

# NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

## PRE-JUNE 2009 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 16-18 June 2009. 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 this 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 postal or email 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](mailto:NDPSC@health.gov.au). Facsimile 02- 6289 2500  
The closing date for submissions is **21 May 2009**.

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 *Therapeutic Goods Act 1989*. **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-June 2009 meeting notice will invite further public submissions on substances that are the subject of an amendment to the Schedules at the June 2009 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](mailto:NDPSC@health.gov.au)

### SUBSTANCES TO BE CONSIDERED FOR SCHEDULING

#### 1 FORESHADOWED DECISIONS FROM THE PREVIOUS MEETING

(Please refer to the February 2009 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/records.htm> )

- 1.1 Hydroquinone – consideration of scheduling, including a proposal to amend the current scheduling of hydroquinone for external therapeutic use (i.e. in skin bleaching products) (see item 11.2 of the February 2009 Record of Reasons).

- 1.2 Arbutin (glycosylated hydroquinone) – consideration of scheduling (see item 11.2 of the February 2009 Record of Reasons).
- 1.3 Codeine – consideration of scheduling, including a proposal to delete the Schedule 2 entry and amend the Schedule 3 entry (see item 1.8.1 of the February 2009 Record of Reasons). **Please note that public submissions for this item need not be restricted by or limited to this stated proposal.**
- 1.4 *Piper methysticum* (Kava) – consideration of scheduling, including a proposal to exempt the dried root or rhizome from scheduling (see item 12.1.5 of the February 2009 Record of Reasons).
- 1.5 Cannabidiol – consideration of scheduling, including a proposal to include cannabidiol in Schedule 8 when prepared and packed for therapeutic use (see item 12.1.6 of the February 2009 Record of Reasons).
- 1.6 Magnesium sulfate – consideration of scheduling, including a proposal to include magnesium sulfate in Schedule 3 for human therapeutic use in divided oral preparations for constipation (see item 12.1.7 of the February 2009 Record of Reasons).

---

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

- 2.1 Monepantel – consideration of scheduling, including a proposal to classify as a Schedule 5 substance.
- 2.2 Saflufenacil – consideration of scheduling, including a proposal to classify as a Schedule 6 substance.

---

## 3 OTHER AGRICULTURAL/VETERINARY, INDUSTRIAL AND DOMESTIC CHEMICALS

- 3.1 Guanidine – consideration of scheduling, including a proposal to restrict the Schedule 4 entry to therapeutic use only, to include a new parent entry in Schedule 6 and to include a new entry in Appendix E, Part 2 (see item 5.1.2 of the February 2009 Record of Reasons).

---

## 4 SUBSTANCES REFERRED BY THE REGISTRATION PROCESSES FOR PRESCRIPTION MEDICINES

- 4.1 Doripenem – consideration of scheduling.
- 4.2 Japanese encephalitis virus vaccine – consideration of scheduling.
- 4.3 Human Papillomavirus vaccine – consideration of scheduling.

---

## 5 OTHER PHARMACEUTICALS

- 5.1 Rabeprazole – consideration of scheduling including a proposal to reschedule rabeprazole from Schedule 4 to Schedule 3 (and inclusion in Appendix H) in preparations containing 10mg or less of rabeprazole for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days supply.
- 5.2 Loperamide – consideration of scheduling including a proposal to reschedule loperamide in undivided preparations for therapeutic use containing not more than 0.02 % loperamide in a pack size of no greater than 100mL with a recommended daily dose not exceeding 16 mg of loperamide for patients 12 years or over.
- 5.3 Fexofenadine – consideration of scheduling including a proposal to exempt fexofenadine in preparations for oral use for the short term (less than 5 days) treatment of seasonal allergic rhinitis in pack sizes of not more than 10 dosage units.
- 5.4 Succimer (meso-2, 3-dimercaptosuccinic acid/ (R, S)-2, 3-dimercapto-butanedioic acid/ DMSA) – consideration of scheduling, including a proposal to include succimer in Schedule 4.
- 5.5 HMG-CoA reductase inhibitors ('statins') – consideration of scheduling, including a proposal for a Schedule 4 class entry for HMG-CoA reductase inhibitors ('statins').

---

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

(Please refer to the Minutes of the MCC. The minutes can be accessed through <http://www.medsafe.govt.nz/profs/class/minutes.asp>)

- 6.1 Golimumab – consideration of scheduling.
- 6.2 Lacosamide – consideration of scheduling.
- 6.3 Liraglutide – consideration of scheduling.
- 6.4 Prasugrel – consideration of scheduling.

---

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

- 7.1 Di-iodohydroxyquinoline (iodoquinol) – consideration of scheduling, including whether the Appendix C entry for di-iodohydroxyquinoline is captured by the Appendix C entry for clioquinol.
- 7.2 Somatropin – review of all Schedule 4 and Appendix B entries to ensure consistency.

---

8. **MATTERS NOT EXPECTED TO LEAD TO AN AMENDMENT OF THE SUSDP, FOR WHICH THE NDPSC INVITE PUBLIC SUBMISSIONS.**

Nil.