EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Poisons Standard—July 2023) Instrument 2023

The *Therapeutic Goods Act 1989* ("the Act") provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy, 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—July 2023) Instrument 2023* ("the Instrument") repeals and replaces the *Therapeutic Goods (Poisons Standard—June 2023) Instrument 2023* ("the Former Instrument"), which had been in effect since 1 June 2023.

The purpose of the Instrument is principally to incorporate a number of changes to existing entries and to include a number of specified substances in the current Poisons Standard for the first time. In particular, the Instrument gives effect to scheduling decisions relating to psilocybine and *N, α* -dimethyl-3,4-(methylenedioxy)phenylethylamine *(MDMA), by including these substances in Schedule 8 to the current Poisons Standard so they may be available in very limited, prescribed circumstances and for particular indications (i.e. MDMA for post-traumatic stress disorder or psilocybine for treatment-resistant depression).

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 Poisons Standard is also prohibited.

Purpose

The Instrument incorporates a number of changes to existing entries in the current Poisons Standard, and includes a number of specified substances in the current Poisons Standard for the first time. A number of these changes were made following the provision of advice from the ACMS, 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.

New and amended schedule entries
The Instrument introduces new schedule entries in Schedule 8 to the Poisons Standard for existing substances, MDMA and psilocybine, with associated additional controls specified in clause 5 and clause 10 of Appendix D to the Poisons Standard. Consequential amendments have been made to the Schedule 9 entries for MDMA and psilocybine, to create an exception when the substances are included in Schedule 8.

The Instrument also includes a minor amendment to the schedule entry for pentobarbital to include the '#' prefix, indicative of the Appendix D listing, as was the original intention of the Scheduling decision. Minor typographical errors have been corrected for references to human chorionic gonadotrophin and sodium laureth-6 carboxylate.

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*;

- 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

The changes to be implemented in relation to psilocybine and MDMA follow from applications to amend the Poisons Standard received in July 2020 and March 2022.

Public comment was invited in relation to the proposed amendments that were referred to the June 2022 meeting of the ACMS, from 29 April 2022 to 27 May 2022 respectively. A further invitation to comment on the interim decision not to amend the Poisons Standard regarding psilocybine and MDMA was published on 21 October 2022, with a closing date of 24 November 2022. Notification of the final decisions made in relation to these substances was published on the TGA website on 3 February 2023.

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 July 2023.