



Australian Government  
Department of Health  
Therapeutic Goods Administration

# Questions and answers about the prescription medicines registration process for Category 1 and 2 applications (other than for only additional trade names)

## Prescription medicines registration process questions and answers

Version 1.3, August 2014

**TGA** Health Safety  
Regulation



# About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <<https://www.tga.gov.au>>.

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## Version history

<b>Version</b>	<b>Description of change</b>	<b>Author</b>	<b>Effective date</b>
V1.0	Original publication	OPM	2010
V1.1	Inclusion of new questions	OPM	01/01/2011
V1.2	Inclusion of new questions	OMA	24/01/2012
V1.3	Revisions to align with process refinements, inclusion of new questions	OMA	22/08/2014

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## What updates have been made to information on the prescription medicine registration process?

On 3 June 2013, the TGA rolled out a series of updates to information on the prescription medicine registration process for Category 1 and Category 2 applications (formerly known as the Streamlined Submission Process) other than applications only for additional trade names. These updates:

- remove reference to 'transitional' processes, 'draft' documents and other superseded information
- describe the TGA's ongoing business practices in relation to applications to register prescription medicines
- present the information in a web-friendly format to make it easier for sponsors to search and navigate the prescription medicines registration process requirements
- describe recent refinements to the prescription medicine registration process. Note that these refinements relate to the registration process, rather than requirements
- can be accessed from the TGA website pages on [Prescription medicines](#).

## What updates have been made to the Australian Regulatory Guidelines for Prescription Medicines (ARGPM)?

The [ARGPM](#) is being progressively replaced with a collection of webpage guidance on the administrative and technical requirements for applications to register a new prescription medicine or to vary the details of a registered prescription medicine.

Updates to the administrative parts of the ARGPM have been completed with the roll-out on 3 June 2013 of updated key documents on the prescription medicines registration process (see [What are the key requirements and main documents of the prescription medicine registration process?](#) below).

The technical aspects (appendices) of the ARGPM have been replaced as part of a progressive roll-out which was completed in July 2014.

Subscribe to updates on the [ARGPM](#) page to receive email alerts about updates to TGA guidance.

## About the prescription medicine registration processes

The prescription medicine registration process described here applies to Category 1 and Category 2 applications to register a new prescription medicine or to make changes to an already registered medicine that involve clinical, nonclinical or bioequivalence data. It does not apply to Category 1 applications to register additional trade names. See also [Which application types are not included in the prescription medicine registration process described here?](#)

- [What are the key features of the prescription medicine registration process?](#)
- [Which application types are included in the prescription medicine registration process?](#)

- [Which application types are not included in the prescription medicine registration process described here?](#)
- [What are the key requirements and main documents of the prescription medicine registration process?](#)
- [Who will I contact at the TGA with queries about my pre-submission or application?](#)

## What are the key features of the prescription medicine registration process?

The prescription medicine registration process consists of eight phases with eight milestones. Each phase has established time periods within an overall evaluation plan. The evaluation plan is specified in the Planning Letter issued by the TGA and any revisions as a result of changes to milestones dates are set out in subsequent TGA correspondence at milestones 2, 3 or 5. This process is managed by the TGA to ensure timeframes are met and complete documentation is provided. For further information see [Prescription medicine registration process](#).

Activity	Description
Pre-submission (Milestone 1)	Applicants are required to provide planning data at the pre-submission phase, in accordance with the requirements of the <a href="#">Pre-submission Planning Form</a> (PPF). This data provides TGA with the necessary level of understanding of the proposed application to enable effective resource planning (see also <a href="#">Information for applicants completing a pre-submission planning form</a> ).
Application lodgement	Applicants must lodge well-planned, high quality, complete dossiers in accordance with requirements described in <a href="#">Mandatory requirements for an effective application</a> , <a href="#">General dossier requirements for prescription medicines</a> and other applicable documents. See <a href="#">What are the key requirements and main documents of the prescription medicine registration process?</a>
Application (Milestone 2)	Applications must meet the TGA requirements for format and content. For further information see: <ul style="list-style-type: none"> <li>· <a href="#">Section 23</a> and <a href="#">Section 9D</a> instruments</li> <li>· <a href="#">What are the key requirements and main documents of the prescription medicine registration process?</a></li> </ul>
First round assessment (Milestone 3)	Applicants will be provided with the first round assessment reports at milestone 3, either four (applications for generics) or five (all other applications) months after the commencement of the evaluation phase. Applicants may notify TGA of any perceived errors of fact or major omissions in the reports within 14 calendar days if there is no request for information at Milestone 3 or at the same time as the response to the consolidated set of questions is submitted if there is a request for information at Milestone 3.

Activity	Description
Consolidated set of questions for applicants (Milestone 3)	A consolidated s. 31 request for information is sent to applicants at the same time as the first round assessment reports are provided (ie, at milestone 3).
Consolidated response to questions (Milestone 4)	Applicants must respond to the request within the timeframe (30 or 60 calendar days) nominated in the PPF.
Second round assessment reports (Milestone 5)	<p>Second round assessment reports that take into account responses to s. 31 questions are issued to applicants:</p> <ul style="list-style-type: none"> <li>• one month after the s. 31 response is received (applications other than generics <b>not referred</b> to the Advisory Committee on Prescription Medicines (ACPM));</li> <li>• two months after the s. 31 response is received (generic applications that are <b>not referred</b> to ACPM); or</li> <li>• at the same time as the Delegate's Request for ACPM advice is sent (applications <b>referred</b> to the ACPM).</li> </ul> <p>Notification of errors or omissions in assessment reports may be provided by applicants within 14 calendar days (applications <b>not referred</b> for ACPM advice) or at the same time the response to the Delegate's Request for ACPM advice is submitted (applications <b>referred</b> for ACPM advice).</p>
Advisory committee (Milestone 6)	Delegates may seek the advice of the ACPM. Meeting outcomes are issued.
Delegate's decision (Milestone 7)	<p>For applications referred to the ACPM for advice: the applicant will be notified of the decision 6 weeks after the ACPM meeting.</p> <p>For generic medicine applications: the applicant will be notified of the decision 6 weeks after the second round assessment reports are sent to the applicant.</p> <p>For other applications: the applicant will be notified of the decision by the date indicated in the evaluation plan.</p>
No additional data or supplementary data	<p>The documentation presented at submission is taken as the complete application. There is no further opportunity to deliver new data, with the exception of data relating to new safety signals or in response to specific TGA requests for data.</p> <p>Any new data, for example, to extend the shelf-life must be lodged as a separate application post-approval.</p>

Activity	Description
Single point of contact	Case managers in the Evaluation Management Section are responsible for all administrative aspects of an application from the time the PPF is received. Case managers can be contacted via email to: <a href="mailto:streamlinedsubmission@tga.gov.au">streamlinedsubmission@tga.gov.au</a>

## Which application types are included in the prescription medicine registration process?

The prescription medicine registration process described here applies to applications to register a new prescription medicine, or to make changes to an already registered medicine that involves clinical, nonclinical or bioequivalence data.

For the following applications, a [Pre-submission planning form](#) (PPF) is required and must be lodged and reviewed by TGA prior to the application being lodged:

### Category 1 applications, including:

- new chemical entities
- new biological entities
- similar biological medicinal products
- new combination products
- extension of indications
- major variations
- minor variations requiring evaluation of bioequivalence, clinical or nonclinical data
- new generics
- changes to product information requiring evaluation of bioequivalence, clinical or nonclinical data, other than 'safety-related' requests.

### Category 2 applications

- These applications must be supported by previous approvals and independent evaluation reports from two acceptable countries. More information on Category 2 applications and how to prepare overseas evaluation reports for these is located in the CTD Module 1 information on [Overseas evaluation reports](#).

## Which application types are not included in the prescription medicine registration process described here?

The prescription medicines registration process described here does not apply to the following:

- Category 1 applications involving only additional trade name(s)
- Category 3 applications, which, according to TGA requirements, do not need to be supported by clinical, nonclinical or bioequivalence data

For enquiries about the above application types, applicants should contact the [AET.Application.Entry.Team@tga.gov.au](mailto:AET.Application.Entry.Team@tga.gov.au).

- Applications to make minor variations to registered prescription medicines involving:
  - corrections to the ARTG entry
  - 'safety-related' requests
  - minor editorial changes to the Product Information (PI)
  - 'self-assessable' requests
  - other Category 3 changes.

For information about the above application types, applicants should refer to [Minor variations to prescription medicines](#).

## What are the key requirements and main documents of the prescription medicine registration process?

A [Pre-submission planning form](#) must be lodged.

Details of requirements that must be met in the PPF and information to assist applicants fill out and lodge the PPF are available in [Information for applicants completing a pre-submission planning form](#).

The format of the application is prescribed by legislative instruments. These instruments require that applications conform to [Common Technical Document](#) (CTD) format, including the [Administrative information and prescribing information for Australia](#) (CTD Module 1).

Details of the regulatory processes and the regulatory requirements for effective applications are described in:

- [Prescription medicines registration process](#)
- [Mandatory requirements for an effective application](#).

The contents of the dossier are determined from the applicable:

- [CTD documents](#)
- [Australian guidelines](#)
- [EU/ICH guidelines adopted in Australia](#).

Information on general requirements for dossiers, including number of copies and physical specifications is found in the [General dossier requirements for prescription medicines](#).

Important information is also provided as necessary on the TGA website.

## Who will I contact at the TGA with queries about my pre-submission or application?

The prescription medicine registration process for Category 1 and 2 applications (other than for only additional trade names) involves dedicated TGA resources (case managers) allocated to manage each application through the evaluation phases. For all queries, there will be a single contact point to manage all aspects of the current or planned application.

All correspondence should be conducted through the prescription medicine registration mailbox [streamlinedsubmission@tga.gov.au](mailto:streamlinedsubmission@tga.gov.au). Where relevant, the email should include the submission number in the subject line.

The inbox may also be used for general enquiries in relation to the registration process.

## The pre-submission planning stage

- [What do I need to do prior to preparing a PPF?](#)
- [Do I need to have a pre-submission meeting with the TGA?](#)
- [What is a robust scientific justification?](#)
- [How do I obtain approval to lodge an application for a fixed combination product?](#)
- [Do I need to confirm my proposed trade name\(s\) before lodging my pre-submission planning form?](#)
- [How can I ensure that my proposed trade name\(s\) are appropriate?](#)

## What do I need to do prior to preparing a PPF?

Prior to preparing a PPF applicants must ensure that:

- the application will meet all relevant guidelines or appropriate justification(s) will be provided where guidelines have not been met
- where a justification is necessary, a [robust scientific justification](#), addressing all issues, is provided
- the application will meet all the relevant requirements listed in the [Mandatory requirements for an effective application](#)
- GMP licence or clearance requirements as outlined in [CTD Module 1.7](#) are met for all manufacturers and finished product testing facilities involved in the active ingredient and product
- where applicable, the following have been lodged with the TGA prior to PPF lodgement and the relevant advice has been received from the TGA:
  - a [notification of a proprietary ingredient](#) for each new proprietary ingredient
  - an [application form](#) to propose a new chemical name (AAN), biological name (ABN), and or herbal name (AHN) for each new non-proprietary ingredient
  - request for orphan drug designation
  - request for submission as a literature based submission
  - justification for fixed combination

More information on the requirements listed above can be found in [Section 4](#) of the Prescription medicines registration process.

## Do I need to have a pre-submission meeting with the TGA?

A pre-submission meeting is not a requirement, however, a pre-submission meeting between TGA Delegates and applicants who intend to submit an application to the OMA is recommended in certain cases, including:

- Similar biological medicinal products
- Orphan drug applications
- Literature based submissions
- Fixed combination submissions

Guidelines for meetings with the TGA are provided in Guidance 5 of the ARGPM: [Pre-submission meetings with TGA](#).

## What is a robust scientific justification?

A robust scientific justification will:

- clearly identify the standard or guideline or part of the standard or guideline that is not being met
- specifically address why the standard or guideline is not being met
- have a contemporary scientific basis
- include citations to the relevant reference documents, including TGA documents where appropriate
- address all issues if a guideline includes a proforma or identifies a minimum list of issues that must be included in a justification.

If references to studies or the scientific literature are included in a justification, copies of the references must be included in the dossier. Studies previously submitted to the TGA may be included as a reference to the application which included those studies (cite the previous application number and location of the studies in the previous dossier).

The TGA will determine if sufficient scientific justification is provided for not meeting a particular standard or guideline.

## How do I obtain approval to lodge an application for a fixed combination product?

Applicants must write to the TGA justifying the particular combination and the type and extent of data to be submitted. The request must identify the relevant clinical evaluation unit and be emailed to [streamlinedsubmission@tga.gov.au](mailto:streamlinedsubmission@tga.gov.au).

The justification must be lodged with the TGA for consideration well in advance of the lodgement of a PPF.

The justification should focus on the issues outlined in parts 5 and 6 of the *Guideline on clinical development of fixed combination medicinal products* (CPMP/EWP/240/95 Rev 1). Applicants will be advised in writing if the fixed dose combination is acceptable for review. This advice must be received before the PPF can be lodged. This written advice must be attached to the PPF.

Further information can be found in TGA guidance for [Fixed combination prescription medicines](#).

Where the TGA considers that the fixed dose combination is not acceptable for review, the PPF should not be lodged. The applicant will be advised of the reasons in writing, which may be used as a basis for further discussion with the TGA.

## **Do I need to confirm my proposed trade name(s) before lodging my pre-submission planning form?**

No. Where a proposed trade name(s) has not yet been confirmed, this should be indicated in the 'Further information' field in section 2.3 of the PPF.

However, the PPF must indicate the total number of trade names that are to be included in the application. Note that it is not possible to increase the total number of trade names after the PPF has been submitted as this increases the scope of the submission. (see also [Can I lodge more data in support of my application once the application has been lodged?](#))

Proposed trade name(s) must be confirmed before lodging the application so that appropriate labels, product information documents and consumer medicine information documents can be included in the dossier (see also [Can I change a trade name during the evaluation process?](#)).

## **How can I ensure that my proposed trade name(s) are appropriate?**

The TGA requires applicants to include proposed trade names in their dossiers, and if available at the time, on the PPF.

The TGA strongly advises that prior to lodging a PPF or dossier, applicants:

- perform a search on the public [ARTG](#) view to confirm the proposed trade name is not already registered
- perform a search on the public ARTG view to confirm the proposed trade name is not similar to a trade name(s) already registered, for example, to ensure it does not look-like or sound-like an existing trade name
- assess the proposed trade name against section 12 of the [Best practice guideline on prescription medicine labelling, CTD Module 1.5.4](#) and other applicable guidelines
- prepare (but do not submit unless requested) at least one alternative name for each product should the TGA evaluation identify issues with the proposed trade name(s).

This procedure is recommended for all proposed trade names, irrespective of whether they have been approved elsewhere in the world.

This procedure is expected to provide applicants with a level of confidence, but will not guarantee the acceptance of the proposed trade name. The TGA will evaluate the proposed trade name during the assessment phases.

## Pre-submission planning form (PPF)

- [Which applications require a PPF?](#)
- [How do I fill out and lodge a PPF?](#)
- [How far in advance of lodging an application can the PPF be lodged?](#)
- [What are the Module 2 requirements?](#)
- [The PPF states that I need to attach Module 2.n or equivalent. What does 'equivalent' mean?](#)
- [How do I submit details of drug and plasma master files?](#)
- [Who will assess my PPF?](#)
- [When will a PPF be considered 'not effective'?](#)

### Which applications require a PPF?

The prescription medicine registration process described here applies to applications to register a new prescription medicine or to make changes to an already registered medicine that involve clinical, nonclinical or bioequivalence data. (See [Which application types are included in the prescription medicine registration process?](#))

Applicants must ensure they are always using the current version of the [PPF](#). TGA's preference is for the Word version of the PPF to be used.

### How do I fill out and lodge a PPF?

Information to assist applicants filling out a PPF is found in [Information for applicants completing a pre-submission planning form](#).

The lodgement of the PPF is a two-step process:

- electronically complete the [PPF](#) available on the TGA website
- submit the PPF and the associated supporting data using the pre-submission facility in the [TGA eBusiness Services \(eBS\)](#) online services website.

The PPF must only be lodged via eBS.

A printout of the eBS lodgement details must be provided in Module 1.2.2 of the dossier when it is lodged. (Refer to [CTD Module 1](#) Administrative information and prescribing information for Australia document for more information.)

### How far in advance of lodging an application can the PPF be lodged?

A PPF must be lodged at least 2¼ months prior to lodgement of the dossier, allowing the TGA to identify milestone dates and plan resource requirements. For specific times and further information see the [Prescription medicines registration process](#).

## What are the Module 2 requirements?

Module 2 summarises the information that will be provided in the quality (Module 3), nonclinical (Module 4) and clinical (Module 5) modules of the dossier. Information on the requirements for Module 2 summaries, and on the sections of Module 2 that may be required for each application type can be found at:

- [Module 2 Common Technical Document Summaries](#)
- [Module 2 \(Summaries Module\)](#)
- [Information about the experts](#)

## The PPF states that I need to attach Module 2.n or equivalent. What does 'equivalent' mean?

An 'equivalent' document is one that:

- may be in either draft or final version (see below)
- contains all of the information specified in the relevant subsection of Module 2
- does not need to be in the format or structure specified by the relevant subsection of Module 2.

The TGA considers a 'draft' version of a document is a document that has been through the applicant's standard scientific quality assurance.

For example, an applicant's internal document used for the initial consideration of the viability of a new chemical entity product that provides all of the information required by Modules 2.3.S, 2.3.P, 2.4, 2.6.2, 2.6.4, 2.6.6, 2.5, 2.7.1, 2.7.2, 2.7.3 and 2.7.4 but is presented in a different structure would be acceptable for attachment to the PPF.

If an applicant chooses to adopt this approach for the Quality Overall Summary particular attention should be paid to ensuring relevant justifications are included in the document.

## How do I submit details of drug and plasma master files?

Applicants should note that the Drug substance master file (DMF) or Plasma master file (PMF) constitutes an integral part of the dossier and must be accurately identified in the PPF.

If the PPF indicates that the application will be making a reference to a DMF or PMF then it is a TGA requirement that the DMF or PMF number is provided in Section 1.6 of the PPF, and the DMF or PMF is supplied to the TGA in hard copy and electronically.

**Note:** It is the applicant's responsibility to ensure that the DMF or PMF arrive at the TGA at approximately the same time as the dossier, and that any subsequent information requested by the TGA in relation to the DMP or PMF, such as responses to s. 31 questions, are also provided by the due date.

For more information on DMF or PMF requirements see:

- [Appendix A](#) of the Mandatory requirements for an effective application
- [Module 1.6](#) of CTD Module 1 Administrative information and prescribing information for Australia

- Guidance 11 of the ARGPM: [Drug Master Files and Certificates of Suitability of a Monograph of the European Pharmacopoeia for drug substances](#).

## Who will assess my PPF?

The PPF contains administrative and technical information that provides TGA with the necessary level of understanding of the proposed application to enable effective resource planning. The Application Entry Team in TGA confirms the accuracy of various administrative details.

The PPF is assessed by senior technical staff in the appropriate areas of TGA (such as the clinical, nonclinical and quality areas) to determine if aspects of the application comply, or are likely to comply, with requirements outlined in:

- [Mandatory requirements for an effective application](#)
- [Australian guidelines](#)
- [EU/ICH guidelines adopted in Australia](#).

Following the technical review, the Case Management team conducts an overall review to determine whether or not the PPF is effective and will advise the applicant of the outcome.

For more information on how TGA assesses the information in a PPF, see the section on 'What will TGA do with this information' in the [Information for applicants completing a pre-submission planning form](#).

## When will a PPF be considered 'not effective'?

The PPF will be considered 'not effective' if:

- it is not fully completed or it contains wrong or incomplete information about key requirements (see [Information for applicants completing a pre-submission planning form](#))
- the necessary information (for example, Module 2 or equivalent) is not provided as attachments to allow the scope of the application to be assessed
- the PPF and supporting information do not meet relevant legislative requirements or key technical requirements (see [What are the key requirements and main documents of the prescription medicine registration process?](#)).

Please note: to the extent that the PPF is a reflection of the dossier to be submitted, [Mandatory requirements for an effective application](#) apply equally to the PPF.

If the PPF is 'not effective', the TGA will issue a letter outlining the reasons why it was 'not effective'.

## The TGA planning letter

- [What is a TGA planning letter and when will I receive it?](#)
- [How will I know the milestone dates?](#)
- [Can these milestone dates be varied?](#)

- [Can I change any details about the application after I have received my planning letter from the TGA?](#)

## What is a TGA planning letter and when will I receive it?

A TGA Planning Letter is sent to applicants within six weeks of the TGA processing a complete, effective PPF. This letter provides the date by which the application, including full dossier, must be lodged and the target dates for key milestones (the evaluation plan).

## How will I know the milestone dates?

The TGA Planning Letter is issued at milestone 1 and contains target dates for all key milestones, such as the release of the consolidated set of s. 31 questions.

Applicants will be issued an updated evaluation plan if there are changes to milestone dates after the application is accepted for evaluation.

The prescription medicine registration process, including milestone definitions and time periods between milestones, is described in the [Prescription medicine registration process](#).

Applicants should note that when a milestone date falls on a weekend or public holiday, the effective milestone date is the next working day.

## Can these milestone dates be varied?

Under the prescription medicine registration process, milestone dates are indicative only. There are many scenarios that impact on the final milestone dates that the TGA provides in the Planning Letter for a particular application.

The Planning Letter indicates the TGA has considered the information provided in the PPF, planned the evaluation and committed the appropriate resources. The TGA will notify applicants if change is required to a milestone date.

Applicants should note that changes to one milestone date may impact on the due dates for subsequent milestones.

## Can I change any details about the application after I have received my planning letter from the TGA?

The scope of an application can be reduced after a Planning Letter is issued, but it cannot be increased because the TGA uses information provided in the PPF to plan the evaluation of the application and to determine required resources.

For example, if a PPF identifies four proposed indications for registration and the applicant decides that they do not wish to proceed with one of the indications, this is acceptable as the scope of the application is reduced.

If an applicant decides that they want to add a new indication, this is not acceptable as it increases the scope of the application.

An increase in the number of trade names from that identified on the PPF is also an increase in the scope of the application and will not be accepted.

## Application lodgement

- [When does the application need to be lodged?](#)
- [Is there a penalty if I don't lodge the application by the lodgement date?](#)
- [What are the TGA requirements for paper and electronic copies of documents?](#)
- [How should an electronic copy of the dossier be constructed?](#)
- [There are some differences between the information provided in my PPF and the application. What do I do?](#)
- [How will I know if my application has been accepted for evaluation?](#)
- [What will happen if my application is considered 'not effective'?](#)
- [Do I need to provide a new dossier if I re-submit an application that was previously withdrawn or found 'not effective'?](#)

### When does the application need to be lodged?

The TGA Planning Letter will include the date by which the full dossier must be lodged. The application can be lodged anytime between the receipt of the TGA Planning Letter and the required date for lodgement identified in the letter, usually the 7th or 14th day of the month following receipt of the Planning Letter.

Applications for new chemical entities, new combinations, and extensions of indications must be received at TGA by close of business on the 7th day of the month following the issue of the Planning Letter (or the next working day if that day falls on a weekend or public holiday). All other prescription medicine registration applications must be received by close of business on the 14th day of the month (or the next working day if that day falls on a weekend or public holiday).

### Is there a penalty if I don't lodge the application by the lodgement date?

If an application is not lodged by the lodgement date specified in the Planning Letter, it will be found 'not effective' and TGA will reassign the resources which had been allocated to evaluate the application.

Applicants will need to submit a new PPF and pay a new application fee if they wish to pursue the registration process.

### What are the TGA requirements for paper and electronic copies of documents?

The prescribed format, physical aspects, and number of copies required for paper and electronic documents are specified in the General dossier requirements for prescription medicines.

TGA requires paper and electronic documents to be submitted as follows:

Activity	Paper	Electronic	
		On line	CD or DVD
Lodging a PPF		✓ <sup>1</sup>	
Dossier	✓		✓
Individual patient data (if provided at submission)			✓
Responses to first round assessment reports and consolidated s. 31 questions	✓		✓
Responses to second round assessment reports		✓ <sup>2</sup>	

1. via [eBS](#) online services website

2. email to [streamlinedsubmission@tga.gov.au](mailto:streamlinedsubmission@tga.gov.au)

## How should an electronic copy of the dossier be constructed?

The electronic copy of the dossier must be prepared in non-eCTD electronic submission ([NeeS](#) format). The NeeS format for electronic dossiers is acceptable until the eCTD format can be fully implemented by TGA.

The TGA is engaged in a process which will result, in the longer term, in the phasing out of paper dossiers and the lodgement of dossiers in electronic format only.

## There are some differences between the information provided in my PPF and the application. What do I do?

The appropriate action depends on the type and extent of the differences.

Type of difference	Action
Corrections to spelling, grammar, relocation of text within an application document, minor typographical errors that do not impact on the scope or scale of the application	No action required
Changes to documents arising from TGA feedback in the Planning Letter	Changes should be summarised in Module 1.8.3* of the application
Changes that reduce the scope or scale of the application	Changes should be summarised in Module 1.8.3* of the application

**Note:** Any changes that increase the scope or scale of the application will not be accepted.

\*Module 1.8.3 should:

- be included for all applications for which a PPF has been lodged
- contain a declaration that either:
  - states that the application is consistent with the PPF lodged, or
  - lists any inconsistencies with an appropriate explanation
- identify how the applicant has addressed any issues requiring applicant action raised by the TGA in the Planning Letter.

## **How will I know if my application has been accepted for evaluation?**

If the application is considered 'effective', the TGA will issue a Notification Letter identifying the target dates for key milestones (the evaluation plan) and the evaluation fee.

## **What will happen if my application is considered 'not effective'?**

If the application is considered 'not effective', the TGA will issue a letter which will advise why the application was not accepted for evaluation.

An application will not be accepted and will therefore not be evaluated if it does not comply with all the relevant requirements as set out in [Mandatory requirements for an effective application](#), or it has not been prepared in accordance with any requirements of the Secretary under subsections 23(1) or (2) or section 9D(6) of the *Therapeutic Goods Act 1989*. In such cases the application will be deemed 'not effective' and will not be accepted for evaluation by the TGA.

If an applicant wishes to pursue the registration process, a new PPF must be lodged and new application fee paid.

Note: Once a dossier is received by the TGA it is considered to be a Commonwealth record and cannot be returned to the sender.

## **Do I need to provide a new dossier if I re-submit an application that was previously withdrawn or found 'not effective'?**

Yes. If an applicant submits an application that was previously withdrawn or found 'not effective', a new, complete dossier must be re-lodged in both paper and electronic format.

For applications previously deemed 'not effective' solely because the dossier was not lodged by the required date, a complete electronic version of the revised dossier must be lodged. The majority of the paper dossier may be re-used provided Modules 2 to 5 do not need to be updated or otherwise modified with new information. A new paper copy of Module 1 must be provided regardless.

If an applicant wishes to re-use paper copies of specific Modules of the previous dossier, this must first be discussed with, and approval sought through the relevant case manager (contacted at [streamlinedsubmission@tga.gov.au](mailto:streamlinedsubmission@tga.gov.au)). If Modules are to be re-used, the details (including the submission number of the previous application) must be identified in the PPF.

## First round assessment phase

TGA will commence the evaluation phase the day after the applicant has been notified that the application has been accepted for evaluation. Applicants will receive first round assessment reports and a consolidated list of s. 31 questions (if any) at [milestone 3](#).

- [Can I change a trade name during the evaluation process?](#)
- [Can I lodge more data in support of my application once the application has been lodged?](#)
- [Which reports will I receive at the end of the first round assessment phase?](#)
- [How will I provide a response to first round assessment reports?](#)

## Can I change a trade name during the evaluation process?

An applicant may change (but not add) a trade name at any time prior to the milestone 5 date in the evaluation plan (regardless of whether or not reports have been sent). A request to change a trade name during the evaluation process must be accompanied by:

- Revised Module 1.3.1: Australian product information and package insert
- Revised Module 1.3.2: Australian consumer medicines information
- Revised Module 1.3.4: Label mock-ups.

## Can I lodge more data in support of my application once the application has been lodged?

The documentation presented at submission lodgement will be taken as the complete application; there will be no further opportunity to deliver new data after the submission lodgement date.

In order to provide predictable timeframes and allow the TGA to effectively plan evaluation resources, no new data can be provided after the application is accepted, with the following exceptions:

- new safety data - applicants are obligated to inform the TGA as soon as new information becomes available
- the TGA has requested specific data as part of the evaluation process, whether through the s. 31 request process or otherwise.

For the purposes of the prescription medicine registration process, new safety data refers to information that might negatively influence the benefit-risk assessment of a medicinal product. Examples include, but are not limited to:

- an increase in the rate of occurrence of an 'expected,' serious adverse drug reaction which is judged to be clinically important
- a significant hazard to the patient population, such as emergent lack of efficacy with a medicinal product used in treating a life-threatening disease, or a spate of unlisted reports of an uncommon or rare but serious adverse event
- a major safety finding from a newly completed animal study (such as an increased incidence of tumours in treated animals)

- pooled analyses of clinical studies that suggest significant dose or time dependent adverse effects that were neither apparent nor available at the time of lodging the application
- safety data associated with regulatory action in the event of, or to prevent risk to public health associated with use of the product in countries where it is already registered.

Safety data in this context do not include, for example:

- studies which only confirm information previously submitted to the TGA, including extension studies of submitted nonclinical or clinical studies (i.e. the first, second and third dot points above do not apply)
- studies or other data which support the use of the medicine in accordance with the proposed recommendations but which do not identify a new unexpected adverse drug event or an increased incidence of an expected adverse drug event
- pharmaceutical data
- nonclinical studies to justify proposed impurity limits.

## **Which reports will I receive at the end of the first round assessment phase?**

Copies of the first round assessment reports prepared by the quality, nonclinical, clinical and RMP evaluators, as applicable, will be provided at milestone 3, along with a consolidated s. 31 request for information or documents, if required.

## **How will I provide a response to first round assessment reports?**

Applicants should review the first round assessment reports and advise the TGA in writing of any perceived errors of fact or major omissions. Each identified error of fact or omission must be referenced to information previously submitted (Study number and location, for example, Module 3.2.P.4.3 Method validation, p.23). It is not appropriate to submit new data to negate a perceived error of fact or major omission.

Although there is no specific limit to the size of an applicant's response to the report(s), it is expected that the response to any one report should be no more than six single sided A4 pages and in a font no smaller than 12 point.

Notification of any perceived errors of fact or major omission to the assessment reports must be submitted as Module 1.0.2 and should be submitted with, but as separate file(s) to, the response to the s. 31 request.

For those applications where there is no s. 31 request, applicants must provide notification of any perceived errors of fact or major omission by the date specified in the letter provided at milestone 3. Fourteen calendar days from TGA issuing the first round assessment reports will be allowed for this response.

The letter issued at milestone 3 will advise applicants on whether the response should be submitted in hard copy, electronic copy or both.

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## Consolidated section 31 questions

- [What are the consolidated s. 31 questions?](#)
- [How long will I have to respond to the consolidated list of questions?](#)
- [What happens to my application if there is no need to make an s. 31 request for information or documents?](#)
- [What happens if I submit a late or incomplete response to the s. 31 questions asked?](#)

### What are the consolidated s. 31 questions?

The prescription medicine registration process provides for a single request for information under s. 31 of the *Therapeutic Goods Act 1989*, which brings together questions from all the relevant evaluation areas of the TGA. The consolidated s. 31 questions will be provided by the TGA at milestone 3. The consolidated s. 31 questions will be sent at the date identified in the most recent evaluation plan allowing applicants to conduct any necessary preparation activities.

If applicants require clarification of particular questions, this should be requested in writing to [streamlinedsubmission@tga.gov.au](mailto:streamlinedsubmission@tga.gov.au).

### How long will I have to respond to the consolidated list of questions?

Applicants are required to nominate a 30 or 60 (calendar) day response period in the PPF. This will be the response period used by the TGA if the application is accepted for evaluation (s. 31(1B) of the *Therapeutic Goods Act 1989*).

### What happens to my application if there is no need to make an s. 31 request for information or documents?

It is not possible at the pre-submission phase for the TGA to determine whether a s. 31 request for information or documents will be needed, or to estimate how many questions might be contained in such a request. It will therefore be necessary for the TGA to set the milestone dates and plan the allocation of evaluation resources on the assumption that there will be a s. 31 request for documents or information requiring a response from the applicant.

First round assessment reports will be issued and applicants may be asked to provide updated documents such as Product Information and labels, as relevant, at this time.

Applicants should therefore expect that the TGA will meet the milestone dates provided in the most recent evaluation plan even if there is no s. 31 request, unless the TGA contacts the applicant to advise revised timeframes.

The remaining timeline for the application will be set out in the evaluation plan provided in TGA correspondence at this time.

## What happens if I submit a late or incomplete response to the s. 31 questions asked?

Failure to lodge a s. 31 response by the due date or failure to lodge a complete s. 31 response will not necessarily result in a rejection of the application or termination of the evaluation. Evaluation of the application may continue on its merits and where appropriate, may be approved with reduced scope and/or additional conditions of registration. Discussion of the issues with the TGA will allow applicants to make an informed decision on how to proceed in such situations.

## Second round assessment phase

TGA will assess responses to questions raised in the s. 31 letter and prepare second round evaluation reports as applicable. TGA may not evaluate any information or data provided in the response that was not specifically requested by questions raised in the s. 31 letter (other than 'safety data', see [Can I lodge more data in support of my application once the application has been lodged?](#)).

The second round reports will usually include a recommendation regarding approval or otherwise.

- [When will I receive the second round assessment reports?](#)
- [When do I provide a response to second round evaluation reports?](#)
- [What should be included in my response to second round assessment reports?](#)

## When will I receive the second round assessment reports?

Following receipt of the applicant's responses to the first round assessment reports and s. 31 questions, as applicable, the TGA will complete the second round assessment reports:

- within two months for applications for new generic medicines
- within one month for all other applications.

TGA will issue the second round assessment reports:

- at the completion of the second round assessment phase for applications not referred to the Advisory Committee on Prescription Medicines
- with the delegate's Request for ACPM advice for applications referred to the Advisory Committee on Prescription Medicines.

The evaluation phase of the prescription medicines registration process concludes when second round assessment reports are provided to the applicant.

## When do I provide a response to second round evaluation reports?

Applicants have 14 calendar days after the TGA issues the final evaluation report(s) in which to review and advise the TGA of any perceived errors of fact or major omissions.

For applications referred to the ACPM for advice, applicants should provide the notification of any perceived errors of fact or major omission to the assessment report(s) on the date outlined in the accompanying letter and in a document that is separate from the Pre-ACPM response.

The notification of any perceived errors of fact or major omission should be submitted by email to [streamlinedsubmission@tga.gov.au](mailto:streamlinedsubmission@tga.gov.au). The Pre-ACPM response should be provided in the manner indicated in the letter accompanying the Request for ACPM advice.

## What should be included in my response to second round assessment reports?

The response to final assessment reports should be limited to identifying perceived errors of fact or major omissions. It should not include any new data or information that will require evaluation as there is no provision for further evaluation within the timeframe of the evaluation plan.

Each identified perceived error of fact or major omission must be referenced to information previously submitted (Study number and location; for example, Module 3.2.P.4.3 Method validation, p.23). It is not appropriate to submit new data to negate a perceived error of fact or major omission.

Although there is no specific limit to the size of an applicant's response to the report(s), it is expected that the response to any one report should be no more than six single sided A4 pages and in a font no smaller than 12 point.

Responses to the assessment reports must be provided as Module 1.0.2.

If applicants are requested to provide revised documents these should be placed in the appropriate module; for example draft PI, CMI and labels in Module 1.3.

## Special cases

- [Can I apply for priority evaluations or rolling applications?](#)
- [Can I lodge a PPF to vary a product already on the ARTG while there is an application currently under evaluation in relation to the product?](#)
- [Can I lodge a PPF to vary a product before it is on the ARTG?](#)
- [When can a PPF be lodged for a fixed dose combination product?](#)
- [When can a PPF be lodged where the 5 year data protection provisions apply?](#)

## Can I apply for priority evaluations or rolling applications?

There is no formal provision for priority evaluation or rolling applications, therefore applicants should not make a request for these types of applications.

The registration process relies on the in-advance allocation of resources to evaluate applications, thus limiting opportunities for conducting evaluations any faster than the standard registration process.

If an application is for a medicine considered by the TGA to be a significant therapeutic advance or of critical importance and it is genuinely in the public interest for it to be made available as soon as possible, the TGA will, wherever possible, work with the applicant to facilitate early

access to the new medicine, provided the product meets the TGA's quality, safety, and efficacy requirements.

Applicants of such medicines are encouraged to discuss the requirements for the registration of such medicines with the TGA at a pre-submission meeting as early as possible. Guidelines for meetings with the TGA are provided at ARGMP Guidance 5 [Pre-submission meetings with TGA](#).

## **Can I lodge a PPF to vary a product already on the ARTG while there is an application currently under evaluation in relation to the product?**

This depends on the types of applications involved and whether or not there is a dependency between the existing and proposed applications.

For more information, see section 4.3.7 Concurrent applications in the [Prescription Medicine Registration Process](#), or for advice, contact the TGA contact point for the application currently under evaluation [streamlinedsubmission@tga.gov.au](mailto:streamlinedsubmission@tga.gov.au).

## **Can I lodge a PPF to vary a product before it is on the ARTG?**

Applications to amend any details for a product cannot be lodged until the product is listed on the ARTG. Applicants should not assume that an application that will result in a new entry on the ARTG will be approved.

If the proposed application is dependent upon the approval of the earlier application, the earlier application must be approved and the product entered on the ARTG prior to any further PPF being accepted. This also avoids any financial loss for the applicant if the approval of the earlier application is unexpectedly delayed or the earlier application is not approved. This also applies to new products resulting from, for example, container or formulation changes processed as Category 3 applications.

## **When can a PPF be lodged for a fixed dose combination product?**

A PPF for a fixed dose combination product should not be lodged until the TGA Delegate has approved a request from the applicant to lodge an application for a fixed dose combination product.

If the fixed dose combination product contains an NCE that is not currently on the ARTG, then the applicant may:

- wait until the NCE is on the ARTG to lodge the PPF for the fixed combination product
- lodge the PPF and the related application(s) for the new NCE and fixed dose combination product simultaneously, ensuring that the TGA is aware of the links between the applications
- lodge the application to register a new combination after an application to register a component active ingredient has been submitted but prior to that component being registered, ensuring the combination application is a 'stand-alone' application which includes full dossiers for any new chemical entity in the combination and the new

combination. This is not the preferred option, because if there are issues with the monotherapy, these will have an impact on the combination.

## When can a PPF be lodged where the 5 year data protection provisions apply?

The PPF may be lodged prior to the data protection period expiring. However, the application should not be lodged until the 5 year data protection period has expired.

Where data protection provisions apply to a medicine but the applicant has a complete set of data that is not covered by the protection provisions, a PPF and subsequent application can be lodged as if that medicine was a new chemical entity.

## Fees

- [Do I need to pay a fee when lodging a pre-submission planning form?](#)
- [What happens to the application fee if my PPF is 'not effective'?](#)
- [What happens to the application fee if my application is 'not effective' and not accepted for evaluation?](#)
- [Is the evaluation fee payable if I withdraw my application after it has been accepted for evaluation?](#)
- [Do the application and evaluation fees apply to applications to register an orphan drug designated medicine?](#)

## Do I need to pay a fee when lodging a pre-submission planning form?

An application fee is due and payable upon lodgement of the PPF. Please refer to the [Summary of fees and charges](#) to determine the relevant application fee for the application submitted. Sections 9D(7)(f) and 23(2)(a) of the *Therapeutic Goods Act 1989* state that an application is 'not effective' unless the application fee has been paid.

Applicants should submit their payment directly to the TGA finance area using one of the prescribed payment methods and quoting the invoice number (e.g. ONLxxxxxx).

For further information see [Fees and charges for prescription medicines](#).

## What happens to the application fee if my PPF is 'not effective'?

If the TGA considers a PPF 'not effective' and not acceptable, the applicant will forfeit the application fee.

For further information see [Fees and charges for prescription medicines](#).

## What happens to the application fee if my application is 'not effective' and not accepted for evaluation?

If an application is considered 'not effective' and not accepted for evaluation, the applicant will forfeit the application fee.

For further information see [Fees and charges for prescription medicines](#).

## Is the evaluation fee payable if I withdraw my application after it has been accepted for evaluation?

The full evaluation fee is due and payable when the applicant is notified that the TGA considers the application effective and accepted for evaluation.

If the application is withdrawn after this point, the applicant remains liable for the full evaluation fee.

For further information see [Fees and charges for prescription medicines](#).

## Do the application and evaluation fees apply to applications to register an orphan drug designated medicine?

The application and evaluation fees do not apply to applications to register an orphan drug designated medicine, provided that designation has been granted prior to lodgement of the PPF and the indications and dose form are consistent with the designation.

The application and evaluation fees do apply to applications to vary the details of a registered orphan drug designated medicine, for example, an application to change the Product Information.

For further information see [Fees and charges for prescription medicines](#).

## Miscellaneous

- [How will TGA provide formal letters and assessment reports?](#)
- [How can I receive reports by email?](#)
- [Where can I find information about the Advisory Committee on Prescription Medicines \(ACPM\)?](#)
- [Will an AusPAR on my application be published?](#)
- [Can I change the sponsor name or transfer sponsorship of a submission during the evaluation process?](#)

## How will TGA provide formal letters and assessment reports?

TGA no longer provides paper copies of letters and assessment reports. Instead, these are provided by e-mail or copied onto a disc and posted, as follows:

Activity	Electronic	
	email	disc
Planning letter (milestone 1)	✓	
Notification letter (milestone 2)	✓	
s. 31 questions and first round assessment reports (milestone 3)	✓*	✓
Second round assessment reports (milestone 5)	✓*	✓

\*For applicants who have subscribed and are eligible to receive documents via TGA's [secure email service](#) between TGA and non-Government organisations.

TGA will only issue correspondence to personnel who are authorised employees of or agents for the applicant.

The TGA will provide all correspondence to the contact person(s) identified in the PPF. If the contact persons or the contact information changes during the evaluation processes, the TGA case managers should be informed immediately.

## How can I receive reports by email?

Applicants must be registered to receive documents via TGA's [secure email service](#).

## Where can I find information about the Advisory Committee on Prescription Medicines (ACPM)?

Information about the ACPM, including the meeting date schedule is located on the [ACPM](#) page on the TGA website.

To contact the ACPM secretariat, email [acpm.secretariat@tga.gov.au](mailto:acpm.secretariat@tga.gov.au).

## Will an AusPAR on my application be published?

Currently, Australian Public Assessment Reports (AusPARs) are published for all applications referred for advice to the ACPM, except where the application is for a new dosage strength, dose form, dosage instruction or dosage group and the Delegate has advised an AusPAR is not required.

For applications where an AusPAR is required, the AusPAR will be published if the application is:

- approved or partially approved by the TGA
- rejected by the TGA (pending the expiration of the 90 day appeal period and finalisation of any associated Section 60 appeal process)
- withdrawn by the applicant after receipt of the Delegate's Overview.

Information on [AusPARs](#) can be found on the TGA website.

## Can I change the sponsor name or transfer sponsorship of a submission during the evaluation process?

The sponsor's name or sponsorship of a submission (in whole or part) can be changed prior to the milestone 5 date indicated in the evaluation plan regardless of whether or not evaluation reports have been received by the applicant.

Notification ([streamlinedsubmission@tga.gov.au](mailto:streamlinedsubmission@tga.gov.au)) must be accompanied by:

- Revised Module 1.3.1: Australian product information and (if applicable) package insert
- Revised Module 1.3.2: Australian consumer medicines information
- Revised Module 1.3.4: Label mock-ups (if applicable)
- For a change in sponsor name (same legal entity but change of name), a declaration in the Cover letter that, with the exception of a change to the sponsor name, the sponsor (company) has made no other changes that may reasonably be expected to impact on or affect the submission under evaluation
- For a change in sponsorship (different legal entity):
  - a letter from the original sponsor confirming that the new sponsor has access to all previously submitted data
  - letters of access for DMF, PMF and CEP holders regarding access to confidential parts of these documents (Module 1.6.3)
  - copy of forms [Request to transfer the sponsorship of an ARTG entry](#)<sup>1</sup>.

Please note that changes of this type may result in a delay to milestone 5 and subsequent milestones.

Sponsors are reminded of their obligations under the *Therapeutic Goods Act 1989* and its regulations and of the penalties that apply for providing false or misleading information.

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<sup>1</sup> For products already registered, the applicant must also notify the changes to [TGA eBusiness Services](#) using the forms [Request to transfer the sponsorship of an ARTG entry](#).

## **Therapeutic Goods Administration**

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