

EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*
 Poisons Standard June 2018

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 (which under Section 2 of the Poisons Standard consists of 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 comprises of decisions of the Secretary (or the Secretary's delegate) 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 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 Schedule 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 June 2018) in substitution for the previous Poisons Standard - the Poisons Standard March 2018 (which commenced on 1 March 2018).

The Poisons Standard June 2018 incorporates a number of changes compared to the Poisons Standard March 2018. 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.

In relation to substances amended or added to the Poisons Standard June 2018, public comment was invited on matters referred to the November 2016 Joint ACMS-ACCS, March 2017 ACCS and the July 2017 Joint ACMS-ACCS meetings, and the November 2017 ACMS, ACCS and Joint ACMS-ACCS meetings, as follows:

- Invitation to comment in relation to cannabis was advertised on the TGA website on 22 September 2016 at <https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-joint-accs-and-acms-meeting-november-2016> with a closing date of 20 October 2016.
- Invitation to comment in relation to climbazole was advertised on the TGA website on 22 December 2016 at <https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-accs-acms-and-joint-accsacms-meetings-march-2017> with a closing date of 10 February 2017.
- Invitation to comment in relation to *m*-aminophenol, 2-chloro-6-(ethylamino)-4-nitrophenol and 2,4-diaminophenoxy-ethanol was advertised on the TGA website on 3 February 2017 at <https://www.tga.gov.au/consultation-invitation/consultation-further-proposed-amendments-poisons-standard-joint-accs-and-acms-meeting-and-accs-meeting-march-2017> with a closing date of 3 March 2017.
- Invitation to comment in relation to chloroacetamide was advertised on the TGA website on 17 May 2017 at <https://www.tga.gov.au/consultation->

[invitation/consultation-proposed-amendments-poisons-standard-accs-acms-and-joint-accsacms-meetings-july-2017](https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-accs-acms-and-joint-accsacms-meetings-july-2017) with a closing date of 15 June 2017.

- Invitation to comment in relation to cardarine, stenabolic (SR9009) and other synthetic REV-ERB agonists, ibutamoren, cathinones, methydone (MDMC), alpha-pyrrolidinovalerophenone (alpha-PVP), melanotan II, cimicoxib, fluralaner, metofluthrin, alpha-cypermethrin, silver oxide, dinotefuran and afidopyropen was advertised on the TGA website on 6 September 2017 at <https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-accs-acms-and-joint-accsacms-meetings-november-2017> with a closing date of 6 October 2017.

Further public comment was subsequently invited on the delegates' interim decisions on: 2 February 2017 at <https://www.tga.gov.au/scheduling-decision-interim/scheduling-delegates-interim-decisions-and-invitation-further-comment-accsacms-november-2016> with a closing date of 16 February 2017, 17 May 2017 at <https://www.tga.gov.au/scheduling-decision-interim/scheduling-delegates-interim-decisions-and-invitation-further-comment-accsacms-march-2017> with a closing date of 31 May 2017, 15 September 2017 at <https://www.tga.gov.au/scheduling-decision-interim/scheduling-delegates-interim-decisions-and-invitation-further-comment-accsacms-march-and-july-2017> with a closing date of 3 October 2017 and 5 February 2018 at <https://www.tga.gov.au/scheduling-decision-interim/scheduling-delegates-interim-decisions-and-invitation-further-comment-accsacms-november-2017> with a closing date of 5 March 2018.

The delegates' final decisions in relation to these matters were published on the TGA website on: 23 March 2017 at <https://www.tga.gov.au/scheduling-decision-final/scheduling-delegates-final-decisions-march-2017>; 29 June 2017 at <https://www.tga.gov.au/scheduling-decision-final/scheduling-delegates-final-decisions-june-2017>; 31 October 2017 at <https://www.tga.gov.au/scheduling-decision-final/scheduling-delegates-final-decisions-october-2017>; and 10 April 2018 at <https://www.tga.gov.au/scheduling-decision-final/final-decisions-amending-or-not-amending-current-poisons-standard-april-2018>.

Other amendments set out in this instrument added a number of new substances to the Poisons Standard for the first time: atezolizumab, avelumab, baricitinib, benralizumab, blinatumomab, cerliponase alfa, daratumumab, durvalumab, etofenprox, glecaprevir, idebenone, inotuzumab ozogamicin, lifitegrast, metamitron, midostaurin, neratinib, nivolumab, obeticholic acid, olaratumab, palbociclib, pegaspargase, pibrentasvir, ramucirumab, rufinamide, secukinumab, siltuximab, tezacaftor and voxilaprevir. The Appendix B entry for *Bacillus amyloliquefaciens* was also amended. 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.

The Poisons Standard is a legislative instrument for the purposes of the *Legislation Act 2003* (the LA). However, section 42 (disallowance) of the LA 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 June 2018, which means the Poisons Standard June 2018 is effective on and from that day.