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: Conditional Approvals for New Drugs		
Is this FRP Proposed or Active? Choose an item.		
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	1. drugs that treat diseases which are seriously life-threatening and where there is no effective treatment and for which clinical studies confirm the efficacy and forecast the clinical value of the drugs; 2. drugs urgently needed for public health, where their efficacy has been proved in clinical trials; and 3. vaccines needed for a major public health emergency, or urgently needed by the National Health Commission, where the benefits are considered to outweigh risks NB: If the applicant plans to file for a conditional approval, a class II meeting application shall be submitted to the CDE and written opinions shall be obtained before the filing. If the drug is already classed as a BTD drug, a class I meeting will satisfy. If the early meeting with CDE and subsequent evaluation confirm the eligibility for a conditional market approval filing, the applicant may file simultaneously alongside new drug registration application. The drug registration certificate is then issued, along with such post-marketing clinical trial or study requirements including the due date.
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)	70 working days for urgently clinically needed drugs and rare disease products not yet available in China.
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)

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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?	Not applicable
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?	Not applicable
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Not applicable
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?	- In order to encourage the research and development of new drugs for which there is high clinical demand and to accelerate the marketing of drugs where there is urgent clinical need, the applicant may apply for conditional approval. These will be those drugs used to treat serious life-threatening diseases where there is, as yet, no effective treatment, or drugs and vaccines urgently needed for public health purposes, provided the clinical research data show their curative effects and predict clinical value. - The applicant must satisfy the risk management requirements set out in both the DAL and the DRR in order to receive conditional approval for new drugs. With respect to drugs that have been granted

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	conditional approval, marketing authorization holders (MAHs) will need to continue to adopt continuing risk management processes even after the drugs are marketed, clinical trials are completed and research finished within specified time limits, and to submit a supplementary application for approval, pursuant to Article 66 of the DRR. Post-marketing risk management measures, usually in the form of risk management plans, shall contain information on how to identify known risks and potential risks in how the drugs are clinically working, and put forward plans for pharmacovigilance activities that minimize risk, aggregate all drug safety risk information and include measures to reduce risks using information analysis and evaluation.
Date of this update	26 October 2020
References	1. China: Amended Drug Registration Regulation to Strengthen and Streamline New Drug Regulation. https://pharmaboardroom.com/legal-articles/amended-drug-registration-regulation-aims-to-strengthen-and-streamline-regulation-of-new-drugs/ 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.

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