FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Singapore	**Agency Name:** Health Services Authority	
Name of FRP: Verification-CECA Route		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 1/15/2019		
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	Applies to any generic product manufactured in India
Must the product address an unmet medical need or serious condition?	Negotiable
If a fee is required, what is the amount (in US$ equivalent)	FEES: 1. Screening Fee = $565 [USD417] 2. Evaluation Fee (GDA-1) = $10,200 [USD7,525] 3. Evaluation Fee (GDA-2) = $5,150 [USD3,800] - NB: Screening fee is payable upon application submission. Evaluation fee is payable upon acceptance of application for evaluation. All fees for the abridged or verification evaluation route are charged per NDA application submitted. - 1 USD = 1.35543 SGD as at 18 December 2019
Total target (agency) time for assessment (calendar days)	TURNAROUND TIME: 1. Screening (in working days) = 50 2. First Communication (in working days) = 14 3. Evaluation (in working days) = 90 - NB: Screening turnaround time begins from the date of receipt of application dossier. Evaluation turnaround time begins from the date of acceptance for evaluation. Turnaround time may be extended if the applicant's response to the queries is incomplete, and the applicant is required to provide further clarification or additional information.
Total target (company) time for responses to agency questions (If	If deficiencies are identified in an application dossier, a screening query stating the deficiencies will be issued via

FRPath.org Country and FRP Information Input Form	
stated)	Input Request to the applicant. Applicants will be given 20 working days to respond to each Input Request.

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 process applies to any generic product manufactured in India which has been evaluated and approved by HSA's reference drug regulatory agencies, which include EMA, USFDA, Health Canada, TGA and UK MHRA. NB: One of the reference drug agencies must be declared as the primary reference agency. The chosen primary reference agency is defined as the reference drug regulatory agency from which the qualifying supporting documents will be submitted.
How many reference agency decisions are required?	At least one of HSA's reference agencies
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?	GMP Certificate is also required in addition to a CPP. Certain accreditation documents/certificates issued by drug regulatory agencies (e.g. Japan/PMDA Accreditation Certificate of Foreign Drug Manufacturer, US/FDA Establishment License, Canada/Health Canada Establishment License) are not acceptable proof of GMP Compliance.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No, the process is not through an RRI
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 another country. The application must be submitted to HSA within two (2) years from the date of approval by the chosen primary reference agency.
How are queries to the companies sent?	As they arise
Are external reviewers (e.g. non-agency) involved in the assessment?	Yes- as needed
Post-authorization study commitments	Always required

FRPath.org Country and FRP Information Input Form	
For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	- An applicant may request a pre-submission meeting if a face to face consultation with HSA is necessary to address specific submission issues. The request should state the purpose, agenda and proposed date and time for the meeting and be made at least three (3) weeks prior to the meeting date, and relevant meeting documents (e.g. presentation slides, briefing documents, etc.) should be provided at least one (1) week before the meeting. - Biosimilars are only eligible for an abridged route. - Reports obtained from the public domain are deemed unacceptable. Applications submitted to HSA without the unredacted/unedited reports from the primary reference agency will not qualify for the verification evaluation route. The applicant will be required to withdraw and resubmit the application via the abridged route if the applicant intends to pursue the application. - Declaration for GDA Verification and Verification-CECA (CTD/PRISM Section 1.14) – a declaration letter issued by the product owner/applicant must be provided to state that all aspects of the products quality are identical to that currently approved by the chosen reference drug agency at the time of submission. Quality aspects include, but are not limited to, formulation, manufacturing site(s), release and shelf life specifications, and primary packaging. If a Drug Master File is submitted, then a separate declaration letter issued by the applicant must also be provided to state that the DMF submitted to HSA is identical to that submitted to the chosen reference drug agency.
Date of this update	18 December 2019
References	1. Fees and turnaround times for therapeutic products. https://www.hsa.gov.sg/therapeutic-products/fees Accessed on 18 December 2019 2. Main Guidance on therapeutic product registration in Singapore. https://www.hsa.gov.sg/docs/default-source/hprg/therapeutic-products/guidance-documents/guidance-on-therapeutic-product-registration-in-singapore_jan2019.pdf?sfvrsn=cd174383_2 Accessed on 18 December 2019

3. Appendix 5. Target Processing Timelines. https://www.hsa.gov.sg/docs/default-source/hprg/therapeutic-products/guidance-documents/appendix-5_target-processing-timeline.pdf?sfvrsn=2a3259a5_2 Accessed on 18 December 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.