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Better Together: Reliance Practices at Swissmedic

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Global Reliance & Collaboration Landscape

ACCESS Consortium

FDA Orbis

EMA Open

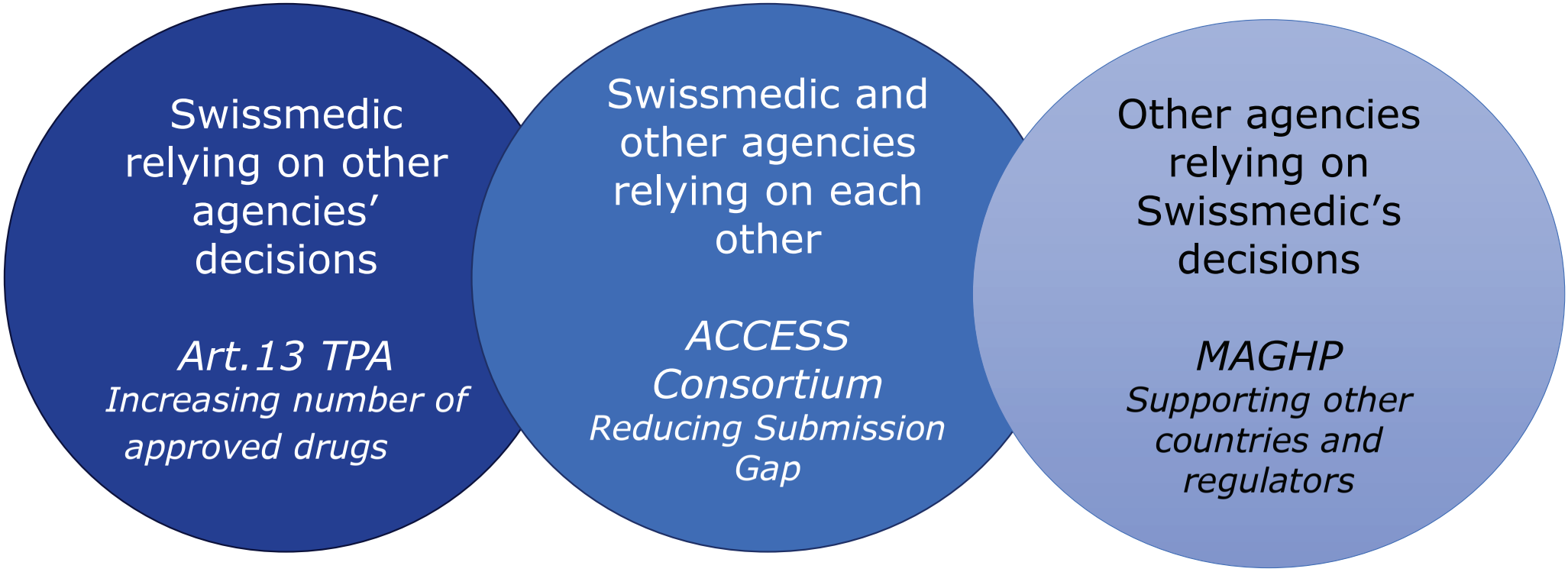
WHO initiatives

- 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

- **Goal**
  Swissmedic uses the full spectrum of reliance modalities to bring more high-quality, safe and effective Medicines to patients faster.

- **Risk-based approach saves ressources**
  Reliance is an important tool 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.

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

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Overview Swissmedic International Authorisation Procedures

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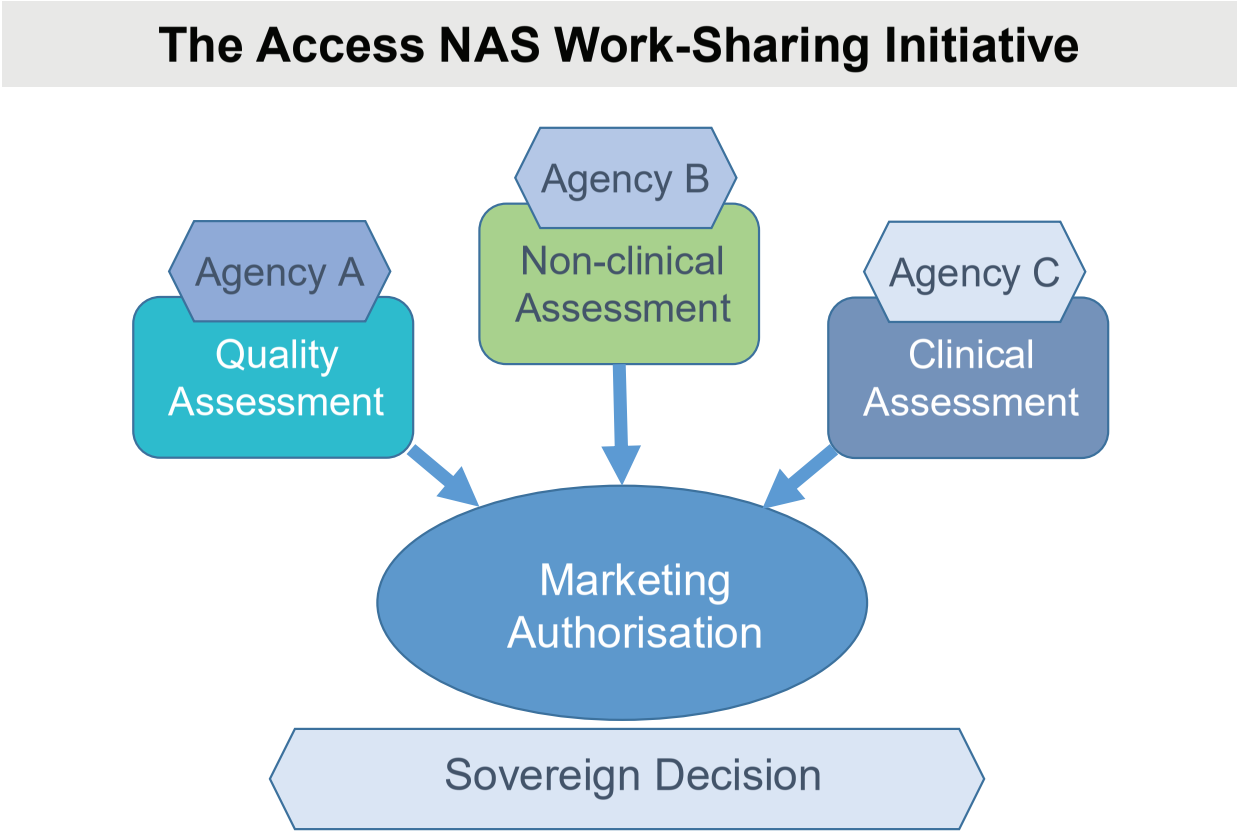
What is the Access Consortium – Work-Sharing Procedure



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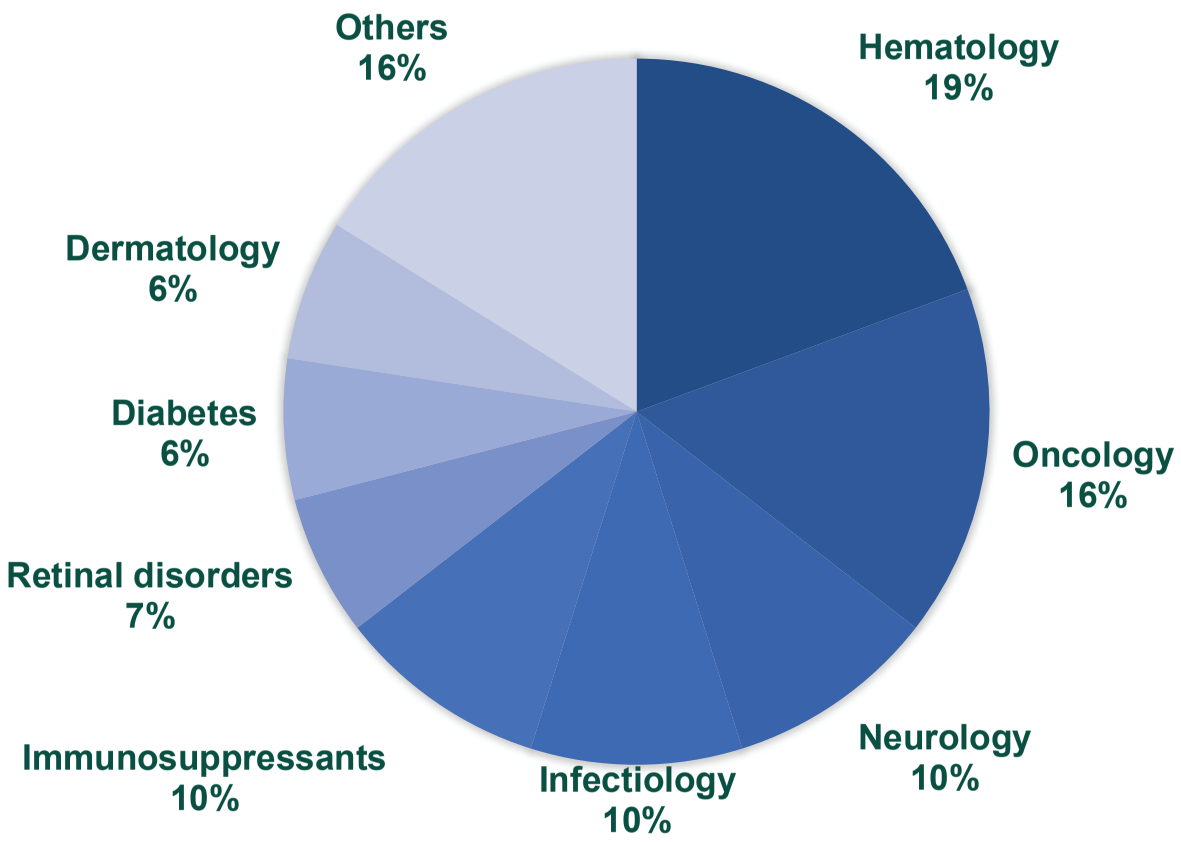
Swissmedic Access applications by disease type 2020 – 2024

n = 31



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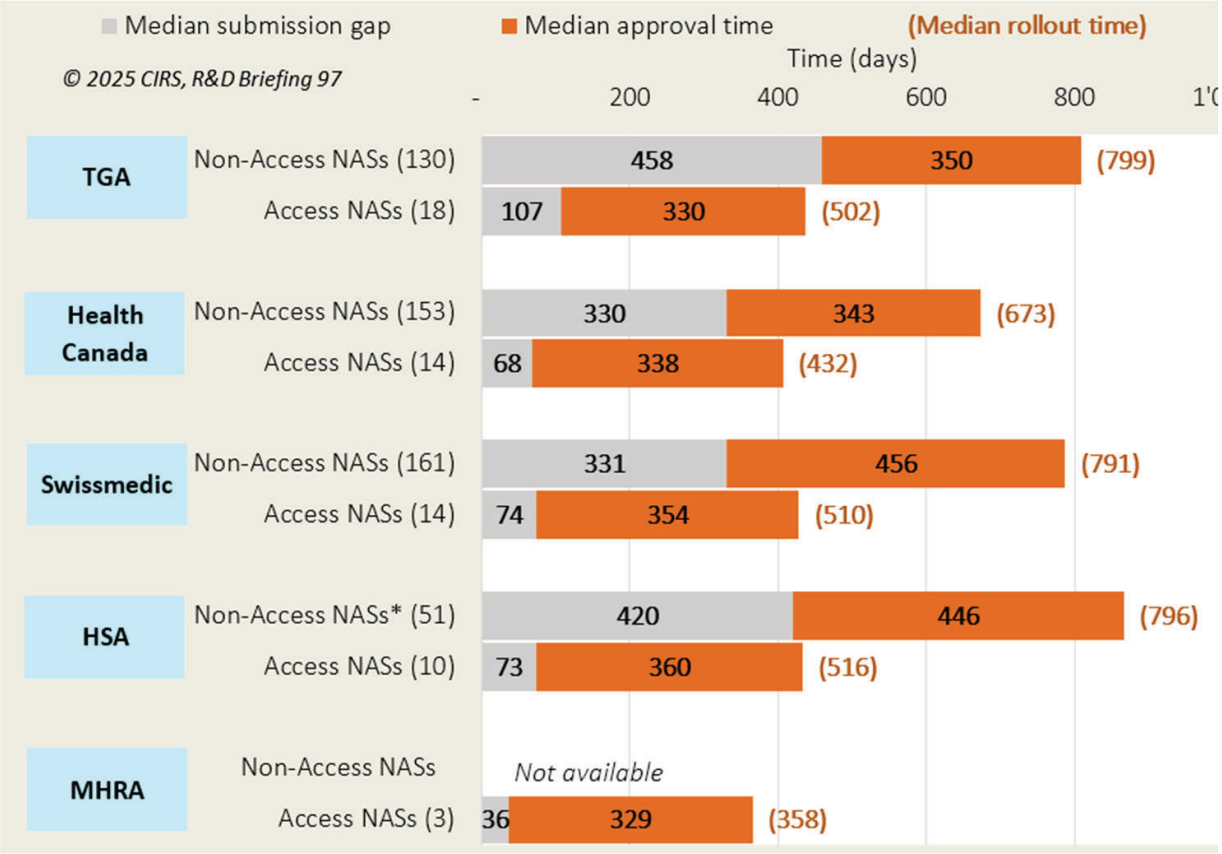
Submission Gap and Approval Times 2019 - 2023



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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 own 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 TPA 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**

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Art. 13 TPA - Scope

Scope - Application Types

- **New Active Substances** (~ 10 – 20 % submitted under Art. 13 TPA)
  - Orphan Drugs
  - medicinal products intended to prevent transmissible infectious diseases
- **Biosimilars** (~ 50 % submitted under Art. 13 TPA)
- **Known Active Substances** (~ 50% submitted under Art. 13 TPA)
- **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 consists of two main components

Meeting Before Submission

- Clarify scientific questions in the **development phase on**
  - quality of APIs and products
  - planning and organisation of preclinical and clinical trials
  - aspects of PV and RMP

Marketing Authorisation Application

- regular Swissmedic marketing authorisation procedure:
  - same **time frames**, procedural steps and evaluation criteria
  - participating **NRAs actively engaged** in assessment
  - **joint review rounds** coordinated by Swissmedic and WHO LP1
  - NRAs have **access to Swissmedic assessment reports**, can provide comments or questions, and contribute country-specific considerations

Folie 17

LP1 WHO unterstützt bei Nominierungsprozess und beteiligt sich mit Fachexperten, Verfahren wird aber Swissmedic-intern koordiniert

Lodovico Paganini; 2026-08-10T05:49:13.103

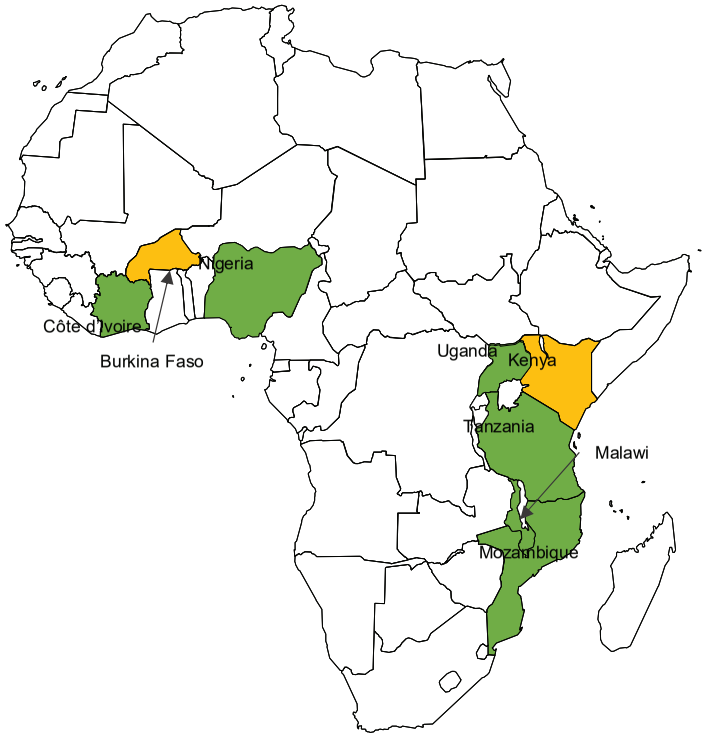
MAGHP – First Success: Carbetocin Ferring (2020)

- 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 **Caribbean Regulatory System**
- **WHO prequalified**

- Advocacy / sensitisation events
- Feedback and lessons learned from industry and participating NRA
- Cooperation and alignement with WHO
- Synergies and exchange with EMA “EU-M4-All”

MAGHP – Recent Example: Riamet/Coartem Baby

- Novel **paediatric formulation** of an **antimalarial medicine**
- 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**
- Submitted to Swissmedic Q1 2024 – approved July 2025
- Applicant submitted dossier to participating NRAs in 2026
- Current Status in participating countries
  - **Green: product approved**
  - Yellow: national procedures ongoing



MAGHP - Benefits

- **No restriction** to specific **indications/therapeutic areas**.
- MAGHP helps build **trust** and **confidence** in the process.
- MAGHP helps **build capacity** at the involved NRAs.
- MAGHP produces **consolidated assessment reports**, with country-specific considerations.
- MAGHP **facilitates and accelerates national marketing authorisations** in low- and middle-income countries

Take home messages

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

  Makes best use of limited resources through a risk-based approach, accelerates patient access, reduces duplication, and supports regulatory convergence

- **Swissmedic practices reliance across multiple levels**

  From national reliance under Art. 13 TPA, through regional collaboration in the Access Consortium, to global initiatives such as MAGHP and ICMRA.

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

  Effective reliance depends on mutual confidence between regulators while preserving each authority's sovereign decision-making.