EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Poisons Standard—February 2023) Instrument 2023

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 in substitution for the current Poisons Standard. The current Poisons Standard includes Schedules containing the names or descriptions of substances, with certain levels of control applying to each Schedule in accordance with the risk associated with the substances in a Schedule.

The *Therapeutic Goods (Poisons Standard—February 2023) Instrument 2023* ("the Instrument") repeals and replaces both the *Therapeutic Goods (Poisons Standard—February 2023) Instrument 2022* ("the Former Instrument"), which was due to commence on 1 February 2023 and will therefore not take effect, and the *Poisons Standard October 2022*, which had been in effect since 1 October 2022.

The purpose of the Instrument is principally to incorporate a number of changes to existing entries and to include a number of specified substances in the current Poisons Standard for the first time. The Instrument retains the changes to the structure and formatting that the Former Instrument would have introduced, which were designed to improve the readability and clarity of the current Poisons Standard without making substantive changes to the content.

Background

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. These decisions are published on the TGA website.

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 Scheduling Policy Framework ("the SPF") provides guidance on whether a decision concerning the scheduling of substances 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 Schedules to the Poisons Standard are incorporated by reference in 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 utilises the scheduling and classification of substances in the current Poisons Standard for some 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 current Poisons Standard, or over-the-counter medicines containing substances included in Schedule 3 and not included in Appendix H of the current Poisons Standard. The advertising of substances included in Schedule 9 or Schedule 10 to the Poisons Standard is also prohibited.

Purpose

The Instrument incorporates a number of changes to existing entries in the current Poisons Standard, and includes a number of specified substances in the current 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.

New schedule entries

The Instrument provides for the inclusion of a number of new substances (i.e. new chemical entities) in the Poisons Standard for the first time, including the following:

- Avacopan, in Schedule 4 to the Poisons Standard;
- Deucravacitinib, in Schedule 4 to the Poisons Standard;
- Edaravone, in Schedule 4 to the Poisons Standard;
- Fenpropidin, in Schedule 6 to the Poisons Standard;
- Lenacapavir, in Schedule 4 to the Poisons Standard;
- Patisiran, in Schedule 4 to the Poisons Standard;
- Tirzepatide, in Schedule 4, and Appendix L, to the Poisons Standard (Appendix L sets out requirements that apply in relation to the dispensing labels of specified medicines).

The Instrument also introduces new schedule entries for existing substances, including a new schedule entry for:

- meloxicam, in Schedule 6 to the Poisons Standard; and
- fluralaner, in Schedule 4 to the Poisons Standard, with a consequential amendment to the Schedule 5 entry for fluralaner.

Amendments to schedule entries

The Instrument includes amendments to existing schedule entries for a number of substances, including the following:

- amendments to the Schedule entries for cetirizine, apronal, tretinoin, and dichloromethane;
- amendments to the nomenclature for MDMA and MDA; and
- the inclusion of helional and ipflufenoquin in Appendix B of the Poisons Standard, which contains a list of substances for which the available information indicates that inclusion in the Poisons Standard is either unnecessary or not the most appropriate means of controlling the risk to public health.

The Instrument also includes amendments to various schedule entries for aspirin, flurbiprofen, and ibuprofen. It is important to note that these amendments are designed solely to improve the readability and clarity of the schedule entries for these substances, and do not alter the substantive content or effect of those schedule entries.

The Instrument also includes minor amendments to the schedule entries for afamelanotide, diethylhexyl phthalate, and phosphonic acid, principally to add clarity and correct typographical errors. For example, the Index entry for diethylhexyl phthalate has been amended to include the cross-reference "DEHP".

Consultation

Proposed amendments referred to an expert advisory committee

Public comment was invited in relation to the proposed amendments that were referred to the March 2022 meeting of the ACMS and the ACCS in joint session ("Joint ACMS-ACCS"). In particular, invitation to comment on the proposed inclusion of a new entry for meloxicam in Schedule 6 to the Poisons Standard was published on the TGA website on 20 December 2021, with a closing date of 31 January 2022. A further invitation to comment on this proposal was published on 19 August 2022, with a closing date of 15 September 2022. The final decision in relation to meloxicam was published on the TGA website on 18 November 2022.

Public comment was also invited in relation to the proposed amendments that were referred to the June 2022 meetings of the ACMS, ACCS and Joint ACMS-ACCS. In particular, public comment was invited on the amendments in relation to cetirizine, apronal, tretinoin, dichloromethane, MDMA, MDA, helional and ipflufenoquin.

Invitation to comment on the proposals outlined above was published on the TGA website on 29 April 2022, with a closing date of 27 May 2022. A further invitation to comment on these proposals was published on 21 October 2022, with a closing date of 24 November 2022. Notification of the final decisions made in relation to these substances was published on the TGA website on 20 January 2023.

Delegate-only decisions

The decisions to include avacopan, deucravacitinib, edaravone, lenacapavir, patisiran and tirzepatide in the Poisons Standard were made as delegate-only decisions, in accordance with the SPF, and were considered sufficiently straightforward as to not require public consultation. Notification of these decisions was published on the TGA website on 20 January 2023.

The decisions made in relation to fenpropidin and fluralaner were made as delegate-only decisions, pursuant to Subdivision 3D.3 of Part 6 of the *Therapeutic Goods Regulations 1990*, and notification of these decisions was published on the TGA website on 20 January 2023.

The decisions in relation to improving the readability and clarity of the various schedule entries for aspirin, ibuprofen and flurbiprofen were made as delegate-only decisions, in accordance with the SPF, but the TGA engaged in targeted consultation on these with 13 stakeholders, including State and Territory Health Departments, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, Consumer Healthcare Products Australia, Accord Australasia, the Australian Medical Association, and the Royal Australian College of General Practitioners, to ensure that the amendments were appropriate and would not change the effect of the relevant schedule entries. The TGA received seven responses in total that were all supportive of the proposed amendments. Some feedback provided by these stakeholders was incorporated into the final amendments, where it did not result in a change to the substantive content or effect of the schedule entries.

The minor amendments with respect to afamelanotide, diethylhexyl phthalate, and phosphonic acid were considered sufficiently minor as not to require public consultation.

The Instrument is a legislative instrument for the purposes of the *Legislation Act 2003* ("the Legislation Act"). However, section 42 of the Legislation Act relating to disallowance does not apply (subsection 52D(4A) of the Act refers). As the new Poisons Standard 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 Instrument commences on 1 February 2023.