EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Poisons Standard—October 2026) Instrument 2026

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 2026) Instrument 2026* (the Instrument) repeals and replaces the *Therapeutic Goods (Poisons Standard—June 2026) Instrument 2026*, which had been in effect since 1 June 2026. 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 included in the current Poisons Standard for the first time, the Instrument incorporates entries for:

- in Schedule 4—11 new chemical entities;
- in Schedule 5—2 new entries;
- in Schedule 6—3 new entries; and
- in Schedule 9—*6-methylnicotine.*

In relation to substances that are already included in the current Poisons Standard, the Instrument amends the existing entries for the following scheduled substances:

- in Schedule 4—*Somapacitan*; and
- in Schedule 10—*Lead compounds*.

The Instrument also makes a small number of minor, editorial amendments and corrections. Specifically, these minor amendments are to correct the spelling of *orelabrutinib*, correct the omission of the Schedule 4 notation used for substances that are also listed in Appendix D, and amend the index entry for *sodium tetradecylsulfate*, to identify that the substance is included in Schedule 4.

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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 to the Poisons Standard, signifying the degree of risk and the level of 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 the ACMS or the 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 to, 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 provides for the inclusion of several specified substances in the current Poisons Standard for the first time. Some of these changes have been 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 have been made following a delegate-only decision.

New schedule entries

The Instrument introduces entries in the current Poisons Standard for eight 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 only be available from a pharmacist on prescription.

These new schedule entries for new chemical entities are:

- *Bempedoic acid*;
- *Efanesoctocog alfa;*

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- *Eplontersen*;
- *Gadoquatrane*;
- *Gepotidacin mesilate*;
- *Olutasidenib;*
- *Tapinarof; and*
- *Teplizumab.*

The Instrument also incorporates the inclusion of *teplizumab* into Appendix F (warning statements and general safety directions for poisons) and Appendix L (requirements for dispensing labels for medicines). This means that *teplizumab* must be labelled with specified warning labels, in addition to being labelled with additional warning statements, at the time of dispensing. In relation to Appendix F, the inclusion of *teplizumab* has introduced two new warning statements, namely:

- item 39—do not use during pregnancy and do not use for at least 30 days prior to planned pregnancy; and
- item 40—do not breastfeed during treatment and for at least 30 days after the last dose.

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

- in Schedule 4—*enflicoxib,* to provide that all preparations of *enflicoxib* are a prescription-only medicine;
- in Schedule 4—*lonapegsomatropin,* to provide that all preparations of *lonapegsomatropin* are a prescription-only medicine and to ensure possession without authority is illegal through inclusion of *lonapegsomatropin* in clause 5 of Appendix D;
- in Schedule 4—*somatrogon,* to provide that all preparations of *somatrogon* are a prescription-only medicine and to ensure possession without authority is illegal through inclusion in clause 5 of Appendix D;
- in Schedule 5—*Camellia sinensis extract (green tea extract),* to provide that all preparations for oral use of this substance (except for preparations for human therapeutic use when compliant with the required advisory statements for medicine labels, or in preparations containing 300 mg or less of epigallocatechin-3-gallate per maximum recommended daily dose) require appropriate packaging with warning and safety directions on the label. The substance is also listed in clause 4 of Appendix F, with two new warning statements prescribed in clause 1 Appendix F. The Instrument cross-references both substances to each other in the Index.
- in Schedule 5—*spidoxamat,* to provide that all preparations of *spidoxamat* require appropriate packaging with simple warning and safety directions on the label;
- in Schedule 6—*dimethyl disulfide,* to provide that preparations of *dimethyl disulfide* for agricultural use as a soil fumigant require distinctive packaging with strong warnings and safety directions on the label;
- in Schedule 9—*6-methylnicotine,* to provide that all preparation, manufacture, possession, sale and use of *6-methylnicotine* is prohibited, due to its high risk of dependency, abuse, misuse or illicit use; and
- in clause 3 of Appendix B—*bacillus paralicheniformis*, to provide that all preparations of *bacillus paralicheniformis* are exempt from Scheduling requirements.

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The Instrument also introduces new entries for *BPA glycidyl dimethacrylate* and *BPA glycidyl diacrylate* in preparations for cosmetic use to the current Poisons Standard, along with entries in clause 3 of Appendix E and clause 4 of Appendix F for both substances. Appendix E pertains to the required first aid instructions for poisons, while Appendix F pertains to the warning statements and general safety directions that must accompany poisons.

Amendments to existing scheduling arrangements

The Instrument amends the entry for *lead compounds* in Schedule 10. The effect of this change is to reduce the permissible concentration cut-off of *lead compounds* in anti-fouling paints from 0.1% to 0.06%, calculated on the non-volatile content of the paint.

Other minor amendments

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

- in relation to *orelabrutinib*—amend the Schedule 4 entry to correct the spelling of the substance from the erroneous spelling *orebrutinib* when it was added as a new chemical entity in the previous Poisons Standard update;
- in relation to *sodium tetradecylsulfate*—amend the index to correctly include *sodium tetradecylsulfate* in Schedule 4; and
- in relation to *enzalutamide, macitentan* and *pomalidomide*—amend the Schedule 4 entries for these substances to correctly adopt the notation used within Schedules 4 and 8, which denote a substance's inclusion in Appendix D.

An amendment has also been made to the Reader's guide and section 28 to replace references to the *Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines* and the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines* as those instruments have been repealed and replaced. The new references are to the *Therapeutic Goods (Standard for Labelling of Prescription Medicines) (TGO 115) Order 2026* and the *Therapeutic Goods (Standard for Labelling of Non-Prescription Medicines) (TGO 116) Order 2026*.

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).

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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.

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Consultation

Proposed amendments referred to an expert advisory committee

Public comment was invited in relation to the proposed amendments to the scheduling of *Camellia sinensis extract (green tea extract)*. The proposed amendments were referred to the November 2022 meeting of the Joint ACMS-ACCS.

Invitation to comment on the proposed amendments was published on the TGA website on 1 September 2022, with a closing date of 29 September 2022. A further invitation to comment on the interim decision regarding the proposed amendments was published on the TGA website on 3 February 2023, with a closing date of 3 March 2023. An additional invitation to comment on the 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 19 February 2025. The final decision was to create a new Schedule 5 entry for oral use products, except in preparations containing 300 mg or less of *epigallocatechin-3-gallate* per maximum recommended daily dose or for therapeutic use when compliant with the required advisory statements for medicine labels. The final decision also required warning statements through new Appendix F.

Lead compounds

In March 2021, an application to amend the Schedule 10 entry for *lead compounds* to reduce the permissible level in paints from 0.1% to 0.009% was referred to the Advisory Committee on Chemicals Scheduling (ACCS #30).

Invitation to comment on these proposed amendments was published on the TGA website on 24 December 2020, with a closing date of 27 January 2021. A further invitation to comment on the interim decision regarding the proposed amendments was published on the TGA website on 20 July 2021, with a closing date of 17 August 2021. Subsequently, the 2021 Final Decision amended the scheduling of lead to reduce the maximum permissible level of lead in paints to 0.009% (equivalent to 90 ppm or 90 mg/kg).

In consideration of significantly reduced exposure pathways from anti-fouling and anticorrosion paints compared to other paints, and the time required to develop low *lead* containing paints, anti-fouling and anti-corrosive paints were exempted from this requirement and retained the previous maximum permissible level of 0.1% lead in them. The 2021 Final Decision foreshadowed that the exemption for anti-fouling and anti-corrosive paints would be repealed by 1 October 2023, in effect providing a two-year transition period for industry to develop anti-fouling and anti-corrosive paints containing 0.009% or less of lead.

However, due to limited availability of alternatives to copper compounds, the predominant active ingredient and source of *lead* in anti-fouling paints, an application to retain the exemption for anti-fouling paints was received. Invitation to comment on the proposed amendments to the Final Decision 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 3 August 2023, with a closing date of 1 September 2023. A Final Decision was made to amend the 2021 Final Decision and was published on the TGA website on 18 September 2023. The final decision outlined that a maximum limit of 0.009% lead was applied to anticorrosive paints only (effective 1 October 2023). The 2023 Final Decision foreshadowed further amendments to the scheduling of lead to reduce the permissible maximum level of *lead* in anti-fouling paints to 0.06% by 1 October 2026.

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March 2025 ACMS/ACCS/ACMS-ACCS meeting cycle

Public comment was invited in relation to the proposed amendments to the scheduling of *acrylates* and *methacrylates* based on *bisphenol A (BPA)*. The proposed amendments were referred to the March 2025 meeting of the ACCS.

Invitation to comment on these proposed amendments was published on the TGA website on 17 January 2025, with a closing date of 17 February 2025. A further invitation to comment on the interim decision regarding the proposed amendments was published on the TGA website on 18 December 2025, with a closing date of 23 January 2026.

The scheduling delegate's final decisions concerning these proposed amendments were published on the TGA website on 25 May 2026. The Delegate decided to create new Schedule 6 entries with respect to *BPA glycidyl dimethacrylate* and *BPA glycidyl diacrylate*, with the primary purpose of increasing consumer awareness through the use of signal headings, thereby reducing the risk of unintentional exposure to the substances – particularly in cosmetic products. The Delegate also decided to include additional warning statements and safety directions regarding skin sensitisation to further support effective risk management.

June 2025 ACMS/ACCS/ACMS-ACCS meeting cycle

Public comment was invited in relation to the proposed amendments to the scheduling of *6-methylnicotine,* extracts and essential oils primarily composed of *somatrogon, lonapegsomatropin* and *somapacitan*. The proposed amendments were referred to the June 2025 meetings of the ACMS and Joint ACMS-ACCS.

Invitation to comment on these proposed amendments was published on the TGA website on 14 May 2025, with a closing date of 13 June 2025. A further invitation to comment on the interim decision regarding the proposed amendments was published on the TGA website on 9 June 2026, with a closing date of 10 July 2026.

The scheduling delegate's final decisions concerning these proposed amendments were published on the TGA website on 25 September 2026. The delegate decided to confirm their interim decision and create new Schedule 4 entries with respect to *somatrogon* and *lonapegsomatropin*. The Delegate also decided to include additional controls on possession or supply of these poisons, as well as *somapacitan*, through Appendix D. The Schedule 4 entry for *somapacitan* will be amended to include notation used for substances that are also listed in Appendix D. The delegate also decided to confirm their interim decision and create a new Schedule 9 entry with respect to *6*-methylnicotine.

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.

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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 2026.

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