



Medicinal Product Authorisation and Vigilance Sector

Dr Eveline Trachsel

Head of Medicinal Product Authorisation and Vigilance Sector

Eveline Trachsel, pharmacist, Dr.sc.nat., eMBA

Head of Medicinal Product Authorisation and Vigilance Sector

I am committed to excellent, forward-looking healthcare delivery in Switzerland that guarantees everyone rapid access to safe, effective and high-quality medicinal products.

I attach importance to ensuring Switzerland retains its international healthcare leadership in the future and benefits from the best innovations.



Education

- **Business sense / digital transformation (eMBA)**



- **Scientific expertise (Pharmacist, PhD)**



Experience

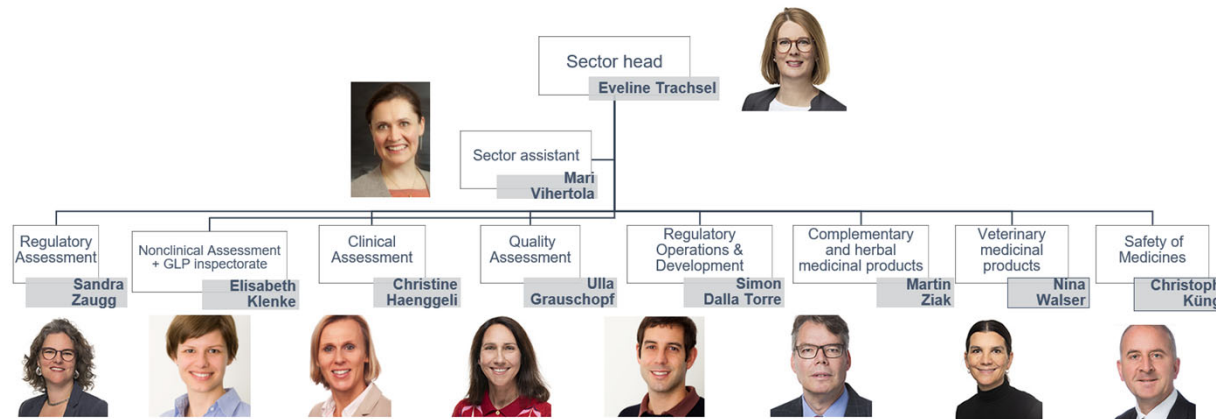
- **Therapeutic products agency** since 1 Jan. 2024

Head of Medicinal Product Authorisation and Vigilance Sector/ MB member

- **Pharmaceutical industry 8 years** (Scientific Advisor – Disease Area Head – Medical Director – MB member)
- **Clinical development 3 years** (Clinical Research Manager)
- **Biotech 5 years** (Project Manager / Board Member)



Medicinal Product Authorisation and Vigilance – New sector from 1 Jan. 2024

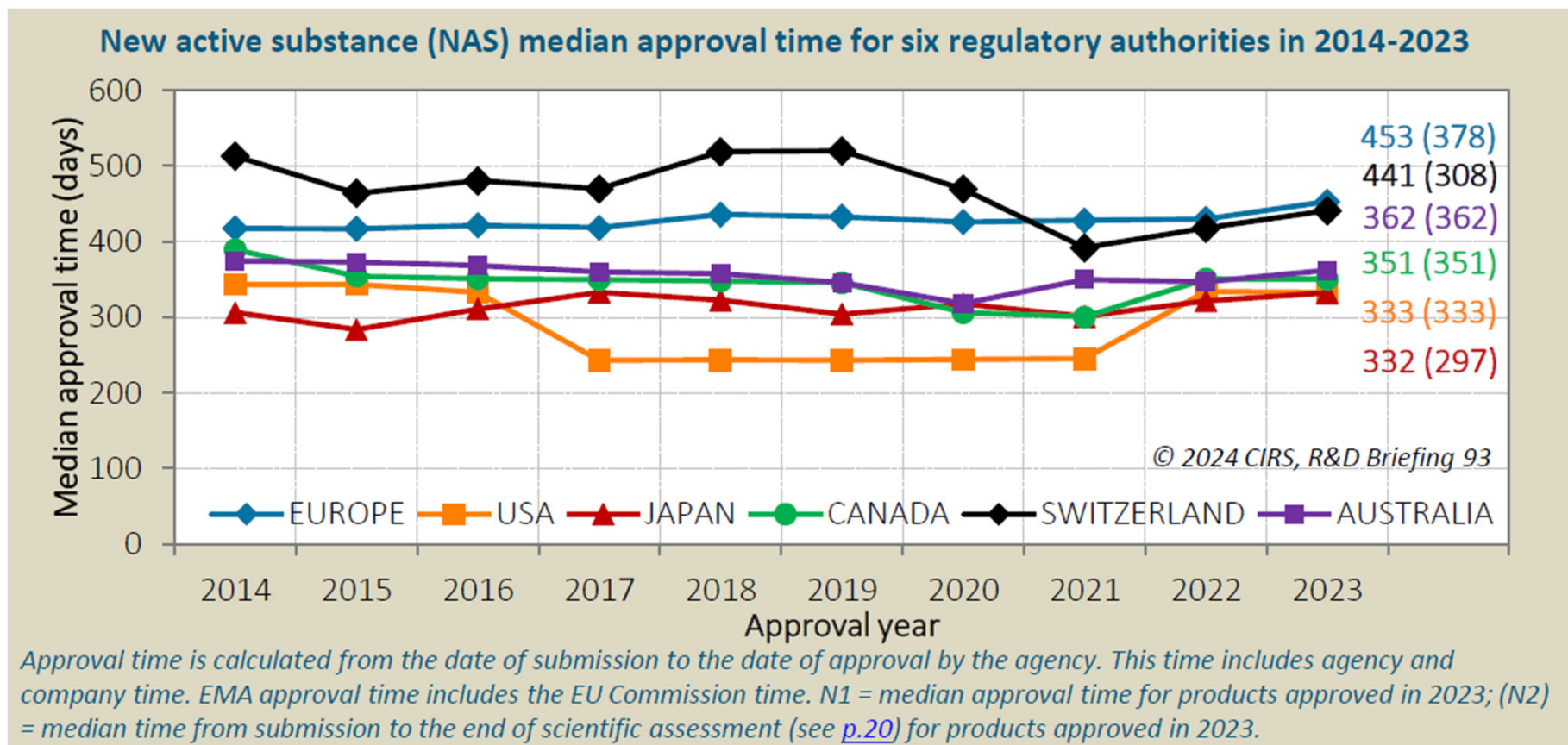


- Committed team of almost 200 people
- Dedicated to patient wellbeing
- Safety of Medicines Division now part of Medicinal Product Authorisation and Vigilance Sector
→ Synergies across entire medicinal product life cycle

Our shared goal

To give patients in Switzerland the fastest possible access to high-quality, safe and effective medicinal products.

Swissmedic is in the top league of regulatory authorities



How we achieve more for patients by working together

- **Shorten turnaround times**

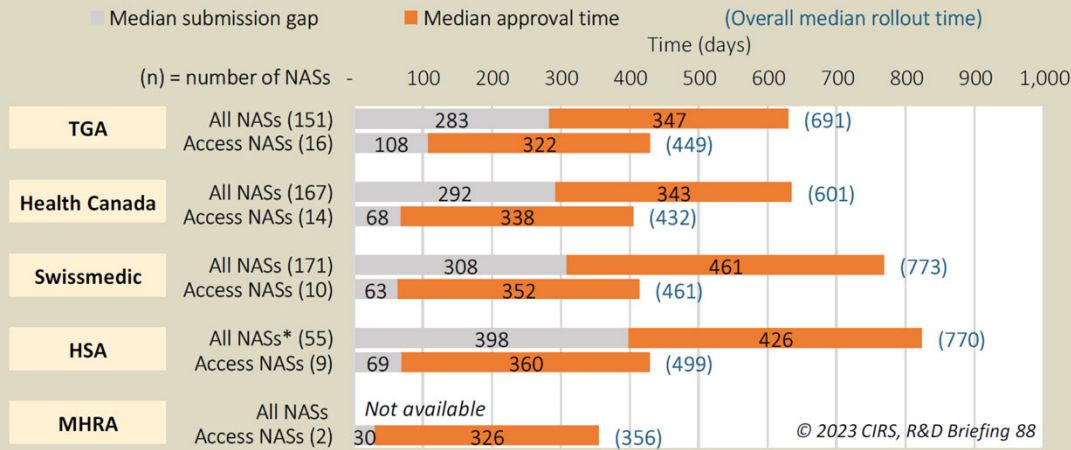
- Optimise labelling phase (increased informal dialogue)
- Leverage international procedures
- Optimise company meetings

- **Reduce submission gap**

- Leverage international procedures
- Step up early scientific dialogue to avoid rejections
- Intensify clinical research in Switzerland

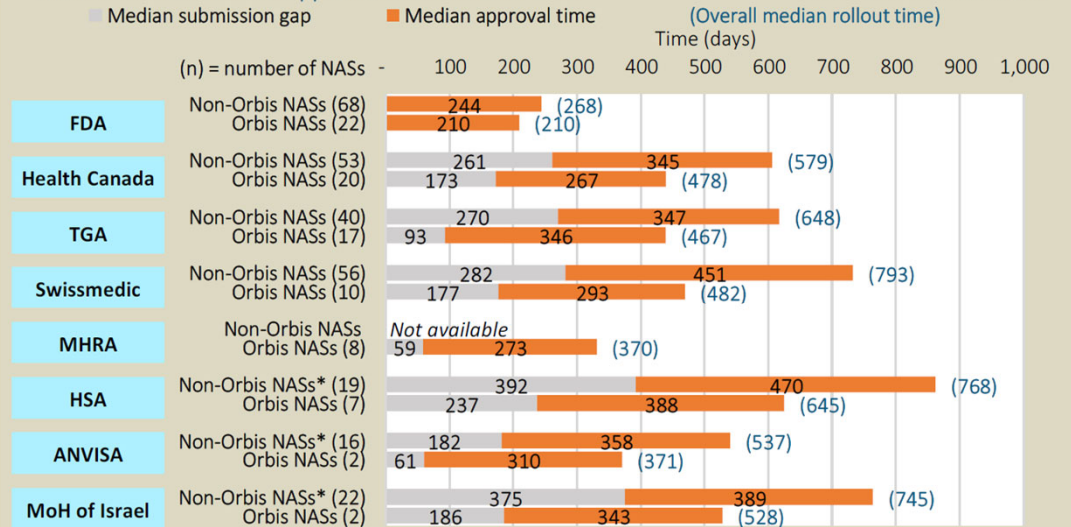
International procedures reduce the submission gap

Figure 13: Median submission gap and median approval time for all NASs approved compared to those approved via the Access Consortium between 2018-2022



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 15: Median submission gap and median approval time for NASs approved by Project Orbis compared to other anti-cancer NASs approved between 2019-2022



Submission gap is calculated as the time from the date of submission at the first regulatory agency to the date of regulatory submission to the target agency. Four products were considered MLEs to FDA and considered NAS to other agencies within the Project Orbis initiative, for these cases, the FDA submission date 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.

Medicinal Product Authorisation and Vigilance Sector leadership team



Simon Dalla Torre **Sandra Zaugg** **Mari Vihertola** **Martin Ziak** **Elisabeth Klenke**
ROD RA AA CHM NCA

Nina Walser **Ulla Grauschopf** **Eveline Trachsel** **Christoph Küng** **Christine Haenggeli**
VMP QA AU SOM CA