# Therapeutic Goods (Medicinal Cannabis Products—Approvals and Authorities) (Information) Specification 2021

I, Jane Cook, as delegate of the Minister for Health and Aged Care, make the following specification.

Dated 19 November 2021

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

# Contents

## 1 Name

This instrument is the *Therapeutic Goods (Medicinal Cannabis Products—Approvals and Authorities) (Information) Specification 2021*.

## 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Note: This table relates only to the provisions of this instrument as originally made.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 subsection 61(5D) of the *Therapeutic Goods Act 1989*.

## 4 Definitions

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

(a) Secretary.

In this instrument:

***Act*** means the *Therapeutic Goods Act 1989*.

***active ingredient*** has the same meaning as in the Regulations.

***authorised prescriber authority*** means an authority under subsection 19(5) of the Act.

Note: Subsection 19(5) of the Act provides that the Secretary may authorise a medical practitioner to supply specified therapeutic goods for use in the treatment of humans, or a specified class of such goods, to a class or classes of recipients specified in the authority.

***category 1*** means the category of medicinal cannabis product that is a cannabidiol medicinal cannabis product where:

(a) cannabidiol comprises 98% or more of the total cannabinoid content of the medicine; and
(b) any cannabinoids, other than cannabidiol, in the medicine are only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the medicine; and
(c) the medicine contains no other active ingredients.

***category 2*** means the category of medicinal cannabis product that is a cannabidiol-dominant medicinal cannabis product where:
(a) cannabidiol derived from cannabis comprises 60% or more and less than 98% of the total cannabinoid content of the medicine; and
(b) other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and
(c) the medicine contains no other active ingredients.

***category 3*** means the category of medicinal cannabis product that is a balanced medicinal cannabis product where:
(a) cannabidiol derived from cannabis comprises 40% or more and less than 60% of the total cannabinoid content of the medicine; and
(b) other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and
(c) the medicine contains no other active ingredients.

***category 4*** means the category of medicinal cannabis product that is a tetrahydrocannabinol-dominant medicinal cannabis product where:
(a) cannabinoids other than cannabidiol (including tetrahydrocannabinol) derived from cannabis comprise 60% or more and 98% or less of the total cannabinoid content of the medicine; and
(b) cannabidiol derived from cannabis comprises 2% or more and 40% or less of the total cannabinoid content of the medicine; and
(c) the medicine contains no other active ingredient.

***category 5*** means the category of medicinal cannabis product that is a tetrahydrocannabinol medicinal cannabis product where:
(a) cannabinoids other than cannabidiol (including tetrahydrocannabinol) comprise more than 98% of the total cannabinoid content of the medicine; and
(b) cannabidiol comprises less than 2% of the total cannabinoid content of the medicine; and
(c) the medicine contains no other active ingredient.

***medicinal cannabis products*** has the same meaning as in the Regulations.

***Regulations*** means the *Therapeutic Goods Regulations 1990*.

***relevant category***, in relation to a medicinal cannabis product, means one of the following categories, as applicable:
(a) category 1;
(b) category 2;

(c) category 3;
(d) category 4;
(e) category 5.

***SAS B approval*** means an approval under paragraph 19(1)(a) of the Act.

Note: Paragraph 19(1)(a) of the Act provides that the Secretary may grant an approval for the importation into, or the exportation from, Australia or the supply in Australia of specified therapeutic goods that are not registered goods, listed goods or exempt goods for use in the treatment of another person.

***therapeutic goods information*** has the meaning given by subsection 61(1) of the Act.

## 5 Release of therapeutic goods information

The kinds of therapeutic goods information set out in the table in Schedule 1 are specified for the purpose of subsection 61(5C) of the Act.

Note: Kinds of therapeutic goods information specified under subsection 61(5D) of the Act may be released by the Secretary to the public under subsection 61(5C).

# Schedule 1—Specified kinds of therapeutic goods information

Note: See section 5.

| Column 1 | Column 2 |
|---|---|
| **Item** | **Kinds of information** |
| 1 | information relating to a medicinal cannabis product that is the subject of an authorised prescriber authority or a SAS B approval, including the following:<br>(a) active ingredient;<br>(b) dosage form;<br>(c) product name;<br>(d) relevant category;<br>(e) sponsor name; |