

EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Poisons Standard Amendment No. 1 of 2014

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 purpose of this instrument is to amend the Poisons Standard 2013. The amendments to the Poisons Standard 2013 set out in Schedule 1 of this instrument consist of decisions made by a delegate of the Secretary. These amendments commence on 1 February 2014.

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 Appendix C of the Poisons Standard is also prohibited.

The amendments to the Poisons Standard 2013 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 ACMS and 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 <http://www.tga.gov.au/industry/scheduling-spf.htm>.

Public comment was invited on those matters referred to the ACMS, the ACCS and a joint meeting of the ACCS and the ACMS, which related to proposals to amend the Poisons Standard in relation to the following substances:

- Adrenaline, bupivacaine and lignocaine - the invitation to comment in relation to these substances was advertised on the TGA website (www.tga.gov.au) from 29 November 2012, and closed on 17 January 2013;
- Lurasidone - the invitation to comment in relation to this substance was advertised on the TGA website (www.tga.gov.au) from 24 April 2013, and closed on 23 May 2013; and
- 1,2-benzenediol (catechol), 3-iodo-2-propynyl, butyl carbamate (iodocarb), cocoyl glycinate, deltamethrin, hexyloxyethanol, hydroquinone, monobenzene and pradofloxacin - the invitation to comment in relation to these substances was advertised on the TGA website (www.tga.gov.au) from 13 June 2013, and closed on 11 July 2013.

Public submissions in relation to adrenaline, bupivacaine and lignocaine were taken into consideration at the March 2013 joint meeting of the ACCS and the ACMS. Further public comment was subsequently invited on the delegate's interim decisions on 23 May 2013, with a closing date of 6 June 2013. The delegate's final decisions in relation to these matters were published on the TGA website on 27 June 2013.

The delegates decided that these decisions should be implemented from 1 February 2014.

Public submissions in relation to other substances were taken into consideration at the July 2013 meetings of the ACCS, the ACMS and a joint meeting of the ACCS and the ACMS. Further public comment was subsequently invited on the delegate's interim decisions on 26 September 2013, with a closing date of 14 October 2013. The delegate's final decisions in relation to these matters were published on the TGA website on 31 October 2013.

In each case, the delegate decided that these decisions should be implemented from 1 February 2014.

Other amendments set out in this instrument added the new substances afatinib dimaleate, dabrafenib mesilate, dolutegravir, mirabegron, ocriplasmin, pradofloxacin, romidepsin, trametinib dimethyl sulfoxide, trastuzumab emtansine, tylosin, vedolizumab and vortioxetine to the Poisons Standard for the first time, and made editorial changes to the entries in the Poisons Standard for besifloxacin, loteprednol, pasireotide, vilanterol and bistrifluron.

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 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.