EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Poisons Standard June 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.

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 June 2022*, in substitution for the previous Poisons Standard, the *Poisons Standard February 2022*. The *Poisons Standard June 2022* repeals and replaces the *Poisons Standard February 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. 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 June 2021 ACCS and Joint ACMS-ACCS meetings, and the November 2021 ACMS and Joint ACMS-ACCS meetings, as follows:

- an invitation to comment in relation to lead acetates and 6-methoxy-N2-methyl-2,3-pyridinediamine was published on the TGA website on 4 May 2021, with a closing date of 4 June 2021. A further invitation to comment in relation to these proposals was published on 13 October 2021, with a closing date of 11 November 2021;
- an invitation to comment in relation to sodium nitrite was published on the TGA website on 27 April 2021, with a closing date of 27 May 2021. A further invitation to comment in relation to this proposal was published on 12 October 2021, with a closing date of 11 November 2021; and
- an invitation to comment in relation to astodrimer sodium, flurbiprofen and cis-jasmone was published on the TGA website on 6 September 2021, with a closing date of 7 October 2021. A further invitation to comment in relation to these proposals was published on 10 March 2022, with a closing date of 11 April 2022.

The final decisions in relation to lead acetates and 6-methoxy-N2-methyl-2,3-pyridinediamine were published on the TGA website on 20 December 2021. The final decision in relation to sodium nitrite was published on the TGA website on 19 January 2022. The final decisions in relation to astodrimer sodium, flurbiprofen and cis-jasmone were published on the TGA website on 23 May 2022.

The *Poisons Standard June 2022* also incorporates seven new substances in the Poisons Standard for the first time, including specific entries for belzutifan, diroximel fumarate, enfortumab vedotin, lurbinectedin, mavacamten, ponatinib, and somapacitan in Schedule 4, as New Chemical Entities (NCEs). Five COVID-19 treatments are also incorporated into the Poisons Standard for the first time, having previously been captured under the group entry for monoclonal antibodies: casirivimab, cilgavmab, imdevimab, regdanvimab and tixagevimab. In addition, dimpropyridaz and inpyrfluxam are also incorporated in the Poisons Standard for the first time as delegate only decisions. Amendments to the existing entries for aminocyclopyrachlor and iron compounds are also incorporated, as delegate only decisions.

Notification of amendments to the Poisons Standard in relation NCEs and final decisions (without interim decision) made pursuant to regulation 42ZCZU (delegate-only decisions) were published on the TGA website on 13 April 2022.

A further minor amendment with respect to the presentation of debitterised neem seed oil has also been incorporated in the *Poisons Standard June 2022* to improve consistency.

The decisions to incorporate new substances in the Poisons Standard for the first time, and to make minor amendments and corrections, 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 June 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 June 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 June 2022* commences on 1 June 2022.