EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order (No. 2) 2022

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 is administered by the Therapeutic Goods Administration ("the TGA") within the Department of Health and Aged Care.

Subsection 10(1) of the Act relevantly 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. Subsection 10(3A) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1) of the Act.

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 Medicinal Cannabis) (TGO 93) Order 2017* ("the Principal Order") is an order made under section 10 of the Act for the purpose of establishing a ministerial standard for medicinal cannabis products. The Principal Order specifies the minimum requirements for the quality and safety of medicinal cannabis products.

The purpose of the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order (No. 2) 2022* ("the Amendment Order") is to amend the Principal Order to make minor updates, primarily to improve clarity and flexibility. In particular, the amendments introduced by the Amendment Order incorporate the *New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods* ("the New Zealand Code of GMP") as an acceptable manufacturing quality standard for medicinal cannabis products, specifies related requirements for medical cannabis products manufactured in New Zealand and makes a small number of clarifications.

Background

The Australian Government is responsible for regulating the quality, safety and efficacy of therapeutic goods. 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 by reference to a range of matters including the manufacture of therapeutic goods, and by otherwise applying

default standards that are constituted by statements in three international pharmacopoeias defined in the Act.

The Principal Order applies to medicinal cannabis products, whether imported into Australia or manufactured domestically, and is intended to provide an assurance to medical practitioners and patients that medicinal cannabis products meet minimum quality requirements.

The Principal Order was amended in March 2022 to ensure the safety and quality of medicinal cannabis products available for use by patients in Australia, whether manufactured in Australia or overseas.

Feedback on those amendments was subsequently received from stakeholders, and it became apparent that some minor corrections to the Principal Order were required. The Amendment Order addresses these matters by making several minor changes to the text of Principal Order, as follows:

- Correcting an error in the 'Table of specified tests' in Schedule 1 to the Principal Order. The test method indicated for heavy metals is incorrectly stated as 'Ph Eur 2.4.8', and should instead be 'Ph Eur 2.4.27'. A note informing the public of this inadvertent error has already been placed on the TGA's website.
- Clarifying the wording in the Principal Order to avoid any doubt around the application of child-resistant closure requirements. The Principal Order refers to the child-resistant closure requirements in *Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines 2017* (TGO 95). TGO 95 does not apply to topical creams, and the Amendment Order clarifies that the child-resistant closure requirements in TGO 95 are not intended to apply to medicinal cannabis products that are topical creams.
- Clarifying the wording in the Principal Order to confirm that the labelling requirements apply to medicinal cannabis products that are finished products only. It is not intended that these labelling requirements apply to intermediate products at each stage of the manufacture of a medicinal cannabis product. The Amendment Order also makes a minor amendment to remove the requirement that the label of all medicinal cannabis products state the quantity of active ingredient in anhydrous form.
- Including the New Zealand Code of GMP as an acceptable standard for the manufacturing quality of medical cannabis products and requiring that a medicinal cannabis product manufactured in New Zealand must be manufactured at a manufacturing site that either holds a licence or certification from Medsafe or has written confirmation from the TGA that the manufacturing complies with the PIC/S Guide to GMP (i.e., the *Guide to Good Manufacturing Practice for Medicinal Products* (PE 009-15, 1 May 2021) published by PIC/S)). Given that the New Zealand Code of GMP is in effect equivalent to the PIC/S Guide to GMP, it is appropriate that the New Zealand Code of GMP is added to subsection 13(2) of the Principal Order.
- Clarifying that the manufacturing quality requirements in section 13 of the Principal Order do not apply to plant material or oil extracted directly from the cannabis plant, where such products are for use as starting material in the manufacture of another medicinal cannabis product that is manufactured in accordance with section 13 or under a manufacturing licence issued under Part 3-3 of the Act. Currently, Australian manufacturers of herbal materials and oil are exempt from the requirement to hold a manufacturing licence issued under Part 3-3 of the Act only when the herbal material or oil is used as starting materials at a manufacturing site that is licensed under

Part 3-3 of the Act. The Amendment Order clarifies that medicinal cannabis products that are plant material or oil directly from the cannabis plant do not need to comply with manufacturing quality requirements where they are used in the manufacture of another product that does comply with such requirements (under the Principal Order or a manufacturing licence issued under Part 3-3 of the Act).

- Clarifying that the microbiological quality requirements in section 16 that apply to medicinal cannabis products that are in oral dosage form, also apply to medicinal cannabis products that are administered by inhalation.

In so doing the Amendment Order:

- supports the safety and quality of medicinal cannabis products in Australia;
- better balances the regulatory requirements applying to medicinal cannabis products manufactured in Australia with those applying to imported medicinal cannabis products;
- promotes transparency and certainty for industry about the precise requirements that apply to medicinal cannabis products; and
- provides greater confidence for patients and health practitioners in relation to the safe use and quality of medicinal cannabis products in Australia.

Incorporation by reference

Subsection 10(4) of the Act relevantly provides that, despite subsection 14(2) of the *Legislation Act 2003*, an order (or 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 the documents that are incorporated by reference in the Amendment Order, the intended manner of incorporation and where they may be obtained.

Incorporation of the New Zealand Code of GMP by reference

The definition of *New Zealand Code of GMP* in section 4 (introduced by item 1 of Schedule 1 to the Amendment Order) incorporates the *New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods*. The intended manner of incorporation is as this document is in force or existing from time to time. This principally reflects that New Zealand manufacturers would be complying with the most recent version of this document as part of their regulatory obligations in New Zealand. The New Zealand *Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods* is available for free from the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) website (www.medsafe.govt.nz/regulatory/Guideline/NZRGMPart1.asp).

Incorporation of the Medicines Act 1981 (NZ) by reference

Subsection 13(3) (amended by item 4 of Schedule 1 to the Amendment Order) refers to the *Medicines Act 1981 (NZ)*. The intended manner of incorporation is as in force or existing from time to time. This principally reflects that New Zealand manufacturers would be complying with the most recent version of this document as part of their regulatory obligations in New Zealand. The *Medicines Act 1981 (NZ)* is available for free from the New

Zealand Parliamentary Counsel Office website (www.legislation.govt.nz/act/public/1981/0118/latest/DLM53790.html).

Incorporation of child-resistant packaging requirements by reference

Section 14 (repealed and replaced by item 6 of Schedule 1 to the Amendment Order) incorporates by reference sections 7, 8, 9 and 10 of the *Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines 2017* (TGO 95) ("TGO 95"). The intended manner of incorporation is as in force from time to time. TGO 95 is a legislative instrument, which similarly constitutes a standard for the purposes of section 10 of the Act, and sets out the requirements for child-resistant packaging. TGO 95 is available for free from the Federal Register of Legislation website (www.legislation.gov.au).

Consultation

A policy impact analysis was not prepared in relation to the making of the Amendment Order as its regulatory impact is minor and machinery in nature.

The changes made by the Amendment Order correct a small number of errors in the Principal Order, and otherwise clarify the application of the Principal Order to medicinal cannabis products. The amendments do not represent substantive changes to the content of the Principal Order. Several of the changes were prompted by external feedback received by the TGA during 2022, including feedback from Medsafe in relation to New Zealand manufacturing standards and certifications, as well as feedback from several manufacturers in relation to the application of microbiological requirements to products that are administered by inhalation.

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

The Amendment 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 Amendment Order is a disallowable legislative instrument, and commences on the day after it is registered on the Federal Register of Legislation.

Attachment A

Details of the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order (No. 2) 2022*

Section 1 – Name
This section provides that the name of the instrument is the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order (No. 2) 2022* ("the Amendment Order").

Section 2 – Commencement
This section provides that the Amendment Order commences on the day after it is registered.

Section 3 –Authority
This section provides that the legislative authority for making the Amendment Order is section 10 of the *Therapeutic Goods Act 1989* ("the Act"). Subsection 10(3A) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1) of the Act.

Section 4 –Schedules
This section provides that each instrument that is specified in Schedule 1 to the Amendment Order is amended as set out in the applicable items in that Schedule. The Amendment Order makes amendments to the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* ("the Principal Order").

Schedule 1 – Amendments

Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017

Item 1– Subsection 4(1)
This item introduces two new definitions in subsection 4(1) of the Principal Order, to include a definition of 'Medsafe' and a definition of 'New Zealand Code of GMP', which are later referred to in items 3 and 4 of the Amendment Order.

The definition of 'Medsafe' refers to the New Zealand Medicines and Medical Devices Safety Authority within the New Zealand Ministry of Health.

The definition of 'New Zealand Code of GMP' refers to the document *New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods*, published by Medsafe, as in force or existing from time to time. The reference to this document as in force from time to time is considered appropriate as manufacturers in New Zealand would need to be complying with the version of the NZ Code of GMP that is in force in New Zealand at a particular time.

Item 2 – Subsection 13(1)
This item amends subsection 13(1) of the Principal Order to exclude plant material and oil directly from the cannabis plant from the application of the manufacturing quality requirements only where those products are for use as starting material in the manufacture of another medicinal cannabis products that is manufactured in accordance with the manufacturing quality requirements in the Principal Order for products manufactured

overseas or a manufacturing licence issued under Part 3-3 of the Act for products manufactured domestically.

Subsection 13(1) provides that the manufacturing quality requirements do not apply to medicinal cannabis products that are herbal material, or medicinal cannabis products that are oil directly from the cannabis plant, that are used as starting material to produce another medicinal cannabis product. The manufacture of such oil or herbal material – that is starting material used to produce a medicinal cannabis product – is not required to meet the manufacturing requirements in new section 13. This is to align with domestically manufactured oil and herbal material that is starting material, which is exempt from Part 3-3 of the Act in item 2 of Schedule 7 to the *Therapeutic Goods Regulations 1990* ("the TG Regulations").

Subsection 13(1) was introduced to ensure equal regulatory treatment of such starting material that is domestically manufactured and starting material that is imported. The exemption in item 2 of Schedule 7 to the TG Regulations, however, is limited to starting material that is used by a licenced manufacturer. This amendment would bring subsection 13(1) into alignment with item 2 of Schedule 7 to the TG Regulations, by providing that the manufacturing quality requirements in section 13 do not apply to plant material and oil directly from the cannabis plant where they are for use as starting material in the manufacture of another product that does comply with the manufacturing quality requirements in section 13 of the Principal Order (for product manufactured overseas) or Part 3-3 of the Act (for product manufactured in Australia).

Item 3 – At the end of subsection 13(2)
This item amends subsection 13(2) of the Principal Order to add the New Zealand Code of GMP to the list of manufacturing standards that a medicinal cannabis product manufactured outside Australia must be manufactured in accordance with. Subsection 13(2) imposes a requirement that imported medicinal cannabis products must be manufactured in accordance with manufacturing standards contained in the PIC/S Guide to GMP, or equivalent standards in the specified European Commission Directives, South African Guide to GMP, United States legislation or Canadian legislation. This establishes equivalent regulatory requirements for imported product and domestically manufactured product. This amendment recognises the New Zealand Code of GMP as an equivalent manufacturing standard and, accordingly, one that is acceptable for imported products manufactured in New Zealand.

Item 4 – After paragraph 13(3)(e)
This item introduces new paragraph (ea) to subsection 13(3) of the Principal Order, to provide that a medicinal cannabis product manufactured in New Zealand must be manufactured at a site that is the subject of either: a valid Licence to Manufacture Medicines issued by Medsafe under the *Medicines Act 1981* (NZ); a valid certificate of good manufacturing practice issued by Medsafe; or written confirmation from the TGA that the site operates in accordance with the PIC/S Guide to GMP. This requirement is designed to ensure that medicinal cannabis products manufactured in New Zealand meet minimum benchmarks of manufacturing safety and quality.

Item 5 – Subsection 13(4)
This item makes a minor editorial amendment to subsection 13(4) of the Principal Order to include a reference to a licence, as some of the manufacturing requirements in section 13 are for manufacture at a site with an appropriate manufacturing licence. Under subsection 13(4)

as amended, the certification, licence or written authority must relate to the relevant medicinal cannabis product imported, relate to each manufacturing site where it was manufactured and be current at the time it was manufactured (i.e. it must not have lapsed, or been suspended or cancelled).

Item 6 – Section 14
This item repeals section 14 of the Principal Order, and replaces it with a new section 14, which provides clarification, in new subsection 14(1), that the child resistant packaging requirements do not apply to medicines to which TGO 95 does not apply, including topical creams. TGO 95 sets out requirements for child-resistant packaging and closures for therapeutic goods. However, section 7 of TGO 95 provides that TGO 95 does not apply to certain therapeutic goods including topical creams. The child-resistant packaging requirements in section 14 of the Principal Order are not intended to apply to therapeutic goods that would not otherwise be subject to the requirements in TGO 95. Accordingly, the effect of this amendment is to clarify in subsection 14(1) that the requirements in subsection 14(2) (that is, compliance with sections 8, 9 and 10 of TGO 95) do not apply to products that are mentioned in section 7 of TGO 95 and would therefore not be subject to the child-resistant packaging requirements in TGO 95 anyway.

Item 7 – Subsection 15(1)
This item amends subsection 15(1) of the Principal Order to exclude medicinal cannabis products that are not finished products from the labelling requirement in subsection 15(2). The effect of this amendment is to clarify that only medicinal cannabis products that are finished products must comply with the labelling requirements in subsection 15(2). It is not intended that intermediate, unfinished products that are produced at various stages of the manufacturing process need to comply with the labelling requirements.

Item 8 – Paragraph 15(2)(f)
This item amends paragraph 15(2)(f) of the Principal Order to remove the reference to the quantity of each active ingredient needing to be stated as the anhydrous form. The effect of this is to remove the requirement that the label of all medicinal cannabis products state the quantity of active ingredient in anhydrous form. The label of such products must include the quantity of each active ingredient, but the requirement for it to be stated in anhydrous form has been removed.

Item 9 – Subparagraph 15(2)(g)(i)
This item makes a minor amendment to subparagraph 15(2)(g)(i) of the Principal Order, to excludes medicinal cannabis products that are in the form of an oil (not ‘essential oil’), from the requirement in subparagraph 15(2)(g)(i) that the label of a medicinal cannabis product must contain the weight of the plant preparation and the minimum weight of the plant material from which it was prepared. This item removes the word “essential” from the phrase “essential oil”.

Item 10 – Section 16
This item amends section 16 of the Principal Order to clarify that the microbiological quality requirements in section 16 that apply to medicinal cannabis products that are in oral dosage form, also apply to medicinal cannabis products that are administered by inhalation.

Item 11 – Clause 2 of Schedule 1 (table item 3, column 3)
This item makes a correction to table item 3, column 3, in the 'Table of specified tests' in clause 2 of Schedule 1 to the Principal Order. This item replaces the reference 'Ph Eur 2.4.8' with the correct reference to 'Ph Eur 2.4.27'.

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 Medicinal Cannabis) (TGO 93) Amendment Order (No. 2) 2022

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 the legislative instrument

The *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order (No. 2) 2022* ("the amendment instrument") is made by a delegate of the Minister under section 10 of the *Therapeutic Goods Act 1989* ("the Act").

The purpose of the amendment instrument is to amend the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* ("the principal instrument") to make minor updates, primarily to improve clarity and flexibility. In particular, the amendments introduced by the amendment instrument incorporate the *New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods* ("the New Zealand Code of GMP") as an acceptable manufacturing quality standard for medicinal cannabis products, specifies related requirements for medical cannabis products manufactured in New Zealand and makes a small number of clarifications.

The principal instrument applies to medicinal cannabis products, whether imported into Australia or manufactured domestically, and is intended to provide an assurance to medical practitioners and patients that medicinal cannabis products meet minimum quality requirements.

The principal instrument was amended in March 2022 to ensure the safety and quality of medicinal cannabis products available for use by patients in Australia, whether manufactured in Australia or overseas.

Feedback on those amendments was subsequently received from stakeholders, and it became apparent that some minor corrections to the principal instrument were required. The amendment instrument addresses these matters by making several minor changes to the text of principal instrument, as follows:

- Correcting an error in the 'Table of specified tests' in Schedule 1 to the principal instrument. The test method indicated for heavy metals is incorrectly stated as 'Ph Eur 2.4.8', and should instead be 'Ph Eur 2.4.27'. A note informing the public of this inadvertent error has already been placed on the TGA's website.
- Clarifying the wording in the principal instrument to avoid any doubt around the application of child-resistant closure requirements. The principal instrument refers to the child-resistant closure requirements in *Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines 2017* (TGO 95). TGO 95 does not apply to topical creams, and the amendment instrument clarifies that the child-resistant

closure requirements in TGO 95 are not intended to apply to medicinal cannabis products that are topical creams.

- Clarifying the wording in the principal instrument to confirm that the labelling requirements apply to medicinal cannabis products that are finished products only. It is not intended that these labelling requirements apply to intermediate products at each stage of the manufacture of a medicinal cannabis product. The amendment instrument also makes a minor amendment to remove the requirement that the label of all medicinal cannabis products state the quantity of active ingredient in anhydrous form.
- Including the New Zealand Code of GMP as an acceptable standard for the manufacturing quality of medical cannabis products and requiring that a medicinal cannabis product manufactured in New Zealand must be manufactured at a manufacturing site that either holds a licence or certification from Medsafe or has written confirmation from the TGA that the manufacturing complies with the PIC/S Guide to GMP (i.e., the *Guide to Good Manufacturing Practice for Medicinal Products* (PE 009-15, 1 May 2021) published by PIC/S)). Given that the New Zealand Code of GMP is in effect equivalent to the PIC/S Guide to GMP, it is appropriate that the New Zealand Code of GMP is added to subsection 13(2) of the principal instrument.
- Clarifying that the manufacturing quality requirements in section 13 of the principal instrument do not apply to plant material or oil extracted directly from the cannabis plant, where such products are for use as starting material in the manufacture of another medicinal cannabis product that is manufactured in accordance with section 13 or under a manufacturing licence issued under Part 3-3 of the Act. Currently, Australian manufacturers of herbal materials and oil are exempt from the requirement to hold a manufacturing licence issued under Part 3-3 of the Act only when the herbal material or oil is used as starting materials at a manufacturing site that is licensed under Part 3-3 of the Act. The amendment instrument clarifies that medicinal cannabis products that are plant material or oil directly from the cannabis plant do not need to comply with manufacturing quality requirements where they are used in the manufacture of another product that does comply with such requirements (under the principal instrument or a manufacturing licence issued under Part 3-3 of the Act).
- Clarifying that the microbiological quality requirements in section 16 that apply to medicinal cannabis products that are in oral dosage form, also apply to medicinal cannabis products that are administered by inhalation.

In so doing the amendment instrument:

- supports the safety and quality of medicinal cannabis products in Australia;
- better balances the regulatory requirements applying to medicinal cannabis products manufactured in Australia with those applying to imported medicinal cannabis products;
- promotes transparency and certainty for industry about the precise requirements that apply to medicinal cannabis products; and
- provides greater confidence for patients and health practitioners in relation to the safe use and quality of medicinal cannabis products in Australia.

Human rights implications

The amendment 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 standard of

physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

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 to 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 amendment instrument takes positive steps to promote the right to health by helping to ensure the safety and quality of medicinal cannabis products supplied in Australia. The amendment instrument does this through requiring imported medicinal cannabis products to meet international benchmarks of good manufacturing practice, and prescribes the minimum benchmark for products manufactured in New Zealand. The amendments ensure the principal instrument better balances the regulatory requirements applying to medicinal cannabis products manufactured in Australia with those applying to imported medicinal cannabis products, providing greater confidence for patients and health practitioners in relation to the quality and safe use of medicinal cannabis products that are available in Australia, whether manufactured in Australia or overseas.

Conclusion

This instrument is compatible with human rights because it promotes the right to health and otherwise does not raise any other human rights issues.