

NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

CORRIGENDA TO THE OUTCOME OF CONSIDERATIONS BY THE NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE AT ITS FEBRUARY 2002 MEETING OF PROPOSALS FOR AMENDMENT TO THE STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS

Notice under subsection 52D(4) Therapeutic Goods Act 1989 (the Act)

The National Drugs and Poisons Schedule Committee (NDPSC) hereby gives notice, pursuant to subsection 52D(4) of the Act, that an amendment has been made to the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). Further to Gazette Notice (GN) 18 published on 8 May 2002, the following corrections to Part A (Amendments to the SUSDP, Part 4 in respect of substances mentioned in the pre-meeting Gazette Notice) and Part C (Amendments to the SUSDP, Part 4 subject to post-meeting public submissions) are notified.

Please note that the basis for amendments to the SUSDP can be found in the *Record of the Reasons*. The February 2002 *Record of the Reasons*, which also contains other outcomes arising from the meeting, can be accessed through:

<http://www.health.gov.au/tga/docs/html/ndpsc/ndpsc.htm>

Hard copies of the document can be obtained from The Secretary NDPSC, telephone 02 6270 4400.

PART A – AMENDMENTS TO PART 4 – THE SCHEDULES OF THE SUSDP

The amendments set out in Part A were made in respect of substances mentioned in the Gazette of 16 January 2002 as substances to be considered for scheduling at the February 2002 meeting. These amendments are subject to the receipt of further public submissions from persons who made a pre-meeting public submission in relation to substances listed in Part A.

Accordingly, these persons are invited to make a further submission to:

The Secretary
National Drugs and Poisons Schedule Committee
PO Box 100
Woden ACT 2606

or Facsimile 02 6270 4353; or e-mail NDPSC@health.gov.au.

Submissions must be made by **5 June 2002** and address a matter mentioned in section 52E of the Act and be relevant to the reasons for the making of the decision.

If a submission is made to the Committee in respect of a substance set out below, the Committee must consider the submission and then: confirm the amendment; vary the

amendment; or set aside the amendment, replace it with a new scheduling decision and publish notice of the decisions under section 52D of the Act. (If a new scheduling decision is made and notice of it published under section 52D, the post-meeting public consultation process commences again). Subject to the matters set out above, the amendments in Part A come into effect on 1 September 2002, unless otherwise indicated.

The Schedule 2 amendment for iron compounds, which was included in Part C in GN 18, should have been listed in Part A.

Schedule 2 – Amendment

IRON COMPOUNDS – amend entry to read:

IRON COMPOUNDS (excluding iron oxides when present as an excipient, up to 1 per cent in undivided preparations or up to 10 mg per dosage unit in divided preparations) for human internal use **except**:

- (a) when included in Schedule 4; or
- (b) when labelled with a recommended daily dose of 24 mg or less of iron:
 - (i) in undivided preparations supplied in packs each containing 750 mg or less of iron; or
 - (ii) in divided preparations:
 - (A) containing more than 5 mg of iron per dosage unit in packs each containing 750 mg or less of iron; or
 - (B) containing 5 mg or less of iron per dosage unit.

PART C – AMENDMENTS TO PART 4 OF THE SUSDP SUBJECT TO POST-MEETING PUBLIC SUBMISSIONS

The amendments set out in Part C were subject to post-meeting public submissions. The public consultation process in respect of these amendments has now concluded.

The effective date for the following amendments was inadvertently listed as 1 September 2002 in GN 18 but should have been 1 June 2002.

Schedule 2 – Amendments

ACICLOVIR – delete entry.

ATROPA BELLADONNA – amend entry to read:

ATROPA BELLADONNA (belladonna):

- (a) for external use in preparations containing 0.03 per cent or less of total solanaceous alkaloids; or
- (b) for oral use:

- (i) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (ii) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit, when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

ATROPINE – amend entry to read:

ATROPINE (excluding atropine methonitrate):

- (a) for oral use:
 - (i) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
 - (ii) in divided preparations containing 0.03 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (b) in preparations containing atropine sulfate when packed and labelled for the treatment of organophosphorous poisoning:
 - (i) in tablets each containing 0.6 mg or less of atropine sulfate in packs of 20 tablets; or
 - (ii) in preparations for injection each containing 0.6 mg per ml or less of atropine sulfate in packs of 5.

DATURA spp. – amend entry to read:

DATURA spp. for oral use:

- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

except when separately specified in these Schedules.

DATURA STRAMONIUM – amend entry to read:

DATURA STRAMONIUM (stramonium) for oral use when:

- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous

alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or

- (b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids;

except for smoking or burning.

DATURA TATULA – amend entry to read:

DATURA TATULA (stramonium) for oral use:

- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids;

except for smoking or burning.

DUBOISIA LEICHHARDTII – amend entry to read:

DUBOISIA LEICHHARDTII for oral use:

- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

DUBOISIA MYOPOROIDES – amend entry to read:

DUBOISIA MYOPOROIDES for oral use:

- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

HYOSCINE – amend entry to read:

HYOSCINE (excluding hyoscine butylbromide):

- (a) for transdermal use in preparations containing 2 mg or less of total solanaceous alkaloids per dosage unit: or
- (b) for oral use:
 - (i) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids, when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
 - (ii) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

HYOSCYAMINE – amend entry to read:

HYOSCYAMINE:

- (a) for external use in preparations containing 0.03 per cent or less of total solanaceous alkaloids; or
- (b) for oral use:
 - (i) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids, when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
 - (ii) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

HYOSCYAMUS NIGER – amend entry to read:

HYOSCYAMUS NIGER for oral use:

- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids; or
- (b) in divided preparations containing 0.03 mg of total solanaceous alkaloids or less per dosage unit when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.

Schedule 4 – Amendment

ACICLOVIR – amend entry to read:

ACICLOVIR **except** in preparations containing 5 per cent or less of aciclovir for the treatment of *Herpes labialis* in packs containing 10 g or less.