**POISONS STANDARD AMENDMENT No. 2 OF 2013**

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 2013 in the manner set out in Schedule 1.

The amendments to the Poisons Standard 2013 as set out in Schedule 1 commence on 1 September 2013.

(Signed by)

ANTHONY GILL

Delegate of the Secretary to the Department of Health and Ageing

Dated this 22nd day of July 2013

**Schedule 1-Amendments to the Poisons Standard 2013**

STANDARD

FOR THE

UNIFORM SCHEDULING

OF

MEDICINES AND POISONS

**No. 4**

**AMENDMENT No. 1**

Effective Date – 1 September 2013

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

Publication approval number: 10329

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 in May 2012 and June 2013. The basis of these amendments can be found in the ‘Reasons for scheduling delegate’s final decisions’, which can be accessed from the TGA website at <http://www.tga.gov.au/industry/scheduling-decisions-final.htm>.

Further inquiries should be directed to:

The Secretary

Medicines and Poisons Scheduling Secretariat (MDP88)

Office of Health Protection

Department of Health and Ageing

GPO Box 9848

CANBERRA ACT 2601

or by email to SMP@health.gov.au

Media Liaison Unit

Australian Government Department of Health and Ageing

**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. 4 and recommends that these amendments be adopted by the States and Territories with effect from 1 September 2013 unless otherwise stated.

# Part 4 – The Schedules

## Schedule 2 – Amendment

*The following amended entry for paracetamol arose from a decision of the delegate published in May 2012, with a delayed implementation date of 1 September 2013.*

PARACETAMOL for therapeutic use **except:**

1. when included in Schedule 4;
2. in individually wrapped powders or sachets of granules each containing 1000 mg or less of paracetamol as the only therapeutically active constituent (other than phenylephrine and/or guaiphenesin or when combined with effervescent agents) when:
3. enclosed in a primary pack that contains not more than 10 such powders or sachets of granules;
4. compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
5. not labelled for the treatment of children 6 years of age or less; and
6. not labelled for the treatment of children under 12 years of age when combined with phenylephrine and/or guaiphenesin; or
7. in tablets or capsules each containing 500 mg or less of paracetamol as the only therapeutically active constituent (other than phenylephrine and/or guaiphenesin or when combined with effervescent agents) when:
8. packed in blister or strip packaging or in a container with a child-resistant closure;
9. in a primary pack containing not more than 20 tablets or capsules;
10. compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
11. not labelled for the treatment of children 6 years of age or less; and
12. not labelled for the treatment of children under 12 years of age when combined with phenylephrine and/or guaiphenesin.

## Schedule 4 – New Entries

ACLIDINIUM BROMIDE.

CRIZOTINIB.

LOTEPREDNOL ETABONATE.

PERTUZUMAB.

PRALATREXATE.

REGORAFENIB.

RUXOLITINIB.

VANDETANIB.

VISMODEGIB.

## Schedule 5 – New Entries

CHLORFENAPYR in preparations containing 0.5 per cent or less of chlorfenapyr.

CYAZOFAMID.

DECOQUINATE.

SULFOXAFLOR in preparations containing 25 per cent or less of sulfoxaflor.

## Schedule 6 – New Entries

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

## Schedule 6 – Amendments

ABAMECTIN – Amend entry to read:

ABAMECTIN:

1. in preparations for pesticidal use containing 4 per cent or less of abamectin **except** when included in Schedule 5; or
2. in slow-release plastic matrix ear tags for livestock use containing 1 g or less of abamectin.

CHLORFENAPYR – Amend entry to read:

CHLORFENAPYR in preparations containing 36 per cent or less of chlorfenapyr **except** when included in Schedule 5.

PYROXASULFONE – Amend entry to read:

PYROXASULFONE.

## Schedule 7 – New Entry

CARBONYL SULFIDE when packed and labelled for use as a fumigant.

## Schedule 7 – Amendments

CHLORFENAPYR – Amend entry to read:

CHLORFENAPYR **except** when included in Schedules 5 or 6.

PYROXASULFONE – Delete entry

## Schedule 8 – New Entry

LISDEXAMFETAMINE.

# PART 5 – THE appendices

## Appendix B, Part 3 – New Entries

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 **REASON AREA
 DATE OF FOR OF
SUBSTANCE ENTRY LISTING USE**

*Eubacterium* sp. strain DSM11798 Sep 2013 a 2.4

*Megasphaera elsdenii* strain 41125 Sep 2013 a 2.4

## Appendix D, Paragraph 1 – New Entry

NABIXIMOLS.

## Appendix D, Paragraph 3 – Amendment

NABIXIMOLS – Delete entry

## Appendix J, Part 2 – New Entry

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**POISONS CONDITIONS**

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Carbonyl sulphide 1