EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Poisons Standard Amendment No. 1 of 2013

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 1 May 2013.

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 the Therapeutic Goods Regulations 1990 (the 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 changes to existing entries, and the inclusion of a number of specified substances in the Poisons Standard for the first time.

A number of these changes were made following the provision of advice from the ACCS and the ACMS, in accordance with the procedures set out in Subdivision 3D.2 of Part 6 of the Regulations for amending the Poisons Standard when a proposed amendment is referred to an expert advisory committee. The Scheduling Policy Framework (SPF) provides guidance to assist delegates in making a decision on whether a matter would benefit from being referred to an advisory committee for advice. A copy of the SPF is available from http://www.tga.gov.au/industry/scheduling-spf.htm.

Public comment was invited on those matters referred to the ACCS and the ACMS, which related to proposals to amend the Poisons Standard in relation to the substances carbamide peroxide, diclofenac, hydrogen peroxide, ostarine, retigabine, selective androgen receptor modulators (SARM), teriflunomide, thymol and vitamin D. The invitation to comment in relation to these substances was advertised on the TGA website (www.tga.gov.au) from 14 August 2012, and closed on 12 September 2012. Public submissions were taken into consideration at the October 2012 meeting of the ACMS. Further public comment was subsequently invited on the delegate's interim decisions in relation to those substances on 7 January 2013, with a closing date of 21 January 2013. The delegate's final decisions in relation to those substances were published on the TGA website on 13 February 2013. The delegate decided that the decisions should commence from 1 May 2013.

Other amendments set out in this instrument added a number of new substances to the Poisons Standard for the first time, including for example alogliptin, besifloxacin hydrochloride, canagliflozin, crofelemer, cyantraniliprole, dimethyl fumarate, ivacaftor, micafungin, olodaterol, pasireotide, pasireotide disaspartate, prucalopride, retapamulin, tildipirosin, vilanterol and vilanterol trifenatate. These decisions were delegate-only decisions that were not open to public consultation, as they were considered (in accordance with the SPF) to be sufficiently straightforward, as not to require public consultation. For some of these previously unscheduled substances, consultation in relation to scheduling was undertaken with the sponsor of the substance. The delegate's final decisions in relation to these matters were published on the TGA website on 13 February 2013 and 6 March 2013. The delegate decided that these decisions should commence from 1 May 2013.

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.