

## **NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE**

### **OUTCOME OF CONSIDERATIONS BY THE NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE AT ITS OCTOBER 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 (Parts 1-3 and Part 5);
- Part C – Amendments to the SUSDP, Part 4 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 3 (unless otherwise indicated), which should be available from Info Access in March 2003, telephone 132 447. Additionally, Amendment 2 was recently published and should be available from Info Access.

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>

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#### **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 35 of 4 September 2002 as substances to be considered for scheduling at the October 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 **2 January 2003** 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 May 2003, unless otherwise indicated. Entries prefixed with the symbol “+” will come into effect on 1 September, 2003 and are also subject to the public consultation procedures set out above.

## **SCHEDULE 2**

### **New Entry**

FLURBIPROFEN in divided preparations for topical oral use containing 10mg or less of flurbiprofen per dosage unit.

### **Amendments**

ACETYLCYSTEINE – amend entry to read:

ACETYLCYSTEINE in preparations for oral use **except** when labelled with a recommended daily dose of 1 g or less of acetylcysteine.

IBUPROFEN – amend entry to read:

IBUPROFEN in preparations for oral use when labelled with a recommended daily dose of not more than 1200mg of ibuprofen:

- (a) in divided preparations in packs of 100 or less dosage units each containing 200mg or less of ibuprofen; or
- (b) in liquid preparations when sold in the manufacturer’s original pack each containing 4 grams or less of ibuprofen.

## **SCHEDULE 3**

### **Amendments**

BUDESONIDE – amend entry to read:

BUDESONIDE in aqueous nasal sprays delivering 50 micrograms or less of budesonide per actuation when the maximum recommended daily dose is no greater than 400 micrograms and when packed in a primary pack containing 200 actuations or less, for the short-term prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years and over.

FLURBIPROFEN – delete entry

MOMETASONE – amend entry to read:

MOMETASONE in aqueous nasal sprays delivering 50 micrograms or less of mometasone per actuation when the maximum recommended daily dose is no greater than 200 micrograms and when packed in a primary pack containing 200 actuations or less, for the short-term prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years and over.

#### **SCHEDULE 4**

##### **New Entries**

AGALSIDASE ALFA.

BIMATOPROST.

EFLORNITHINE.

ERTAPENEM.

#INSULIN-LIKE GROWTH FACTORS **except** when separately specified in this Schedule.

OMALIZUMAB.

PARECOXIB.

POLYACRYLAMIDE in preparations for injection or implantation:

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

RASBURICASE.

RILUZOLE.

TENOFOVIR.

VALGANCICLOVIR.

VORICONAZOLE.

##### **Amendments**

ACETYLCYSTEINE – amend entry to read:

ACETYLCYSTEINE **except**:

- (a) when included in Schedule 2; or
- (b) in preparations for oral use when labelled with a recommended daily dose of 1 g or less of acetylcysteine.

BENZYLPENICILLIN – amend entry to read:

BENZYLPENICILLIN.

DIHYDROSTREPTOMYCIN – amend entry to read:

DIHYDROSTREPTOMYCIN.

FLURBIPROFEN – amend entry to read:

FLURBIPROFEN **except** when included in Schedule 2.

IBUPROFEN – amend entry to read:

IBUPROFEN **except**:

- (a) when included in Schedule 2; or
- (b) in preparations for dermal use.

INSULIN-LIKE GROWTH FACTOR I – amend to read:

#INSULIN-LIKE GROWTH FACTOR I

NOVOBIOCIN – amend entry to read:

NOVOBIOCIN.

PHENETHICILLIN – amend entry to read:

PHENETHICILLIN.

PHENOXYMETHYLPENICILLIN – amend entry to read:

PHENOXYMETHYLPENICILLIN.

PROCAINE PENICILLIN – amend entry to read:

PROCAINE PENICILLIN.

STREPTOMYCIN – amend entry to read:

STREPTOMYCIN.

## **SCHEDULE 5**

### **New Entries**

AZADIRACHTA INDICA EXTRACTS (neem extracts), extracted from neem seed kernels using water, methanol or ethanol, in preparations containing 5 per cent or less of total limonoids, for agricultural use.

<sup>†</sup>DICHLOROISOCYANURIC ACID containing 40 per cent or less of available chlorine, **except** in:

- (a) liquid preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statements:

**WARNING** – Ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products;

- (b) liquid preparations containing less than 2 per cent of available chlorine; or
- (c) other preparations containing 4 per cent or less of available chlorine.

EXTRACT OF LEMON EUCALYPTUS, being acid modified oil of lemon eucalyptus (*Corymbia citriodora*), **except** in preparations containing 40 per cent or less of extract of lemon eucalyptus.

TETRACONAZOLE in preparations containing 20 per cent or less of tetraconazole.

### **Amendments**

+CALCIUM HYPOCHLORITE – delete entry.

+CHLORINATED LIME – delete entry.

+CHLORINATING COMPOUNDS – amend entry to read:

CHLORINATING COMPOUNDS containing 20 per cent or less of available chlorine, **except:**

- (a) when separately specified in these Schedules;
- (b) sodium hypochlorite;
- (c) liquid preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statements:

**WARNING** – Ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products;

- (d) liquid preparations containing less than 2 per cent of available chlorine; or
- (e) other preparations containing 4 per cent or less of available chlorine.

+DICHLOROISOCYANURATES – delete entry.

+SODIUM HYPOCHLORITE – delete entry.

+TRICHLOROISOCYANURIC ACID – delete entry.

### **SCHEDULE 6**

#### **New Entries**

AZADIRACHTA INDICA (neem) or its extracts or its derivatives **except:**

- (a) in preparations for human internal use;
- (b) when included in Schedule 5;
- (c) 'debitterised neem seed oil';
- (d) in preparations for human dermal therapeutic use containing cold pressed neem seed oil, when in a container fitted with a child resistant closure and labelled with the statements:
  - " Not to be taken"
  - "Keep out of the reach of children"

"Do not use if pregnant or likely to become pregnant"; or

- (e) in other preparations for dermal use containing 1 per cent or less of cold pressed neem seed oil.

**+CHLORINATING COMPOUNDS except:**

- (a) when included in Schedule 5;
- (b) when separately specified in these Schedules;
- (c) sodium hypochlorite;
- (d) in liquid preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statements:

**WARNING** – Ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products;

- (e) in liquid preparations containing less than 2 per cent of available chlorine; or
- (f) in other preparations containing 4 per cent or less of available chlorine.

**CHLOTHIANIDIN.**

**+DICHLOROISOCYANURIC ACID except:**

- (a) when included in Schedule 5;
- (b) in liquid preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statements:

**WARNING** – Ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products;

- (c) in liquid preparations containing less than 2 per cent of available chlorine; or
- (d) in other preparations containing 4 per cent or less of available chlorine

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

**Amendments**

**BENZYL PENICILLIN** – delete entry.

**BROMOCHLORODIMETHYLHYDANTOIN** – delete entry.

**DIHYDROSTREPTOMYCIN** – delete entry.

**DIQUAT** – amend entry to read:

**DIQUAT** in preparations containing 20 per cent or less of diquat.

MOXIDECTIN – amend to read:

MOXIDECTIN for external use:

- (a) for the treatment of cats and dogs in preparations containing 2.5 per cent or less of moxidectin when packed in single dose tubes; or
- (b) for the treatment of animals in preparations containing 2 per cent or less of moxidectin.

NOVOBIOCIN – delete entry.

PHENETHICILLIN – delete entry.

PHENOXYMETHYLPENICILLIN – delete entry.

PROCAINE PENICILLIN – delete entry.

STREPTOMYCIN – delete entry.

## **SCHEDULE 7**

### **New Entries**

DIQUAT **except** when included in Schedule 6.

FLUMIOXAZIN.

### **Amendments**

<sup>†</sup>TRICHLOROISOCYANURIC ACID – delete entry.

### **Appendix C – New Entry**

AZADIRACHTA INDICA (neem) or its extracts or its derivatives, in preparations for human internal use **except** 'de-bitterised neem seed oil'.

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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 May 2003, unless otherwise indicated.

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

#### **New entry**

"**De-bitterised neem seed oil**" means highly purified neem oil containing only fatty acids and glycerides of fatty acids.

### **4. PART 5 – APPENDICES**

#### **Appendix D, Paragraph 5 – New Entry**

INSULIN-LIKE GROWTH FACTORS.

## Appendix E, Introduction - Amendment

Amend by adding immediately after the heading “**Poisons Information Centre Telephone Numbers**”:

Companies should use the poisons information centre telephone number(s) appropriate to the country(ies) of sale for the product, that is Australia or New Zealand or both. These are 13 1126 for Australia and 03 4747 000 for New Zealand. A new free-call number (0800 764 766) is being introduced in New Zealand. Use of the old number (03 4747 000) shall be phased out by May 2005.

## Appendix E, Part 1 – Amendment

Statement “A” – amend statement to read:

A For advice, contact a Poisons Information Centre (Phone *eg Australia 13 1126; New Zealand 03 4747 000 [Not after May 2005] or 0800 764 766*) or a doctor (at once).

## Appendix E, Part 2 – New entry

AZADIRACHTA INDICA (neem) or its extracts or its derivatives when included in Schedule 6.

Standard Statement.....A, E1

## Appendix E Part 2 – Amendment

Phenols – amend entry to read:

	<u>NEW</u>	<u>OLD</u>
Phenols		a,c,j,s
• 25 per cent and less	A,G3,E2,S3	
• above 25 per cent	A,G3,E2,S4	

## Appendix F, Part 1 - New Entry

96. CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. If symptoms persist or recur within two weeks, consult a doctor.

## Appendix F, Part 3 – New entry

AZADIRACHTA INDICA (neem) or its extracts or its derivatives when included in Schedule 6.

Warning Statement.....67

## Appendix F, Part 3 – Amendments

Cimetidine – amend to read:

Cimetidine when included in Schedule 3.

Warning Statement.....70, 96

Famotidine – amend entry to read:

Famotidine when included in Schedule 2.

Warning Statement.....96

Nizatidine – amend entry to read:

Nizatidine when included in Schedule 2.

Warning Statement.....96

Ranitidine – amend to read:

Ranitidine when included in Schedule 2.

Warning Statement.....96

### **Appendix H - Amendments**

Flurbiprofen – delete entry

Hydrocortisone – amend entry to read:

Hydrocortisone.

### **Appendix I – Amendment**

Paragraph 5 – amend to read:

5. A person must not manufacture, sell, supply, or use a paint containing a pesticide **except** a fungicide, algicide, bactericide or antifouling agent.

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

No amendments arising from the NDPSC June 2002 meeting were subject to post-meeting public submissions.

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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 3, and come into effect on 1 May 2003.

### **Schedule 2 - Editorial Amendment**

CICLOPIROX – correct entry to read:

CICLOPIROX in preparations for dermal use containing 2 per cent or less of ciclopirox.

### **Schedule 3 – Editorial Amendments**

MACROGOL 3350 – correct entry to read:

MACROGOL 3350 in preparations for oral use for bowel cleansing prior to diagnostic medical and surgical procedures.

SODIUM PHOSPHATE – correct entry to read:

SODIUM PHOSPHATE in preparations for oral use for bowel cleansing prior to diagnostic medical and surgical procedures.

#### **Schedule 9 – Editorial amendment**

8-METHOXYCARBONYL-4A,8A-DIMETHYL-6-ACETOXY- 5-KETO-  
3,4,4B,7,9,10,10A-SEPTAHYDRO-3-(4-FURANYL)- 2,1-NAPHTHO[4,3-  
E]PYRONE \*(SALVINORIN A) – correct entry to read:

METHYL (2*S*, 4*aR*, 6*aR*, 7*R*, 9*S*, 10*aS*, 10*bR*)-9-ACETOXY-6*a*,10*b*-DIMETHYL-4,10-  
DIOXO-DODECAHYDRO-2-(3-FURYL)-2*H*-NAPHTHO[2,1-*c*]PYRAN-7-  
CARBOXYLATE \*(SALVINORIN A).

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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)**

The following antibiotic substances listed outside of Schedule 4 of the SUSDP have been identified for review. Please note submissions received will be forwarded to the Expert Advisory Group on Antibiotic Resistance (EAGAR) for review prior to consideration by the NDPSC. Details of the EAGAR data requirements for submissions relating to these antibiotics are outlined at the end of the timetable.

- a) Submissions for review at the June 2003 Meeting must be received by 28/02/03 for: apramycin, cefadroxil, penethamate hydriodide, thiostrepton and phthalylsulfathiazole.
- b) Submissions for review at the October 2003 Meeting must be received by 23/06/03 for: avilamycin, bambarmycin (flavophospholipol) and olaquinox – not listed in S4.
- c) Submissions for review at the February 2004 Meeting must be received by 03/11/03 for: diaveridine, neomycin, roxarsone not listed in S4 and tiamulin.
- d) Submissions for review at the June 2004 Meeting must be received by 27/02/03 for: sulfacetamide, sulfadiazine, sulfadimidine, sulfamerazine, sulfaquinoxaline/ sulfonamides and sulfathiazole.
- e) Submissions for review at the October 2004 Meeting must be received by 25/06/03 for: Chlortetracycline, Oxytetracycline and Tetracycline.

#### **EAGAR Data Requirements**

Sponsors must submit 5 copies of each submission. Information should be provided under each of the headings:

#### **BACKGROUND DATA**

Product

Class

Mode of Action

Mechanism(s) of Resistance

Transfer of Resistance

Co-Transfer of Resistance

Registered Formulations (human and agricultural)

Current scheduling

Human Importance

Animal Importance

**SCHEDULING ASSESSMENT**

Sponsor Proposed Scheduling

Current usage volumes

Current resistance rates in humans

Current resistance rates in animals/agriculture

Importance in human medicine (if use is non-human use)

    Importance in Veterinary Medicine

    Importance in/and other non human uses

Importance in treatment of systemic infection (for human use)

Cross-resistance to agents in same class

Cross-resistance to agents in other antibiotic class

**(2) Reinstatement of Appendix B**

The NDPSC intends to reinstate Appendix B for substances exempt from scheduling. The Record of the Reasons for this proposal can be accessed through the NDPSC web site (see above). If you are unable to access the Record of the Reasons on-line, please contact the NDPSC Secretariat (see above for telephone number) to arrange access to a hard copy.

**(3) Rotenone (Derris) and Cubé**

The NDPSC will be reviewing the scheduling of rotenone (Derris) and cubé at the June 2003 meeting. The Record of the Reasons for this proposal can be accessed through the NDPSC web site (see above). If you are unable to access the Record of the Reasons on-line, please contact the NDPSC Secretariat (see above for telephone number) to arrange access to a hard copy.