7.14 *Hyoscyamus niger* – Consideration of Appendix G.
- 7.15 Mercury - Consideration of scheduling.

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 Amisulpride – Consideration of a proposal to include amisulpride in Appendix K of the SUSDP.
- 8.2 Fluconazole – Consideration of applying Appendix F Warning Statement to Schedule 3 only and review of the Appendix H status of fluconazole.
- 8.3 Consideration of inclusion of a paragraph in Part 3 relating to the requirements for retail storage of Schedule 5 and 6 poisons.
- 8.4 Orlistat – Consideration of a proposal to include orlistat in Appendix H.
- 8.5 Consideration of inclusion of ‘aromatic amines’ as an approved name for amines used as curing agents for epoxy resins as set out in the table in Part 1, paragraph 7(1)(k)(iii).