



Australian Government

Department of Health

Therapeutic Goods Administration

Preparing your biologicals application for inclusion in the ARTG

Australian Regulatory Guidelines for Biologicals
(ARGB)

Version 1.1, November 2020

TGA Health Safety
Regulation

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To assist you in applying to include a biological in the ARTG, we have outlined the regulatory process and summarised the requirements for you to successfully submit your biologicals application.

Classify your biological

To complete the biologicals application form, you need to have **correctly** classified your biological. We strongly recommend you:

- confirm your product is regulated as a biological, refer to: [What is regulated as a biological](#)
- classify your biological, refer to: [Classification of biologicals](#)
- if necessary, confirm your classification by completing the [Request for advice on biologicals form](#) and submit it to us for discussion with you.



Your application will only be accepted for evaluation if it has been classified appropriately, as defined under section 32DDA of the [Therapeutic Goods Act 1989](#).

Request a pre-submission meeting

[Pre-submission meetings](#) are available to **all sponsors** considering supplying a biological.

We highly recommend a pre-submission meeting with us for all **Class 3 & 4** biologicals, including for **CTA applications**.

Register as a TGA client

If you are not already a TGA client, you need to obtain access to TGA Business Services and register both:

1. your details
2. **all** your manufacturers – including:
 - a. all testing facilities you use for donor infectious disease testing
 - b. all microbiology testing facilities
 - c. sterilisation and/or irradiation facilities
 - d. any packaging facilities.



All of your manufacturer's must be registered with TGA Business Services **prior** to completing your application form, so you can select them from our database.

Manufacturing requirements

As the sponsor of a Class 2, 3 or 4 biological, it is your responsibility to ensure all of your manufacturers comply with our [manufacturing requirements](#). This applies to **all**:

- testing facilities you use for donor infectious disease testing
- microbiology testing facilities
- sterilisation and/or irradiation facilities
- packaging facilities.

In the dossier you need to submit evidence that all manufacturers are GMP certified by TGA or the certification process has been initiated. GMP accreditation must be approved prior to any decision on your application.

Australian manufacturers

If any of your Australian manufacturers **do not** already hold a **current** manufacturing licence, as the sponsor, you **must**:

- ensure they have at least **started** the licencing application process
- provide the manufacturer's licence application number as **evidence** with your biologicals submission.

Overseas manufacturers

If you are using overseas manufacturers, as the sponsor, you **must**:

- have at least started the GMP certification process
- provide the manufacturer's certification application number as evidence with your biologicals submission.



Time frames for licencing and clearances

You need to be aware of the timeframe involved in obtaining a manufacturing licence or clearance.

Single or multiple ARTG entries

Sometimes multiple products can be included in the ARTG under a single entry.

The criteria to determine if your biologicals can be included in the ARTG as, multiple products under a single ARTG entry, is outlined in:

- [Separate and distinct biologicals](#)

Check this guidance to determine whether your goods will be listed under a single ARTG entry or will need to be included separately. An application is required for each separate and distinct product.



The definition of **separate and distinct goods** is based on regulation 11A of the [Therapeutic Goods Regulations 1990](#).

Biologicals combined or packaged with another therapeutic good

Some biologicals may be supplied with other therapeutic goods. Regulatory requirements differ depending on how the biological is supplied. To clarify the requirements, check:

- [Biologicals packaged or combined with another therapeutic good](#)

Supporting documentation

Applications for inclusion of a biological on the ARTG are required to submit documentation. This requirement differs depending on the class of biological.

- Class 2, 3 and 4 biologicals are required to submit a complete dossier together with evidence of manufacturing compliance.
- Class 1 biologicals are required to submit documentation outlined in [Applying for inclusion of a Class 1 biological on the ARTG](#).

Dossier requirements

If you are applying for a Class 2, 3 or 4 biological you must submit a dossier to support the quality, safety and efficacy of your product, in accordance with the:

- [Dossier requirements for Class 2, 3 and 4 biologicals](#).

Where specific requirements apply to only certain classes of biologicals, they are indicated in the guidance document.

Multiple applications as a single submission

Each application relates to a single ARTG entry, but multiple applications can be submitted at the same time and considered a 'simultaneous submission' where certain conditions, specified below, are met.

A single **simultaneous submission** can be submitted to for your multiple applications, if all applications:

- are for the same class of biological
- have the same sponsor billing address
- have the same principal manufacturer undertaking the release for supply step
- for Class 1 or Class 2 biologicals conform to the same product standards
- for Class 3 or Class 4 biologicals have the same active ingredient.

Reduction or waiver of the evaluation fees may apply to applications associated with a simultaneous submission, where part of the dossier supporting the applications is sufficiently similar for their evaluation to be abridged.

Guidance on how to submit multiple applications as a single submission are provided in the [guidance on the application form](#).

If the applications do not meet these criteria then you cannot make a simultaneous submission. However, if the applications are from the same sponsor they may still be treated as **abridged applications**.

Abridged applications

Under the following circumstances your application may be treated as an abridged submission:

- part of the dossier supporting the applications is sufficiently similar for their evaluation to be abridged
- your cover letters for the applications refer to each other and you request that the applications be considered together
- you explain how the applications are similar.

Reduction or waiver of the evaluation fees may apply to abridged applications.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication, using material from the previous ARGB and incorporating recent legislative changes.	Biological Science Section Regulatory Guidance Team	July 2018
V1.1	Minor updates to reflect CTA name change	Biological Science Section	November 2020

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Reference/Publication # D18-10614941