

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Things that are Biologicals) Specification 2019

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 (“TGA”) within the Australian Government Department of Health.

As part of that system of controls, Part 3-2A of the Act regulates therapeutic goods that are biologicals and outlines a process for their inclusion in the Australian Register of Therapeutic Goods (“the Register”). Part 3-2A also outlines processes for exempting certain biologicals from the requirement to be included in the Register, suspending or cancelling biologicals from the Register, requiring the recall or public notification of problems with biologicals, and providing for the obtaining of information or documents about biologicals.

Under subsection 32A(1) of the Act, a biological is a thing that either comprises, contains or is derived from human cells or tissues, or that is specified in a legislative instrument made by the Secretary under subsection 32A(2) of the Act.

The *Therapeutic Goods (Things that are Biologicals) Specification 2019* (“the Specification”) is made under subsection 32A(2) of the Act to specify the things that are biologicals for the purposes of subparagraph 32A(1)(a)(ii) of the Act.

The purpose of the Specification is to make it clear that faecal microbiota transplant (“FMT”) products are biologicals. The Specification also repeals and replaces the *Therapeutic Goods (Things that are Biologicals) Specification 2017 (No.1)* (“the former Specification”), to incorporate the things in the former Specification and thereby enable all things that have been specified by the Secretary as biologicals to be housed in the one instrument.

Background

FMT products are principally donated human stool, and related therapeutic materials derived from human stool, that are manufactured through the processing of such stool. FMT products may include fresh or banked human stool that may be introduced to a recipient’s bowel by a range of methods, including a colonoscopy or rectal enema. Alternatively, FMT products may be orally ingested following filtration, centrifugation and encapsulation, or as otherwise appropriately manufactured.

FMT products have been shown to be effective in repopulating the bacterial microenvironment in a recipient’s bowel with healthy microorganisms. Treatment has been highly successful in cases of recurrent *Clostridioides difficile* infection (a bacterial infection) and ulcerative colitis (a chronic, relapsing-remitting mucosal inflammatory bowel disease).

When used to treat, prevent or alleviate such diseases, FMT products are considered to be therapeutic goods for the purposes of the Act. FMT products that contain human epithelial cells of the colon (colonocytes) are considered to be biologicals for the purposes of section 32A of the Act. This is the case even where the presence of these cells is incidental to the mechanism of action of the FMT product in treating the relevant disease or condition. In such instances, FMT products are subject to regulation as biologicals under Part 3-2A of the Act.

Until recently, however, as FMT products are an emerging spectrum of therapeutic goods, they have not been previously subject to regulation within Australia.

On 1 January 2020, amendments to the *Therapeutic Goods Regulations 1990* (“the Regulations”), made by the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* (“Amendment Regulations”), introduce a definition for FMT products, and a tailored regulatory framework for such products. The definition of ‘faecal microbiota transplant product’ introduced by these amendments is a thing that comprises, contains or is derived from human stool, and is for introduction into a person for a therapeutic use.

Under the Amendment Regulations, FMT products that are principally manufactured, tested and provided to a patient in a hospital setting under the supervision or direction of a medical practitioner will be Class 1 biologicals. Section 33B of the Act provides that Part 3-3 of the Act does not apply to Class 1 biologicals, and so they are not required to be covered by a manufacturing licence.

These measures will be enhanced with the expected commencement of a standard for FMT products in the first quarter of 2020, to be made by the Minister under section 10 of the Act. This standard will set out important requirements relating to, in particular, the screening of prospective stool donors and testing of subsequent FMT products before they are used in a person.

The Specification is principally intended to clarify, by putting it beyond doubt, that FMT products are biologicals. Examples of such products may include, for example, fresh stool collected from a healthy donor that has been screened for the absence of pathogens and infectious diseases, or such stool that has also been homogenised with a solution such as saline and then frozen for future use.

The Specification also repeals and replaces the former Specification to enable all the things that are currently specified as being biologicals for the purposes of subparagraph 32A(1)(a)(ii) of the Act to be housed in one instrument. The Specification includes the things specified in the former Specification, being things that comprise or contain live animal cells, tissues or organs.

Consultation

A regulation impact statement was not required in relation to the development of this Specification (OBPR ID 25297).

TGA conducted a public consultation on a range of options for regulating FMT products between January and March 2019. There were 22 submissions received, with the majority supporting the regulation of these products as biologicals. Feedback was incorporated into the amendments relating to FMT products made by the Amendment Regulations, for example, to only require higher risk products (i.e. Class 2, 3 and 4 biologicals) to be covered by a manufacturing licence.

Details of the Specification are set out in **Attachment A**.

The Specification 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 Specification is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after registration on the Federal Register of Legislation.

Details of the *Therapeutic Goods (Things that are Biologicals) Specification 2019*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Things that are Biologicals) Specification 2019* (“the Specification”).

Section 2 – Commencement

This section provides that the Specification commences on 1 January 2020.

Section 3 – Authority

This section provides that the legislative authority for making the Specification is subsection 32A(2) of the *Therapeutic Goods Act 1989* (“the Act”).

Section 4 – Definitions

This section provides the definitions of certain terms used in the Specification. In particular, this section defines ‘faecal microbiota transplant product’ as having the same meaning as in the *Therapeutic Goods Regulations 1990*. It also notes that the term ‘biological’ is defined in section 3 of the Act.

Section 5 – Things that are biologicals

This section provides that the things mentioned in Schedule 1 are specified to be biologicals for the purposes of subparagraph 32A(1)(a)(ii) of the Act.

Section 6 – Repeals

This section provides that each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule. The purpose of this section is to repeal the *Therapeutic Goods (Things that are Biologicals) Specification 2017 (No.1)*.

Schedule 1

This Schedule specifies things that are biologicals for the purposes of section 5, and identifies for this purpose a thing that comprises or contains live animal cells, tissues or organs, and a thing that is a faecal microbiota transplant product.

Schedule 2

This Schedule specifies the *Therapeutic Goods (Things that are Biologicals) Specification 2017 (No.1)* for the purposes of section 6, with the effect that the whole of that instrument is repealed.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Things that are Biologicals) Specification 2019

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 (Things that are Biologicals) Specification 2019* (“the instrument”) is made under subsection 32A(2) of the *Therapeutic Goods Act 1989* (“the Act”).

The purpose of the instrument is to make it clear that faecal microbiota transplant products are biologicals under the Act. The instrument also repeals and replaces the *Therapeutic Goods (Things that are Biologicals) Specification 2017 (No.1)* (“the former instrument”), to incorporate the things specified in the former instrument and thereby enable all of the products that have been specified as biologicals for the purposes of subparagraph 32A(1)(a)(ii) of the Act to be housed in one instrument.

Faecal microbiota transplant (“FMT”) products are principally donated human stool, and related therapeutic materials derived from human stool, that are manufactured through the processing of such stool. FMT products may include fresh or banked human stool that may be introduced to a recipient’s bowel by a range of methods, including a colonoscopy or rectal enema. Alternatively, FMT products may be orally ingested following filtration, centrifugation and encapsulation, or as otherwise appropriately manufactured.

FMT products have been shown to be effective in repopulating the bacterial microenvironment in a recipient’s bowel with healthy microorganisms. Treatment has been highly successful in cases of recurrent *Clostridioides difficile* infection (a bacterial infection) and ulcerative colitis (a chronic, relapsing-remitting mucosal inflammatory bowel disease).

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The instrument also repeals and replaces the former instrument to enable all the things that are currently specified as being biologicals for the purposes of subparagraph 32A(1)(a)(ii) of the Act to be housed in one instrument. The instrument includes the things specified in the former instrument, being things that comprise or contain live animal cells, tissues or organs.

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 supporting the introduction of a tailored framework for the regulation of FMT products under the Act and Regulations as biologicals. This will allow for the introduction of appropriate standards for the safety and quality of FMT products, and will also allow for regulatory action to be taken in relation to such products where they do not comply with such standards or are otherwise unsafe, in order to protect the health of consumers.

Conclusion

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and does not raise any other human rights issues.

Jane Cook, delegate of the Minister for Health