



Australian Government

Department of Health

Therapeutic Goods Administration

Priority review designations

Medical devices (including IVDs)

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TGA Health Safety
Regulation

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Introduction

This guidance is intended to assist applicants seeking designation for Priority Review of either TGA conformity assessment, or inclusion in the Australian Register of Therapeutic Goods (ARTG) of a medical device.

Applications which are granted a Priority Review designation will be allocated 'front-of-queue' priority throughout the relevant assessment process. This includes TGA business processes associated with applications for conformity assessment, and inclusion on the ARTG for medical devices.

Designation decisions lapse after six (6) months, unless we receive an application for either TGA conformity assessment or ARTG inclusion during this time. Information about TGA conformity assessment and ARTG inclusion applications can be found at [Standards, guidelines & publications \(medical devices & IVDs\)](#).

Criteria for Priority Review designation

To gain Priority Review designation, medical devices **must meet all three** of the following criteria:

1. Serious condition

The intended purpose of the new device is the monitoring, treatment, prevention or diagnosis of a life threatening or seriously debilitating condition; **and**

2. Unmet need

Either:

- i. no medical devices with that intended purpose are of a kind included in the Register, or
- ii. if one or more medical devices with that intended purpose are of a kind included in the Register (the existing devices) - there is substantial evidence demonstrating that the safety or performance of the new device when used for that intended purpose provides a significant improvement compared to the existing devices; **and**

3. Breakthrough technology OR clinical advantage OR public health (in vitro device only) - at least one of the following applies to the new device:

- i. the new device is a breakthrough technology **and** there is evidence that it offers a major clinical advantage* over existing technology; **or**
- ii. there is evidence that the device offers a major *clinical* advantage* over existing alternatives included in the Register; **or**
- iii. the new device is an IVD medical device and its early availability in Australia will result in a major public health benefit.

*Engineering or pre-clinical evidence is insufficient on its own; there must be evidence of a major clinical advantage.

Demonstrating eligibility

Consider whether the medical device meets the three eligibility criteria of serious condition, unmet needs, and major therapeutic advantage. You'll need to **make a concise, persuasive argument against all three criteria**.

Criterion 1 – Serious condition

Identify the severity of the disease or condition, based on **objective and quantifiable** medical information and analysis.

Criterion 2 – Unmet need

Discuss the current 'state of the art' in treatment of the condition, and how your device will help treat affected patients. Describe how, and to what extent, your medical device is expected to fulfil a major or urgent unmet medical need.

You should provide:

- Details of any relevant similar medical device(s) and a brief analysis of similarities and differences between your device and similar devices; **or**
- A declaration that there are no similar medical devices in the ARTG with the same intended purpose, along with a brief summary of searches completed to establish this.

Document the expected **patient population** and present evidence that your medical device will provide an **advantage over existing available treatment(s)** by addressing whichever is relevant:

- Improved performance for the population relevant to the intended purpose; or
- A better safety profile for the population relevant to the intended purpose, or
- Treats an otherwise excluded patient population.

Criterion 3 – Breakthrough technology / clinical advantage / public health

Provide a succinct summary of the available evidence with respect to:

- the magnitude of the demonstrated improvement in safety and/or performance
- the impact on patient outcomes taking into account both safety and performance
- the magnitude of the advance in relation to other medical devices in the ARTG. Where no product is in the ARTG, the comparison should occur against the standard of care.

To meet criterion 3, your new medical device **needs to meet at least one of the following**:

i) Breakthrough technology with major clinical advantage:

Provide summary demonstrating novelty and advance in the treatment associated with the use of your device.

The clinical advantages may include, for example, reduction in the need for hospitalisation, improved quality of life, better effectiveness of the treatment, etc.¹

¹<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf>

The comparison with the existing treatments for the same indications should include:

- Specific examples of improvements against existing available treatments (based, for example, on summary of design analysis and/or studies available); and
- Best quality clinical data available documenting health benefits to the indicated patient population.

ii) Clinical advantage over existing alternatives included in the ARTG:

The justification for this point should address one or more of the following:

- Improved performance for the population relevant to the indications and intended purpose;
or
- Better safety outcomes for the target population.

Safety aspects

In the case of novel medical devices, it might not be practicable to demonstrate a magnitude of improvement based on established safety and performance endpoints. You should still however clearly outline any **actual** safety and performance issues of the existing treatments for the condition you state your device will be used for, and explain how your new medical device will counteract these safety and performance issues, and support your argument by the best evidence available (including **summaries** of the study reports available).

iii) FOR IVDS ONLY: Early availability in Australia will result in a major public health benefit

Your application should include justification on how the IVD will improve the health of the Australian public. We expect that your justification will be supported by the following:

- Documentation of the improved sensitivity and specificity of the IVD compared to existing IVDs in the ARTG, including magnitude of improvements and endpoints, predictive values and/or likelihood ratios.
- Estimated patient population that will benefit from the improved diagnosis and/or treatment.

For the claim of improved performance or safety, we will evaluate whether there is a high probability that the Australian population will experience a clinically relevant benefit. Therefore, your reasoning should be based on the best evidence available, including **summaries** of full study reports and respective analysis.

The evidence must be considered in light of both the particular characteristics of the condition (number of affected patients; transmission of the disease) and other available diagnostics (or methods of treating the identified condition/preventing spread).

Designation process



Note

Priority designation is a formal decision by the TGA to assign priority to the assessment of an application to include a medical device in the ARTG.

Granting of priority designation **does not guarantee approval for the application itself.**

Who and what the designation is specific to

The Priority Applicant designation is specific to the:

- person who is the priority applicant (as a result of either section 41ECA or 41 FKA of the *Therapeutic Goods Act 1989*); and
- medical device (in respect of design, material, physical characteristics, and a particular manufacturer); and
- intended purpose of the device.

How to apply

Obtain a Client ID number

Before you can complete your application form, you'll need to obtain a TGA Client ID number. Guidance on how to do this can be found in: [TGA Business services: getting started with the TGA](#).

Application form

The [application form](#) must be completed and submitted along with your justification and any supporting information.

Preparing the designation application

You will need to provide a short justification against all three eligibility criteria outlined above, stating why the new medical device will be a major improvement over existing treatments.

Your application for priority designation should be persuasive, in principle, without the need for further information.

Supporting documentation can be provided as attachments and can include the following:

- **Summaries** of clinical evidence where it provides support against the relevant eligibility criteria.
- **Summaries** of other important safety data obtained in the preclinical and clinical setting.

**NOTE**

The application, including attachments, should be concise. Do not include full clinical or technical reports.

Indicate whether you are also applying for any related medical device priority review and/or medicines priority review.

- Confirm that an application for conformity assessment or ARTG inclusion can be submitted within six (6) months of receiving advice of designation for Priority Review. If an application for ARTG inclusion has not been submitted within six months of receiving designation advice, the designation will lapse.
- If you have regulatory approvals from other jurisdictions, please include this information in your application.
- If you plan to seek both regulatory approval and reimbursement, you may wish to indicate whether you agree that all documents provided to TGA or developed during TGA assessment can be shared with the relevant committee (Medical Services Advisory Committee (MSAC) or Prostheses List Advisory Committee (PLAC)).

Pre-submission meeting

If necessary, you may seek to have a pre-submission meeting with us prior to finalising your application for Priority Review designation.

Where a pre-submission meeting has been arranged, please provide us with a briefing package to ensure we all gain the maximum benefit from the meeting. Please include an agenda and a draft of your designation application (including summaries of relevant supporting documents) highlighting any questions that you have for the TGA, at least one week prior to the meeting.

Content of the designation application

It is your responsibility to provide TGA with sufficient evidence to allow the decision-maker to be satisfied that the eligibility criteria have been met.

In order to be eligible, your designation application must contain sufficient information for TGA to make a decision.

For any attachments, use the format outlined in the TGA's [General dossier requirements](#).

Submitting your designation application

Submit your designation application to PriorityDevices@health.gov.au using the subject line "Device Priority Review – Sponsor/Applicant – Name of device".

Please ensure that:

- The application form is completed
- Information provided justification against all three eligibility criteria
- Summaries of relevant supporting documentation are attached if required.

Ideally the main body of the application (apart from the application form) would not exceed **10 pages**.

**Please note**

You can include several new medical devices of the **same type** in one application for Priority Review if they all fulfil the eligibility criteria **and are not** currently assessed under a routine pathway.

Medical devices of the 'same type' can be devices in the same product family, or multiple devices designed to be used together.

Payment of the fee

As of 1 January 2018, the fee for a Priority Review designation application is \$9,660.*

Once you have emailed us your application you will be sent an invoice for the fee which must be paid before we begin reviewing your application. Payments can be made via EFT, credit card (preferred) or cheque, and instructions on how to pay will be provided with the invoice.



Do not send payment before you receive an invoice from us.

We **do not** refund fees for designation applications that are withdrawn before the decision is made, or are assessed as ineligible for designation.

* TGA fees and charges are regularly reviewed, and increase from time to time. Please refer to the [TGA schedule of fees and charges \(medical devices\)](#) for the most up-to-date application fee.

What happens next?**How we will assess your designation application**

After you have submitted your designation application, we will check the information provided and confirm whether it is sufficient to allow us to assess the application. The focus of the assessment will be to determine whether the application and supporting documentation establishes that the eligibility criteria are met and we will determine the strength of the justification on a case-by-case basis.

The timeframe for TGA's assessment and decision making on your designation application is up to 20 working days.

TGA may seek external advice from time to time when assessing designation applications.

Requests for further information

We may require additional information or clarification from you while we're reviewing your application. These requests will include details of the TGA contact for your response.

You will need to provide any additional information to us within the time specified. Otherwise we will make our decision based on the information originally provided.

Notifying you of our decision

You will generally be notified of our decision within four (4) weeks (20 working days) of receipt of your application (excluding any additional time taken for you to respond to TGA requests).

After the delegate has made a decision, you will be advised of the outcome as soon as practicable in writing via a notification letter issued via email which will include:

- Details of designation(s) eligible/ineligible and the relevant indication
- A statement of reasons for designation decisions (for ineligible decisions only)
- The date on which the designation (if approved) lapses (six months after the date on which you are notified of the designation decision)
- Details of your appeal rights

Maintaining a valid designation

It is your responsibility to ensure that your designation application includes all relevant information and that the justifications provided in the designation application are supported by the data in your subsequent application for TGA Conformity Assessment or ARTG inclusion.

We will consider the information provided by you at the time of assessing your designation application, and then will re-assess as part of the application process.



Note

Your designation will not be affected where a similar competitor product is the subject of a concurrent designation application.

How long does a designation last?

Designation decisions will lapse after six (6) months, unless TGA receives the applications for either TGA conformity assessment or ARTG inclusion during this time.

Withdrawing your designation application

You may withdraw your designation application at any time before we issue a designation decision.

To withdraw the application, email PriorityDevices@health.gov.au and include:

- A statement that you wish to withdraw a designation application
- The designation application number
- The sponsor's name

Withdrawn applications are **not eligible for a refund** of the Priority review designation fee.

Revocation of designation

Designation for Priority Review may be revoked if the conformity assessment or ARTG inclusion application (whatever is relevant) is not submitted to the TGA within six (6) months after the designation is granted or if application is not effective.

Publication of designation decisions

If the application for Priority Review designation has been approved, the sponsor will be notified as soon as practicable.

Designation decisions will be published on the TGA website after you have been notified.

We will not publish details of designation applications that are assessed as not eligible, or those that are withdrawn before we make a decision.

Re-lodgement of lapsed designation

If you wish to seek Priority review designation following a lapsed designation (for a medical device and intended purpose that has been previously designated but where the validity of the designation has lapsed) you will need to lodge a new designation application.

We will re-assess the new application against the same eligibility criteria, as some aspects such 'comparison against existing therapeutic goods' may have changed since the original designation decision was made.

For re-lodged applications, you are required to provide the reference number for any relevant previous designation application.

Glossary

Life-threatening: a prominent feature of the condition is serious illness from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of treatment based on mortality and life expectancy data in Australia.²

Examples of life-threatening diseases or conditions include but are not limited to: chronic or active hepatitis, myocardial infarction, malignancies, and trauma.³

Major therapeutic advance: an improvement in the safety and/or efficacy of a medicine or improved safety and/or performance of a medical device, that is of a magnitude well beyond the minimum threshold of clinical significance. The impact on patient outcomes for the indicated population will take into account effects of both efficacy/performance and safety. The magnitude of the demonstrated improvement in safety (and/or efficacy/performance) will be assessed in relation to other therapeutic goods registered for the indicated population.

Seriously debilitating condition: 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 quantifiably medical or epidemiologic information, such as a condition resulting in permanent physical or mental impairment. Short lived and/or self-limiting morbidity is not considered seriously debilitating.

Examples include malignancies, Amyotrophic lateral sclerosis (ALS), stroke, and large ST segment elevation myocardial infarction (STEMI; while patients with STEMI and stroke can improve with medication and rehabilitation, the effects are not reversible and can be debilitating if severe enough).³

² Priority review designation eligibility criteria – Including supporting documentation (Prescription Medicines) - <https://www.tga.gov.au/publication/priority-review-designation-eligibility-criteria>

³ Adapted from <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf>

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch, Therapeutic Goods Administration	02/01/2018
V1.1	Application form now provided online.	Medical Devices Branch, Therapeutic Goods Administration	13/02/2018

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