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Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Taiwan (Chinese Taipei)	**Agency Name:** Taiwan Food and Drug Administration (TFDA)	
Name of FRP: Accelerated Approval		
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?	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 chemical entities, new combination, new indication and new administration route.	
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)	Priority Review: 240 days Priority + Abbreviated: 150 days	
Total target (company) time for responses to agency questions (If stated)	Click here to enter text.	
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?	Click here to enter text.	
How many reference agency decisions are required?	Click here to enter text.	
Does this FRP require	Unredacted	

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submission of Assessment Reports from prior decisions?	
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?	For applications of new therapeutic compound, new administration route, new dosage form, new dose or new strength, FSC from the country of origin has to be submitted prior to license acquirement. If the country of origin is a member of the A10 countries, then the submission of the FSC from the country of origin also satisfies the submission of CPP. If the CPP submitted by the applicant states the same manufacturer's name, address, formulation, dosage form and contents as the information of the new drug in the application, then the submission of CPP also satisfies the requirement of submission of the FSC from the country of origin. According to the "Regulations for Registration of Medicinal Products", Article 7, A10 countries include Germany, US, UK, France, Japan, Switzerland, Canada, Australia, Belgium, and Sweden or the CPP issued by the EMA (European Medicine's Agency).
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?	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?	Accelerated Approval (all 4 criteria below need to be met): 1. New chemical entities, new combination, new indication and new administration route. 2. An application for a drug which addresses unmet medical need in the treatment of serious conditions and providing major clinical advance. 3. An application for a drug which addresses unmet medical need with orphan drug designation in advanced countries.

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	4. An application that demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. - Applications which are not prepared in CTD format or without complete administrative or technique documents are subject to Refusal to File (RTF) decisions. - For the NCE drug application, a post-approval risk management plan is required.
Date of this update	14 JANUARY 2020
References	1. Regulations for Registration of Medicinal Products. https://www.fda.gov.tw/ENG/lawContent.aspx?cid=5060&id=3144 Accessed on 6 January 2020 2. Fee-Charging Standards for the Review of Medicament and Cosmetic Advertisements. Accessed on 6 January 2020. 3. Taiwan Drug Approval Process. https://www.fda.gov.tw/eng/newsContent.aspx?id=22247 Accessed on 6 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.