Australian Government
Department of Health
Therapeutic Goods Administration

Unapproved biologicals: pathways for access

Australian Regulatory Guidelines for Biologicals (ARGB)

Version 1.0, July 2018

TGA Health Safety Regulation

Contents

This guidance is for people who wish to access biologicals that are not included on the Australian Register of Therapeutic Goods (ARTG), and are not otherwise exempt from being in the ARTG.

Biologicals that have been entered on the ARTG have been evaluated for quality, safety and efficacy. However, if you want to access a biological that is not included on the ARTG (an 'unapproved' biological), there are several pathways, 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)

You do not need to use an unapproved goods pathway if the biological is exempt from being included in the ARTG. For example, certain autologous human cells and tissues are exempt.

The pathways for accessing 'unapproved' biologicals **cannot** be used to facilitate the commercial supply of therapeutic goods.

Who uses the pathways

Most of the access pathways require a medical or dental practitioner to make the notification or a request for approval. Patients cannot make the notifications or applications themselves.

To determine which pathway, if any, is appropriate, health practitioners can use:

- Guidance tool for access to unapproved therapeutic goods

Authorised prescriber scheme

In some circumstances a medical practitioner may be granted authority to become an authorised prescriber:

- of a specified unapproved biological
- to specific patients, or class of patients, in their immediate care with a particular medical condition.

The authorised prescriber must obtain approval from a Human Research Ethics Committee (HREC) or endorsement from a specialist college. The information will be reviewed by us to determine whether there are any safety concerns and that the requirements under the scheme have been met. You must receive an approval letter from us before supply can occur. Find out more about the Authorised Prescriber Scheme.

Special access scheme

You can use the Special Access Scheme for any regulated therapeutic good for a single patient on a case-by-case basis. Find out more about the three pathways in the Special Access Scheme (SAS).

Clinical trials

There are two clinical trials schemes:

- clinical trial notification (CTN) scheme
- CTX scheme: an application scheme that is **mandatory** for a trial of any Class 4 biological, **unless** use of the biological in the clinical trial:
  - is supported by evidence from previous clinical use

  OR
  - has been approved for an equivalent indication from a national regulatory body with comparable regulatory requirements.

Before conducting a clinical trial you need to consider whether your product is a Class 4 biological:

- check Schedule 16 *Therapeutic Goods Regulations 1990* to determine if you have a Class 4 biological.

For more information:

- Choosing between CTN and CTX schemes
- Clinical trials.

Manufacture in accordance with appropriate GMP

All biologicals that are accessed through unapproved goods pathways, must be manufactured in accordance with appropriate good manufacturing practice, unless there is an exemption in place. For example, there is an exemption from manufacturing in a GMP accredited facility for unapproved biologicals used in first-in-human clinical trials.

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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