

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Poisons Standard—February 2023) Instrument 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 the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of 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 52F) 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 2022* (“the new Poisons Standard”) repeals and replaces the *Poisons Standard October 2022* (“the former Poisons Standard”). The purpose of the new Poisons Standard is to introduce a new format for the Poisons Standard, designed to improve the readability and clarity of the instrument. The new Poisons Standard reflects a re-draft of the former Poisons Standard to align with modern drafting conventions, without changing its effect or making substantive changes to the content of the former Poisons Standard.

In particular, it is important to note that the new Poisons Standard does not include any changes to the scheduling of substances in comparison to the former Poisons Standard. The changes made in the new Poisons Standard include: streamlining the structure; improving the readability and clarity of the provisions at the start of the instrument; and updating formatting.

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.

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 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>. Advice from ACCS or ACMS is sought in accordance with the procedures set out in Subdivision 3D.2 of the *Therapeutic Goods Regulations 1990* for amending the current Poisons Standard when a proposed amendment is referred to an expert advisory committee.

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 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 redrafting of the Poisons Standard was undertaken by the Office of Parliamentary Counsel, to ensure that the new Poisons Standard aligns with modern drafting conventions to the extent possible, and is clearer and easier to understand. The changes made fall into three categories: structure, readability and clarity, and formatting.

Structure

The new Poisons Standard reflects a streamlined structure that improves navigation within the current Poisons Standard.

The former Poisons Standard contained the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) as Schedule 1 to the former Poisons Standard. The SUSMP contained a number of Parts, with Parts 1 to 3 containing definitions and substantive provisions, Part 4 containing the Schedules, and Part 5 containing the Appendices.

The new Poisons Standard contains the content of the SUSMP within the instrument itself, not as a schedule. The Reader’s Guide remains at the start of the instrument, followed by the provisions that are contained within Part 1 (Preliminary and interpretation) and Part 2 (Controls on substances). The Schedules, Appendices and Index to the instrument follow, i.e. they are no longer contained within a Part.

Subsection 1(2) provides that the new Poisons Standard may be cited as the relevant version of the SUSMP, to maintain historical references to the SUSMP that are external to the Poisons Standard, and section 5 clarifies that the Reader’s Guide and Index are not part of the instrument.

Some of the provisions within Parts 1 to 3 of the former Poisons Standard have been reordered in Parts 1 and 2 of the new Poisons Standard - for example, all provisions relating to storage are grouped together in Division 3 of Part 2, and all provisions relating to supply are together in Division 8 of Part 2. This has resulted in some renumbering of the provisions.

Readability and clarity

The provisions in the former Poisons Standard have been redrafted in the new Poisons Standard to provide for improved readability, clarity and consistent use of language. The content of the Reader's Guide in the former Poisons Standard that expresses a substantive requirement has been moved into a substantive provision, and content in the Appendices that is guidance (i.e. not a substantive requirement) has been moved to the Reader's Guide. Provisions giving effect to the Appendices have also been included, and some provisions of the former Poisons Standard have been divided into separate provisions for greater clarity.

Some of the changes include, for example, the following:

- referring simply to the “Act” and “Register”, instead of referring to these in full, as they are defined terms;
- changing numbers expressed in words to figures, and “per cent” to “%”, “litres” to “L”, “kilograms” to “kg” and “millilitres” to “mL” where these are preceded by a number, in accordance with National Measurement legislation;
- omitting references to sale where “sale and supply” are referred to, as the definition of “supply” in the Act includes sale and applies to the use of the term in the current Poisons Standard;
- removing definitions of terms that are already defined in the Act or *Acts Interpretation Act 1901*, such as “poison”, “therapeutic good” and “writing”.

Definitions that have been redrafted for greater clarity include:

- “appropriate authority” (this definition has been redrafted to avoid the need for further updates to accommodate name or title changes, without changing the meaning of the term);
- “child-resistant closure” (this definition has been redrafted to more clearly outline the orders under subsection 10(3) of the Act that are relevant to this term, without changing its meaning);
- “main label” (in particular, this definition has been redrafted to more clearly specify what is meant by the main label of a product, without changing the meaning of this term).

Definitions of “dental practitioner”, “medical practitioner”, “midwife” and “nurse” have been introduced for clarity and consistency with other kinds of health practitioners that are defined in the Poisons Standard.

Minor editorial changes and corrections have also been made.

Formatting

All other changes in the new Poisons Standard are formatting amendments to align with modern drafting conventions. The reformatting of the Index and Schedules significantly reduce the length of the instrument. The definitions, provisions, headings and tables have been reformatted to the contemporary style used in instruments.

Consultation

State and territory health departments, the Australian Industrial Chemicals Introduction Scheme (AICIS) and the Australian Pesticides and Veterinary Medicines Authority (APVMA) were first informed about the proposed redrafting of the current Poisons Standard in 2021. In November and December 2021, the TGA held a series of meetings with each state and territory health department to outline the proposal to introduce an improved format for the Poisons Standard, and the proposed redrafting process. All states and territories, AICIS and APVMA were provided with an exposure draft immediately following each meeting in November and December 2021, and given the opportunity to provide comments. All

responses were supportive of the proposed new Poisons Standard. A number noted concerns or provided suggestions. Where this feedback would not involve a substantive change to the Poisons Standard, and was in alignment with modern drafting conventions, it was incorporated into the new Poisons Standard.

Some state and territory health departments indicated that consequential legislative amendments may need to be made to state and territory legislation, and requested a delay to the commencement of the new Poisons Standard to allow for such amendments to be made. Accordingly, the new Poisons Standard will only commence on 1 February 2023 to accommodate these requests.

At the direction of the Victoria health department, SafeVic was consulted in August and September 2022 and identified minor consequential legislative amendments that may be needed to legislation that SafeVic administers.

The new Poisons Standard 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 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 new Poisons Standard commences on 1 February 2023.