Priority review designations
Medical devices (including IVDs)

Version 1.2, August 2018
The purpose of this guidance is to help manufacturers and sponsors understand how the TGA interprets regulations, and thus indicate how to comply.

This is a guide only, and manufacturers and sponsors are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia. If necessary, seek professional advice as it is the responsibility of each manufacturer or sponsor to understand and comply with these requirements.

This document will evolve over time and updates and clarifications will be included as required. Feedback on the guidance is always welcome.
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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 ARTG, or
   
   ii. if one or more medical devices with that intended purpose are of a kind included in the ARTG (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 ARTG; 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

You need to justify the severity of the disease in Australia (i.e. its seriously debilitating or life-threatening nature), based on **objective** and **quantifiable** medical information.

Your designation application must justify the:

- **life-threatening** nature of the disease or condition based on figures of mortality and life expectancy in Australia

- **seriously debilitating** nature of the condition based on morbidity over the course of the disease and its consequences on patients’ day-to-day functioning
The serious debilitation or fatal outcome should be a prominent feature of both the target disease or condition and the manufacturers intended purpose of the medical device, i.e. affect an important portion of the target population. The intended purpose is the proposed intended purpose for ARTG inclusion, based on the proposed intended purpose at the time of the designation application.

**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

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

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¹ Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions - https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf
• 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 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:

- Application Form – Priority Review Designation (Medical Devices)

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”.

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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.

Lapsing or revocation of the designation

Lapsing

For your application to be eligible for the Priority review pathway, the relevant designation must be active at the time of submitting your application.

Eligible Priority review designations will automatically lapse six calendar months after the date that you are notified of the designation decision, as outlined in sections 4.3D and 5.4C of the Therapeutic Goods (Medical Devices) Regulations 2002, unless the TGA receives the applications for either TGA conformity assessment or ARTG inclusion during this time.

Eligible Priority review designations will also lapse under any of the following circumstances:

- the priority applicant withdraws the application for TGA conformity assessment or ARTG inclusion
• the application lapses in accordance with s 41EG of the Act (TGA conformity assessment application) or in accordance with s 41FK of the Act (ARTG inclusion application)

• the application for TGA conformity assessment or ARTG inclusion is finally determined.

Revocation

TGA reserves the right to revoke the designation prior to the end of the six month lapsing period under sections 4.3E and 5.4D of the Therapeutic Goods (Medical Devices) Regulations 2002. This may occur if:

• we have not received the application for TGA conformity assessment or ARTG inclusion, OR

• the submission has been received but it is not effective; AND

• TGA is satisfied that the medical device no longer meets the eligibility criteria.

However, we will not routinely review designation decisions during their validity.

If TGA decides to revoke your designation, you will be advised in writing as soon as practicable after the decision has been made. Decisions regarding revocation of designations are appealable under regulation 10.7 of the Therapeutic Goods (Medical Devices) Regulations 2002 by the applicant only.

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.

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 advantage

An improvement in the 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 performance and safety. The magnitude of the demonstrated improvement in safety (and/or performance) will be assessed in relation to other therapeutic goods approved for supply in Australia 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


³ Adapted from Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions - https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf
Flowchart of designation process

This flowchart is a visual representation of the process described in this guidance.

Optional pre-submission meeting
Ideally, this should be scheduled prior to submission for TGA Conformity Assessment / ARTG entry

Notification of intent to lodge a determination application

Determination application
Ensure you are ready to submit an application for TGA Conformity Assessment / ARTG entry within 6 months

Assessment of determination application
Assessment against relevant eligibility criteria

Determination decision by Chief Medical Advisor

Eligible
Submission for registration (Front of queue)

Ineligible
Standard pathway
Withdrawal
Address deficiencies and reapply
Appeal

*Our assessment of a determination application will not commence until payment of the application fee has been confirmed.
# Version history

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<tr>
<th>Version</th>
<th>Description of change</th>
<th>Author</th>
<th>Effective date</th>
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<tbody>
<tr>
<td>V1.0</td>
<td>Original publication</td>
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<td>02/01/2018</td>
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<tr>
<td>V1.1</td>
<td>Application form now provided online.</td>
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<tr>
<td>V1.2</td>
<td>Addition of flowchart illustrating priority review process; update of application form details; update of details on lapsing/revocation of designations, addition of information for Criterion 1.</td>
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