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: GDA Abridged 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	NMEs, generics, Biosimilars
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) = $3,965 [USD2,925] 3. Evaluation Fee (GDA-2) = $2,265 [USD1,670] - 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. Evaluation (in working days) = 240 - 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 stated)	If deficiencies are identified in an application dossier, a screening query stating the deficiencies will be issued via Input Request to the applicant. Applicants will be given 20

FRPath.org Country and FRP Information Input Form		
	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?	Any drug regulatory agency	
How many reference agency decisions are required?	This process applies to any new or generic product that has been evaluated and approved by at least one drug regulatory agency	
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?	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?	Proof of approval is not required for Generic Drug Applications (GDAs) undergoing an abridged evaluation for finished products manufactured (up to primary packaging) in Singapore. For an abridged evaluation of an imported GDA, - Proof of approval by any drug regulatory agency is required. Proof of approval must come in the form of an official approval letter or equivalent document (e.g. Certificate of Pharmaceutical Product, CPP) which certifies the registration status of the drug product , and - the SPC, PI and/or PIL approved by the drug regulatory agency that issued the approval letter.	
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	Always required	

FRPath.org Country and FRP Information Input Form	
commitments	
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. - The applicant can apply for priority review. The request should be made at the point of application submission and accompanied by justifications. - Submission of a Risk Mitigation Plan (RMP) is mandatory for all biosimilar applications.
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=2a32259a5_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.