



## **Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order 2022**

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I, Tracey Duffy, as delegate of the Minister for Health and Aged Care, make the following order.

Dated 25 March 2022

Tracey Duffy  
First Assistant Secretary  
Medical Devices and Product Quality Division  
Health Products Regulation Group  
Department of Health

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## 1 Name

This instrument is the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order 2022*.

## 2 Commencement

- (1) Each provision of this instrument 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.

<b>Commencement information</b>		
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Provisions</b>	<b>Commencement</b>	<b>Date/Details</b>
1. The whole of this instrument	28 March 2022.	28 March 2022

Note: This table relates only to the provisions of this instrument as originally made.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

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

## 3 Authority

This instrument is made under section 10 of the *Therapeutic Goods Act 1989*.

## 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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## Schedule 1—Amendments

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

#### 1 Section 4 (before subsection (1))

Insert:

Note: A number of expressions used in this order are defined in subsection 3(1) of the Act, including the following:

- (a) batch;
- (b) British Pharmacopoeia;
- (c) container;
- (d) European Pharmacopoeia;
- (e) export only medicine;
- (f) label;
- (g) manufacture;
- (h) Register;
- (i) sponsor;
- (j) standard;
- (k) therapeutic goods;
- (l) United States Pharmacopoeia–National Formulary.

#### 2 Subsection 4(1)

Insert:

*acceptance criteria*, in relation to microbiological quality, are interpreted as:

- (a)  $10^1$  CFU: maximum acceptable count is 20;
- (b)  $10^2$  CFU: maximum acceptable count is 200;
- (c)  $10^3$  CFU: maximum acceptable count is 2000, and so forth.

*batch number* means a number, or a combination of numerals, symbols or letters, which is given by a manufacturer to a batch of a medicinal cannabis product, to uniquely identify that batch and from which it is possible to trace that batch through all stages of manufacture and distribution.

*batch number prefix* means the prefix which precedes the batch number and has the following characteristics:

- (a) clearly indicates that the information following the prefix is the batch number; and
- (b) is in the following form: ‘BATCH NUMBER’, ‘BATCH NO.’, ‘BATCH’, ‘B’, ‘(B)’, ‘B/N’, ‘LOT NUMBER’, ‘LOT NO.’, or ‘LOT’, or words or symbols to this effect, including a mixture of lower and upper case letters.

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### 3 Subsection 4(1) (at the end of the definition of *cannabis plant*)

Add:

Note: Subspecies of the cannabis plant, *Cannabis sativa*, include *Cannabis sativa subsp. sativa*, *Cannabis sativa subsp. ruderalis* and *Cannabis sativa subsp. indica*.

### 4 Subsection 4(1)

Insert:

***EU Member State*** means a member state of the European Union.

***EU Directive 2001/83/EC*** means *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use*, as in force or existing from time to time.

***EU Directive 2003/94/EC*** means *Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use*, as in force or existing at 28 March 2022.

***excipient***, for a medicinal cannabis product, means an ingredient that is not an active ingredient.

***expiry date*** has the same meaning as in the Regulations.

***expiry date prefix*** means a prefix which precedes the expiry date and has the following characteristics:

- (a) clearly indicates that the information following the prefix is the expiry date;
- (b) is in the following form: 'EXPIRY DATE', 'EXPIRY', 'EXPIRES', 'EXP. DATE', 'EXP', 'Use by' or 'Use before' or words to this effect, including a mixture of lower and upper case letters;
- (c) is not in the following form: 'Best by' or 'Best before' or words to this effect.

### 5 Subsection 4(1) (definition of *incidental minor excipients*)

Repeal the definition.

### 6 Subsection 4(1)

Insert:

***licensing authority*** means a body empowered to issue a certificate or other document to the effect that the body is satisfied that a manufacturing site complies with requirements for good manufacturing practice of therapeutic goods.

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**PIC/S** means the Pharmaceutical Inspection Co-operation Scheme established in 1995 as an extension to the Pharmaceutical Inspection Convention.

**PIC/S Guide to GMP** means the document *Guide to Good Manufacturing Practice for Medicinal Products* (PE 009-15, 1 May 2021) published by PIC/S, as in force or existing from time to time, and includes the Annexes to that document other than the following:

- (a) Annex 4 (Manufacture of veterinary medicinal products other than immunologicals);
- (b) Annex 5 (Manufacture of immunological veterinary medical products);
- (c) Annex 14 (Manufacture of medicinal products derived from human blood or plasma).

**plant material** means dried or fresh material of the cannabis plant that has not undergone any refinement, including dried flos.

Note: Refinement does not include cutting or grinding material of the cannabis plant.

**plant preparation** means material of the cannabis plant that has undergone some refinement, excluding material of the cannabis plant that has been refined to a single cannabinoid.

Note: Refinement does not include cutting or grinding material of the cannabis plant.

**processing aid** means a substance used in the manufacture of a medicinal cannabis product that is not intended to remain in the final formulation of the product (although trace amounts may remain in the product).

**quantity of the medicinal cannabis product** means:

- (a) where the medicinal cannabis product consists of discrete dosage units, such as tablets or capsules or sachets—the stated number of units in the container;
- (b) where the medicinal cannabis product is:
  - (i) a solid or semi-solid—the stated weight in the container;
  - (ii) a liquid—the stated volume of fill in the container;
  - (iii) a pressurised metered-dose preparation or dry powder inhaler—the stated number of deliverable doses in the container;
  - (iv) a non-pressurised metered dose preparation—the minimum number of deliverable doses in the container;
- (c) where the medicinal cannabis product is a product of any of the kinds referred to in paragraph (b) and the product consists of a number of identical containers within the primary pack—the number of containers (for example, 5 x 10 mL vials);



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- (d) for each of the individual containers within the primary pack, the quantity of the medicinal cannabis product to be included on the individual container label would be as described in paragraph (b) (for example, the stated volume of fill in the container).

***South African Guide to GMP*** means the document *4.01 - South African Guide to GMP* (July 2019, V7), published by the South African Health Products Regulatory Authority, as in force or existing from time to time.

## **7 Subsection 4(1) (definition of *stated content*)**

Repeal paragraphs (b) to (d), substitute:

- (b) disclosed to the Secretary in an application under section 19 of the Act for an approval or authority in relation to the medicinal cannabis product; or
- (c) disclosed to the Secretary in a notification under regulation 12A of the Regulations; or
- (d) purported to be present in a medicinal cannabis product that is extemporaneously compounded or repackaged by a pharmacist for a particular patient; or

## **8 Subsection 4(1)**

Insert:

***TGO 95*** means the *Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017* (TGO 95).

***Therapeutic Goods Administration*** has the same meaning as in the Regulations.

## **9 Subsection 4(1) (note at the end)**

Repeal the note.

## **10 Subsection 4(2)**

Omit “ingredients” (first occurring), substitute “substances”.

## **11 Subsection 6(2)**

Repeal the subsection, substitute:

- (2) This order does not apply to medicinal cannabis products that are:
- (a) export only medicines; or
- (b) mentioned in item 1 of Schedule 5 to the Regulations; or
- (c) mentioned in items 4, 8, 10, 11 or 12 of Schedule 5A to the Regulations, subject to compliance with the conditions specified in those items.

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## 12 At the end of section 7

Add:

Note: The *Pharmaceutical Preparations (2619)* monograph incorporates applicable requirements contained in other monographs that also need to be complied with, for example *Herbal Drugs (1433)*.

## 13 Section 8

Repeal the section, substitute:

### 8 Active ingredients and cannabinoids

Each active ingredient and any other cannabinoid (that is not an active ingredient) in a medicinal cannabis product must comply with the following:

- (a) the active ingredient or other cannabinoid must be from the cannabis plant; and
- (b) the chemical structure of the active ingredient or other cannabinoid must not be modified or transformed in any way (including by chemical or other means).

Note: Modification or transformation does not include decarboxylation of naturally occurring acid forms of cannabinoids.

## 14 Subsection 11(2)

Omit “incidental minor excipients”, substitute “a processing aid”.

## 15 Subsection 12(2) (note)

Repeal the note, substitute:

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.

## 16 After section 12

Insert:

### 13 Manufacturing quality

- (1) This section does not apply to the manufacture of a medicinal cannabis product that is:
  - (a) plant material; or
  - (b) oil extracted directly from the cannabis plant;  
used as starting material in the manufacture of another medicinal cannabis product.
- (2) Each step of manufacture in relation to a medicinal cannabis product that occurs outside Australia must be in accordance with one or more of the following:
  - (a) the PIC/S Guide to GMP;

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- (b) Article 47 of EU Directive 2003/94/EC;
  - (c) Article 47 of EU Directive 2001/83/EC;
  - (d) the South African Guide to GMP;
  - (e) *Part 211—Current Good Manufacturing Practice for Finished Pharmaceuticals of Subchapter C—Drugs: General*, in *Chapter I—Food and Drugs Administration of Title 21—Food and Drugs*, in the *United States Code of Federal Regulations*, as in force or existing from time to time;
  - (f) *Division 2 – Good Manufacturing Practices* in Part C of the *Food and Drug Regulations* (Canada), as in force or existing from time to time.
- (3) A medicinal cannabis product that is manufactured outside Australia must be manufactured at a site that is the subject of one or more of the following:
- (a) for a medicinal cannabis product manufactured in the United Kingdom—a valid certificate of good manufacturing practice issued to the manufacturer of the product by the Medicines and Healthcare products Regulatory Agency of the United Kingdom or a licensing authority of an EU Member State;
  - (b) for a medicinal cannabis product manufactured in an EU Member State—a valid certificate of good manufacturing practice issued to the manufacturer of the product by a licensing authority of an EU Member State;
  - (c) for a medicinal cannabis product manufactured in Canada—either:
    - (i) written confirmation from Health Canada that the manufacturing site operates in accordance with *Part 5: Good Production Practices of the Cannabis Regulations* SOR/2018-144 (Canada), as in force or existing from time to time, and:
      - (A) a valid certificate of good manufacturing practice issued to the manufacturer of the product by a licensing authority of an EU Member State; or
      - (B) written confirmation from the Therapeutic Goods Administration that the manufacturing site operates in accordance with the PIC/S Guide to GMP; or
    - (ii) a Drug Establishment Licence issued by Health Canada for the relevant medicinal cannabis product manufactured at the site;

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- (d) for a medicinal cannabis product manufactured in South Africa—written confirmation from the South African Health Products Regulatory Authority that the manufacturing site operates in accordance with the South African Guide to GMP;
  - (e) for a medicinal cannabis product manufactured in Israel—a valid certificate of good manufacturing practice issued to the manufacturer of the product by the Israel Ministry of Health;
  - (f) for a medicinal cannabis product manufactured in any other country—written confirmation from the Therapeutic Goods Administration that the manufacturing site operates in accordance with the PIC/S Guide to GMP.
- (4) A certificate or written confirmation mentioned in subsection (3) must:
- (a) cover the relevant medicinal cannabis product; and
  - (b) relate to each manufacturing site where the medicinal cannabis product was manufactured; and
  - (c) have been current at the time the medicinal cannabis product was manufactured.

## **14 Child-resistant packaging**

A medicinal cannabis product, other than a medicinal cannabis product in the form of plant material, must comply with the requirements specified in the following sections of TGO 95:

- (a) section 8 (general requirements); and
- (b) where the product is in a reclosable package—section 9 (reclosable packages); and
- (c) where the product is in a non-reclosable package—section 10 (non-reclosable packages).

## **15 Labels**

- (1) A medicinal cannabis product must be labelled in accordance with this section.
- (2) The label of a medicinal cannabis product, other than a medicinal cannabis product that is extemporaneously compounded or repackaged by a pharmacist for a particular patient, must contain all the following information:
  - (a) the name of the medicinal cannabis product;
  - (b) the name and contact details of the sponsor of the medicinal cannabis product;
  - (c) the storage conditions applicable to the medicinal cannabis product;

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- (d) the batch number of the medicinal cannabis product preceded by the batch number prefix;
  - (e) the expiry date of the medicinal cannabis product preceded by the expiry date prefix;
  - (f) the name of each active ingredient of the medicinal cannabis product, and the quantity of each active ingredient (including appropriate units) stated as the anhydrous form;
  - (g) for each active ingredient of a medicinal cannabis product that is a plant preparation—all of the following:
    - (i) the weight of the plant preparation, and the minimum dry weight or fresh weight of the plant material from which it was prepared (including the word ‘minimum’), except where the plant preparation is an essential oil;
    - (ii) the plant species;
    - (iii) the plant part;
    - (iv) the preparation type;Example: “*Cannabis sativa leaf dry extract 5 mg, derived from Cannabis sativa leaf dry 500 mg minimum, containing THC 30 mg*”.
  - (h) for each active ingredient of a medicinal cannabis product that is plant material—all of the following:
    - (i) the minimum dry weight or minimum fresh weight of plant material (including the word ‘minimum’);
    - (ii) the plant species;
    - (iii) the plant part;Example: “*Cannabis sativa flower dry 500 mg minimum, containing THC 30 mg*”.
  - (i) the dosage form of the medicinal cannabis product;
  - (j) the quantity of the medicinal cannabis product.
- (3) The label of a medicinal cannabis product that is extemporaneously compounded or repackaged by a pharmacist for a particular patient must state the name and quantity of each active ingredient that is purported to be present in the medicinal cannabis product.
- (4) All of the information that is displayed on the label of a medicinal cannabis product must be:
- (a) in English; and
  - (b) legible; and
  - (c) visible and not obscured; and
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- (d) durable.

## 16 Microbiological attributes

A medicinal cannabis product in oral dosage form must comply with the relevant acceptance criteria for microbiological quality of one of the following:

- (a) the British Pharmacopoeia, Appendix XVI. D Microbiological Quality of Non-Sterile Pharmaceutical Preparations and Substances for Pharmaceutical use, when tested by the methods of:
- (i) the British Pharmacopoeia, Appendix XVI B. Microbiological Examination of Non-Sterile Products: 2. Microbial Enumeration Tests; and
  - (ii) the British Pharmacopoeia, Appendix XVI B. Microbiological Examination of Non-Sterile Products: 1. Test for Specified Micro-organisms; or
- (b) the European Pharmacopoeia, Microbiological Quality of Non-Sterile Pharmaceutical Preparations and Substances for Pharmaceutical use (5.1.4), when tested by the methods of:
- (i) the European Pharmacopoeia, Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests (2.6.12); and
  - (ii) the European Pharmacopoeia, Microbiological Examination of Non-Sterile Products: Test for Specified Micro-organisms (2.6.13); or
- (c) the United States Pharmacopeia–National Formulary, chapter <1111>, MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: ACCEPTANCE CRITERIA FOR PHARMACEUTICAL PREPARATIONS AND SUBSTANCES FOR PHARMACEUTICAL USE, when tested by the methods of:
- (i) the United States Pharmacopeia–National Formulary, chapter <61> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: MICROBIAL ENUMERATION TESTS; and
  - (ii) the United States Pharmacopeia–National Formulary, chapter <62> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: TESTS FOR SPECIFIED MICROORGANISMS; or
- (d) the Special European Pharmacopoeia (Ph. Eur.) provision for oral dosage forms containing raw materials of natural (animal, vegetal or mineral) origin for which antimicrobial pre-treatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 1000 CFU per g or CFU per mL.

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## **17 Application, savings and transitional provisions**

Sections 13, 14, 15 and 16 apply to medicinal cannabis products released for supply in Australia on or after 1 July 2023.

### **17 Clause 2 of Schedule 1 (table item 3, column 3)**

Omit “2.4.27”, substitute “2.4.8”.

### **18 Clause 2 of Schedule 1 (table item 3, column 4)**

Omit “ppm” (all occurrences), substitute “mg/kg”.

### **19 Note after the table in Schedule 1 (including the heading)**

Repeal the note.

### **20 At the end of clause 2 of Schedule 1**

Add:

Note: In accordance with the European Pharmacopoeia, the unit mg/kg is the m/m measurement equivalent to ppm.

## ***Therapeutic Goods (Microbiological Standards for Medicines) (TGO 100) Order 2018***

### **21 At the end of section 7**

Add:

; or (e) is a medicine to which the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* applies.

Note: Microbiological standards for medicinal cannabis products are outlined in the *Therapeutic Goods Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017*.