FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Serbia	**Agency Name:** Medicines and Medical Devices Agency of Serbia	
Name of FRP: Marketing Authorization Issuance according to the Accelerated Procedure and with conditions		
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?	Choose an item.	
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	Application for obtaining marketing authorization with abbreviated documentation consists of at least: 1. generic medicinal product; 2. generic hybrid medicinal product; 3. Biologically similar medicinal product.	
Must the product address an unmet medical need or serious condition?	Negotiable	
If a fee is required, what is the amount (in US$ equivalent)	Amounts of fees for issuing a conditional marketing authorization for medicinal product, marketing authorization under exceptional circumstances and temporary marketing authorization: UNIT = RSD a) pharmaceutical form, strength, and package of the medicine 460.000,00 [USD 4,340] b) each additional pharmaceutical form 240.000,00 [USD 2,265] c) each additional strength of the same pharmaceutical form of the medicine 150.000,00 [USD 1,415] d) each type of additional inner package of the same pharmaceutical form and strength 30.000,00 [USD 284] e) each additional package size 30.000,00 [USD 284]	
Total target (agency) time for assessment (calendar days)	Within the period of 150 days, after receiving the complete application, the Agency is obliged to decide whether to grant a marketing authorization or deny a marketing authorization application, based on the opinions and evaluation of the documentation on medicinal product quality, safety and efficacy.	
Total target (company) time for responses to agency	If the application for a marketing authorization issued following an accelerated procedure is incomplete, the Agency shall notify the	

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questions (If stated)	applicant that additional information be submitted within 30 days from the date the written notice has been received.	
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?	The centralized procedure for obtaining a marketing authorization in the European Union from the European Medical Evaluation Agency.	
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?	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. Applicant for medicinal product issuance with abbreviated documentation can apply for a marketing authorization after at least eight years have elapsed from the date when the global license for the reference medicinal product, the applicant refers to, had been issued in Republic of Serbia, the European Union or countries that have the same or similar requirements for the issuance of the license. After ten years from the date of issuance of the global license for the reference medicinal product have elapsed, an applicant can obtain a marketing authorization with abbreviated documentation.	
How are queries to the companies sent?	Choose an item.	
Are external reviewers (e.g. non-agency) involved in the assessment?	No-all done internally	
Post-authorization study commitments	Choose an item.	

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For how long is the initial approval or designation valid?	4-5 years
Any other details you wish to provide?	- Since Serbia is not a member of the EU, in this phase of the development of pharmaceutical regulatory system for granting centralized authorization or marketing authorization based on mutual recognition is not yet possible. Although Serbia is not yet a member of the EU, when marketing medicinal products, there is a possibility of recognizing and accepting expert opinions and performed clinical trials, in line with the Declaration of Helsinki, as well as the study on bioequivalence and bioavailability, with the applications processed in accordance with the internationally recognized standards, and with medicinal products that have already been marketed. - The Agency, with prior approval of the Minister responsible for public health, provides a list of experts for medicinal products and medical devices in order to assess the documentation of medicinal products and medical devices, and/or research documentation on quality, safety and efficiency of medicinal products and medical devices, and prepare the expert report in the process of issuing marketing authorization, and/or medical device license, and for medicinal products used exclusively in veterinary medicine (in further text: veterinary medicinal product) – with the prior approval of the Minister in charge of the veterinary affairs. Experts from the list (referred to in Paragraph 1 of this Article) shall be elected among experts in the field of medicinal products and medical devices. - Marketing authorization issued following an expedited procedure remains valid for five years, starting from the date the decision to grant the marketing authorization is made, unless this Law stipulates otherwise. - Marketing authorization shall be issued following an accelerated procedure for: 1) medicinal product used in human medicine, and of the highest interest for public health protection, but above all, particularly in relation to therapeutic innovation; 2) medicinal product for which a license has already been issued following centralized procedure. **CONDITIONAL MARKETING AUTHORIZATION[2]:** - With prior arrangement with the applicant, the Agency can issue a marketing authorization conditioning the applicant to meet specific obligations, which the Agency inspects once every 12 months starting from the date of issuance of a conditional marketing authorization. Obligations to be

	fulfilled by the applicant listed under Paragraph 1 of this Article, as well as the time for which the conditional marketing authorization was issued, are published on the website of the Agency within eight days from issuance date of a conditional marketing authorization. - Marketing authorization referred to in Paragraph 1 of this Article shall be valid for 12 months and can be renewed until the requirements listed in Article 29, Paragraph 1, Item 4) of this Law are met or if the benefit from the medicinal product application to public health outweighs the risks incurred due to the lack of specific information on clinical trials. In urgent cases where the public health is affected, conditional marketing authorization can exceptionally be issued without any information prescribed in Article 29, Paragraph 1 Items 2) and 3) of this Law. **Article 29 is on Page 23/118 of Reference 2* - Every six months during a conditional marketing authorization validity period, the marketing authorization holder shall submit to the Agency a periodic report on safety of a medicinal product for which a conditional marketing authorization is issued. If the requirements referred to in Article 29, Paragraph 1, Item 4) of this Law or requirements listed in Article 29, Paragraph 1, Items 2) and 3) of this Law are met, the Agency issues a marketing authorization valid for five years pursuant to this Law. Conditional marketing authorization can be issued following an accelerated procedure referred to in Article 34 of this Law.
Date of this update	17 JANUARY 2020.
References	1. PRICELIST ("Official Gazette of the Republic of Serbia", No. 95/2017). https://www.alims.gov.rs/eng/files/2019/02/Cenovnik_Pricelist.pdf Accessed on 17 January 2020. 2. Law on medicines and medical devices ("The Official Gazette of the Republic of Serbia", 30/2010; 107/2012-other law and 113/2017-other law). https://www.alims.gov.rs/eng/files/2013/04/Law-on-Medicines-and-Medical-Devices-2010.doc Accessed on 17 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.