EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Poisons Standard October 2015

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, 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 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 associated with them 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 included in Schedule 3 and not included in

Appendix H of the Poisons Standard. The advertising of substances included in Schedule 9 or Schedule 10/Appendix C of the Poisons Standard is also prohibited.

The purpose of this instrument is to prepare a new Poisons Standard (cited as the Poisons Standard October 2015) in substitution for the previous Poisons Standard. The previous Poisons Standard that is being substituted is the Poisons Standard July 2015 (which commenced on 1 July 2015).

The Poisons Standard October 2015 also incorporates a number of new changes not previously included in the Poisons Standard July 2015. These amendments involve changes to existing entries.

A number of these changes were made following the provision of advice from the ACCS, in accordance with the procedures set out in Subdivision 3D.2 of Part 6 of the *Therapeutic Goods Regulations 1990* 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 expert advisory committee for advice. A copy of the SPF is available from https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals.

Public comment was invited on those matters referred to the March 2013 ACCS meeting, the November 2014 joint meeting of the ACMS and the ACCS and the March 2015 meetings of each of the ACCS and the ACMS. These meetings related to proposals to amend the Poisons Standard in relation to the following substances:

- 2-amino-5-ethylphenol - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 17 October 2013, and closed on 14 November 2013;
- 1-Butanol - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 25 September 2014, and closed on 23 October 2014;
- 1-Propanol - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 25 September 2014, and closed on 23 October 2014;
- 4-Aminopropiophenone - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 29 January 2015, and closed on 27 February 2015;
- Flupyradifurone - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 29 January 2015, and closed on 27 February 2015;
- Metofluthrin - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 29 January 2015, and closed on 27 February 2015;
- Hydrocortisone in combination with aciclovir - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from13 November 2014, and closed on 11 December 2014;

- Ranitidine - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from13 November 2014, and closed on 11 December 2014; and
- Esomeprzaole - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from13 November 2014, and closed on 11 December 2014.

Further public comment was subsequently invited on the delegates' interim decisions on 27 February 2014 with a closing date of 13 March 2014, 5 February 2015 with a closing date of 19 February 2015 and 4 June 2015, with a closing date of 18 June 2015.

The delegates' final decisions in relation to these matters were published on the TGA website on 14 April 2014, 27 March 2015 and 23 July 2015, with the delegate deciding that these decisions should be implemented from 1 February 2015 for 2-amino-5-ethylphenol, and from1October 2015 in the case of each of the other substances mentioned above.

Other amendments set out in this instrument added a number of new substances to the Poisons Standard for the first time, including cholic acid, dinotefuran, ibrutinib, levomilnacipran, milnacipran, naloxegol and netupitant, and changes to the entry in the Poisons Standard for pyriofenone.

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 to not require public consultation. For some of these previously unscheduled substances, consultation in relation to scheduling was undertaken with the sponsor of the substance.

The Poisons Standard October 2015 also includes a small number of editorial amendments in accordance with the recommendations of the Australian Health Ministers' Advisory Council (AHMAC) Out of Session item 645 titled Uniform controls on Poisons on 7 August 2014.

These decisions were not open to public consultation, as they were considered, in accordance with the SPF, to be sufficiently straightforward as to not require public consultation.

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.

The instrument commences on 1 October 2015.