Australian Government
Department of Health
Therapeutic Goods Administration

Autologous human cells and tissues products regulation

Australian Regulatory Guidelines for Biologicals (ARGB)

Version 2.0, July 2019

TGA Health Safety Regulation

Contents

This guidance is for sponsors of autologous human cells and tissues (HCT) products. It explains how we apply regulation based on the risk associated with the product and when some autologous HCTs may be excluded from TGA regulation or exempt from some TGA regulations.

What are autologous HCT products?

Human cell and tissue (HCT) products are those that comprise, contain or are derived from human cells and tissues.

Autologous human cell and tissue (HCT) products are those that are removed from, and applied to, the **same person**, i.e. the donor and the recipient are the same. One group of autologous HCT products is those commonly referred to as 'stem cell treatments'.

Examples of autologous HCT products

Some examples of human cell and tissue products that can be autologous:

- blood and blood components (red cells, plasma, serum, platelets, platelet-rich plasma [PrP], platelet-rich fibrin [PRF] and conditioned serum)
- skin grafts for treatment of burns
- bone grafts
- genetically-altered lymphocytes to target cancers
- adipose-derived cell extracts (including stromal vascular fraction (SVF))

External regulatory oversight of autologous HCTs

This document specifies only TGA regulatory requirements. Other regulatory requirements that may apply to these products include:

- Australian Health Practitioner Regulation Agency (AHPRA)
- state, territory and national medical and dental boards or councils
- the Australian Competition and Consumer Commission (ACCC)
- states and territory management and administration of public hospitals
- state and territory licensing of private hospitals

Three levels of TGA regulation

The level of regulation for autologous HCT products is based on the level of risk to the public. The level may vary due to the level of external governance and clinical oversight, or depending on the manufacturing processes or intended use of the autologous HCT product.

To determine how your autologous product will be regulated check if it is:

1. excluded from TGA regulation
2. regulated by TGA with exemptions from some requirements
3. fully regulated by TGA (as a medicine or biological)

For autologous HCT products that are **not excluded** from TGA regulation, the product will be one of the following:

- a medicine, if it fits the definition of blood, blood component or haematopoietic progenitor cells (HPCs)
- a biological

Biologicals and excluded autologous HCTs **must not be advertised** to consumers.

Regulatory pathways for autologous human cells and tissues products

Regulatory pathway	Excluded from TGA regulation	Regulated by TGA with some exemptions (medicine* or biological)	Fully regulated by TGA (medicine* or biological)
Eligibility criteria	• not to be advertised to consumers • manufactured and used in a hospital • collected, manufactured and used by persons under the supervision of the medical or dental practitioner who has clinical care of the patient	• manufactured **outside** of a hospital • collected, manufactured and used by persons under the supervision of the medical or dental practitioner who has clinical care of the patient • minimally manipulated • homologous use • single indication in a single clinical procedure	• Where the criteria for exclusion or exemption are not met

*Medicine: if meets the definition of blood, blood component or haematopoietic progenitor cells (HPC)

Fully regulated by TGA

If an autologous HCT product is not excluded or not exempt, then it is fully regulated as either a biological or blood component.

Check whether your product is a blood, blood component or HPC.

If your autologous HCT product is not a blood component, then it will be regulated as a biological. Please refer to the Australian Regulatory Guidelines for Biologicals (ARGB).

Checking if your product is blood, blood component or HPC

'Blood' and 'blood components' and haematopoietic progenitor cells (HPC) are defined in the latest 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 the therapeutic components of blood (red cells, white cells, platelets, plasma, serum, platelet-rich plasma [PRP], platelet-rich fibrin [PRF], conditioned serum) that can be prepared by centrifugation, filtration and freezing, but not including haematopoietic progenitor cells.
- *Haematopoietic progenitor cells* means self-renewing or multi-potent stem cells, or both, capable of maturation into haematopoietic lineages, lineage-restricted pluripotent progenitor cells, or committed progenitor cells.

If not excluded or exempt, autologous blood, blood components and haematopoietic progenitor cells (HPC) are regulated as a medicine in the same way as non-autologous blood, blood components and HPCs.

If your product does not fit the appropriate definition, then it will be regulated as a biological.

Version history

Version	Description of change	Authors	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
V2.0	Updates to reflect regulatory changes to conditioned serum	Biological Science Section Regulatory Guidance Team	July 2019

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