FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Kazakhstan	**Agency Name:** National Center for medicines, medical devices and medical equipment expertise	
Name of FRP: Expedited Registration		
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	Medicinal Products
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)	At all stages of the expedited procedure for the examination of the medical agent carried out in a period not exceeding one hundred and twenty calendar days, including: 1) primary expertise - not more than twenty calendar days; 2) analytical expertise to fifty days; 3) Specialized Pharmacopeia expertise - not more than forty calendar days, including confirmation of the authenticity of the translation of marking layouts packaging, labels, stickers (not more than two working days); 4) special pharmacological expertise - not more than forty calendar days, including verification of the authenticity or translating instructions for medical use (not more than ten calendar days); 5) a conclusion on the safety, efficiency and quality of medical agents, the draft outcome document examination

	of Medical Agents - not more than ten calendar days. With the exclusion of one stage of the remaining stages of the examination dates are stored. The terms of the examination of the medical agent does not include the time to fill the incompleteness of the registration dossier submitted by the applicant of documents and materials on request at any stage of the examination, as well as the organization of the assessment of the conditions of production and quality assurance system for enterprise-manufacturer, requests expert committees and harmonization applicant outcomes.
Total target (company) time for responses to agency questions (If stated)	If the requested materials or written grounds for another deadline, but not exceeding sixty calendar days are not provided by the applicant, the expert organization ceases the process of registration and informs the public authority and the applicant about its decision within 10 days.

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 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?	Submit a Certificate of pharmaceutical product (CPP), issued in accordance with WHO recommendation (notarial certification). In its absence the applicant will submit: • Certificate (marketing authorization) about registration in manufacturing country (notarial certification); • GMP certificate with indication of date and results of the last inspection (notarial certification); • Certificate, allowing the free sale (export).
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.

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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?	Choose an item.
Any other details you wish to provide?	- The applicant must provide reasonable evidence of necessity and possibility to perform expertise in expedited procedure, confirmed by authorized organ. - Medicinal product expertise in expedited procedure will be performed by: exclusion of individual expertise stages; acceleration of expertise performance. - Medicinal product expertise in expedited procedure will be performed on the basis of a contract between expert organization and applicant.
Date of this update	19 JANUARY 2020
References	1. Kazakhstan legislation. https://aipm.kz/en/2016-07-11-17-52-27/kazakhstan-legislation/424-order-of-the-minister-of-health-and-social-protection-of-the-republic-of-kazakhstan-no-10-dated-january-14-2015.html Accessed on 19 January 2020. 2. Expertise of medicines. https://www.ndda.kz/category/ekspertiza_ls Accessed on 19 January 2020. 3. Safety and quality evaluation. https://www.ndda.kz/category/about_sert Accessed on 19 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.