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Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Eurasian Economic Union (EAEU)	**Agency Name:** Eurasian Economic Union (EAEU)	
Name of FRP: Decentralized Procedure		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 2/12/2016		
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	All products.	
Must the product address an unmet medical need or serious condition?	Negotiable	
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 decentralized procedure should take not more than 210 calendar days. More time may be required for answering additional requests and in the case of other complications.	
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?	Accepted Reference Agencies: Armenia, Belarus, Kazakhstan, Kirghizstan, and Russia. NB: The applicant chooses one state as a reference state which will be responsible for a full-fledged cycle of procedures, including tests and inspections, resulting in an expert report. In other	

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	designated states (recognition states) only examination of the expert report from the reference state and particular modules of the uniform technical document takes place. Under the decentralized procedure, both processes happen simultaneously and this is suitable for medicines which are introduced on the EAEU market for the first time.
How many reference agency decisions are required?	1 - Only examination of the expert report from the reference state and particular modules of the uniform technical document takes place.
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?	Click here to enter text.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	Armenia, Belarus, Kazakhstan, Kirghizstan, Russia.
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Click here to enter text.
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?	- The Agreement, which came into legal effect on 12 February 2016, requires that medicines allowed on the EAEU market (Armenia, Belarus, Kazakhstan, Kirghizstan, Russia) must first be registered under the Rules and listed in the Unified list of registered medicines of the EAEU. This requirement applies equally to the whole EAEU market and to the territories of individual member states. - No single centralized registration is envisaged in the EAEU. Instead, mutual recognition and a decentralized procedure are provided for. Both are conducted on the

member-state level by authorized governmental bodies.
- These procedures are based on corresponding procedures existing in the EU.
- The applicant chooses one state as a reference state which will be responsible for a full-fledged cycle of procedures, including tests and inspections, resulting in an expert report. In other designated states (recognition states) only examination of the expert report from the reference state and particular modules of the uniform technical document takes place.
- Under the decentralized procedure, both processes happen simultaneously and this is suitable for medicines which are introduced on the EAEU market for the first time.
- Registration in the reference state is valid initially for 5 years. Subject to confirmation of registration (re-registration), a registration certificate can generally be issued for an indefinite term. In the recognition state the validity period is the same as in the reference state.

** There is a special procedure for bringing the registration dossiers of medicines registered in the member states before 31 December 2020 into conformity with EAEU requirements. The deadline for completing the procedure is 31 December 2025. The procedure is simplified and takes 100 calendar days. If a medicine is registered in more than one member state, the applicant must choose which one will be the reference state; in other states the registration update will be carried out under the recognition model.
As a result of the procedure, registration is issued for an indefinite term if a medicine has already been registered in 3 member states for 5 years and longer. Should this not be the case, the general rule applies.
** The procedures laid down in the Rules will replace corresponding procedures existing now on the national level. However, national legislation will still serve as a regulatory basis for the new procedures as the Rules specify the general features of the system, set main principles and in many matters refer to the national laws of the member states, which therefore allows for jurisdiction shopping.
During the transitional period until 2021 both national and EAEU procedures are available for applicants. After that, national applications will not be accepted.
Medicines registered under national procedure are only allowed on the territory of that particular member state. National registration certificates are valid throughout their validity periods, but no longer than 31 December 2025. Extending the validity of

	and amending these registrations under national rules is possible within the same timeframe. For a medicine to be allowed on the market of the EAEU or a particular member state beyond that deadline, its dossier must be brought into conformity with EAEU requirements.
Date of this update	4 February 2020
References	1. Launch of Eurasian Economic Union (EAEU) medicines registration procedure. https://www.bnt.eu/en/news/legal-news/2602-launch-of-eurasian-economic-union-eaeu-medicines-registration-procedure Accessed on 4 February 2020. 2. In the EAEU, a common medicines market is launched. http://www.eurasiancommission.org/en/nae/news/Pages/5-05-2017.aspx Accessed on 4 February 2020. 3. REGISTRATION OF MEDICINES IN THE EURASIAN ECONOMIC UNION. https://www.regulatorypharmanet.com/eaeu/ Accessed on 4 February 2020. 4. Registration of medicines in the Eurasian Economic Union. https://gratanet.com/publications/registration-of-medicines-in-the-eurasian-economic-union Accessed on 4 February 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.