Australian Government
Department of Health
Therapeutic Goods Administration

What is regulated as a biological

Australian Regulatory Guidelines for Biologicals (ARGB)

Version 3.0, January 2020

TGA Health Safety Regulation

Contents

This guidance is to help you understand what therapeutic goods will be **regulated as a biological**.

Is my product a therapeutic good?

If you are new to the regulatory environment, we have developed a decision tool to help you decide if your product is a therapeutic good and if so, what type (medicine, medical device or biological):

- Is my product a therapeutic good?

Related information: Classification of biologicals

Types of products regulated as biologicals

Products that are regulated as biologicals include, but are not limited to:

- tissue-based products (skin, bone, ocular, cardiovascular, amnion)
- cell-based products (genetically modified, in vitro cell expansion or depletion)
- immunotherapy products containing human cells
- combination products (e.g. a cell therapy and a medical device)
- products that comprise or contain live animal cells, tissues or organs (e.g. pancreatic islet cells isolated from pigs)
- autologous human cells and tissue products (including stem cells)
- faecal microbiota transplant(FMT) products (a thing that comprises, contains or is derived from human stool)

How we define biologicals

For your product to meet our definition of a biological, it must be:

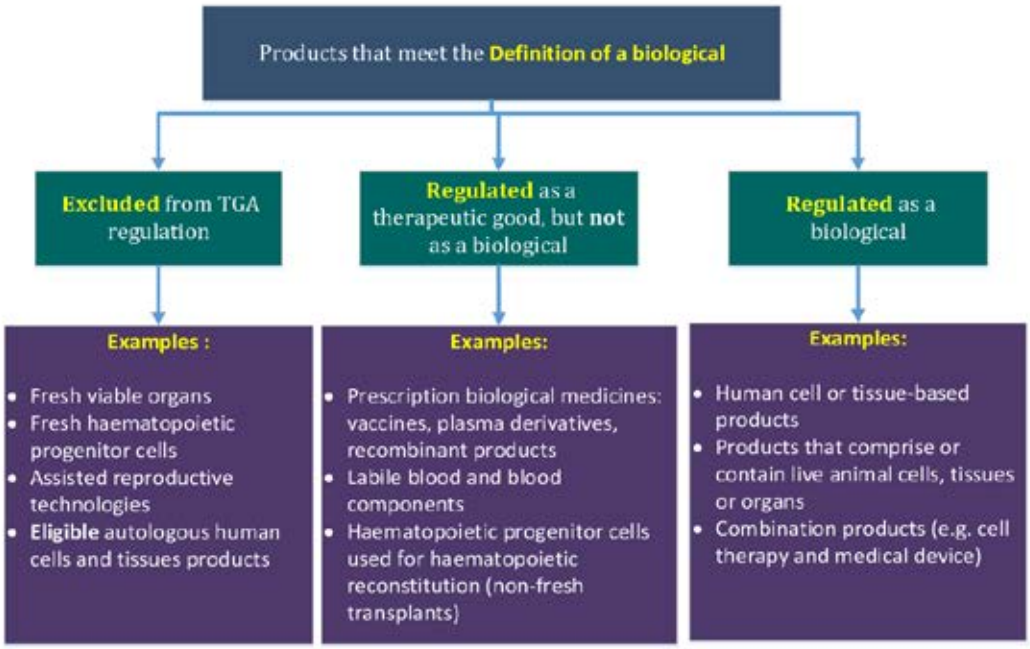
- a thing made from, or that contains, human cells or human tissues, and that is used to:
  - treat or prevent disease, ailment, defect or injury
  - diagnose a condition of a person
  - alter the physiological processes of a person
  - test the susceptibility of a person to disease
  - replace or modify a person's body parts
- faecal microbiota transplant products
- a thing that comprises or contains live animal cells, tissues or organs

How we regulate biologicals

Even though your product may meet the definition of a biological, it may not be regulated as a biological.

You need to check if your biological is:

- Excluded from TGA regulation
- Regulated as a therapeutic good, but not as a biological
- Regulated as a biological



Excluded from TGA regulation

Excluded goods are not subject to any of the requirements in the Therapeutic Goods Act 1989, including:

- good manufacturing practice (GMP)
- inclusion on the Australian Register of Therapeutic Goods (ARTG)
- adverse event reporting
- compliance with TGA standards for therapeutic goods

The following biologicals are excluded goods:

- Eligible autologous human cells and tissues products
- Fresh viable human organs
- Fresh haematopoietic progenitor cells (HPCs)
- Reproductive tissue for assisted reproductive therapy

These products are excluded from regulation under the *Therapeutic Goods Act 1989* by reference in the Therapeutic Goods (Excluded Goods) Determination 2018.

Equipment used in manufacturing

Even though your biological may be excluded from our regulation, **equipment and materials** used for the manufacture of the product **may** be therapeutic goods to which therapeutic goods legislation applies and may be subject to regulation by us. For example, IVF solutions are regulated as a medical device.

Eligible autologous human cells and tissues products

We will **not regulate** autologous HCT products if they meet all of the following criteria:

1. collected from a patient who is under the clinical care of a medical or dental practitioner registered under a law of a State or an internal Territory
2. manufactured by that medical or dental practitioner, or by a person or persons under the professional supervision of that medical or dental practitioner in a hospital (except storage and testing), for that patient who must be a patient of that hospital
3. not advertised to consumers

Where one or more criteria are not met, including advertising to consumers, regulation by TGA will apply.

These criteria are in the Therapeutic Goods (Excluded Goods) Determination 2018.

These biologicals are not regulated by us because the Government has decided that there is appropriate external regulation for them.

For more information on the exclusion of certain autologous HCT, including guidance on the terms used in the eligibility criteria, go to Autologous human cell and tissue products excluded from TGA regulation.

Fresh viable human organs

We do not regulate fresh viable human organs, or parts of human organs, for direct donor-to-host transplantation and used in accordance with applicable laws and standards.

The purpose of this item is to exclude organs for direct donor-to-host transplantation from the operation of the therapeutic goods legislation. It should be noted that **only the organs** are excluded from the definition of therapeutic goods. Equipment and material used for manufacturing may still be subject to regulation.

Fresh haematopoietic progenitor cells (HPCs)

We do not regulate fresh viable human HPCs for direct donor-to-host transplantation for the purpose of haematopoietic reconstitution.

Examples:

- bone marrow cells
- cord blood

The term 'haematopoietic progenitor cell' has been used deliberately. We no longer use the term 'bone marrow' to reflect current terminology and practice in the field of HPC transplantation.

Only HPCs are excluded from the definition of therapeutic goods. Equipment and material used for manufacturing may still be subject to regulation.

Reproductive tissue for assisted reproductive therapy

Reproductive tissue for use in assisted reproductive therapy is not regulated by TGA.

Examples of products that are excluded goods:

- sperm
- eggs
- embryos for in vitro fertilisation (IVF) and other assisted reproductive technologies (ARTs)

This exclusion reflects the decision of the Australian Health Ministers' Conference in July 2008 that reproductive tissues should not be regulated by TGA because use of these tissues was already coherently and consistently managed.

Products regulated as a therapeutic good, but not as a biological

Some products, even though they meet the definition of a biological are:

- ü regulated by us as **therapeutic goods**
- û not regulated as biologicals

The Secretary can declare specific therapeutic goods to either be or not be biologicals.

Things that are not biologicals

The following goods are declared **not to be biologicals**:

- biological medicines (regulated as prescription medicines):
  - vaccines (that do not contain viable human cells)
  - recombinant products
  - plasma derived products (or that contain plasma derived products)
- blood and blood components (regulated as medicines under the Therapeutic Goods (Manufacturing Principles) determination):
  - blood means whole blood collected from a single human donor and processed either for transfusion or further manufacturing
  - blood components means therapeutic components of blood (red cells, white cells, platelets, plasma) that can be prepared by centrifugation, filtration and freezing, but not including haematopoietic progenitor cells
- HPCs used for haematopoietic reconstitution (regulated as medicines under the Therapeutic Goods (Manufacturing Principles) determination):
  - HPCs mean self-renewing or multipotent stem cells, or both, capable of maturation into haematopoietic lineages, lineage-restricted pluripotent progenitor cells, or committed progenitor cells
  - includes HPCs derived from cord blood
- in vitro diagnostic devices (IVDs)
- samples of human cell or tissue that are solely for diagnostic purposes in the same individual

These are defined in the Therapeutic Goods (Things that are not Biologicals) Determination.

Products regulated as biologicals

For your product to be **regulated** as a biological, it **must**:

- Ü be a therapeutic good, as defined in the *Therapeutic Goods Act 1989*
- Ü either meet the definition of a biological, or be specified by a legislative instrument to be a biological

Your product will **not be regulated** as a biological if it is:

- Û an excluded good
- Û regulated as a therapeutic good, but not as a biological

If your product is regulated as a biological, pathways to supply biologicals will explain the levels of regulation applied.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication incorporating new legislative changes and information previously published on the TGA website.	Biological Science Section Regulatory Guidance Team	July 2018
V1.1	Revision incorporating clarification to exclusion criteria as per Therapeutic Goods Amendment (Excluded Goods) Determination 2019.	Biological Science Section Regulatory Guidance Team	June 2019
V2.0	Updates to reflect regulatory changes to conditioned serum	Biological Science Section Regulatory Guidance Team	July 2019
V2.1	Updated links	Biological Science Section	September 2019
V3.0	Revision incorporating regulatory requirements for FMT products	Biological Science Section	January 2020

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Reference/Publication #