Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order (No. 2) 2022

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

Dated 2 December 2022

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

Contents

1 Name

This instrument is the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order (No. 2) 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.

Commencement information

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

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

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

1 Subsection 4(1)

Insert:

Medsafe means the New Zealand Medicines and Medical Devices Safety Authority within the New Zealand Ministry of Health.

New Zealand Code of GMP means the document *New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods*, published by Medsafe, as in force or existing from time to time.

2 Subsection 13(1)

Omit "used as starting material in the manufacture of another medicinal cannabis product.", substitute:

for use as starting material in the manufacture of another medicinal cannabis product manufactured in accordance with:

(c) subsections (2) and (3); or

(d) a licence under Part 3-3 of the Act.

3 At the end of subsection 13(2)

Add:

; (g) the New Zealand Code of GMP.

4 After paragraph 13(3)(e)

Insert:

(ea) for a medicinal cannabis product manufactured in New Zealand—one of the following:

(i) a valid Licence to Manufacture Medicines issued under the *Medicines Act 1981* (NZ), as in force or existing from time to time;

(ii) a valid certificate of good manufacturing practice issued to the manufacturer of the product by Medsafe;

(iii) written confirmation from the Therapeutic Goods Administration that the manufacturing site operates in accordance with the PIC/S Guide to GMP;

5 Subsection 13(4)

After "certificate", insert ", licence".

6 Section 14

Repeal the section, substitute:

14 Child-resistant packaging

(1) This section does not apply to a medicinal cannabis product that is:

(a) plant material; or

(b) mentioned in section 7 of TGO 95.

(2) A medicinal cannabis product 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).

7 Subsection 15(1)

After "product", insert "that is a finished product".

8 Paragraph 15(2)(f)

Omit "stated as the anhydrous form".

9 Subparagraph 15(2)(g)(i)

Omit "essential".

10 Section 16

Omit "in oral dosage form", substitute "that is in oral dosage form or for administration by inhalation".

11 Clause 2 of Schedule 1 (table item 3, column 3)

Omit "2.4.8", substitute "2.4.27".