



**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

**Copyright**

© Commonwealth of Australia 2018

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <[tga.copyright@tga.gov.au](mailto:tga.copyright@tga.gov.au)>.

# Contents

<b>Pathways for supply</b>	<b>4</b>
<b>Exempt biologicals</b>	<b>4</b>
<b>'Unapproved' biologicals</b>	<b>4</b>
<b>Biologicals included on the ARTG</b>	<b>5</b>

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

<b>Version</b>	<b>Description of change</b>	<b>Authors</b>	<b>Effective date</b>
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**

PO Box 100 Woden ACT 2606 Australia  
Email: [info@tga.gov.au](mailto:info@tga.gov.au) Phone: 1800 020 653 Fax: 02 6203 1605  
<https://www.tga.gov.au>

Reference/Publication #D18-10668301