FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Switzerland	**Agency Name:** SwissMedic	
Name of FRP: Swissmedic Article 13		
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	At the request of the applicant, the assessment according to Art. 13 TPA will be applied to all authorisation applications for medicinal products with known active substances and biosimilars, and also to its applications for extensions or variations according to section 6, provided that these satisfy the conditions stated in Art. 16 - 20 TPO
Must the product address an unmet medical need or serious condition?	Negotiable
If a fee is required, what is the amount (in US$ equivalent)	If the authorisation holder submits an application for the assessments of foreign authorities to be taken into account in accordance with Art. 13 TPA in conjunction with Art. 16 - 20 TPO, and the requirements described in the guidance document are met, and if Swissmedic's decision can be based on the results of the reference authority's assessment, the overall fees applicable to individual cases are reduced by 60% in accordance with Art. 10 FeeO-Swissmedic
Total target (agency) time for assessment (calendar days)	Click here to enter text.
Total target (company) time for responses to agency questions (If stated)	During the formal control, Swissmedic checks whether the requirements for the application of Art. 13 TPA according to section 3 are fulfilled and that the required complete documentation exists. It also checks whether the documentation requirements according to Art. 16 TPO were respected. The applicant is informed about the rejection of the application of Art. 13 HMG or about any formal complaints. The applicant must present its statement on the negative preliminary decision to Swissmedic – or, as the case may be, submit the missing documentation – within 30 days.

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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?	According to Swissmedic, reference agencies are the foreign authority which has already authorised the medicinal product in question, and whose evaluation is used by the applicant as the basis for the authorization of the product in Switzerland.
How many reference agency decisions are required?	Variable
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?	The product may have been marketed in another country. If an applicant requests the authorisation, extension or a variation of an authorisation for a medicinal product or procedure for which authorisation has already been granted in a country with a comparable control system for medicinal products, Swissmedic will take into consideration the results of the assessments carried out by the foreign regulatory agency provided that certain requirements are fulfilled. Consideration of the results of foreign authorisation procedures is intended to assist in processing authorisations of medicinal products in Switzerland in such a way that medicinal products already authorised in foreign countries are made available to patients in Switzerland as rapidly as possible, and also to ensure the targeted, risk-assessed use of Swissmedic's resources (Art. 1 para. 2 letter c and Art. 1 para. 3 letter a TPA).
How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g. non-agency) involved in the assessment?	Choose an item.
Post-authorization study commitments	Always required

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For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	- The complete and final Assessment Report of the reference authority must be submitted to Swissmedic. If the foreign reference authority provides the applicant in Switzerland only with an Assessment Report that is not wholly legible, Swissmedic will accept the submission of this incomplete Assessment Report. However, in these situations Swissmedic reserves the right to conduct its own scientific assessment for the inaccessible parts of the Assessment Report, while referring to the underlying documentation. The corresponding extra work involved will usually lead to a time-based surcharge and correspondingly higher fees.
Date of this update	31 May 2020
References	

*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.