# EXPLANATORY STATEMENT

*Therapeutic Goods Act 1989*

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

The *Therapeutic Goods Act 1989* ("the Act") provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act is administered by the Therapeutic Goods Administration ("the TGA") within the Australian Government Department of Health ("the Department").

Section 61 of the Act provides that the Secretary may release specified kinds of therapeutic goods information to the public, and certain organisations, bodies or authorities. Subsection 61(1) of the Act provides that therapeutic goods information means, for the purposes of the section, information relating to therapeutic goods, which is held by the Department and relates to the performance of the Department's functions.

Under subsection 61(5C) of the Act, the Secretary may release to the public kinds of therapeutic goods information specified under subsection 61(5D) of the Act. Subsection 61(5D) provides that the Minister may, by legislative instrument, specify kinds of therapeutic goods information for the purposes of subsection 61(5C) of the Act.

The *Therapeutic Goods (Medicinal Cannabis Products—Approvals and Authorities) (Information) Specification 2021* ("the Instrument") is a legislative instrument made under subsection 61(5D) of the Act. It specifies kinds of therapeutic goods information that the Secretary may release to the public under subsection 61(5C) of the Act. Consequently, the Instrument promotes transparency by supporting the publication of information relating to the supply of medicinal cannabis products in Australia.

In general terms, the Instrument identifies therapeutic goods information relating to medicinal cannabis products that are not included in the Australian Register of Therapeutic Goods ("the Register") but that are accessible through the authorised prescriber scheme or the special access Category B (SAS B) scheme, in Australia. The term "medicinal cannabis products" is defined in the *Therapeutic Goods Regulations 1990* ("the Regulations") to mean therapeutic goods that contain, or are manufactured from, any part of a plant of the genus *Cannabis*, including for example the flowers, fruiting tops, seeds, stems and leaves of the plant.

Specifically, the Instrument facilitates the publication of information about medicinal cannabis products that have been the subject of:

- an authority by the Secretary under subsection 19(5) of the Act authorising a medical practitioner to supply specified goods that are not registered goods, listed goods or exempt goods for use in the treatment of humans, or a specified class of such goods, to the class or classes of recipients specified in the authority (this is the principal basis of the authorised prescriber scheme); or
- an approval by the Secretary under paragraph 19(1)(a) of the Act for a health practitioner to supply specified therapeutic goods that are not registered goods, listed goods or exempt goods for use in the treatment of another person (this is the principal basis of the SAS Category B scheme).

The Instrument specifies a range of principally product-based information that the Secretary may release about such medicinal cannabis products, including the active ingredient of the medicinal cannabis product, the category of the medicinal cannabis product (principally based on the percentage of cannabidiol or tetrahydrocannabinol in such a product), the dosage form, the product name and the

sponsor. The information will be published on the TGA website pursuant to decisions made under subsection 61(5C) of the Act.

The information is focussed on the medicinal cannabis products and does not include information about individual patients or practitioners to which an authorised prescriber authority or SAS B approval relates.

**Background**

While there are two medicinal cannabis products that are included in the Register, the majority of medicinal cannabis products that are prescribed to patients in Australia are supplied through the following "unapproved" pathways:

- the Authorised Prescriber pathway, under which medical practitioners may apply to the Secretary for an authorisation to supply unapproved goods to a specified class of persons (this pathway is underpinned by subsection 19(5) of the Act in relation to medicines);
- the SAS Category A pathway, under which medical practitioners may supply unapproved therapeutic goods to critically ill patients and notify the Secretary of having done so within 28 days of supply (this pathway is underpinned by section 18 of the Act and regulation 12A of the Regulations in relation to medicines); and
- the SAS B pathway, under which a health practitioner (this term is defined in subsection 3(1) of the Act and is not limited to medical practitioners) may apply to the Secretary for approval for the use of unapproved therapeutic goods in the treatment of a patient who is not critically ill (this pathway is underpinned by paragraph 19(1)(a) of the Act in relation to medicines).

In recent years, there has been considerable public interest in the provision of information on the kinds of medicinal cannabis products that are the subject of authorised prescriber authorities and SAS B approvals. The release of therapeutic goods information that this Instrument enables is for the purpose of improving awareness in relation to access to medicinal cannabis products under the authorised prescriber and SAS Category B pathways, and assisting medical practitioners, health practitioners and pharmacists to identify the medicinal cannabis products that may be lawfully supplied.

**Consultation**

In November 2021 the TGA contacted sponsors, prescribers, State and Territory Health departments and health professional peak organisations to advise them of the changes to the access framework and application processes relating to unapproved' medicinal cannabis products that are to commence on 22 November 2021 and that the publication of the information authorised by the Instrument supports. In addition, web content, guidance and forms have been published, a series of webinars for both health professionals and sponsors has been organised, and other outreach activities will continue to support health professionals. Prescribers, pharmacists and State and Territory Health departments welcomed the announcements, noting the increased flexibility the changes will deliver in allowing streamlined brand substitution to manage stock shortages and discontinuations without the need for the prescribers to seek a new approval from the TGA. Responses from sponsors have been mixed, principally in relation to the timing of the measures.

A regulation impact statement was not required in relation to the development of the Instrument, as the matter of specifying kinds of therapeutic goods information under section 61 of the Act is the subject of a standing exemption from the regulation impact statement process (Office of Best Practice Regulation ID 15070).

Details of the Instrument are set out in **Attachment A.** The Instrument is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B.** The Instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences the day after registration on the Federal Register of Legislation.

**Attachment A**

**Details of the *Therapeutic Goods (Medicinal Cannabis Products—Approvals and Authorities) (Information) Specification 2021***

**Section 1 Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Medicinal Cannabis Products—Approvals and Authorities) (Information) Specification 2021* ("the Instrument").

**Section 2 Commencement**

This section provides that the Instrument commences the day after it is registered on the Federal Register of Legislation.

**Section 3 Authority**

This section provides that the legislative authority for making the Instrument is subsection 61(5D) of the *Therapeutic Goods Act 1989* ("the Act").

**Section 4 Definitions**

This section provides the definitions for certain terms used in the Instrument, including 'authorised prescriber authority', 'relevant category' in relation to a medicinal cannabis product, and 'SAS B approval'. The section also provides that a number of terms have the same meaning as in the *Therapeutic Goods Regulations* 1990, including 'active ingredient' and 'medicinal cannabis products'. This section also notes that 'Secretary' has the meaning given in subsection 3(1) of the Act.

**Section 5 Release of therapeutic goods information**

This section provides that 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. The effect of this section is to enable the Secretary to release to the public therapeutic goods information of the kind set out in the table in Schedule 1 to the Instrument.

**Schedule 1 Specified kinds of therapeutic goods information**

This Schedule specifies the kinds of therapeutic goods information, for the purposes of section 5 of the Instrument, which may be released to the public by the Secretary under subsection 61(5C) of the Act.

The kinds of information specified is information relating to a medicinal cannabis product that is the subject of an authorised prescriber authority or SAS B approval, including:

- active ingredient;
- dosage form;
- product name;
- the relevant category of medicinal cannabis product; and
- sponsor name.

**Attachment B**

**Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011.*

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

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Overview of legislative instrument**

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**Human rights implications**

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights ("the ICESCR"). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The instrument takes positive steps to promote the right to health by helping to ensure greater transparency and awareness about access to medicinal cannabis products through "unapproved" pathways, demonstrating that such products are able to be accessed in those ways, and over time providing greater insight into the practices of supply of such products for the treatment of persons, and the regulatory processes related to accessing such products, in Australia.

**Conclusion**

This instrument is compatible with human rights because it supports the right to health and does not raise any other human rights issues.