

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Poisons Standard—February 2025) Instrument 2025

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 provides that the Secretary may 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 2025) Instrument 2025* (“the Instrument”) repeals and replaces the *Therapeutic Goods (Poisons Standard—October 2024) Instrument 2024*, which had been in effect since 1 October 2024. The purpose of the Instrument is principally to incorporate revised scheduling arrangements for several substances that are included in the current Poisons Standard, and to include several specified substances in the current Poisons Standard for the first time.

In relation to substances that are already included in the current Poisons Standard, the Instrument amends or removes the existing entries, and in some cases introduces new entries, for the following scheduled substances:

- *allyl esters*;
- *bromoxynil*;
- *desloratadine*;
- *hydroxychloroquine*;
- *nicotinic acid*;
- *paracetamol*;
- *sulfonamide antibiotics*.

In relation to substances that are included in the current Poisons Standard for the first time, the Instrument incorporates entries for:

- in Schedule 2— *bisacodyl*;
- in Schedule 4— *molidustat*, *animal blood products*, and 14 new chemical entities.

The Instrument also incorporates minor amendments to the Index entries for *cineole*, *hydroxychloroquine*, *isotretinoin*, and *rescalure*, and to add clarity and assist in searchability of those substances, and corrects a very minor editorial error in the numbering of paragraphs in the Schedule 4 entry for nicotine.

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 several existing entries in the current Poisons Standard and provides for the inclusion of several 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 introduces entries in the current Poisons Standard for 14 new chemical entities. These are included in Schedule 4 (“prescription-only medicines”), meaning that the use or supply of these substances should occur by or on the order of persons permitted by State or Territory legislation to prescribe, and the substances should be available from a pharmacist on prescription. These new schedule entries are:

- *abaloparatide*;
- *cipaglucosidase alfa*;
- *dexrazoxane*;
- *efgartigimod alfa*;
- *elacestrant dihydrochloride*;
- *fedratinib*;

- *garadacimab*;
- *inebilizumab*;
- *marstacimab*;
- *momelotinib*;
- *palopegteriparatide*;
- *rozanolixizumab*;
- *sodium citrate dihydrate*; and
- *zolbetuximab*.

The Instrument also introduces entries in the current Poisons Standard for:

- in Schedule 2 — *bisacodyl* to provide that all oral preparations of *bisacodyl* are pharmacy medicines, except packs of 20 tablets or less which would still be available for purchase from supermarkets and convenience stores;
- in Schedule 4 — *animal blood products* to provide that *animal blood products* for veterinary use are a prescription-only medicine;
- in Schedule 4 and Appendix D, clause 5 — *molidustat* to provide that *molidustat* is a prescription-only medicine, with increased access restrictions such that possession without authority is illegal;
- in Schedule 5 — *nicotinic acid* to provide that *nicotinic acid* when labelled and packaged for agricultural chemical use has appropriate packaging with simple warnings and safety directions on the label; and
- in Schedule 7 — *bromoxynil* to provide that except when included in Schedule 6 for preparations containing 1.5% or less *bromoxynil*.

Amendments to existing scheduling arrangements

The Instrument makes changes to the entry for *allyl esters* in Schedule 6 to the current Poisons Standard. The effect of these changes is to include two additional *allyl esters*, *allyl phenoxyacetate* and *allyl (cyclohexyloxy) acetate*, in the group entry.

The Instrument also makes changes to the entry for *nicotinic acid* in Schedule 4 to the current Poisons standard. The effect of these changes is to include preparations of *nicotinic acid* for animal therapeutic use when packed and labelled for injection as prescription-only medicines.

The Instrument revises the entry for *sulfonamides* in Schedule 4 to the current Poisons Standard to clarify the status of *sulfonamide antibiotics* when used in a variety of settings, including therapeutic and industrial use.

The Instrument amends the entry for *desloratidine* in Schedule 2 (“Pharmacy medicines”) and Schedule 4 (“Prescription-only medicines”) to include additional exceptions to allow general sale for the treatment of seasonal allergic rhinitis in adults and children 6 years of age and over, if in packs containing 10 dosage units or less and labelled with a recommended daily dose not exceeding 5 mg.

The Instrument revises the entry for *bromoxynil* in Schedule 6 to the current Poisons Standard to clarify that preparations containing 1.5% or less of *bromoxynil* are included in Schedule 6.

The Instrument amends the entry for *hydroxychloroquine* to remove the Appendix D, clause 8 entry restricting supply to authorised health practitioners, in alignment with the removal of similar restrictions on *ivermectin* following a final decision in May 2023.

The Instrument makes changes to the entries for *paracetamol* in Schedule 2 (“Pharmacy medicines”), Schedule 3 (“Pharmacist only medicines”) and Schedule 4 (“Prescription only

medicines”) to the current Poisons Standard. The effect of these changes is to include *paracetamol* as:

- a pharmacy medicine when in a primary pack containing more than 16 tablets or capsules and up to 50 tablets or capsules in blister or strip packaging;
- a pharmacy medicine when in individually wrapped powders or sachets of granules enclosed in a primary pack containing not more than 25 wrapped powders or sachets of granules;
- a pharmacist only medicine when in non-modified release tablets or capsules containing not more than 500 mg *paracetamol* and in a primary pack containing more than 50 and up to 100 tablets;
- a pharmacist only medicine when in tablets or capsules enclosed in a primary pack containing more than 100 tablets or capsules intended only as a bulk medicine pack and labelled ‘For dispensing only’ and ‘This pack is not to be supplied to a patient’;
- a pharmacist only medicine when in individually wrapped powders or sachets of granules enclosed in a primary pack containing not more than 50 wrapped powders or sachets of granules except when the primary pack contains not more than 25 wrapped powders and it is included in a pharmacy medicine;
- a pharmacist only medicine when in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 50 wrapped powders or sachets of granules intended only as a bulk medicine pack and labelled ‘For dispensing only’ and ‘This pack is not to be supplied to a patient’; and,
- a prescription only medicine in all the circumstances specified in Schedule 4.

Other minor amendments

The Instrument also 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:

- in relation to *rescalure* — to insert a cross reference to insect sex pheromone, for clarity and to assist searchability;
- in relation to *isotretinoin* — to correctly reference the Appendix D, clause 2 entry (the Index incorrectly referenced Appendix D, clause 5); and
- in relation to *cineole* — to correctly reference the Schedule 6 entry (the Index incorrectly referenced Schedule 7).

The Instrument also incorporates an editorial amendment to an existing entry in the current Poisons Standard. The purpose of this amendment is, in relation to nicotine, to correct a typographical error in the numbering of the paragraphs in the Schedule 4 entry.

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 8124.4:2020, *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 1928-2007, *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 8317:2015, *Child-resistant packaging—Requirements and testing procedures for reclosable packages*;
- Canadian Standards Association Standard CSA Z76.1:21, *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 proposed amendments to the scheduling of paracetamol which was referred to the November 2022 meeting of the ACMS. The proposal

was to amend the Schedule 2, 3 and 4 entries for *paracetamol* to reduce the maximum size of packs of immediate release paracetamol from:

- 20 tablets/capsules to 16 for unscheduled products;
- 100 tablets/capsules to 32 for Schedule 2 products.

Equivalent and proportionate changes would also apply to preparations of wrapped powders and sachets of granules that contain *paracetamol*.

Invitation to comment on this proposed amendment was referred to the November 2022 meeting of the ACMS and was published on the TGA website on 14 September 2022, with a closing date of 14 October 2022. A further invitation to comment on the interim decision in respect of the proposed amendments was published on the TGA website on 3 February 2023, with a closing date of 3 March 2023.

The scheduling delegate's final decisions concerning the proposed amendments were published on the TGA website on 3 May 2023. The delegate decided to amend the Schedule 2, 3 and 4 entries of the Poisons Standard for *paracetamol* as proposed.

Public comment was invited in relation to the following proposed amendments that were referred to the June 2024 meetings of the ACCS and Joint ACMS-ACCS:

- to amend the Schedule 6 entry for *allyl esters* to include *allyl phenoxyacetate*; *allyl amyl glycolate*; *allyl (2-methylbutoxy)acetate*; and *allyl (cyclohexyloxy)acetate*.
- to amend the Schedule 4 entry for *sulfonamides* in Schedule 4 to clarify the status of *sulfonamides* when used in a variety of settings, including therapeutically and industrially.

Invitation to comment on these proposed amendments (i.e., those referred to the June 2024 meeting of the ACCS and Joint ACMS-ACCS) was published on the TGA website on 23 April 2024, with a closing date of 22 May 2024. A further invitation to comment on the interim decisions regarding these proposed amendments was published on the TGA website on 19 September 2024, with a closing date of 18 October 2024.

The scheduling delegate's final decisions concerning these proposed amendments were published on the TGA website on 16 December 2024. The delegate decided to:

- amend the Schedule 6 entry for *allyl esters* to include *allyl phenoxyacetate* and *allyl (cyclohexyloxy) acetate*, but not amend the Poisons Standard with respect to *allyl amyl glycolate* or *allyl (2-methylbutoxy)acetate*, which will continue to be captured under the Schedule 7 and Appendix J entries for *allyl alcohol*.
- amend the Schedule 4 entry for *sulfonamides* to clarify the status of *sulfonamide antibiotics* when used in a variety of settings, including therapeutically and industrially.

Public comment was also invited in relation to the proposed amendments to the scheduling of *bisacodyl* that was referred to the June 2023 meeting of the ACMS. The proposal was to create a new Schedule 2 entry for *bisacodyl* for oral use except in divided preparations in packs containing 20 tablets or less.

Invitation to comment on this proposed amendment was referred to the June 2023 meeting of the ACMS and 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 in respect of the proposed amendments was published on the TGA website on 5 October 2023, with a closing date of 2 November 2023.

The scheduling delegate's final decisions concerning the proposed amendments were published on the TGA website on 15 December 2023. The delegate decided to create a new Schedule 2 entry in the Poisons Standard with respect to *bisacodyl* for oral use except in divided preparations in packs containing 20 tablets or less.

Public comment was also invited in relation to the proposed amendments to the scheduling of *animal blood products* that was referred to the November 20a23 meeting of the ACCS. The proposal was to create a new Schedule 4 entry for *animal blood products* for veterinary use.

Invitation to comment on the proposed amendment was referred to the November 2023 meeting of the ACCS and was published on the TGA website on 1 September 2023, with a closing date of 29 September 2023. A further invitation to comment on the interim decision in respect of the proposed amendments was published on the TGA website on 3 April 2024, with a closing date of 17 April 2024.

The scheduling delegate's final decisions concerning the proposed amendments were published on the TGA website on 13 September 2024. The delegate decided to create a new Schedule 4 entry in the Poisons Standard with respect to *animal blood products* for veterinary use.

Other amendments

The remaining amendments to the Poisons Standard were made as delegate-only decisions. 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.

Other details

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 February 2025.