



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

POISONS STANDARD AMENDMENT No. 1 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 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 May 2013.

(Signed by)

ANTHONY GILL

Delegate of the Secretary to the Department of Health and Ageing

Dated this 14th day of March 2013

Schedule 1- Amendments to the Poisons Standard 2012

STANDARD
FOR THE
UNIFORM SCHEDULING
OF
MEDICINES AND POISONS

No. 3

AMENDMENT No. 5

Effective Date – 1 May 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 November 2012 and in February and March 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 www.tga.gov.au/industry/scheduling-decisions.htm.

Further inquiries should be directed to:

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

The Secretary to 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 May 2013.

PART 4 – THE SCHEDULES

SCHEDULE 2 – AMENDMENT

DICLOFENAC – Amend entry to read:

DICLOFENAC when:

- (a) in divided preparations for oral use containing 12.5 mg or less of diclofenac per dosage unit in a pack containing 20 or less dosage units and labelled with a recommended daily dose of 75 mg or less of diclofenac;
- (b) in preparations for dermal use containing 4 per cent or less of diclofenac **except** in preparations for dermal use containing 1 per cent or less of diclofenac or for the treatment of solar keratosis; or
- (c) in transdermal preparations for topical use containing 140 mg or less of diclofenac.

SCHEDULE 3 – NEW ENTRY

VITAMIN D for human internal therapeutic use in preparations containing 175 micrograms or less of vitamin D per recommended single weekly dose **except** in preparations containing 25 micrograms or less of vitamin D per recommended daily dose.

SCHEDULE 4 – NEW ENTRIES

ALOGLIPTIN.

BESIFLOXACIN HYDROCHLORIDE.

CANAGLIFLOZIN.

CROFELEMER.

DIMETHYL FUMARATE.

ENOBOSARM.

IVACAFTOR.

MICAFUNGIN.

OLODATEROL.

PASIREOTIDE.

PASIREOTIDE DIASPARTATE.

PRUCALOPRIDE.

RETAPAMULIN.

RETIGABINE.

#SELECTIVE ANDROGEN RECEPTOR MODULATORS (SARM).

TERIFLUNOMIDE.

TILDIPIROSIN.

VILANTEROL.

VILANTEROL TRIFENATATE.

SCHEDULE 4 – AMENDMENT

VITAMIN D – Amend entry to read:

VITAMIN D for human internal therapeutic use **except:**

- (a) in preparations containing 25 micrograms or less of vitamin D per recommended daily dose ; or
- (b) when included in Schedule 3.

SCHEDULE 5 – NEW ENTRY

CYANTRANILIPROLE.

SCHEDULE 6 – NEW ENTRY

THYMOL when packed and labelled for the control of *Varroa* mites in bee hives.

PART 5 – THE APPENDICES

APPENDIX C – NEW ENTRIES

CARBAMIDE PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 18 per cent of carbamide peroxide **except** in preparations manufactured for, and supplied solely by, registered dental practitioners as part of their dental practice.

HYDROGEN PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide **except** in preparations manufactured for and supplied solely by registered dental practitioners as part of their dental practice.

APPENDIX D, PARAGRAPH 5 – NEW ENTRY

SELECTIVE ANDROGEN RECEPTOR MODULATORS (SARM), including those separately specified in Schedule 4.

APPENDIX F, PART 3 – NEW ENTRY

Poison	Warning statement
Teriflunomide	7, 62, 87

APPENDIX K – NEW ENTRY

RETIGABINE

APPENDIX L – NEW ENTRY

Column 1 Substance	Column 2 Warning statement
Teriflunomide.	7, 62 and 87

EDITORIAL AMENDMENTS AND ERRATA

PART 4 – THE SCHEDULES

SCHEDULE 2 - AMENDMENT

FEXOFENADINE – Amend entry to read:

FEXOFENADINE 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:

- (a) in a primary pack containing 10 dosage units or less and not more than 5 days' supply; and
- (b) labelled with a recommended daily dose not exceeding 120 mg of fexofenadine.

SCHEDULE 4 - AMENDMENTS

FEXOFENADINE – Amend entry to read:

FEXOFENADINE **except**:

- (a) 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:
 - (i) in a primary pack containing 10 dosage units or less and not more than 5 days' supply; and
 - (ii) labelled with a recommended daily dose not exceeding 120 mg of fexofenadine.

FORMOTEROL – Amend entry to read:

EFORMOTEROL.

PART 5 – THE APPENDICES

APPENDIX L – AMENDMENTS

Column 1 Substance	Column 2 Warning statement
Acitretin – Amend entry to read: Acitretin:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
Adapalene – Amend entry to read: Adapalene:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
Ambrisentan – Amend entry to read: Ambrisentan	7, 62 and 76
Bexarotene – Amend entry to read: Bexarotene:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77
Bosentan – Amend entry to read: Bosentan	7, 62 and 76
Etretinate – Amend entry to read: Etretinate:	
(i) for oral use.	7, 62 and 76
(ii) for topical use.	62 and 77

Appendix L – Amendments (continued)**Column 1****Substance****Column 2****Warning statement**

Isotretinoin – Amend entry to read:

Isotretinoin:

- | | |
|-----------------------|--------------|
| (i) for oral use. | 7, 62 and 76 |
| (ii) for topical use. | 62 and 77 |

Leflunomide – Amend entry to read:

Leflunomide	7, 62 and 76
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Lenalidomide – Amend entry to read:

Lenalidomide:

- | | |
|-----------------------|--------------|
| (i) for oral use. | 7, 62 and 76 |
| (ii) for topical use. | 62 and 77 |

Sitaxentan – Amend entry to read:

Sitaxentan	7, 62 and 76
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Thalidomide – Amend entry to read:

Thalidomide:

- | | |
|-----------------------|--------------|
| (i) for oral use. | 7, 62 and 76 |
| (ii) for topical use. | 62 and 77 |

Tretinoin – Amend entry to read:

Tretinoin:

- | | |
|-----------------------|--------------|
| (i) for oral use. | 7, 62 and 76 |
| (ii) for topical use. | 62 and 77 |