EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Standard for MDMA) (TGO 112) Order 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 is administered by the Therapeutic Goods Administration (the TGA) within the Australian Government Department of Health and Aged Care (the Department).

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Subsection 10(2) provides that an order establishing a standard for therapeutic goods may be specified by reference to the quality of the goods, or the procedures to be carried out in the manufacture of the goods, among other matters. An order may also require that a matter relating to the standard be determined in accordance with a particular test.

Importantly, a person who imports, exports or supplies therapeutic goods that do not conform to an applicable standard may be subject to offence and civil penalty provisions in sections 14 and 14A of the Act. The Secretary may, however, give consent in writing in relation to the importation, exportation or supply of therapeutic goods that do not conform to an applicable standard, in accordance with those sections.

The *Therapeutic Goods (Standard for MDMA) (TGO 112) Order 2024* (the Order) is made under section 10 of the Act. The purpose of the Order is to establish a ministerial standard for MDMA hydrochloride and MDMA hydrochloride products. The Order is designed to specify minimum benchmarks to ensure the quality of such goods for Australian patients, principally by reference to labelling requirements, assay limits and specified tests for the active pharmaceutical ingredient (API) and finished product.

Background

The Australian Government is responsible for regulating the quality, safety and efficacy or performance of therapeutic goods. In relation to therapeutic goods other than medical devices, this is achieved in part by requiring compliance with the default standards under the Act and specifying ministerial standards under section 10 of the Act. Such standards may relate to a range of matters including for instance the quality of the goods, procedures to be carried out in their manufacture, and requiring that matters be determined in accordance with a particular test.

Prior to 1 July 2023, MDMA was only included in Schedule 9 (Prohibited substances) to the Poisons Standard, which limited its use to authorised research and analytical purposes only. On 3 February 2023, a delegate of the Secretary made a decision to amend the MDMA entries in the Poisons Standard. As a result of this scheduling decision, from 1 July 2023, MDMA was added to Schedule 8 to the Poisons Standard, permitting its use as a Controlled drug for the treatment of post-traumatic stress disorder (PTSD), subject to additional controls specified for MDMA in Appendix D to the Poisons Standard.

Under these additional controls, MDMA in preparations for human use may be supplied only for the treatment of PTSD by a medical practitioner who is registered under state or territory legislation as a specialist psychiatrist, or for use in a clinical trial that is approved by, or notified to, the Secretary. For all other uses MDMA remains covered by the entry for it in Schedule 9 to the Poisons Standard.

There are currently no products containing MDMA that have been approved by the TGA for inclusion in the Australian Register of Therapeutic Goods (the Register). As such, and in light of the controls in Appendix D, access to MDMA may only occur through relevant TGA pathways for accessing unapproved therapeutic goods, being clinical trials or the Authorised Prescriber (AP) scheme. Unapproved therapeutic goods accessed through these pathways have not been evaluated by the TGA for safety, quality and efficacy.

Purpose

Concerns have arisen that there are currently no product standards, such as pharmacopoeial monographs, setting out quality requirements for MDMA, either as an API or a finished product. The Order is designed to address these concerns by establishing a ministerial standard for MDMA hydrochloride and MDMA hydrochloride products, whether imported into Australia or manufactured domestically. In doing so the Order is intended to provide an assurance to medical practitioners and patients that MDMA hydrochloride medicines meet minimum quality requirements.

The Order will contribute to the quality and efficacy of MDMA hydrochloride and MDMA hydrochloride products by ensuring that these goods are manufactured uniformly according to minimum standards. Standardisation is necessary to assure medical practitioners and patients that MDMA hydrochloride as an API or a finished product will be manufactured to a consistent and reproducible quality, which is essential to support the known safety and efficacy of any medicine.

The Order will also contribute to the quality of the MDMA hydrochloride products to which it applies through requiring that the average content of MDMA hydrochloride is within specified limits, and requiring that such products meet specified outcomes after undergoing a range of specified kinds of tests, for instance tests for the purity of MDMA hydrochloride and tests for heavy metals and residual solvents.

Incorporation by reference

Subsection 10(4) of the Act relevantly provides that, despite subsection 14(2) of the *Legislation Act 2003* (the Legislation Act), an order (or a variation of an order) under this provision may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

The following identifies and explains each of the documents that are incorporated by reference in the Order, how they may be accessed and the intended manner of incorporation.

Pharmacopoeia

The Order incorporates by reference the European Pharmacopoeia and the United States Pharmacopeia-National Formulary, which are default standards for the purposes of the Act. The note in section 4 of the Order makes it clear that each is defined in subsection 3(1) of the Act.

The definitions of the pharmacopoeia in subsection 3(1) of the Act refer to the publications of each as being in force from time to time. The intention in the Order is therefore to adopt the defined meaning of the European Pharmacopoeia and the United States Pharmacopeia-National Formulary as set out in subsection 3(1) of the Act. These pharmacopoeia are therefore incorporated as in force or existing from time to time, in accordance with these provisions, an approach permitted by subsection 10(4) of the Act. They may be accessed from https://pheur.edqm.eu/home and www.uspnf.com/.

While unfortunately these pharmacopoeia are not available for free, it is anticipated that persons most affected by their adoption in the Order (sponsors and manufacturers of MDMA hydrochloride and MDMA hydrochloride products) would be in possession of these documents in order to import, supply or manufacture such goods. As important international benchmarks for the safety and quality

of therapeutic goods, it would be infeasible from a regulatory perspective, particularly in relation to the quality of MDMA hydrochloride and MDMA hydrochloride products that are not entered in the Register and that have therefore not been subject to pre-market scrutiny before being available for patients in Australia, to not adopt such benchmarks on the basis that they are not available for free.

In addition, by prior written arrangement with the TGA, members of the public may request to view the pharmacopoeia without charge at the TGA office in Fairbairn, ACT.

It should also be noted that the National Library's Trove online system (www.trove.nla.gov.au) allows users to identify libraries in Australia that are open to the public where editions, in most cases earlier editions, of these pharmacopoeia may be viewed.

Members of the public may also approach any library that participates in inter-library loans with those libraries to request an inter-library loan, or to obtain a photocopy of a particular part or monograph for personal study or research, but not for commercial purposes. Fees may apply in relation to the making of such a request. Enquiries should be made with local libraries, State libraries or the National Library.

ICH Q3D guideline document

The Order also incorporates by reference the ICH Harmonised Guideline: *Guideline for Elemental Impurities Q3D* (the ICH Q3D guideline document), developed by the International Council for Harmonisation of Technical requirements for Pharmaceuticals for Human Use.

The ICH Q3D guideline document sets out processes to assess and control elemental impurities in new drug products and new drug products containing existing substances, including by establishing a Permitted Daily Exposure for each element of toxicological concern.

The ICH Q3D guideline document is incorporated as in force from time to time, in accordance with subsection 10(4) of the Act. The ICH Q3D guideline document is available for free from the ICH website at www.ich.org/.

Consultation

Between 8 December 2023 and 31 January 2024, the TGA undertook public consultation in relation to the development of the Order, including releasing a draft version of the Order, to seek comments on the appropriateness of the proposed technical requirements specified in the draft Order. 25 submissions were received from various stakeholders including sponsors, manufacturers, industry organisations, health care practitioners, pharmacists, patients and members of the public.

The consultation confirmed there was broad in-principle support for the Order. Some submissions suggested additional tests or tightening of some assay limits, or to employ USP or ICH guidelines as alternatives to European pharmacopeial methods and limits or sought further clarity on the requirements. Some submissions expressed concern about capacity to comply with the Order once in place, and proposed the inclusion of transitional arrangements. These suggestions were considered carefully, and a number were reflected in the final Order, including in particular that the Order commences on 6 January 2025 to allow time for stakeholders to prepare to comply.

Other details

Details of the Order are set out in **Attachment A.**

The Order is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Order is a disallowable legislative instrument for the purposes of the Legislation Act and commences on 6 January 2025.

The Office of Impact Analysis advised that an Impact Analysis was not required in relation to the making of the Order as its making is unlikely to have a more than minor regulatory impact (OIA23-05637).

The TGA published a technical barrier to trade notification (G/TBT/N/AUS/165, Attachment C) on the World Trade Organization's (WTO) notification platform in relation to the Order. The period for response was from 18 December 2023 to 31 January 2024, and no submissions were received from WTO Members.

Attachment A

Details of the *Therapeutic Goods (Standard for MDMA) (TGO 112) Order 2024*

Part 1—Preliminary

This Part provides for the name of the *Therapeutic Goods (Standard for MDMA) (TGO 112) Order 2024* (the Order), its commencement, authority and application, the therapeutic goods for which the Order constitutes a standard, and definitions for key terms used in the Order.

Section 1 – Name

This section provides that the name of the Order is the *Therapeutic Goods (Standard for MDMA) (TGO 112) Order 2024*, and that the Order may also be cited as TGO 112.

Section 2 – Commencement

This section provides that the Order commences on 6 January 2025.

Commencement in January 2025 is intended to provide sufficient time for manufacturers and sponsors to ensure their goods comply with the requirements introduced by the Order.

Section 3 – Authority

This section provides that the legislative authority for making the Order is section 10 of the *Therapeutic Goods Act 1989* (the Act).

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order.

Section 4 – Definitions

This section provides the definitions of key terms used in the Order, including, 'Act', 'active ingredient', 'batch number', 'capsule', 'ICH Q3D guideline document', 'manufacturing licence' and 'MDMA hydrochloride'.

This section also notes that a number of terms used in the Order, including 'batch', 'container', 'European Pharmacopoeia', 'label', 'manufacture', 'sponsor', 'standard' and 'United States Pharmacopeia-National Formulary' are defined in subsection 3(1) of the Act, and therefore have the same meaning as in the Act.

Section 5 – Standard

This section provides that the matters specified in the Order constitute a standard for MDMA hydrochloride and MDMA hydrochloride products.

Section 6 – Application

This section specifies the goods to which the Order does and does not apply.

Subsection 6(1) provides that, subject to subsection (2) the Order applies to:

- MDMA hydrochloride; and
- MDMA hydrochloride products.

Subsection 6(2) provides that the Order does not apply to:

- Therapeutic goods that are the subject of an approval under paragraph 19(1)(b) of the Act (this provision underpins the importation and supply of unapproved therapeutic goods for use in clinical trials that are required to be approved to the Secretary); or
- therapeutic goods mentioned in item 1 of Schedule 5 to the *Therapeutic Goods Regulations 1990* (the Regulations) (this item underpins the TGA's personal importation scheme, under which a person may lawfully import an unapproved therapeutic good for their personal use or the use of a member of their immediate family, subject to specified limitations); or
- Therapeutic goods mentioned in items, 3, 4, 8, 10, 11 or 12 of Schedule 5A to the Regulations, subject to compliance with the conditions specified in those items (these items exempt therapeutic goods from the requirement to be registered or listed in the Register in specified circumstances, including for instance for use in a clinical trial that is required to be notified to the Secretary, or where the goods are imported by particular persons or are part of particular medical supplies of a visiting ship or aircraft).

Part 2—Requirements for MDMA hydrochloride

This Part specifies requirements for MDMA hydrochloride in the form of an active pharmaceutical ingredient (API).

Section 7 – Application of this part

This section provides that this Part applies to MDMA hydrochloride.

Section 8 – Assay limits

This section specifies the assay limits that apply to the purity of MDMA hydrochloride and chloride in relation to MDMA hydrochloride.

Section 9 – Tests

This section provides that for each item in the table in Schedule 1, MDMA hydrochloride must comply with the requirements specified in column 4 using the test method specified in column 3, in relation to the test specified in column 2.

Part 3—Requirements for MDMA hydrochloride products

This Part specifies requirements for MDMA hydrochloride in the form of a finished product.

Section 10 – Applications of this part

This section provides that this Part applies to MDMA hydrochloride products.

Section 11 – General

This section provides that MDMA hydrochloride products must contain MDMA hydrochloride as the only active ingredient and be manufactured in the dosage form of a capsule for oral administration.

Section 12 – Assay limits

This section specifies the average range of concentration of MDMA hydrochloride for MDMA hydrochloride products in a pooled sample of a minimum of 20 capsules.

Section 13 – Tests

Subsection 13(1) provides that, subject to subsection (2), for each item in the table in Schedule 2, a MDMA hydrochloride product must comply with the requirements specified in column 4 using the test method specified in column 3, in relation to the test specified in column 2.

Subsection 13(2) sets out an exemption to the above requirement for an extemporaneously compounded MDMA hydrochloride product that complies with the conditions specified in paragraphs 13(2)(a) and (b).

Section 14 – Information to be included on the label

Subsection 14(1) provides that the label of an MDMA hydrochloride product, other than an MDMA hydrochloride product that has been extemporaneously compounded, must contain all of the information specified in paragraphs 14(1)(a)-(j).

Subsection 14(2) specifies that all of the information required to be on the label of an MDMA hydrochloride product must be in English and must be legible, clearly visible and not obscured, and durable.

Schedule 1 – Specified tests for MDMA hydrochloride

This Schedule specifies the tests, test methods and requirements that apply to MDMA hydrochloride.

Schedule 2 – Specified tests for MDMA hydrochloride products

This Schedule specifies the tests, test methods and requirements that apply to MDMA hydrochloride products.

Attachment B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

Therapeutic Goods (Standard for MDMA) (TGO 112) Order 2024

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of legislative instrument

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Subsection 10(2) provides that an order establishing a standard for therapeutic goods may be specified by reference to the quality of the goods, or the procedures to be carried out in the manufacture of the goods, among other matters. An order may also require that a matter relating to the standard be determined in accordance with a particular test.

Importantly, a person who imports, exports or supplies therapeutic goods that do not conform to an applicable standard may be subject to offence and civil penalty provisions in sections 14 and 14A of the Act. The Secretary may, however, give consent in writing in relation to the importation, exportation or supply of therapeutic goods that do not conform to an applicable standard, in accordance with those sections.

The *Therapeutic Goods (Standard for MDMA) (TGO 112) Order 2024* (the Order) is made under section 10 of the Act. The purpose of the Order is to establish a ministerial standard for MDMA hydrochloride and MDMA hydrochloride products. The Order is designed to specify minimum benchmarks to ensure the quality of such goods for Australian patients, principally by reference to labelling requirements, assay limits and specified tests for the active pharmaceutical ingredient (API) and finished product.

Background

The Australian Government is responsible for regulating the quality, safety and efficacy or performance of therapeutic goods. In relation to therapeutic goods other than medical devices, this is achieved in part by requiring compliance with the default standards under the Act and specifying ministerial standards under section 10 of the Act. Such standards may relate to a range of matters including for instance the quality of the goods, procedures to be carried out in their manufacture, and requiring that matters be determined in accordance with a particular test.

Prior to 1 July 2023, MDMA was only included in Schedule 9 (Prohibited substances) to the Poisons Standard, which limited its use to authorised research and analytical purposes only. On 3 February 2023, a delegate of the Secretary made a decision to amend the MDMA entries in the Poisons Standard. As a result of this scheduling decision, from 1 July 2023, MDMA was added to Schedule 8 to the Poisons Standard, permitting its use as a Controlled drug for the treatment of post-traumatic stress disorder (PTSD), subject to additional controls specified for MDMA in Appendix D to the Poisons Standard.

Under these additional controls, MDMA in preparations for human use may be supplied only for the treatment of PTSD by a medical practitioner who is registered under state or territory legislation as a specialist psychiatrist, or for use in a clinical trial that is approved by, or notified to, the Secretary. For all other uses MDMA remains covered by the entry for it in Schedule 9 to the Poisons Standard.

There are currently no products containing MDMA that have been approved by the TGA for inclusion in the Australian Register of Therapeutic Goods (the Register). As such, and in light of the controls in Appendix D, access to MDMA may only occur through the certain TGA pathways for accessing unapproved therapeutic goods, being clinical trials or the Authorised Prescriber (AP) scheme. Unapproved therapeutic goods accessed through these pathways have not been evaluated by the TGA for safety, quality and efficacy.

Purpose

Concerns have arisen that there are currently no product standards, such as pharmacopoeial monographs, setting out quality requirements for MDMA, either as an API or a finished product. The Order is designed to address these concerns by establishing a ministerial standard for MDMA hydrochloride and MDMA hydrochloride products, whether imported into Australia or manufactured domestically. The Order is intended to provide an assurance to medical practitioners and patients that MDMA hydrochloride medicines meet minimum quality requirements.

The Order will contribute to the quality and efficacy of MDMA hydrochloride and MDMA hydrochloride products by ensuring that these goods are manufactured uniformly according to minimum standards. Standardisation is necessary to assure medical practitioners and patients that MDMA hydrochloride as an API or a finished product will be manufactured to a consistent and reproducible quality, which is essential to support the known safety and efficacy of any medicine.

The Order will also contribute to the quality of the MDMA hydrochloride products to which it applies through requiring that the average content of MDMA hydrochloride is within specified limits, and requiring that such products meet specified outcomes after undergoing a range of specified kinds of tests, for instance tests for the purity of MDMA hydrochloride and tests for heavy metals and residual solvents.

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health.

In *General Comment No.14: The Right to the Highest Attainable Standard of Health (Art.12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Order takes positive steps to promote the right to health by helping to ensure the quality of MDMA hydrochloride and MDMA hydrochloride products supplied in Australia. The Order does this through specifying the procedures to be carried out in the manufacture of the goods and testing limits for both the active pharmaceutical ingredients (API) and finished products, to ensure their consistency and quality.

The introduction of a minimum standard for MDMA hydrochloride is particularly important as MDMA hydrochloride products that are available for supply in Australia are not included in the Register and, as such, have not been subjected to a process of pre-market scrutiny before being made available for Australian patients.

Conclusion

The Order is compatible with human rights because it maintains and supports the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.