



Therapeutic Goods Amendment (Standard for Medicinal Cannabis) Order 2019

I, Jane Cook, as delegate of the Minister for Health, make the following order.

Dated 27 March 2019

Jane Cook
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods Amendment (Standard for Medicinal Cannabis) Order 2019*.

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	31 March 2019.	31 March 2019

Note: This table relates only to the provisions of this instrument as originally made.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 Amendments

Each instrument that is specified in Schedule 1 to this instrument is amended as set out in the applicable items in that Schedule.

Schedule 1—Amendments

Note: See section 4.

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

1 Section 1

Omit “*Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)*”, substitute “*Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017*”.

2 Section 4 (definition of *stated content*)

Omit the definition, substitute:

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.

3 Section 12 (note at the end)

Omit “*Therapeutic Goods Order No. 78 Standard for Tablets and Capsules*”, substitute “*Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019*”.