

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

made under subsection 10(1) of the

Therapeutic Goods Act 1989

**Compilation No. 1**

**Compilation date:** 31 March 2019

**Includes amendments up to:** *Therapeutic Goods Amendment (Standard for Medicinal Cannabis) Order 2019*

**About this compilation**

**This compilation**

This is a compilation of the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* that shows the text of the law as amended and in force on 31 March 2019 (the ***compilation date***).

The notes at the end of this compilation (***the endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

**Uncommenced amendments**

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

**Application, saving and transitional provisions for provisions and amendments**

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

**Modifications**

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

**Self‑repealing provisions**

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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1 Name of order

This order is the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017*.

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:

1. an excipient or processing aid in the manufacture of ingredients for medicinal cannabis products; or
2. 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) disclosed to the Secretary in a notification under regulation 12A of the Regulations, whether or not the quantity or proportion of each active ingredient is reproduced on the label or any supplementary material for that product which is the subject of the notification; or

(d) 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

(e) 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:

1. European Pharmacopoeia;
2. label;
3. manufacture;
4. Register;
5. standard; and
6. 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:

1. each active ingredient; and
2. 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 (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019* 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 arsenicNot more than 0.5 ppm of cadmiumNot more than 5.0 ppm of leadNot 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

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

**Abbreviation key—Endnote 2**

The abbreviation key sets out abbreviations that may be used in the endnotes.

**Legislation history and amendment history—Endnotes 3 and 4**

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

**Misdescribed amendments**

A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation “(md)” added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation “(md not incorp)” is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

|  |  |
| --- | --- |
| ad = added or inserted | o = order(s) |
| am = amended | Ord = Ordinance |
| amdt = amendment | orig = original |
| c = clause(s) | par = paragraph(s)/subparagraph(s) |
| C[x] = Compilation No. x |  /sub‑subparagraph(s) |
| Ch = Chapter(s) | pres = present |
| def = definition(s) | prev = previous |
| Dict = Dictionary | (prev…) = previously |
| disallowed = disallowed by Parliament | Pt = Part(s) |
| Div = Division(s) | r = regulation(s)/rule(s) |
| ed = editorial change | reloc = relocated |
| exp = expires/expired or ceases/ceased to have | renum = renumbered |
|  effect | rep = repealed |
| F = Federal Register of Legislation | rs = repealed and substituted |
| gaz = gazette | s = section(s)/subsection(s) |
| LA = *Legislation Act 2003* | Sch = Schedule(s) |
| LIA = *Legislative Instruments Act 2003* | Sdiv = Subdivision(s) |
| (md) = misdescribed amendment can be given | SLI = Select Legislative Instrument |
|  effect | SR = Statutory Rules |
| (md not incorp) = misdescribed amendment | Sub‑Ch = Sub‑Chapter(s) |
|  cannot be given effect | SubPt = Subpart(s) |
| mod = modified/modification | underlining = whole or part not |
| No. = Number(s) |  commenced or to be commenced |

Endnote 3—Legislation history

| Name | Registration | Commencement | Application, saving and transitional provisions |
| --- | --- | --- | --- |
| *Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)* | 23 Mar 2017 (F2017L00286) | 24 Mar 2017 | — |
| *Therapeutic Goods Amendment (Standard for Medicinal Cannabis) Order 2019* | 28 Mar 2019 (F2019L00447) | 31 Mar 2019 | — |

Endnote 4—Amendment history

| Provision affected | How affected |
| --- | --- |
| s 1  | am F2019L00447 |
| s 2  | rep LA s 48D |
| s 4  | am F2019L00447 |
| s 12  | am F2019L00447 |