Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

POISONS STANDARD AMENDMENT No. 1 OF 2010

The National Drugs and Poisons Schedule Committee, acting in accordance with its power under paragraph 52D(2)(a) of the *Therapeutic Goods Act 1989*, 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 May 2010.

(signed by)
DR RUTH LOPERT
CHAIR
NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

Dated this 14th day of April 2010

Schedule 1- Amendments to the Poisons Standard 2009

STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS

No. 24

AMENDMENT No. 3

Effective Date – 1 May 2010

Australian Government

Department of Health and Ageing

ISBN: 978-1-74241-174-3

Published by the Australian Government under the *Therapeutic Goods Act 1989*.

Publication approval number: 6491

Australian Government
Department of Health and Ageing

The amendments listed in this document were finalised at the October 2009 and February 2010 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:

The Secretary
National Drugs and Poisons Schedule Committee
GPO Box 9848
CANBERRA ACT 2601

Or by email: NDPSC@health.gov.au

Media Liaison Unit
Australian Government Department of Health and Ageing

TABLE OF CONTENTS

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 May 2010 unless otherwise stated. The amendments arise from decisions made by the Committee at its October 2009 meeting and confirmed at the February 2010 meeting except where separately specified.

PART 4 – THE SCHEDULES

SCHEDULE 2 – AMENDMENT

(The following entry for codeine was a decision at the June 2009 meeting, varied at the October 2009 meeting for a deferred implementation date of 1 May 2010.)

CODEINE – Amend entry to read:

CODEINE in preparations for the treatment of coughs and colds when:

(a) not combined with any other opiate substance;

(b) compounded with one or more other therapeutically active substances, of which at least one is phenylephrine and not more than one is an analgesic substance:

  (i) in divided preparations containing 10 mg or less of codeine per dosage unit; or

  (ii) in undivided preparations containing 0.25 per cent or less of codeine;

(c) labelled with a recommended daily dose not exceeding 60 mg of codeine; and

(d) in packs containing not more than 6 days of supply at the maximum dose recommended on the label.

SCHEDULE 3 – NEW ENTRY

CHLORAMPHENICOL for ophthalmic use only.

SCHEDULE 3 – AMENDMENT

(The following entry for codeine was a decision at the June 2009 meeting, varied at the October 2009 meeting for a deferred implementation date of 1 May 2010. This entry also incorporates an editorial change identified at the February 2010 meeting under item 21.2.)

CODEINE – Amend entry to read:

CODEINE when:

(a) not combined with any other opiate substance;

(b) compounded with one or more other therapeutically active substances, of which not more than one is an analgesic substance:

(i) in divided preparations containing 12 mg or less of codeine per dosage unit; or

(ii) in undivided preparations containing 0.25 per cent or less of codeine;

(c) labelled with a recommended daily dose not exceeding 100 mg of codeine; and

(d) in packs containing not more than 5 days of supply at the maximum dose recommended on the label,

except when included in Schedule 2.

SCHEDULE 4 – NEW ENTRIES

CLEVIDIPINE.

MIFEPRISTONE.

NEBIVOLOL.

RED YEAST RICE for human therapeutic use.

ROBENACOXIB.

USTEKINUMAB.

VACCINIA VIRUS VACCINE.

SCHEDULE 4 – AMENDMENT

CHLORAMPHENICOL – Amend entry to read:

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

SCHEDULE 5 – NEW ENTRIES

ABSCISIC ACID.

IPCONAZOLE in preparations containing 2 per cent or less of ipconazole.

THIOPHANATE-METHYL in preparations containing 25 per cent or less of thiophanate-methyl.

SCHEDULE 6 – NEW ENTRIES

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

THIOPHANATE-METHYL **except** when included in Schedule 5.

SCHEDULE 8 – NEW ENTRY

NABIXIMOLS (botanical extract of *Cannabis sativa* which includes the following cannabinoids: tetrahydrocannabinol, cannabidiol, cannabinol, cannabigerol, cannabichromene, cannabidiolic acid, tetrahydrocannabinolic acid, tetrahydrocannabivarol, and cannabidivarol, where tetrahydrocannabinol and cannabidiol (in approximately equal proportions) comprise not less than 90 per cent of the total cannabinoid content) in a buccal spray for human therapeutic use.

PART 5 – APPENDICES

APPENDIX D – PARAGRAPH 3 – NEW ENTRY

NABIXIMOLS.

APPENDIX K – NEW ENTRY

Nabiximols

EDITORIAL AMENDMENTS AND ERRATA

SCHEDULE 3 – AMENDMENT

PANTAPRAZOLE – Amend entry to read:

PANTOPRAZOLE in oral preparations containing 20 mg or less of pantoprazole per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days supply.

RABEPRAZOLE – Amend entry to read:

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

SCHEDULE 4– AMENDMENT

AMBRISENTAN – Amend entry to read:

AMBRISENTAN.