

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order 2022

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 Department of Health.

Subsection 10(1) of the Act relevantly provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Subsection 10(2) provides that an order establishing a standard for therapeutic goods may be specified by reference to the quality of the goods, or the procedures to be carried out in the manufacture of the goods, among other matters. An order may also require that a matter relating to the standard be determined in accordance with a particular test. Subsection 10(3A) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1) of the Act.

Importantly, a person who imports, exports or supplies therapeutic goods that do not conform to an applicable standard may be subject to offence and civil penalty provisions in sections 14 and 14A of the Act. The Secretary may, however, give consent in writing in relation to the importation, exportation or supply of therapeutic goods that do not conform to an applicable standard, in accordance with those sections.

The *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* (“the Principal Order”) is an order made under section 10 of the Act for the purpose of establishing a ministerial standard for medicinal cannabis products. The Principal Order specifies the minimum requirements for the quality and safety of medicinal cannabis products.

The purpose of the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order 2022* (“the Amendment Order”) is to amend the Principal Order to make a number of safety-related updates, and improve clarity. In particular, the amendments introduced by the Amendment Order establish standards for the manufacturing quality, labelling, child-resistant packaging and microbiological attributes of medicinal cannabis products, clarify a number of existing definitions, and clarify that cannabinoids in a medicinal cannabis product must be taken directly from the cannabis plant and must not be synthetically modified in any way.

Background

The Australian Government is responsible for regulating the quality, safety and efficacy of therapeutic goods. This is achieved in part by requiring compliance with the default standards under the Act and specifying ministerial standards under section 10 of the Act by reference to a range of matters including the manufacture of therapeutic goods, and by otherwise applying default standards that are constituted by statements in three international pharmacopoeias defined in the Act.

The Principal Order applies to medicinal cannabis products, whether imported into Australia or manufactured domestically, and is intended to provide an assurance to medical practitioners and patients that medicinal cannabis products meet minimum quality requirements.

However, a ‘level playing field’ for imported and domestically produced medicinal cannabis products does not currently exist in Australia because only medicinal cannabis products manufactured in Australia are required to be manufactured in accordance with good manufacturing practice requirements. Concerns have arisen in relation to this and in relation to transparency and awareness around the contents of, and amount of active ingredients in, the medicinal cannabis products available in Australia and the absence of accurate and reliable information on the labels of such products to inform patients. There are also concerns of insufficient controls on the product quality and oversight of manufacture of imported medicinal cannabis products. The Amendment Order is designed to address these concerns and ensure the safety and quality of medicinal cannabis products available for use by patients in Australia, whether manufactured in Australia or overseas.

The Amendment Order addresses these concerns by specifying a range of labelling and packaging requirements for all medicinal cannabis products, and establishing standards for manufacturing quality for imported products, to align those with the standards required of domestically produced medicinal cannabis products.

The Amendment Order also introduces a number of new labelling requirements for medicinal cannabis products, to better support the safe use of such products and to assist consumers and health practitioners to identify and understand their key components. The labelling requirements differ between medicinal cannabis products for general supply and medicinal cannabis products that are extemporaneously compounded or repackaged by a pharmacist for a particular patient. For medicinal cannabis products that are not extemporaneously compounded or repackaged for a particular patient, the information required to be set out on the label includes the name of the product, the name of the sponsor, the name of each active ingredient, the quantity of each active ingredient, the dosage form, the quantity of the medicinal cannabis product, batch number, expiry date and storage conditions. The Amendment Order requires labels of extemporaneously compounded or repackaged medicinal cannabis products, prepared by a pharmacist, to state the name and quantity of each active ingredient. Other requirements for labels on these goods are set out in relevant state and territory legislation.

The Amendment Order also provides further clarification that cannabinoids in medicinal cannabis products must only be derived from the cannabis plant and not synthetically modified.

In so doing the Amendment Order:

- supports the safety and quality of medicinal cannabis products in Australia;
- better balances the regulatory requirements applying to medicinal cannabis products manufactured in Australia with those applying to imported medicinal cannabis products;
- promotes transparency in relation to the active ingredients and other important characteristics of medicinal cannabis products; and

- provides greater confidence for patients and health practitioners in relation to the safe use of medicinal cannabis products in Australia through an increased understanding of the contents and formulation of such products.

Incorporation by reference

Subsection 10(4) of the Act relevantly provides that, despite subsection 14(2) of the *Legislation Act 2003*, an order (or variation of an order) under this provision may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument of other writing as in force of existing from time to time.

The following identifies and explains that the documents that are incorporated by reference in the Amendment Order, and the intended manner of incorporation.

Incorporation of GMP Guidance by reference

The Amendment Order incorporates the following documents by reference:

- the definition of ‘PIC/S Guide to GMP’ in section 4 (introduced by item 6 of Schedule 1 to the Amendment Order) incorporates the PIC/S *Guide to Good Manufacturing Practice for Medicinal Products* (PE 009-15, 1 May 2021), which sets out standards that apply to the manufacture of medicines and similar products intended for human use. The intended manner of incorporation is as in force from time to time. This document is available for free from the TGA website (www.tga.gov.au);
- the definition of ‘EU Directive 2003/94/EC’ in section 4 (introduced by item 4 of Schedule 1 to the Amendment Order) incorporates the European Commission *Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use*. The intended manner of incorporation is as in force at the time the Amendment Order is made. This document is available for free from the EUR-lex website (<https://eur-lex.europa.eu>);
- the definition of ‘EU Directive 2001/83/EC’ in section 4 (introduced by item 4 of Schedule 1 to the Amendment Order) incorporates the European Commission *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use*. The intended manner of incorporation is as in force from time to time. This document is available for free from the EUR-lex website (<https://eur-lex.europa.eu>);
- the definition of ‘South African Guide to GMP’ in section 4 (introduced by item 6 of Schedule 1 to the Amendment Order) incorporates the document *4.01 - South African Guide to GMP* (July 2019, V7), published by the South African Health Products Regulatory Authority. The intended manner of incorporation is as in force from time to time. This document is available for free from the South African Health Products Regulatory Authority website (www.sahpra.org.za/);

- section 13 (introduced by item 16 of Schedule 1 to the Amendment Order) incorporates part of *Title 21—Food and Drugs*, in the *United States Code of Federal Regulations*. The intended manner of incorporation is as in force from time to time. The *United States Code of Federal Regulations* are available for free from the United States National Archives Office of the Federal Register website (www.archives.gov/federal-register/);
- section 13 (introduced by item 16 of Schedule 1 to the Amendment Order) refers to *Division 2 – Good Manufacturing Practices* in Part C of the *Food and Drug Regulations* (Canada). The intended manner of incorporation is as in force from time to time. The *Food and Drug Regulations* (Canada) are available for free from the Government of Canada Justice Laws Website (<https://laws-lois.justice.gc.ca/eng/>);
- section 13 (introduced by item 16 of Schedule 1 to the Amendment Order) incorporates *Part 5: Good Production Practices* of the *Cannabis Regulations* SOR/2018-144 (Canada). The intended manner of incorporation is as in force from time to time. The *Cannabis Regulations* SOR/2018-144 are available for free from the Government of Canada Justice Laws Website (<https://laws-lois.justice.gc.ca/eng/>).

Incorporation of child-resistant packaging requirements by reference

The Amendment Order incorporates by reference section 8, section 9 and section 10 of the *Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines 2017* (TGO 95) (“TGO 95”). The intended manner of incorporation is as in force from time to time. TGO 95 is a legislative instrument, which similarly constitutes a standard for the purposes of section 10 of the Act, and sets out the requirements for child-resistant packaging. TGO 95 is available for free from the Federal Register of Legislation website (www.legislation.gov.au).

Incorporation of pharmacopoeia by reference

Item 16 of the Amendment Order, introducing section 16, incorporates by reference each of the British Pharmacopoeia (“the BP”), the European Pharmacopoeia (“the Ph. Eur.”) and United States Pharmacopoeia-National Formulary (“the USP”), which provide default standards for the purposes of the Act. The Amendment Order also incorporates by reference monographs within these pharmacopoeia.

The note in Item 1 of Schedule 1 to the Amendment Order, adding a note at the start of section 4, makes it clear that each of these pharmacopoeia are those as defined in subsection 3(1) of the Act.

The definitions of the pharmacopoeia in subsection 3(1) of the Act refer to the publications of each as in effect immediately before the commencement of the relevant definitions in the Act, and to any subsequent amendments or editions. The intention in the Amendment Order is therefore to adopt the defined meaning of the pharmacopoeia as set out in subsection 3(1) of the Act. Those pharmacopoeia may be accessed from www.pharmacopoeia.com, www.edqm.eu/en and www.uspnf.com. While unfortunately the pharmacopoeia are not available for free, it is anticipated that the persons most affected by their adoption in the Amendment Order (sponsors and manufacturers of medicinal cannabis products, and other interested persons in the medicinal cannabis products industry using the Amendment Order)

would be in possession of these documents in order to import, supply or manufacture such products. As important international benchmarks for the safety and quality of therapeutic goods, it would be infeasible from a regulatory perspective (particularly in relation to the safety of medicinal cannabis products that are not, for the most part, entered on the Australian Register of Therapeutic Goods and as such not subjected to pre-market scrutiny before being available for patients in Australia) to not adopt such benchmarks on the basis that they are not available for free.

In addition, by prior written arrangement with the TGA, members of the public may request to view the pharmacopoeia without charge at the TGA office in the ACT.

It should also be noted that the National Library's Trove online system (www.trove.nla.gov.au) allows users to identify libraries in Australia that are open to the public where editions (in most cases, earlier editions) of these pharmacopoeia may be viewed (for example, the University of Tasmania or the University of Western Australia in relation to the British Pharmacopoeia).

Members of the public may also approach any library that participate in inter-library loans with those university libraries to request an inter-library loan, or to obtain a photocopy of a particular part or monograph for personal study or research (but not for commercial purposes), with a payment of a fee. Enquiries should be made directly with local libraries, state libraries and the National Library.

Consultation

The Office of Best Practice Regulation ("OBPR") advised that a regulatory impact statement was not required in relation to the making of the Amendment Order (OBPR21-01261).

The TGA undertook two rounds of consultation during the development of the amendments to TGO 93 that are reflected in the Amendment Order. The first, held in late 2020 to early 2021, was a public consultation on proposed reforms to the regulation of medicinal cannabis products in Australia. Forty-eight stakeholders provided feedback in response to the release of a consultation paper and request for submissions. Submissions were received predominantly from manufacturers and sponsors of medicinal cannabis products, as well as from health industry bodies, health practitioner representative bodies, pharmacists and herbalists, and government organisations, such as Novachem, Medicinal Cannabis Industry Association, Australian Medicinal Cannabis Association, Consumer Healthcare Products, Pharmaceutical Society of Australia, The Pharmacy Guild of Australia, Pain Australia, Australian Commission of Safety and Quality in Health Care, Queensland Health and NSW Ministry of Health. There was majority support for the proposed reforms, including in relation to better harmonising applicable regulatory requirements for imported medicinal cannabis products with those applying in relation to medicinal cannabis products that are manufactured in Australia.

Further, targeted, consultations were subsequently undertaken with 14 stakeholders including industry groups and health practitioner representative bodies, on the details of the proposed amendments in March 2022. Six responses were received, from medicinal cannabis and non-prescription medicine industry groups, health professional organisations including the Pharmaceutical Society of Australia and patient groups, with broad in-principle support for the reforms. The feedback received was taken into account when finalising the

amendments to TGO 93 and to inform development of an updated guidance document to assist in applying the requirements of the Principal Order.

Details of the Amendment Order are set out in **Attachment A**.

The Amendment Order is compatible with the 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 Amendment Order is a disallowable legislative instrument, and commences on 28 March 2022.

Details of the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order 2022*

Section 1 – Name

This section provides that the name of the Amendment Order is the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order 2022* (“the Amendment Order”).

Section 2 – Commencement

This section provides that the Amendment Order commences on 28 March 2022.

Section 3 – Authority

This section provides that the legislative authority for making the Order is section 10 of the *Therapeutic Goods Act 1989*. Subsection 10(3A) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1) of the Act.

Section 4 – Schedules

This section provides that each instrument that is specified in Schedule 1 to the Amendment Order is amended as set out in the applicable items in that Schedule. The Amendment Order makes amendments to the:

- *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* (“the Principal Order”); and
- *Therapeutic Goods (Microbiological Standards for Medicines) (TGO 100) Order 2018* (“TGO 100”).

Schedule 1 – Amendments

Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017

Items 1 and 9 – Section 4 (before subsection (1)) and subsection 4(1) (note at the end)

These items move the note that was at the end of subsection 4(1) to the start of section 4 and add a few further terms that are defined in the Act.

Items 2, 4, 6 and 8– Subsection 4(1)

These items introduce new definitions in subsection 4(1) of the Principal Order, including definitions of ‘acceptance criteria’, ‘batch number’, ‘expiry date’, ‘excipient’, ‘licensing authority’, ‘processing aid’ and ‘quantity of the medicinal cannabis products’.

The definition of ‘plant material’ refers to a medicinal cannabis product that is comprised of dried material from the cannabis plant that has not been refined. A medicinal cannabis product in the form of plant material may include dried flos or dried leaves from the cannabis plant, which has not been refined in any way – it is simply material harvested from the cannabis plant that has been dried. The cutting or gridding of material from the cannabis plant is not considered refinement in this context.

The definition of ‘plant preparation’ refers to material of the cannabis plant that has undergone refinement, other than material of the cannabis plant that has undergone refinement to a single cannabinoid. If material from the cannabis plant has undergone some

level of refinement (which does not include cutting or grinding) it would be a plant preparation unless the refinement produces a single cannabinoid. For example, a medicinal cannabis product containing 100% cannabidiol would not be a plant preparation.

Item 3 – Subsection 4(1) (definition of *cannabis plant*)

This item adds a note at the end of the definition of ‘cannabis plant’ to clarify that *Cannabis sativa subsp. sativa*, *Cannabis sativa subsp. ruderalis* and *Cannabis sativa subsp. indica* are subspecies of the cannabis plant.

Items 5 and 14 – Subsection 4(1) (definition of *incidental minor excipients*) and subsection 11(2)

Item 5 repeals the definition of ‘incidental minor excipient’ as the definition is unclear and is intended to refer to a processing aid. Item 14 amends subsection 11(2) to replace the reference to incidental minor excipients with a reference to a processing aid.

Item 7 – Subsection 4(1) (definition of *stated content*)

This item amends paragraphs (b) to (d) of the definition of ‘stated content’ by replacing these paragraphs. New paragraphs (b) and (c) no longer refer to labelling as the amendments in this Amendment Order introduce new labelling requirements. New paragraph (d) no longer refers to item 6 of Schedule 5 to the *Therapeutic Goods Regulations 1990*, which has been amended to exclude medicinal cannabis products by the *Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022*.

Item 10 – Subsection 4(2)

This item makes a minor amendment to subsection 4(2) to refer to substances instead of ingredients.

Item 11 – Subsection 6(2)

This item replaces subsection 6(2) to provide that the Principal Order does not apply to medicinal cannabis products that are export only medicines. Export only medicines would not be subject to the requirements in the Principal Order as they are not for supply in Australia but they would instead be subject to any requirements of the country to which they are being exported.

Item 12 – At the end of section 7

This item adds a note at the end of section 7 to clarify that monographs referred to in the *Pharmaceutical Preparations* (2619) monograph also need to be complied with.

Item 13 – Section 8

This item replaces section 8 to clarify that all cannabinoids in a medicinal cannabis product, whether an active ingredient or not, must be from the cannabis plant and not modified or transformed in any way. The requirement that the cannabinoids must be from the cannabis plant has the effect of prohibiting cannabinoids that are synthetically-produced and not derived from extraction from the cannabis plant. Further, the requirement that the chemical structure of the cannabinoids must not be modified or transformed in any way has the effect of prohibiting the supply of naturally-derived cannabinoids that have had their chemical structure altered.

The prohibition on synthetically produced cannabinoids and modification of cannabinoids extracted from the cannabis plant has been introduced to support the safety of medicinal

cannabis products supplied in Australia. Little is known about the safety and efficacy of medicinal cannabis products that contain cannabinoids that are not naturally-derived, or that are naturally-derived but are modified.

Item 15 – Subsection 12(2) (note)

This item makes a very minor formatting amendment to the note at the end of subsection 12(2).

Item 16 – After section 12

This item introduces requirements relating to manufacturing quality, child resistant packaging, labelling and microbiology attributes, as well as an application provision.

New section 13 contains the manufacturing quality requirements. The new requirements apply to medicinal cannabis products that are imported. Domestically manufactured medicinal cannabis products are already required to meet Good Manufacturing Practice as Australian manufacturers must hold a manufacturing licence issued under Part 3-3 of the Act. Therefore, the requirements in new section 13 are intended to impose equivalent standards on imported medicinal cannabis products. Medical practitioners and pharmacists can then be confident that all medicinal cannabis products supplied in Australia have been manufactured to certain minimum standards.

Subsection 13(1) provides that the manufacturing quality requirements do not apply to medicinal cannabis products that are herbal material, or medicinal cannabis products that are oil from the cannabis plant, that are used as starting material to produce another medicinal cannabis product. The manufacture of such oil or herbal material - that is starting material used to produce a medicinal cannabis product - is not required to meet the manufacturing requirements in new section 13. This is because oil and herbal material that is starting material, and is domestically manufactured, is exempt from Part 3-3 of the Act in item 2 of Schedule 7 to the *Therapeutic Goods Regulations 1990*. This subsection has been introduced to ensure equal regulatory treatment of such starting material that is domestically manufactured and imported.

New subsection 13(2) imposes a requirement that imported medicinal cannabis products must be manufactured in accordance with standards for Good Manufacturing Practice (“GMP”) contained in the PIC/S Guide to GMP, or equivalent standards in the specified European Commission Directives, South African Guide to GMP, United States legislation or Canadian legislation. The effect of this is to establish equivalent regulatory requirements for imported product and domestically manufactured product.

New subsection 13(3) imposes a requirement that imported medicinal cannabis products must be manufactured at a manufacturing site that holds an appropriate certificate or written authority issued by a licensing authority, as specified in this subsection for the particular country in which manufacture occurred. Under new subsection 13(4), such certification or written authority must relate to the relevant medicinal cannabis product imported, relate to each manufacturing site where it was manufactured and be current at the time it was manufactured (i.e. it must not have lapsed, or been suspended or cancelled).

New section 14 provides requirements for child resistant packaging. These requirements apply to medicinal cannabis products that are not plant material (i.e. plant preparations only).

Plant preparations must comply with the requirements specified in sections 8, 9 and 10 of TGO 95 as applicable.

New section 15 introduces labelling requirements for medicinal cannabis products. The requirements differ between medicinal cannabis products extemporaneously compounded or repackaged by a pharmacist for a particular patient and all other medicinal cannabis products. For medicinal cannabis products that are not extemporaneously compounded or repackaged by a pharmacist, such products must be labelled with the information listed in new subsection 15(2), including the name of the product, name of the sponsor, storage conditions, batch number, expiry date, name of the active ingredients, quantity of each active ingredient as prescribed in this subsection and the cannabis plant from which it was produced, the dose form and the quantity of the medicinal cannabis product. These requirements promote transparency about the characteristics of a medicinal cannabis product and supports the reliability of information on labels. It also provides medical practitioners and pharmacists with greater confidence prescribing and dispensing by knowing precisely what a patient is receiving.

For medicinal cannabis products that are extemporaneously compounded or repackaged by a pharmacist for a particular patient, these products must be labelled with the name and quantity of each active ingredient. The labelling requirements for these products are more limited as a pharmacist is compounding these products in accordance with a medical practitioner's prescription.

New subsection 15(4) requires that the information on the label of a medicinal cannabis product must be in English and must be legible, visible, not obscured, and durable.

New section 16 provides requirements for medicinal cannabis products relating to microbiological attributes. These requirements are the same as those in TGO 100 with an additional option to comply with the 'Special European Pharmacopoeia (Ph. Eur.) provision for oral dosage forms containing raw materials of natural (animal, vegetal or mineral) origin for which antimicrobial pre-treatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 1000 CFU per g or CFU per mL'.

New section 17 provides that the new requirements for manufacturing quality in section 13, child resistant packaging in section 14, labelling in section 15 and microbiological attributes in section 16 only apply to medicinal cannabis products released for supply in Australia after 1 July 2023. Accordingly, sponsors have until 1 July 2023 to ensure that medicinal cannabis products supplied in Australia on or after 1 July 2023 will comply with the new requirements.

Items 17 to 18 – Clause 2 of Schedule 1 (table item 3, columns 3 and 4)

These items make minor amendments to Clause 2 of Schedule 1. Item 17 makes a minor correction and item 18 makes a minor editorial amendment to change the relevant units to mg/kg.

Item 19 – Note after the table in Schedule 1 (including the heading)

This item removes the note after the table in Schedule 1 to avoid confusion with the note added by item 20. This note does not provide any useful information and is not necessary to remain in the Principal Order.

Item 20 – At the end of clause 2 of Schedule 1

This item introduces a note to clause 2 of Schedule 1 to clarify that the unit mg/kg is the m/m measurement equivalent to ppm.

Therapeutic Goods (Microbiological Standards for Medicines) (TGO 100) Order 2018

Item 21 – At the end of section 7

This item amends section 7 of TGO 100 to clarify that TGO 100 does not apply to medicinal cannabis products and notes that the microbiological requirements for medicinal cannabis products are instead contained in the Principal Order.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order 2022

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 the legislative instrument

The *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Amendment Order 2022* (“the amendment instrument”) is made by a delegate of the Minister under section 10 of the *Therapeutic Goods Act 1989* (“the Act”).

The purpose of the amendment instrument is to amend the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* (“principle instrument”) to make a number of safety-related updates, and improve clarity. In particular, the amendments introduced by the amendment instrument establish standards for the manufacturing quality, labelling, child-resistant packaging and microbiological attributes of medicinal cannabis products, clarify a number of existing definitions, and clarify that cannabinoids in a medicinal cannabis product must be taken directly from the cannabis plant and must not be synthetically modified in any way.

The principal instrument applies to medicinal cannabis products, whether imported into Australia or manufactured domestically, and is intended to provide an assurance to medical practitioners and patients that medicinal cannabis products meet minimum quality requirements.

However, a ‘level playing field’ for imported and domestically produced medicinal cannabis products does not currently exist in Australia because only medicinal cannabis products manufactured in Australia are required to be manufactured in accordance with good manufacturing practice requirements. Concerns have arisen in relation to this and in relation to transparency and awareness around the contents of, and amount of active ingredients in, the medicinal cannabis products available in Australia and the absence of accurate and reliable information on the labels of such products to inform patients. There are also concerns of insufficient controls on the product quality and oversight of manufacture of imported medicinal cannabis products. The amendment instrument is designed to address these concerns and ensure the safety and quality of medicinal cannabis products available for use by patients in Australia, whether manufactured in Australia or overseas.

The amendment instrument addresses these concerns by specifying a range of labelling and packaging requirements for all medicinal cannabis products, and establishing standards for manufacturing quality for imported products, to align those with the standards required of domestically produced medicinal cannabis products.

The amendment instrument also introduces a number of new labelling requirements for medicinal cannabis products, to better support the safe use of such products and to assist

consumers and health practitioners to identify and understand their key components. The labelling requirements differ between medicinal cannabis products for general supply and medicinal cannabis products that are extemporaneously compounded or repackaged by a pharmacist for a particular patient. For medicinal cannabis products that are not extemporaneously compounded or repackaged for a particular patient, the information required to be set out on the label includes the name of the product, the name of the sponsor, the name of each active ingredient, the quantity of each active ingredient, the dosage form, the quantity of the medicinal cannabis product, batch number, expiry date and storage conditions. The amendment instrument requires labels of extemporaneously compounded or repackaged medicinal cannabis products, prepared by a pharmacist, to state the name and quantity of each active ingredient. Other requirements for labels on these goods are set out in relevant state and territory legislation.

The amendment instrument provides further clarification that cannabinoids in medicinal cannabis products must only be derived from the cannabis plant and not synthetically modified.

In so doing the amendment instrument:

- supports the safety and quality of medicinal cannabis products in Australia;
- better balances the regulatory requirements applying to medicinal cannabis products manufactured in Australia with those applying to imported medicinal cannabis products;
- promotes transparency in relation to the active ingredients and other important characteristics of medicinal cannabis products; and
- provides greater confidence for patients and health practitioners in relation to the safe use of medicinal cannabis products in Australia through an increased understanding of the contents and formulation of such products.

Human rights implications

The amendment 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 standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

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 amendment instrument takes positive steps to promote the right to health by helping to ensure the safety and quality of medicinal cannabis products supplied in Australia. The amendment instrument does this through requiring imported medicinal cannabis products to meet international benchmarks of good manufacturing practice, and by requiring information designed to assist both patients and their health practitioners on the labels of medicinal cannabis products. These improvements are particularly important in the context of medicinal cannabis products as most such products that are available for supply in Australia are not

included in the Australian Register of Therapeutic Goods and, as such, are not subjected to a process of pre-market scrutiny before being available.

Conclusion

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