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Progress update on the MAGHP Procedure

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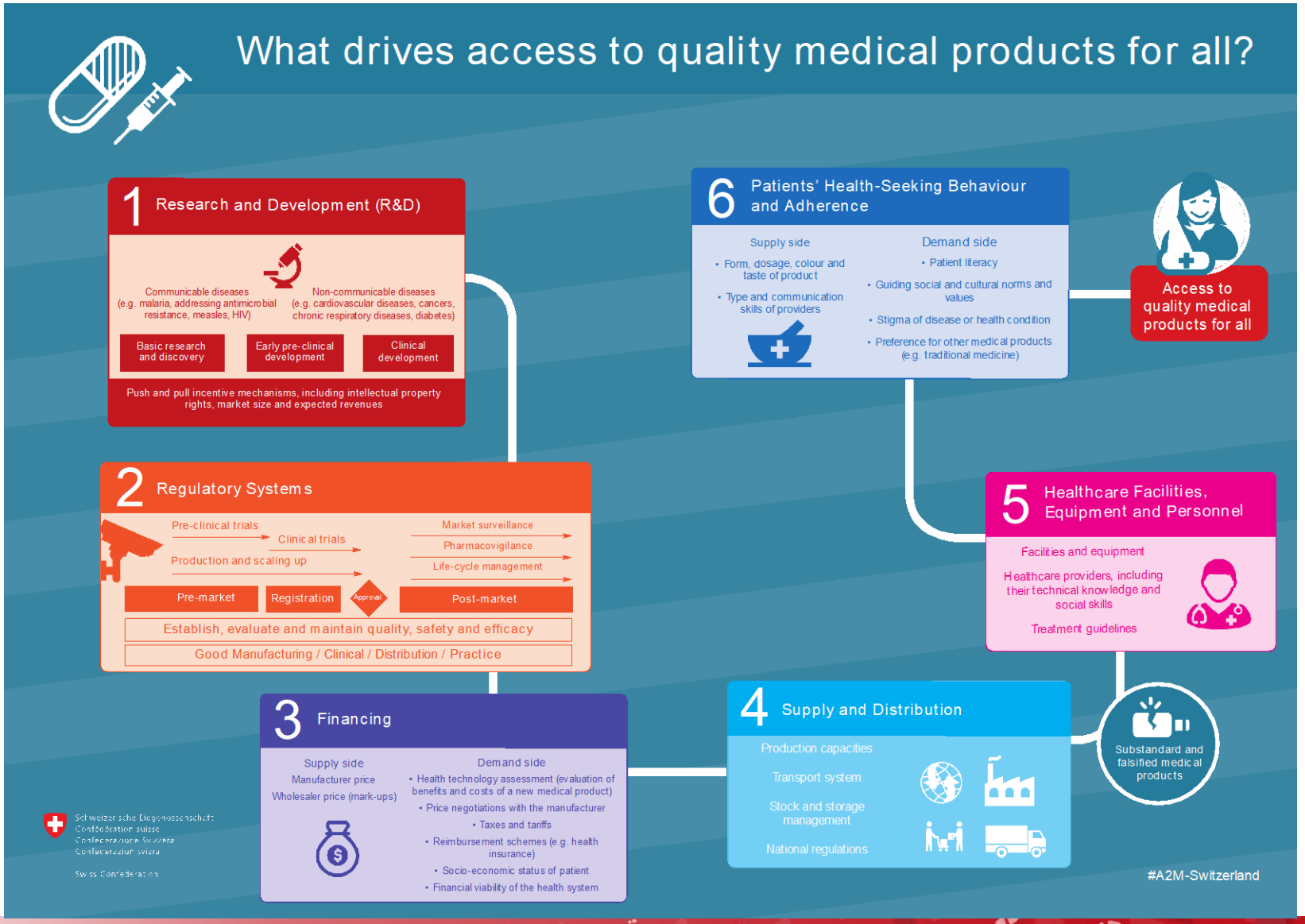
Outline

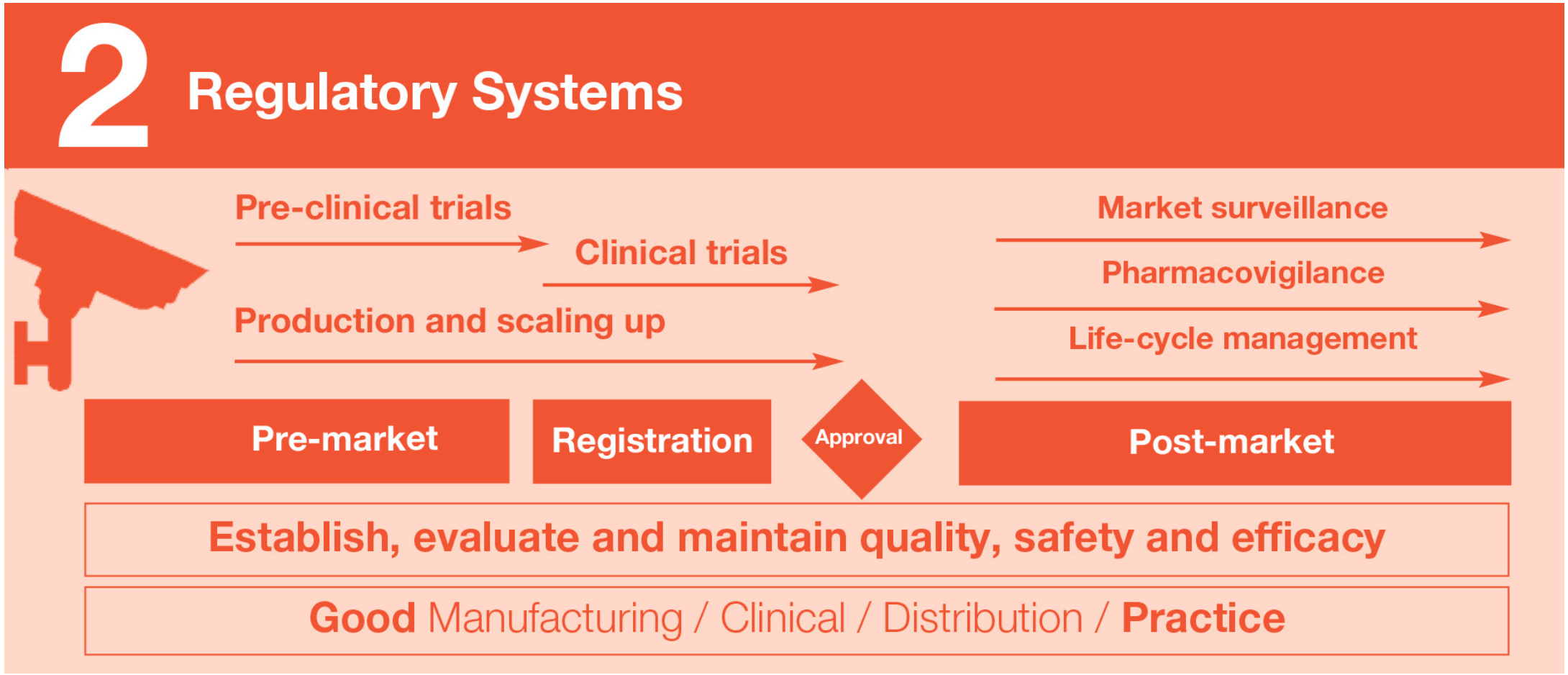
- Introduction and Overview
- Project Components
- Project II: MAGHP Procedure
- Case study: Ongoing MAGHP application
- Lessons learned
- MAGHP-Light

Overview Development Cooperation at Swissmedic

- **Context**
  - Swissmedic engages actively in development cooperation.
  - Swiss Agency for Development and Cooperation as a key partner in project implementation.
  - In line with the Swiss Health Foreign Policy
- **Basis**
  - Swissmedic strategic goals → approved by the Swiss Federal Council
  - Memorandum of Understanding (MoU) with the Federal Departement of Foreign Affairs and the Bill & Melinda Gates Foundation.
- **Goal**
  - 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.

Swiss Health Foreign Policy

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Regulatory Systems
Pre-clinical trials
Clinical trials
Production and scaling up
Market surveillance
Pharmacovigilance
Life-cycle management
Pre-market
Registration
Approval
Post-market
Establish, evaluate and maintain quality, safety and efficacy
Good Manufacturing / Clinical / Distribution / Practice

Objective 7:
The regulatory systems of low- and middle-income countries are strengthened.

Swissmedic takes its Corporate Social Responsibility (CSR) seriously and, in return for payment and as part of its remit stated in the TPA, provides services for other authorities and international organisations, provided these do not jeopardise its independence or ability to function (Article 69 para. 2 TPA). These are wholly funded by third-party resources (not by the Swiss government or by the companies liable for fees or supervisory levies).

Together with the WHO, SDC and other partners, Swissmedic is involved in regional, continental and global initiatives to promote and strengthen the regulatory systems in low- and middle-income countries[2]. Corresponding initiatives are designed to harmonise, at the regional level, the regulatory principles of authorisation and supervision of therapeutic products based on international standards. This also supports national authorities in building up effective regulatory systems.

Project Components

Project No. 1 Since 2015	• Support to the implementation of the African Medicines Regulatory Harmonization (AMRH)
Project No. 2 Since 2015	• Swissmedic procedure for scientific advice and for Marketing Authorization for Global Health Products (MAGHP Procedure)
Project No. 3 Since 2018	• Capacity building trainings/activities for foreign NRAs (Regulatory Training, Swissmedic GMP Training, Guided Inspections)

Funding from the BMGF secured through Q1 2023

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Marketing Authorisation for Global Health Products (MAGHP)

Marketing Authorisation for Global Health Products

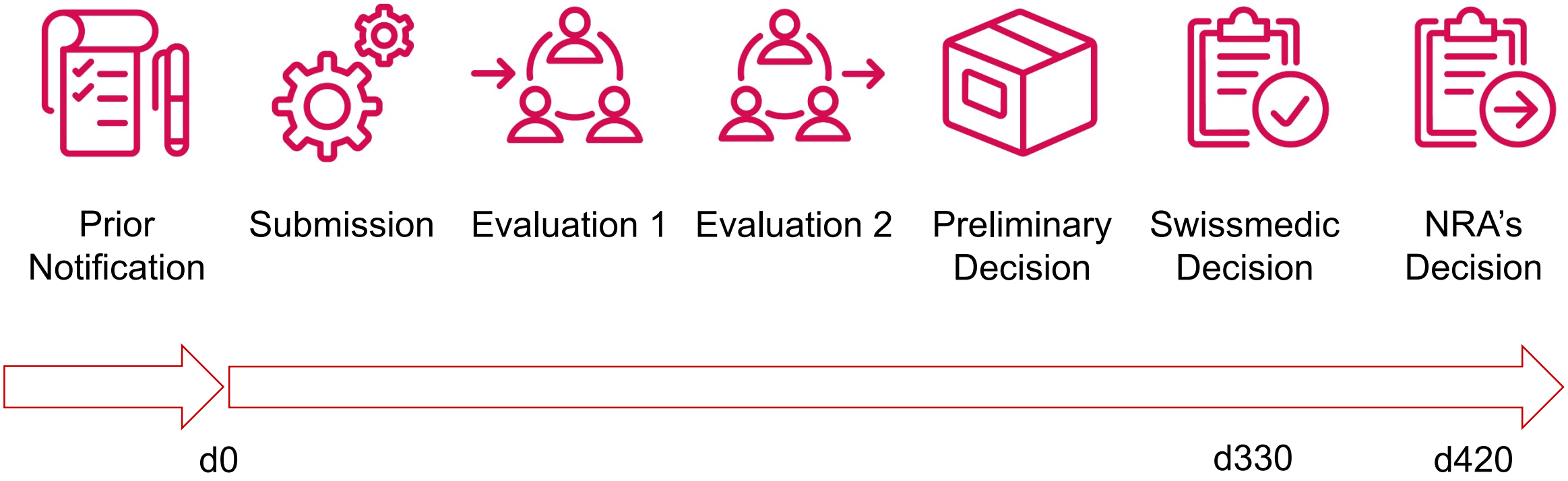
The MAGHP is based on the approach of involving regional National Regulatory Agencies (NRAs) and the WHO in the Swissmedic assessment process.

The procedure consists of two independent components:

- **Scientific Advice**
  To clarify scientific questions in the development phase regarding the planned submission.

- **Marketing Authorisation**
  The procedure follows the regular Swissmedic marketing authorisation procedure (same time frames, procedural steps and evaluation criteria) with the difference that concerned NRAs and the WHO are involved. The result is an **authorisation for the Swiss market**.

Procedural Milestones



Scope and eligible products

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

A 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**)

Focus on medical need in the sub-Saharan region, although there is **no strict restriction** to certain indications.

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*

*Internal meetings at Swissmedic

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

NRAs/WHO decide about their participation.

Benefits

- The procedure helps building **trust** and **confidence** in the process.
- It helps **building capacitiy** at the involved NRAs.
- It is expected to **facilitate and speed up the granting of national marketing authorisations** following Swissmedic's approval (by "well-informed reliance").
- It results in a Swiss Marketing Authorisation.
- **No restriction to specific indications**.

Case Study

- Assessment of a new drug with known API
  - Carbetocin Ferring, injectable solution for prevention of postpartum uterine atony following vaginal delivery
  - API Carbetocin in the indication *prevention of uterine atony following delivery of the infant by Caesarean section under epidural or spinal anesthesia* already authorised in Switzerland since 2008 (see Pabal, injectable solution)

- Partners involved: Kenya, South Sudan, Tanzania, Zanzibar, Uganda, Nigeria, Democratic Republic of Congo, Ethiopia* and Sierra Leone*

*joined the procedure at a later stage

Milestones achieved

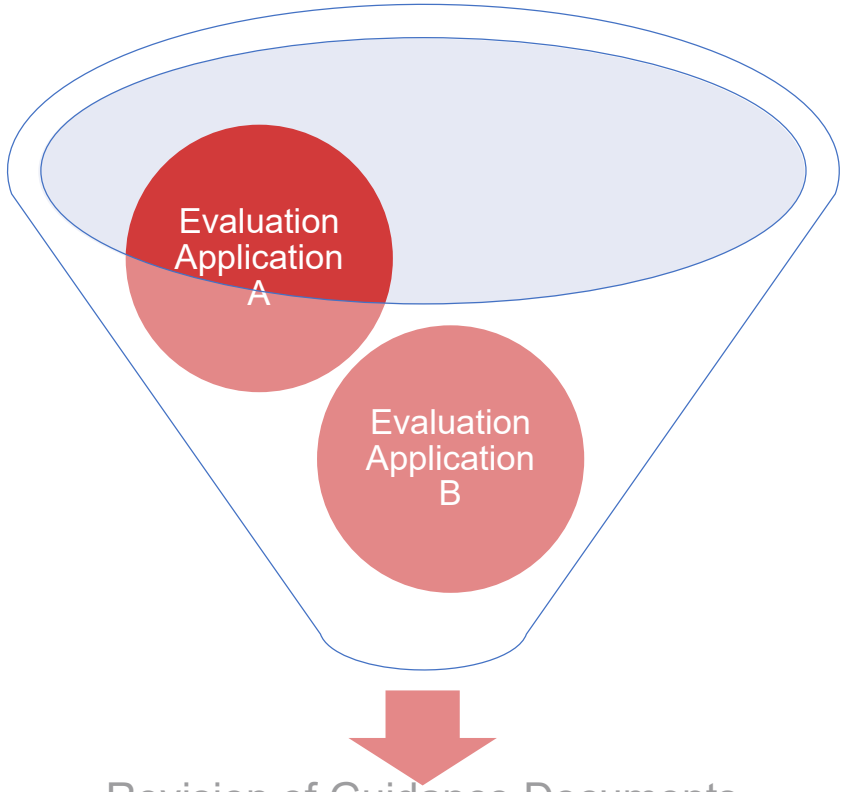
- Pre Submission Meeting with applicant
- Submission on 21st September 2018
- 4 virtual meetings (2 procedural meetings, 1st and 2nd Case Team Meeting)
- Assessment concluded and authorisation issued on 27th April 2020
- First authorisation of a new products within the MAGHP Procedure
  - Communication on website on 13th May
- **First NRAs granted authorisation within the expected timelines upon receipt of dossier**

Next Steps

- Applicant submits dossier to the all involved NRAs (ongoing)
- Remaining NRAs to grant national authorisation within 90 calendar days from receipt of the dossier
- Lessons learned and debriefing call with applicant, involved NRAs and WHO

Pilot phase and collection of lessons learned

- During the pilot phase experiences and feedbacks are collected
- Revision of the guidance document(s) after evaluation of the first review processes (the procedure is extended/improved).
- Processes and tools are evaluted and improved if necessary



Revision of Guidance Documents
Procedurals and administrative improvements
Optimisation of collaborations

Changes and improvements

- Clarified roles of parties involved
- Considered new means of communication and integration of participants
- Step-wise expansion of geographical scope
- Extended MAGHP to consider accelerated assessment procedures

➢ First procedural changes have been reflected in the revised guidance documents and MAGHP flyer

➢ Improvement is a constant process

Benefits and Challenges

- ✓ The MAGHP 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 for marketing authorisation by NRAs can be reduced.

- ❖ Coordination and role of the involved parties
- ❖ Geographical scope of the procedure
- ❖ Dossier assessment considering settings in Switzerland
- ❖ Early submission of the dossier in targeted NRAs
- ❖ Expand means of communication (e.g. WebEx, Skype)

Open points

- Lifecycle management and post-marketing changes
- Lack of a compelling contractual agreement with NRAs
- Inclusion of all countries with a medical need for specific product
- …

Update MAGHP Light

Background

- Pandemic brought up question, whether MAGHP is applicable/suitable for Covid-19 medicines
- Not directly applicable due to high urgency of corresponding requests
- Alternative suggestion: Leaner and more agile MAGHP procedure → MAGHP light
- Implementation incl. statement on webpage and Swissmedic Journal on 1st October 2020

Process

- Explicitly applicable to all submissions in the fast track and temporary authorisation procedures
- Not restricted to Covid-19 medicines/vaccines
- Modalities of interaction between Swissmedic and NRAs limited to access to information/documentation
  ➢shorter timelines set by the accelerated procedures
- No further requirements on the follow-up processes by the authorities involved

Further information

- networking@swissmedic.ch

- Swissmedic Development Cooperation

- Swissmedic webpage on MAGHP Procedure
  - General information on *MAGHP*
  - Guidance Document *Authorisation Procedure MAGHP*
  - Guidance Document *Scientific Advice MAGHP*