

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (Standard for Medicinal Cannabis) Order 2019

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.

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. Offence and civil penalties may apply if therapeutic goods (other than medical devices) that do not comply with an applicable standard are imported, exported or supplied. The Secretary may, however, consent in writing to the import, export or supply of such goods notwithstanding their non-compliance (sections 14 and 14A of the Act refer).

Without limiting the generality of subsection 10(1), subsection 10(2) relevantly provides that an order establishing a standard for therapeutic goods may be specified by reference to a variety of matters including the quality of the goods and the procedures to be undertaken in the manufacture of those goods. In addition, an order may require matters relating to the standard to be determined in accordance with a particular test.

The *Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)* (“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.

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. The *Therapeutic Goods Amendment (Standard for Medicinal Cannabis) Order 2019* (“the Amendment Order”) is made by a delegate of the Minister under subsection 10(3A) of the Act.

The purpose of the Amendment Order is to amend the Principal Order to make a small number of consequential amendments, principally to reflect the recent repeal and replacement of the *Therapeutic Goods Order No.78 Standard for Tablets and Capsules* (“TGO 78”), which the Principal Order references, by substituting that reference with a reference to the new *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019* (“TGO 101”).

Background

The Australian Government is responsible for regulating the quality, safety and efficacy of therapeutic goods. This is principally achieved by specifying ministerial standards for the manufacture of those products, and otherwise applying default standards specified in international pharmacopoeias.

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 are manufactured in accordance with minimum quality requirements.

Subsection 12(2) of the Principal Order specifies assay limits that apply to medicinal cannabis products, depending on the dosage form (e.g. herbal final form). Paragraph 12(2)(b) of the Principal Order specifies assay limits for medicinal cannabis products in tablet or capsule form that are not included in the Australian Register of Therapeutic Goods (“the Register”).

Section 12 of the Principal Order contains a note that is designed to be a reminder that registered medicinal cannabis products in tablet or capsule form must comply with the assay limits specified in TGO 78.

TGO 78 was recently repealed and replaced by TGO 101, with effect from 31 March 2019, as a consequence of TGO 78 being due to sunset on 1 April 2019 under the sunset provisions of the *Legislation Act 2003*. The Amendment Order therefore makes a minor, consequential amendment to the Principal Order to replace the reference to TGO 78 in the note at the end of section 12 with a reference to TGO 101.

The Amendment Order also makes an unrelated minor consequential amendment to the Principal Order to reflect the disallowance of item 1 of Schedule 1 to the *Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016* (“the Amendment Regulation”) in June 2017.

Previously, item 1 of Schedule 1 to the Amendment Regulation had amended regulation 12A of the *Therapeutic Goods Regulations 1990* to preclude the supply by medical practitioners of therapeutic goods containing certain cannabis-related substances in circumstances where those goods were not included in the Register and supply is made to patients who are seriously ill.

The disallowance motion (which was agreed to by Parliament on 13 June 2017) had the effect of removing the amendment to regulation 12A by omitting the words that precluded the supply of medicinal cannabis products under that section. Following disallowance, regulation 12A could be relied upon to authorise the supply of medicinal cannabis products to seriously ill patients in Australia.

As such, the Amendment Order makes a minor, consequential amendment to the definition of ‘stated content’ (in relation to each active ingredient in a medicinal cannabis product) by including reference to the ‘stated content’ that is disclosed to the Secretary in a statement given by a medical practitioner under regulation 12A.

The Amendment Order contains a final minor amendment to replace the name of the Order with “*Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017*”. The wording of the new name is consistent with the names of other orders recently made under section 10 of the Act and reflects the Office of Parliamentary Counsel’s recommended approach to naming legislative instruments in Drafting Direction 1.1A ‘Names of instruments and provision units of instruments’.

Consultation

The measures in the Amendment Order are minor and consequential in nature. Apart from updating the name of the Order, the amendments are solely designed to reflect the replacement of TGO 78 by TGO 101 and the effect of the disallowance motion. Given the amendments do not involve any new regulatory steps or administrative requirements for industry), the TGA considered that it was not necessary for the amendments to be the subject of consultation.

However, public consultation was undertaken between 17 December 2018 and 8 February 2019 in relation to TGO 101, with a draft of that instrument, and an associated guidance document, released for comment on the TGA's website (www.tga.gov.au) for this period. Twenty four submissions were received, with a wide spectrum of views expressed in relation to technical issues, but overall there was support for the need for an updated instrument to replace TGO 78. A number of changes were made to the final version of TGO 101 to incorporate feedback received.

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 31 March 2019.

Details of the *Therapeutic Goods Amendment (Standard for Medicinal Cannabis) Order 2019*

Section 1 Name

This section provides that the name of the Amendment Order is the *Therapeutic Goods Amendment (Standard for Medicinal Cannabis) Order 2019*.

Section 2 Commencement

This section provides that the Amendment Order commences on 31 March 2019.

Section 3 Authority

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

Section 4 Amendments

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.

Schedule 1 Amendments

This Schedule amends the *Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)* to introduce an updated name for that instrument and to make consequential amendments to the definition of ‘stated content’ in section 4 and the note at the end of section 12, to reflect (respectively):

- the recent repeal and replacement of the *Therapeutic Goods Order No.78 Standard for Tablets and Capsules* by the *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019*; and
- the disallowance of item 1 of Schedule 1 to the *Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016* in June 2017.

Statement of Compatibility with Human Rights

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

Therapeutic Goods Amendment (Standard for Medicinal Cannabis) Order 2019

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 Amendment (Standard for Medicinal Cannabis) Order 2019* is made by a delegate of the Minister under section 10 of the *Therapeutic Goods Act 1989* (“the Act”).

The purpose of the instrument is to amend the *Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)* (“the principal instrument”) to make a small number of consequential amendments, principally to reflect the recent repeal and replacement of the Therapeutic Goods Order No.78 *Standard for Tablets and Capsules* (“TGO 78”), which the principal instrument references, by substituting that reference with a reference to the new *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019* (“TGO 101”).

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 are manufactured in accordance with minimum quality requirements.

Subsection 12(2) of the principal instrument specifies assay limits that apply to medicinal cannabis products, depending on the dosage form (e.g. herbal final form). Paragraph 12(2)(b) of the principal instrument specifies assay limits for medicinal cannabis products in tablet or capsule form that are not included in the Australian Register of Therapeutic Goods (“the Register”).

Section 12 contains a note that is designed to be a reminder that registered medicinal cannabis products in tablet or capsule form must comply with the assay limits specified in TGO 78.

TGO 78 was recently repealed and replaced by TGO 101, with effect from 31 March 2019, as a consequence of TGO 78 being due to sunset on 1 April 2019 under the sunset provisions of the *Legislation Act 2003*. The instrument therefore makes a minor, consequential amendment to the principal instrument to replace the reference to TGO 78 in the note at the end of section 12 with a reference to TGO 101.

The instrument also makes an unrelated minor consequential amendment to the principal instrument to reflect the disallowance of item 1 of Schedule 1 to the *Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016* (“the Amendment Regulation”) in June 2017.

Previously, item 1 of Schedule 1 to the Amendment Regulation had amended regulation 12A of the *Therapeutic Goods Regulations 1990* to preclude the supply by medical practitioners of therapeutic goods containing certain cannabis-related substances in circumstances where those goods were not included in the Register and supply is made to patients who are seriously ill.

The disallowance motion (which was agreed to by Parliament on 13 June 2017) had the effect of removing the amendment to regulation 12A by omitting the words that precluded the supply of medicinal cannabis products under that section. Following disallowance, regulation 12A could be relied upon to authorise the supply of medicinal cannabis products to seriously ill patients in Australia.

As such, the Amendment Order makes a minor, consequential amendment to the definition of ‘stated content’ (in relation to each active ingredient in a medicinal cannabis product) by including reference to the ‘stated content’ that is disclosed to the Secretary in a statement given by a medical practitioner under regulation 12A.

The instrument contains a final minor amendment to replace the name of the principal instrument with a new name that is more consistent with current drafting best practice, and the names of other orders recently made under section 10 of the Act.

Human rights implications

As the instrument does not make any changes to the principal instrument other than those outlined above, it does not engage any of the applicable rights or freedoms.

Conclusion

This instrument is compatible with human rights because it does not raise any human rights issues.

Jane Cook, delegate of the Minister for Health