EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Poisons Standard February 2020

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 Australian Government 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 a delegate of the Secretary 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 ("ACMS") (section 52B of the Act refers) and the Advisory Committee on Chemicals Scheduling ("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.

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 February 2020*, in substitution for the previous Poisons Standard, the *Poisons Standard December 2019* (which commenced on 1 December 2019, and which is repealed and replaced by this new Poisons Standard).

The *Poisons Standard February 2020* incorporates a number of changes compared to the *Poisons Standard December 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 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 amendments made to existing entries that are reflected in the *Poisons Standard February 2020*, public comment was invited on matters referred to the June 2018 ACMS meeting, June 2019 ACMS meeting and June 2019 ACCS meeting as follows:

- the invitation to comment in relation to alkyl nitrites was advertised on the TGA website on 12 April 2018, with a closing date of 10 May 2018;
- the invitation to comment in relation to 1,4-dimethylpentylamine (DMPA), phenpromethamine and sanguinarine was advertised on the TGA website on 11 April 2019, with a closing date of 13 May 2019; and
- the invitation to comment in relation to broflanilide, saflufenacil, sarolaner and trifludimoxazin was advertised on the TGA website on 24 April 2019, with a closing date of 24 May 2019.

The delegates' final decisions were published on the TGA website in relation to:

- alkyl nitrites on 6 June 2019;
- broflanilide 1,4-dimethylpentylamine (DMPA), phenpromethamine, saflufenacil, sanguinarine, sarolaner and trifludimoxazin on 28 November 2019; and
- a number of delegate-only decisions related to agricultural and veterinary chemicals, including bixlozone, metcamifen, polyacrylamide and thymol on 28 November 2019.

The *Poisons Standard February 2020* also incorporates the introduction of a number of new substances to the Poisons Standard for the first time. These include a number of specific entries for acalabrutinib, alanylglutamine, baloxavir marboxil, enasidenib,

entrectinib, gilteritinib, siponimod, sodium glycerophosphate hydrate, upadacitinib, vonicog alfa and voretigene neparvovec in Schedule 4.

The Appendix K entry for risankizumab was removed as a delegate only decision based on information provided by the applicant.

A small number of minor amendments were also included in this instrument, including editorial amendments to the current entries for methylchloroisothiazolinone, methylisothiazolinone and mercuric nitrate.

A cross reference was also added to the index entries for 1,4-dimethylpentylamine (DMPA) and alkylamines with stimulant properties for 1,4- dimethylamylamine (DMAA). DMPA is also known as DMAA, however the cross reference was inadvertently omitted from the final decision for DMPA, as an administrative error.

The decisions to introduce the new substances and to make the above technical and minor amendments 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 consultation.

The *Poisons Standard February 2020* 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 February 2020* commences on 1 February 2020.