



## **Internationale Zusammenarbeit MAGHP Verfahren**

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Stakeholder Engagement



# **Marketing Authorisation** for Global Health Products (MAGHP)



# MAGHP - A Collaborative Approach for Global Health

- MAGHP offers a **collaborative pathway** for the assessment of **essential medicines** for populations of the global South.
- MAGHP involves **National Regulatory Agencies** (NRAs) and the **World Health Organization** (WHO) in the Swissmedic assessment process.
- MAGHP builds **trust and confidence**, facilitating national marketing authorisations after Swissmedic approval.
- MAGHP contributes to **building capacities** within the participating NRAs.

# MAGHP consist of two main components

## Scientific Advice

- To clarify scientific questions in the **development phase** regarding a planned submission
  - on quality of APIs and products
  - on the planning and organisation of preclinical investigations and clinical trials
  - on aspects of PV and RMP



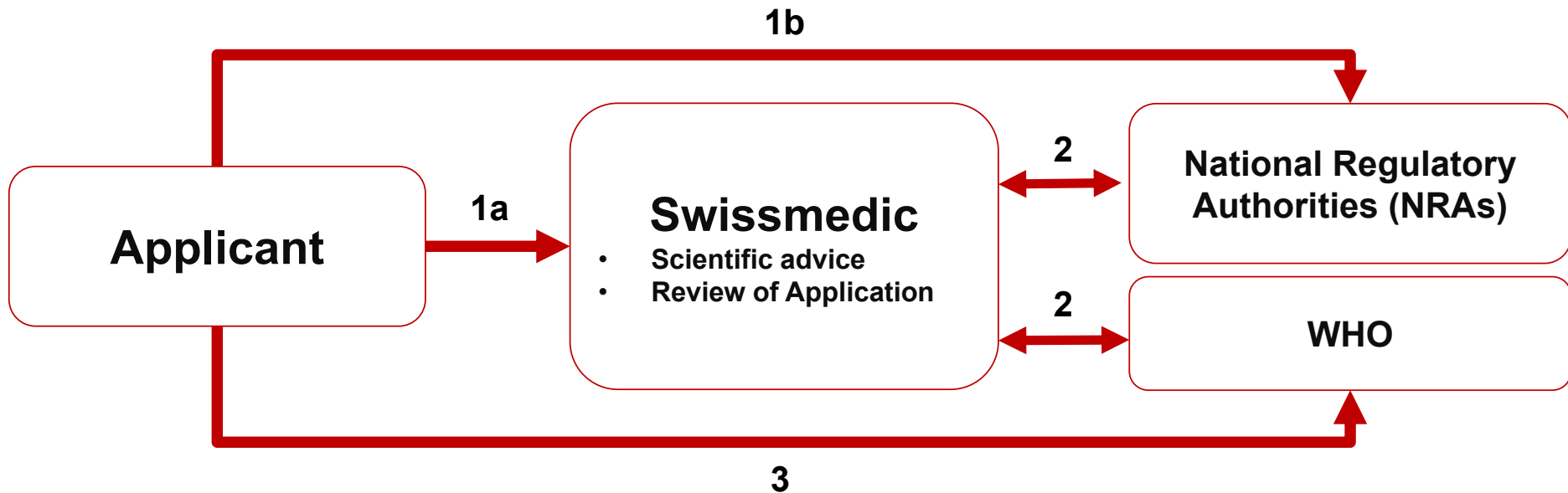
## Marketing Authorisation Application

- The procedure follows the regular Swissmedic marketing **authorisation procedure**
  - same time frames, procedural steps and evaluation criteria
  - results in an authorisation for the Swiss market
- ❖ with the difference that concerned NRAs and the WHO are involved

## Scope and eligible products

- Goal is to **accelerate access** to medicinal products targeting a concrete medical need in endemic regions
- Involvement of **NRAs of affected countries** in the global South is considered
- Eligible applications types
  - ✓ **new active substance** (NAS)
  - ✓ **known active substance**
  - ✓ **new indication**
- **No restriction** to specific **therapeutic areas**

# Overview MAGHP Procedure



- 1 Submission of documentation and applicant's agreement to exchange confidential information
- 2 Provision of MA dossier and all related material on a secured «SharePoint» platform; interactions at defined milestones and ad-hoc
- 3 Request for WHO Collaborative Registration Procedure

# Involvement and Interactions

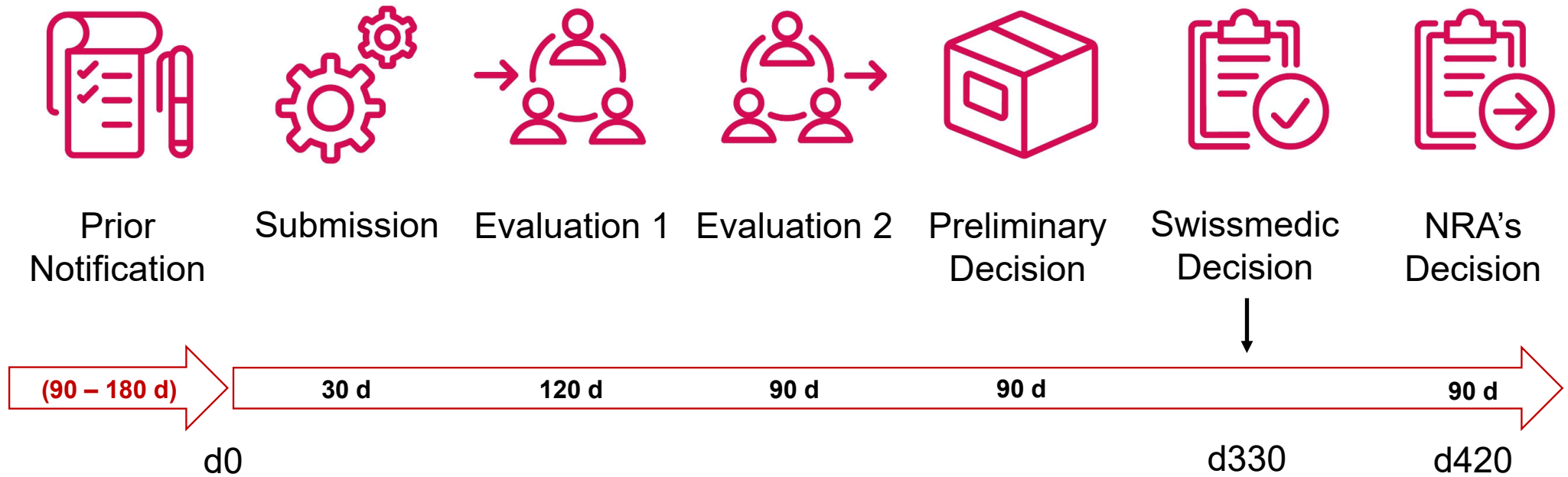
NRAs and WHO are involved in the process as follows:

- **Get access to information**
  - Full documentation as submitted by the applicant (product dossier)
  - Swissmedic assessment reports and List of Questions (LoQ)
- **Provide input**
  - Evaluating/writing assessment reports
  - Adding questions to LoQ
- **Participate in meetings**
  - Scientific advice/pre-submission meeting
  - Case team meetings
  - Experts review board

The choice about the NRAs/WHO to be involved follows the applicant's request.

NRAs/WHO decide about their participation.

# Procedural Milestones



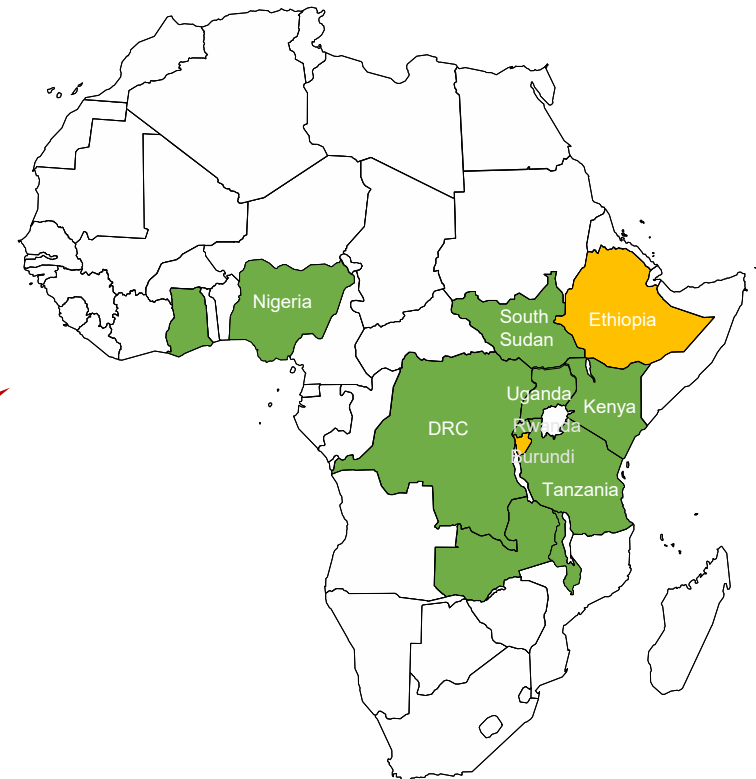


# MAGHP – Case Study

- Product for **prevention of postpartum uterine atony** following vaginal delivery approved
- 7 NRAs granted authorization, 3 of these within less than 90 days – **Median approval time = 5.5 months**
- Approval through **WHO Collaborative Registration Procedure** in Malawi, Ghana and Zambia
- Positive recommendation from **Caribbean Regulatory System**
- **WHO Prequalified**



- Advocacy/sensitisation events
- Feedbacks and lessons learned from Industry and targeted NRAs
- Cooperation and alignment with WHO
- Synergies and exchange with EMA EU-M4-All



## Scientific Advices - Updates



**Cryptosporidium - 2023**

**Artemetherum-Lumefantrinum neonate - 2023**

**Leishmaniasis - 2024**

**Artemether-lumefantrine-amodiaquine - 2024**

## Ongoing MAGHP procedures

### Ongoing procedure - ophthalmic anesthetic

- Submitted Q1 2024
- Assessment ongoing
- 1 NRA from Africa involved

### Ongoing procedure - malaria treatment in babies

- Submitted Q1 2024
- NRAs onboarding process ongoing
- 8 participating NRAs from Africa
- WHO Global Malaria Programme involved

## Cooperation with WHO

- Continous **exchange** with **WHO** and **optimization** of synergies
- Use of **SRA Collaborative Registration Procedure** (CRP) is strongly encouraged as a vehicle to facilitate provisions of assessment and inspection reports following the MAGHP
- SRA CRP enables to **increase** the **outreach** of the procedure
- SRA CRP allows for an effective **management of the post-authorization changes**
- MAGHP outcomes are considered for the **Prequalification abridged pathway**



# Benefits



- **No restriction** to specific **indications/therapeutic areas**.
- The procedure helps building **trust** and **confidence** in the process.
- It helps **building capacity** at the involved NRAs.
- It produces **consolidated assessment reports**, with country-specific considerations.
- It is expected to **facilitate and speed up the granting of national marketing authorisations** in LMICs following Swissmedic's approval (by “well-informed reliance”).

## Further information



[Development Cooperation – Regulatory Systems Strengthening \(swissmedic.ch\)](#)

Dedicated sub-page on [MAGHP Procedure](#)

- [Guidance Document Authorisation Procedure MAGHP](#)
- [Guidance Document Scientific Advice MAGHP](#)



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