# EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

*Poisons Standard June 2016*

The *Therapeutic Goods Act 1989* (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 medicines and poisons in Australia. The Therapeutic Goods Administration (TGA) is responsible for administering the TG Act.

Subsection 52D(2) of the TG Act provides for 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 the 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 over their availability, in to 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 of the Poisons Standard is also prohibited.

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.

The purpose of this instrument is to prepare a new Poisons Standard (cited as the Poisons Standard June 2016) in substitution for the previous Poisons Standard. The previous Poisons Standard that is being substituted is the Poisons Standard March 2016 (which commenced on 1 March 2016).

The Poisons Standard June 2016 incorporates a number of new changes to the Poisons Standard March 2016. These amendments principally involve 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/or the ACMS, 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.

Public comment was invited on those matters referred to the August 2015 and November 2015 ACCS meetings, the November 2015 and March 2016 ACMS meetings and the August 2015 joint meeting of both the ACMS and the ACCS. These meetings related to proposals to amend the Poisons Standard in relation to the following substances:

- Methylisothiazolinone (MI) - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 27 May 2015, and closed on 25 June 2015.
- Methylchloroisothiazolinone (MCI) - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 27 May 2015, and closed on 25 June 2015.
- 4-Amino-*m*-cresol - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 27 May 2015, and closed on 25 June 2015.
- 4-Amino-2-hydroxytoluene - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 27 May 2015, and closed on 25 June 2015.
- 2-Amino-6-chloro-4-nitrophenol - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 27 May 2015, and closed on 25 June 2015.
- Amisulbrom - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 1 October 2015, and closed on 29 October 2015.

- 1,3-Dichloropropene - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 1 October 2015, and closed on 29 October 2015.
- C.I. Direct Orange 1 - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 1 October 2015, and closed on 29 October 2015.
- A list of Azo dyes that may release carcinogenic aromatic amines by azo reduction - the invitation to comment in relation to these substances was advertised on the TGA website (www.tga.gov.au) from 1 October 2015, and closed on 29 October 2015.
- Isethionate - the invitation to comment in relation to these substances was advertised on the TGA website (www.tga.gov.au) from 1 October 2015, and closed on 29 October 2015.
- 1-(1,1-Dimethylethyl)-2-methoxy-4-methyl-3,5-dinitrobenzene (musk ambrette) - the invitation to comment in relation to these substances was advertised on the TGA website (www.tga.gov.au) from 1 October 2015, and closed on 29 October 2015.
- Oxathiapiprolin - the invitation to comment in relation to these substances was advertised on the TGA website (www.tga.gov.au) from 1 October 2015, and closed on 29 October 2015.
- Topramezone - the invitation to comment in relation to these substances was advertised on the TGA website (www.tga.gov.au) from 1 October 2015, and closed on 29 October 2015.
- Naproxen - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 6 August 2015, and closed on 3 September 2015.
- Lansoprazole, omeprazole and rabeprazole - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 1 October 2015, and closed on 29 October 2015.
- Flubromazolam - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 1 October 2015, and closed on 29 October 2015.
- Performance and image enhancing drugs: Thymosin Beta 4 (Thymosin β4), TB-500 and Fibroblast growth factors - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 1 October 2015, and closed on 29 October 2015.
- Paracetamol - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 6 August 2015, and closed on 3 September 2015.

Further public comment was subsequently invited on the delegates' interim decisions on these items either on 1 October 2015 with a closing date of 15 October 2015 and 3 February 2016 with a closing date of 18 February 2016, or 5 April 2016 with a closing date of 19 April 2016.

The delegates' final decisions in relation to these matters were published on the TGA website on 19 November 2015, 8 December 2015, 17 March 2016 and 16 May 2016 with the delegate deciding that these decisions should be implemented from 1 June 2016 in the case of each of the 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 Selexipag, Vorapaxar, Alirocumab, Elbasvir, Grazoprevir, Hexyl Aminolevulinate (as hydrochloride), Idarucizumab, Lesinurad and Ranolazine and changes to the entry in the Poisons Standard for Clothianidin, Cloquintocet acid, Sarolaner and Mandestrobin.

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 June 2016 also includes a number of editorial amendments, including corrections of typographical errors and amendments to update the names of various medicines and chemicals listed on the TGA's website (www.tga.gov.au) to bring those more into line with the names used for those substances internationally (https://www.tga.gov.au/updating-medicine-ingredient-names). For example:

- Amphetamine was replaced with Amfetamine;
- Oestrogens was replaced with Estrogens;
- Trimeprazine was replaced with Alimemazine; and
- Epinephrine was replaced with Adrenaline (Epinephrine).

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 June 2016.