EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Poisons Standard June 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 Act is administered by the Therapeutic Goods Administration ("the TGA"), within the Department of Health.

Part 6-3 of the Act (sections 52AA to 52EC) 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 empowers the Secretary to amend the current Poisons Standard (which consists of the Standard for the Uniform Scheduling of Medicines and Poisons (section 2 of the Poisons Standard refers)) 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 reflects decisions of the Secretary (or the Secretary's delegate) regarding the classification of medicines and poisons into the different Schedules, signifying the degree of risk and the 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 of the Act refers) and the Advisory Committee on Chemicals Scheduling ("the ACCS") (section 52C of the Act refers), 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 the substances and the level of control recommended 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.

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The *Scheduling Policy Framework* ("the SPF") provides guidance on whether a decision concerning the scheduling of substances under 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 June 2019*, in substitution for the previous Poisons Standard, the *Poisons Standard February 2019* (which commenced on 1 February 2019, and which is repealed and replaced by this new Poisons Standard).

The *Poisons Standard June 2019* incorporates a number of changes compared to the *Poisons Standard February 2019*. 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 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 amendments made to existing entries in, or substances added to, the *Poisons Standard June 2019*, public comment was invited on matters referred to the November 2017 Joint ACCS-ACMS meeting, the November 2017 ACCS meeting, the November 2018 Joint ACCS-ACMS meeting, the November 2018 ACMS meeting and the November 2018 ACCS meeting, as follows:

- the invitation to comment in relation to polihexanide and phenyl methyl pyrazolone was advertised on the TGA website on 6 September 2017, with a closing date of 6 October 2017;
- a further public comment was subsequently invited on the delegates' interim decision on 5 February 2018;
- the invitation to comment in relation to nabiximols, racetams, naphthalene, salts of boric acid, atranol and chloratranol, solvent yellow 33 and 2-chloro-p-phenylenediamine was advertised on the TGA website on 31 August 2018, with a closing date of 28 September 2018; and
- a further public comment was subsequently invited on the delegates' interim decisions on 10 September 2018.

The delegates' final decisions in relation to polihexanide and phenyl methyl pyrazolone were published on the TGA website (www.tga.gov.au) on 10 April 2018, together with two delegate-only decisions that related to agricultural and veterinary chemicals *N,N*-Dimethyloctanamide and *N,N* dimethyldecanamide.

The delegates' final decisions in relation to nabiximols, racetams, naphthalene, salts of boric acid and 2-chloro-p-phenylenediamine were published on the TGA website (www.tga.gov.au) on 26 April 2019. The delegates' final decisions in relation to atranol and chloratranol and solvent yellow 33 were deferred until further notice pending the completion of a review of cosmetic chemical and fragrance ingredients.

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A number of delegate-only decisions that related to agricultural and veterinary chemicals, including grapiprant, spiropidion, tiafenacil, sodium salicylate, lidocaine, bupivacaine and 6-benzyladenine, were published on the TGA website (www.tga.gov.au) on 14 May 2019.

The amendments set out in this instrument added a number of new substances to the Poisons Standard for the first time. These included a number of specific entries for racetams, phenyl methyl pyrazolone, *N,N*-dimethyloctanamide, *N,N*-dimethyldecanamide, galcanezumab, doravirine, abemaciclib, plitidepsin, isavuconazole, semaglutide, cenegermin, grapiprant, spiropidion and tiafenacil.

A small number of technical amendments that did not involve moving substances from one schedule to another were also made to the current entries for the agricultural veterinary chemicals sodium salicylate, lidocaine, bupivacaine and 6-benzyladenine.

A small number of minor amendments were also included in this instrument, including for example editorial amendments to the current entries for hydrofluoric acid, temazepam, midazolam, selexipag and sucroferric oxyhydroxide.

The decisions to introduce the new substances and to make the technical and minor amendments outlined above 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 June 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 Act). As 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 June 2019* commences on 1 June 2019.

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