EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Poisons Standard Amendment No. 4 of 2012

The *Therapeutic Goods Act 1989* (the TG Act) provides for the establishment and maintenance of a system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The TG Act also provides for a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and to ensure the safe handling, of poisons in Australia. The Therapeutic Goods Administration (the TGA) is responsible for administering the TG Act.

Subsection 52D(2) of the TG Act authorises the Secretary to the Department of Health and Ageing, or a delegate of the Secretary, to amend the current Poisons Standard (known as the Standard for the Uniform Scheduling of Medicines and Poisons), or to prepare a document (a new Poisons Standard) that includes schedules containing the names or descriptions of substances, in substitution for the current Poisons Standard.

Part 6-3 of the TG Act provides the basis for a uniform system of access controls for goods containing scheduled substances. The scheduling of substances allows restrictions to be placed on their supply to the public, in the interests of public health and safety. The scheduling of substances is aimed at minimising the risks of poisoning from, and the misuse or abuse of, scheduled substances.

The TG Act establishes two expert advisory committees, the Advisory Committee on Medicines Scheduling (the ACMS) (section 52B) and the Advisory Committee on Chemicals Scheduling (the ACCS) (section 52C), which provide advice and make recommendations to the Secretary (or a delegate of the Secretary) on matters relating to medicines and chemicals scheduling decisions.

The Poisons Standard consists of decisions of the Secretary, or a delegate of the Secretary, regarding the classification of poisons into nine different Schedules signifying the degree of control recommended to be exercised over their availability to the public.

The purpose of this instrument is to amend the Poisons Standard 2012. The amendments to the Poisons Standard 2012 set out in Schedule 1 of this instrument consist of decisions made by a delegate of the Secretary. These amendments commence on 22 November 2012.

The Schedules contained in the Poisons Standard are referred to under State and Territory legislation for regulatory purposes. This enables restrictions to be placed on the supply of scheduled substances to the public, according to the degree of risk and the degree of control recommended to be exercised over their availability in the interest of public health and safety.

The Commonwealth also takes into account the scheduling and classification of substances in the Poisons Standard for regulatory and enforcement purposes under the TG Act.

For example, the TG Act and Regulations prohibit the publication of advertisements to consumers about prescription medicines included in Schedule 4 or 8 of the Poisons Standard or over the counter medicines that are included in Schedule 3 and not

included in Appendix H of the Poisons Standard. The advertising of substances included in Schedule 9 or Appendix C of the Poisons Standard is also prohibited.

The amendments to the Poisons Standard 2012 set out in this instrument consist of two editorial amendments to correct errors that were inadvertently made to the Poisons Standard by *Poisons Standard Amendment No. 3 of 2012*, in relation to the scheduling of loratadine.

The amendments in *Poisons Standard Amendment No. 3 of 2012* (which was registered on the Federal Register of Legislative Instruments on 16 August 2012, and commenced on 1 September 2012) were intended to reflect a scheduling decision which was published on the TGA's website (www.tga.gov.au) on 30 May 2012.

That decision exempted from scheduling solid dose oral preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in a primary pack containing 5 dosage units or less and labelled with a recommended daily dose not exceeding 10 mg of loratadine.

Due to a drafting error, the amendment in *Poisons Standard Amendment No. 3 of 2012* did not include wording clarifying that loratadine in *all* preparations for oral use was to be captured in Schedule 2.

As such, the relevant entry inadvertently captured liquid oral preparations in Schedule 4 and only exempted from scheduling solid dose preparations (tablets) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in a primary pack containing 5 dosage units or less and labelled with a recommended daily dose not exceeding 10 mg of loratadine.

This instrument therefore amends the relevant entries in the Poisons Standard 2012 regarding loratadine to make it clear that all preparations for oral use are to be classified as Schedule 2, including liquid preparations, with divided preparations for the treatment of seasonal rhinitis in adults and children 12 years of age and over when in a primary pack containing 5 dosage units or less and labelled with a recommended daily dose not exceeding 10mg of loratadine to be exempt from scheduling.

The decision to amend the Poisons Standard in the manner set out in this instrument was a delegate-only decision. This decision was not considered to require referral to a scheduling advisory committee as it related to an editorial amendment to correct an error. It was also considered to be important to address the inadvertent up-scheduling to Schedule 4 of liquid oral loratadine preparations as soon as possible following the matter coming to the regulator's attention.

Sponsors of affected products, and relevant State and Territory authorities, were contacted as soon as the error was identified, to explain the situation.

The Poisons Standard is a legislative instrument for the purposes of the *Legislative Instruments Act 2003* (the LIA). However, section 42 (disallowance) of the LIA does not apply (refer to subsection 52D(4A) of the TG Act).

As this instrument is not disallowable, subsection 9(1) of the *Human Rights (Parliamentary Scrutiny) Act* 2011 does not require that the instrument be accompanied by a statement of compatibility with the human rights recognised under that Act.