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Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Moldova	**Agency Name:** Medicines and Medical Devices Agency (MMDA)	
Name of FRP: Simplified Registration Procedure		
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	Simplified registration procedure is applicable in case if submitted registration dossier is completely identical to the latest dossier accepted in one of the reference countries. In case of filing the dossier specific for the market or region, medicinal product should be submitted according to standard registration procedure.
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)	Obvious advantages of the simplified procedure are shortened examination timelines of up to 60 days, no need to provide registration samples and standards, no need in laboratory analysis.
Total target (company) time for responses to agency questions (If stated)	Applicant should provide complete response to observations within 90 days. Timelines for reply may be extended by a written application of the Applicant for not more than 30 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?	Simplified registration procedure is stipulated by legislation of Moldova for medicinal products registered by the EMA in at least one of the countries of European Economic Area or registered in Switzerland, USA, Canada, Japan, Australia.
How many reference agency decisions	1+

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are required?	
Does this FRP require submission of Assessment Reports from prior decisions?	Unredacted
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?	Yes, the product has to have been marketed in another country, specifically the accepted reference agencies mentioned.
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?	4-5 years
Any other details you wish to provide?	- The regulations on authorization of medicines (further - the Provision) are developed based on the Law No. 1409-XIII of December 17, 1997 on drugs (The official monitor of the Republic of Moldova, 1998, No. 52-53, of the Art. 368), with further changes and amendments, the Law No. 1456-XII of May 25, 1993 on pharmaceutical activities (pereopublikovano: The official monitor of the Republic of Moldova, 2005, No. 59-61, of the Art. 200), with further changes and amendments, for the purpose of ensuring efficacy, quality and safety of the medicines permitted to delivery in the pharmaceutical market and also for the purpose of ensuring economic and social protection of consumers and pharmakobezopasnost of the country. - Validity period of Registration Certificate is 5 years. Medicinal product may be used in medical practice until its expiry date. Registration Certificate may be revoked by the Ministry of Health in the event if medicinal product has not been supplied to the country within three (3) years from the date of issue

	of the Registration Certificate. - Documents can be submitted in Romanian or English or Russian language. SmPC should be submitted with translation into Romanian. Draft of package leaflet should be prepared in accordance with the national form in Romanian language. Package labeling should be submitted in Romanian language as well. Additional languages are allowed in the case that the information is identical to the text in Romanian. For medicinal products intended for administration by healthcare personnel, for example: for hospital preparations (anesthetics, solutions for infusion, vaccines, radiopharmaceuticals, blood derivatives or blood serums), or orphan drugs, or drugs used for substitution therapy, primary and secondary packaging in the language/ languages of international importance is allowed.
Date of this update	31 May 2020
References	1. Moldova. https://cratia.ua/en/registration-medical-products-countries-former-soviet-union-cis-and-middle-asia/moldova.html Accessed on 31 May 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.

By submitting this form, I agree that the information is true to the best of my knowledge and I consent that it can be used without restriction by FRPath