Benefits

- ✓ The MAGHP results in a Swiss Marketing Authorisation.
- ✓ There is no restriction to specific indications.
- ✓ The involvement of NMRAs establishes trust and confidence in the process and helps building capacity.
- ✓ Timelines of WHO and marketing authorisation by NMRAs can be reduced.

Where to find detailed information on the MAGHP?

Please refer to our website
www.swissmedic.ch/development-cooperation:

- Guidance document Scientific Advice MAGHP
- Guidance document Authorisation Procedure MAGHP

Contact
You have further questions?
You have a candidate for the MAGHP?
Swissmedic Networking is looking
forward to getting in contact with you:
E-Mail: **networking@swissmedic.ch**

Swissmedic
Swiss Agency for Therapeutic Products
Networking
Hallerstrasse 7
3000 Bern 9 – Switzerland
Internet: **www.swissmedic.ch/development-cooperation**

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Schweizerisches Heilmittelinstitut
Institut Suisses des porduits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

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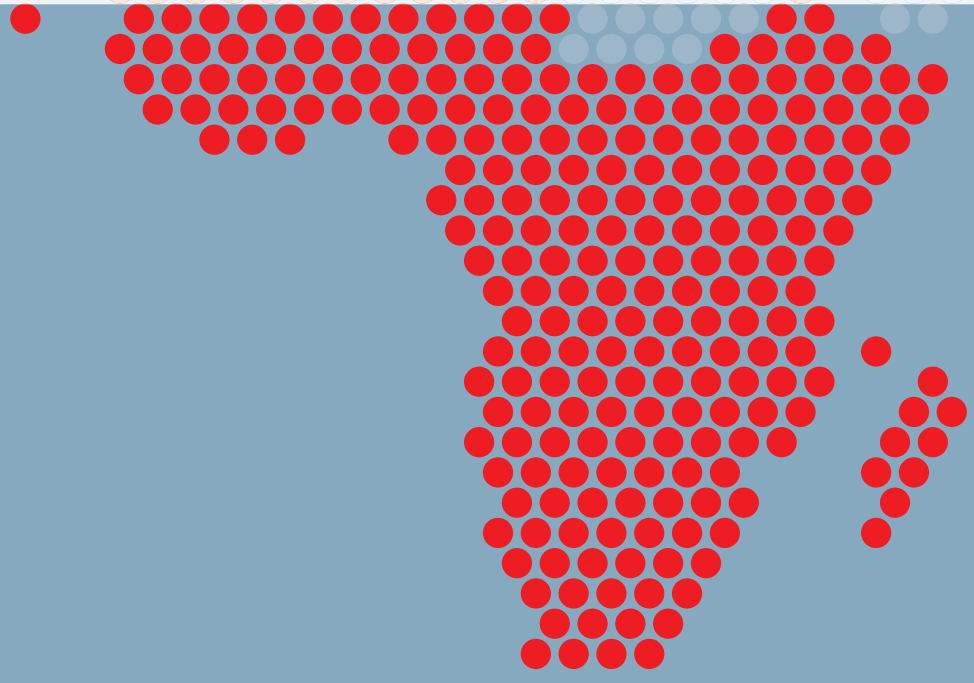
Marketing Authorisation for Global Health Products (MAGHP)



Marketing Authorisation for Global Health Products – MAGHP

Swissmedic actively engages in development cooperation. This is based on the revised mandate of the Institute and the Memorandum of Understanding (MoU) with the Bill & Melinda Gates Foundation.
The cooperation focuses on improving and accelerating access to essential therapeutic products in resource constrained countries by strengthening the regulatory systems. The Marketing Authorisation for Global Health Products is one component of this cooperation.

What it is

The MAGHP is based on the approach of involving regional National Medicines Regulatory Agencies (NMRAs) and the WHO in the Swissmedic assessment process. This helps building trust and confidence in the process and is expected to facilitate the granting of national marketing authorisations following Swissmedic's approval.

The procedure consists of two independent components:

1. **Scientific Advice:**
   To clarify scientific questions in the development phase regarding the planned submission
2. **Marketing Authorisation:**
   The procedure follows the regular Swissmedic marketing authorisation procedure with the difference that concerned NMRAs and the WHO are involved.

For both components, NMRAs and the WHO can either actively participate or follow the procedure as observer. Active participation implies full access to the applicant's documentation and active involvement in the procedure. Documents are shared on a Collaboration Platform hosted by Swissmedic.

Scope and eligible products

The MAGHP focuses on the sub-saharan region of Africa.

Your medicinal product is eligible for the MAGHP in case it is

- a medicinal product with a new active pharmaceutical ingredient (new API)
- a medicinal product with a known active pharmaceutical ingredient in a new indication
- a medicinal product with a known active pharmaceutical ingredient (known API)

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Marketing Authorisation for Global Health Products – MAGHP

Process and milestones

1 PRIOR NOTIFICATION

Request for MAGHP procedure (90–180 days)
Around six to three month before the planned submission date, the applicant submits a prior notification.

2 SUBMISSION

Validation (30 days)
Upon submission of the application, Swissmedic contacts the NMRAs concerned and WHO to determine active participation or passive observership.

3 EVALUATION 1

Evaluation 1 (120 days)
Evaluation phase 1 results in the List of Questions (LoQ).
NMRAs involved and WHO get preliminary evaluation reports, have the possibility to comment on the dossier and can participate in Case Team meetings.

4 EVALUATION 2

Evaluation 2 (90 days)
Evaluation phase 2 results in the preliminary decision after having reviewed the answers to the LoQs.
NMRAs involved and WHO get draft evaluation reports, have the possibility to comment on the dossier and can participate in the Case Team meeting prior to preliminary decision.

5 PRELIMINARY DECISION

Labeling (90 days)
During the labelling phase, texts for the Summary of Product Characteristics (SmPC), the Patient Information Leaflet (PIL) and packaging are finalised.

6 SWISSMEDIC DECISION

Swissmedic's final decision is sent to the applicant and made available to NMRAs concerned and WHO.

7 NMRA'S AND WHO'S DECISION

NMRAs concerned and WHO confirm their decisions according to their own procedures.