

EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*
 Poisons Standard October 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 October 2018) in substitution for the previous Poisons Standard - the Poisons Standard June 2018 (which commenced on 1 June 2018).

The Poisons Standard October 2018 incorporates a number of changes compared to the Poisons Standard June 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 October 2018, public comment was invited on matters referred to the March 2018 ACCS, ACMS and Joint ACMS-ACCS meetings, November 2017 ACMS, ACCS and Joint ACMS-ACCS meetings, July 2017 Joint ACMS-ACCS, March 2017 ACCS, and the November 2016 Joint ACMS-ACCS meetings, as follows:

- Invitation to comment in relation to eprinomectin, moxidectin, mefentrifluconazole, vinyl acetate, diclofenac, fluticasone and cannabidiol was advertised on the TGA website on 21 December 2017 at <https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-accs-acms-and-joint-accs-acms-meetings-march-2018>, with a closing date of 2 February 2018; and
- Invitation to comment in relation to quinine and its salts 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>, with a closing date of 15 June 2017.

Further public comment was subsequently invited on the delegates' interim decisions on 7 June 2018 at <https://www.tga.gov.au/scheduling-decision-interim/publication-interim-decisions-amending-or-not-amending-current-poisons-standard-june-2018>, with a closing date of 5 July 2018, and on 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.

The delegates' final decisions in relation to these matters were published on the TGA website on 23 August 2018 at <https://www.tga.gov.au/scheduling-decision-final/scheduling-delegates-final-decisions-march-2017>, and 31 October 2017 at <https://www.tga.gov.au/scheduling-decision-final/scheduling-delegates-final-decisions-october-2017>.

Other amendments set out in this instrument added a number of new substances to the Poisons Standard for the first time - *Cyprinid herpesvirus-3*, safinamide and tilmanocept. A new Appendix K entry for sodium oxybate was also created. 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.

Appendix J has also been updated. The Australian Health Ministers' Advisory Council (AHMAC) endorsed the updates to Appendix J on 8 December 2017. These updates were recommended by the Interjurisdictional Working Group Poisons Control (IJWGPC). The IJWGPC was established by AHMAC to implement a national approach to poisonous chemical controls prepared in response to recommendation 5.2 of the 2008 Productivity Commission Research Report on Chemicals and Plastics Regulation. This Report required that State and Territory Governments uniformly adopt regulatory controls over poisons through either a template or model approach, as published in the Poisons Standard. The review of Appendix J completes the actions that were agreed to by AHMAC on 8 March 2013 to achieve national consistency of controls on poisons. As part of the Appendix J review, the IJWGPC examined the contemporary use patterns and availability of the Schedule 7 poisons listed in Appendix J. The IJWGPC consulted widely and subsequently recommended a number of proposals to update Appendix J and facilitate consistent controls over the availability and use of the high risk poisons listed in Appendix J. Most of these recommendations were therefore progressed as delegate-only decisions that were not open to a second round of public consultation due to the extensive consultation already carried out by the IJWGPC.

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 October 2018, which means the Poisons Standard October 2018 is effective on and from that day.