

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Poisons Standard—October 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 or performance, 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—October 2023) Instrument 2023* (“the Instrument”) repeals and replaces the *Therapeutic Goods (Poisons Standard—July 2023) Instrument 2023* (“the Former Instrument”), which had been in effect since 1 July 2023. 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.

In relation to existing entries in the current Poisons Standard, the Instrument incorporates amendments to:

- in Part 2 — the general requirements for *anti-corrosive paints* in section 66, to reduce the maximum permissible level of lead in such paints to 0.009 per cent;
- in the Index — the entries for certain substances in Schedules 9 and 10, to incorporate references to the Chemical Abstracts Services numbers of those substances;
- in Schedule 3 — the entry for *salbutamol*, to remove additional access restrictions that were imposed during the COVID-19 pandemic; and
- in Schedule 10 — the entry for *lead compounds*, to complement the amendment made in respect of *anti-corrosive paints* in Part 2.

The Instrument also makes editorial amendments to the Index in relation to a small number of substances with existing entries in the current Poisons Standard. These amendments are:

- in relation to *allylprodine* — to omit the incorrect reference to Schedule 10 in this Index entry, and replace it with a reference to Schedule 9;
- in relation to *1-(1,1-dimethylethyl)-2-methoxy-4-methyl-3,5-dinitrobenzene* — to omit the Index entry for this substance (immediately after the entry for *dimethipin*), as this is a duplicate entry; and
- in relation to *2,4-dinitrophenol* — to insert an entry in the Index for this substance, which was inadvertently omitted.

In relation to substances that have been introduced in the Poisons Standard for the first time, the Instrument introduces the following entries:

- in Schedule 9 — several substances in the ‘*nitazene*’ drug class;
- in Schedule 4 — *vadadustat* (which is also included in clause 5 of Appendix D), *velagliflozin* and a number of new chemical entities; and
- in Schedule 2 — *choline salicylate* for oromucosal preparations.

Finally, the Instrument includes a new entry in Appendix A of the current Poisons Standard, the effect of which is to exempt *treatment layers of coated metal articles* from the controls on substances prescribed by Part 2 of the current Poisons Standard. However, this exemption does not apply to articles intended for use in the collection of drinking water that do not comply with the health and safety requirements of the Australian Standard AS 4020:2018, *Testing of products for use in contact with drinking water*.

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: 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 current Poisons Standard is also prohibited.

Purpose

The Instrument incorporates changes to a number of existing entries in the current Poisons Standard, and provides for the inclusion of a number of specified substances in the current Poisons Standard for the first time. Some of these changes are made following the provision of advice from the ACMS or the ACCS, in accordance with the procedures set out in Subdivision 3D.2 of Part 6 of the *Therapeutic Goods Regulations 1990* (“the Regulations”)

for amending the Poisons Standard when a proposed amendment is referred to an expert advisory committee. Other changes are made following a delegate-only-decision.

New schedule entries

The Instrument provides for the inclusion in the current Poisons Standard of a number of substances in the ‘nitazene’ drug class. Specifically, entries for the following substances have been included in Schedule 9 (“controlled substances”) to the current Poisons Standard:

- *butonitazene*;
- *etodesnitazene*;
- *etonitazepipne*;
- *etonitazepyne*;
- *flunitazene*;
- *isotonitazene*;
- *metodesnitazene*;
- *metonitazene*; and
- *protonitazene*.

The Chemical Abstracts Service number (“CAS number”) for each of these substances has also been included in the Index entry for the substance. This is consistent with changes made by the Instrument in relation to certain other substances that are already listed in Schedule 9 and Schedule 10 to the current Poisons Standard.

The Instrument also incorporates entries in the current Poisons Standard for a number of new chemical entities. Specifically, it incorporates entries for the following new chemical entities in Schedule 4 (“prescription-only medicines”) to the current Poisons Standard:

- *concizumab*;
- *givosiran*;
- *glofitamab*;
- *imlifidase*;
- *mirikizumab*;
- *olipudase alfa*;
- *rimegepant*;
- *spesolimab*;
- *selpercatinib*;
- *tafasitamab*;
- *tagraxofusp*;
- *teclistamab*; and
- *tirbanibulin*.

In addition, the Instrument provides for the inclusion of entries in the current Poisons Standard for:

- in Schedule 4 — *velagliflozin*, which is beneficial in the treatment of diabetes in companion animals, with the effect that products containing this substance must not be supplied by a person other than (relevantly) a veterinarian;
- in Schedule 4 and clause 5 of Appendix D — *vadadustat*, with the effect that a person must not possess a product containing this substance without authority (e.g., a valid prescription) under a law of the relevant jurisdiction; and

- in Schedule 2 — *choline salicylate* in preparations for oromucosal use, meaning that such preparations can only be supplied by certain health practitioners (e.g., pharmacists), or a person licensed to supply the product under the law of the relevant jurisdiction.

Finally, the Instrument incorporates a new entry in Appendix A of the current Poisons Standard in relation to *treatment layers of coated metal articles*. The effect of this entry is that such articles are exempt from the controls on substances imposed by Part 2 of the current Poisons Standard. However, this exemption does not apply in relation to articles intended for use in the collection of drinking water that do not comply with the health and safety requirements of the Australian Standard AS 4020:2018 *Testing of products for use in contact with drinking water*.

Amendments to existing schedule entries

The Instrument incorporates changes to the Index entries for certain substances in Schedule 9 and Schedule 10 to the current Poisons Standard (“the relevant substances”). Specifically, these changes are to incorporate references to the CAS numbers for the relevant substances.

A CAS number is a unique numerical identifier designated to a substance, which provides a common link between the various nomenclature that may be used to describe that substance. In particular, CAS numbers enable persons to cross-reference substances that are considered by a scheduling delegate, against the same substance (which may be described differently) by a comparable overseas regulatory body (e.g., the EU Scientific Committees on Consumer Safety and Products).

CAS numbers have previously been included in the Poisons Standard in relation to a small number of substances across the various Schedules to the Poisons Standard. However, there has been little consistency to date in relation to the way in which CAS numbers have been included for these substances. For example, while CAS numbers for some substances have only been included in the Index, CAS numbers for other substances are only referred to in the substantive (i.e., schedule) entries for those substances.

The changes made by the Instrument to the relevant substances reflect the TGA’s adoption of a new, standardised approach to the inclusion of CAS numbers (and other synonyms) in the Poisons Standard. This standardised approach is intended to enhance the readability of the Poisons Standard, by making it easier for the reader to ascertain precisely which substance is the subject of a particular entry.

This standardised approach will apply to substances being included in the Poisons Standard for the first time, as well as those with existing entries in one or more Schedules. The standardised approach involves including CAS numbers in the index entry for the relevant substance. The Instrument incorporates CAS numbers for substances in Schedules 9 and 10. It is intended that the CAS numbers for substances in other Schedules (namely, Schedules 5, 6, and 7) will be included in future updates to the Poisons Standard.

By way of example, the CAS numbers for *methylrosanilinium chloride* (and its associated substances) have been amended to following the new standardised approach. CAS numbers have been added to the Index entry for *methylrosanilinium chloride* and its associated substances (i.e., the triarylmethane dyes referred to in the Schedule 10 entry). For consistency, the CAS numbers for *methylrosanilinium chloride* (and its associated substances) have been removed from the entry for that substance in Schedule 10.

The Instrument also incorporates amendments to a number of existing entries for, and requirements relating to, certain substances in the current Poisons Standard. Specifically, these amendments are made to:

- in Part 2, section 66 — the general requirements in relation to *anti-corrosive paints*, to reduce the maximum permissible level of lead in such paints from 0.1 per cent to 0.009 per cent (equivalent to 90 ppm or 90 mg/kg);
- in Schedule 10 — the entry for *lead compounds* to, in effect, prohibit the possession, use, or supply of *anti-corrosive paints* containing more than 0.009 per cent of lead calculated on the non-volatile content of the paint; and
- in Schedule 3 — the entry for *salbutamol*, to remove the additional restrictions on the supply of this substance that were imposed during the COVID-19 pandemic, as there are no current or projected shortages of medicines with this substance.

The changes to the current Poisons Standard in respect of *anti-corrosive paints* are necessary to protect public health from the known adverse effects of lead exposure and align the maximum permissible level of lead in such paints with that of paints and tinters generally. Importantly, however, no change has been made in relation to the scheduling of lead in relation to *anti-fouling paints*. Consequently, the maximum permissible level of lead in *anti-fouling paints* remains 0.1 per cent (equivalent to 1,000 ppm or 1,000 mg/kg).

Finally, the Instrument incorporates editorial amendments to the Index in relation to a small number of substances with existing entries in the current Poisons Standard. The purpose of these amendments is to:

- in relation to *allylprodine* — omit the incorrect reference to Schedule 10 in the Index entry for this substance, and replace it with a reference to Schedule 9;
- in relation to *1-(1,1-dimethylethyl)-2-methoxy-4-methyl-3,5-dinitrobenzene* — omit a duplicate Index entry for this substance (located immediately after the Index entry for *dimethipin*); and
- in relation to *2,4-dinitrophenol* — insert an entry in the Index for this substance, which had previously and inadvertently omitted.

Incorporation by reference

Subsection 52D(4B) of the Act relevantly provides that, despite subsection 14(2) of the *Legislation Act 2003* (“the Legislation Act”), an instrument made under paragraph 52D(2)(a) or (b) may make provision in relation to a matter by applying, adopting or incorporating any matter contained in an instrument or other writing as in force or existing from time to time.

The Instrument incorporates the following documents by reference, in the manner outlined:

- United States Code of Federal Regulations, Title 16, Section 1700.15, *Poison prevention packaging standards* and Section 1700.20, *Testing procedure for special packaging*. The intended manner of incorporation is as in force from time to time, as specifically provided for in paragraph (b)(iv) of the definition of *child-resistant packaging* in section 6 of the Instrument. This document is freely available from the Code of Federal Regulations website (www.ecfr.gov); and
- National Transport Commission, *Australian Code for the Transport of Dangerous Goods by Road & Rail*. The intended manner of incorporation is as it exists from time to time, as identified in section 10 of the Instrument. This document is freely available from the National Transport Commission website (www.ntc.gov.au).

The following documents are also incorporated by reference, with the intended manner of incorporation being as they exist from time to time, as provided in section 10 of the Instrument:

- Australian Standard AS 1928-2007, *Child-resistant packaging – Requirements and testing procedures for reclosable packages* (ISO 8317:2015, MOD);
- International Organization for Standardization Standard ISO 8317:2015, *Child-resistant packaging—Requirements and testing procedures for reclosable packages*;
- Australian Standard AS 2216-1997, *Packaging for poisonous substances*;
- Australian Standard AS 4710-2001, *Packages for chemicals not intended for access or contact with their contents by humans*;
- Australian Standard AS 1580-301.1-2005, *Paints and related materials – Methods of test – Non-volatile content by mass*;
- Australian Standard AS 8124.4-2003, *Safety of toys, Part 4: Experimental sets for chemistry and related activities*;
- Australian/New Zealand Standard AS/NZS ISO 8124.3:2012, *Safety of toys Part 3: Migration of certain elements* (ISO 8124-03:2010, MOD);
- Australian Standard AS 1928-2001, *Child-resistant packages*;
- Australian Standard AS 4020:2018, *Testing of products for use in contact with drinking water*;
- British Standards Institution Standard BS EN ISO 8317:2004, *Child-resistant packaging—Requirements and testing procedures for reclosable packages*;
- Canadian Standards Association Standard CSA Z76.1-06, *Reclosable Child-Resistant Packages*;
- Personal Care Products Council of America, *International Cosmetic Ingredient Dictionary & Handbook*; and
- *Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022*, published by the Australian Pesticides and Veterinary Medicines Authority.

However, these documents are not publicly available for free. Rather, they can, by prior written arrangement where possible and without charge, be viewed by members of the public at the TGA office in Fairbairn, ACT. While these documents are not available for free, it is anticipated that the persons most affected by their adoption in the current Poisons Standard would likely be in possession of these documents. As important benchmarks for the safety of therapeutic goods and other consumer goods, it would be infeasible from a regulatory perspective to not adopt such benchmarks on the basis that the publications are not available for free.

Consultation

Proposed amendments referred to an expert advisory committee

Public comment was invited in relation to the following proposed amendments that were referred to the November 2021 meetings of the ACMS and ACCS:

- the proposal to amend the entries for *chromates* and *chromium trioxide* in Schedule 6 to the current Poisons Standard, to except small amounts of chromium compounds when present in the treatment layers of coated metal; and
- the proposal to include *choline salicylate* for human therapeutic or cosmetic use in Schedule 3 to the current Poisons Standard.

Invitation to comment on these proposed amendments was published on the TGA website on 6 September 2021, with a closing date of 7 October 2021. A further invitation to comment on the interim decisions in respect of these proposed amendments was published on the TGA website on 10 March 2022, with a closing date of 11 April 2022.

The scheduling delegate's final decisions concerning these proposed amendments were published on the TGA website on 23 May 2022. In relation to the *chromates* and *chromium trioxide* proposal, the delegate decided to amend Appendix A to include an entry for treatment layers of coated metal articles. In relation to the *choline salicylate* proposal, the delegate decided to amend Schedule 2 to include an entry for *choline salicylate* in preparations for oromucosal use.

Public comment was separately invited in relation to a proposal to amend Poisons Standard to reduce the maximum permissible limit of lead in *anti-fouling paints* from 0.1 per cent to 0.06 per cent. This proposed amendment was referred to the June 2023 meeting of the ACMS and ACCS (in joint session).

Invitation to comment on the proposed amendment was published on the TGA website on 18 April 2023, with a closing date of 17 May 2023. A further invitation to comment on the interim decision was published on the TGA website on 3 August 2023, with a closing date of 1 September 2023.

The scheduling delegate's final decision concerning the proposed amendment was published on the TGA website on 18 September 2023. The delegate decided not to amend the Poisons Standard in respect of *anti-fouling paints* as proposed by the applicant. Instead, the delegate decided to amend the Poisons Standard in respect of *anti-corrosive paints*, to reduce the maximum permissible level of lead in *anti-corrosive paints* to 0.009 per cent.

Delegate-only decisions

The following decisions were made as delegate-only decisions under regulation 42ZCZU of the Regulations, and in accordance with the SPF:

- the decision to include the specified *nitazenes* in Schedule 9 to the current Poisons Standard;
- the decision to include *velagliflozin*, and the specified new chemical entities, in Schedule 4 to the current Poisons Standard;
- the decision to include *vadadustat* in Schedule 4 and clause 5 of Appendix D to the current Poisons Standard; and
- the decision to amend the entry for *salbutamol* in Schedule 3 to the current Poisons Standard.

Public comment was not invited in relation to any of the proposals to which these decisions relate, nor were any of those proposals referred to an expert advisory committee for their advice.

The decision in relation to the specified *nitazenes* was made based on the clear and immediate public health risks associated with these substances — namely, their propensity to cause dependency, and to be abused, misused, and used illicitly — and the fact that there is no current legitimate use of the substances that would be unduly restricted by their inclusion in Schedule 9.

The remaining proposed amendments (i.e., those in relation to *velagliflozin*, *vadadustat*, the specified new chemical entities, and *salbutamol*) were considered sufficiently straightforward as to not require expert advice or public consultation.

Decision to include CAS numbers for certain substances in Schedules 9 and 10

The TGA sought public and industry feedback in relation to the proposed incorporation of CAS numbers in the Poisons Standard, as part of its review of chemical scheduling of cosmetic and fragrance ingredients which was conducted in 2019 (“the 2019 review”). This proposal was supported by all submissions received by the TGA, on the basis that its implementation would greatly improve identification of substances captured by Poisons Standard entries. Further information on the 2019 review can be found on the TGA website.

On 8 December 2022, the TGA sent a statement of action to Accord Australasia. The TGA proposed — as a first step in the implementation of its standardised approach to the incorporation of CAS numbers — to amend the Index entries for the relevant substances in Schedules 9 and 10, with a selective and progressive implementation of CAS numbers for substances in other Schedules (i.e., Schedules 5, 6, and 7) to follow.

On 20 June 2023, the TGA consulted on the proposal to incorporate CAS numbers for selected substances in the Poisons Standard. Specifically, the TGA provided stakeholders with a list of the relevant substances in Schedules 9 and 10, and the CAS numbers the TGA was proposing to include for those substances.

Stakeholders that were consulted include the Australian Medical Association, Australian Industrial Chemicals Introduction Scheme, Royal Australian College of General Practitioners, Pharmaceutical Society of Australia, Consumer Healthcare Products Australia, Australian Competition and Consumer Commission, Australian Border Force, Australian Pesticides and Veterinary Medicines Authority, Accord Australasia, Chemistry Australia, and the Pharmacy Guild of Australia. State and Territory Health Departments were also consulted.

Consultation closed on 1 August 2023. All respondents supported the inclusion of CAS numbers for the relevant substances in Schedules 9 and 10 of the Poisons Standard.

The Instrument is a legislative instrument for the purposes of 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 Instrument 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 October 2023.