Therapeutic Goods (Medicinal Cannabis Products) (Information) Specification 2021

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

Dated 4 August 2021

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods (Medicinal Cannabis Products) (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Note: This table relates only to the provisions of this instrument as originally made.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) current Poisons Standard;
(b) health practitioner;
(c) indications;
(d) Secretary.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

active ingredient has the same meaning as in the Regulations.

authorised prescriber application means an application for 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.

authorised prescriber report means a report provided to the Secretary in accordance with regulation 47B of the Regulations by a person authorised under subsection 19(5) of the Act.

medical practitioner has the same meaning as in subsection 19(9) of the Act.

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

Regulations means the *Therapeutic Goods Regulations 1990*.

relevant product means a medicinal cannabis product that is the subject of one of the following:

(a) an authorised prescriber application;
(b) an authorised prescriber report;
(c) a SAS A notification;
(d) a SAS B application.

SAS A notification means a statement referred to in subparagraph 12A(2)(a)(iii) of the Regulations that is sent to the Secretary in accordance with subregulation 12A(3) of the Regulations.

Note: Regulation 12A is made for the purposes of subsection 18(1) of the Act, and exempts certain medicines for use in life-threatening cases from the operation of Part 3-2A of the Act.

SAS B application means an application made in accordance with subsection 19(2) of the Act for 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	the number of submissions, being authorised prescriber applications, SAS A notifications and SAS B applications made in relation to relevant products, by reference to one or more of the following: (a) a time period; (b) the relevant pathway for the applications or notifications; (c) the status of the applications or notifications, such as approved, withdrawn, refused, pending and received; (d) the number of medical practitioners or health practitioners who made the applications or notifications; (e) the states or territories in which the practitioners mentioned in paragraph (d) are located; (f) the speciality (if any) of the practitioners mentioned in paragraph (d); (g) the numbers of patients to whom authorised prescriber reports, SAS A notifications or SAS B applications relate by age range; (h) the number of patients to whom authorised prescriber reports, SAS A notifications or SAS B applications relate by gender; (i) the indications specified in the applications or notifications in relation to the relevant products; (j) the dosage forms of the relevant products; (k) the name and strength of the active ingredients of the relevant products; (l) the schedule to the current Poisons Standard (otherwise known as the SUSMP Schedule) in which a substance contained in the relevant products is included; (m) the number of patients for whom repeat approvals in relation to a SAS B application have been granted