Australian Government
Department of Health
Therapeutic Goods Administration

Priority registration process

For prescription medicines with priority determination

Version 1.2, August 2018

TGA Health Safety Regulation

Contents

This guidance assists sponsors in understanding the process for submitting applications for priority registration. It outlines the key differences between the priority registration process and the standard prescription medicines registration process. Therefore this guidance should be read in conjunction with guidance on the standard prescription medicines registration process.

Introduction

The standard prescription medicines registration process consists of eight phases with eight milestones**.** The priority registration process also has eight phases but with some modifications to reduce timeframes:

- the priority registration process has greater flexibility between phases. Milestones are dynamic which allows the application to progress to the next phase more quickly
- you will receive rolling questions during the evaluation phase. If you are able to respond to all rolling questions by the end of the first round of evaluation, then a stop clock will not be applied and the evaluation can proceed to the next phase
- there are more flexible arrangements for accessing expert advice

As per the standard prescription medicines registration process, we will provide you with updates to the evaluation plan as needed to reflect any changes in timeframes.

Priority registration process

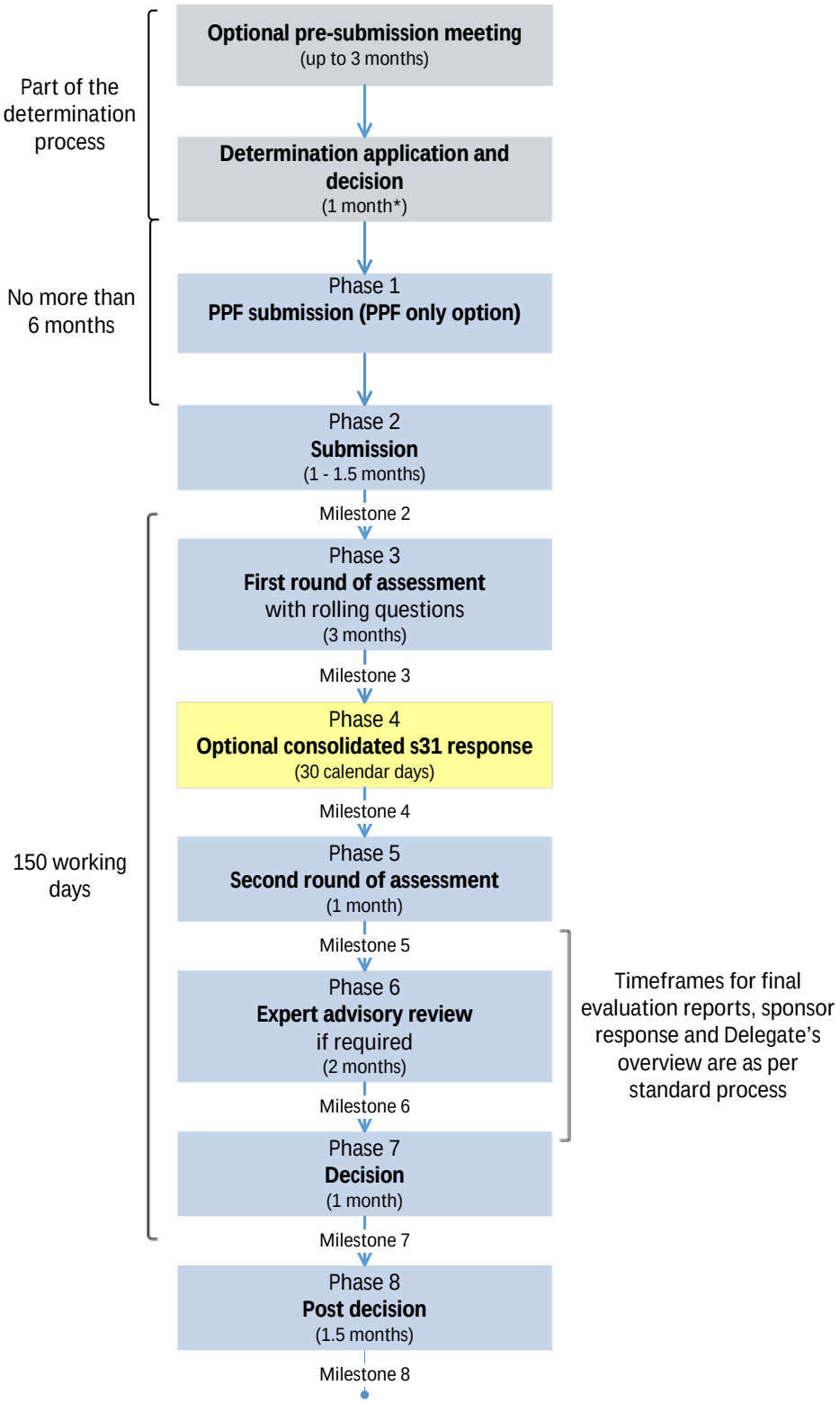
Internal business practice (milestone process) for the standard registration process aims to process submissions within a target timeframe of **220 working days.** The priority registration process is designed with a target timeframe of **150 working days.**

The timeframe is calculated from acceptance for evaluation through to the delegate's decision.

You are responsible for providing TGA with all necessary information in a timely manner. If you cannot meet this requirement, we may convert the submission to the standard prescription medicines registration process (see 'Exit criteria' for more information).

Priority registration process diagram

Note: the timeframes in the diagram below represent maximum timeframes for each phase of the process as a guideline only. Not all steps may be necessary for every priority review submission for registration.



*Note: The determination assessment and decision making process has a **target** timeframe of 20 working days

Eligibility for priority registration

Before you lodge your submission for registration using the priority registration process, you will need to:

- ensure that a priority determination is in force for the medicine at the time of making a section 23 registration application. The registration application is 'made' when it is submitted using the approved form or manner and is accompanied by specified information (the dossier). The determination will cease to be in force six months from the date we notify you of our decision to make the priority determination, unless the determination is revoked or a section 23 application is made.

- inform us of any material changes that may mean that the criteria for priority determination are no longer met, or that the section 23 registration application will not be made while the determination is in force. We will assess this information and advise whether the determination should be revoked on the basis of this or any other information.

If you submit a registration application without a valid priority determination, your registration application will be treated as a standard application and will be processed according to the standard registration process timeframe.

Priority determination must be in force

Priority determinations cannot be extended. If you wish to reapply for a priority determination that has ceased to be in force, you must submit a new priority determination application and pay the applicable fee.

If you do not intend to re-apply for priority determination, you may apply for registration via the standard prescription medicines registration process (including the PPF-only option).

Application and evaluation fees

Application and evaluation fees are higher for the priority registration process than the standard prescription medicines registration process. The fee amounts are published at the fees and payments section of the TGA website (and Schedule 9 of the *Therapeutic Goods Regulations 1990* (the Regulations).

The processes for invoicing and payment of these fees are the same as in the standard prescription medicines registration process.

Fee waivers for medicines with a valid orphan drug designation apply to the application and evaluation fees for the priority registration process, provided that the priority therapeutic indication is identical to, or a subset of, the orphan indication.

Exit criteria from the priority pathway

Exit criteria have been established to define circumstances that may affect your priority registration application. These exit criteria may be triggered at any time during the registration process and may result in TGA converting the application from the priority registration process to the standard prescription medicines registration process (after assessment of the relevant circumstances).

Exit criteria are:

- failure to respond to our requests for additional information as part of a formal S31 request within 30 calendar days; OR

- identification of significant safety concerns that require further assessment (noting that the assessment of safety in the priority pathway will not be any less robust than for the standard prescription medicines registration pathway); OR
- submission of unsolicited or more extensive data than what is required during evaluation (excluding the provision of new safety related data, which you must bring to our attention); OR
- you are unlikely to meet the Good Manufacturing Practice (GMP) requirements for registration (i.e. obtaining either an Australian manufacturing licence, GMP certification or GMP clearance)

If the exit criteria are triggered and a decision is made to convert the submission to the standard registration process, the priority review target timeframe of 150 working days would no longer apply.

In this situation, a mutual stop-clock would be applied and subsequent milestones in the registration process would require adjustment. As in any other situation where the scheduled milestones in the registration process change, you will be provided with an updated Evaluation Plan.

No fees are refunded when a priority registration application is converted to the standard prescription medicines registration process due to triggering of exit criteria.

Phase 1: Pre-submission Planning Form (PPF)

For priority registration submissions, this phase differs from the standard prescription medicine registration process in the following ways:

- the PPF for priority registration will use the PPF-only pre-submission phase option (the PPF-only option). You will be required to fill in the sections relevant to active priority determinations when submitting the PPF via the pre-submission form in TGA Business Services
- processing of your PPF will commence when it is received. This is different from the standard prescription medicine registration PPF-only process where the PPFs are processed on the first day of each month and allows us to prioritise your submission
- in the PPF you will commit to a 30-day stop-clock for the section 31 response as part of the Priority review registration pathway. This is different to the standard registration process where you can nominate either 30 or 60 calendar days to prepare your response

As in the PPF-only process, there will be no formal Milestone 1. You should proceed to lodge your entire submission for registration as soon as the complete submission number is visible in the TGA Business Services portal (eBS). This will occur once TGA has added the relevant stream number based on your proposed indication (i.e. 'PM-yyyy-xxxxx-z-stream number').

Please contact the TGA application entry team at AET.Application.Entry.Team@health.gov.au for assistance if you have any difficulties or questions regarding your submission.

Phase 2: Submission phase

Advise the TGA application entry team on (AET.Application.Entry.Team@health.gov.au) as soon as possible of any changes to the planned lodgment date for your submission for registration (which you previously provided in the determination application form). This assists us to allocate the required resources so that validation and evaluation processes can begin as soon as possible after we receive your submission for registration.

You can submit your dossier **at any time** after lodging your application. Unlike the standard pathway, priority submissions will not be batched on a monthly basis.

Lodgement of your submission for registration

The submission phase is the same as in the standard prescription medicine registration process except for the following:

- your priority registration submission must be in the eCTD format
- you must include a copy of the 'priority determination notification letter' in Module 1.5.2 of the submission to allow these details to be captured in eCTD
- ensure that your submission supports the evidence that was presented in the determination application to demonstrate that you continue to meet the eligibility criteria for priority determination
- ensure that you have provided evidence of GMP for all manufacturing sites relevant to your priority submission. 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.

Evidence of GMP is required to be eligible for priority review and we will consider whether you have met this requirement during the preliminary assessment of your submission.

We will evaluate if your submission passes preliminary assessment within the statutory time frame of 40 working days (subregulation 16B(2)) of the Regulations).

Evaluation plan

We will provide you with notification of our acceptance of the submission in a notification letter at Milestone 2 as per the standard prescription medicines registration process if your submission passes preliminary assessment. The Milestone 2 letter contains an evaluation plan with estimated dates, however there are no formal milestones for the priority registration process other than the Milestone 2 date (start of the TGA clock) and the Milestone 7 date (decision and end of the TGA clock).

The Milestone 3–7 dates in the evaluation plan are only indicative dates for evaluation timeframes. There are no formal Milestone 3, 4 or 5 dates for priority submissions. The Milestone 7 date in the evaluation plan assumes that there will be a 30 day stop-clock for responding to Section 31 questions. The Milestone 7 date may therefore change depending on the actual evaluation timeframes.

Please note that as per the usual process, the evaluation plan will be subject to change during the registration process and you should always refer to the most recent letter for up-to-date timeframes.

The evaluation phase will commence as soon as possible after the submission for registration has been accepted for evaluation.

The evaluation clock will commence once you have been notified that the submission for registration has been accepted for evaluation.

Applications without priority determination

In order to use the priority registration pathway, all applications in your submission must have a priority determination. Any related applications that do not have priority determination (either because they are ineligible or because you did not apply for determination) must be lodged separately via the standard prescription medicines registration process.

If your registration submission includes both priority and standard applications, it will be considered to be a submission under the standard pathway and you will not be eligible for priority review.

Partner medicines

For 'partner medicines' (i.e. medicines that are used in combination but are not fixed-dose combinations), you will need to submit separate registration applications for each medicine using the appropriate application type. Any applications submitted for priority registration must have a valid priority determination.

Good Manufacturing Practice (GMP) requirements

At the time of lodging a submission for priority registration you will need to:

- provide details of existing Australian manufacturing licences, overseas GMP certification or GMP clearances for all manufacturing sites relevant to the priority registration submission; OR
- provide evidence that you have applied to obtain either an Australian manufacturing license, GMP certification, or GMP clearance as appropriate for all manufacturing sites.

It is your responsibility to follow up on lodged GMP applications and ensure all requirements are met before the registration decision (Milestone 7). If we determine that you are unlikely to meet GMP requirements for registration by Milestone 7, exit criteria will be triggered and your submission will be converted to the standard pathway.

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

Batch release testing of biological medicines

All biological medicines are risk assessed and then assigned to different level of batch release on the basis of that risk as summarised in the guideline Testing of biological medicines.

For biological medicines in the priority registration process, the batch release testing process will be initiated with TGA Laboratories branch following acceptance of the submission for evaluation. This will avoid situations where ongoing laboratory testing may later cause delays at Milestone 8 (Post-decision phase).

Phase 3: First round assessment

This phase is the same as for the standard prescription medicines registration process except for the following:

The duration of this phase will be approximately three months, whereas five months is allowed for the standard prescription medicine registration process.

Rolling questions

You will receive questions throughout the evaluation period (referred to as 'rolling questions') as soon as the evaluators have questions arising from their assessments. Given the nature of the evaluation process, it is not possible to predict in advance when questions will be asked during the period of the first round assessment.

TGA will continue to progress the evaluation while you prepare your responses to rolling questions. We will not link these rolling questions to a stop clock unless there are exceptional circumstances requiring us to do so.

Responding to rolling questions

You are required to provide your responses to rolling questions to us in a timely manner. The usual timeframe for responses is 14 calendar days **and will not exceed 30 calendar days**.

If you require additional time to provide a response, please contact streamlined submissions at streamlinedsubmission@health.gov.au.

Your responses to rolling questions must be submitted as validated eCTD sequences of the dossier to esubmissions@health.gov.au and streamlinedsubmission@health.gov.au. We will not evaluate responses provided to us in PDF format via email, except for Product Information (PI) negotiations.

You may provide us with a consolidated response (new eCTD sequence) to multiple requests for answers to rolling questions if the due dates are close.

Evaluation reports

In contrast to the standard registration process, first round assessment reports will not be provided at the end of the first round of assessment, or with the consolidated section 31 request (if required). However, sufficient context will be provided with rolling questions and/or the consolidated section 31 request for information to assist you in providing timely responses.

Phase 4: Consolidated section 31 request response

This phase is the same as for the standard prescription medicine registration process except for the following:

Section 31 request for information

Any rolling questions identified two weeks prior to completion of phase 3 (Milestone 3) and/or any unanswered questions will be summarised into a consolidated section 31 request and will result in a 30-day stop clock to allow you to prepare the response. If you do not respond within the 30-day stop clock, your submission will be transitioned to the standard prescription medicines registration pathway as outlined in the Priority exit criteria.

If there are no outstanding questions at this stage, no section 31 stop clock will occur and the submission will immediately proceed to the next phase (i.e. both phases of evaluation will be combined and the entire evaluation may be completed within four months).

Phase 5: Second round assessment

This phase is the same as for the standard prescription medicine registration process.

When the evaluation is complete, you will receive the final evaluation report that includes consideration of your responses to the section 31 questions.

You will have at least two weeks after receipt of the final evaluation report to notify us of any errors of fact or major omissions in the report. If you choose to provide a response, this must be submitted as a validated eCTD sequence of the dossier.

Phase 6: Expert advisory review

This phase is the same as for the standard prescription medicine registration process except for the following:

- the date on which your submission will reach this phase is subject to change as a consequence of the duration of the evaluation phase and whether a section 31 stop clock is required or not. You will be provided with updates to your Evaluation Plan during the registration process as required.
- the priority pathway allows for flexibility in the expert advisory review phase. All submissions are initially scheduled to be considered by the Advisory Committee on Medicines (ACM) or Advisory Committee on Vaccines (ACV), although committee advice will not always be required. In order to meet timeframes for the priority review process, the submission may be considered either at a scheduled Committee meeting or out of session.
- we may also seek expert advice other than through ACM or ACV.

The evaluation process involves assessments of different aspects of the dossier which may in some cases occur in parallel or sequentially. The delegate may seek independent advice in relation to the application. If this occurs, it may not be possible to change dates even where a milestone has been reached earlier than expected.

Regardless of the administrative mechanism for obtaining expert advice, the timeframes and procedures for exchange of information between you and TGA during this phase are the same as for the standard prescription medicines registration process.

As in the standard registration process, you will receive a copy of the delegate's overview of the submission.

Phase 7: Decision

This phase is the same as for the standard prescription medicine registration process.

Phase 8: Post-decision

This phase is the same as for the standard prescription medicine registration process.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Prescription Medicines Authorisation Branch	01/07/2017
V1.1	Minor corrections	Prescription Medicines Authorisation Branch	07/07/2017
V1.2	Change designation to determination Clarification of GMP requirements Insert new priority registration process diagram Other minor corrections	Prescription Medicines Authorisation Branch	02/08/2018

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