Australian Government
Department of Health
Therapeutic Goods Administration

Priority determination

A step-by-step guide for prescription medicines

Version 1.1, August 2018

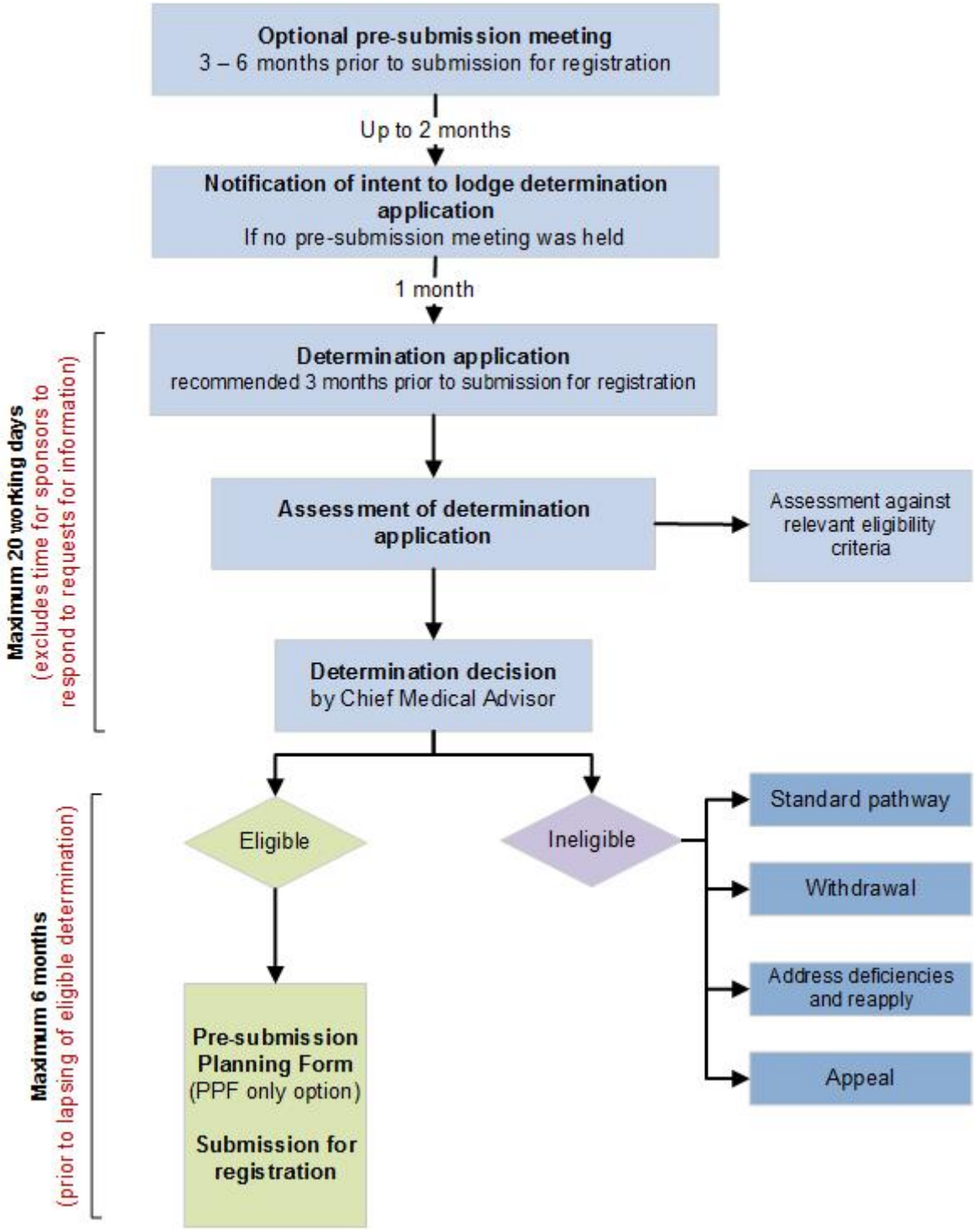
TGA Health Safety Regulation

Contents

This guidance is for sponsors intending to use the priority review registration pathway. This guidance assists sponsors with the process of applying for a priority determination, which is the first step of the priority review registration pathway.

For information on the eligibility criteria and supporting documentation requirements for priority determination, please see the eligibility criteria and supporting documentation guidance.

Priority determination process



Priority determination

Purpose of determination

As a sponsor, you must submit an application for priority determination and have this application approved before you can lodge a registration submission for priority review.

Determination is a formal process that allows us to make a decision under regulation 16R(1) of the *Therapeutic Goods Regulations 1990* (the Regulations) regarding whether the medicine is eligible for registration via the priority review pathway.

The determination application is the formal application made using a specified form requesting assessment against the relevant eligibility criteria and a decision from TGA under regulation 16Q.

A priority determination is a prerequisite of the priority registration pathway but does not guarantee acceptance of the registration application or subsequent registration on the Australian Register of Therapeutic Goods (ARTG).

When to submit your priority determination application

We recommend that you submit your application for determination three months prior to the date you plan to lodge your submission for registration.

Benefits of determination

A valid priority determination must be held in order for benefits resulting from determination to apply to a submission for registration on the ARTG.

Determination ensures that access to the priority review registration pathway is only available to medicines that meet the eligibility criteria. Determination provides a consistent and transparent process for making this assessment.

Priority determination can provide:

- access to expedited assessment via the priority registration pathway
- a consistent and transparent process for assessment against the eligibility criteria

Eligibility requirements

Eligibility criteria for the priority determination are set out in subregulation 16R(2). See our guidance on priority determination eligibility criteria.

Implementation arrangements

As part of the implementation of the Priority review pathway we have developed implementation arrangements that apply from 1 July 2017.

Administrative requirements

To obtain priority determination, you need to ensure that you meet the relevant administrative requirements outlined in the section below. The administrative requirements must be satisfied in addition to the clinical eligibility criteria.

These requirements are captured in the determination application form, and must be met in order for your determination application to be eligible for assessment.

Failure to meet these administrative requirements may affect TGA's ability to expedite the assessment of your priority determination application.

Ensure that active ingredient(s) have an approved name

When recording the active ingredient(s):

- Check each active ingredient has one of the following approved terms:
  - Australian Approved Name (AAN)
  - Australian Approved Biological Name (ABN)
- Use the approved ingredient names in the application for priority determination.

If the active ingredient(s) is not on the approved list, you can submit a proposal for a new ingredient name to the TGA before, or in parallel to, your application for priority determination.

- Make an application for an approved name using the relevant form:
  - AAN
  - ABN
- Use the proposed name (AAN/ABN) in the application form for priority determination, including the word 'proposed' in brackets after the name.

Note: Applications for priority determination cannot be finalised until an approved name has been allocated to the active ingredient(s).

Provide Good Manufacturing Practice (GMP) assurance

You must provide assurance that all of the manufacturing sites relating to the product in your determination application have appropriate clearance or licenses or that the applicable GMP applications have been lodged with the TGA.

This includes either:

- existing approved Australian manufacturing licence or overseas GMP certification; OR
- GMP clearance; OR
- verification that you have applied to obtain either an Australian manufacturing license, overseas GMP certification, or GMP clearance as appropriate.

For additional assistance, refer to the Good Manufacturing Practice application decision tree or the Clearance Application Assistance Tool.

Determination application and assessment

See the Priority determination process diagram for an overview of the determination process.

Step 1: Provide early notification of your determination application

Early notification

If you have not previously contacted TGA about your intended determination application, you are strongly encouraged to notify us at least one month prior to lodgement.

Early notification will assist us with resource planning which contributes to the timely assessment of your determination application and subsequent submission for registration.

You can make this notification informally by sending an email to AET.Application.Entry.Team@health.gov.au, including details of the planned application:

- type of determination to be sought
- the name(s) of the active ingredient
- the sponsor's name
- the proposed priority indication

Pre-submission meetings

In place of early notification, you may choose to request a pre-submission meeting with TGA, to discuss your planned priority determination application and subsequent application for registration. The content and procedures for these meetings are as per the standard prescription medicines pre-submission meetings process.

Pre-submission meetings can be a useful opportunity for you to obtain advice from us about the intent of the eligibility criteria for priority determination. However, TGA cannot provide binding advice at a pre-submission meeting on whether your application will be granted a priority determination.

We recommend that pre-submission meetings occur up to three months prior to lodgement of your determination application.

Provide details of any pre-submission discussions in the PPF and the dossier (Module 1.8.1) as per the usual process.

If the pre-submission meeting is more than six months from the planned date of the submission for registration lodgement, then we suggest that an email is also sent to the Application Entry Team, as described in the 'early notification' section.

Step 2: Access to TGA Business Services (TBS)

If you already have a TGA client ID number and password to access TGA Business services (TBS) as a submitter, go to Step 3.

Obtaining access to TBS

Determination applications are created and lodged by people with submitter access through the TGA Business Services portal.

You will need the following in order to access the portal and create and submit applications:

- a TGA Client Identification (Client ID) number
- password access to our TGA Business services portal
- submitter access to the TBS portal

If you do not have a TGA Client ID or access to our business services:

- go to TGA Business services: getting started with TGA and complete and submit the organisation details form.

Step 3: Submitting your determination application

We recommend that you submit your application for determination three months prior to the date you plan to lodge your submission for registration.

Before you begin your determination application, please check whether you have previously attended a pre-submission meeting with the TGA and/or notified TGA of your intent to lodge (see Step 1).

Under Section 16Q of the Regulations, in order to be eligible, your determination application must:

- contain sufficient information for TGA to make a decision, AND
- be submitted using the approved form (the designation/determination application e-form) AND
- be accompanied by the determination application fee if applicable

Using the designation/determination application e-form

You can access the designation/determination application e-form through your TBS account. See the designation/determination application e-form guidance for further guidance on filling out the form.

It is your responsibility to ensure that your determination application includes all relevant information and that the justifications provided in the application are supported by the data in your submission.

For any attachments, use the format outlined in Part A and Part B of the General dossier requirements for prescription medicines.

Payment of the priority determination fee

A fee applies to priority determination applications. The priority determination fee amount is published at the fees and payments section of the TGA website (and Part 2, Schedule 9 of the Regulations).

When you submit your determination application through the TBS portal, an invoice for the determination fee will automatically be sent to you (the submitter) and the billing contact (if an email address has been previously provided) within 90 minutes. The invoice will also be available to people with Finance access on the TBS portal.

The balance of the determination fee must be paid in full via one of the TGA's payment options before we issue a determination decision (see subregulation 16Q(3)(b)).

We do not refund fees for determination applications that are withdrawn by the sponsor before a decision is made or are assessed as ineligible for the determination.

Applying for orphan drug designation and priority determination

To be eligible for a waiver or refund of the priority determination fee, you must already hold a valid orphan drug designation **or** apply for orphan drug designation at the same time as the priority determination.

The proposed therapeutic indication for priority determination must be identical to, or a subset of, the orphan indication. See the priority determination eligibility criteria guidance for further information on related applications.

Please note that, where applications are lodged simultaneously for priority determination and orphan drug designation, we will make each decision separately against the relevant eligibility criteria.

If you apply for both priority determination and orphan drug designation simultaneously, you will be required to pay the determination fee (a single fee is payable for priority determination only, given that there is no fee for orphan drug designation).

If we approve your application for orphan drug designation the priority determination fee will be refunded (regulation 43AD of the Regulations).

If you are applying for priority determination of a medicine that already has a valid orphan drug designation and the orphan indication is the same as, or is broader than, the priority indication that you are applying for, your priority determination fee will be waived (regulation 45 (12) (d) of the Regulations).

We do not refund the priority determination fee if you obtain orphan drug designation as part of a separate application **after** the priority determination decision has been made.

Applying for both priority and provisional determination

You may not apply for provisional determination of a medicine for which you are seeking priority determination. This is because the eligibility criteria for the priority pathway require a complete dossier, while the provisional pathway is available to sponsors with preliminary clinical data.

Step 4: TGA assessment of the determination application

Our target timeframe for assessment and decision making on your determination application is 20 working days.

The timeframe for assessment begins on the day that you pay the determination fee. Where the determination application is for both priority determination and orphan drug designation, the timeframe begins on the day of designation/determination application receipt. We will begin assessment on the following working day for applications received outside of business hours.

After you have submitted your determination application using the e-form, we will check the information provided to determine whether it is sufficient to allow us to evaluate the application.

We will check that:

- the determination fee invoice has been issued (and the fee has been paid, if applicable)
- the application form has been completed in full, including declarations
- the application form meets the administrative requirements
- you have separately addressed each eligibility criterion with clear, robust and scientific justifications
- your application contains justifications that are up to date
- your application includes supporting data and references where required

We will not formally notify you of the results of this checking process; however, you may receive requests for further information.

If you have any questions during the determination application assessment period, please contact AET.Application.Entry.Team@health.gov.au.

How we will assess your determination application

We will review applications for determination against the eligibility criteria set out in subregulation 16R(2) of the Regulations.

The focus of the assessment will be to determine whether the application and supporting documentation establishes that the eligibility criteria are met. We may seek independent expert advice if required.

A recommendation from the relevant Clinical Evaluation Unit will be referred to TGA's Chief Medical Advisor, who is the delegated decision-maker for determination applications.

Requests to the sponsor for further information

We may request additional information or clarification from you during the course of our assessment. These requests will include a time frame for response which is determined on a case-by-case basis, and details of TGA contacts for your response. The usual time frame for your response will be approximately five working days.

You are responsible for providing evidence in support of your application.

The determination assessment and decision-making timeframe of 20 working days applies only to TGA time spent. Any time taken for you to respond to requests will extend the overall assessment and decision-making timeframe. If no response is received in the specified time period, TGA will make a decision based on the available information.

Withdrawing your determination application

You may withdraw your determination application at any time before we notify you of our decision.

To withdraw the application, email AET.Application.Entry.Team@health.gov.au.

Your email should include:

- a statement that you wish to withdraw a priority determination application
- the determination application number
- the name of the active ingredient(s)
- the sponsor's name
- the proposed indication for priority determination

Withdrawn applications are not eligible for a refund of the priority determination fee.

Step 5: Notifying sponsors of the determination decision

If we assess that your application for determination is **eligible**, the determination will be **approved**.

After we have made a decision, we will advise you via email of the outcome as soon as practicable (subregulation 16R(4)).

Your decision letter will include:

- the name of the priority applicant
- each active ingredient of the medicine to which the determination relates
- the priority indication
- notice that at the time of lodging your submission for registration, you must have lodged all of the required evidence in support of the GMP application for all manufacturing sites relevant to the priority registration application.

If the delegate decides to refuse to make the priority determination, in addition to the items above, your decision letter will also include:

- reasons for the decision to refuse to make a priority determination
- details of your appeal rights

How to appeal the determination decision

The priority determination decision is appealable under regulation 48 of the Regulations.

Appeals following refusal to make a priority determination may be lodged by the **applicant only** (regulation 48 (2AA)) within 90 days of the determination decision being issued.

Further information on how to seek internal review by TGA or external review by the Administrative Appeals Tribunal is available on our website.

Publication of determination outcomes

We will publish details of medicines with approved priority determination on our website.

Publication will include:

- the name of the medicine
- the applicant's name
- the priority determination indication
- determination effective date and date on which it ceases to be in force ('lapse date')

Determination decisions will be published as soon as possible after you have been notified.

We will not publish information on applications where the delegate has refused to make a priority determination or those that are withdrawn before we make a decision.

Period during which the priority determination is in force

Your priority determination comes into force on the day on which we notify you of our decision and remains in force for **six months** (refer subregulation 16S of the Regulations) unless:

- it is revoked by the TGA (see 'revocation of priority determination' below) or
- you make an application under section 23 of the *Therapeutic Goods Act 1989* (the Act) for the registration of the medicine.

If you submit a section 23 registration application which passes preliminary assessment before the end of the 6 month period, the priority determination remains in force until:

1. you decide to withdraw the application; or
2. the application for registration lapses in accordance with subsection 24(2) of the Act; or
3. you inform us in writing that you wish to have the priority determination treated as having been refused; or
4. a decision on the registration application is made (i.e. it is 'finally determined').

Please note that the above does not prevent the TGA from converting the submission from priority to standard during the registration process as a result of the exit criteria being triggered.

Revocation of priority determination

The TGA reserves the right to revoke a priority determination (subregulation 16T of the Regulations) if:

- we have not received an application for registration under section 23 of the Act; OR
- an application for registration has been received but the application does not pass preliminary assessment; AND
- TGA is satisfied that the medicine no longer meets the eligibility criteria for priority review.

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

If TGA decides to revoke your priority determination, you will be advised of the decision and the reasons for the decision in writing as soon as practicable.

Decisions regarding revocation of priority determination are appealable under regulation 48 of the Regulations by the **applicant only**.

No extensions of priority determination

Priority determinations cannot be extended. If you wish to use the priority pathway and your priority determination is no longer in force, you must submit a new determination application and pay another determination fee (if applicable).

Re-applying for priority determination

We will re-assess the new determination application against the eligibility criteria, as some aspects such as 'comparison against existing therapeutic goods' may have changed since the first assessment of your priority determination application.

You will be required to provide the reference number/s for previous determination applications in your new application for determination.

If you require further assistance regarding the determination process

If you have read the guidance and still need our assistance, contact AET.Application.Entry.Team@health.gov.au.

Submitting your application for registration

You will have six months from the date we notify you of our decision to grant a priority determination to submit an application for registration of the medicine under section 23 of the Act. The section 23 application is considered to be made at the time the application is received by TGA in an approved form or manner and accompanied by specified information (the dossier). The priority determination must be in force on the date the section 23 application is made for the benefits of determination to apply.

We encourage you to provide your submission for registration on the date you specified in the determination application form. Applications for priority registration must be provided in eCTD format and must use the PPF-only pre-submission process.

Please notify us as soon as possible at AET.Application.Entry.Team@health.gov.au if it comes to your attention that the date of your submission for registration is likely to vary from the date specified on your determination application form.

Guidance on submitting your Pre-submission Planning Form (PPF) and the priority registration process can be found on the TGA website.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Prescription Medicines Authorisation Branch	01/07/2017
V1.1	Update to process diagram Update to amend 'designation' to 'determination' Other editorial changes and minor text updates	Prescription Medicines Authorisation Branch	03/08/2018

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