

NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

OUTCOME OF CONSIDERATIONS BY THE NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE AT ITS JUNE 2007 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).

The notice is divided into four parts:

- Part A – Amendments to the SUSDP, Part 4 in respect of substances mentioned in the pre-meeting Gazette Notice;
- Part B – Other amendments to the SUSDP (Parts 1-3 and Part 5);
- Part C – Amendments to the SUSDP subject to post-meeting public submissions; and
- Part D – Errata.

Please note that the basis for amendments to the SUSDP can be found in the Record of Reasons. The Record of Reasons, which also contains other outcomes arising from the NDPSC meeting, can be accessed through: <http://www.tga.gov.au/ndpsc>. Hard copies of the document can be obtained from the NDPSC Secretariat, tel 02 6160 3200.

The amendments arising from this notice will be incorporated into SUSDP 22 Amendment 2 effective 1 January 2008 (unless otherwise indicated), which should be available for purchase from National Mailing and Marketing Pty Ltd in November 2007, telephone (02) 6269 1035 (or using the subscription order form available at the following webpage <http://www.tga.gov.au/ndpsc/susdp.htm>).

Please note that SUSDP 22, Amendment 1 will soon be available from National Mailing and Marketing Pty Ltd.

Invitation to make a post-meeting submission

The amendments set out in Part A and B were made in respect of substances or issues mentioned in the Commonwealth of Australia Gazette No.16, 24 April 2007 (and Special Gazette No.88, 9 May 2007 with regards to pyriprole only) as substances to be considered for scheduling at the June 2007 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 or B.

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

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

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 (word or unsecured PDF is preferred). Correspondence from the Committee will similarly be via email where possible.

Submissions must be made by **15 August 2007**, address a matter mentioned in section 52E of the Act and be relevant to the reasons for the making of the decision.

If a further submission is made to the Committee by an eligible person 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.

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

Subject to the matters set out above, the amendments in Part A come into effect on **1 January 2008**, unless otherwise indicated.

Schedule 2 – New Entries

PROPAMIDINE for ophthalmic use.

DIBROMOPROPAMIDINE for ophthalmic use.

Schedule 2 – Amendment

PARACETAMOL – amend entry to read:

PARACETAMOL for therapeutic use **except:**

- (a) when included in Schedule 4;
- (b) in individually wrapped powders or sachets of granules each containing 1000 mg or less of paracetamol as the only therapeutically active constituent (other than phenylephrine or when combined with effervescent agents) when:
 - (i) enclosed in a primary pack that contains not more than 12 such powders or sachets of granules;
 - (ii) compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
 - (iii) not labelled for the treatment of children 6 years of age or less; and
 - (iv) not labelled for the treatment of children under 12 years of age when combined with phenylephrine; or
- (c) in tablets or capsules each containing 500 mg or less of paracetamol as the only therapeutically active constituent

other than (other than phenylephrine or when combined with effervescent agents) when:

- (i) packed in blister or strip packaging or in a container with a child-resistant closure;
- (ii) in a primary pack containing not more than 25 tablets or capsules;
- (iii) compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (iv) not labelled for the treatment of children 6 years of age or less; and
- (v) not labelled for the treatment of children under 12 years of age when combined with phenylephrine.

Schedule 3 – Amendments

PROMETHAZINE – amend entry to read:

PROMETHAZINE in oral preparations **except**:

- (a) when included in Schedule 2; or
- (b) for the treatment of children under 2 years of age.

TRIMEPRAZINE – amend entry to read:

TRIMEPRAZINE:

- (a) in solid oral preparations **except** when include in Schedule 2; or
- (b) in liquid oral preparations containing 10 mg or less of trimeprazine per mL,

except for the treatment of children under 2 years of age.

Schedule 4 – New Entries

ABATACEPT.

ALISKIREN.

DARUNAVIR.

DASATINIB.

DIBROMOPROPAMIDINE for therapeutic use **except** where included in other schedules.

FOSAPREPITANT.

GALSULFASE.

LAPATINIB.

NEPAFENAC.

NILOTINIB.

PALIPERIDONE.

PARICALCITOL.

PROPAMIDINE for therapeutic use **except** where included in other schedules.

RANIBIZUMAB.

RIMEXOLONE.

RIMONABANT.

RUBOXISTAURIN.

SITAXENTAN.

TRILOSTANE.

VILDAGLIPTIN.

Schedule 4 – Amendments

LANTHANUM – amend entry to read:

LANTHANUM for therapeutic use.

MERCURIC OXIDE – delete entry.

PARACETAMOL:

- (a) when combined with aspirin or salicylamide or any derivative of these substances **except** when separately specified in these Schedules;
- (b) in tablets or capsules containing more than 665 mg of paracetamol; or
- (c) in individually wrapped powders or sachets of granules each containing more than 1000 mg of paracetamol.

POTASSIUM CHLORIDE – amend entry to read:

POTASSIUM CHLORIDE in oral preparations for human therapeutic use **except**:

- (a) when containing less than 550 mg of potassium chloride per dosage unit;
- (b) in preparations for oral rehydration therapy;
- (c) in preparations for oral use for bowel cleansing prior to diagnostic medical and surgical procedures; or
- (d) in preparations for enteral feeding.

Schedule 5 – New Entry

PYRASULFOTOLE.

Schedule 5 – Amendments

CLOTHIANIDIN – amend entry to read:

CLOTHIANIDIN in preparations containing 20 per cent or less of clothianidin.

HYDROCARBONS, LIQUID – amend entry to read:

HYDROCARBONS, LIQUID, including kerosene, diesel (distillate), mineral turpentine, white petroleum spirit, toluene, xylene and light mineral and paraffin oils (but excluding their derivatives), **except:**

- (a) toluene and xylene when included in Schedule 6;
- (b) benzene and liquid aromatic hydrocarbons when included in Schedule 7;
- (c) food grade and pharmaceutical grade white mineral oils;
- (d) in solid or semi-solid preparations;
- (e) in preparations containing 25 per cent or less of designated solvents;
- (f) in preparations packed in pressurised spray packs;
- (g) in adhesives packed in containers each containing 50 grams or less of adhesive;
- (h) in writing correction fluids and thinners for writing correction fluids packed in containers having a capacity of 20 mL or less; or
- (i) in other preparations when packed in containers with a capacity of 2 mL or less.

Schedule 6 – New Entry

PYRIPROLE.

Schedule 6 – Amendment

CLOTHIANIDIN – amend entry to read:

CLOTHIANIDIN **except** when included in Schedule 5.

PART B – OTHER AMENDMENTS TO THE SUSDP (PARTS 1-3 AND PART 5)

Subject to the matters set out above, the amendments in Part B come into effect on **1 January 2008**, unless otherwise indicated.

PRINCIPLES OF SCHEDULING

READING THE SCHEDULES – amend section to read:

Schedule entries have been designed to be as simple as possible while retaining readability, legal integrity and as much freedom from ambiguity and contradiction as possible. As a result they are expressed in a number of ways, though this number has been kept to a minimum. It is necessary to keep this variety of expression in mind when searching or interpreting Schedule entries.

Firstly, poisons are now scheduled individually using their approved names wherever practicable although exceptions are necessary in some cases. Some of those are mentioned overleaf. Older group entries are being revised and replaced by individual entries as time permits although in some of these cases a group term has also been retained to deal with any members of the group or class that may have escaped attention but should be scheduled.

Secondly, schedule entries have been expressed in either positive or negative terms and care must be taken to distinguish between the two different forms of expression. Thus, selenium is in Schedule 6 only when one of the clauses in this schedule entry applies, while fluorides are in Schedule 6 unless one of the exempting clauses applies.

Where exceptions are included in an entry these have been emphasised by printing the word “except” in bold type.

Where the schedule entries for a poison make a specific exclusion or exemption, the requirements of this Standard do not apply to that poison within the constraints of that exclusion or exemption although controls under other legislation such as pesticide registration may apply.

Where a schedule entry for a poison requires a specific statement to be included on a label as a condition for a product to qualify for an exemption ('reverse scheduling'), then in cases where it is impracticable for a supplier to use the exact wording of such a statement, its wording may be varied provided that the full intent and meaning of the statement is not changed.

Where a poison has been included in more than one Schedule the principal entry, where practicable, has been included in the most restrictive Schedule with references to the other Schedule(s) involved.

It is important to remember that a Schedule entry includes preparations containing the poison in any concentration and all salts and derivatives of the poison unless it specifically states otherwise. (See Interpretation PART 1 [paragraph 1(2)]).

It is important to note that a substance is not classed as a derivative on the basis of a single, prescriptive set of criteria. Classification of a substance as a derivative of a Scheduled poison relies on a balanced consideration of factors to decide if a substance has a similar nature (e.g. structurally, pharmacologically, toxicologically) to a Scheduled poison or is readily converted (either physically or chemically) to a Scheduled poison. However, a substance is only considered a derivative of a Scheduled poison if it is not individually listed elsewhere in the Schedules, or captured by a more restrictive group or class entry. Additionally, some entries specifically exclude derivatives. Once a substance is determined to be a derivative of a Scheduled poison, the same scheduling requirements as the Scheduled poison, including limits on access, supply and availability, will apply.

Finally, when using the Standard to determine the scheduling status of a poison it may be necessary to search each relevant Schedule as well as Appendices A, B and C and the Index. In this process if the poison is not found under its “approved name” it may be shown under a group term such as:

Group	Example
the parent acid of salts	“oxalic acid” to find sodium oxalate
the radical of a salt	“chromates” to find potassium chromate
the element	“arsenic” to find arsenic trioxide
a chemical group with similar toxicological or pharmacological activity	“hydrocarbons, liquid” to find kerosene
a pharmacological group	“anabolic steroidal agents” to find “androsterone”

PART 1 – INTERPRETATION

Paragraph 1.(3) – amend to read:

- (3) Unless the contrary intention appears where a concentration, strength or quantity is specified in a schedule or an appendix to this Standard in respect of a substance:
 - (a) if the substance is present as a salt, active principle or derivative (including an ester or ether), the concentration, strength or quantity is calculated as the equivalent amount of the substance that is listed in the Schedule or Appendix;
and
 - (b) the expression “one per cent” means:

- (i) in the case of a liquid preparation, 1 gram of the substance per 100 millilitres of the preparation; or
 - (ii) in the case of a solid, semi-solid or pressurised spray aerosol preparation, 1 gram of the substance per 100 grams of the preparation; and
 - (iii) any expression of greater or lesser percentages shall have a corresponding meaning; and
- (c) in the case of codeine such concentration, strength or quantity is calculated as anhydrous codeine.

PART 2 – LABELS AND CONTAINERS

Paragraph 8.(2) – amend to read:

- (2) if the poison is for a purpose or purposes other than human therapeutic use and:
- (a) if the poison is in a pressurised spray aerosol preparation, as the mass of the poison per stated mass of the preparation;
 - (b) if the poison is a liquid in a liquid preparation, as the mass or volume of the poison per stated volume of the preparation;
 - (c) if the poison is a liquid in a solid or semi-solid preparation, as the mass or volume of the poison per stated mass of the preparation;
 - (d) if the poison is a solid or semi-solid in a liquid preparation, as the mass of the poison per stated volume of the preparation;
 - (e) if the poison is a solid or semi-solid in a solid or semi-solid preparation, as the mass of the poison per stated mass of the preparation;
 - (f) if the poison is a gas in a liquid preparation, as the mass of the poison per stated volume of the preparation;
 - (g) if the poison is a gas in a solid or semi-solid preparation, as the mass of the poison per stated mass of the preparation;
 - (h) if the poison is a gas in a gaseous preparation, as the mass of the poison per stated mass of the preparation;

PART 5 – APPENDICES

Appendix A – New Entry

DEXTRANS, GELATIN - SUCCINYLATED & ETHERIFIED STARCHES used as plasma substitutes/ blood volume expanders.

Appendix B – Amendments

DIBROMPROPAMIDINE – delete entry.

PROPAMIDINE – delete entry.

Appendix D – Part 6 – New entry

SITAXENTAN for human use.

Appendix K – New entry

Paliperidone

PART C – AMENDMENTS TO THE SUSDP THAT WERE SUBJECT TO FURTHER PUBLIC SUBMISSIONS

The amendments set out in Part C have been made in response to post-meeting public submissions. The public consultation process in respect of these amendments has now concluded. The amendments in Part C will be published in SUSDP 22 Amendment 1 which will come into effect on **1 September 2007** unless otherwise indicated.

Schedule 2 – Amendments

The following entry for hydrocortisone and hydrocortisone acetate incorporates an editorial change made at the June 2007 meeting.

HYDROCORTISONE and HYDROCORTISONE ACETATE – amend entry to read:

HYDROCORTISONE and HYDROCORTISONE ACETATE, but excluding other salts and derivatives, in preparations for human dermal use containing 0.5 per cent or less of hydrocortisone in packs containing 30 g or less of such preparations containing:

- (a) no other therapeutically active substance; or
- (b) an antifungal as the only other therapeutically active substance.

RANITIDINE – amend entry to read:

RANITIDINE in preparations supplied in the manufacturer's original pack containing not more than 14 days supply **except** in divided preparations for oral use containing

150mg or less of ranitidine per dosage unit in the manufacturer's original pack containing not more than 14 dosage units.

Schedule 3 – Amendment

The following entry for hydrocortisone and hydrocortisone acetate incorporates an editorial change made at the June 2007 meeting.

HYDROCORTISONE and HYDROCORTISONE ACETATE – amend entry to read:

HYDROCORTISONE and HYDROCORTISONE ACETATE, but excluding other salts and derivatives, in preparations containing 1 per cent or less of hydrocortisone:

- (a) for human dermal use, in packs containing 30 g or less of such preparations; and
 - (i) containing no other therapeutically active substance; or
 - (ii) containing an antifungal but no other therapeutically active substance; or
- (b) for human rectal use, when combined with a local anaesthetic but no other therapeutically active substance except unscheduled astringents:
 - (i) in undivided preparations, in packs of 35 grams or less; or
 - (ii) in packs containing 12 or less suppositories,

except when included in Schedule 2.

Schedule 4 – Amendment

The following entry for hydrocortisone and hydrocortisone acetate incorporates an editorial change made at the June 2007 meeting.

HYDROCORTISONE – amend entry to read:

HYDROCORTISONE:

- (a) for human use **except** when included in Schedule 2 or 3; or
- (b) for veterinary use.

RANITIDINE – amend entry to read:

RANITIDINE **except**:

- (a) when included in Schedule 2; or
- (b) in divided preparations for oral use containing 150mg or less of ranitidine per dosage unit when supplied in the

manufacturer's original pack containing not more than 14 dosage units.

SELENIUM – amend entry to read:

SELENIUM:

- (a) for human oral use with a recommended daily dose of more than 300 micrograms; or
- (b) for the treatment of animals **except**:
 - (i) when included in Schedule 6 or 7;
 - (ii) in solid, slow release bolus preparations each weighing 100 g or more and containing 300 mg or less of selenium per dosage unit;
 - (iii) in other divided preparations containing 30 micrograms or less of selenium per dosage unit;
 - (iv) as elemental selenium, in pellets containing 100 g/kg or less of selenium; or
 - (v) in feeds containing 1 g/tonne or less of selenium.

VITAMIN A – amend entry to read:

VITAMIN A for human therapeutic or cosmetic use **except**:

- (a) in preparations for topical use containing 1 per cent or less of vitamin A;
- (b) in preparations for internal use containing 3000 micrograms retinol equivalents or less of vitamin A per daily dose; or
- (c) in preparations for parenteral nutrition replacement.

*The following decision for orlistat, made at the February 2007 meeting, was confirmed at the June 2007 meeting. Further to this, the June 2007 meeting agreed that the implementation date for this amendment would be **1 October 2007**.*

Appendix H – Amendment

Orlistat – delete entry.

PART D – ERRATA

The Committee agreed to minor editorial amendments to the wording of these schedule entries to clarify the intent or implementation of the original decision or to adopt contemporary nomenclature. These corrections will be incorporated into SUSDP 22 Amendment 1, and come into effect on **1 September 2007** unless otherwise specified.

Schedule 3 – Amendment

NICOTINIC ACID – amend entry to read:

NICOTINIC ACID for human therapeutic use in divided preparations containing 250 mg or less of nicotinic acid per dosage unit **except**:

- (a) in preparations containing 100 mg or less of nicotinic acid per dosage unit; or
- (b) nicotinamide.

Schedule 4 – Amendments

DROTECOGIN – amend entry to read:

DROTRECOGIN.

METHYLANDROSTANOLONE – amend entry to read:

METHYLANDROSTANOLONE.

ORGANOPHOSPHORUS COMPOUNDS – amend entry to read:

ORGANOPHOSPHORUS COMPOUNDS with anticholinesterase activity for human therapeutic use except:

- (a) when separately specified in these Schedules; or
- (b) preparations containing 2 per cent or less of malathion for external use.

Schedule 5 – Amendments

INDOXACARB – amend entry to read:

INDOXACARB (Includes the R and S enantiomers) in preparations containing 1 per cent or less of indoxacarb.

MALDISON – amend entry to read:

MALATHION in preparations containing 10 per cent or less of malathion **except**:

- (a) for human therapeutic use; or
- (b) in dust preparations containing 2 per cent or less of malathion.

Schedule 6 – Amendments

MALDISON – amend entry to read:

MALATHION **except:**

- (a) when included in Schedule 5;
- (b) for human therapeutic use; or
- (c) in dust preparations containing 2 per cent or less of malathion.

Appendix H – Amendment

Nicotine – delete entry.
