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Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Sri Lanka	**Agency Name:** Sri Lankan National Medicines Regulatory Authority (NMRA)	
Name of FRP: Fast Track Review		
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	Fast tract review for medicines is considered in following situations; 1. Drugs used for orphan diseases, drugs considered as "orphan" to Sri Lanka by the NMRA 2. Drugs for emergency situations shall have priority for evaluation and registration
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	FEES - Under the Regulation No. 2052/33, January 05, 2018 published under NMRA Act. - The Authority may charge any applicant such costs as it may incur for the purpose of carrying out any evaluation or investigation prior to the registration of any product. - Any payment made shall not be refundable once the application has been submitted and payment confirmed. - Applications without the correct fees will not be processed.
Total target (agency) time for assessment (calendar days)	The application submitted for registration will be screened chronologically according to date of submission to the Authority, and the applicant will be notified of the results of its evaluation within 28 working days of its submission to the Authority
Total target (company) time for responses to agency questions (If	Click here to enter text.

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stated)		
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?	Yes at time of submission	
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	No alternate documentation can be submitted. A Certificate of a Pharmaceutical Product (CPP) issued by a competent authority in the exporting country should be provided in Module 1 in accordance with the format recommended by the W.H.O. The CPP should be valid at the time of submission, country specific and be the original.	
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?	Click here to enter text.	
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?	- Sri Lanka is a LMIC in South Asian region and vast majority of the medicines used in the country are generic medicines. The medicines regulation in Sri Lanka underwent a major revision recently with the implementation of a new National Medicines Regulatory	

	Authority Act of 2015 passed in parliament and the establishment of a new National Medicines Regulatory Authority (NMRA) in 2015. The NMRA replaced the Cosmetics Devices and Drugs Authority (CDDA) and the CDDA Act of 1982.
Date of this update	31 May 2020
References	1. Guideline on Registration of Medicines. https://nmra.gov.lk/images/PDF/draft_guidelines/Guideline-on-registration-of-medicine.pdf Accessed on 31 May 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.