

## **EXPLANATORY STATEMENT**

Subject: *Therapeutic Goods Act 1989*  
*Poisons Standard February 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 (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 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 February 2018) in substitution for the previous Poisons Standard - the Poisons Standard October 2017 (which commenced on 1 October 2017).

The Poisons Standard February 2018 incorporates a number of changes compared to the Poisons Standard October 2017. 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.

Public comment was invited on matters referred to the July 2015 ACMS, March 2016 ACMS, July 2016 ACMS, and July 2017 ACMS, ACCS & Joint ACCS-ACMS meetings as follows:

- Invitation to comment in relation to codeine was advertised on the TGA website on two occasions: 1 April 2015 at <https://www.tga.gov.au/consultation-invitation/consultation-invitation-public-comment-acms-meeting-july-2015> with a closing date of 7 May 2015; and 10 December 2015 at <https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-codeine> with a closing date of 29 January 2016.
- Invitation to comment in relation to ulipristal was advertised on the TGA website on 7 April 2016 at <https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-acms-meeting-july-2016>) with a closing date of 6 May 2016.
- Invitation to comment in relation to esomeprazole, epidermal growth factor, Stiripentol, phenibut, vaccines - plasmid DNA, isofetamid, pydiflumetofen, *Duddingtonia flagrans* Strain IAH 1297, lambda-cyhalothrin, *Bacillus amyloliquefaciens* Strain QST 713, butyl benzyl phthalate and basic red 76 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: 1 October 2015 at <https://www.tga.gov.au/scheduling-decision->

[interim/scheduling-delegates-interim-decisions-and-invitation-further-comment-acms-october-2015](https://www.tga.gov.au/scheduling-delegates-interim-decisions-and-invitation-further-comment-acms-october-2015) with a closing date of 15 October 2015; 15 September 2016 at <https://www.tga.gov.au/scheduling-decision-interim/scheduling-delegates-interim-decisions-and-invitation-further-comment-accsacms-july-2016> with a closing date of 29 September 2016; and 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 dates of 3 October 2017.

The delegates' final decisions in relation to these matters were published on the TGA website on: 20 December 2016 at <https://www.tga.gov.au/scheduling-decision-final/scheduling-delegates-final-decision-codeine-december-2016>; 27 October 2016 at <https://www.tga.gov.au/scheduling-decision-final/scheduling-delegates-final-decisions-july-2016>; and 31 October 2017 at <https://www.tga.gov.au/scheduling-decision-final/scheduling-delegates-final-decisions-october-2017>; with the delegate deciding that each of these decisions should be implemented from 1 February 2018.

Other amendments set out in this instrument added a number of new substances to the Poisons Standard for the first time: alectinib, bictegravir, binimetinib, cabozantinib, cinnarizine, encorafenib, erenumab, ertugliflozin, ferric derisomaltose, florpyrauxifen-benzyl, insulin degludec, letermovir, lotilaner, nusinersen, patiromer sorbitex calcium, peramivir, reslizumab, ribociclib, stiripentol, tafenoquine succinate, telotristat ethyl, tipiracil, trifluridine, recombinant varicella zoster virus glycoprotein E antigen and apalutamide. 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 February 2018, which means the Poisons Standard February 2018 is effective on and from that day.