FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: China	**Agency Name:** National Medical Products Administration	
Name of FRP: Prioritized Drug Review and Approval Pathway		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 2/24/2016		
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	• Registration applications for drugs with "apparent clinical value," such as (i) innovative drugs not marketed anywhere in the world; (ii) innovative drugs for which manufacturing is transferred to China; and (iii) drugs with advanced formulation technologies, innovative treatment methods and "apparent" treatment advantages; • Clinical trial applications for generic drugs that are submitted three years prior to expiration of the relevant patents or manufacturing applications for generic drugs that are submitted one year prior to expiration of the relevant patents; • Clinical trial applications for new drugs that are under parallel clinical trial applications in the U.S. and the EU and have been approved for clinical trials there; • Registration applications for drugs that are under parallel application in the EU and the U.S. with the same production line and have passed on-site inspections by those agencies; • Registration applications for new drugs developed under special national scientific research and development programs; • Registration applications for drugs for preventing or treating HIV, tuberculosis, viral hepatitis, rare diseases, malignant tumors, pediatric drugs and drugs for diseases specifically affecting seniors; • Registration applications for drugs with urgent clinical demand and supply shortages. A detailed list of such drugs will be proposed by China's National Health and Family Planning Commission and the Ministry of Industry and Information Technology; and • Registration applications for foreign pediatric drugs that have been approved in the U.S., the EU and

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	surrounding regions of China, supported with clinical data developed in those countries and regions.
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)	The target approval time set is 6 months or less. However, in 2018, the average drug approval took just over three years and drugs that received priority status took 16 months for approval.
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?	It is dependent on the product/process. In some cases, the EU and/or USFDA is the reference agency and in other cases, there is no reference agency required.
How many reference agency decisions are required?	Not applicable
Does this FRP require submission of Assessment Reports from prior decisions?	Choose an item.
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Choose an item.
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?	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?	Variable
How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g. non-agency) involved in the assessment?	No-all done internally
Post-authorization study commitments	Always required
For how long is the initial approval or	Choose an item.

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designation valid?	
Any other details you wish to provide?	- The prioritized review process will include (i) definitive timelines for the start of technical review, sample testing, on-site inspection, review conclusion and approval decision-making; and (ii) meetings with the reviewer to exchange information, discuss study data, as well as to seek regulatory guidance for the product development. - Companies conducting clinical trials may, after completion of Phase I and II trials, discuss with the reviewer the study results and its Phase III study plan, and may move to Phase III trials without any further approval if they agree upon the Phase III plan with the reviewer. For drugs targeting life-threatening diseases with no currently available effective treatment, companies may, through consultation with the CDE reviewer and based on early phase clinical data, obtain a conditional approval of the drug before completion of Phase III confirmatory trials.
Date of this update	26 October 2020
References	1. China Food and Drug Administration Creates a Prioritized Drug Review and Approval Pathway. https://www.sidley.com/~/media/update-pdfs/2016/03/20160302_china-food-and-drug-administration-creates-a-prioritized-drug-review-and-approval-pathway.pdf Accessed on 26 October 2020. 2. Provisions for Drug Registration (SFDA Order No. 28). http://subsites.chinadaily.com.cn/nmpa/2019-07/25/c_390595.htm Accessed on 26 October 2020. 3. How Is China's Drug Approval Agency Outpacing International Counterparts? It's Complicated. https://www.mercatus.org/bridge/commentary/how-chinas-drug-approval-agency-outpacing-international-counterparts Accessed on 26 October 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.