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

Therapeutic Goods Act 1989

I, LARRY KELLY, a delegate of the Minister for Health for the purposes of subsection 10(1) of the *Therapeutic Goods Act 1989*, having consulted the Therapeutic Goods Committee in accordance with subsection 10(4) of that Act, make the following order.

Dated 21 March 2017

(Signed by)

LARRY KELLY

Delegate of the Minister for Health

1 Name of order

This order is the *Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)*.

2 Commencement

(1) Each provision of this order specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this order	The day after this order is registered.	

Note: This table relates only to the provisions of this order as originally made. It will not be amended to deal with any later amendments of this order.

(2) Any information in column 3 of the table is not part of this order. Information may be inserted in this column, or information in it may be edited, in any published version of this order.

3 Authority

This order is made under subsection 10(1) of the *Therapeutic Goods Act 1989*.

4 Interpretation

(1) In this order:

Act means the *Therapeutic Goods Act 1989*.

active ingredient has the same meaning as in the Regulations.

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.

incidental minor excipients means any substance used as:

(a) an excipient or processing aid in the manufacture of ingredients for medicinal cannabis products; or

(b) a processing aid in the manufacture of medicinal cannabis products.

medicinal cannabis products means therapeutic goods that contain, or are manufactured from, any part of the cannabis plant.

Regulations means the *Therapeutic Goods Regulations 1990.*

stated content, in relation to each active ingredient in a medicinal cannabis product, means the quantity or proportion of each active ingredient that is:

(a) specified on the label to be present in the medicinal cannabis product in accordance with any decision made by the Secretary under section 25 of the Act in relation to that product; or

(b) disclosed to the Secretary in an application under section 19 of the Act for the approval or authority of a medicinal cannabis product, whether or not the quantity or proportion of each active ingredient is reproduced on the label or any supplementary material for that product approved or authorised under that section; or

(c) 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

(d) notified to be present in a medicinal cannabis product for the purposes of item 3 of Schedule 5A to the Regulations.

Note A number of expressions used in this order are defined in the Act, including the following:

(a) European Pharmacopoeia;

(b) label;

(c) manufacture;

(d) Register;

(e) standard; and

(f) therapeutic goods.

(2) Without limiting the meaning of ***active ingredient*** in subsection (1), the following ingredients are taken to be active ingredients for the purposes of this order (whether or not those ingredients are specified, disclosed, purported or notified to the Secretary to be active ingredients):

(a) any tetrahydrocannabinol present in a medicinal cannabis product, the quantity or proportion of which (together with any corresponding acid) is greater than or equal to 1.0% w/w or w/v of the product; and

(b) any other cannabinoid present in a medicinal cannabis product, the quantity or proportion of which (together with any corresponding acid) is greater than or equal to 2.0% w/w or w/v of the product.

5 Standard

This order constitutes a standard for medicinal cannabis products.

6 Application

(1) Subject to subsection (2), this order applies to:

(a) medicinal cannabis products; and

(b) any ingredients used in the manufacture of those products, including, but not limited to, the cannabis plant.

(2) This order does not apply to medicinal cannabis products that are mentioned in:

(a) item 1 of Schedule 5 to the Regulations; or

(b) items 4, 8, 10, 11 or 12 of Schedule 5A to the Regulations, subject to compliance with the conditions specified in those items.

7 Monograph

The standard constituted by the statements in the monograph titled *Pharmaceutical Preparations (2619)* in the European Pharmacopoeia applies with respect to:

(a) medicinal cannabis products; and

(b) any ingredients used in the manufacture of those products, including, but not limited to, the cannabis plant;

but does not apply to the extent of any inconsistency with this order.

8 Active ingredients and cannabinoids

The following ingredients present in medicinal cannabis products must be manufactured from the cannabis plant only:

(a) each active ingredient; and

(b) any cannabinoid (whether or not that cannabinoid is an active ingredient, or taken to be an active ingredient, for the purposes of this order).

9 Decontamination

Any decontaminating treatment of the cannabis plant used in the manufacture of medicinal cannabis products must not:

(a) adversely affect the quality of medicinal cannabis products; or

(b) make use of, or otherwise contain, ethylene oxide.

10 Identification

The cannabis plants used in the manufacture of medicinal cannabis products must be positively identified using each of the following identification methods:

(a) macroscopic examination; and

(b) microscopic examination; and

(c) chromatographic procedures.

11 Adulteration

(1) Medicinal cannabis products and any ingredients used in the manufacture of those products, including, but not limited to, the cannabis plant, must not contain any substance that results in the adulteration of those products or ingredients.

(2) For the purposes of subsection (1), adulteration includes the addition of, or substitution with, any substance that is extraneous to the formulation of the product, other than incidental minor excipients.

(3) In determining whether adulteration has occurred, it is irrelevant whether or not the addition or substitution is intended to improve, fortify or debase the medicinal cannabis product or any ingredients used in the manufacture of that product, including, but not limited to, the cannabis plant.

12 Tests

(1) The tests mentioned in Schedule 1 are specified with respect to the cannabis plants used in the manufacture of medicinal cannabis products for the purposes of this order.

(2) The following assay limits are specified for the purposes of this order:

(a) in relation to a medicinal cannabis product in herbal final form – the average content of each active ingredient, together with any corresponding acid, in a representative sample of the product must be not less than 80.0 per cent and not more than 120.0 per cent of the stated content of that active ingredient; and

(b) in relation to a medicinal cannabis product in tablet or capsule form, where that product is not included on the Register – the average content of each active ingredient, together with any corresponding acid, in a pooled sample of not fewer than 20 tablets or capsules must be not less than 90.0 per cent and not more than 110.0 per cent of the stated content of that active ingredient; and

(c) in relation to a medicinal cannabis product in any other dosage form – the average content of each active ingredient, together with any corresponding acid, in a representative sample of the product must be not less than 90.0 per cent and not more than 110.0 per cent of the stated content of that active ingredient.

Note The assay limits specified in the **Therapeutic Goods Order No. 78 *Standard for Tablets and Capsules*** apply with respect to registered medicinal cannabis products in tablet or capsule form.

Schedule 1 Specified tests

(subsection 12(1))

1 Interpretation

(1) For each item specified in column 1 of this table, the parameter specified in column 2 must comply with the limits specified in column 4 under the test method from the European Pharmacopoeia specified in column 3.

(2) With the exception of item 2 of this table, each limit specified in column 4 applies on a dried basis.

2 Table of specified tests

Specified tests

Column 1 Item	Column 2 Parameter	Column 3 Test method	Column 4 Limits
1	Aflatoxins	Ph Eur 2.8.18	Not more than 2 µg/kg of aflatoxin B1 and not more than 4 µg/kg for the sum of aflatoxins B1, B2, G1, G2
2	Foreign matter	Ph Eur 2.8.2	Not more than 2.0%
3	Heavy metals	Ph Eur 2.4.27	Not more than 3.0 ppm of arsenic Not more than 0.5 ppm of cadmium Not more than 5.0 ppm of lead Not more than 0.5 ppm of mercury
4	Ochratoxin A	Ph Eur 2.8.22	Not more than 20 µg/kg
5	Pesticides	Ph Eur 2.8.13	Not more than the limits specified in Ph Eur 2.8.13
6	Total ash	Ph Eur 2.4.16	Not more than 20.0%

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislation kept under the *Legislation Act 2003*. See http://www.legislation.gov.au