FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Vietnam	**Agency Name:** Drug Administration of Vietnam (DAV)	
Name of FRP: Abridged Procedure		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 9/1/2019		
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	According to Circular No. 32/2018/TT-BYT, there are two abridged procedures applicable when registering drugs in Vietnam: a quick evaluation procedure and an abbreviated evaluation procedure.
	
	The **quick procedure** can be applied to the following drugs:
	• Rare drugs listed by the Minister of Health.
	• Drugs serving urgent needs for national defence and security, epidemic control or disaster relief.
	• Domestic drugs that are manufactured by production lines that satisfy GMP, GMP-EU, or GMP-PIC/S standards and equivalent standards within 18 months from the issuance date of the GMP certificate.
	• Vaccines that are approved by WHO and vaccines used for national expanded immunisation programs.
	• Specialty drugs and drugs with special dosage forms where no more than two similar drugs (with the same active ingredients, dosage form, content or concentration) have an unexpired marketing authorisation in Vietnam when the application is submitted, including:
	  • antineoplastic drugs;
	  • next-gen antiviral drugs;
	  • next-gen antibiotics; and
	  • drugs for treatment of haemorrhagic fever, tuberculosis, or malaria.
	• Drugs that can be domestically manufactured, including:
	  • antineoplastic drugs, vaccines, biologicals, and	

<table>
<tr><th colspan="4">FRPath.org Country and FRP Information Input Form</th></tr>
<tr><td></td><td colspan="3">next-gen antiviral drugs that are manufactured in Vietnam under a processing agreement or technology transfers agreement;
• herbal drugs under national, ministerial or provincial research which has been accepted and drugs wholly obtained from domestic herbal ingredients that satisfy GACP standards; and
• new domestic drugs that have undergone clinical trial in Vietnam.
• New drugs (treatment for cancer, next-gen antiviral drugs, and next-gen antibiotics) and biologicals.
• Brand-name drugs that are manufactured in Vietnam under a processing agreement or technology transfer agreement.
The abbreviated procedure can be applied to drugs that satisfy all of the following conditions:
• Drugs manufactured at a local facility that is periodically evaluated by the DAV.
• Drugs on the list of non-prescription drugs.
• Drugs without modified-release dosage form.
• Drugs not used directly on the eyes.
Applicants who have drugs satisfying these conditions can apply for an abridged procedure in the application form of the drug registration dossier.</td></tr>
<tr><td>Must the product address an unmet medical need or serious condition?</td><td colspan="3">Yes</td></tr>
<tr><td>If a fee is required, what is the amount (in US$ equivalent)</td><td colspan="3">Click here to enter text.</td></tr>
<tr><td>Total target (agency) time for assessment (calendar days)</td><td colspan="3">According to Circular No. 32/2018/TT-BYT, there are two abridged procedures applicable when registering drugs in Vietnam: a quick evaluation procedure and an abbreviated evaluation procedure. The timeline for these evaluation procedures is only six months from the receipt date of a complete drug registration dossier, while it is 12 months for the normal evaluation procedure.</td></tr>
<tr><td>Total target (company) time for responses to agency questions (If stated)</td><td colspan="3">Click here to enter text.</td></tr>
<tr><td colspan="4">Select one of the following (* see definitions at end of document)</td></tr>
<tr><td>Is this a verification review (a recognition pathway)?*</td><td>Is this an abridged* review (selected dossier portions)? (a reliance pathway)?*</td><td>Is this a full* review of all parts of the dossier?</td></tr>
<tr><td>☐</td><td>☒</td><td>☐</td></tr>
<tr><td>If this is a reliance or recognition pathway, what are the accepted reference agencies?</td><td colspan="3">European Medicines Agency (EMA), drug regulatory authorities of USA, Japan, France, Germany, Sweden, England, Switzerland, Australia, Canada, Belgium, Austria, Ireland, Denmark and The</td></tr>
</table>

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	Netherlands.
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?	In the cases where the CPP is issued by a drug regulatory authority other than a national level authority, the applicant shall provide legal documents proving that the issuing authority is fully competent and that the national-level drug regulatory authority of the home country does not issue CPPs according to its domestic law.
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.
How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g. non-agency) involved in the assessment?	Yes- always
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?	- The effective period of a marketing authorization is five (5) years from the issuance date or renewal date. The effective period of the marketing authorization for the following drugs is 3 years: (i) New drugs and vaccines that apply for the marketing authorization for the first time, reference biologicals and similar biologicals that apply for the marketing authorization in Vietnam for the first time; (ii) Drugs having the same active ingredient(s), concentration, content or dosage form as that of the new drug which has not been granted a 5-year marketing authorization; (iii) Any drug other than those mentioned in Point a and Point b of this Clause if a report on their safety

	and efficacy is not submitted when applying for renewal of the marketing authorization because the drug has not been marketed in reality or the quantity of drug used, quantity of patients or use duration is insufficient according to the Advisory Board, or the health facility recommends extension of monitoring of the safety and efficacy of the drug; (iv) The cases in which the monitoring of safety and efficacy of the drug should be continued as recommended by the Advisory Board. - Requirement of two CPPs for new chemical entities and imported biologics: With regard to new chemical entities and imported biologics (excluding probiotics - digestive enzymes), the applicant must submit the CPP issued by the manufacturing country and another CPP issued by one of the Stringent Regulatory Authorities, certifying that such drugs are licensed for circulation and physically circulated in the market.
Date of this update	5 February 2020.
References	1. MARKETING AUTHORIZATION OF DRUGS AND MEDICINAL INGREDIENTS. https://boftcms.trade.gov.tw/ckfinder/connector?command=Proxy&type=Files&currentFolder=%2F&fileName=%E8%B6%8A%E5%8D%97%E8%97%A5%E5%93%81%E6%B3%95%E8%A6%8F1080606.pdf&cache=31536000 Accessed on 5 February 2020. 2. Change in Drug Registration in Vietnam. https://www.tilleke.com/resources/change-drug-registration-vietnam Accessed on 5 February 2020. 3. Vietnam's Ministry of Health Issues a New Circular Regulating the Registration of Drugs and Drug Materials. https://www.bakermckenzie.com/en/insight/publications/2019/04/vietnams-ministry-of-health-issues-a-new-circular Accessed on 5 February 2020. 4. Medicinal product regulation and product liability in Vietnam: overview. https://ca.practicallaw.thomsonreuters.com/6-518-6504?transitionType=Default&contextData=(sc.Default)&firstPage=true&bhcp=1 Accessed on 5 February 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.