

## EXPLANATORY STATEMENT

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Poisons Standard—June 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—June 2025) Instrument 2025* (the Instrument) repeals and replaces the *Therapeutic Goods (Poisons Standard—February 2025) Instrument 2025*, which had been in effect since 1 February 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 removes the existing entries, and in some cases introduces new entries, for the following scheduled substances:

- *amygdalin*;
- *Atropa belladonna*;
- *folpet*;
- *hydrocyanic acid*;
- *niclosamide*.

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

- in Schedule 4—*fuzapladib sodium*, *ilunocitinib*, and 12 new chemical entities;
- in Schedule 5—*1,4-dimethylnaphthalene*;
- in Schedule 10—*Wild Cherry Bark*.

The Instrument also incorporates minor amendments to the Index entries for *captafol*, *MDMA*, and *psilocybine*, and makes a small number of minor editorial amendments and

corrections, including to remove the erroneous wording for containers with a child-resistant closure in the Schedule 2 entry for *paracetamol*.

## **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](http://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 12 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:

- *datopotamab deruxtecan*;
- *elafibranor*;
- *futibatinib*;
- *inavolisib*;
- *landiolol*;
- *lazertinib*;
- *pegunigalsidase alfa*;
- *repotrectinib*;
- *sepiapterin*;
- *teprotumumab* (which is also included in clause 4 of Appendix F, and clause 2 of Appendix L);
- *tezepelumab*;
- *velmanase alfa*.

The inclusion of a *teprotumumab* in Appendix F (warning statements and general safety directions for poisons), means that this substance must be labelled with warning statements and general safety directions for poisons (other than human medicines, agricultural and veterinary chemicals and chemicals packed and sold solely for industrial, dispensary, manufacturing or laboratory use). Additionally, the inclusion of *teprotumumab* in Appendix L (requirements for dispensing labels for medicines), means that a medicine for human use that contains this substance must be labelled with additional warning statements at the time of dispensing.

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

- in Schedule 4—*fuzapladib sodium*, to provide that all preparations of *fuzapladib sodium* are a prescription-only medicine;
- in Schedule 4—*ilunocitinib*, to provide that all preparations of *ilunocitinib* are a prescription-only medicine;
- in Schedule 5—*1,4-dimethylnaphthalene*, to provide that *1,4-dimethylnaphthalene* when used in agricultural chemicals requires appropriate packaging with simple warning and safety directions on the label;
- in Schedule 5—*niclosamide*, to provide that tablet or paste preparations of *niclosamide* for use in companion animals require appropriate packaging with simple warning and safety directions on the label;
- in Schedule 6—*niclosamide*, to provide that *niclosamide* requires distinctive packaging with strong warnings and safety directions on the label, except preparations for human therapeutic use, or as a tablet or paste in companion animals; and
- in Schedule 10—*Wild Cherry Bark*, to provide that preparations of *Wild Cherry Bark* containing more than 10 mg/kg of amygdalin or 10 mg/kg of hydrocyanic acid are prohibited as substances of such danger to health as to warrant prohibition of supply and use.

### *Amendments to existing scheduling arrangements*

The Instrument amends the entry for *amygdalin* in Schedule 10 to the current Poisons Standard. The effect of this change is to allow trace concentrations (10 mg/kg or less) of *amygdalin* to be unscheduled.

The Instrument also makes changes to the entry for *Atropa belladonna* in Schedule 2 to the current Poisons Standard. The effect of this change is to restrict oral use preparations of *Atropa belladonna* to individuals over 6 years of age. Preparations of *Atropa belladonna* intended for oral use in children under 6 years of age will be a prescription-only medicine (Schedule 4).

The Instrument removes the entry for *folpet* in Schedule 7 to the current Poisons Standard, and introduces a new entry in Schedule 6 for all *folpet* preparations.

The Instrument amends the entries for *hydrocyanic acid* in Schedule 7 and Schedule 4 of the current Poisons Standard to allow trace concentrations (10 mg/kg or less) to be unscheduled. Additionally, the amendment of the Schedule 7 entry for this substance clarifies that salts and derivatives of hydrocyanic acid, other than cyanides specifically captured in that Schedule, are unscheduled.

### *Other minor amendments*

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 *captafol*—remove an erroneous reference to Appendix J, clause 1;
- in relation to *MDMA*—correctly reference the Appendix D, clause 9 entry (the Index incorrectly referenced Appendix D, clause 10); and
- in relation to *psilocybine*—correctly reference the Appendix D, clause 9 entry (the Index incorrectly referenced Appendix D, clause 10).

The Instrument incorporates a minor editorial amendment to remove the words ‘or in a container with a child-resistant closure’ in sub-subparagraph (e)(iii)(A) of the existing Schedule 2 entry for *paracetamol*. The purpose of this amendment is to reflect the final decision, in relation to paracetamol, published in May 2023 (and updated with clarification in February 2025), that those words be removed, and to require tablet and capsule preparations on general sale to be in blister packaging.

The Instrument also makes a minor editorial amendment to remove the erroneous capitalisation of ‘tHE pH’ and ‘A pH’, by replacing those words with ‘the pH’ and ‘a pH’, respectively, in a small number of substances in Schedules 5, 6 and 10 to the current Poisons Standard.

### **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](http://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](http://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 *amygdalin*, *hydrocyanic acid*, and *Wild Cherry Bark*. The proposed amendments were referred to the June 2023 meetings of the Joint ACMS-ACCS.

Invitation to comment on these proposed amendments 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 regarding the proposed amendments was published on the TGA website on 5 October 2023, with a closing date of 2 November 2023. An additional invitation to comment on alternative proposed amendments was published on 1 March 2024, with a closing date of 12 April 2024.

The scheduling delegate's final decisions concerning these proposed amendments were published on the TGA website on 20 February 2025. The delegate decided to:

- amend the Schedule 10 entry for *amygdalin* to exempt preparations for therapeutic use containing 10 mg/kg or less of *amygdalin*;
- amend the Schedule 7 entry for *hydrocyanic acid* to exempt preparations for therapeutic use containing 10 mg/kg or less of *hydrocyanic acid* and exempt its salts and derivatives other than cyanides separately specified in the Schedule;
- amend the Schedule 4 entry for *hydrocyanic acid* to exempt therapeutic use preparations for therapeutic use containing 10 mg/kg or less of *hydrocyanic acid*; and
- create a new Schedule 10 entry for *Wild Cherry Bark* for therapeutic use except when in preparations containing 10 mg/kg or less of *amygdalin* and 10 mg/kg or less of *hydrocyanic acid*.

Public comment was invited in relation to the proposed amendments to the scheduling of *niclosamide* which was referred to the March 2024 meeting of the ACCS. The proposal was to create a new Schedule 5 entry for *niclosamide* when in tablet or paste preparations for companion animals, and a new Schedule 6 entry for *niclosamide* except when included in Schedule 2 or Schedule 5.

Invitation to comment on this proposed amendment was referred to the March 2024 meeting of the ACCS and was published on the TGA website on 5 January 2024, with a closing date of 5 February 2024. A further invitation to comment on the interim decision in respect of the proposed amendments was published on the TGA website on 26 July 2024, with a closing date of 23 August 2024.

The scheduling delegate's final decisions concerning the proposed amendments were published on the TGA website on 27 September 2024. The delegate decided to amend the current Poisons Standard in respect of *niclosamide*, consistent with the proposal set out above.

Public comment was invited in relation to the proposed amendments to the scheduling of *Atropa belladonna* which was referred to the November 2024 meeting of the ACMS. The proposal was to delete the Schedule 2 entry for *Atropa belladonna* from the current Poisons Standard, with the effect of making all preparations of *Atropa belladonna* Schedule 4.

Invitation to comment on this proposed amendment was referred to the November 2024 meeting of the ACMS and was published on the TGA website on 23 September 2024, with a closing date of 22 October 2024. A further invitation to comment on the interim decision in respect of the proposed amendments was published on the TGA website on 14 March 2025, with a closing date of 4 April 2025.

The scheduling delegate's final decisions concerning the proposed amendments were published on the TGA website on 19 May 2025. The delegate decided to amend the Schedule 2 entry of the current Poisons Standard for *Atropa belladonna* to restrict oral use preparations to adults and children over 6 years of age.

#### *Other amendments*

The remaining amendments to the current 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 June 2025.