FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Ukraine	**Agency Name:** State Service of Ukraine on Medicines and Drugs Control (SMDC)	
Name of FRP: Expedited Review		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 10/30/2015		
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	All products that meet the criteria for expedited review: medicinal products intended exclusively for treatment of tuberculosis, HIV/AIDS, virus hepatitis, oncology, orphan diseases.
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)	Specialized expert evaluation is conducted not more than 45 working days from the moment of submitting the registration dossier. This period does not include: - the period of assessment of the Application and the registration form; - payment of the government levy and receiving the payment confirmation; - preliminary expert evaluation of completeness of the dossier for registration; - the time required for the Applicant to respond to the observations; - final actions after expert evaluation (verification/proofreading of drafts of the registration certificate and its addenda); - period of signing the Order of the MOH on registration of the medicinal product. The above actions take an average of 2 to 4 months, and, accordingly, extend the resulting period for registration.
Total target (company) time for responses to agency questions (If stated)	Maximum 30 working days.

Select one of the following (* see definitions at end of document)

Is this a verification review	**Is this an abridged* review**	**Is this a full* review of all parts**

FRPath.org Country and FRP Information Input Form		
(a recognition pathway)?*	**(selected dossier portions)? (a reliance pathway)?***	**of the dossier?**
☐	☒	☐

If this is a reliance or recognition pathway, what are the accepted reference agencies?	The competent authorities of the United States of America, Switzerland, Japan, Australia, Canada, and the competent authority of the European Union under the centralized procedure.
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?	In addition to a CPP, the applicant must submit the official assessment report for the medicinal product drawn up by a competent regulatory authority or the WHO (WHOPAS).
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?	Yes- as needed
Post-authorization study commitments	Always required
For how long is the initial approval or designation valid?	See details Section below
Any other details you wish to provide?	- With effect from 30 October 2015, a new order of the Ministry of Healthcare of Ukraine [1] (the "Order") introduced a number of significant changes to Ukrainian drug review and authorization process. These include the following: - Cancellation of every 5-year re-registration for finished medicinal products. Going forward, on the first successful renewal of a marketing authorization ("MA"), it can get an unlimited validity. Another 5-year expiry can be given to MA as an exception, in case there are pharmacovigilance concerns. - The expedited process is established as an option

	for granting of MAs to medicinal products intended exclusively for treatment of tuberculosis, HIV/AIDS, virus hepatitis, oncology, orphan diseases - The Order: streamlines the general authorization process for medicinal products approved by the EMA under centralized procedure; several types of WHO prequalified drugs (HIV/AIDS, tuberculosis, vaccines, toxoids); as well as certain original (innovative) products (tuberculosis, HIV/AIDS, virus hepatitis, oncological and orphan diseases) registered in the U.S., Switzerland, Japan, UK and Australia; - In order to prevent issuance of an MA, patent infringement has to be confirmed by a court judgement that has entered into force. Copy of such judgement should be provided to the MOH and its expert institution. This clarification closes the legal ambiguity in this respect and is generally supported by prevailing market practice; - The Order arguably permits pharmaceutical companies to not only conduct R&D, but also file the registration dossier of a generic medicinal product before expiry of the reference product 5-year data exclusivity period, in order to obtain the MA after the exclusivity expires. This rule is, however, rather ambiguous and may require additional clarifications from the regulator. - The Applicant is also required to comply with all national requirements for the management of the safety and quality of the medicinal product in Ukraine, namely: assign a contact person responsible for pharmacovigilance in Ukraine, maintain a pharmacovigilance system during the validity of the registration certificate; receive the conclusion of the State Service of Ukraine on Medicines and Drugs Control (SMDC) for the compliance of manufacturing site with GMP requirements.
Date of this update	18 JANUARY 2020.
References	1. Ukrainian Ministry of Healthcare changes authorization process for medicinal products. https://epam.ru/eng/legal-updates/view/ukrainian-ministry-of-healthcare-changes-authorization-process-for-medicinal-products Accessed on 18 January 2020. 2. Abridged registration procedures. https://cratia.ua/en/state-registration-medicines-

and-active-pharmaceutical-ingredients/abridged-registration-procedures Accessed on 18 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.