FRPath.org
Where the Roads to Accelerated Assessments Converge

| *FRPath.org Country and FRP Information Input Form* | | |
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| **Country:** Australia | **Agency Name:** Therapeutic Goods Administration (TGA) | |
| **Name of FRP:** Priority Registration Process | | |
| **Is this FRP Proposed or Active?** Active | | |
| **Date FRP was officially enacted:** Click here to enter a date. | | |
| **1. Facilitates activities during development** | **2. Accelerates the regulatory review process** | **3. Relies on or recognizes a prior regulatory decision** |
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| **Is a Guidance or SOP describing how to apply this FRP publicly available?** | Yes- see reference below |
| **When should the FRP be requested?** | Before the marketing authorisation submission |
| **Does the agency provide assistance/advice to the sponsor?** | Yes- For any product type |
| **For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products** | There are a number of eligibility criteria for the priority review pathway. Most importantly: (i) The medicine must be a new treatment for a serious or life-threatening condition; (ii) Substantial research evidence must show that the medicine provides a significant benefit compared to existing treatments at the time of application.<br>Some of the medicines TGA have approved through the priority review pathway are used in the treatment of conditions such as prostate cancer and specific types of lung cancer, skin cancer, and haemophilia.<br><br>Before you lodge your submission for registration using the priority registration process, you will need to:<br>1. 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 TGA notifies the applicant of their decision to make the priority determination, unless the determination is revoked or a section 23 application is made.<br>2. inform TGA 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. TGA will assess this information and advise whether the determination should be revoked on the basis of this or any other |

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| | information.<br>If the applicant submits a registration application without a valid priority determination, their registration application will be treated as a standard application and will be processed according to the standard registration process timeframe. |
| **Must the product address an unmet medical need or serious condition?** | Yes |
| **If a fee is required, what is the amount (in US$ equivalent)** | - 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).<br>- The processes for invoicing and payment of these fees are the same as in the standard prescription medicines registration process.<br>- 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. |
| **Total target (agency) time for assessment (calendar days)** | 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**.<br>*The timeframe is calculated from acceptance for evaluation through to the delegate's decision. |
| **Total target (company) time for responses to agency questions (If stated)** | TGA expects applicants to respond to their requests for additional information as part of a formal S31 request within **30 calendar days**. |

**Select one of the following (* see definitions at end of document)**

| **Is this a verification review (a recognition pathway)?*** | **Is this an abridged* review (selected dossier portions)? (a reliance pathway)?*** | **Is this a full* review of all parts of the dossier?** |
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| **If this is a reliance or recognition pathway, what are the accepted reference agencies?** | No, this process is not a reliance or recognition pathway. |
| **How many reference agency decisions are required?** | Not applicable. |
| **Does this FRP require submission of Assessment Reports from prior decisions?** | Unredacted |

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| **Is a CPP (Certificate of Pharmaceutical Product) required for approval?** | Choose an item. |
| **Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?** | Click here to enter text. |
| **If this process is through a Regional Regulatory Initiative, which countries participate in this process?** | No, this process is not through a Regional Regulatory Initiative. |
| **Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?** | Provide a list of countries in which a similar application has been submitted including:<br>- dates of submission (if available)<br>- the status of these regulatory activities.<br>- List must include the status of similar regulatory activities in any overseas jurisdiction.<br>Include details of:<br>- approvals (with indications), including approvals on appeal<br>- deferrals or delays (with reasons)<br>- withdrawals (with reasons)<br>- rejections or 'refusals to approve' (with reasons)<br>- determination and/or designation approvals or rejections (or other equivalent overseas status).<br>For applications submitted to agencies in the European Union include:<br>- the type of application (centralised, mutual recognition, decentralised, or national)<br>- for centralised applications, the rapporteur and co-rapporteur<br>- for mutual recognition and decentralised applications, the reference member state. |
| **How are queries to the companies sent?** | As they arise |
| **Are external reviewers (e.g. non-agency) involved in the assessment?** | Yes- as needed |
| **Post-authorization study commitments** | Always required |
| **For how long is the initial approval or designation valid?** | Choose an item. |
| **Any other details you wish to provide?** | - TGA recommends that the applicant submit their application for determination three months prior to the date they plan to lodge their submission for registration.<br>- The standard prescription medicines registration process consists of eight phases with eight milestones. The priority registration process also |

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| | has eight phases but with some modifications to reduce timeframes:<br>1. the priority registration process has greater flexibility between phases. Milestones are dynamic which allows the application to progress to the next phase more quickly<br>2. the applicants will receive rolling questions during the evaluation phase. If the applicants 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<br>3. there are more flexible arrangements for accessing expert advice<br>- As per the standard prescription medicines registration process, TGA will provide the applicant with updates to the evaluation plan as needed to reflect any changes in timeframes.<br>- The applicant can submit their dossier at any time after lodging their application. Unlike the standard pathway, priority submissions will not be batched on a monthly basis.<br>- The applicant 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 the applicant prepares their responses to rolling questions. TGA will not link these rolling questions to a stop clock unless there are exceptional circumstances requiring TGA to do so.<br>- 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. TGA may also seek expert advice other than through ACM or ACV. |
| **Date of this update** | 19 APRIL 2020 |

**References**

1. Priority registration process. https://www.tga.gov.au/publication/priority-registration-process Accessed on 19 April 2020.
2. Fast track approval pathways. https://www.tga.gov.au/fast-track-approval-pathways Accessed on 19 April 2020.
3. Priority review of prescription medicines. https://www.tga.gov.au/hubs/fast-track-approvals/priority-review-prescription-medicines Accessed on 19 April 2020.
4. Priority determination. https://www.tga.gov.au/publication/priority-determination#submitting Accessed on 19 April 2020.

*Definitions:

Verification review: A checklist review based on recognition of a prior regulatory decision. Recognition is the routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of economy A is sufficient to meet the regulatory requirements of economy B.

Abridged review: An abbreviated review of selected portions of the dossier and the reliance on prior assessment decisions. Reliance is the act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision

Full review: A comprehensive review of all components of the dossier. This may or may not be CPP-dependent. This may form part of a reliance or recognition pathway.