

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Poisons Standard—October 2024) Instrument 2024

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 2024) Instrument 2024* (“the Instrument”) repeals and replaces the *Therapeutic Goods (Poisons Standard—June 2024) Instrument 2024*, which had been in effect since 1 June 2024. The purpose of the Instrument is principally to revise the 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 substances:

- *azelaic acid*;
- *carbendazim*;
- *dimethylacetamide*;
- *ethylmorphine*;
- *glycopyrronium*;
- *moxidectin*;
- *nicotine*; and
- *tranexamic acid*.

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

- in Schedule 3— *cytisine*;
- in Schedule 4— *cytisine*, *vatinoxan hydrochloride* and 11 new chemical entities;
- in Schedule 5— *epyrifenacil*, *homobrassinolide*, *metarylpicoxamid*;
- in Schedule 6— *palmitoylethanolamide (excluding derivatives)*;

- in Schedule 8—*thiafentanil*; and
- Schedule 9—*ephedrine, diphendine, isophenidine, methoxphenidine, propylphenidine*.

The Instrument also incorporates minor amendments to update the Australian and international standards referred to in:

- the definition of ***Child-resistant packaging***; and
- item 4 of clause 1 of Appendix A, Exempt preparations and products.

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.

The instrument also incorporates changes made to the current Poisons Standard by the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* which amends the entries for nicotine in the Poisons Standard with effect from 1 October 2024.

New schedule entries

The Instrument introduces entries in the current Poisons Standard for 11 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:

- *capivasertib*;
- *danicopan*;
- *fruquintinib*;
- *iptacopan*;
- *lumasiran*;
- *odevixibat*;
- *pinaverium bromide*;
- *ritlecitinib*;
- *sotatercept*;
- *vorasidenib*; and
- *vutrisiran*.

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

- in Schedule 3 and Appendix H, clause 1 — *cytisine* to provide that divided oral preparations of *cytisine* with a recommended daily dose of 9 mg or less as an aid in withdrawal from tobacco smoking in adults are pharmacist-only medicines and are permitted to be advertised;
- in Schedule 3 — *nicotine* in therapeutic vaping goods in final dosage form for smoking cessation or the management of nicotine dependence to provide that such goods are pharmacist-only medicines when the controls intended to safeguard patient health and safety are met as well as ensuring appropriate health practitioner supervision of the supply;
- in Schedule 4 — *cytisine* and *vatinoxan hydrochloride* to provide that *cytisine* is a prescription-only medicine, except when included in Schedule 3, and that *vatinoxan hydrochloride* is a prescription-only medicine;
- in Schedule 5 — *epyrifenacil*, *metarylpicoxamid*, and *homobrassinolide*, to provide that preparations containing these substances require appropriate packaging with simple warnings and safety directions on the label;
- in Schedule 6 — *palmitoylethanolamide* (excluding its derivatives), to provide that preparations containing this substance require distinctive packaging with strong warnings and safety directions on the label except preparations for therapeutic use or dermal cosmetic use containing 1% or less of *palmitoylethanolamide*.
- in Schedule 8 — *thiafentanil*, to provide that this substance is a prescription-only medicine and impose additional restriction on manufacture, supply, distribution and possession; and
- in Schedule 9 — *diphenidine*, *ephenidine*, *isophenidine*, *methoxphenidine*, and *propylphenidine*, to provide that these substances are for medical or scientific

research, or for analytical, teaching or training purposes. Manufacture, possession, supply or use of these substances without authority is illegal.

Amendments to existing scheduling arrangements

The Instrument makes changes to the entry for *moxidectin* in Schedule 5 to the current Poisons Standard. The effect of these changes is that preparations containing 25 mg or less of this substance for external use in the treatment of cats and dogs when packed in single dose tubes are in Schedule 5.

The Instrument also makes changes to the entry for *dimethylacetamide* in Schedule 5 to the current Poisons standard. The effect of these changes is that *dimethylacetamide* in preparations containing 40% or less of *dimethylacetamide* in single dose flow-limited tubes of 5 mL or less for dermal application to companion animals are now in Schedule 5 instead of Schedule 6.

The Instrument revises the entries for *nicotine* in Schedule 4 and Schedule 7 to the current Poisons Standard to exempt nicotine included in Schedule 3 from the entries in Schedules 4 and 7 of the Poisons Standard. The Instrument also makes subsequent changes to the Index to include Schedule 3 in the Index entry for *nicotine*.

The Instrument amends the entry for *carbendazim* in Schedule 7 (“Dangerous poisons”) to increase the concentration limit for exemption from 0.1% to 0.35%. This allows paints, jointing compounds and sealants containing 0.35% or less of *carbendazim* to be exempted from classification as a Schedule 7 poison.

The Instrument also incorporates amendments to the existing entries in the current Poisons Standard for *ethylmorphine* by removing the entry for this substance in Schedule 2 and removing subsequent references to the Schedule 2 entry from Schedule 4 and 8 and the Index. The effects of these changes is that:

- *ethylmorphine* preparations when compounded with one or more other therapeutically active substances are classified as Schedule 4 when containing not more than 100 mg of *ethylmorphine* per dosage unit in divided preparations or containing not more than 2.5% of *ethylmorphine* in undivided preparations; and
- any other preparation of *ethylmorphine* is a Schedule 8 substance and restrictions on manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence will apply.

The Instrument revises the entry for *tranexamic acid* in Schedule 4 to the current Poisons Standard by:

- exempting preparations containing up to 3% *tranexamic acid* for dermal cosmetic use from the Schedule 4 entry for the substance; and
- removing the cross reference to *cetyl tranexamate hydrochloride* from the index entry to *tranexamic acid*.

Under the amended entry, all cosmetic preparations for dermal applications containing up to 3% *tranexamic acid* will be unscheduled.

The Instrument also makes changes to the existing entries in the current Poisons Standard for *glycopyrronium* by removing the Schedule 3 (“Pharmacist only”) entry and Index to remove the reference to the Schedule 3 entry. The effect of these changes is that all *glycopyrronium* preparations are now captured under the Schedule 4 entry for the substance.

The instrument also revises the entries for *azelaic acid* by:

- creating a new Schedule 5 entry for *azelaic acid*;
- amending the Schedule 2, Schedule 3 and Schedule 4 entries for *azelaic acid*;

- introducing first aid instructions and safety directions for *azelaic acid* in Appendix E and Appendix F; and
- cross-referencing to *nonanedioic acid*.

The effect of these revisions is that:

- dermal preparations of *azelaic acid* for human therapeutic use are available as Schedule 2 medicines;
- other therapeutic preparations of *azelaic acid* are available as Schedule 4 medicines; and
- all other preparations containing *azelaic acid* are available as Schedule 5 substances.

All preparations of *azelaic acid* are required to carry first aid instructions and safety directions on the labels.

Other minor amendments

The Instrument also refers to newer editions of standards incorporated by reference in the current Poisons Standard. These amendments are:

- to update the definition of ***Child-resistant packaging*** in section 6 to refer to the Australian Standard AS 1928-2007, British Standards Institution Standard BS EN ISO 8317:2015 and Canadian Standards Association Standard CSA Z76.1:21; and
- item 4 of clause 1 of Appendix A (Exempt preparations and products) to refer to Australian Standard AS 8124.4:2020.

The purpose of these amendments is to update references to Australian and international standards in the Instrument.

As a result of these changes, to be considered a child-resistant packaging, a packaging must be recloseable and meet the requirements of standards including British Standards Institution Standard BS EN ISO 8317:2015 *Child-resistant packaging—Requirements and testing procedures for reclosable packages* or Canadian Standards Association Standard CSA Z76.1:21 *Reclosable Child-Resistant Packages*.

Further, for a blister or strip packaging in which a unit of use is individually protected until the time of release to be considered a child-resistant packaging, the blister or strip packaging must satisfy the requirements of section 3 (*Requirements for non-reclosable packages*) of Australian Standard AS 1928-2007, *Child-resistant packages*.

Regarding general exemptions from the controls on substances (paragraph 11(a) of the current Poisons Standard) CHEMISTRY SETS for toy and educational use that satisfy the requirements of Australian Standard AS 8124.4-2020, *Safety of toys, Part 4: Experimental sets for chemistry and related activities* are exempted from this instrument.

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. The TGA is in the process of acquiring a copy of the CSA Z76.1:21, *Reclosable child-Resistant Packages* that may then be viewed 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

The Office of Impact Analysis advised that an Impact Analysis was not required in relation to the amendments to the versions of the standards referred to in the Instrument, as these amendments are seeking to align to international standards (OIA24-08350).

Proposed amendments referred to an expert advisory committee

Public comment was invited in relation to the proposed amendments to the scheduling of *azelaic acid* which was referred to the March 2023 meeting of the ACCS. The proposal was to create a new entry for *azelaic acid* in Schedule 5; amend the entry for *azelaic acid* in Schedule 2 and 4 to specify therapeutic use of *azelaic acid*; amend the entry for *azelaic acid* in Schedule 2 to exempt preparations containing 1% or less of *azelaic acid* for non-human use; and to exclude derivatives from the entries for *azelaic acid*.

Invitation to comment on this proposed amendment referred to the March 2023 meeting of the ACCS was published on the TGA website on 5 January 2023, with a closing date of 3 February 2023. A further invitation to comment on the interim decision in respect of the proposed amendments was published on the TGA website on 13 July 2023, with a closing date of 10 August 2023.

The scheduling delegate's final decisions concerning the proposed amendments was published on the TGA website on 4 September 2023. The delegate decided to create a new entry for *azelaic acid* in Schedule 5 and amend the entry for *azelaic acid* in Schedule 2 and 4 to specify therapeutic use and human therapeutic use of *azelaic acid* respectively. The decision also included a new entry in Appendix E to require first aid instructions and a new entry in Appendix F to require safety directions.

Public comment was invited in relation to the following proposed amendments were referred to the November 2023 meetings of the ACMS and Joint ACMS-ACCS:

- to create a new entry for *glycopyrrolonium* in Appendix H to permit advertising; and
- to create a new entry for *palmitoylethanolamide* in Schedule 6 to require appropriate packaging with simple warnings and safety directions on the label.

Invitation to comment on these proposed amendments (i.e., those referred to the November 2023 meeting of the ACMS and Joint ACMS-ACCS) 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 decisions regarding these 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 these proposed amendments were made on 23 and 25 September 2024 respectively (and will be published on the TGA website before 1 October 2024). The delegate decided to:

- remove the Schedule 3 entry, and amend the Schedule 4 entry to capture all preparations for *glycopyrrolonium*; and
- create a new Schedule 6 entry for *palmitoylethanolamide* that excludes preparations for therapeutic use or dermal cosmetic use containing 1% or less of *palmitoylethanolamide*.

Public comment was also invited in relation to the following proposed amendments to the current Poisons Standard that were referred to the March 2024 meeting of the ACMS and Joint ACMS-ACCS:

- the proposal to create a new Schedule 2 entry for *cytisine* when in divided preparations for oral use containing 1.5 mg or less of *cytisine* per dosage unit, and a new Schedule 4 entry for *cytisine* for all other preparations;

- the proposal to remove the Schedule 2 entry for *ethylmorphine* and make consequential amendments to Schedule 4 and Schedule 8; and
- the proposal to amend the Schedule 4 entry for *tranexamic acid* to exclude preparations containing 3% or less of *tranexamic acid* (replacing *cetyl tranexamate hydrochloride*) for dermal cosmetic use.

Invitation to comment on these proposed amendments (i.e., those referred to the March 2024 meeting of the ACMS and Joint ACMS-ACCS) 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 decisions in respect of these 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 these proposed amendments were made on 25 September 2024 (and will be published on the TGA website before 1 October 2024).

The delegate decided to:

- create a new Schedule 3 entry in divided oral and oromucosal preparations with a recommended daily dose of 9 mg or less of *cytisine* as an aid in withdrawal from tobacco smoking in adults, and a new Schedule 4 entry for *cytisine* for all other preparations;
- remove the Schedule 2 entry for *ethylmorphine* and make consequential amendments to Schedule 4 and Schedule 8; and
- to amend the Schedule 4 entry for *tranexamic acid* to exclude preparations containing 3% or less of *tranexamic acid* (replacing *cetyl tranexamate hydrochloride*) for dermal cosmetic use.

Other amendments

Consultation on the amendments to the entry of nicotine was not undertaken as the amendments reflect those made by the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* to the *Therapeutic Goods (Poisons Standard—June 2024) Instrument 2024*.

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 October 2024.