FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Bhutan	**Agency Name:** Drug Regulatory Authority Royal Government of Bhutan	
Name of FRP: Expedited Registration		
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	**Conditions for Expedited Registration:** 1. Minimum of 5 products with valid registration status registered with DRA for minimum of 2 years at the time of application; 2. No past record of product recall or withdrawal from Bhutan (Voluntarily recalls by Manufacturers do not apply); 3. Not more than 2 post registration change applied for a single product in one year; and 4. For parenteral products, at least ONE parenteral product to be registered amongst the 5 valid products. **Out of Scope:** The following category of products are not applicable for Expedited Registration: 1. Vaccines 2. Biologics & Biotechnology Products 3. Blood & Blood Products 4. Health Supplements *Priority review may be given for treatment of disease conditions that are local public health concerns. This may include medicines for cancer, HIV, dengue, tuberculosis, hepatitis and malaria. The request for priority review should be made at the time of submitting the dossiers along with justification which warrants a priority review. DRA, however reserves the right to deny a request for priority review if it is deemed appropriate. This will be communicated to the applicant

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Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	The Authority shall collect the product registration fee prescribed at the time of issuance of registration certificate. A fee of Nu.500/- [USD 7] should be paid per product application.
Total target (agency) time for assessment (calendar days)	Review of applications will follow a queue system. However, the Authority may fast-track the registration under exceptional circumstances as deemed appropriate. The registration certificate shall be issued within **sixty calendar days** from the date of receipt of complete required documents unless otherwise a longer period is required, in which case, the parties shall be informed..
Total target (company) time for responses to agency questions (If stated)	A period of **6 months** will be given within which the applicant should submit the additional information/clarification required for each correspondence from the DRA.

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?	This 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?	Choose an item.
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?	Medicinal products, excluding *gSo-ba Rig-pa* and traditional medicines, require a WHO Model Certificate of Pharmaceutical Product.
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?	
How are queries to the companies	Choose an item.

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sent?	
Are external reviewers (e.g. non-agency) involved in the assessment?	
Post-authorization study commitments	Always required
For how long is the initial approval or designation valid?	See details Section below
Any other details you wish to provide?	- NMRA Website: www.dra.gov.bt - The documents required for registration should be in English or Dzongkha - The registration of a product shall be valid for a period of three years and shall be specified on the certificate by the Authority. - A product will be registered only if it satisfies all requirements of the DRA, especially with respect to safety, efficacy and quality of the product. Other criteria that may be taken into consideration include: (i) Either that the product is needed or not. Aspects like potential for abuse, number of registered products, different dosage form, etc. are considered; (ii). Therapeutic advantage. - The Authority may, when necessary, conduct laboratory tests of the medicinal product prior to registration. The cost of which shall be borne by the applicant. - Note: (1) The documents must be in soft copy burnt on a CD-RW & should include the completed application form with the actual date of application. Color scans of the package, label and insert must be included instead of hard copy specimens; (2) The application form for ER Registration can be downloaded from this link: http://dra.gov.bt/wp-content/uploads/2017/08/Form-for-Expedited-Registration-of-Medicines.pdf
Date of this update	4 APRIL 2020
References	1. Guidelines for application for Registration of Medicinal Products 2006(DRA). Accessed on 4 April 2020. 2. Bhutan Medicines Rules and Regulation 2019. Accessed on 4 April 2020. 3. GUIDELINE - Registration of Medicinal Products 2nd Edition, 2013. DRUG REGULATORY AUTHORITY ROYAL GOVERNMENT OF BHUTAN.

Accessed on 4 April 2020.

4. Conditions for ER Registration & Documentary Requirements thereunder. https://drive.google.com/file/d/0Bzj2O5Bryu-LVnpZQ3lKLU5uYUhjRFk2ODFKSGpocG9fQm1J/view Accessed on 4 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.