Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

POISONS STANDARD AMENDMENT No. 3 OF 2011

I, ANTHONY GILL, a delegate of the Secretary to the Department of Health and Ageing for the purposes of paragraph 52D(2)(a) of the *Therapeutic Goods Act 1989* (the Act) and acting in accordance with the Secretary's power under that paragraph of the Act, hereby amend the Poisons Standard 2011 in the manner set out in Schedule 1.

The amendments to the Poisons Standard 2011 as set out in Schedule 1 commence on 1 September 2011.

(signed by)

ANTHONY GILL
Delegate of the Secretary to the Department of Health and Ageing

Dated this 30th day of AUGUST 2011

Schedule 1- Amendments to the Poisons Standard 2011

STANDARD FOR THE UNIFORM SCHEDULING OF MEDICINES AND POISONS

No. 2

AMENDMENT No. 1

Effective Date – 1 September 2011

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The amendments listed in this document are a result of decisions made by the Secretary of the Department of Health and Ageing or the Secretary's delegate. The basis of these amendments can be found in the 'Reasons for scheduling delegate's final decisions', which can be accessed from the scheduling website:

www.tga.gov.au/industry/scheduling-decisions.htm

Further inquiries should be directed to:

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PART A – AMENDMENTS TO THE SUSMP NO. 2

Amendments to the Standard for the Uniform Scheduling of Medicines and Poisons

The Secretary of the Department of Health and Ageing directs that the amendments below be applied to the Standard for the Uniform Scheduling of Medicines and Poisons No. 2 and recommends that these amendments be adopted by the States and Territories with effect from 1 September 2011.

PART 4 – THE SCHEDULES

SCHEDULE 2 – AMENDMENTS

FEXOFENADINE – Amend entry to read:

FEXOFENADINE in preparations for oral use **except** in preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

(a) in a primary pack containing 10 dosage units or less; and

(b) labelled with a recommended daily dose not exceeding 120 mg fexofenadine.

IBUPROFEN – Amend entry to read:

IBUPROFEN in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen:

(a) in liquid preparations when sold in the manufacturer's original pack containing 8 grams or less of ibuprofen; or

(b) in divided preparations, each containing 200 mg or less of ibuprofen, in packs of not more than 100 dosage units **except** when:

(i) as the only therapeutically active constituent other than an effervescent agent;

(ii) packed in blister or strip packaging or in a container with a child resistant closure

(iii) in a primary pack containing not more than 25 dosage units;

(iv) not labelled for the treatment of children 6 years of age or less; and

(v) compliant with the requirements of the *Required Advisory Statements for Medicine Labels*.

SCHEDULE 3 – NEW ENTRY

PARACETAMOL when combined with ibuprofen in a primary pack containing 30 dosage units or less.

SCHEDULE 4 - AMENDMENTS

DIMETHYL SULFOXIDE – Amend entry to read:

DIMETHYL SULFOXIDE (excluding dimethyl sulfone) for therapeutic use **except**:

(a) when included in Schedule 6; or

(b) in *in vitro* test kits.

FEXOFENADINE – Amend entry to read:

FEXOFENADINE **except:**

(a) when included in Schedule 2; or

(b) in preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

(i) in a primary pack containing 10 dosage units or less; and

(ii) labelled with a recommended daily dose not exceeding 120 mg fexofenadine.

PARACETAMOL – Amend entry to read:

PARACETAMOL:

(a) when combined with aspirin or salicylamide or any derivative of these substances **except** when separately specified in these Schedules;

(b) when combined with ibuprofen in a primary pack containing more than 30 dosage units;

(c) in slow release tablets or capsules containing more than 665 mg of paracetamol;

(d) in non-slow release tablets or capsules containing more than 500 mg of paracetamol;

(e) in individually wrapped powders or sachets of granules each containing more than 1000 mg of paracetamol; or

(f) for injection.

SCHEDULE 4 – NEW ENTRIES

APIXABAN.

CANAKINUMAB.

ECULIZUMAB.

FINGOLIMOD.

MAVACOXIB.

TICAGRELOR.

TOCERANIB.

VERNAKALANT.

SCHEDULE 5 – NEW ENTRY

BISPYRIBAC **except** in preparations containing 10 per cent or less of bispyribac.

SCHEDULE 5 – AMENDMENT

EMODEPSIDE – Amend entry to read:

EMODEPSIDE in preparations:

(a) for external treatment of animals containing 2.5 per cent or less of emodepside; or

(b) for oral treatment of animals containing 30 mg or less of emodepside per dosage unit.

SCHEDULE 6 – NEW ENTRIES

FLUMIOXAZIN when contained in water soluble bags individually packed in sealed sachets.

PROQUINAZID.

SCHEDULE 6 – AMENDMENT

DIMETHYL SULFOXIDE – Amend entry to read:

DIMETHYL SULFOXIDE (excluding dimethyl sulfone):

(a) when not for therapeutic use; or

(b) for treatment of animals:

(i) when combined with no other therapeutic substance(s);

(ii) in liquid preparations containing copper salicylate and 1 per cent or less methyl salicylate as the only other therapeutic substances; or

(iii) in clay poultice containing 2 per cent or less of dimethyl sulfoxide.

SCHEDULE 7 – AMENDMENT

FLUMIOXAZIN – Amend entry to read:

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

PART 5 – THE APPENDICES

APPENDIX K – NEW ENTRIES

ASENAPINE

RUPATADINE

TAPENTADOL

EDITORIAL AMENDMENTS AND ERRATA

SCHEDULE 2 – AMENDMENT

MERCUROCHROME – Amend entry to read:

MERCUROCHROME in preparations for external use containing 2 per cent or less of mercurochrome **except** when included in Schedule 6.

APPENDIX B – AMENDMENT

PRAZIQUANTEL – delete entry.

APPENDIX H – AMENDMENT

AMOROLFINE – delete entry.