FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Thailand	**Agency Name:** Thai Food and Drug Administration (Thai FDA)	
Name of FRP: Abridged Evaluation of New Drugs		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 10/1/2015		
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	New Drugs, NCEs.	
Must the product address an unmet medical need or serious condition?	Yes	
If a fee is required, what is the amount (in US$ equivalent)	Click here to enter text.	
Total target (agency) time for assessment (calendar days)	NCEs and other New Drugs = 200 Working Days; Priority Review NCEs and other New Drugs = 150 Working Days.	
Total target (company) time for responses to agency questions (If stated)	Applicants are required to respond within 30 days.	
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?	US FDA, EMA, EU (Centralized System), MHRA (UK), SwissMedic, TGA (Australia), Health Canada, PMDA (Japan). *The application must be submitted within two years from the approval date of the benchmark or reference agency. The same pharmaceutical products and the proposed indications, dosage regimens, patient groups and/or directions for use must be the same as those approved by the reference agency. Full assessment reports	

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	of the benchmark/reference agency and all list of questions and answers during the assessment process, together with post-approval variations and related documents in English must be submitted.
How many reference agency decisions are required?	Click here to enter text.
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?	Click here to enter text.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	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?	Yes, the product has to have been marketed in another country.
How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g. non-agency) involved in the assessment?	Yes- as needed
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?	- Certificate of Free Sale should be issued/legalized by the competent authorized officer and endorsed by Thai Embassy/Thai consular Office residing in correlation to the country where the documents being issued. - Currently, marketing authorization drug licenses are valid indefinitely, as long as the accompanying drug manufacturing or drug import license is still valid. Amendment No. 6 of the Drug Act, which came into force on October 13, 2019, prescribes that marketing authorization drug licenses have a validity of seven years, and can be renewed. - After obtaining a market authorization license, new drugs (original products) must undergo a mandatory Safety

	Monitoring Program (SMP). During the SMP, new drugs can only be dispensed in hospitals. The company manufacturing the original drug must provide periodic safety updates to the Thai FDA for the first two years. After the committee evaluates these reports over the two-year period, the drug can be released from the SMP and re-classified. SMPs are not required for generic drugs. - Thai FDA Notification on New Drugs using Reference Drug Regulatory Authority Assessment was issued in July 2015. It has come into effect since October 1, 2015. - There are 4 experts for 1 New Drug Application (Abridged): 2 Experts for quality part (Manu 1, QC 1); 1 Expert for nonclinical part; 1 Expert for clinical part. Generally, there is a review by experts and internal reviewers.
Date of this update	6 February 2020.
References	1. REGULATORY REQUIREMENTS & MARKETING AUTHORIZATION OF GENERIC DRUGS IN SINGAPORE & THAILAND. https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=12&cad=rja&uact=8&ved=2ahUKEwiN5evvsLrnAhVRalAKHfnmCB8QFjALegQIBRAB&url=https%3A%2F%2Fwww.researchgate.net%2Fpublication%2F326597291_REGULATORY_REQUIREMENTS_MARKETING_AUTHORIZATION_OF_GENERIC_DRUGS_IN_SINGAPORE_THAILAND&usg=AOvVaw3VQFtydAKQfxqhWIp1dwvA Accessed on 5 February 2020. 2. Drug Regulation in Thailand. https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=15&cad=rja&uact=8&ved=2ahUKEwiN5evvsLrnAhVRalAKHfnmCB8QFjAOegQIBBAB&url=https%3A%2F%2Fwww.fda.gov.tw%2Ftc%2Fincludes%2FGetFile.ashx%3Fid%3Df636695447955896008&usg=AOvVaw2A-UNvUr_Cw5kPcodtmEIF Accessed on 5 February 2020. 3. Drug Registration in Malaysia, Thailand, other Asia markets. https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=16&cad=rja&uact=8&ved=2ahUKEwiN5evvsLrnAhVRalAKHfnmCB8QFjAPegQICBAB&url=https%3A%2F%2Fwww.pacificbridgemedical.com%2Fregulatory-services%2Fpharmaceutical%2Fproduct-registration%2Fothers%2F&usg=AOvVaw37yYIlUvGQwojqy1aN8v1y Accessed on 5 February 2020. 4. Regulatory, Pricing and Reimbursement Overview: Thailand. https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=17&cad=rja&uact=8&ved=2ahUKEwiN5evvsLrnAhVRalAKHfnmCB8QFjAQegQIBxAB&url=https%3A%2F%2Fpharmaboardroom.com%2Flegal-articles%2Fregulatory-pricing-and-reimbursement-overview-

thailand%2F&usg=AOvVaw2yxKFKzqBwHglRoD5aGghZ Accessed on 5 February 2020.

5. Drug act B.E.2510 and its amendments. http://www.fda.moph.go.th/sites/drug/EN/Shared%20Documents/law/DrugAct2510.pdf Accessed on 18 January 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.