Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Application for a biologicals (priority applicant) determination

Please note: A signed, scanned, pdf version of this application form must be submitted to bloodandtissues@health.gov.au (together with any supporting information).

Upon receipt of the application form you will be sent an invoice for the application fee. An application is not taken to be made until the fee has been paid and any necessary supporting information is provided.

This form is intended to be used to apply for a biologicals (priority applicant) determination. The TGA will assess the information you provide against the requirements for a determination in the *Therapeutic Goods Regulations 1990*. A priority applicant determination is required to access the priority pathway for the inclusion of biologicals in the Australian Register of Therapeutic Goods (ARTG).

Before submitting an application:

1. Refer to the following guidance:
   - Biologicals (priority applicant) determination: A step-by-step guide
   - Biologicals (priority applicant) determination eligibility criteria and supporting documentation requirement
2. Ensure that any attachments meet the formatting requirements outlined in the general dossier requirements for all therapeutic goods.

Applicant

Client ID	
Applicant name	
Sponsor organisation	
Regulatory correspondence address	
Billing address	

Primary contact person

Given name	
Family name	
Telephone number	
Email address	

Secondary contact person (optional)

Given name	
Family name	
Telephone number	
Email address	

Priority applicant determination — Eligibility criteria

Please attach documentation supporting each of the relevant criteria and requirements to this form. The eligibility criteria are specified in sub regulation 16W(2) of the *Therapeutic Goods Regulations 1990* and are summarised below.

Table heading	Table heading	Select options that apply
Relevant class	The biological is a Class 2,3 or 4 biological. Note: this is an application requirement in subregulation 16V(1).	☐Yes *If 'not', you are ineligible to apply*
New biological or new use	The biological is separate and distinct from the biologicals included in the Register	☐ Yes ☐ No
Life-threatening or seriously debilitating condition	The proposed intended use or therapeutic indication is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition AND	☐ Yes ☐ No
Comparison against existing therapeutic goods:	Either: (i) No therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part for provisionally registered goods); OR	☐ Yes ☐ No
	(ii) If one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part for provisionally registered goods) - there is substantial evidence demonstrating that the biological provides a significant improvement in the efficacy or safety of the treatment, prevention or diagnosis of the condition compared to those goods; AND	☐ Yes ☐ No
Major therapeutic advance	There is substantial evidence demonstrating that the biological provides a major therapeutic advance.	☐ Yes ☐ No

Attach supporting documentation

The relevant supporting documentation should be attached when submitting this application form via email.

The detailed guidance on the eligibility criteria and relevant supporting documentation in the 'Biologicals (priority applicant) determination eligibility criteria and supporting documentation requirement' should be consulted prior to submitting the application.

The attached documentation should include justifications against the relevant eligibility criteria and the justifications, should not exceed the page limit specified in the guidance. In addition, the supporting documentation should include pivotal study summaries.

Please make sure that any attachments meet the formatting requirements outlined in the general dossier requirements for all therapeutic goods.

Details of the biological

Name of active ingredient(s) If ACN or ABN is not available then provide INN or USAN	
Class of Biological	
Proposed Indication or intended use	
Trade name (if applicable)	
Is the product for: Prevention Diagnosis; or Treatment	☐ Yes ☐ Yes ☐ Yes
If applicable, list the other ingredients	
If applicable, provide details about any overseas regulatory submissions for the product and any access to priority pathways granted by comparable overseas regulators:	
Has an overseas regulatory agency refused to approve the biological for use for the (proposed priority) condition or intended use for a reason related to its safety or efficacy?	☐ Yes ☐ No *If Yes, please provide details:*

Administration

Manufacturing site clearances	
Can you give an assurance that all the Manufacturing Sites relating to the biological specified for this application have the appropriate GMP clearances/licences? **OR**	☐ Yes
That clearance/licence applications have been *lodged* OR *will be lodged* with the TGA *	☐ Lodged
If clearance/licence applications have been lodged to the TGA please provide the relevant GMP reference number(s): * Please note, it is your responsibility to provide evidence of GMP clearance / licence to the TGA before your product can be included on ARTG.	

Proposed date for submission of section 32DD application to include the biological in the Register.	

Application checklist

Please note: This checklist is intended to assist you to provide all the necessary information to allow the TGA to make an informed decision on your application.

1. Is your intended application for only one biological product with one priority indication?

☐ Yes ☐ No

If no, you should submit separate applications for each biological/ indication

2. Is the proposed biological separate and distinct from the therapeutic goods already included in the ARTG?

☐ Yes ☐ No

The priority pathway is only available to separate and distinct biologicals from the products already in the register

3. Have you prepared a cover letter* for your application?

☐ Yes ☐ No

* You may enclose a cover letter with your application. In the cover letter you should explain the nature of your application. Specifically, you should provide a brief background on your product and the intended use or indication, detail of your pre-submission meeting, and GMP status of the manufacturing sites. You should also include information in relation to your plan to submit application for inclusion. You may include any other relevant information such as overseas submissions etc. that may assist in assessing your request.

4. Have you included supporting information about the life-threatening or seriously debilitating* nature of the condition)?

☐ Yes ☐ No

*A prominent feature of the condition (i.e. affecting an important portion of the target population) is morbidity with a well-established, major impact on the functioning of the person based on objective and quantifiable medical or epidemiological information. Short lived and/or self-limiting morbidity is not considered seriously debilitating.

5. Have you included a comparison against therapeutic goods already registered* or included in the ARTG for the prevention, diagnosis, or treatment of the proposed condition?

- Declaration that there are no therapeutic goods already registered* or included in the ARTG for the condition ☐ Yes ☐ No
- **OR**: Details of registered* or included therapeutic goods ☐ Yes ☐ No
- **AND** supporting information about improved safety and/ or efficacy ☐ Yes ☐ No

*The comparison does not need to considere provisionally registered goods.

6. Have you included supporting information that demonstrates the biological will provide a major therapeutic advance (based on substantial evidence)?

☐ Yes ☐ No

7. Do you anticipate you will be ready to submit the application for inclusion of your biological within six (6) months of any determination being made?

☐ Yes ☐ No

The priority applicant determination will lapse (cease to be in force) in 6 months' time and there is no provision to extend this timeline. If you fail to submit your inclusion application before the determination lapses you would be required to apply for a new determination to access the priority pathway.

8. Have you included a bibliography containing all published references referred to in your application?

☐ Yes ☐ No

Declaration and signature

I acknowledge that the Criminal Code provides for offences and penalties for providing false or misleading information or documents to a Commonwealth entity.

I understand that to obtain a priority applicant determination, it is my responsibility to include all necessary supporting documentation with my application.

I understand that for the application to be taken to be made, and for a determination evaluation to commence I must pay the application fee in full.

I declare that the information provided in, and accompanying, this application form is, to the best of my knowledge, complete, current, and correct.

Name			
Signature		Date	