Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

POISONS STANDARD AMENDMENT No. 3 OF 2009

The National Drugs and Poisons Schedule Committee, acting in accordance with its power under paragraph 52D(2)(a) of the *Therapeutic Goods Act 1989* (the Act), amends the Poisons Standard 2009 in the manner set out in Schedule 1.

The amendments to the Poisons Standard 2009 as set out in Schedule 1 commence on 1 January 2010.

(signed by)

Signed
DR RUTH LOPERT
CHAIR
NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

Dated this 2nd day of December 2009

Schedule 1- Amendments to the Poisons Standard 2009

Schedule 1

STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS

No. 24

AMENDMENT No. 2

Effective Date - 1 January 2010

Australian Government

Department of Health and Ageing

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The amendments listed in this document were finalised at the June and October 2009 meetings of the National Drugs and Poisons Schedule Committee (NDPSC) except where separately specified. The basis of these amendments can be found in the 'Record of the Reasons', which can be accessed from the NDPSC website:

http://www.tga.gov.au/ndpsc

Further inquiries should be directed to:

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Schedule 1

Media Liaison Unit
Australian Government Department of Health and Ageing

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Schedule 1

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

The National Drugs and Poisons Schedule Committee directs that the amendments below be applied to the *Standard for the Uniform Scheduling of Drugs and Poisons* No.24 and recommends that these amendments be adopted by the States and Territories with effect from 1 January 2010 unless otherwise stated. The amendments arise from decisions made by the Committee at its June 2009 meeting and confirmed at the October 2009 meeting except where separately specified.

PART 4 – THE SCHEDULES

SCHEDULE 2 – AMENDMENT

LOPERAMIDE – Amend entry to read:

LOPERAMIDE in divided preparations for oral use in packs of 20 dosage units or less.

SCHEDULE 3 – NEW ENTRIES

MAGNESIUM SULFATE for human therapeutic use in divided oral preparations **except** when containing 1.5 g or less of magnesium sulfate per recommended daily dose.

RABEPRAZOLE in oral preparations containing 10 mg or less of rabeprazole for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days of supply.

SCHEDULE 4 – NEW ENTRIES

DORIPENEM.

GOLIMUMAB.

HMG-CoA REDUCTASE INHIBITORS (including "statins") **except** when separately specified in these Schedules.

HUMAN PAPILLOMAVIRUS VACCINE.

JAPANESE ENCEPHALITIS VACCINE.

LACOSAMIDE.

LIRAGLUTIDE.

PRASUGREL.

SUCCIMER.

SCHEDULE 4 – AMENDMENTS

GUANIDINE – Amend entry to read:

GUANIDINE for therapeutic use.

RABEPRAZOLE – Amend entry to read:

RABEPRAZOLE **except** when included in Schedule 3.

SCHEDULE 5 – NEW ENTRY

MONEPANTEL.

SCHEDULE 6 – NEW ENTRIES

GUANIDINE **except**:

(a) when included in Schedule 4; or

(b) in preparations containing 1 per cent or less of guanidine.

(The following entry for methyldibromo glutaronitrile was a decision of the June 2008 meeting, varied at the October 2008 meeting for a delayed implementation date of 1 January 2010.)

† METHYLDIBROMO GLUTARONITRILE **except** in preparations intended to be in contact with the skin, including cosmetic use.

SCHEDULE 7 – NEW ENTRY

SAFLUFENACIL.

PART 5 – APPENDICES

APPENDIX C – NEW ENTRY

(The following entry for methyldibromo glutaronitrile was a decision of the June 2008 meeting, varied at the October 2008 meeting for a delayed implementation date of 1 January 2010.)

Schedule 1

METHYLDIBROMO GLUTARONITRILE in preparations intended to be in contact with the skin, including cosmetic use.

APPENDIX C – AMENDMENT

DI-IODOHYDROXYQUINOLINE (iodoquinol) – delete entry.

APPENDIX E, PART 2 – NEW ENTRY

POISON……STANDARD STATEMENT

(The following entry for guanidine also incorporates an editorial change identified at the October 2009 meeting under item 21.2.)

Guanidine when included in Schedule 6…….A,G3,E2,S1

APPENDIX F, PART 3 – NEW ENTRY

(The following entry for methyldibromo glutaronitrile was a decision of the June 2008 meeting, varied at the October 2008 meeting for a delayed implementation date of 1 January 2010.)

POISON STANDARD STATEMENT	**WARNING AND SAFETY DIRECTIONS**
Methyldibromo glutaronitrile 28	1,4,7

EDITORIAL AMENDMENTS AND ERRATA

SCHEDULE 4 – AMENDMENT

SUGAMADEX – Amend entry to read:

SUGAMMADEX.

SCHEDULE 5 – AMENDMENT

ENILCONAZOLE – Delete entry.

APPENDIX D – AMENDMENT

Appendix D, Paragraph 3 – Amend entry to read:

Schedule 1

3. Poisons available only from or on the prescription or order of a medical practitioner authorised or approved by the Secretary of the Commonwealth Department of Health and Ageing under section 19 of the *Therapeutic Goods Act 1989*.