

# **NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE**

## **OUTCOME OF CONSIDERATIONS BY THE NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE AT ITS June 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).

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;
- Part C – Amendments to the SUSDP, subject to post-meeting public submissions;
- Part D – Errata; and
- Part E – Notice of future reviews.

Please note that the basis for amendments to the SUSDP can be found in the *Record of the Reasons*. The *Record of the Reasons*, which also contains other outcomes arising from the NDPSC 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.

The amendments arising from this notice will be incorporated into SUSDP 17 Amendment 2 (unless otherwise indicated), which should be available for purchase from Info Access in December 2002, telephone 132 447.

To promote timely communications with stakeholders, the NDPSC has created an e-mail subscription list. Subscribers will be notified by e-mail of new information on the NDPSC website including pre- and post-meeting gazette notices, record of the reasons, advice on the publication of the SUSDP and other information relating to NDPSC operations. For further information follow the “**Subscribe by email:**” link at: <http://www.health.gov.au/tga/docs/html/ndpsc/ndpsc.htm>

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

The amendments set out in this Part A were made in respect of substances mentioned in the Commonwealth of Australia Gazette No GN 18 of 8 May 2002 as substances to be considered for scheduling at the June 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](mailto:NDPSC@health.gov.au).

Submissions must be made by **28 August 2002** and address matter(s) 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 January 2003, unless otherwise indicated.

## **SCHEDULE 2**

### **Amendments**

**HYOSCINE BUTYLBROMIDE** – Amend entry to read:

**HYOSCINE BUTYLBROMIDE** as the only therapeutically active substance, in divided preparations for oral use, containing 20 mg or less of hyoscine butylbromide per dosage unit in a pack containing 200 mg or less of hyoscine butylbromide.

**PSEUDOEPHEDRINE** – amend entry to read:

**PSEUDOEPHEDRINE** in preparations (other than preparations for stimulant, appetite suppression or weight-control purposes), with a recommended daily dose of 240 mg or less of pseudoephedrine:

- (a) in undivided preparations containing 60 mg or less of pseudoephedrine per recommended dose; or
- (b) when in combination with other therapeutically active substances; or
- (c) in slow release preparations.

## **SCHEDULE 3**

### **New entry**

PSEUDOEPHEDRINE in preparations (other than preparations for stimulant, appetite suppression or weight-control purposes), with a recommended daily dose of 240 mg or less of pseudoephedrine, where pseudoephedrine is the only therapeutically active substance in divided preparations containing 60 mg or less of pseudoephedrine per recommended dose in a pack containing 30 or less dosage units, **except** in slow release preparations.

#### **SCHEDULE 4**

##### **New Entries**

AGALSIDASE BETA.

DROTRECOGIN ALFA.

FONDAPARINUX.

INSULIN-LIKE GROWTH FACTOR I.

IPRIFLAVONE.

MODAFINIL.

OLOPATADINE.

POLYLACTIC ACID in preparations for injection:

- (a) for tissue augmentation; or
- (b) for cosmetic use.

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

TIOTROPIUM.

TRAVOPROST.

##### **Amendment**

PSEUDOEPHEDRINE – amend entry to read:

PSEUDOEPHEDRINE **except** when included in Schedule 2 or 3.

#### **SCHEDULE 5**

##### **New entries**

BETACYFLUTHRIN in aqueous preparations containing 2.5 per cent or less of betacyfluthrin.

PRALLETHRIN (cis:trans=20:80) in preparations containing 10 per cent or less of prallethrin **except** in insecticidal mats containing 1 per cent or less of prallethrin.

RACTOPAMINE in animal feed premixes containing 10 per cent or less of ractopamine.

### **Amendment**

3-IODO-2-PROPYNYL BUTYL CARBAMATE – amend entry to read:

3-IODO-2-PROPYNYL BUTYL CARBAMATE (Iodocarb) when in preparations containing 10 % or less of 3-iodo-2-propynyl butyl carbamate **except** when in aqueous preparations.

## **SCHEDULE 6**

### **New Entries**

ACETAMIPRID.

3-IODO-2-PROPYNYL BUTYL CARBAMATE (Iodocarb) **except:**

- (a) when included in Schedule 5; or
- (b) in aqueous preparations containing 10 per cent or less of 3-iodo-2-propynyl butyl carbamate.

### **Amendments**

ARSENIC – amend entry to read:

ARSENIC:

- (a) in ant poisons containing 0.4 per cent or less of arsenic;
- (b) in animal feed premixes containing 4 per cent or less of arsenic; or
- (c) in preparations for the treatment of animals **except** thiacetarsamide when included in Schedule 4;

**except** where separately specified in this Schedule.

BETACYFLUTHRIN – amend entry to read:

BETACYFLUTHRIN in preparations containing 12.5 per cent or less of betacyfluthrin **except** when included in Schedule 5.

COPPER COMPOUNDS – amend entry to read:

COPPER COMPOUNDS **except:**

- (a) when separately specified in these Schedules;
- (b) in preparations for human internal use containing 5mg or less of copper per recommended daily dose;
- (c) pigments where the solubility of the copper compound(s) in water is 1 gram per litre or less;
- (d) in feed additives containing 1 per cent or less of copper;  
or
- (e) in other preparations containing 5 per cent or less of copper compounds.

PRALLETHRIN – amend entry to read:

PRALLETHRIN (cis:trans=20:80) **except**:

- (a) when included in Schedule 5; or
- (b) in insecticidal mats containing 1 per cent or less of prallethrin.

## **SCHEDULE 7**

### **Amendment**

BETACYFLUTHRIN – amend entry to read:

BETACYFLUTHRIN **except** when included in Schedule 5 or 6.

## **SCHEDULE 8**

No entries

## **SCHEDULE 9**

No entries

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

The amendments in Part B will come into effect on 1 January 2002, unless otherwise indicated.

### **1. PART 1 - INTERPRETATION**

Part 1 Interpretation, Paragraph 2 – new entry:

- (j) any substance present as an impurity in a pesticide, at a concentration at or below the maximum content for that substance, specified for the pesticide in the current version of the *Minimum Compositional Standards (MCS) for Technical Grade Active Constituents* or its successor, as published by the National Registration Authority for Agricultural and Veterinary Chemicals.

**2. PART 2 – LABELS AND CONTAINERS**

No entries

**3. PART 3 – MISCELLANEOUS REGULATIONS**

No entries

**4. PART 5 – APPENDICES**

**Appendix H - New entry**

Pseudoephedrine.

**Appendix H – Amendment**

Hyoscine butylbromide – delete entry.

**Appendix K - New entry**

Ziprasidone

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**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, unless the amendment has been set aside and replaced with a new scheduling decision.

The amendments in Part C will come into effect on 1 September 2002, unless otherwise indicated.

**SCHEDULE 3**

**New entry**

CLOBETASONE (clobetasone-17-butyrate) in preparations for dermal use containing 0.05 per cent or less of clobetasone in packs containing 30 g or less of such preparations.

#### **SCHEDULE 4**

##### **Amendment**

CLOBETASONE – amend entry to read:

CLOBETASONE (clobetasone-17-butyrate) **except** when included in Schedule 3.

##### **Appendix F, Part 1 – New entry**

95. CAUTION - Do not use for children under 12 years old unless a doctor has told you to.

##### **Appendix F, Part 3 – New entry**

Clobetasone when included in Schedule 3.....95,72,73,74,75

##### **Appendix H - New entry**

Clobetasone.

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### **PART D – ERRATA**

The NDPSC has agreed to minor changes in wording of these decisions to clarify the intent or implementation of the original decision. These corrections will be incorporated into SUSDP 17 Amendment 2, and come into effect on 1 January 2003.

#### **Schedule 4**

POLYSULPHATED GLYCOAMINOGLYCANS – Correct entry to read:

POLYSULPHATED GLYCOAMINOGLYCANS in preparations for injection, **except** when separately specified in these Schedules.

#### **Schedule 6**

CREOSOTE – amend entry to read:

CREOSOTE **except:**

- (a) when included in Schedule 2;
- (b) in preparations for human therapeutic use containing 10 per cent or less of creosote; or

- (c) in other preparations containing 3 per cent or less of phenols and homologues of phenol boiling below 220°C.

### **Appendix C**

CONIUM MACULATUM – amend entry to read:

CONIUM MACULATUM (coniine) for therapeutic use.

### **Appendix D, Paragraph 5**

ERYTHROPOIETINS – amend entry to read:

ERYTHROPOIETINS **except** when separately specified in this Appendix.

### **Appendix G**

STRYCHNOS IGNATII – delete entry.

STRYCHNOS NUX VOMICA – delete entry.

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## **PART E – NOTICE OF FUTURE REVIEWS**

This advice is provided to alert interested parties of reviews planned by the NDPSC and deadlines for submission of relevant information for consideration.

### **1. Antibiotics for consideration following recommendations of the Joint Expert Advisory Committee on Antibiotic Resistance (JETACAR)**

Selected antibiotics for consideration - Closing date for submission **8 November 2002**.

Avoparcin, bacitracin, cuprimyxin, erythromycin, hygromycin, nalidixic acid, nisin, spiramycin.

The Scheduling of the above antibiotics is to be reviewed at the February 2003, NDPSC meeting. Interested parties are invited to provide submissions to the Secretary NDPSC by 8 November 2002.

Please note submissions will be forwarded to the Expert Advisory Group on Antibiotic Resistance (EAGAR) of the National Health and Medical Research Council (NHMRC) for evaluation prior to consideration by the NDPSC.

### **2. Scheduling of Neem Derivatives**

The scheduling of Neem derivatives will be considered at the October 2002 meeting of NDPSC. For further information see the NDPSC website at:

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