

**POISONS STANDARD AMENDMENT No. 5 OF 2012**

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 2012 in the manner set out in Schedule 1.

The amendments to the Poisons Standard 2012 as set out in Schedule 1 commence on 1 January 2013.

(Signed by)

ANTHONY GILL

Delegate of the Secretary to the Department of Health and Ageing

Dated this 13th day of December 2012

**Schedule 1-Amendments to the Poisons Standard 2012**

STANDARD

FOR THE

UNIFORM SCHEDULING

OF

MEDICINES AND POISONS

No. 3

AMENDMENT No. 4

Effective Date – 1 January 2013

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The amendments listed in this document are a result of decisions made by a delegate of the Department of Health and Ageing in September, October and November 2012. 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 www.tga.gov.au/industry/scheduling-decisions.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: 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. 3 (SUSMP 3) and recommends that these amendments be adopted by the states and territories with effect from 1 January 2013.

# PART 4 – THE SCHEDULES

## SCHEDULE 2 – AMENDMENTS

CETIRIZINE – Amend entry to read:

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

1. in a primary pack containing not more than 5 days’ supply; and

(b) labelled with a recommended daily dose not exceeding 10 mg of cetirizine.

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:

1. in liquid preparations when sold in the manufacturer’s original pack containing 8 grams or less of ibuprofen; or
2. in divided preparations, each containing 200 mg or less of ibuprofen, in packs of not more than 100 dosage units **except** when:
3. as the only therapeutically active constituent (other than phenylephrine or when combined with an effervescent agent**)**;
4. packed in blister or strip packaging or in a container with a child-resistant closure;
5. in a primary pack containing not more than 25 dosage units;
6. compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
7. not labelled for the treatment of children 6 years of age or less; and
8. not labelled for the treatment of children under 12 years of age when combined with phenylephrine.

## SCHEDULE 4 – NEW ENTRIES

ABIRATERONE ACETATE.

BOCEPREVIR.

FIDAXOMICIN.

RIDAFOROLIMUS.

TELAPREVIR.

## SCHEDULE 4 – AMENDMENTS

CETIRIZINE – Amend entry to read:

CETIRIZINE **except**

1. when included in Schedule 2; or

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

1. in a primary pack containing not more than 5 days’ supply; and

(ii) labelled with a recommended daily dose not exceeding 10 mg of cetirizine.

TRANEXAMIC ACID – Amend entry to read:

TRANEXAMIC ACID **except** in preparations containing 3 per cent or less of cetyl tranexamate hydrochloride for dermal cosmetic use.

## SCHEDULE 5 – NEW ENTRIES

PENFLUFEN.

AMINOCYCLOPYRACHLOR.

# PART 5 – THE APPENDICES

## APPENDIX L – NEW ENTRY

**Column 1 Column 2**

**Substance Warning Statement**

Fingolimod. 76

# EDITORIAL AMENDMENTS AND ERRATA

# PART 4 – THE SCHEDULES

## SCHEDULE 2 - AMENDMENT

CICLOPIROX – Amend entry to read:

CICLOPIROX:

1. in preparations for dermal use containing 2 per cent or less of ciclopirox **except** in preparations for the treatment of tinea pedis; or
2. in preparations for application to the nails containing 8 per cent or less of ciclopirox.