EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Poisons Standard—June 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—June 2024) Instrument 2024* ("the Instrument") repeals and replaces the *Therapeutic Goods (Poisons Standard—February 2024) Instrument 2024*, which had been in effect since 1 February 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 a number of 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 the existing entries, and in some cases introduces new entries, for the following substances:

- *adrenaline*;
- *astodrimer sodium*;
- *bilastine*;
- *celecoxib*;
- *dioxane*;
- *meloxicam*;
- *naratriptan*; and
- *nicotine*.

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

- in Schedule 4—*BPC-157*, *capromorelin*, and 14 new chemical entities; and
- in Schedule 5—*benzoic acid*.

The Instrument also incorporates minor amendments to the Index entries for *omberacetam* and *menotrophin*, to add clarity and assist in searchability of those substances.

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 a number of 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:

- *abrocitinib*;
- *bulevirtide*;
- *clascoterone*;
- *elranatamab*;

- *etranacogene dezaparvovec*;
- *etrasimod*;
- *fezolinetant*;
- *lebrikizumab*;
- *lecanemab*;
- *maribavir*;
- *nelarabine*;
- *relugolix*;
- *tebentafusp*; and
- *zilucoplan.*

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

- in Schedule 5 — *benzoic acid* (excluding its salts and derivatives), to provide that preparations containing more than 1% of this substance, and which are for agricultural use, require appropriate packaging with simple warnings and safety directions on the label; and
- in Schedule 4 and Appendix D, clause 5 — *BPC-157* and *capromorelin*, to provide that these substances are prescription-only medicines, possession of which without authority (e.g., other than in accordance with a legal prescription) is illegal.

Amendments to existing scheduling arrangements

The Instrument makes changes to the entries for *adrenaline* in Schedule 3 ("pharmacist-only medicines") and Schedule 4 to the current Poisons Standard. The effect of these changes is that preparations containing this substance are:

- prescription-only medicines if they are topical preparations indicated for the treatment of wounds in humans, or otherwise contain more than 1% of adrenaline; and
- pharmacist-only medicines if they contain 1% or less of adrenaline, unless they are not for injection and contain 0.02% or less of adrenaline.

The Instrument removes the entry for *dioxane* in clause 1 of Appendix G to the current Poisons Standard and amends the entry for that substance in Schedule 6. The effect of these changes is that dioxane is a Schedule 6 poison except:

- in preparations for cosmetic or human internal therapeutic use containing 0.001% (10 mg/kg) or less of dioxane; or
- in other preparations containing 0.01% (100 mg/kg) or less of dioxane.

The Instrument revises the entries for *nicotine* in Schedule 4 and Schedule 7 to the current Poisons Standard to restrict the range of oromucosal and transdermal nicotine preparations that are excluded from those entries. The effect of the changes is that such preparations are only excluded if they are for human therapeutic use when included in the Australian Register of Therapeutic Goods as an aid in withdrawal either from tobacco smoking or nicotine vaping.

The Instrument also incorporates amendments to the existing entries in the current Poisons Standard for:

- *astodrimer sodium* — by revising the entry for this substance in Schedule 3, and introducing a new entry in Schedule 2, to provide that this substance is:
    - a pharmacy medicine when used in a nasal spray; and
    - a pharmacist-only medicine, except when used in a nasal spray or condom lubricant;

- *bilastine* — by revising the entries for this substance in Schedules 3 and 4, and introducing a new entry in Schedule 2, to provide that bilastine in oral preparations is:
    - a pharmacy medicine when labelled with a recommended daily dose not exceeding 20 mg bilastine for the treatment of adults and children aged 12 years and over;
    - a pharmacist-only medicine when labelled with a recommended daily dose not exceeding 10 mg bilastine for the treatment of children 6-11 years of age; and
    - a prescription-only medicine in all other cases.
- *meloxicam* — by revising the entry for this substance in Schedule 6 to include injectable preparations containing 1% or less of meloxicam (when combined with a veterinary vaccine containing bacterial antigens and for single use in lambs undergoing husbandry procedures at marking), which were previously Schedule 4 prescription animal remedies;
- *naratriptan* — by revising the entry for this substance in Schedule 4 and introducing entries in Schedule 3 and clause 1 of Appendix H, to provide for the availability – as pharmacist-only medicines – of divided oral preparations (containing 2.5 mg or less naratriptan per dosage unit) for the acute relief of migraine in patients who have a stable, well-established pattern of symptoms. Such preparations are permitted to be advertised;
- *celecoxib* — to amend both the Schedule 3 and Schedule 4 entries to correct minor typographical errors.

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 to:

- in relation to *omberacetam* — to insert a cross reference to *noopept* and *N-Phenylacetyl-L-prolylglycine ethyl ester* for clarity and to assist searchability; and
- in relation to *menotrophin* — to insert a cross reference to *human menopausal gonadotrophin* to add clarity and to assist searchability.

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 8124.4-2003, *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 1928-2001, *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 8317:2004, *Child-resistant packaging—Requirements and testing procedures for reclosable packages*;
- Canadian Standards Association Standard CSA Z76.1-06, *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 amendment to the scheduling of *dioxane*, which was referred to the March 2023 meeting of the ACCS. That is, the proposal to remove the entry for *dioxane* in Appendix G to the current Poisons Standard, which exempts the substance from scheduling when present at or below concentration of 100 mg/kg.

Invitation to comment on this proposed amendment 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 this 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 this proposed amendment was published on the TGA website on 4 September 2023. The delegate decided to delete the Appendix G entry and amend the Schedule 6 entry for *dioxane* to except preparations for cosmetic or human internal therapeutic use containing 0.001% or less of dioxane; or in other preparations containing 0.01% or less of dioxane.

Public comment was also invited in relation to the following proposed amendments to the current Poisons Standard that were referred to the November 2023 meeting of the ACMS and Joint ACMS-ACCS:

- the proposal to amend the entry for *astodrimer sodium* in Schedule 3 to exclude astodrimer sodium when used in a nasal spray;
- the proposal to amend the entry for *bilastine* in Schedule 3 in oral preparations when labelled with a recommended daily dose not exceeding 20 mg of bilastine for the treatment of adults and children 6 years of age and older;
- the proposal to create new entries for *BPC-157* in Schedule 4 and Appendix D, clause 5;
- the proposal to create a new entry for *naratriptan* in Schedule 3 when in divided oral preparations containing 2.5 mg or less of naratriptan per dosage unit and when sold in a pack containing not more than 2 dosage units for the acute relief of migraine in patients who have a stable, well-established pattern of symptoms. The proposal included naratriptan in Appendix H, clause 1;
- the proposal to amend the entry for *adrenaline* in Schedule 4 to capture topical preparations for wound management in humans; or other preparations containing more than 1% of adrenaline. The proposal included consequent amendments to Schedule 3;
- the proposal to create new entries for *benzoic acid* in Schedule 5, Schedule 6 and Schedule 7. The proposal included preparations of benzoic acid containing greater than 10% of benzoic acid in Schedule 7, preparations of benzoic acid containing less than 10% of benzoic acid in agricultural and veterinary chemical products in Schedule 6, and preparations of benzoic acid containing less than 1% of benzoic acid in agricultural and veterinary chemical products in Schedule 5; and
- the proposal to amend the entry for *meloxicam* in Schedule 6 to include injectable vaccines containing bacterial antigens and 1% or less of meloxicam for single use in lambs undergoing husbandry procedures at marking.

On 31 October 2023 an application was received which proposed the inclusion of a new entry in Schedule 2 for *bilastine* in oral preparations that are labelled with a recommended daily dose not exceeding 20 mg of bilastine for the treatment of adults and adolescents 12 years of age and older. This application was consolidated with the earlier bilastine application (which proposed to amend the entry for bilastine in Schedule 3) and also referred to the November 2023 meeting of the ACMS.

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 in respect of 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 published on the TGA website on 22 May 2024. The delegate decided to:

- create a new Schedule 2 entry, and amend the Schedule 3 entry for astodrimer;
- create a new Schedule 2 entry, and amend the Schedule 3 and 4 entries for bilastine;
- create a new Schedule 3 and Appendix H, clause 1 entry, and amend the Schedule 4 entry for naratriptan;
- create a new Schedule 4 and Appendix D, clause 5 entry for BPC-157 and capromorelin;
- create a new Schedule 5 entry for benzoic acid (excluding its salts and derivatives);
- amend the Schedule 3 and Schedule 4 entries for adrenaline;
- amend the Schedule 6 entry for meloxicam;
- amend the Schedule 6 entry for dioxane;
- make editorial amendments for omberacetam, menotrophin and celecoxib; and
- create new Schedule 4 entries for 14 new chemical entities.

Discussion of nicotine scheduling at the ACMS

At the request of a committee member, the scheduling of nicotine was discussed at the March 2024 meeting of the ACMS, in the context of compliance and enforcement options related to the importation, supply and advertisement of nicotine pouches. The scheduling delegate's final decision concerning the amendment to the entries for *nicotine* in Schedule 4 and Schedule 7 of the current Poisons Standard is a delegate-only decision. This decision was published on the TGA website on 24 May 2024.

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 2024.