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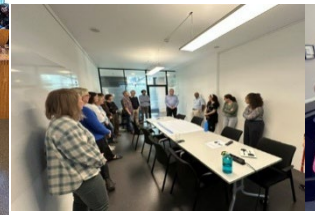
Medicinal Product Authorisation and Vigilance: We are consolidating all medicinal product groups and harnessing synergies

Eveline Trachsel
Head of Medicinal Product Authorisation and Vigilance Sector

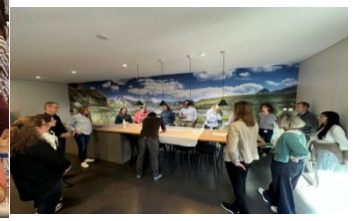
We are responsible for medicinal product authorisation and safety





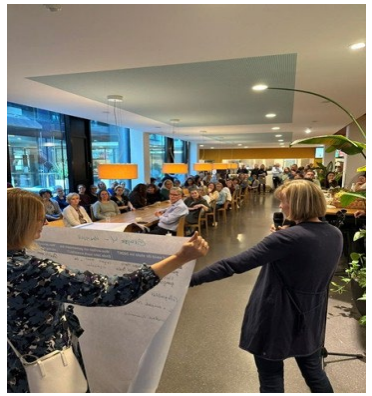












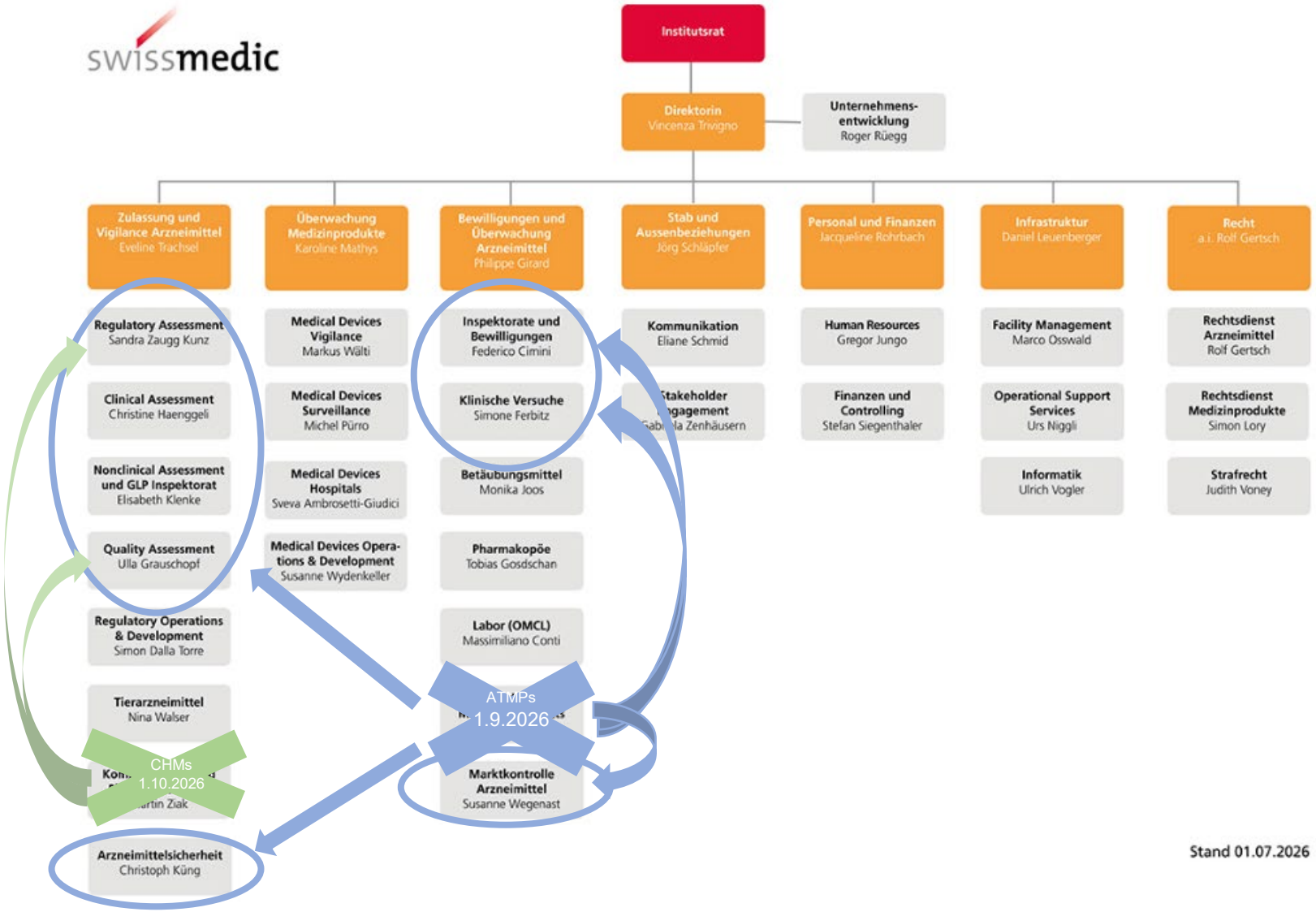
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Measures to harmonise authorisation procedures

- As announced at the end of last year, Swissmedic has taken measures to strengthen its financial position and optimised the use of resources.
- In the second half of 2026, Swissmedic brought together all functions responsible for authorising human medicinal products (incl. **ATMPs** and **CHMs**) in the relevant specialist divisions of the Medicinal Product Authorisation and Vigilance Sector.
- The specialist expertise regarding ATMPs and CHMs is retained, applications are assessed by the existing experts in their new divisions. Both subject areas remain important and will be handled in the same way as all other medicinal products and specialities in future.
- Nothing will change for companies other than that the processes will be even better harmonised. The Innovation Office will continue in adjusted form (mainly virtual).



Expertise in ATMPs and CHMs is retained

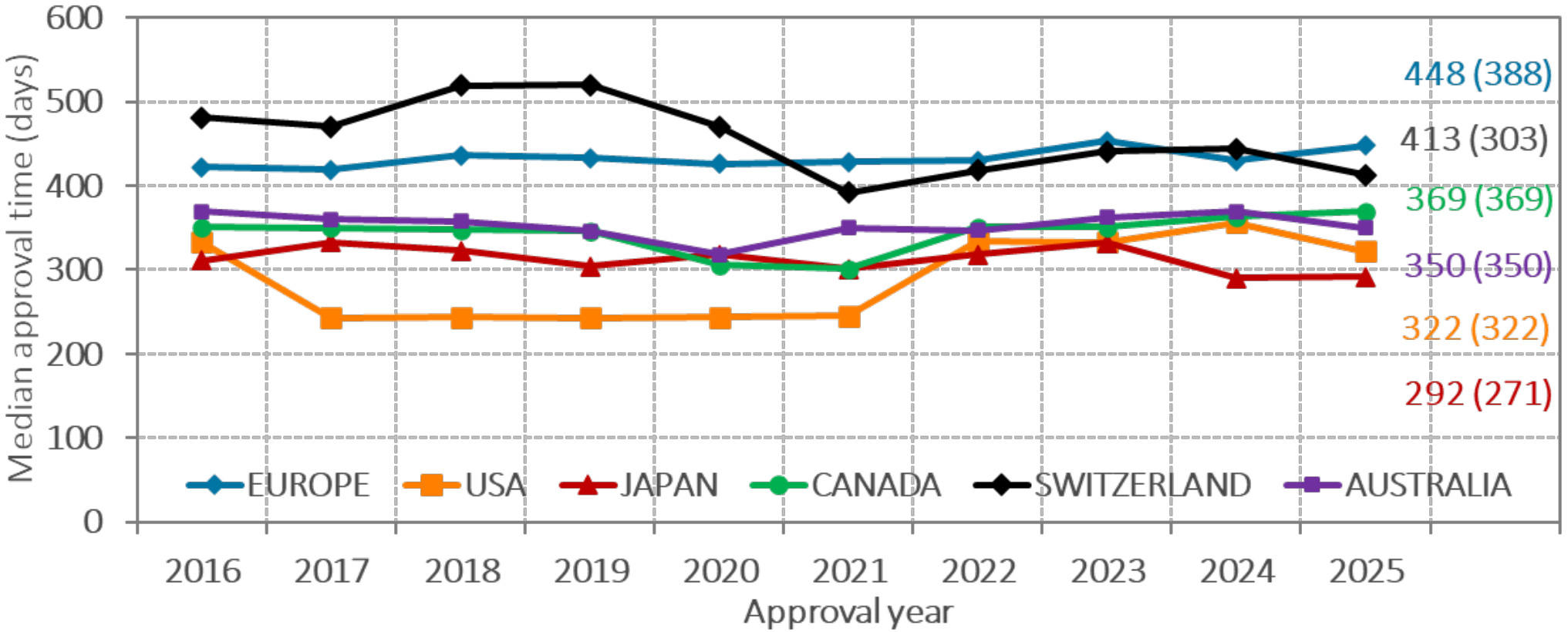


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Swissmedic is a leading regulatory authority

We make high-quality, safe, effective medicinal products available for people and animals in Switzerland as quickly as possible and ensure their long-term safety.

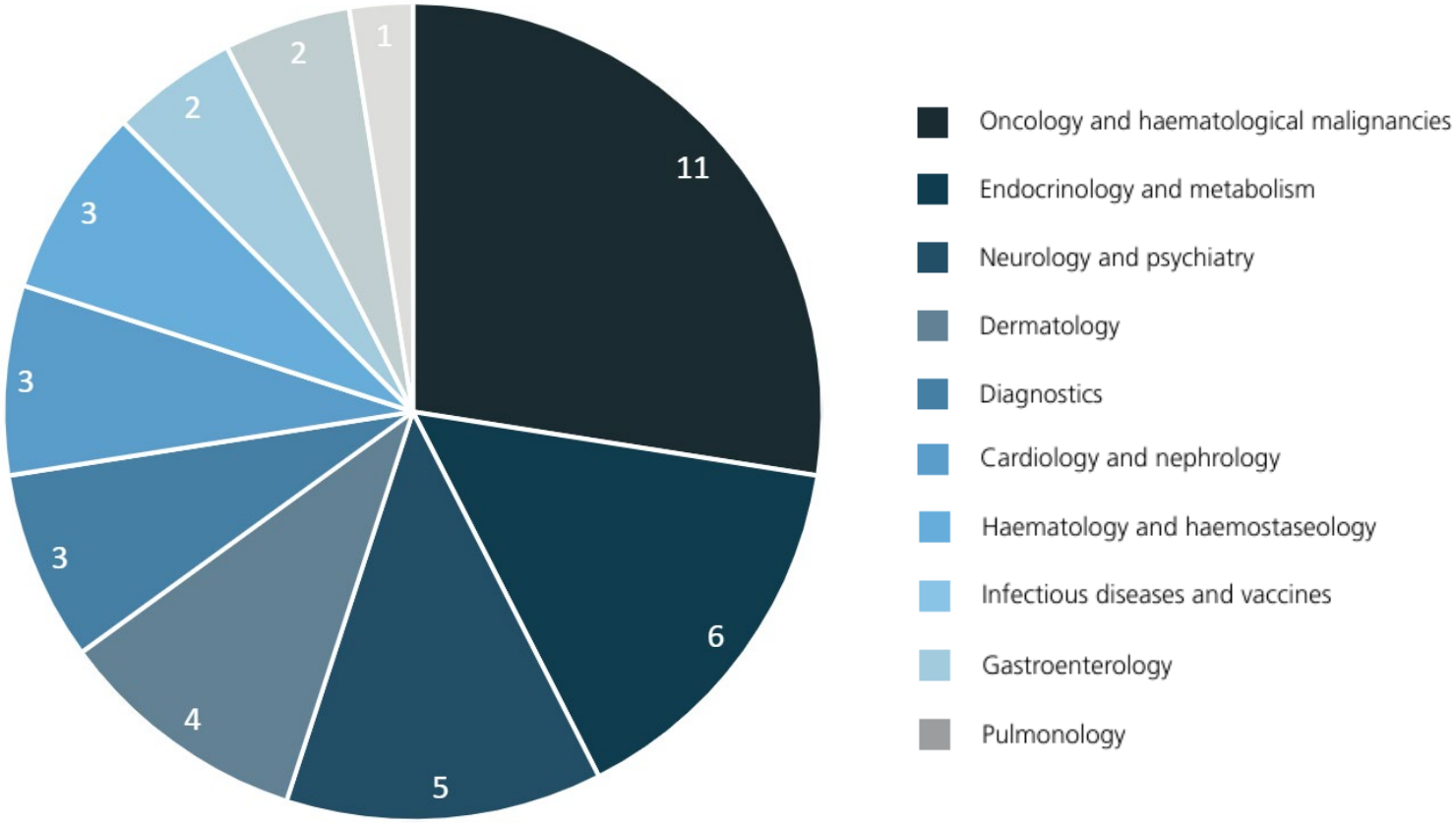
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New Drug Approvals by Six Major Authorities 2016-2025 | CIRS

40 medicinal products with new active substances were authorised in 2025



- Median throughput time 392 CDs → 12% faster than in the previous year, significantly below deadline

➔ 25% of which via international collaborative procedures

- Furthermore, 109 additional indications

➔ 20% of which via international collaborative procedures

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Swissmedic supports the rapid availability of medicinal products

FDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Authorisation

SL listing

BAG
OFSP
UFSP



Submission of application for authorisation by industry

Submission gap	Assessment	Pricing

Availability for Swiss patients

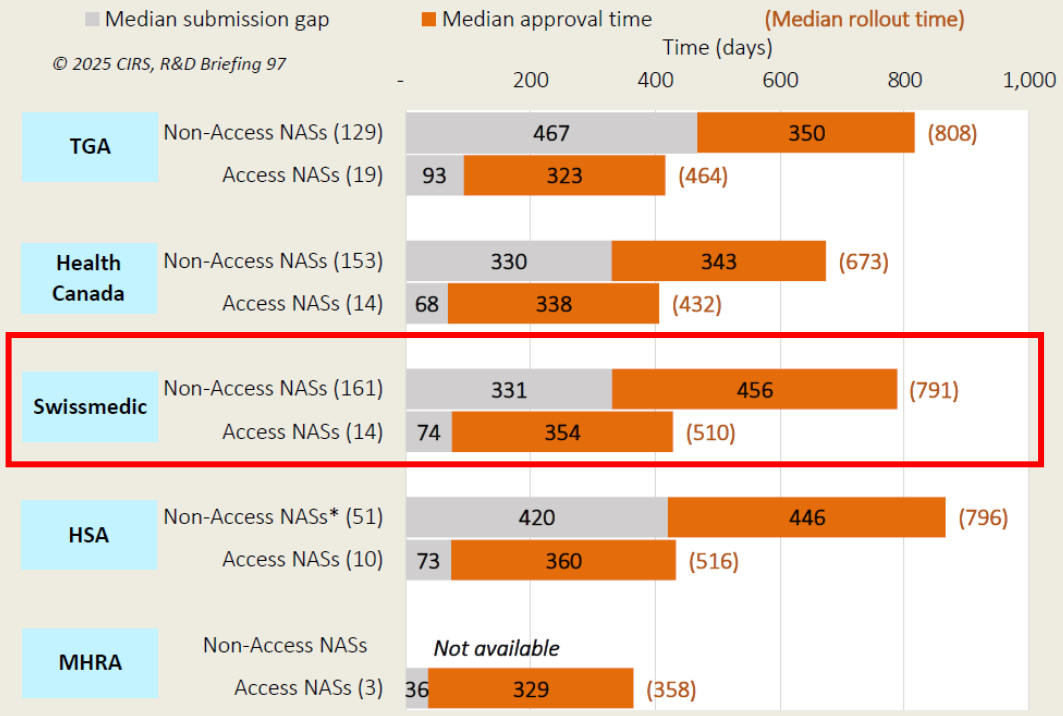
- Dialogue with industry
- Promotion of international authorisation procedures

- Ongoing optimisation of authorisation procedures
- Promotion of accelerated and simplified procedures (Art. 13/14 TPA).

- Support with early dialogue
- Member of the FMC

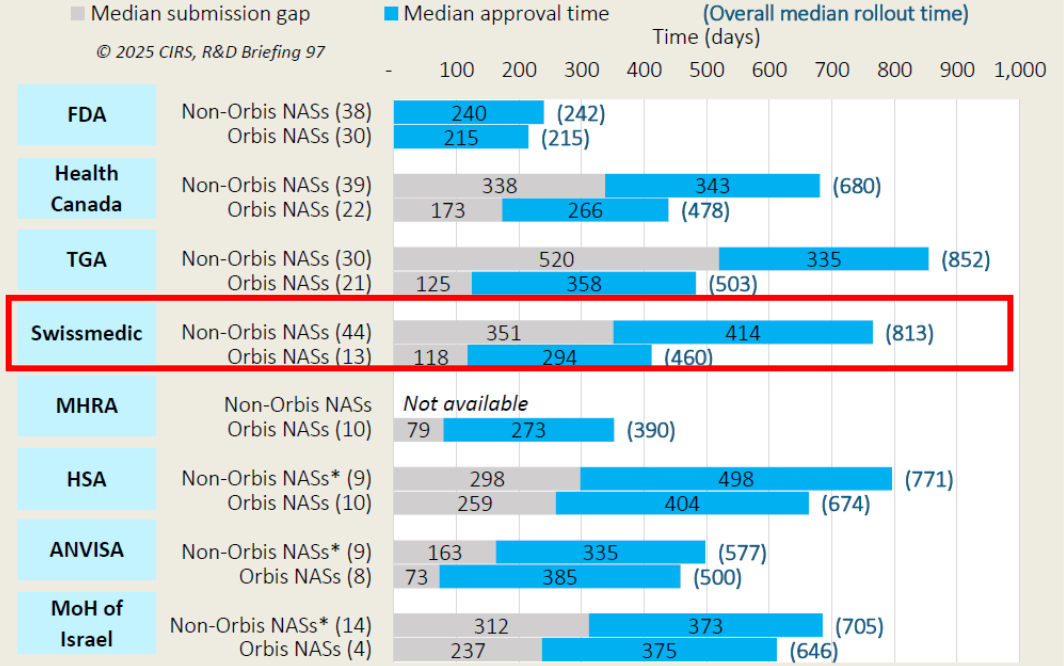
International authorisation procedures reduce the submission gap

Figure 4. Comparison of median submission gap, approval time, and rollout time for NASs approved via Access Consortium vs. Non-Access NASs (2019-2023).



Submission gap *is calculated as the time from the date of submission at the first regulatory agency (out of EMA, FDA, PMDA, Health Canada, Swissmedic and TGA) to the date of regulatory submission to the target agency.* ***Approval time*** *is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time.* ***Rollout time*** *is calculated from the date of submission at the first regulatory agency to the date of regulatory approval at the target agency.*
**The timelines for other NASs were obtained from industry via the CIRS Growth and Emerging Markets Programme.*

Figure 9. Comparison of median submission gap, approval time, and rollout time for NASs approved via Project Orbis vs. other non-Orbis NASs (2019-2023)

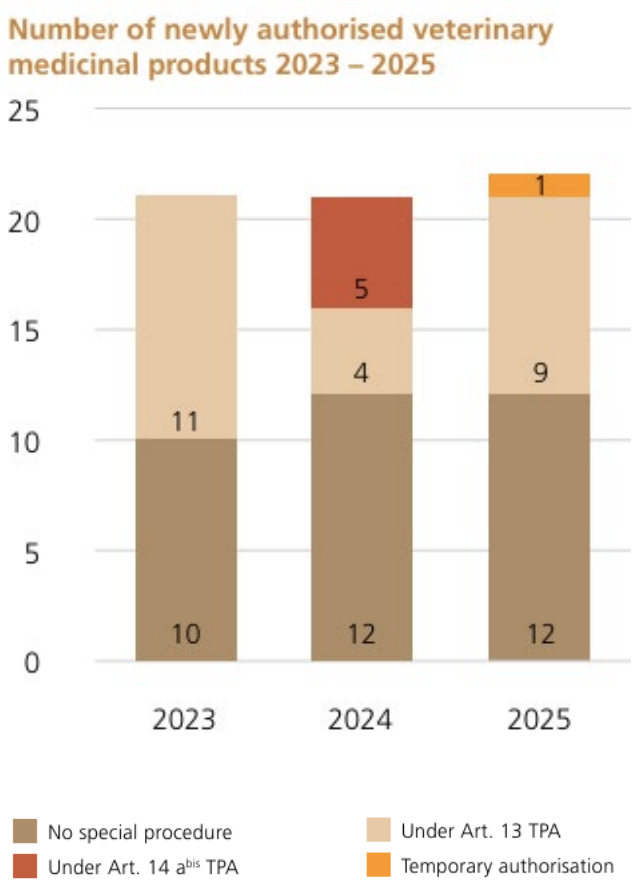


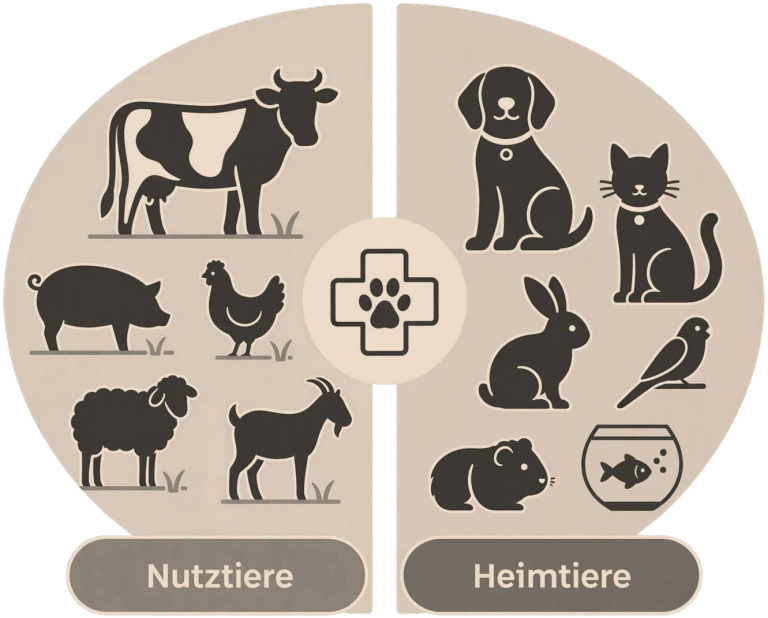
Non-Orbis NASs: *ATC L01 NASs approved outside Project Orbis. For the FDA, only those ATC L01 NASs reviewed by the OCE were considered.* ***Submission gap*** *is calculated as the time from the date of submission at the first regulatory agency (out of EMA, FDA, PMDA, Health Canada, Swissmedic and TGA) to the date of regulatory submission to the target agency. Two products were considered MLEs to FDA and NASs to other agencies within the Project Orbis, for these cases, the submission date of FDA was used instead of the date of submission at the first regulatory agency.* ***Approval time*** *is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time.* ***Rollout time*** *is calculated from the date of submission at the first regulatory agency to the date of regulatory approval at the target agency.* ****:*** *The timelines for other non-Orbis NASs were obtained from industry via the CIRS Growth and Emerging Markets Programme*

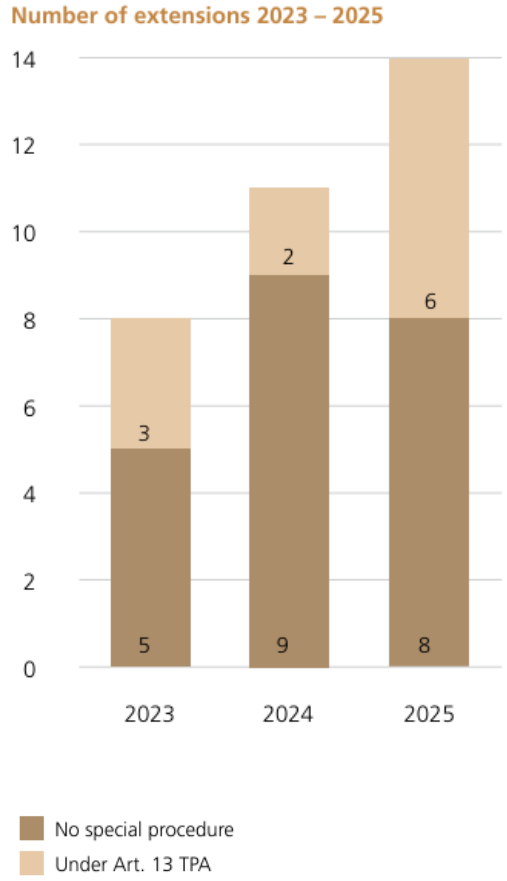
CIRS RD Briefing 97 – Access Consortium and Project Orbis Approvals Across Eight Regulators – Centre for Innovation in Regulatory Science: CIRS

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2025 was a very busy year for our VMP team

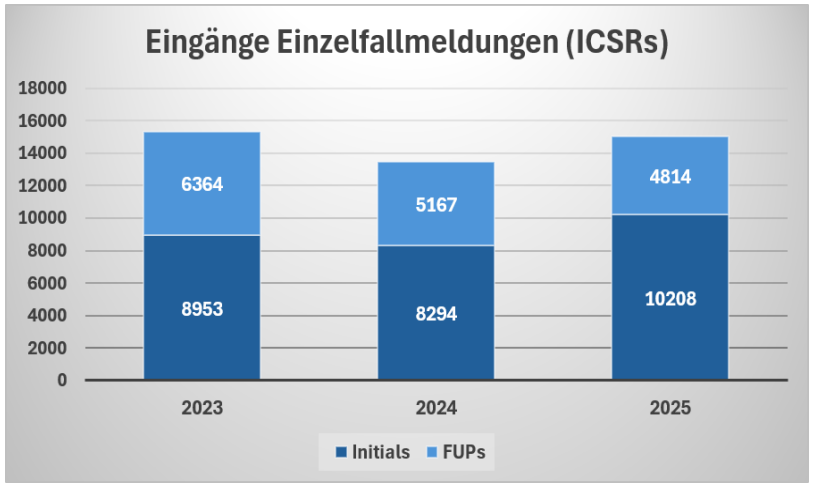


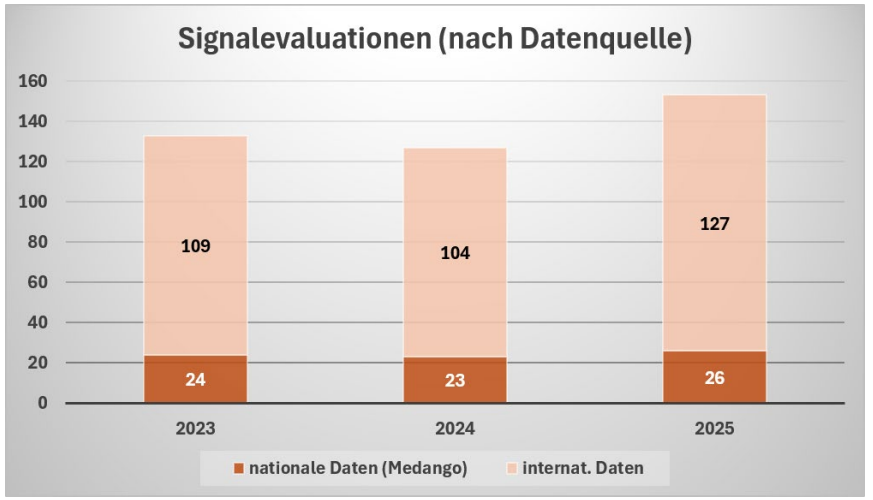


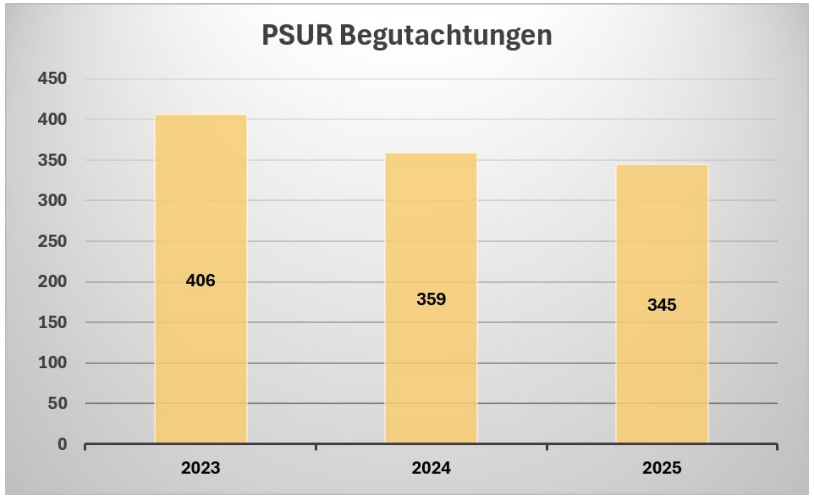


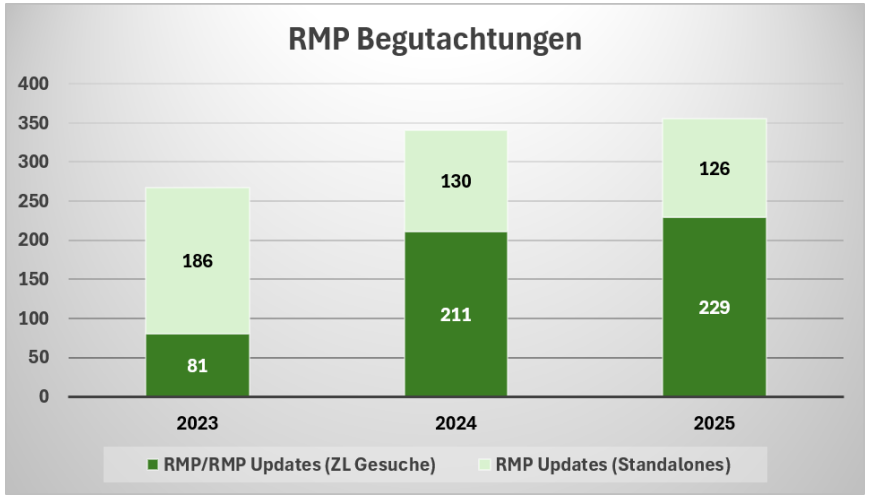
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Our consistent contribution to medicinal product safety



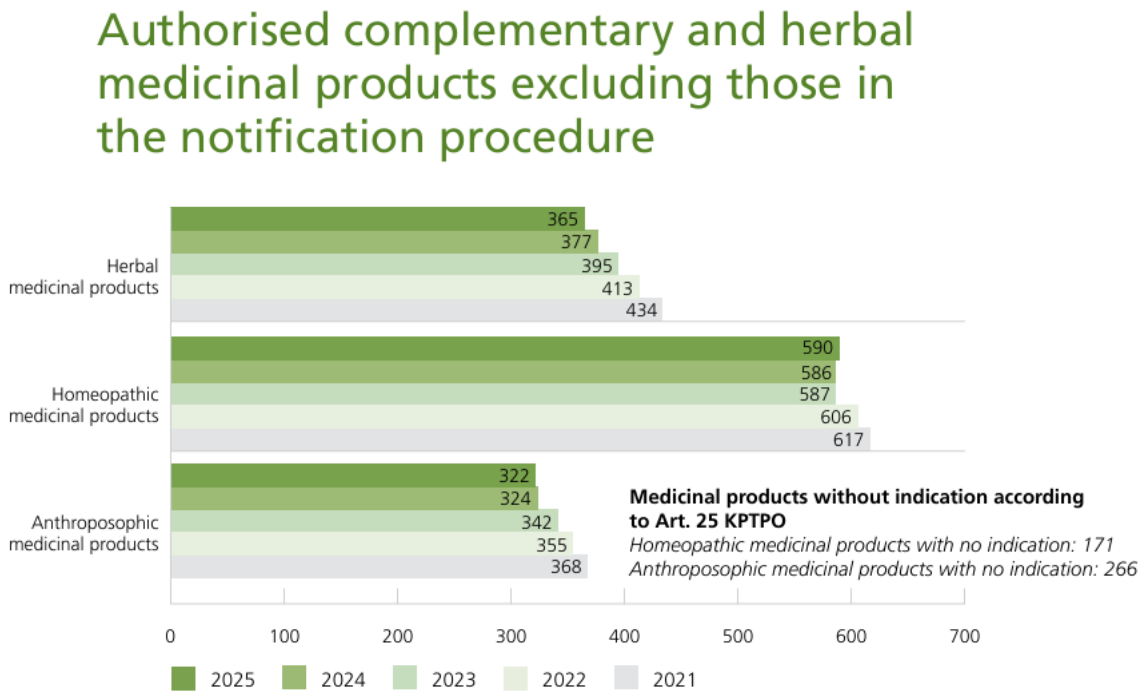




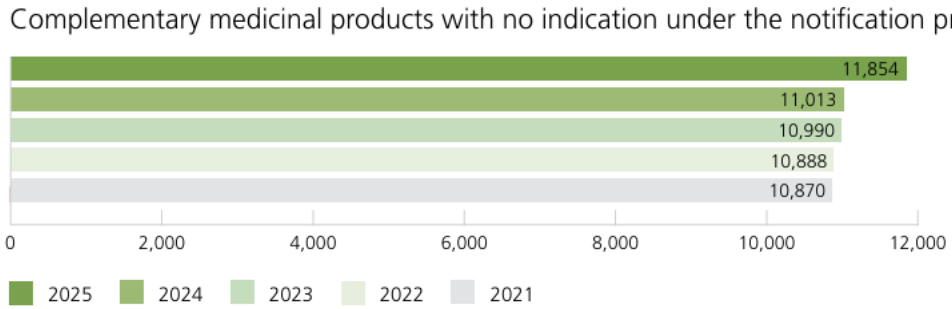


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Review of CHMs 2025





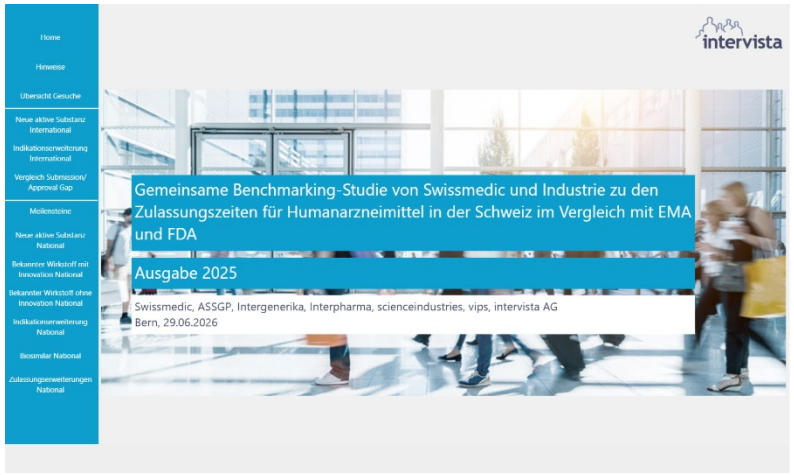


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Benchmarking SMC & industry

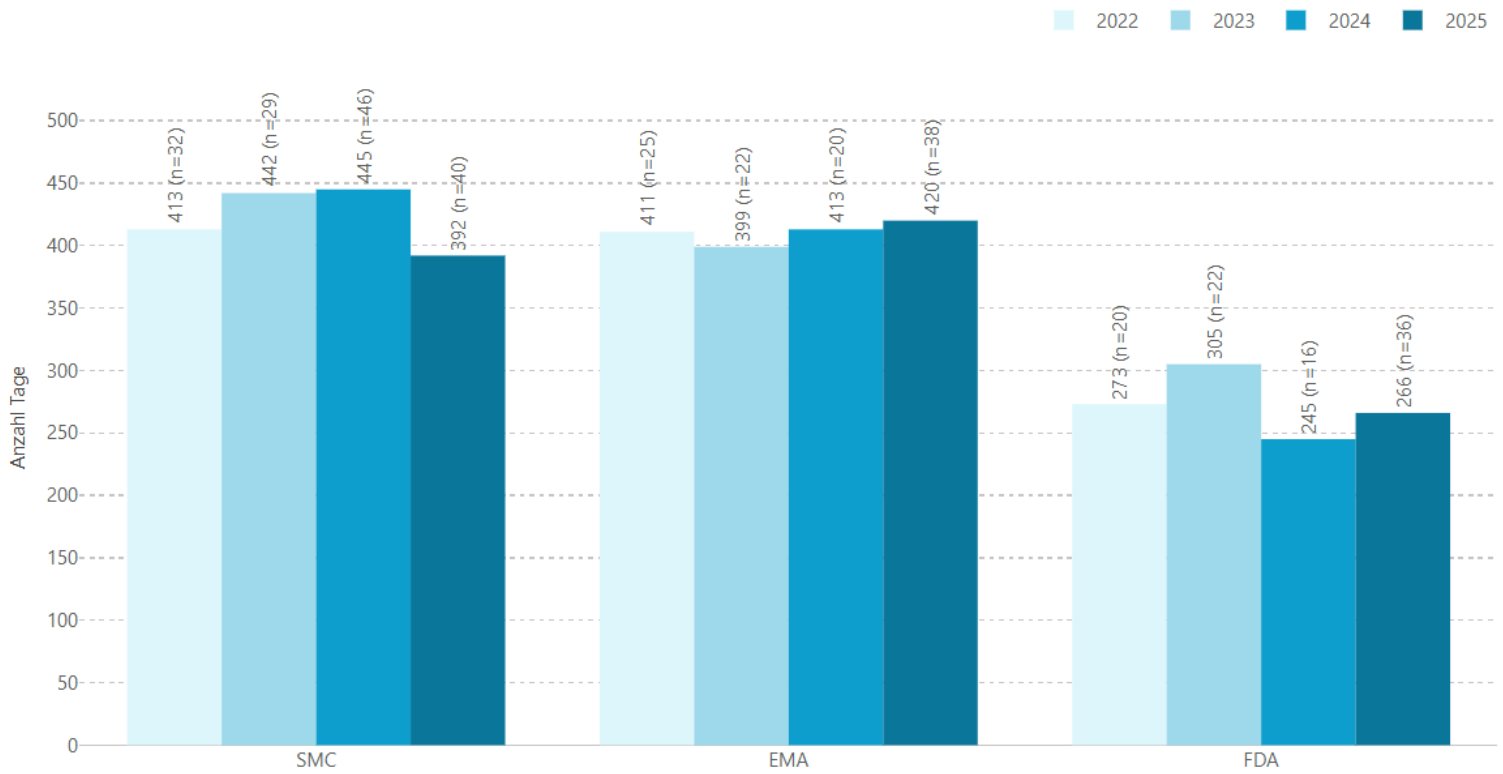
- *Executive Summary – Benchmarking 2025*
  - *Power BI dashboard*





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NA NAS – all procedures: Throughput times

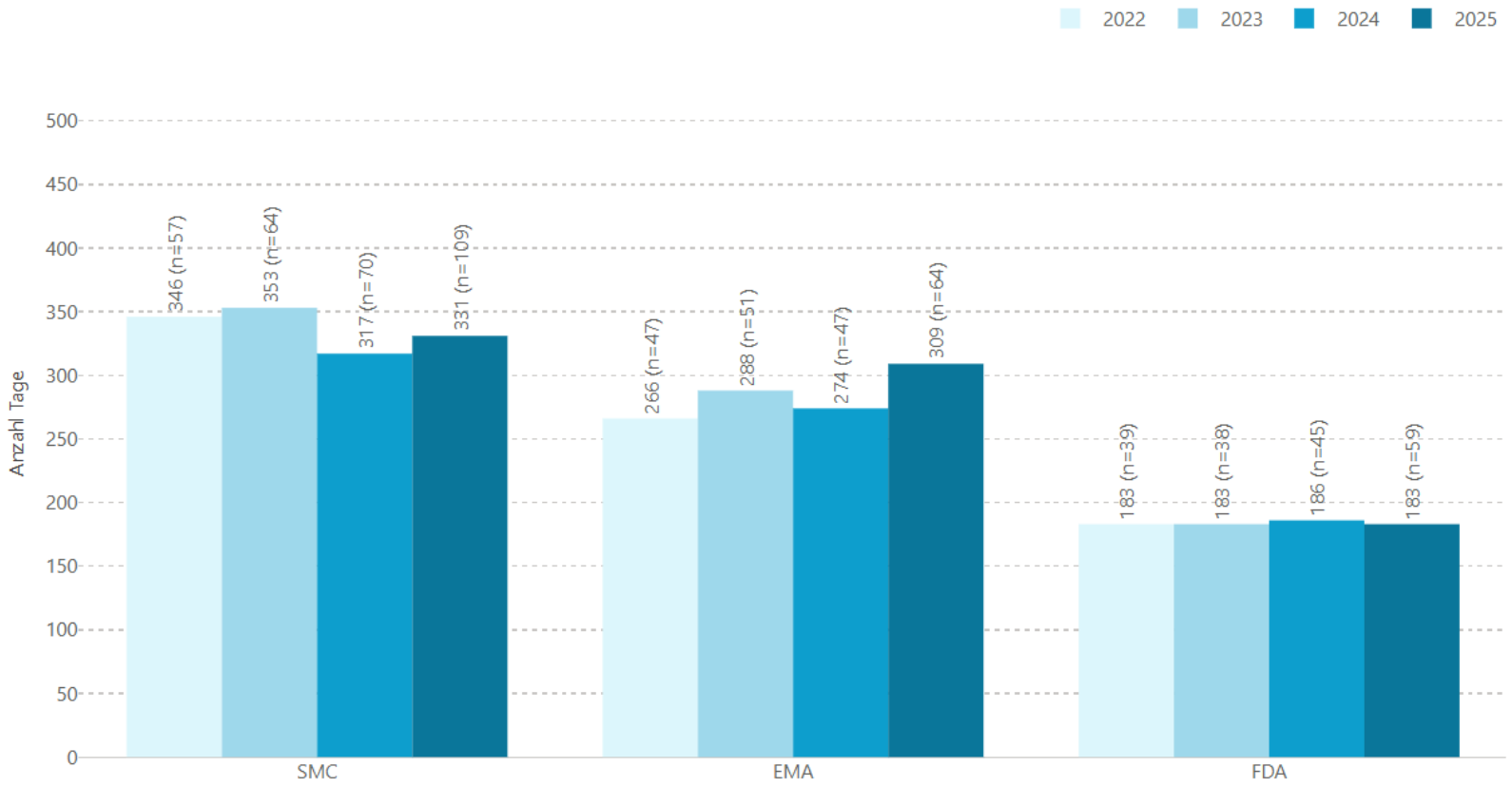


- **40** NA NAS authorised – **13%** fewer than 2024, **2 more than EMA**
- **392 days – 12%** or 52 days shorter than 2024
- International comparison: **7% shorter than EMA**, 47% longer than FDA

Comparison of throughput times of Swissmedic, the EMA and the FDA for new applications for new active substances (NA NAS) across all procedures, 2022–2025 (median values, n: number of applications).

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AIs – all procedures: Throughput times



- **109** AIs authorised**–** **56%** more than 2024
- **331 days + 4%** or 14 days longer than 2024
- International comparison: **7% longer than EMA**, 81% longer than FDA

Comparison of throughput times of Swissmedic, the EMA and the FDA for additional indications (AIs) for all procedures, 2022–2025 (median values, n: number of applications).

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Key figures 2025 – *KAS without innovation*

In 2025, Swissmedic authorised a total of 109 KAS without innovation, representing an increase of 20% year-on-year.

In 50% of cases, the procedure under Art. 13 TPA was applied, resulting in a throughput time of 349 CDs, a reduction of 174 CDs or 33% compared with the standard procedure.

In 95% of applications under Art. 13 TPA, no own assessment of efficacy, safety and quality **is conducted**.

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We involve our most important stakeholders



- **Patient perspectives systematically integrated**

Two extraordinary HMEC members with patient expertise are now available to Swissmedic for authorisation procedures.

- **Equivalent and independent expertise**

The patient experts meet the same requirements as all other eoHMEC members and contribute their documented assessment to the scientific evaluation.

- **Added value for patient-relevant decisions**

The patient expertise has already been applied in the evaluation of authorisation procedures, including to assess additional blood tests and the relevance of clinical endpoints

We bring stakeholders together

- **Bring stakeholders together**
- **Examine different views**
- **Define pragmatic solutions**



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Agenda

Swissmedic Roundtable Innovation (RTI):

Gewässerbelastung durch äusserlich angewendete Antiparasitika bei Heimtieren

Dienstag, 27. Januar 2026, 9:00– 11:45

Swissmedic, Hallerstrasse 7, Bern; Sitzungszimmer H044

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Agenda Swissmedic Roundtable Innovation (RTI) zu

Zukunft Tierimpfstoffe in der Schweiz – gemeinsam Herausforderungen meistern

Dienstag, 24. März 2026, 9:00– 12:00

Swissmedic, Hallerstrasse 7, Bern; Sitzungszimmer H044

We enable solutions

- **Better care for children**
- **Improved access to medications**
- **Pragmatic transitional solution**



Improved access to medicines – particularly paediatric medicinal products – during shortages

Federal Department of Home Affairs (FDHA) press release

29.04.2025

To bridge acute shortages of medicinal products, Switzerland's Cantonal Pharmacists (KAV), the Federal Office of Public Health (FOPH) and Swissmedic have jointly agreed to temporarily extend the meaning of the term "emergency" in Article 49 of the Medicinal Products Licensing Ordinance (MPLO). This means that healthcare professionals can import and store in the short term urgently required medicinal products that are not authorised or not available in Switzerland even if they are not intended solely for one particular patient. The new regulation is a transitional solution that will apply until the legislative provisions currently undergoing amendment take effect. In particular, it will improve supplies of urgently needed paediatric medicinal products.

Address for enquiries

Swissmedic
Media Unit

+41 58 462 02 76

media@swissmedic.ch

Federal Office of Public Health
Media and Communication

+41 58 462 95 05

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An independent, internationally well-networked therapeutic products agency strengthens Switzerland as a centre of pharmaceutical activity

- We are swift and flexible
- We are internationally networked and also focused on Switzerland
- We are essential for ensuring patient safety
- We are not an obstacle but an agency that is open to dialogue and that offers possibilities



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