Australian Government
Department of Health
Therapeutic Goods Administration

# Faecal Microbiota Transplant (FMT) product regulation

## Australian Regulatory Guidelines for Biologicals (ARGB)

Version 1.2, September 2020

TGA Health Safety Regulation

# Contents

This guidance is for sponsors of Faecal microbiota transplant (FMT) products.

# What are Faecal microbiota transplant (FMT) products?

Faecal microbiota transplant (FMT) product is defined in the *Therapeutic Goods Regulations 1990*. It is a thing that:

a. comprises, contains or is derived from human stool; and

b. is for introduction into a person for a therapeutic use.

These include fresh or frozen human stool that may be introduced to the bowel for therapeutic use by a range of methods including rectal enema, sigmoidoscopy, colonoscopy, and nasogastric or nasoduodenal tube. It also includes human stool that has been processed (e.g. encapsulated) to allow oral ingestion.

FMT products are used to repopulate the bacterial microenvironment in a recipient's bowel with healthy microorganisms.

Products that contain only microbes derived from sources other than human stool are not FMT products.

## Regulatory framework for FMT products

All FMT products are regulated as **biologicals**. This includes significantly processed products that are derived from human stool.

Where a strain(s) of microorganisms, known to be present in stool, are characterised and grown from established isolates with standardised consistency, these may be regulated as **medicines**, rather than biologicals.

FMT products that are regulated as **biologicals** are prohibited from being advertised to the public under the *Therapeutic Goods Act 1989* (subsection 42DL(11)).

# Levels of TGA regulation

The level of regulation for FMT products varies with the level of external governance and clinical oversight. Some FMT products are regulated as Class 1 biologicals.

## FMT product regulated as Class 1 Biological

A FMT product is a Class 1 biological if:

- it is collected under the supervision or direction, or in accordance with the requirements, of a medical practitioner registered, in a State or internal Territory, as a medical practitioner; and
- each later step in the manufacture of it is carried out in a hospital by, or under the supervision or direction of, the practitioner (unless the step relates to the storage or testing of the biological, in which case it may instead be carried out by a person under a contract with the hospital in a State or internal Territory); and
- it is for use in a recipient who is a patient of the hospital with the recipient being under the clinical care of the practitioner.

See **Applying for inclusion of a Class 1 biological in the ARTG**

## FMT product regulated as Class 2 Biological

A FMT product is likely to be a Class 2 biological if:

- FMT products is minimally manipulated and manufactured in a facility that is not a hospital or manufactured in one hospital and used in another different hospitals or clinics.

For Class 2 biologicals, these are required to be included in the ARTG and have GMP licensing for all manufacturing and testing facilities. Further guidance on how to apply for an ARTG inclusion is published on our website.

**All other FMT products will be classified as per information on Classification of biologicals.**

Regardless of the level of processing of your FMT product, ensure you comply with the **donor screening requirements**, which are included in the *Therapeutic Goods (Standard for Faecal Microbiota Transplant Products) (TGO 105) Order 2020*. TGO 105 specifies the minimal requirements for donor and product screening to ensure the quality, safety and efficacy of FMT products. Guidance is available on the interpretation of the requirements in TGO 105 and Good Manufacturing Practice (GMP) licensing requirements. For details about the consultation process on TGO 105, refer to Consultation: Draft standards for faecal microbiota transplant (FMT) products.

# Further information

- Guidance on what therapeutic goods will be regulated as a biological
- A form to guide you through the classification of biologicals and capture sufficient information about your product for us to provide advice, if requested

# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication incorporating new legislative changes. | Biological Science Section<br>Regulatory Guidance Team | January 2020 |
| V1.1 | Update on donor screening requirements. | Biological Science Section<br>Regulatory Guidance Team | August 2020 |
| V1.2 | Added links to guidance on interpretation of the requirements in TGO 105 and Good Manufacturing Practice (GMP) licensing requirements | Biological Science Section | September 2020 |

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