EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Poisons Standard February 2019

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act also provides a framework for 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 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 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 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 Act.

For example, the Act prohibits the publication or broadcasting of advertisements to consumers about prescription medicines containing substances included in Schedule 4 or Schedule 8 to 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 (the *Poisons Standard February 2019*) in substitution for the previous Poisons Standard - the *Poisons Standard October 2018* (which commenced on 1 October 2018, and is repealed by this new Poisons Standard).

The *Poisons Standard February 2019* incorporates a number of changes compared to the *Poisons Standard October 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 in, or added to, the *Poisons Standard February 2019*, public comment was invited on matters referred to the March and July 2017 Joint ACCS-ACMS meeting, the June 2018 ACMS meeting, and the June 2018 Joint ACMS-ACCS meeting, as follows:

- Invitation to comment in relation to resorcinol was advertised on the TGA website (www.tga.gov.au) on 3 February 2017, with a closing date of 3 March 2017; and
- Invitation to comment in relation to budesonide, 2-Butoxyethanol, dimethyl sulfoxide, aliphatic allyl esters and astodrimer sodium was advertised on the TGA website on 12 April 2018, with a closing date of 10 May 2018.

Further public comment was subsequently invited on the delegates' interim decisions on 17 May 2017, with a closing date of 31 May 2017, and on 10 September 2018, with a closing date of 11 October 2018.

The delegates' final decisions in relation to these matters were published on the TGA website on 31 October 2017 and 29 November 2018.

Other amendments set out in this instrument added a number of substances to the Poisons Standard for the first time – brigatinib, crisaborole, lanadelumab, romosozumab and benzovindiflupyr. In addition, an amendment was made to the current entry for dicyclanil, and editorial amendments were made to the current entries for fluralaner, 2-phenoxyethanol and triple antigen. 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.

A further set of delegate-only decisions were also incorporated in the *Poisons Standard February 2019* to include 18 Schedule 3 substances in Appendix H for the first time. Until 2018 substances in Schedule 3 were not included in Appendix H, unless an adequate justification was presented as to the reasons for including the substance in Appendix H.

The SPF, which was updated in 2018, states that Schedule 3 substances will be included in Appendix H unless it is determined that advertising is not appropriate for a particular substance (Scheduling Policy Framework, 2018). This change to the SPF was introduced in response to the following recommendation of the 2015 Expert Review of Medicines and

Medical Devices Regulation (MMDR; http://www.health.gov.au/internet/main/publishing.nsf/content/expert-review-of-medicines-and-medical-devices-regulation#recommendations):

> **Recommendation Twelve**
>
> The Panel recommends that the *Schedule 3 Advertising Guidelines* be reviewed, in consultation with State and Territory Governments, and in concert with the review of the *Scheduling Policy Framework,* to:
>
> 1. Provide for the development and adoption of a formal risk-benefit methodology for the assessment of Schedule 3 substances for inclusion on Appendix H of the *Poisons Standard;* and
> 2. Identify synergies between application requirements for re-scheduling and for inclusion of a Schedule 3 substance on Appendix H, so as to streamline these processes and reduce duplication.

To facilitate the transition of substances to Appendix H, a consultation paper inviting comments on proposals to add a number of Schedule 3 substances to Appendix H of the Poisons Standard was published on the TGA website on 4 June 2018, and closed on 9 July 2018. This consultation was the culmination of input from stakeholders at targeted consultation activities held at the TGA in February and March of 2018, and led to the development of draft Guidelines for advertisements for medicines containing Schedule 3 Substances.

Following the consultation, a delegate-only decision was made to include adrenaline, ciclopirox, clobetasone, famciclovir, fluorides, glucagon, isoconazole, ketoprofen, levonorgestrel, naloxone, oxiconazole, paracetamol, podophyllotoxin, podophyllum emodi, podophyllum peltatum, salicylic acid, tioconazole and triamcinolone in Appendix H, thereby permitting the publication or broadcasting of advertisements to consumers about Schedule 3 medicines containing these substances.

The *Poisons Standard February 2019* also introduces Appendix M to the Poisons Standard for the first time. This Appendix is intended to facilitate the down-scheduling of substances from Schedule 4 to Schedule 3 where, for example, there is a community need for access to a medicine that has previously only been accessible with a prescription, but where it is considered that additional controls and oversight by a dispensing pharmacist are needed, in the interests of protecting public health. No substances have been included in Appendix M in the *Poisons Standard February 2019*. As required in the *Scheduling Policy Framework*, any proposals for the inclusion of substances in Appendix M will be referred to ACMS for its expert advice, and will also undergo public consultation.

The *Poisons Standard February 2019* 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 *Poisons Standard February 2019* commences on 1 February 2019.