FRPath.org
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: Abbreviated 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	An application for new chemical entities which fulfills all the following criteria: 1. Approval by two of the three regulatory agencies (US FDA, EMA, or MHLW/PMDA) and with bridging study waiver. 2. Providing full review reports from two of the three regulatory agencies (US FDA, EMA or MHLW/PMDA). 3. Providing Risk Management Plans and updated Post-marketing Commitment reports requested by two of the three regulatory agencies (US FDA, EMA or MHLW/PMDA).	
Must the product address an unmet medical need or serious condition?	Negotiable	
If a fee is required, what is the amount (in US$ equivalent)	New drug application 1) Product registration of a new drug which is of new active pharmaceutical ingredient(s): NT $ 600,000 [USD 20,000] 2) Product registration of a new drug which is of new composition or new administration route: NT $ 50,000 [USD 1,670] 3) Product registration of a new drug which is of a new dosage form, new strength with new indication, new dose unit, or controlled release dosage form, new strength of the same therapeutic compound(s) and the same administration route: NT $ 35,000 [USD 1,170] Generics 1) Product registration of a generic drug that is under post-market surveillance (including drugs within or out-of surveillance period): NT $ 35,000 [USD 1,170] 2) Product registration of a generic drug that is NOT under post-market surveillance: NT $ 20,000 [USD 670]	

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Total target (agency) time for assessment (calendar days)	Abbreviated Review: 180 days Submission → filing meeting (~60 days) → review meeting (~100 days) → notification for completion of review (~130 days) → approval/non-approval by TFDA (~180 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?	US FDA, EMA, or MHLW/PMDA.
How many reference agency decisions are required?	Approval by two of the three regulatory agencies (US FDA, EMA, or MHLW/PMDA.
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 Free Sales Certificate (FSC) from the country of origin and the CPP are not required for the application of New Chemical Entity (NCE) drugs. In cases where the FSC from the country of origin and CPP are submitted for the application, the central health competent authority may adjust the review process according to the actual situation.
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 applicant is required to show proof of approval by two of the three regulatory agencies (US FDA, EMA, or MHLW/PMDA) and with bridging study waiver; provide full review reports from two of the three regulatory agencies (US FDA, EMA or MHLW/PMDA); AND Provide Risk Management Plans and updated Post-marketing Commitment reports requested by two of the three regulatory agencies (US FDA, EMA or MHLW/PMDA).
How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g.	Choose an item.

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non-agency) involved in the assessment?	
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?	- The criterion for accelerated approval pathway and priority review designation was amended from "new chemical entities only" to a broader range as "new chemical entities, new combination, new indication and new administration route". For abbreviated review designation, the "MHLW/PMDA" was added as one of the reference regulatory agencies. - Applications which are not prepared in CTD format or without complete administrative or technique documents are subject to Refusal to File (RTF) decisions. - Applicants of New Chemical Entity (NCE) drugs should submit a CPP issued by any one of the A10 countries*, plus the dossiers of clinical trials to clinically and statistically justify drug safety and effectiveness in the population in Chinese Taipei. 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).
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.