FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Brunei Darussalam	**Agency Name:** Brunei Darussalam Medicines Control Authority (BDMCA)	
Name of FRP: Abridged Route		
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?	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	Applies to any medicinal product classified as GSL (for certain categories* only) and registered in at least one benchmark country. (*antiseptics/skin disinfectants; lozenges/pastilles; health supplements; topical analgesics/counter-irritants; emollients/demulcents; keratolytic; topical nasal decongestants. This list is non-exhaustive.) GSL = General Sale List medicine. All applications for medicinal product registration are to be made by submission of the required documents which are in line with the ASEAN Common Technical Dossier (ACTD) for the registration of pharmaceuticals for human use and ASEAN Common Technical Requirements (ACTR). The application dossier required for an Abridged application will consist of part 1 only: Administrative Data and Product Information.
Must the product address an unmet medical need or serious condition?	No
If a fee is required, what is the amount (in US$ equivalent)	The processing fee of B$200 [US$150] is payable at the point of submission of the application for a medicinal product registration. Processing fee is non-refundable once the application has been submitted, regardless of the final decision by the BDMCA.
Total target (agency) time for assessment (calendar days)	1. Assessment by Product Regulation Team and Drug Registration Committee (DRC) • Generic: 132 working days • New Chemical Entity/Vaccines/Biologics: 246 days 2. Endorsement by Brunei Darussalam Medicines Control Authority (BDMCA): 45 Working days
Total target (company) time for responses to agency questions (If	DRU may request for further information and additional supporting documents from the applicant through the query

stated)	letter. Applicant should make available such information or documentation required for each correspondence **within 60 calendar days** from the date of the screening query letter. Once the feedback has been received, the requested information and documents will be screened for completeness. The application will not proceed for evaluation if no response is received from applicant after the 60 days given. DRU will issue a non-acceptance letter and the documents will be returned. A new application will have to be submitted if the applicant wishes to pursue registration of the product. The stop-clock starts when DRU issues the screening query letter and ends when DRU receives the required documents/information from the applicant. The application will be accepted once the registration dossier is complete. An acknowledgement for the receipt of the application will be issued and a reference number (LOA-P/.../S...) will be generated. The reference number shown in this acknowledgement should be used in all subsequent correspondences relating to the application.

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?	Benchmark regulatory agencies: Australia, Canada, EU (centralised), Malaysia, Singapore, United Kingdom and United States of America.
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 be marketed in a benchmark regulatory agency country
How are queries to the companies sent?	Choose an item.

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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?	4-5 years
Any other details you wish to provide?	- Applications for medicinal product registration are to be made by submission of the letter of intent and by using the prescribed forms issued by the DPS. Application forms can either be obtained from Drug Registration Unit, Drug Administration Section Department of Pharmaceutical Services, Block 2G:8:03, 8th Floor, Ong Sum Ping Condominium, Bandar Seri Begawan, BA1111, Brunei Darussalam or downloaded from the following website: http://www.moh.gov.bn/pharmacyservices/forms.htm - The Product License certificate shall be valid for 5 years. There is no charge in the first year and the fee of B$50 is payable for each subsequent year.
Date of this update	27 October 2020
References	1. GUIDE TO APPLICATION FOR REGISTRATION OF MEDICINAL PRODUCTS 3RD EDITION (DEC 2012). Accessed on 27 October 2020. 2. Importation, Manufacture, Sale and Supply of Medicinal Products into Brunei Darussalam. Accessed on 27 October 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.