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 Marketing Authorisation for Global Health Products (MAGHP) 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?	Before the marketing authorisation 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	High-quality, essential medicines for populations living in low-income countries. The following conditions must be fulfilled in order for an authorisation application to be processed within the framework of an MAGHP procedure: - The authorisation application must concern a medicinal product with a new active pharmaceutical ingredient (new API), a new indication for a medicinal product or for a known active pharmaceutical ingredient (known API). - The clinical and preclinical trials must be completed at the time of application submission. Any results from foreign assessments available to the applicant, particularly assessment reports from the European Medicines Agency (EMA) or the U.S. Food and Drug Administration (FDA), must be included with the submission. *The MAGHP procedure will be tested in a pilot phase for about two years with the EAC NMRAs as active participants. After this period, the procedure may be revised to better suit the needs of the involved parties and may be opened up to allow the active participation of other NMRAs.
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	Fees for the application have to be paid according to the Ordinance on the Fees levied by the Swiss Agency for Therapeutic Products [HGebV; SR 812.214.5], the WHO PQT Guidelines (Prequalification Procedures and Fees) and national Fees regulations of the NMRAs concerned.
Total target (agency) time for	The procedure and timelines follow the regular marketing

assessment (calendar days)	authorisation procedure at Swissmedic. In addition, applicants are requested to submit a prior-notification around six to three months before the planned submission date in order to allow proper planning of resources and involvement of NMRAs in East African countries as well as the WHO PQT. - Decision (Day 330): Swissmedic sends the final decision to the applicant and makes it available to the NMRAs concerned and WHO PQT via the electronic platform. In the case of a positive decision the Swiss marketing authorisation or export registration is granted. - The NMRAs concerned will decide and confirm their decisions within 90 days of the date on which Swissmedic sent the decision to the applicant. (Day 420).
Total target (company) time for responses to agency questions (If stated)	The List of Questions (LoQ) is sent to the applicant on Day 150 of the procedure. The applicant is granted a 90-day period to respond to the LoQ. The applicant may ask for an extension of this period by a maximum of a further 90 days. Within two weeks after receipt of the list of questions, the applicant shall inform Swissmedic of the planned date of submission of its response to the list of questions. The applicant is granted another 90-day period for its response to the preliminary decision. The applicant is expected to agree with any obligation linked to the final decision as well as to fulfil all preconditions associated with the final decision.

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?	Swissmedic acts as a stringent regulatory authority in this cooperation.
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	Click here to enter text.

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documentation to the CPP be used? If so, what types of documents?	
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	The overall goal of this procedure is to accelerate and increase access to high-quality, essential medicines for populations living in low-income countries. The aim is to increase the efficiency of the regulatory review and registration process by focusing stakeholders on value-added activities, and to strengthen the regulatory authorities' ability to protect their citizens' health. Although other regions may be involved, the initial focus will be on supporting regulators in the East African countries with the goal of accelerating the access to medicinal products, mainly for those diseases that disproportionately affect the region. In the context of the Marketing Authorisation for Global Health Products (hereinafter referred to as MAGHP) procedure, this should be achieved by involving National Medicines Regulatory Authorities (hereinafter referred to as NMRAs) of the East African Community (EAC). If a listing for WHO prequalification is possible and intended, the WHO Pre-Qualification Team (hereinafter referred to as WHO PQT) will be involved in this marketing authorisation procedure at Swissmedic too. Swissmedic acts as a stringent regulatory authority in this cooperation. For priority global health products with high relevance it is possible to involve NMRAs of countries outside the EAC as observers in the MAGHP procedure. The expectation is that, if those partners are involved in this first step, the following steps at WHO and at the level of the NMRAs could be abbreviated because: - knowledge about the product has already been acquired and - confidence in the scientific process at Swissmedic has been gained. The MAGHP procedure builds on the existing authorisation process at Swissmedic.
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. As part of the application, submit a Completed form: "Status of marketing authorisations abroad" .
How are queries to the companies sent?	At specified times during the assessment
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	Choose an item.

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designation valid?	
Any other details you wish to provide?	- In 2015, Swissmedic, the Swiss Agency for Therapeutic Products and the Swiss Agency for Development and Cooperation (SDC), started supporting the efforts of the African Medicines Regulatory Harmonization Initiative (AMRH). The aim is to strengthen capacities and harmonized procedures of national medicines regulatory authorities working within a regional regulatory network and thereby to accelerate access to safe and efficacious quality therapeutic products for the African population. - In this context, Swissmedic has set up a Marketing Authorisation for Global Health Products Procedure and a Procedure for Providing Scientific Advice which is accessible to manufacturers interested in developing products specifically for low- and middle-income countries and which could be used to help inform regulatory decisions by regulatory authorities from resource-constrained countries and the WHO. The aim is to help accelerate subsequent WHO pre-qualification and national/regional medicine evaluation and registration. It is expected that the timelines for the WHO-PQ listing and marketing authorisation by the participating regulatory authorities will be significantly reduced because they have access to the outputs of the MAGHP procedure and have gained confidence in using its outcome. Overall, this should lead to a faster access to those medicines for the patients in need. - A request for an MAGHP procedure can be sent to Swissmedic at the earliest six months prior to the expected submission date and must be received at the latest three months prior to the expected date. - For all applications, including those for export only, a Swiss marketing authorisation holder is required. However, an applicant does not necessarily need to be based in Switzerland, but can work through a representative, e.g. a regulatory office. - Furthermore, conducting an MAGHP procedure is only possible if the authorisation application is submitted in CTD format, either in electronic form (eCTD application) or as a paper version with CD/DVD (eDok). Submission in electronic form (eCTD) is preferred. Applicants with limited or no experience with eCTD submit a test sequence in good time (at least 3 weeks before submitting the

	application), in order to avoid exceeding the time limits as a result of technical problems. - The documentation for this procedure shall be submitted in English. Also, assessment reports and Lists of Questions (LoQ) and correspondence will be written in English. - Communication until day 330 (decision) during the MAGHP procedure will be between the applicant and Swissmedic. Communication in the affirmation phase will be between the NMRAs concerned and the applicant directly. Swissmedic will facilitate the contact between the applicant and the NMRAs concerned.
Date of this update	20 April 2020
References	1. The Swissmedic Marketing Authorisation for Global Health Products (MAGHP) Procedure. Accessed on 20 April 2020. 2. SwissMedic Guidance document MAGHP Procedure. Accessed on 20 April 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.