Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

POISONS STANDARD AMENDMENT No. 4 OF 2011

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 2011 in the manner set out in Schedule 1.

The amendments to the Poisons Standard 2011 as set out in Schedule 1 are taken to have commenced on 1 September 2011.

(signed by)
ANTHONY GILL
Delegate of the Secretary to the Department of Health and Ageing

Dated this 27th day of September 2011

Schedule 1- Amendments to the Poisons Standard 2011

STANDARD FOR THE UNIFORM SCHEDULING OF MEDICINES AND POISONS

No. 2

AMENDMENT No. 2

Effective Date – 1 September 2011

Australian Government

Department of Health and Ageing

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The amendments listed in this document are a result of a decision made by the Secretary of the Department of Health and Ageing or the Secretary's delegate. The basis of these amendments can be found in the 'Reasons for delegate's final decisions', which can be accessed from the scheduling website:

www.tga.gov.au/industry/scheduling-decisions-final.htm

Further inquiries should be directed to:

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PART A – AMENDMENTS TO THE SUSMP NO. 2

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. 2 (SUSMP 2) and recommends that these amendments be adopted by the States and Territories from 1 September 2011.

PART 4 – THE SCHEDULES

SCHEDULE 2 – AMENDMENT

FEXOFENADINE – Amend entry to read:

FEXOFENADINE in preparations for oral use **except** in 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 – AMENDMENT

FEXOFENADINE – Amend entry to read:

FEXOFENADINE **except**:

(a) when included in Schedule 2; or

(b) in preparations 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.