

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medicinal Cannabis Products) (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) (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 the supply of medicinal cannabis products through the authorised prescriber and special access schemes 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 aggregated and de-identified statistical information; being, the numbers of applications or notifications (collectively, “submissions”) made in relation to medicinal cannabis products under the authorised prescriber (“AP”), special access scheme category A (“SAS A”) and special access scheme category B (“SAS B”) pathways in Australia. The numbers of submissions are specified in Schedule 1 to the Instrument with reference to one or more parameters including: time periods; the relevant state or territory in which the medicinal cannabis products are prescribed; the indications for which the products have been prescribed; the active ingredients relating to those products; and the status of the submissions (such as approved, withdrawn, refused, pending or received).

The information will be published in a database pursuant to decisions made under subsection 61(5C) of the Act. The database will be made available on the TGA website in a manner that ensures that individual patients and practitioners cannot be identified from the information. The privacy of individuals will be protected by ensuring that only statistical information for certain parameters that generate results of 10 or more submissions will be published. Any searches for parameters that may be used to identify individual patients or practitioners (such as patient gender, patient age range, or the number, and specialty, of medical or health practitioners who make applications or notifications in any particular state or territory) will be reflected in the database as “less than 10 submissions” where those searches generate results between one and nine submissions.

Background

While there are two medicinal cannabis products that are included in the Australian Register of Therapeutic Goods (“the Register”), the majority of medicinal cannabis products that are prescribed to patients in Australia are supplied through the following “unapproved” pathways:

- the AP 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 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);
- 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 statistical information on the use of the AP, SAS A and SAS B pathways for medicinal cannabis products. Such information is recurrently requested by members of the media and the public (including patients, practitioners and researchers) in applications made under the *Freedom of Information Act 1982* (“FOI requests”), and also by parliamentarians during Senate Estimate hearings, parliamentary inquiries and question time.

Consultation

Specific consultation was not considered necessary, and therefore not undertaken, in relation to the making of this Instrument, principally because the Instrument facilitates access to information that is ordinarily published as a matter of course through other means, including statutory and parliamentary processes.

In particular, the Instrument facilitates access to information that is customarily released and published on the TGA’s FOI Disclosure Log in response to numerous FOI requests relating to the supply of medicinal cannabis products in Australia. In addition, the Instrument facilitates access to information that is routinely requested through parliamentary processes and subsequently published in Hansard.

For example, the use of the AP, SAS A and SAS B pathways for medicinal cannabis products was considered at the Senate Community Affairs Committee’s estimates hearing on 27 October 2020. The response provided by the Department to the Committee included the number of approvals across the “unapproved” pathways since the inception of the medicinal cannabis scheme in Australia.

The use of the AP, SAS A and SAS B pathways for medicinal cannabis products (including numbers of prescribers in each state and territory) was also discussed on 29 January 2020 at a hearing of the Senate Community Affairs Reference Committee’s inquiry into current barriers to patient access to medicinal cannabis in Australia. As a consequence of that inquiry, the Senate Community Affairs Reference Committee recommended that the TGA review and improve its resources for health professionals regarding the regulatory process for accessing medicinal cannabis through the AP and SAS pathways (recommendation 6). This Instrument complements those improvements by highlighting the numbers of submissions relating to medicinal cannabis products that are supplied through those pathways.

The provision of similar information in relation to medicinal cannabis products has also arisen in the context of parliamentary question time, for which access to medicinal cannabis products in Australia is a particular focus.

The Instrument responds to the public interest in medicinal cannabis products by enabling greater, and more streamlined, access to information regarding the supply of those products in Australia under the AP, SAS A and SAS B pathways.

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 (OBPR 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.

Details of the *Therapeutic Goods (Medicinal Cannabis Products) (Information) Specification 2021*

Section 1 Name

This section provides that the name of the instrument is the *Therapeutic Goods (Medicinal Cannabis Products) (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 application’, ‘authorised prescriber report’, ‘SAS A notification’ and ‘SAS B application’. The section also notes that a number of terms have the meaning given in subsection 3(1) of the Act, including ‘current Poisons Standard’, ‘health practitioner’ and ‘indications’.

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 includes the number of submissions, being authorised prescriber applications, special access scheme category A (“SAS A”) notifications and special access scheme category B (“SAS B”) applications made in relation to medicinal cannabis products by reference to one or more parameters, including:

- a time period;
- the relevant pathway;
- the status of the applications or notifications;
- the indications specified in the applications or notifications;
- the name and strength of the active ingredients of the relevant products; and
- the relevant state or territory in which the relevant products are prescribed.

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) (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

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”).

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In general terms, the instrument identifies therapeutic goods information relating to the supply of medicinal cannabis products through the authorised prescriber and special access schemes 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.

While there are two medicinal cannabis products that are included in the Australian Register of Therapeutic Goods (“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 (“AP”) 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 special access scheme category A (“SAS 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);
- the special access scheme category B (“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 statistical information on the use of the AP, SAS A and SAS B pathways for medicinal cannabis products. Such information is frequently requested by members of the media and the public (including patients, practitioners and

researchers) in applications made under the *Freedom of Information Act 1982* (“FOI requests”), and also by parliamentarians during Senate Estimate hearings, parliamentary inquiries and question time.

Specifically, the instrument facilitates the publication of aggregated and de-identified statistical information; being, the numbers of applications or notifications (collectively, “submissions”) made in relation to medicinal cannabis products under the authorised prescriber (“AP”), special access scheme category A (“SAS A”) and special access scheme category B (“SAS B”) pathways in Australia. The numbers of submissions are specified in Schedule 1 to the instrument with reference to one or more parameters including: time periods; the relevant state or territory in which the medicinal cannabis products are prescribed; the indications for which the products have been prescribed; the active ingredients relating to those products; and the status of the submissions (such as approved, withdrawn, refused, pending or received).

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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 (“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 practice regarding supply for the treatment of persons and regulatory processes related to such products.

The instrument also engages the right to privacy in Article 16 of the Convention of the Rights of the Child (“CROC”) and Article 17 of the ICESCR. Article 16(1) of the CROC recognises that ‘no child shall be subjected to arbitrary or unlawful interference with his or her privacy, family, home or correspondence, nor to unlawful attacks on his or her honour and reputation’. Article 17(1) of the ICESCR similarly states that ‘no one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation’.

The instrument does not facilitate the publication of information that could amount to an interference of privacy of individuals, on the basis that the instrument only enables decisions of the Secretary under subsection 61(5C) of the Act to release the numbers of submissions made under the “unapproved” pathways in Australia. The instrument does not facilitate the disclosure of names of medical or health practitioners responsible for submissions, or the names of patients who are the subject of those submissions (the latter, not being collected by the TGA as part of the “unapproved” pathways). Rather, as mentioned above, the database is programmed to protect the privacy of individuals reflected in search results for certain parameters that are less than 10 submissions. As such, the database

safeguards personal and sensitive information within the meaning of the *Privacy Act 1988*. Any decision of the Secretary to publish information specified in this instrument under subsection 61(5C) of the Act will therefore promote transparency, consistent with the objects of the *Freedom of Information Act 1982*, without infringing the human right to privacy.

Conclusion

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