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Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Malaysia	**Agency Name:** National Pharmaceutical Regulatory Agency (NPRA)	
Name of FRP: Abridged 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?	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	**New product applications (in the category of New Drug Products, Biologics including biosimilars and Generics)** which fulfils either one of the following conditions; a) Product which is intended for: - Unmet medical needs (e.g. medicines for rare diseases, new vaccines, etc.), - Life-saving such as for treatment/ prevention of serious medical conditions (e.g. anticancer, antiretroviral, etc.), - Treatment/ prevention in pandemic/endemic situations, for the interest of public health, - Emergency supply/crucial for treatment purposes according to the current needs in the country, - Supply to the Ministry of Health Malaysia under circumstances where alternative product with the same active ingredient is unavailable, b) Product which involves a change in the formulation due to the decision/ instruction by the Drug Control Authority (DCA), for the purpose of formulation improvement with appropriate scientific justification(s), c) Product which is the first generic product, or the first locally manufactured generic product.	
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	New Drug Products = 120 working days	

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assessment (calendar days)	Biologics = 120 working days	
Total target (company) time for responses to agency questions (If stated)	- The applicant is allowed to correspond with a maximum of 3 times correspondence within 60 working days in total. NPRA will change the evaluation timeline to the standard timeline if applicant failed to correspond within the stipulated timeline. - Application shall be rejected if the applicant fails to respond to the correspondence from NPRA to submit the required supplementary data/ information or documentation **within six (6) months** from the first correspondence date.	
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?	- European Medicines Agency (EMA) - United States Food and Drug Administration (US FDA) - WHO Prequalified Medicinal Products (specifically new drug products and biologics including biosimilars) covered by the alternative listing procedure (evaluated by US FDA and EMA) may be accepted under this pathway. *Approval by these reference drug regulatory agencies does not oblige the Drug Control Authority (DCA) to approve the application.	
How many reference agency decisions are required?	Abbreviated review applies to a product that has been evaluated and approved by one (1) reference drug agency.	
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?	The CPP is required PLUS the Summary of Product Characteristics (SPC), PI and/or PIL approved by the reference drug regulatory agency that issued the approval letter. *NPRA reserves the right to request additional supporting documents where it is deemed appropriate.	
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?	Yes, the product has to have been marketed in another country. The application must be submitted to the National Pharmaceutical Regulatory Division (NPRA, which acts as the Secretariat to the DCA) within two (2) years from the date of approval in the reference drug regulatory agency.	
How are queries to the companies sent?	As they arise	

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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?	Choose an item.
Any other details you wish to provide?	- Upon confirmation of payment, the application with the submitted data shall be evaluated. Review of applications shall follow a queue system. There shall be separate queues for the different categories of products and/or according to level of claims (e.g. general, medium or high claim for health supplements). - Correspondence via the system shall be sent to the applicant if there is any clarification and further supplementary data/ information or documentation pertaining to the application, if deemed necessary by the Authority. - Non Scheduled Poison Abridged Evaluation is for low risk pharmaceutical products based on these 3 factors: (i) Active ingredient - contains well established active ingredients (ii) Dosage form and route of administration: external preparations and locally acting dosage forms (iii) Indication: used for non-critical conditions only (eg acne, dandruff, counterirritant, antiseptics). Currently, there are 11 categories of products listed in DRGD that are classified as Non Scheduled Poison Abridged Evaluation. - The Abridged Evaluation has simplified registration requirements compared to the Full Evaluation. This category is exempted from certain information in Part I ACTD and Process Validation Report. In addition, Abridged Evaluation does not require Quality Control pre-registration documentation such as the protocol of analysis (PoA) and analytical method validation (AMV) report. However, PoA still needs to be submitted to NPRA for the purpose of post-market surveillance testing after the product is registered. Other than these exemptions, the registration requirements of Abridged Evaluation are the same as Full Evaluation such as the PICS GMP, CPP for imported products, labeling, package insert/RiMUP, certificate of analysis, Zone IVb Stability Data etc. - An application for Priority Review should be submitted via a formal letter addressed to the Director of NPRA once the screening has been approved. - The approval of Priority Review is subjected to the decision of the Drug Evaluation Committee Meeting upon submission of complete product registration documentation and does not exempt applicant from any product registration

	requirements. - The submitted assessment reports must be unredacted or unedited, and should include details of imposed licensing conditions, final product labelling, chemistry and clinical review, and other information in relation to the product's approval. Reports obtained from the public domain are deemed unacceptable. However, NPRA may consider accepting public assessment reports accompanied by redacted information and Q&A provided that the applicant has shown proof and effort to obtain the unredacted assessment reports.
Date of this update	15 JANUARY 2020
References	1. Evaluation of Application. https://npra.gov.my/index.php/en/component/content/article/2-english/uncategorised/1513-step-3-screening-2.html?highlight=WyJwcmlvcmloeSIsInJldmlldyIsInByaW9yaXR5IHJldmlldyJd&Itemid=1391 Accessed on 15 January 2020 2. FAQ : Generic Medicines. https://npra.gov.my/index.php/en/frequently-asked-questions-faqs-pharmacovigilance.html?highlight=WyJhYnJpZGdlZCIsImV2YWx1YXRpb24iLCJhYnJpZGdlZCBldmFsdWFoaW9uIlo= Accessed on 15 January 2020 3. Direktif untuk melaksanakan Guidelines on facilitated registration pathway: abbreviated and verification review. https://npra.gov.my/index.php/en/directive-general/2075-direktif-untuk-melaksanakan-guidelines-on-facilitated-registration-pathway-abbreviated-and-verification-review-2.html?highlight=WyJ2ZXJpZmljYXRpb24iLCJyZXZpZXciLCJ2ZXJpZmljYXRpb24gcmV2aWV3Ilo= Accessed on 15 January 2020. 4. FAQs: NCE. https://npra.gov.my/index.php/en/component/content/article/225-english/1527044-faq-nce.html?highlight=WyJ2ZXJpZmljYXRpb24iLCJyZXZpZXciLCJ2ZXJpZmljYXRpb24gcmV2aWV3Ilo=&Itemid=1391 Accessed on 15 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.