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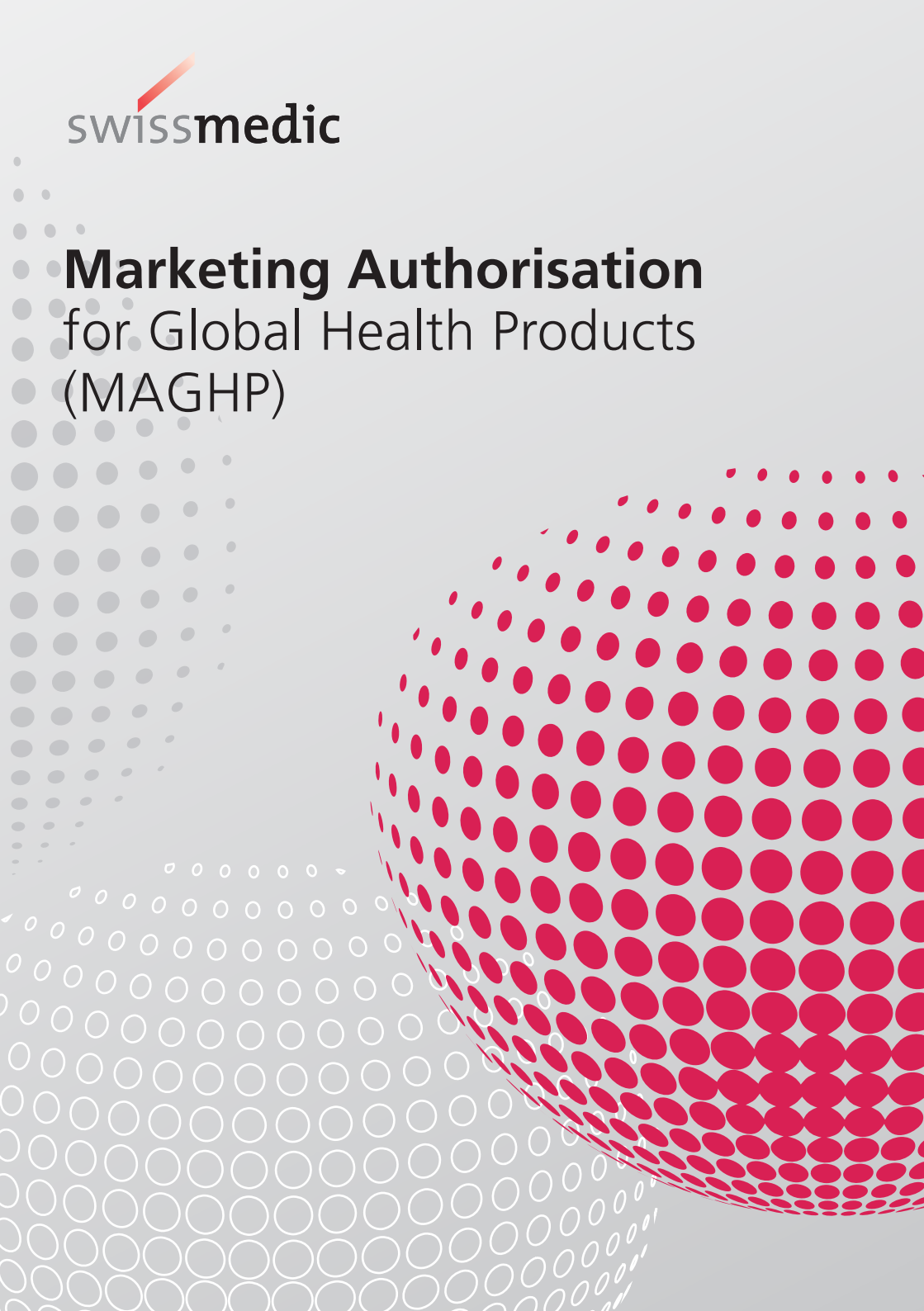
Marketing Authorisation for Global Health Products (MAGHP)



Marketing Authorisation for Global Health Products (MAGHP)

Swissmedic actively engages in development cooperation. This is based on the strategic goals defined by the Federal Council and the Memorandum of Understanding (MoU) with the Bill & Melinda Gates Foundation and the Swiss Agency for Development and Cooperation. 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 actively involving regional National Regulatory Agencies (NRAs) 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:
Standard Procedure: The procedure follows the regular Swissmedic marketing authorisation procedure with the difference that concerned NRAs and the WHO are involved.
Light Procedure: This special procedure is applicable to all applications in the fast track and temporary authorisation procedures.

For both the Scientific Advice and the Standard MAGHP Procedure, targeted NRAs actively participate in the process. Active participation implies full access to the applicant's documentation and active involvement in the procedure. Documents are shared on a secured collaboration platform hosted by Swissmedic. With regard to the MAGHP Light, no active interaction is foreseen during the assessment procedure, due to the short and expedited assessment times.

Scope and eligible products

The MAGHP focuses on the sub-Saharan region of Africa and on medicines for diseases that disproportionately affect this region, although other countries or regions may also be considered. 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)

Standard MAGHP Procedure: Steps 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 NRAs concerned and WHO to determine active participation.

3. EVALUATION 1

Evaluation 1 (120 days)

Evaluation phase 1 results in the List of Questions (LoQs). NRAs involved and WHO get preliminary evaluation reports, have the possibility to comment on the dossier and participate in the Case Team Meeting (CTM).

4. EVALUATION 2

Evaluation 2 (90 days)

Evaluation phase 2 results in the preliminary decision after having reviewed the answers to the LoQs. NRAs involved and WHO get draft evaluation reports, have the possibility to comment on the dossier and participate in the CTM prior to preliminary decision.

5. PRELIMINARY DECISION

Labelling (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

The final decision is sent to the applicant and made available to NRAs concerned and WHO.

7. NRA'S DECISION

NRA's decision phase (90 days)

NRAs concerned confirm their decisions according to their own requirements. NRAs are expected to approve the product within 90 calendar days from receipt of the dossier.

Benefits

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

Where to find detailed information on the MAGHP?

Please refer to our website
www.swissmedic.ch/maghp

- Guidance document Scientific Advice MAGHP
- Guidance document Authorisation Procedure MAGHP (including MAGHP Light)

Contact
You have further questions?
You have a candidate for the MAGHP?
Swissmedic Stakeholder Engagement is looking forward to getting in contact with you:

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