EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Poisons Standard October 2022

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 and Aged Care.

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 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 incorporated by reference 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.

Similarly, 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 to 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 October 2022*, in substitution for the previous Poisons Standard, the *Poisons Standard June 2022*. The *Poisons Standard October 2022* repeals and replaces the *Poisons Standard June 2022*, principally to incorporate a number of changes to existing entries, and to include a number of specified substances in the Poisons Standard for the first time.

Some 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.

Public comment was invited in relation to the proposed amendments in relation to nitrous oxide that were referred to the March 2021 meeting of the ACMS and ACCS in joint session. An invitation to comment in relation to nitrous oxide was published on the TGA website on 24 December 2020, with a closing date of 27 January 2021. A further invitation to comment in relation to this proposal was published on 30 July 2021, with a closing date of 27 August 2021. The final decision in relation nitrous oxide was published on the TGA website on 8 October 2021.

The *Poisons Standard October 2022* also incorporates eight new substances in the Poisons Standard for the first time: asciminib, faricimab, mobocertinib, osildrostat, pemigatnib, vosoritide, cyclobutrifluram and famoxadone.

The *Poisons Standard October 2022* also incorporates an amendment to the Schedule 4 entry for Vaccines for veterinary live virus to make it clear that bovine herpesvirus-1 vaccine is not covered by that entry.

The decisions to incorporate new substances in the Poisons Standard for the first time, and to make a small number of minor amendments and corrections (including the amendment to the Schedule 4 entry for Vaccines for veterinary live virus to exclude bovine herpesvirus-1 vaccine from that entry), were made as delegate-only decisions in accordance with the SPF. These were considered sufficiently straightforward and did not require public consultation.

The *Poisons Standard October 2022* is a legislative instrument for the purposes of the *Legislation Act 2003*. However, section 42 of the *Legislation Act 2003* relating to disallowance does not apply (subsection 52D(4A) of the Act refers). As the *Poisons Standard October 2022* 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.

In providing that disallowance does not apply to an instrument made under paragraphs 52D(2)(a) or (b) of the Act, subsection 52D(4A) of the Act appropriately recognises that instruments made under these paragraphs form part of an intergovernmental scheme, which should not be subject to unilateral disallowance by the Commonwealth Parliament, consistent with section 44 of the Legislation Act. Under this scheme, the current Poisons Standard principally provides a set of recommendations to the states and territories as to the appropriate level of controls that should apply to medicines and poisons.

The states and territories regulate such substances by electing to apply the current Poisons Standard as a law within their own jurisdiction. In this way, the current Poisons Standard does not have direct application in its own right. If the current Poisons Standard was to be subject to disallowance, this would impact the current uniform system of restrictions in Australia relating to the supply of scheduled substances, and would lead to confusion and different approaches across different states and territories with respect to their handling, storage, possession and supply of scheduled substances.

Further, as inclusion of new medicines in the current Poisons Standard is often a consequence of the granting of marketing approval of new medicines under the Act, it is likely that disallowance would also lead to delays for Australian patients in accessing new and effective treatments.

The *Poisons Standard October 2022* commences on 1 October 2022.