FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: New Zealand	**Agency Name:** New Zealand Medicines and Medical Devices Safety Authority (Medsafe)	
Name of FRP: Priority assessment of New Medicine Applications		
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**
☐	☒	☐

Is a Guidance or SOP describing how to apply this FRP publicly available?	Yes- see reference below
When should the FRP be requested?	At the time of the 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 three eligibility criteria for granting priority assessment to a new medicine application. The criteria relate to medicines which address a significant clinical need[1], medicines which could deliver significant cost savings to the taxpayer, and medicines that are manufactured in New Zealand for export. Note that Changed Medicine Notifications are not eligible for priority assessment. [1]Significant clinical need: Requests for priority assessment on the basis of significant clinical need will be considered for applications for products containing new active substances or where alternative products are not available. Vaccines for the prevention of diseases are treated in the same way as other agents for the treatment of diseases. Cost saving does not constitute a significant clinical advantage, hence will not be taken into account when deciding whether a product meets the clinical criteria for priority assessment. The sponsor of a medicine may request priority assessment if the medicine is indicated for the treatment or diagnosis of a serious, life-threatening or severely debilitating disease or condition for which other treatment options are limited. Sponsors may also request priority assessment to address an out-of-stock situation or withdrawal from the market of alternative medicines and it is essential that access to that treatment is maintained. Medsafe has determined that there is capacity for up to four NMAs with priority assessment, on the basis of significant clinical need, to be undergoing evaluation at any one time. Requests for priority assessment on significant clinical need will only be granted if there is resource availability.

FRPath.org Country and FRP Information Input Form	
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	A partial waiver is routinely applied to applications for approval of new non-prescription medicines. A partial fee waiver is also available for applications made under the abbreviated process for new prescription medicines already approved by a recognised overseas regulator. The actual fee payable for an application of a particular type, after application of any applicable standard waiver, is set out in a schedule of fees: Fee Regulations
Total target (agency) time for assessment (calendar days)	Evaluation Timeframes
Total target (company) time for responses to agency questions (If stated)	If deficiencies are identified during the evaluation, an RFI (RFI = Request for Further Information) will be issued. Maintaining priority assessment status is conditional on applicants providing a complete response to an RFI within 28 days. If a sponsor considers that Medsafe's request cannot be responded to within 28 days, they should first contact Medsafe to ensure that the request has been correctly interpreted. In cases where the sponsor cannot obtain the information requested within the 28 day timeframe, it can still be provided after this deadline but the priority status of the application will be revoked. Medsafe considers the 28 day response time to be reasonable as applications should be complete before lodgment. A further benefit of truncating the response time is that the application can be referred back to the original evaluator in most circumstances, with increased efficiency in concluding the evaluation. The 28 day timeframe will be applied to applications that meet the significant clinical need but have been declined due to resource availability.

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?**
☐	☐	☒

If this is a reliance or recognition pathway, what are the accepted reference agencies?	Not applicable
How many reference agency decisions are required?	Not applicable
Does this FRP require submission of Assessment Reports from prior decisions?	Choose an item.
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Choose an item.

FRPath.org Country and FRP Information Input Form	
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	Not applicable
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	Not applicable
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Variable
How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g. non-agency) involved in the assessment?	Choose an item.
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?	- Requests for priority assessment can only be made by the New Zealand sponsor or distributor of the product. Sponsors are encouraged to provide support for claims of significant clinical need by submitting material such as letters of support from PHARMAC, clinicians and consumer support groups
Date of this update	27 October 2020
References	1. Guideline on the Regulation of Therapeutic Products in New Zealand Part 2: Obtaining approval for new and changed medicines and related products Edition 1.1 October 2019.

*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.