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: Abbreviated Evaluation 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**
☐	☒	☒

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	To be eligible for the abbreviated evaluation process the medicine must meet all of the following criteria: - be an Intermediate-risk or High-risk medicine that has been approved by a recognised regulatory authority since 1 January 2001 not be subject to any regulatory action that may result in a suspension or revocation of the market authorisation by any recognised regulatory authority - have the same formulation as the product originally approved by the recognized regulatory authority - have the same dosage and indications as the product originally approved by the recognised regulatory authority (does not apply to generic medicines which must be aligned with the NZ innovator) - have current market authorisation issued by the recognised regulatory authority - have undergone NO MORE THAN TWO of any of the following types of significant change and those changes must have been approved by the recognised regulatory authority: • significant changes in method of manufacture considered as a "Finished product manufacturing process – Grade 2" Changed Medicine Notification • addition of a new finished product testing site • addition of a new finished product manufacturing site • addition of a new active ingredient manufacturing site for which a Drug Master File is required

FRPath.org Country and FRP Information Input Form	
	• addition of a new primary packing site • extension of shelf-life (multiple extensions will be considered as one change as subsequent changes supersede earlier ones).
Must the product address an unmet medical need or serious condition?	Negotiable
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)	The evaluation phase allows Medsafe to seek clarification or further information about any component of the application that affects the safety, quality or efficacy of the product, and the risks and benefits to consumers. In cases where clarification is needed, a consolidated set of questions will be prepared by Medsafe and sent to the sponsor as a RFI letter. RFI = Request for Further Information. The RFI letter will clearly detail the issues and concerns. It will also specify the maximum number of calendar days allowed for the sponsor to provide a formal response. In the case of NMAs, the accompanying evaluation report will further document the outstanding issues. The sponsor's response will need to address all issues raised, and if it is not received within the specified timeframe or is not complete, the evaluation and decision processes will proceed on the basis of the information previously supplied. Once the application has been submitted, the sponsor will not be able to make changes to the application or submit additional data or information, other than that as requested as part of an RFI letter. If sponsors are unable to respond to a RFI within the maximum number of allowable calendar days they must contact Medsafe immediately to negotiate an extension to the response time. Extensions may be granted if the sponsor cannot provide the information due to unforeseen circumstances. Typically, extensions will be for a maximum of two weeks. Sponsors should note that extensions in excess of two weeks seriously impacts on Medsafe's ability to assess medicines in a timely manner, and has flow on effects to the evaluation of all new and changed medicine applications.

FRPath.org Country and FRP Information Input Form		
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?	For the purposes of the abbreviated evaluation process, Medsafe recognises the following regulatory authorities: - Australian Therapeutic Goods Administration (TGA) (excluding applications approved upon appeal) - United States Food and Drug Administration (FDA) - Health Products and Food Branch of Health Canada - Medicines and Healthcare Products Regulatory Agency (MHRA) - European Medicines Agency (centralised procedure only) - EU member states (decentralised or mutual recognition procedure only).
How many reference agency decisions are required?	1
Does this FRP require submission of Assessment Reports from prior decisions?	Unredacted
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Yes at time of submission
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?	Yes, the product must have current market authorisation issued by the recognised regulatory authority.
How are queries to the companies sent?	In batches
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?	- Medsafe offers an abbreviated evaluation procedure in which review of overseas regulatory evaluation reports forms the basis of the evaluation. Therefore,

	the quality and availability of evaluation reports should be a fundamental consideration for applicants wishing to use the abbreviated evaluation process. - The abbreviated evaluation process is intended to be a simpler and quicker process than the standard evaluation process. This is reflected in the application fee. - The abbreviated evaluation process is not intended to be applicable to all medicine applications. For instance, it is known that the FDA does not issue evaluations reports for generic medicine applications. Consequently, it is not possible to submit a generic medicine application through the abbreviated evaluation route if it is based upon FDA approval. - The abbreviated evaluation process is not applicable to low-risk new medicine applications or Changed Medicine Notifications (CMNs). However, Medsafe strongly encourages applicants to consider providing international regulator evaluation reports and evidence of approval if this is available at the time of submission. - Applicants who are not eligible for the abbreviated evaluation process may submit via the standard evaluation process – by submitting a full dataset for assessment as required by the Medicines Act and the Guideline for the Regulation of Therapeutic Products in New Zealand (GRTPNZ). - The application must be supported by a complete dataset as required by the Medicines Act and the GRTPNZ, consisting of Modules 1, 2, 3, 4, and 5 (as applicable). The dataset should reflect the product details being sought for registration - The original dossier submitted to the overseas authority must be in Common Technical Document (CTD) format and the dossier (submitted to Medsafe) must have been updated to incorporate the supporting data for any changes approved by the recognised authority. - The overseas evaluation report(s) must be in English, correspond to CTD structure and a complete record of the assessment (redacted reports are not acceptable). - Evidence of approval by the recognised overseas authority of the medicine and any of the above significant changes to it, is included in the

FRPath.org Country and FRP Information Input Form	
	application to Medsafe. Such evidence in relation to applications from Europe can be in the form of either a marketing authorisation or notification from the authority of either a closed Centralised Procedure, Mutual Recognition Procedure, or Decentralised Procedure.
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.