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Better Together: Reliance Practices at Swissmedic

Simon Dalla Torre, Head of Division Regulatory Operations and Development
Sector Medicinal Product Authorisation and Vigilance

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Global Reliance & Collaboration Landscape

ACCESS Consortium

FDA Orbis

EMA Open

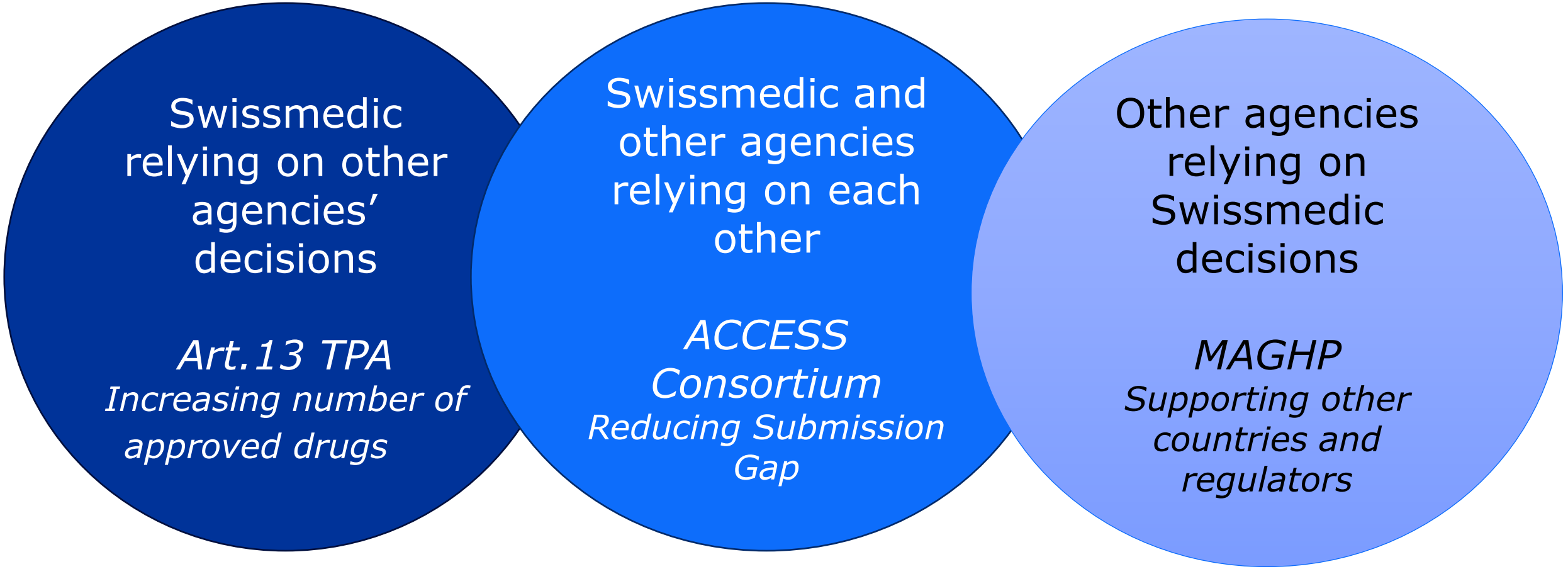
WHO initiatives

- Marketing Authorisation for Global Health Products
- Good Reliance Practices / Collaborative Registration Procedure
- Regulatory Strenghening: WHO Regulatory Training

ICMRA

- PAC Reliance Pilots
- Joint Inspections

Swissmedic uses different modalities of Reliance



Swissmedic uses different modalities of reliance

- Swissmedic uses the full spectrum of Reliance Modalities to bring more **high-quality, safe and effective Medicines** to Patients faster.

- Reliance is an important tool for modern regulatory agencies to make best use of the **global regulatory expertise** and to work in a **risk-based mode**, focusing own **ressources** where they create **most added value**.

- **Regulatory Reliance** is a **complex process** that requires extensive expertise and experience in order to build an independent opinion and come to an informed decision based on thorough assessments **done by others**.

Overview Swissmedic International Authorisation Procedures

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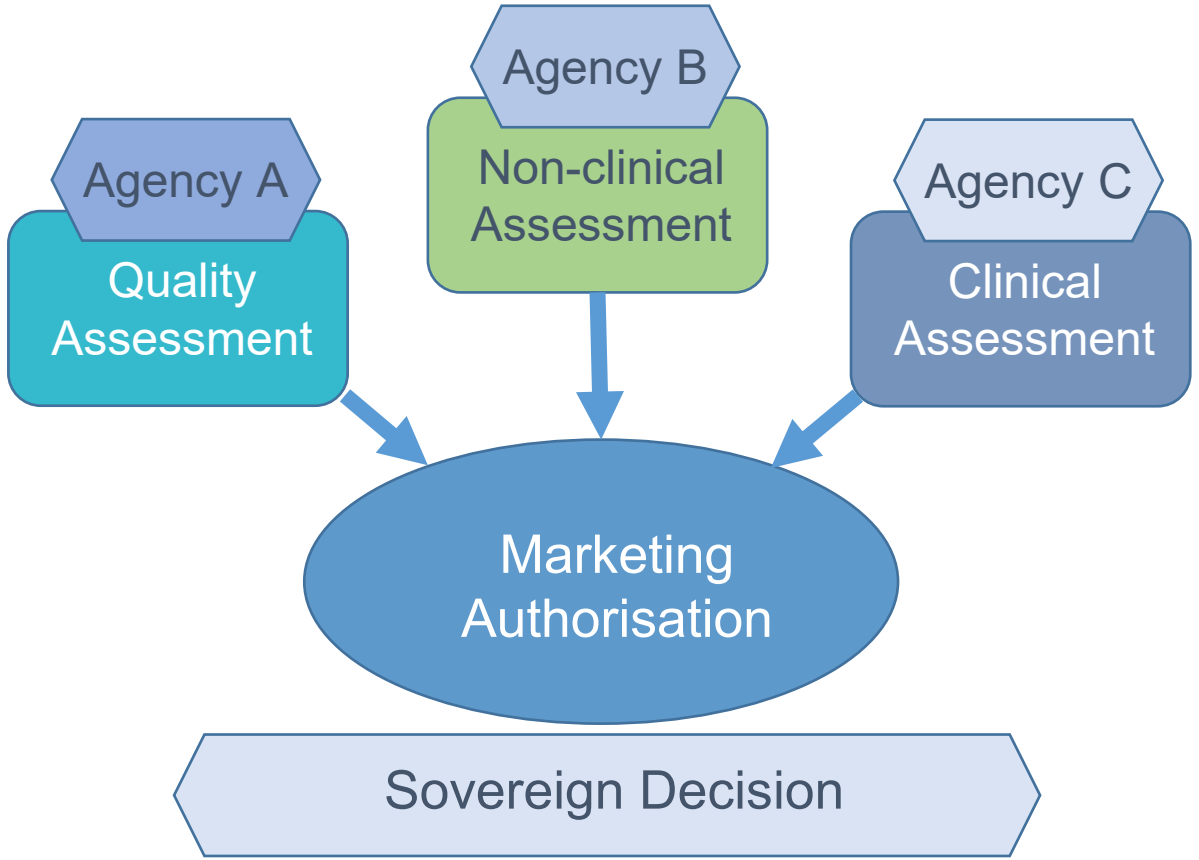
What is the Access Consortium – Work-Sharing Procedure

The Access NAS Work-Sharing Initiative



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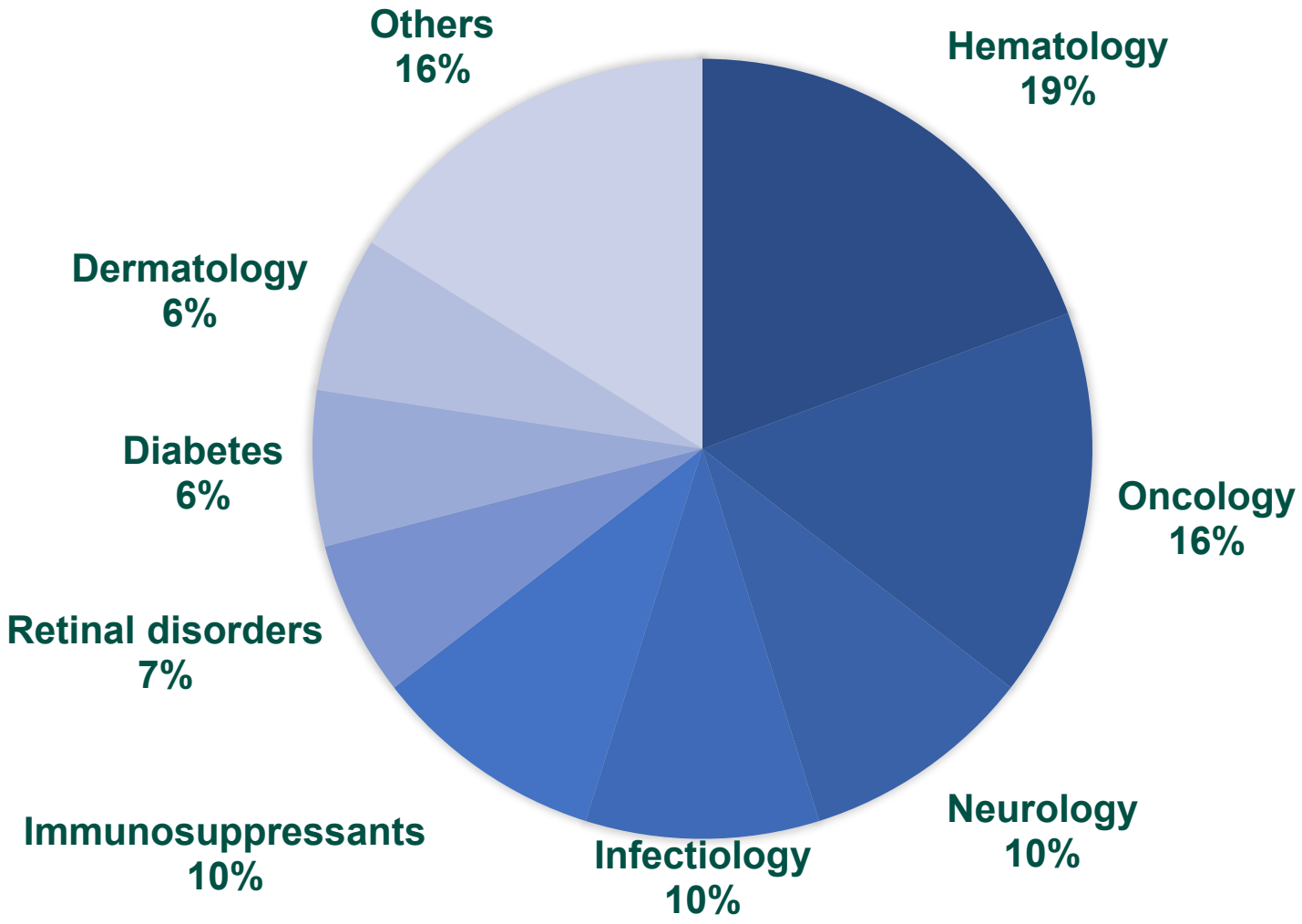
Swissmedic Access applications by disease type 2020 – 2024

n = 31



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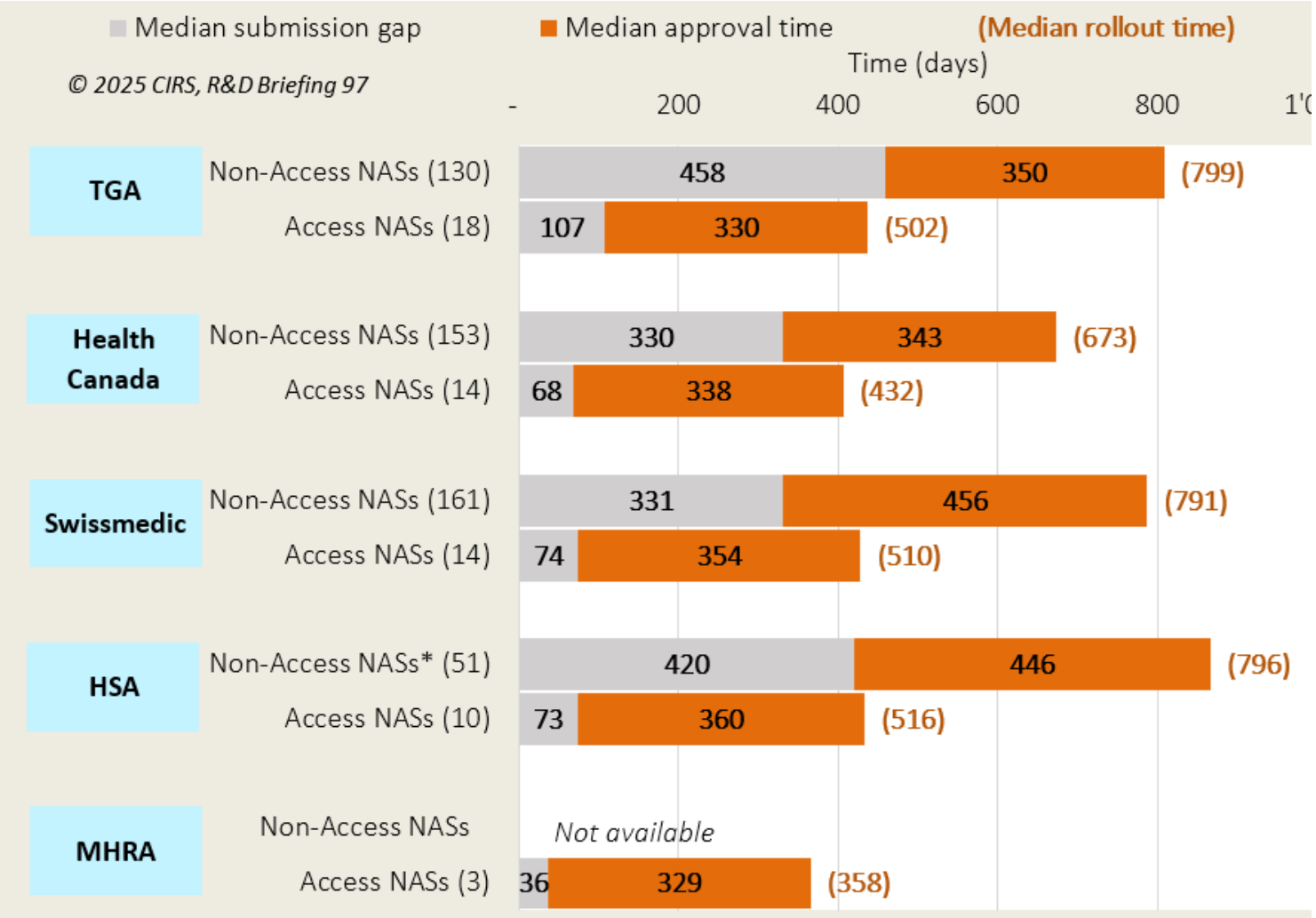
Submission Gap and Approval Times 2019 - 2023



Source: «CIRS R&D Briefing 97»

Benefits of the Access Consortium

Patient

- **Faster patient access** to innovative medicines - reduced submission gaps, accelerated assessments

Regulator

- **Work-sharing** – Optimised use of resources, less duplication of work
- **Regulatory convergence** – learn from best practices to refine regulatory procedures
- **Scientific exchange** – Sharing and expanding scientific expertise

Applicant

- **1 consolidated list of question**
- Market of **150 million people** reached with single Access application

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Swiss National Reliance Procedure

Art. 13 TPA - Criteria

Eligibility Criteria

- The **foreign authority** must be recognized as having "**comparable standards**"

  → List countries with comparable control of human medicinal products

- **Foreign assessment reports**
- **Same medicinal product** (composition, manufacturing process, strength, dosage form)
- **Foreign decision** is no older than **5 years** (→ likely to be changed to 10 years)
- **Complete Scientific Dossier**
- Art. 13 reliance upon **company request** or **ex officio** if criteria are fulfilled

Swissmedic performs a **risk-based approach**
→ in depth assessment only regarding identified **critical aspects**

Art. 13 TPA - Scope

Scope - Application Types

- **New Active Substances** (~ 10 – 20 % of all applications)
  - Orphan Drugs
  - medicinal products intended to prevent transmissible infectious diseases
- **Biosimilars** (~ 50 % of all applications)
- **Known Active Substances** (~ 50% of all applications)
- **Post-marketing variations** (line extensions, Typ II variations, selected 1B variations)

Pros and Cons of Art. 13 TPA

Pros

- **Reduced work burden** for Swissmedic and applicant
- Reduced likelihood for a **list of questions**
- **Faster** overall assessment times
- 60% **reduced application fee**

Cons

- High **submission gap** → late patient access

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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 - Scope

- 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

- Eligible applications types
  - ✓ **new active substance**
  - ✓ **known active substance**
  - ✓ **new indication**

- **No restriction** to specific **therapeutic areas**

MAGHP consist of two main components

Meeting Before Submission

- Clarify scientific questions in the **development phase**
  - 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

- regular Swissmedic marketing authorisation procedure:
  - same time frames, procedural steps and evaluation criteria
  - Swiss marketing
  - participating NRAs actively engaged in assessment through
  - joint review rounds coordinated by Swissmedic and WHO
  - NRAs have access to assessment reports, can provide comments or questions, and contribute country-specific considerations

Completed MAGHP procedures in 2025

Visiclor Eye Gel – ophthalmic anesthetic

- Submitted Q1 2024
- Assessment completed
- Active participation of South African Authority SAHPRA
- Product approved by Swissmedic on 21 February 2025
- Approval in South Africa on 13 May 2025

Riamet/Coartem Baby – antimalarial for infants

- Submitted Q1 2024
- Assessment completed
- Close collaboration with authorities from Burkina Faso, Côte d'Ivoire, Kenya, Malawi, Mozambique, Nigeria, Uganda and Tanzania
- Product approved in Switzerland on 3 July 2025
- Submission/national decision phase in targeted countries ongoing

MAGHP – Riamet/Coartem Baby

- Novel paediatric formulation of an antimalarial medicine (Riamet).
- Specifically developed for infants with bodyweight between 2 kg and 5 kg → addressing critical medical gap
- **8 NRAs** participated in assessment: Burkina Faso, Côte d'Ivoire, Kenya, Malawi, Mozambique, Nigeria, Uganda, and Tanzania
- Close exchange with **WHO Global Malaria Programme**
- Next steps
  - Applicant expected to submit dossier to participating NRAs
  - NRAs expected to approve product in their respective jurisdictions within 90 calendar days from receipt

MAGHP – Cabetocin Ferring

- Product for **prevention of postpartum uterine atony** following vaginal delivery approved
- 8 NRAs granted authorization, 3 of these within less than 90 days – **Median approval time = 5.7 months**
- Approval through «simple» reliance in Rwanda and Burundi
- Approvals through **WHO Collaborative Registration Procedure**
- Positive recommendation from **Carribbean Regulatory System**
- **WHO Prequalified**

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

MAGHP - Benefits

- **No restriction** to specific **indications/therapeutic areas**.
- The procedure helps building **trust** and **confidence** in the process.
- It helps **building capacitiy** 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").

Take home messages

- **Reliance is key to modern, efficient regulation**

  It accelerates patient access, reduces duplication, and fosters global regulatory convergence.

- **Swissmedic practices reliance across multiple levels**

  From national (Art. 13/14 TPA) and regional (Access) to global collaborations such as MAGHP and ICMRA.

- **Trust, transparency, and collaboration are essential**

  Reliance strengthens mutual confidence between agencies while allowing Swissmedic to remain fully sovereign yet globally connected.