

EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Poisons Standard October 2016

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 state and territory governments 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 (**the TGA**), which is part of the Department of Health, is responsible for administering the TG Act.

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.

Subsection 52D(2) of the TG Act (which is in Part 6-3) provides for the Secretary of the Department of Health, 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.

The Poisons Standard consists of decisions 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 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 on matters relating to medicines and chemicals scheduling decisions.

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 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 prohibits the publication or broadcasting of advertisements to consumers about prescription medicines containing substances included in

Schedule 4 or 8 of the Poisons Standard, or over the counter medicines containing substances 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 (the SPF)* provides guidance on whether a decision concerning the Poisons Standard would benefit from being referred to ACMS or ACCS for advice. A copy of the SPF can be found at <https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals>.

The purpose of this instrument is to make a new Poisons Standard (cited as the Poisons Standard October 2016) in substitution for the previous Poisons Standard - the Poisons Standard July 2016 (which commenced on 1 July 2016).

The Poisons Standard October 2016 incorporates a number of changes to the Poisons Standard July 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.1 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 November 2015 ACCS meeting, the March 2016 ACMS and ACCS meetings, and the March 2016 joint meeting of the ACMS and the ACCS. These meetings related to proposals to amend the Poisons Standard in relation to the following substances:

- 4-Amino-3-nitrophenol
- 2,6-Dimethoxy-3,5-pyridinediamine
- p-Methylaminophenol
- 1,5-Naphthalenediol
- 2,7-Naphthalenediol
- 1-Naphthol

(the invitation to comment in relation to the six above substances was advertised on the TGA website (www.tga.gov.au) from 9 October 2015 and closed on 29 October 2015);

- Loratadine
- Paracetamol

(the invitation to comment in relation to the two above substances was advertised on the TGA website (www.tga.gov.au) from 11 November 2015 and closed on 10 December 2016);

- Basic Blue 26
- Benzodiazepine derivatives: dicyclazepam; pyrazolam; clonazepam; deschloroetizolam; flubromazepam; nifoxipam and meclonazepam
- 2-Chloro-5-nitro-N-hydroxyethyl-p-phenylenediamine
- Chrysoidine base
- Crystal Violet

- 2,4-Diamino-5-methylphenetole
- Disperse Yellow 3
- Fluopicolide
- Gentian Violet
- Isopyrazam
- *Lasiodiplodia pseudotheobromae*
- *Macrophomina phaseolina*
- Methylidibromo glutaronitrile
- Methylrosanilinium chloride
- *Neoscytalidium novaehollandiae*
- Potassium hydroxide
- Sodium hydroxide
- *Streptomyces lydicus* WYEC 108
- *Symphytum spp* (comfrey)

(the invitation to comment in relation to the above nineteen substances was advertised on the TGA website (www.tga.gov.au) from 20 January 2016 and closed on 18 February 2016).

Further public comment was subsequently invited on the delegates' interim decisions on 3 February 2016 with a closing date of 18 February 2016, or on 12 May 2016 with a closing date of 26 May 2016.

The delegates' final decisions in relation to these matters were published on the TGA website on 17 March 2016 and 23 June 2016, with the delegate deciding that each of these decisions should be implemented from 1 October 2016.

Other amendments set out in this instrument added a number of new substances to the Poisons Standard for the first time, ixekizumab, *Phleum pratense* pollen extract (timothy-grass pollen extract), velpatasvir, deoxycholic acid, pirfenidone and cyclaniliprole.

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 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/updates/medicine-ingredient-names>). For example:

- Amethocaine was replaced with tetracaine; and
- Amylobarbitol was replaced with amobarbital.

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). Because it 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 2016, which means the Poisons Standard October 2016 is effective on and from that day.