EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Poisons Standard October 2021

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 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.

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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 October 2021*, in substitution for the previous Poisons Standard, the *Poisons Standard June 2021*. The *Poisons Standard October 2021* repeals and replaces the *Poisons Standard June 2021*, 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.

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.

Public comment was invited in relation to the proposed amendments that were referred to the March 2020 ACCS, June 2020 Joint ACMS-ACCS, March 2021 ACCS and March 2021 Joint ACMS-ACCS meetings, as follows:

- an invitation to comment in relation to picramic acid (including its salts) was published on the TGA website on 20 December 2019, with a closing date of 10 February 2020. A further invitation to comment in relation to this proposal was published on 10 June 2020, with a closing date of 9 July 2020; and
- an invitation to comment in relation to nicotine was published on the TGA website on 17 April 2020, with a closing date of 18 May 2020. A further invitation to comment in relation to this proposal was published on 23 September 2020, with a closing date of 12 November 2020; and
- an invitation to comment in relation to lead (in paint), cyflumetofen, isocycloseram, kambo, lidocaine and hemp seed oil 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 these proposals was published on 20 July 2021, with a closing date of 17 August 2021.

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

- picramic acid (including its salts), on 24 August 2020; and
- nicotine, on 21 December 2020; and
- lead (in paint), cyflumetofen, isocycloseram, kambo, lidocaine and hemp seed oil, on 9 September 2021.

Further, minor amendments have been incorporated in the *Poisons Standard October 2021* in relation to bilastine, riociguat and risankizumab. The wording in the Schedule 3 entry for bilastine has been amended to clarify the recommended permitted use for this substance. The Schedule 4 entry for riociguat has been amended to reflect that it is also listed in Appendix D. The Index entry for riociguat has also been amended to reflect that the additional controls on use in Appendix D relate to Part 4 and not Part 5, as previously shown. The Appendix K entry for Risankizumab has been deleted to reflect the delegate's final decision published 14 January 2020.

The *Poisons Standard October 2021* also incorporates a number of new substances to the Poisons Standard for the first time, including specific entries for amifampridine, belumosudil, estetrol monohydrate, finerenone, fostemsavir, inclisiran, pegcetacoplan, pegvaliase, sacituzumab govitecan, sotrovimab, trastuzumab deruxtecan, vericiguat and zanubrutinib in Schedule 4. A number of these substances were also listed in Appendix L, including belumosudil, finerenone and trastuzumab deruxtecan.

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A small number of other, more minor, amendments were also incorporated into the *Poisons Standard October 2021*, principally to clarify the duplicated Appendix F entries for lead compounds in the index.

An amendment has also been incorporated to allow exemptions from the labelling requirements in sections 1.3 to 1.5.3 of Part 2 of Schedule 1 to the current Poisons Standard to be in place for longer than the current 12 months where the exemption relates to a product that is indicated for the treatment or prevention of the disease known as coronavirus disease ("COVID-19"). Under the amendment a labelling exemption for such a product may remain in place for the period specified in the exemption or, where no period is specified, until revoked by the appropriate authority.

This reflects that COVID-19 vaccines and treatments include products manufactured overseas, with overseas labels that may not contain all of the information required under sections 1.3 – 1.5.3. Labelling exemptions made under section 1.5.5 of the Poisons Standard form an important part of ensuring the availability of such products for Australians, supporting the Australian Government's response to the COVID-19 public health emergency. States and territories were consulted and were supportive of this proposal, and did not raise any concerns with the amendment.

The decisions to make minor corrections in relation to bilastine, riociguat and risankizumab, and the incorporation of new substances, were delegate-only decisions in accordance with the SPF. These were considered sufficiently straightforward and did not require any public consultation.

The *Poisons Standard October 2021* 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 2021* 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 2021* commences on 1 October 2021.

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