

## EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

*Poisons Standard 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 2015) in substitution for the previous Poisons Standard. The previous Poisons Standard that is being substituted is the Poisons Standard 2014 (which was registered on the Federal Register of Legislative Instruments on 10 October 2014).

The Poisons Standard 2015 also incorporates a number of new changes to the Poisons Standard 2014. These amendments principally involve changes to existing entries, and the inclusion of a small 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 ACMS and the ACCS, which related to proposals to amend the Poisons Standard in relation to the following substances:

- Calcium hydroxylapatite - the invitation to comment in relation to this substance was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 29 May 2014, and closed on 26 June 2014;
- Macitentan - the invitation to comment in relation to this substance was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 29 May 2014, and closed on 26 June 2014;
- Polycaprolactone - the invitation to comment in relation to this substance was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 29 May 2014, and closed on 26 June 2014;
- Riociguat - the invitation to comment in relation to this substance was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 29 May 2014, and closed on 26 June 2014;
- Suvorexant - the invitation to comment in relation to this substance was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 29 May 2014, and closed on 26 June 2014;
- Triethanolamine - the invitation to comment in relation to this substance was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 29 May 2014, and closed on 26 June 2014;
- Metofluthrin - the invitation to comment in relation to this substance was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 29 May 2014, and closed on 26 June 2014;

- Fosthiazate - the invitation to comment in relation to this substance was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 29 May 2014, and closed on 26 June 2014;
- Phenylenediamines - the invitation to comment in relation to this substance was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 29 May 2014, and closed on 26 June 2014;
- 1,2-Benzenediamine - the invitation to comment in relation to this substance was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 29 May 2014, and closed on 26 June 2014;
- 1,3-Benzenediamine - the invitation to comment in relation to this substance was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 29 May 2014, and closed on 26 June 2014;
- 2,4-Toluenediamine- the invitation to comment in relation to this substance was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 29 May 2014, and closed on 26 June 2014; and
- Cocoyl Glycinate - the invitation to comment in relation to this substance was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 13 June 2013, and closed on 11 July 2013.

Public submissions in relation to these substances were taken into consideration at the meetings of the ACCS, the ACMS and a joint meeting of the ACMS and the ACCS, in July 2014. Further public comment was subsequently invited on the delegates' interim decisions on 18 September 2014 (with a closing date of 2 October 2014), 30 September 2014 (with a closing date of 14 October 2014), and 14 November 2014 (with a closing date of 28 November 2014).

The delegates' final decisions in relation to these matters were published on the TGA website on 23 and 28 October 2014, and 17 and 24 December 2014.

Public submissions in relation to cocoyl glycinate were taken in to consideration at the July 2013 ACCS meeting. Further public comment was subsequently invited on the delegates' interim decision on 26 September 2013 with a closing date of 14 October 2013. The delegates' final decision was published on the TGA website on 8 November 2013.

Other amendments set out in this instrument added a number of new substances to the Poisons Standard for the first time, including benamustine, bosutinib, brentuximab, carglumic acid, elosulfase alfa, fluralaner, macitentan, oclacitinib, pyriofenone, riociguat, simoctocog alfa and suvorexant.

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 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 amendments are:

- renaming Part 2 from ‘Labels and Containers’ to ‘Controls on Medicines and Poisons’;
- incorporating Appendix I (‘Uniform Paint Standard’) into Part 2;
- renaming Appendix C as Schedule 10; and
- restructuring Parts 2 and 3 into sections.

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 the day after registration on the Federal Register of Legislative Instruments.