EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Poisons Standard—October 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, Disability and Ageing.

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 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 2025) Instrument 2025* (the Instrument) repeals and replaces the *Therapeutic Goods (Poisons Standard—June 2025) Instrument 2025*, which had been in effect since 1 June 2025. 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 introduces new entries and in one case also removes the existing entry, for the following scheduled substances:

- *chlorthal-dimethyl;*
- *diethylene glycol;*
- *ethylene glycol;*
- *fenbendazole;*
- *fluticasone propionate;*
- *methenamine.*

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

- in Schedule 4—*atinvicitinib, etomidate, tasipimidine sulfate, verdinexor,* and 8 new chemical entities;
- in Schedule 5— *1-aminocyclopropane-1-carboxylic acid*; and
- in Schedule 6—*(Z,E)-7,9,11-dodecatrienyl formate*.

The Instrument also removes the existing Appendix B, clause 3 entry for *lepidopterous sex pheromones* as a consequence of the new entry for *(Z,E)-7,9,11-dodecatrienyl formate* in Schedule 6, and makes a small number of minor editorial amendments and corrections.

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 current 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* 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 8 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 for new chemical entities are:

- *artesunate;*
- *bibrocathol;*
- *cefiderocol;*
- *delgocitinib;*
- *elinzanetant;*
- *leniolisib;*
- *sebetralstat;* and
- *seladelpar.*

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

- in Schedule 4—*atinvicitinib*, to provide that all preparations of *atinvicitinib* are a prescription animal remedy;
- in Schedule 4—*etomidate*, to provide that all preparations of *etomidate* are a prescription-only medicine;
- in Schedule 4—*tasipimidine sulfate*, to provide that all preparations of *tasipimidine sulfate* are a prescription animal remedy;
- in Schedule 4—*verdinexor*, to provide that all preparations of *verdinexor* are a prescription animal remedy;
- in Schedule 5—*1-aminocyclopropane-1-carboxylic acid*, to provide that all preparations of *1-aminocyclopropane-1-carboxylic acid* require appropriate packaging with simple warning and safety directions on the label, except in plant growth preparations containing 40% or less of *1-aminocyclopropane-1-carboxylic acid*;
- in Schedule 6—*(Z,E)-7,9,11-dodecatrienyl formate*, to provide that all *(Z,E)-7,9,11-dodecatrienyl formate* preparations for agricultural use as an insect pheromone require distinctive packaging with strong warnings and safety directions on the label, except when enclosed in a device which, in normal use, prevents access to its contents.

Amendments to existing scheduling arrangements

The Instrument removes the entry for *chlorthal-dimethyl* in Schedule 5 to the current Poisons Standard and introduces a new entry in Schedule 7 for all *chlorthal-dimethyl* preparations. All *chlorthal-dimethyl* preparations will require special precautions during manufacture, handling or use; should be available only to specialised or authorised users who have the skills necessary to handle them safely; and may be subject to special regulations restricting their availability, possession, storage or use.

The Instrument amends the entries for *diethylene glycol* and *ethylene glycol* in Schedules 5 and 6 to the current Poisons Standard to clarify that these substances are unscheduled when in preparations containing less than 0.25% of *diethylene glycol* or *ethylene glycol* for use in toothpastes and mouthwashes. This is an editorial change that does not change the effect of the entry but rather clarifies that such preparations are unscheduled.

The Instrument creates a Schedule 4 entry for *fenbendazole* in addition to the existing Schedule 5 entry for *fenbendazole* and provides that all preparations of *fenbendazole* for

human use will require a prescription. It does not change the scheduling arrangement for the use of *fenbendazole* for the treatment of animals.

The Instrument amends the entry for *fluticasone propionate* in Schedule 2 to the current Poisons Standard. The effect of this change is to allow *fluticasone propionate* aqueous nasal sprays delivering 50 micrograms or less of fluticasone per actuation up to a maximum recommended daily dose 400 micrograms for the treatment of rhino-conjunctivitis, in addition to the prophylaxis of allergic rhinitis or treatment of allergic rhinitis, for up to 6 months in adults and children 12 years of age and over to be available from a pharmacy.

The Instrument also creates a Schedule 3 entry for *methenamine* for all therapeutic preparations of *methenamine* which is additional to the existing Schedule 5 entry for *methenamine* in cosmetic preparations, and provides that all therapeutic preparations of *methenamine* are to be available from a pharmacist without a prescription.

The Instrument also removes the entry for *lepidopterous sex pheromones* in Appendix B, clause 3, item 141 to the current Poisons Standard as a consequence of the new Schedule 6 entry for *(Z,E)-7,9,11-dodecatrienyl formate*.

Other minor amendments

The Instrument incorporates editorial amendments to the Index in relation to two substances with existing entries in the current Poisons Standard. The purpose of these amendments is to:

- in relation to *Bacillus amyloliquefaciens*—correctly reference the *bacillus velezensis* strain MBI 600 by including the species name; and
- in relation to *piperazine*—correct a typographical error in the spelling of piperazine by replacing ‘piperazne’ with ‘piperazine.’

The Instrument incorporates minor editorial amendments to improve the clarity of the Schedule 5 entries for *rizatriptan*, *sumatriptan*, and *zolmitriptan* by including the name of the substance when referring to the maximum concentration per dosage unit. The purpose of this amendment is to clarify that the maximum concentration is in reference to the total amount of triptan, rather than the total amount of dosage unit which would include excipients.

The Instrument also makes a minor editorial amendment to remove the erroneous Appendix H, clause 1 entry for *esomeprazole*. Appendix H pertains to Schedule 3 medicines permitted to be advertised. The Schedule 3 entry for esomeprazole was deleted in July 1997 and the entry for *esomeprazole* is not relevant.

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 *methenamine*. The proposed amendments were referred to the November 2023 meetings of the ACMS.

Invitation to comment on these proposed amendments 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 regarding 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 decision concerning these proposed amendments were published on the TGA website on 22 May 2024. The delegate decided to create a new Schedule 3 entry for *methenamine* in preparations for therapeutic use.

Other amendments

The remaining amendments to the current Poisons Standard are minor and machinery editorial changes or 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 October 2025.