Australian Government
Department of Health
Therapeutic Goods Administration

Pathways for supply of biologicals

Australian Regulatory Guidelines for Biologicals (ARGB)

Version 1.0, July 2018

TGA Health Safety Regulation

Contents

Not everything that meets our definition of a biological is regulated as a biological. Before reading this guidance, check that your product is **regulated as a biological** by reading:

- What is regulated as a biological

If you are new to the regulatory environment, you may find the following information helpful:

- A summary of supplying therapeutic goods in Australia which is an introductory video.
- Basics of therapeutic goods regulation explains important information sponsors need to know.

Pathways for supply

The pathway for supply of biological products in Australia varies depending on whether your product is:

- exempt from some TGA regulation
- an 'unapproved' biological authorised for supply
- included on the ARTG.

You should also familiarise yourself with the manufacturing principles that will apply to manufacturing sites relating to your product, and the sponsor has certain responsibilities related to GMP clearance and certification for these sites.

Exempt biologicals

Certain autologous human cell and tissue products may be eligible for exemption from some regulatory requirements, but you must:

- meet specific eligibility criteria
- fulfil some regulatory obligations

To understand if your product is eligible and what regulatory requirements you must still comply with, refer to Exempt autologous HCTs.

'Unapproved' biologicals

We encourage supply of biologicals that are on the ARTG because they have been evaluated for quality, safety and efficacy. However, if you need to supply a biological that is not on the ARTG (an 'unapproved' biological'), the following pathways are available, depending on whether the use is:

- as part of a clinical trial (clinical trial schemes)
- for an individual patient (special access scheme)
- by an individual practitioner for multiple patients (authorised prescriber scheme).

For more information see: Access to unapproved biologicals.

Biologicals included on the ARTG

If your biological is **not** otherwise exempt, approved or authorised, then you **must** apply to include your biological on the ARTG.

The process for inclusion on the ARTG is to:

1. Classify your biological
2. Apply to include your biological on the ARTG

Biologicals may also be packaged with or combined with another therapeutic good. These may be defined as either a combination product or a biological kit, composite pack or system/procedure pack.

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

Therapeutic Goods Administration

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