EXPLANATORY STATEMENT

Therapeutic Goods Act 1989
Narcotic Drugs Act 1967

Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022

The Regulations support the safe use of extemporaneously-compounded medicinal cannabis products in Australia and provide clarity to industry.

An object of the *Therapeutic Goods Act 1989* (the TG Act) is to establish and maintain a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods used in, or exported from, Australia. The *Narcotic Drugs Act 1967* (the ND Act) gives effect to certain of Australia's obligations under the Single Convention on Narcotic Drugs, 1961 as in force from time to time. Subsection 63(1) of the TG Act enables the Governor-General to make regulations, not inconsistent with the TG Act, prescribing matters required or permitted by the TG Act or necessary or convenient to be prescribed for carrying out or giving effect to the TG Act. Section 27 of the ND Act enables the Governor-General to make regulations prescribing matters required or permitted to be prescribed by the ND Act or necessary or convenient for carrying out or giving effect to the ND Act.

The *Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022* (the Regulations) amends the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Narcotic Drugs Regulation 2016* (the ND Regulations), principally to implement reforms to the regulation of medicinal cannabis products in Australia, and to make a small number of other, more minor amendments, to the TG Regulations and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to reduce regulatory burden and provide clarity to industry.

The Regulations:

- enable a licence to be issued under the ND Regulations for the manufacture of cannabis drugs and a medicinal cannabis permit to be issued for the supply of cannabis or cannabis resin, where the cannabis drug, cannabis or cannabis resin is to be supplied to a person for the purposes of that person supplying an extemporaneously-compounded (i.e. prepared for a particular patient for that patient's needs) medicinal cannabis product in accordance with the TG Act – with the effect that cannabis drugs that are cultivated or manufactured domestically (like imported product) could be supplied for the extemporaneous compounding of medicinal cannabis products; and
- remove medicinal cannabis products from the current exemption from inclusion in the Australian Register of Therapeutic Goods (the Register) for extemporaneously-compounded medicines, so that such unapproved products need to be accessed through one of the unapproved access pathways –to better ensure the safe use of such products with appropriate regulatory oversight.

The Regulations also make minor amendments including to:

- provide review rights for decisions under the TG Regulations relating to approvals for the import or export of therapeutic goods comprised of mercury, or the revocation or variation of such approvals;
- remove the requirement for European-specific unique device identifiers of medical devices to be included on patient implant cards for implantable medical devices or

active implantable medical devices, as this requirement will be postponed until the development of the Australian Unique Device Identification system; and

- clarify that medicines listed in Schedule 10 to the current Poisons Standard cannot be accessed via the Special Access Scheme – Category A pathway (the pathway for accessing unapproved therapeutic goods for a seriously ill patient) as such medicines are not suitable for, and therefore prohibited from, sale, supply and use under state and territory legislation.

Details of the Regulations are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised. The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on the day after they are registered on the Federal Register of Legislation, except Schedule 1 which commences on 31 March 2022 and Schedule 2 which commences the later of the day after registration and the day on which the *Minamata Convention on Mercury (Consequential Amendments) Regulations 2021* commence (provided those regulations do commence).

Consultation

The TGA undertook public consultation on the proposed reforms to the regulation of medicinal cannabis products in Australia, including with manufacturers, other sponsors, industry professional associations, various state and territory government departments, chief pharmacists, and patient and advocate bodies. Forty-eight stakeholders provided feedback to the consultation paper, predominantly manufacturers and sponsors, as well as health industry bodies and professional societies, pharmacists and herbalists, and government organisations. There was variation in the level of support for changes relating to the extemporaneous compounding reforms, with pharmacists and their professional societies objecting to significant changes to the compounding exemptions. These amendments allow for extemporaneous compounding of medicinal cannabis products to continue where the prescriber has an approval or authority under the Act, which addresses the mains concerns raised in consultation about safe use and not limiting access to these goods.

In relation to removing the requirement for European-specific unique device identifiers on patient implant cards, discussions were held with the medical device Regulatory and Technical Consultative Forum in November 2021. Members were supportive of the proposal to postpone until the Australian Unique Device Identification system is implemented. The TGA consulted with the Department of Agriculture, Water and the Environment on review rights for decisions relating to the import and export of mercury to ensure consistency across relevant Commonwealth legislation.

Authority: Subsection 63(1) of the *Therapeutic Goods Act 1989* and subsection 27(1) of the *Narcotic Drugs Act 1967*

ATTACHMENT

Details of the *Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022*

Section 1 – Name

This section provides that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022.*

Section 2 – Commencement

This section provides for the Regulations to commence on the day after registration on the Federal Register of Legislation, except Schedule 1 which commences on 31 March 2022 and Schedule 2 which commences the later of the day after registration and the day on which the *Minamata Convention on Mercury (Consequential Amendments) Regulations 2021* commence (provided those regulations do commence).

Section 3 – Authority

The Regulations are made under the *Therapeutic Goods Act 1989* (the Act).

Section 4 – Schedules

This section gives legal effect to the amendments in the Schedules.

Schedule 1 – Extemporaneously-compounded medicinal cannabis products

Narcotic Drugs Regulation 2016

Items [1] and [2]– After paragraph 4B(b) and after paragraph 11(c)
These items amend regulation 4B and regulation 11 to introduce new paragraphs (b) and (c) respectively. These amendments allow the domestic medicinal cannabis industry to supply cannabis drugs for the extemporaneous compounding of medicinal cannabis products.

Currently, supply of domestic medicinal cannabis is prohibited for extemporaneous compounding due to the risk of misuse. Almost all extemporaneously-compounded medicinal cannabis products are made from imported medicinal cannabis starting material. However, other amendments in this Schedule to increase regulatory oversight of the extemporaneous compounding of medicinal cannabis products are intended to support the safe supply of medicinal cannabis products and supports enabling the domestic medical cannabis industry to supply medicinal cannabis for extemporaneous compounding. This measure has the effect of supporting the domestic medicinal cannabis industry by providing a level playing field for domestic and imported medicinal cannabis for extemporaneous compounding.

Under the *Narcotic Drugs Act 1967* (the ND Act), a medicinal cannabis licence may authorise the cultivation, production and/or manufacture of cannabis for medicinal or scientific purposes. It is a requirement of the grant of a licence that authorises the

manufacture of a cannabis drug, as well as an ongoing condition of that licence, that the supply by that licence holder of a cannabis drug is only for the purposes of certain permitted supplies authorised by the ND Act and ND Regulations ('permitted supply' being in section 4(1) of the ND Act).

Item 1 amends regulation 4B of the ND Regulations to provide a permitted supply, for the purposes of paragraph (e) of the definition 'permitted supply' in subsection 4(1) of the ND Act), where the supply is to a person for the purposes of that person supplying an extemporaneously-compounded medicinal cannabis product in accordance with the TG Act. The effect of this is that the supply of a cannabis drug by the holder of a licence under the ND Act that authorises the manufacture of a cannabis drug may be for the purposes of extemporaneous compounding of a medicinal cannabis product. This amendment facilitates a manufacturer licenced under the ND Act to lawfully supply, for example, an extract of cannabis to a private compounding pharmacist where the extemporaneously-compounded medicinal cannabis product is to be supplied in accordance with the TG Act.

Item 2 makes a similar amendment to regulation 11 to facilitate the supply of cannabis by a licensed cannabis cultivator under the ND Act (who would be authorised to produce the cannabis, but not authorised to manufacture cannabis drugs) to a person for the purposes of that person supplying an extemporaneously-compounded medicinal cannabis product in accordance with the TG Act. Subparagraph 9(4)(d)(ii) of the ND Act provides that a medicinal cannabis permit that relates to a licence that authorises the production of cannabis or cannabis resin (but not manufacture of a cannabis drug) must be refused if the Secretary is not satisfied on reasonable grounds that the production of the cannabis or cannabis resin is for a purpose prescribed by the Regulations. The effect of this item is, for example, to allow a permit holder to supply cannabis to a person for the purpose of that person supplying an extemporaneously-compounded medicinal cannabis product in accordance with the TG Act.

Therapeutic Goods Regulations 1990

Item [3] – In the appropriate position in Part 9
This item amends Part 9 of the TG Regulations to introduce Division 18 which includes an application provision for the amendments made in item 4. New regulation 86 provides that the amendments to Schedule 5 to the TG Regulations made by this Schedule do not apply in relation to a medicinal cannabis product that is extemporaneously-compounded before 28 April 2022. This is to enable prescribers sufficient time to obtain an approval or authority under section 19 of the TG Act to supply an unapproved therapeutic good.

Item [4] - Schedule 5 (at the end of the cell at table item 6, column 2)
This item amends item 6 of Schedule 5 to the TG Regulations to exclude medicinal cannabis products from the exemption, from inclusion in the Register, for extemporaneously-compounded medicines. This provides appropriate regulatory oversight for the extemporaneous compounding of medicinal cannabis products.

Currently, medical practitioners and pharmacists involved in extemporaneous compounding are exempt from the requirement to hold a manufacturing licence issued under Part 3-3 of the TG Act on the basis of items 1, 2 and 3 of Schedule 8 to the TG Regulations. In addition, extemporaneously-compounded medicines are not required to be included in the Register on the basis of item 6 of schedule 5 to the TG Regulations. Accordingly, prescribers are not

required to seek an approval under the Special Access Scheme for unapproved therapeutic goods or an authority under the Authorised Prescriber Scheme.

The lack of regulatory oversight of the supply of extemporaneously-compounded medicinal cannabis products has raised a number of concerns. There is currently no visibility of the conditions for which these medicinal cannabis products are being compounded, the appropriateness of the use, the patient groups being prescribed, the number of prescriptions written, the active ingredients and quantities included in the dispensed product, or who is extemporaneously compounding medicinal cannabis products. Further, the TGA is not able to assess the quality and safety of extemporaneously-compounded medicinal cannabis products and may not receive reports of adverse events experienced by patients.

To address these risks, and maintain the availability of extemporaneously-compounded medicinal cannabis products in Australia, it is appropriate for extemporaneously-compounded medicinal cannabis products to be accessed in the same manner as other unapproved medicines – through one of the special access pathways for unapproved medicines provided for under the TG Act. Excluding extemporaneously-compounded medicinal cannabis products from the exemption from inclusion in the Register in item 6 has the effect that such medicines could only be accessed through one of the pathways for access to unapproved medicines, particularly the Special Access Scheme Category B pathway (SAS B) and the Authorised Prescriber (AP) scheme.

Under the SAS B and AP schemes, the TGA assess applications for such an approval or authority to supply extemporaneously-compounded medicinal cannabis products and practitioners are required to submit adverse event reports as a condition of an approval or authority, supporting the continuing monitoring of potential safety concerns associated with use of medicinal cannabis products. Further, the TGA would be informed of the indications for which such a product is being prescribed, have the ability to refuse SAS B or AP applications, and would be aware of the number of prescriptions filled by extemporaneous compounding (to address the risks of bulk manufacture and related safety concerns).

Schedule 2 – Minamata Convention on Mercury

Therapeutic Goods Regulations 1990

Items [1] to [13]– Amendments to regulation 48
These items amend regulation 48 of the TG Regulations to provide review rights for decisions relating to the import and export of mercury, which was an inadvertent omission from the *Minamata Convention on Mercury (Consequential Amendments) Regulations 2021* (the Minamata Regulations) which amended the TG Regulations to implement the Minamata Convention on Mercury (Minamata Convention).

Item 58 of the Minamata Regulations inserts a new Part 2CA into the TG Regulations that allows the Secretary to grant an application for approval to import or export mercury that is a therapeutic good only if the Secretary is satisfied that it is consistent with specified requirements designed to reflect Australia's obligations under Article 3 of the Minamata Convention.

A decision to refuse to approve or to vary or revoke an approval is intended to be subject to review rights, consistent with the *Agricultural and Veterinary Chemicals (Administration) Regulations 1995*. Accordingly, these amendments introduce review rights, for applicants or approval-holders, for decisions under regulations 10JE and 10JF of the TG Regulations to not approve an application to import or export a therapeutic good that is mercury, or to vary or revoke such an approval.

These items also make a number of minor, consequential editorial amendments to regulation 48 to insert subheadings and refer to an eligible person which is now defined in subregulation 48(1).

Item [14] – at the end of Division 18 of Part 9
This item introduces Division 18 to Part 9 of the TG Regulations to provide for the application of the amendments made by this Schedule. New regulation 87 provides that the amendments of regulation 48 made by Schedule 2 of these regulations apply in relation to initial decisions made on or after the commencement of this regulation.

Schedule 3 – Other amendments

Therapeutic Goods (Medical Devices) Regulations 2002

Items [1] to [2] – Subclause 13A.2(2) of Schedule 1 (table item 1, column headed "Information", paragraphs (c) and (d))
This item amends subclause 13A.2(2) of Schedule 1 to the MD Regulations to remove the requirement for a unique device identifier on patient implant cards.

Clause 13A.2(2) requires a manufacturer or sponsor to include a unique device identifier on a patient implant card for any device that has a unique device identifier. Unique device identifier is defined as meaning, in short, a unique device identifier issued in accordance with EU Medical Devices Regulation 2017/745 of the European Parliament and of the Council.

As unique device identifiers are not harmonised globally, there are some concerns about complying with the unique device identifier requirement in clause 13A.2 and potential confusion for consumers. Manufacturers may apply a unique device identifier from another jurisdiction if a European unique device identifier has not been assigned. Patients would then not know where information about the device can be accessed. Patients will need to know where and how to search for information using the particular unique device identifier.

Accordingly, it is proposed that the requirement for a unique device identifier on patient information cards be postponed until the Australian Unique Device Identification system has been implemented.

Item [3] –Dictionary (Definition of *unique device identifier*)
These items repeal the definition of 'unique device identifier' in the Dictionary to the MD Regulations as, with the above amendment, this terms is no longer used in the MD Regulations.

Therapeutic Goods Regulations 1990

Item [4] – Subregulation 12A(1)
This item amends subregulation 12A(1) of the TG Regulations to provide that medicines in Schedule 10 to the current Poisons Standard are excluded from the exemption in regulation 12A, commonly known as the Special Access Scheme Category A (SAS A) pathway. This amendment reflects that it is not appropriate for medicines in Schedules 9 and 10 to the current Poisons Standard to be accessed through the SAS A scheme as they are prohibited from sale, supply and use under the Poisons Standard and state and territory legislation.

Statement of Compatibility with Human Rights

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

Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022

The *Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022* (the Regulations) are 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 the Legislative Instrument

The Regulations are made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act), and section 27 of the *Narcotic Drugs Act 1967* (the ND Act).

The purpose of the *Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022* (the Regulations) is to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Narcotic Drugs Regulation 2016* (the ND Regulations), principally to implement reforms to the regulation of medicinal cannabis products in Australia and support the safe use of extemporaneously compounded medicinal cannabis products in Australia, and to make a small number of other, more minor amendments, to the TG Regulations and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to reduce regulatory burden and provide clarity to industry.

The Regulations have the effect of:

- enabling a licence to be issued under the ND Regulations for the manufacture of cannabis drugs and a medicinal cannabis permit to be issued for the supply of cannabis or cannabis resin, where the cannabis drug, cannabis or cannabis resin is to be supplied to a person for the purposes of that person supplying an extemporaneously compounded (i.e. prepared for a particular patient for that patient's needs) medicinal cannabis product in accordance with the TG Act – with the effect that cannabis drugs that are cultivated or manufactured domestically (like imported product) can be supplied for the extemporaneous compounding of medicinal cannabis products; and
- removing medicinal cannabis products from the current exemption from inclusion in the Australian Register of Therapeutic Goods (the Register) for extemporaneously compounded medicines, so that unapproved extemporaneously compounded medicinal cannabis products are accessed through one of the unapproved access pathways (i.e. the Special Access Scheme Category B pathway or Authorised Prescriber scheme) – this is designed to better ensure the safe use of such products with appropriate regulatory oversight.

The Regulations also make a small number of more minor amendments, principally to:

- provide review rights for decisions under the TG Regulations relating to approvals for the import or export of therapeutic goods that are mercury, or the revocation or variation of such approvals;
- remove the requirement for European-specific unique device identifiers of medical devices to be included on patient implant cards for implantable medical devices or active implantable medical devices, as this requirement will be postponed until the development of the Australian Unique Device Identification system; and

- clarify that medicines listed in Schedule 10 to the current Poisons Standard cannot be accessed via the Special Access Scheme – Category A pathway (the pathway for accessing unapproved therapeutic goods for a critically ill patient) as such medicines are not suitable for, and therefore prohibited from, sale, supply and use under state and territory legislation.

Human rights implications

The Regulations engage 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 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 Regulations take positive steps to support the right to health by:

- supporting the safe use of extemporaneously compounded medicinal cannabis products in Australia, in a manner that enables the continued supply of medicinal cannabis products for patients that require such treatment while improving oversight - this will for instance better enable the identification of safety signals and help reduce the risk of misuse associated with such products;
- postponing the implementation of a requirement for unique device identifiers of medical devices to be included on patient implant cards until the development of the Australian Unique Device Identification system, to prevent avoid confusing patients if a manufacturer were to apply a unique device identifier from another jurisdiction; and
- clarifying that substances in Schedule 10 to the Poisons Standard, that are prohibited from sale, supply and use under the Poisons Standard and state and territory legislation, cannot be accessed through the Special Access Scheme Category A (SAS A) pathway for accessing unapproved therapeutic goods because these substances are of such danger to health as to warrant the prohibition on sale, use and supply.

Conclusion

The Regulations are compatible with human rights because they maintain and support the right to health in Article 12 of the ICESCR as outlined above, and do not raise any other human rights issues.

Greg Hunt, Minister for Health and Aged Care