

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

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

The *Therapeutic Goods Act 1989* (“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, or exported from, Australia.

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.

Without limiting the generality of subsection 10(1) of the Act, 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 particular tests.

Subsection 10(4) of the Act relevantly provides that the Minister must not make an order under subsection 10(1), or vary or revoke an order made under subsection 10(1), unless consultation has taken place with a committee established by the regulations to advise the Minister on standards.

The *Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)* (“Order”) is made under subsection 10(1) of the Act, following consultation with the former Therapeutic Goods Committee. The purpose of the Order is to establish a ministerial standard for medicinal cannabis products. The Order is necessary in the absence of any international quality standard applying to medicinal cannabis products at the time of making the Order.

The Order applies to both domestic and international manufacturers to ensure that all medicinal cannabis products meet the quality standard, whether or not those products are imported or manufactured domestically. The Order is intended to provide assurance to medical practitioners and patients that medicinal cannabis products manufactured in accordance with the Order meet minimum quality requirements.

Background

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

The order will contribute to the safety and efficacy of medicinal cannabis products by ensuring that these products are manufactured uniformly according to a quality standard. Standardisation is necessary to assure medical practitioners and patients that medicinal cannabis products will be manufactured to a consistent and reproducible quality. This will enable reliable interpretations to be made by medical practitioners as to the efficacy of medicinal cannabis products in clinical settings.

Consultation

The Order was prepared in consultation with the former Therapeutic Goods Committee established under the *Therapeutic Goods Regulations 1990* (“Regulations”) to advise the Minister on standards.

The Office of Best Practice Regulation advised that a regulation impact statement was not required in relation to the Order, as the matter of determining a standard for medicinal cannabis was

sufficiently covered in an earlier regulation impact statement relating to the regulatory framework for medicinal cannabis (OBPR ID 19882).

However, prior to making this order, the Therapeutic Goods Administration (“TGA”) conducted public consultation, consultation with all states and territories and targeted stakeholder engagement with existing manufacturers.

The consultation related to the matters that should be specified in the Order. Four written submissions were received from members of the public, and a number of further targeted consultations were undertaken with industry to ensure that the quality standard would not impose undue regulatory burden on existing or emerging manufacturers, or unnecessarily affect patient access to medicinal cannabis products.

Details of the Order are set out in Attachment A.

The Order is compatible with 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 former Therapeutic Goods Committee was consulted as required under subsection 10(4) of the Act prior to making of this Order.

The Order is a disallowable legislative instrument and commences on the day after registration on the Federal Register of Legislation.

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

Section 1 – Name

This section provides that the name of the Order is the *Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)*.

Section 2 – Commencement

This section provides that the Order commences the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the Order is subsection 10(1) of the *Therapeutic Goods Act 1989* (“Act”).

Section 4 – Interpretation

This section provides definitions for certain terms used in the Order. Most notably, the term “medicinal cannabis products” means therapeutic goods that contain, or are manufactured from, any part of the cannabis plant; and the term “cannabis plant” means any plant, or part of a plant, of the genus *Cannabis*, including, but not limited to, the flowers, fruiting tops, seeds, stems and leaves of the plant.

The term “active ingredient” has the same meaning as in the *Therapeutic Goods Regulations 1990* (“Regulations”). However, without limiting the meaning of that term, subsection 4(2) of the Order relevantly provides that any cannabinoid present in a medicinal cannabis product is taken to be an active ingredient for the purposes of the Order (whether or not that cannabinoid is expressly purported to be responsible for the product’s physiological or pharmacological action), if the quantity or proportion of the cannabinoid (together with any corresponding acid) is greater than or equal to 2.0% w/w or w/v of the product and, in the case of tetrahydrocannabinol, greater than or equal to 1.0% w/w or w/v of the product.

The purpose of subsection 4(2) is to prevent a combined entourage effect of cannabinoids present in medicinal cannabis products in small but material amounts, in situations where those cannabinoids are not expressly purported by the sponsor to be responsible for the product’s physiological or pharmacological action.

To avoid any doubt, subsection 4(2) is not intended to limit the meaning of the term “active ingredient”. Rather, it is intended to clarify its meaning within the context of medicinal cannabis products. The quantity or proportion of cannabinoids specified in subsection 4(2) reflect levels at which those cannabinoids have been shown or purported to have a physiological or pharmacological effect. The clarification is important in the interests of public health, particularly in the case of tetrahydrocannabinol, where the psychoactive potential of that cannabinoid has been shown to have adverse effects on patients.

Section 5 – Standard

This section provides that the Order constitutes a standard for medicinal cannabis products. This is consistent with the terms of subsection 10(1) of the Act.

Section 6 – Application

This section clarifies that the Order applies to medicinal cannabis products and any ingredients used in the manufacture of those products, including, but not limited to, the cannabis plant. However, the Order does not apply to medicinal cannabis products that are mentioned in item 1 of Schedule 5 to the Regulations, or items 4, 8, 10, 11 or 12 of Schedule 5A to the Regulations.

Section 7 – Monograph

This section provides that the standard constituted by the statements in the general monograph of the European Pharmacopoeia, titled *Pharmaceutical Preparations (2619)*, applies with respect to medicinal cannabis products, and any ingredients used in the manufacture of those products, but does not apply to the extent of any inconsistency with the Order.

This section is consistent with the terms of section 13 of the Act in so far as the general monograph constitutes a default standard within the meaning of section 3; and any requirements in that default standard apply to medicinal cannabis products with the exception of any requirements that are inconsistent with the Order.

The reference to the European Pharmacopoeia in the Order is to the meaning of that term as defined in subsection 3(1) of the Act, which includes additions or amendments made to the publication of that name, or new editions of that publication, from the effective date of publication by the Council of Europe or any replacement body.

The European Pharmacopoeia is available online at: <http://online.phEur.org>. At the time of making this Order, it is understood that a subscription fee is required to access the current edition of this publication. It is expected that manufacturers of medicinal cannabis products acquire access to the European Pharmacopoeia as part of an overall understanding of, and compliance with the regulatory regime for medicinal cannabis products. Further, versions of this publication may be available through libraries.

Section 8 – Active ingredients and cannabinoids

This section provides that each active ingredient and any cannabinoid present in a medicinal cannabis product, whether or not that cannabinoid is an active ingredient, or taken to be an active ingredient for the purposes of the Order, must be manufactured from the cannabis plant only.

The purpose of this section is to ensure that active ingredients and cannabinoids present in medicinal cannabis products are derived from the cannabis plant only. This section is principally intended to prevent the derivation of any active ingredients or other cannabinoids from synthetic substances.

Section 9 – Decontamination

This section provides that any decontaminating treatment of the cannabis plant must not adversely affect the quality of medicinal cannabis products or make use of, or otherwise contain, ethylene oxide.

The purpose of this section is to prevent the use of any decontaminating treatment, including ethylene oxide, which will negatively affect the quality of the finished product.

Section 10 – Identification

This section provides that the cannabis plants used in the manufacture of medicinal cannabis products must be positively identified using macroscopic examination, microscopic examination and chromatographic procedures. These methods must be performed conjunctively rather than

disjunctively. The purpose of this section is to ensure that the plants used in the manufacture of medicinal cannabis products belong to the genus *Cannabis*.

Section 11 – Adulteration

Subsection 11(1) provides that medicinal cannabis products or ingredients used in the manufacture of those products must not contain any substance that results in the adulteration of those products or ingredients.

Subsection 11(2) provides that adulteration, for the purposes of subsection 11(1), includes the addition or substitution of any substance that is extraneous to the formulation of the product, other than substances which are incidental minor excipients.

The term “incidental minor excipients” is defined in section 4 of the Order to mean any substance used as an excipient or processing aid in the manufacture of ingredients for medicinal cannabis products, or as a processing aid in the manufacture of medicinal cannabis products.

Subsection 11(3) provides that the motivation for the adulteration is irrelevant. It is sufficient that the adulteration has occurred whether or not it is intended to improve, fortify or debase medicinal cannabis products or the ingredients used in their manufacture.

The purpose of this section is to prevent the adulteration of medicinal cannabis products with substances such as tobacco, calamus or glass.

Section 12 – Tests

Subsection 12(1) provides that the tests specified in Schedule 1 apply to the cannabis plants used in the manufacture of medicinal cannabis products.

Subsection 12(2) specifies the assay limits that apply to medicinal cannabis products depending on the dosage form. For example, in relation to medicinal cannabis products in herbal final form, the average content of each active ingredient (together with any corresponding acid) in a representative sample of the product must not be less than 80.0 per cent and not more than 120.0 per cent of the stated content of the active ingredient.

The term “stated content” is defined in section 4 of the Order to mean the quantity or proportion of each active ingredient that is specified in a label in accordance with a decision under section 25, disclosed to the Secretary in an application under section 19 of the Act, purported to be present in a medicinal cannabis product that is dispensed or extemporaneously compounded in the manner mentioned in item 6 of Schedule 5 to the Regulations, or notified to be present in a medicinal cannabis product for the purposes of item 3 of Schedule 5A to the Regulations.

The assay limits specified in paragraphs 12(2)(b) and 12(2)(c) for medicinal cannabis products in tablet, capsule or any other dosage form are tighter than those specified in paragraph 12(2)(a) for medicinal cannabis products in herbal final form. This is consistent with pharmacopoeial norms. The limits for medicinal cannabis in herbal final form are wider to allow for natural variations in the cannabis plant, as with any other botanical species.

To avoid any doubt, the content of the active ingredient must include any corresponding acid such that assay is performed on the total content of the active ingredient, which is the sum of both the cannabinoid and its respective acid.

Finally, the note to section 12 is a reminder that medicinal cannabis products, which are registered in tablet or capsule form must comply with the assay limits specified in the *Therapeutic Goods Order No. 78 – Standard for Tablets and Capsules* for registered products.

Schedule 1 – Specified tests

This Schedule specifies the six tests that apply to the cannabis plants used in the manufacture of medicinal cannabis products. Subclause 1(1) provides that the parameters specified in column 2 of the table must comply with the limits specified in column 4 under the test method from the European Pharmacopoeia specified in column 3 of the table.

Subclause 1(2) confirms that each limit specified in column 4 of the table applies on a dried basis, with the exception of item 2 which relates to foreign matter.

Clause 2 comprises the table of specified tests.

Statement of compatibility with human rights

This statement is prepared in accordance with subsection 9(1) of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

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

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

This instrument is made under subsection 10(1) of the *Therapeutic Goods Act 1989* (“Act”) by a delegate of the Minister for Health.

The matters specified in the instrument constitute a standard for medicinal cannabis products. The instrument is specified by reference to *inter alia* the quality of medicinal cannabis products and the procedures to be undertaken in their manufacture. In addition, the instrument requires certain matters to be determined in accordance with particular tests.

The instrument is intended to provide assurance to medical practitioners and patients alike that medicinal cannabis products are required to meet minimum quality requirements. Standardisation is necessary to assure medical practitioners and patients that medicinal cannabis products will be manufactured to a consistent and reproducible quality. This consistency will enable reliable interpretations to be made by medical practitioners as to the efficacy of medicinal cannabis products in clinical settings.

The instrument applies to medicinal cannabis products and any ingredients used in the manufacture of those products, including, but not limited to, the cannabis plant. However, the Order does not apply to medicinal cannabis products that are covered by specified exemptions from the requirement to be registered or listed in the Australian Register of Therapeutic Goods – for example, the exemption specified in item 10 of Schedule 5A to the *Therapeutic Goods Regulations 1990* for therapeutic goods imported by a medical practitioner or a member of a medical team (being one or more persons under the professional supervision of a medical practitioner. The term “medicinal cannabis products” is defined in the instrument to mean therapeutic goods that contain, or are manufactured from, any part of the cannabis plant; and the term “cannabis plant” means any plant, or part of a plant, of the genus *Cannabis*, including, but not limited to, the flowers, fruiting tops, seeds, stems and leaves of the plant.

The instrument applies the statements in the general monograph of the European Pharmacopoeia, titled *Pharmaceutical Preparations (2619)*, to medicinal cannabis products, and any ingredients used in the manufacture of those products, but not to the extent of any inconsistency with the instrument. The instrument also specifies requirements relating to decontamination, identification, adulteration and testing (including specific test requirements). For example, any decontaminating treatment of cannabis plants used in the manufacture of medicinal cannabis products must not adversely affect the quality of the medicinal cannabis product, or make use of or otherwise contain ethylate oxide.

Human rights implications

This instrument does not engage any of the applicable rights or freedoms.

Conclusion

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

Larry Kelly, delegate of the Minister for Health