



Switzerland presentation

International Medication Safety Network Annual Meeting 2022

Irene Scholz / Thomas Stammschulte
Pharmacovigilance Unit

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

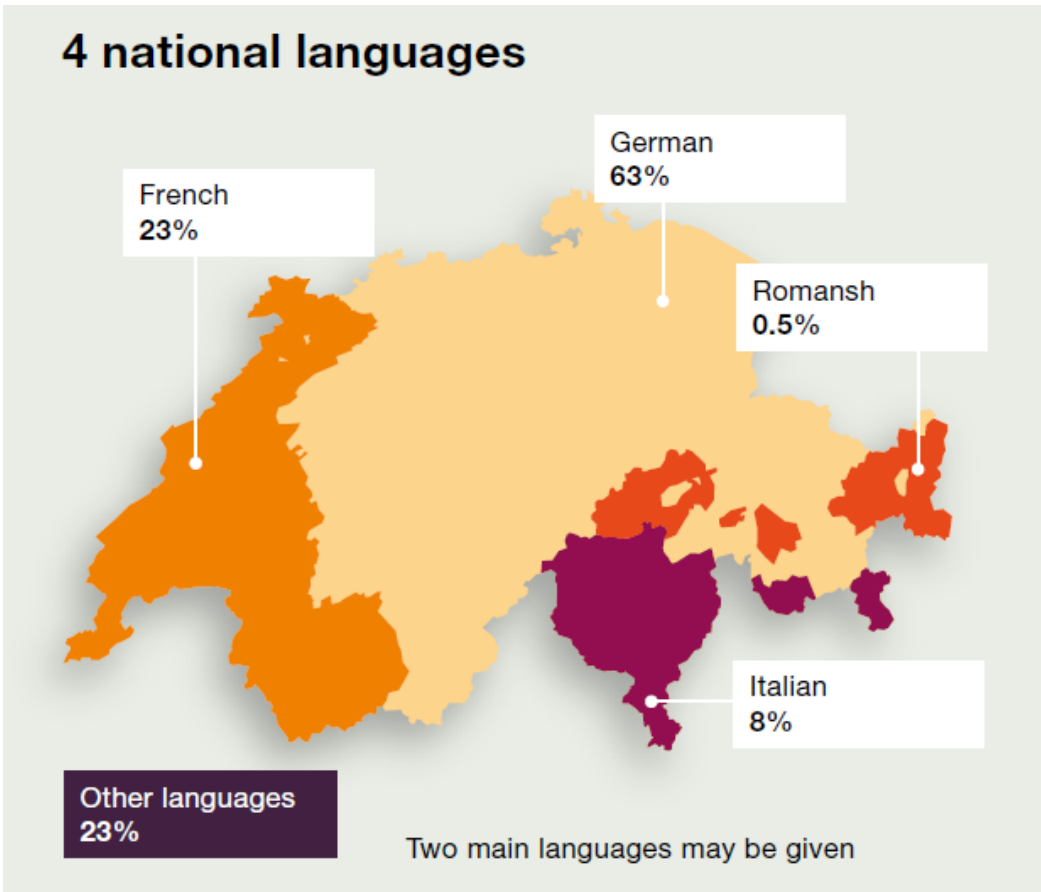
Hallerstrasse 7, 3012 Bern
www.swissmedic.ch



Source: Google Maps



Population



Population (2021) \approx 8.7 million

Switzerland is a multi lingual country. There are four national languages (DE, FR, IT, RO) and many other languages are spoken. Many people speak two main languages.

Source: <https://www.bk.admin.ch/bk/en/home/dokumentation/the-swiss-confederation--a-brief-guide.html>, p. 8

Swissmedic: 20th anniversary in 2022

- Established in January 2002 as the first Federal authority on therapeutic products along with the coming into force of the Act on Therapeutic Products
- Prior to 2002, regulation of medicinal products was a cantonal responsibility
- Scope of Products
 - **Medicinal products** for human and veterinary use (synthetic, biotechnology, biologic, stable blood products, transplant products, traditional and herbal medicines, ...)
 - **Medical devices** (instruments, apparatus, in vitro diagnostics, software and other goods or substances)

Legal status and governance

- Public Institution of the Federal Government
- Affiliated to the Federal Department of Home Affairs
- The Agency Council, Swissmedic's strategic body, represents its interests before the said Department and the Federal Council
- **Independent in organization and management**
- The Agency Council also approves Swissmedic's budget, annual accounts and annual report

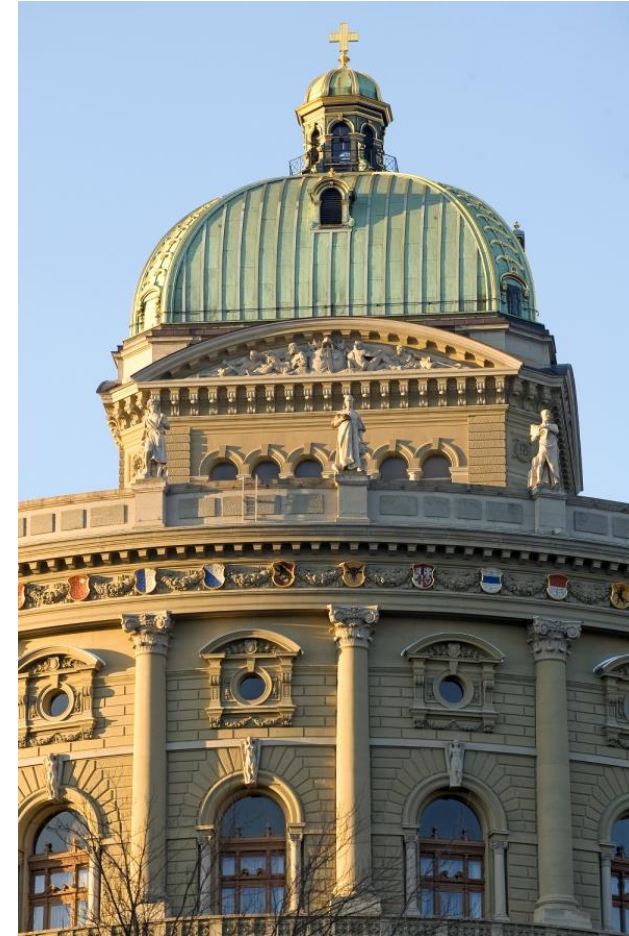
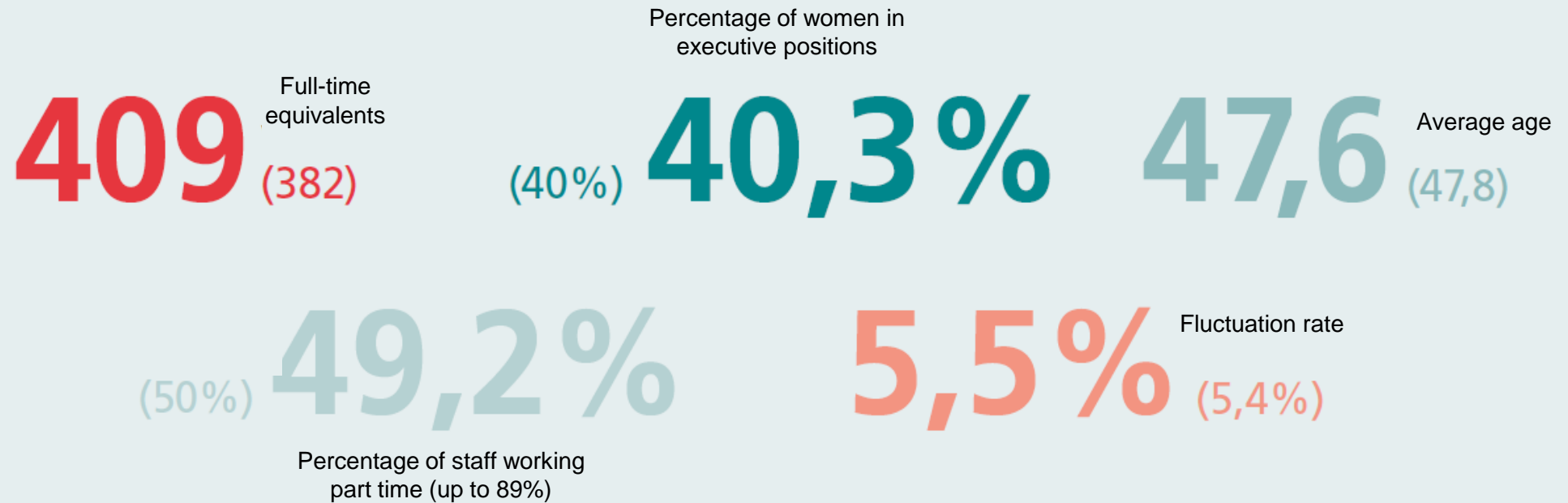


Image of the Parliament Building: The South Facade
<http://www.parlament.ch/d/service-presse/fotogalerie/suedfassade/PublishingImages/bundeshaus-sued-09-g.jpg>

Facts & Figures (2021)



International collaboration



SWISSmedic

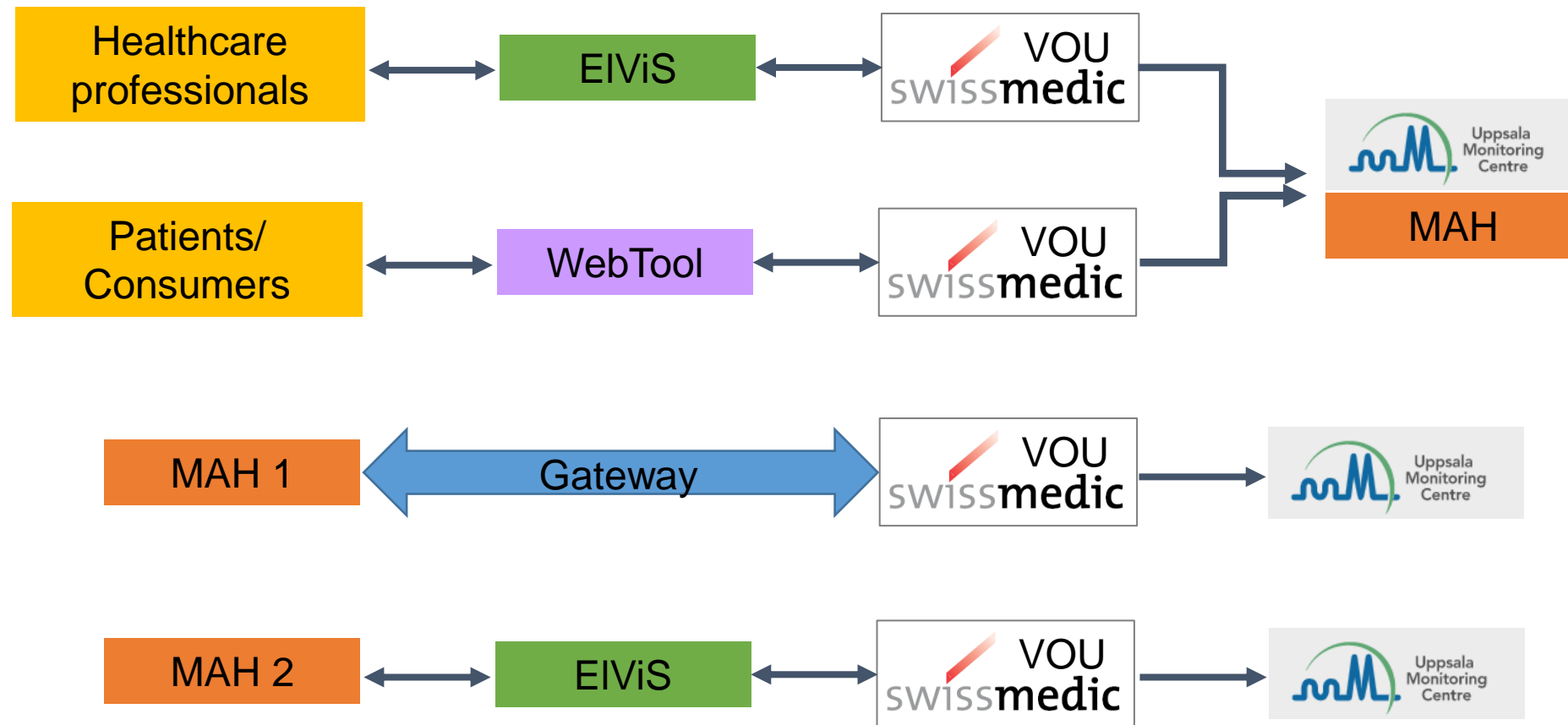


Therapeutic Products Act, TPA, Art. 59

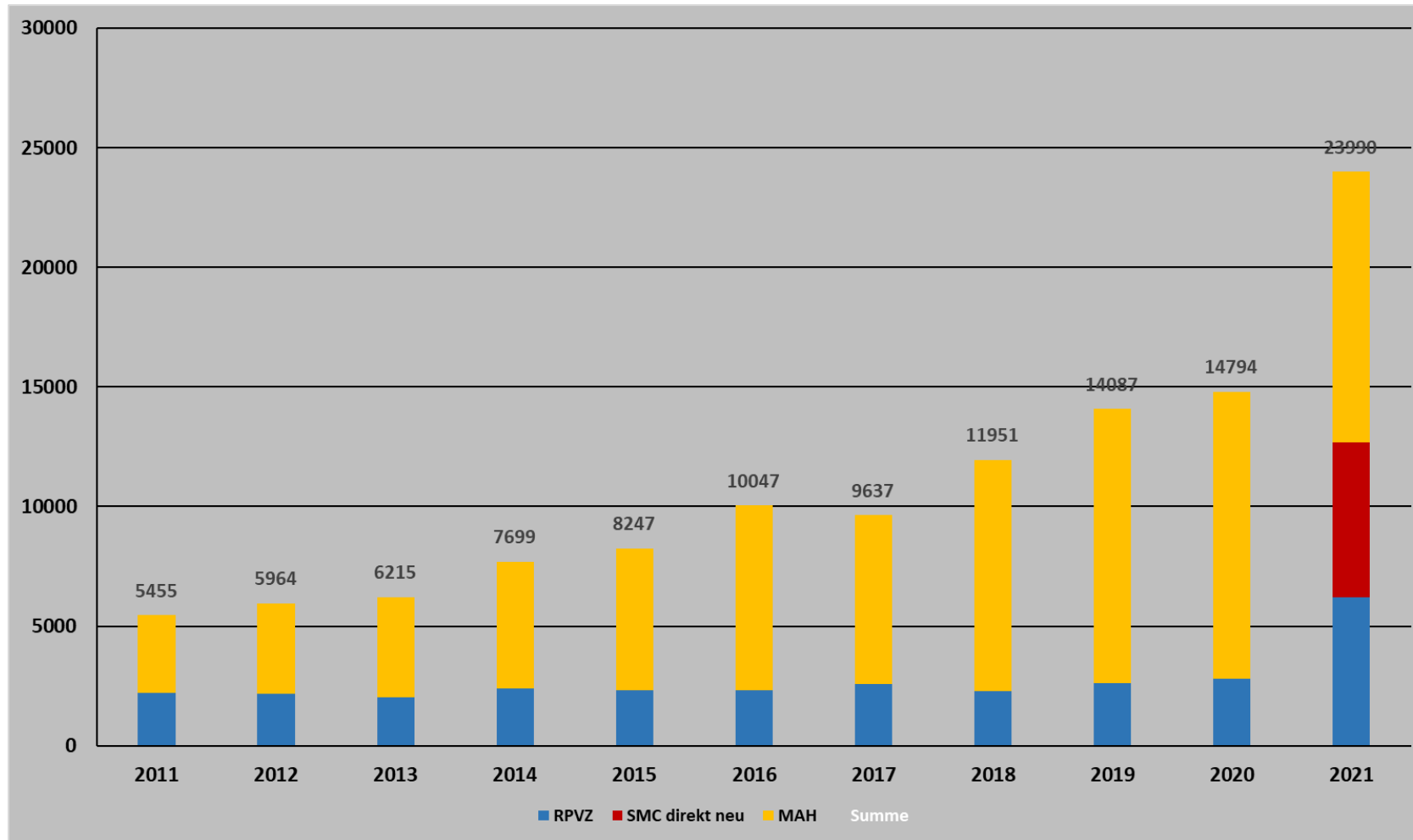
³ Any person who professionally dispenses therapeutic products or administers them to humans or animals or who is entitled to do so as medical personnel must notify the Agency of any serious and previously unknown adverse effects and incidents, observations of other serious and previously unknown facts or quality defects that are of significance for drug safety.¹³⁸

⁴ Consumers, patients and their organisations as well as interested third parties, may notify the Agency for adverse events and reactions with therapeutic products.

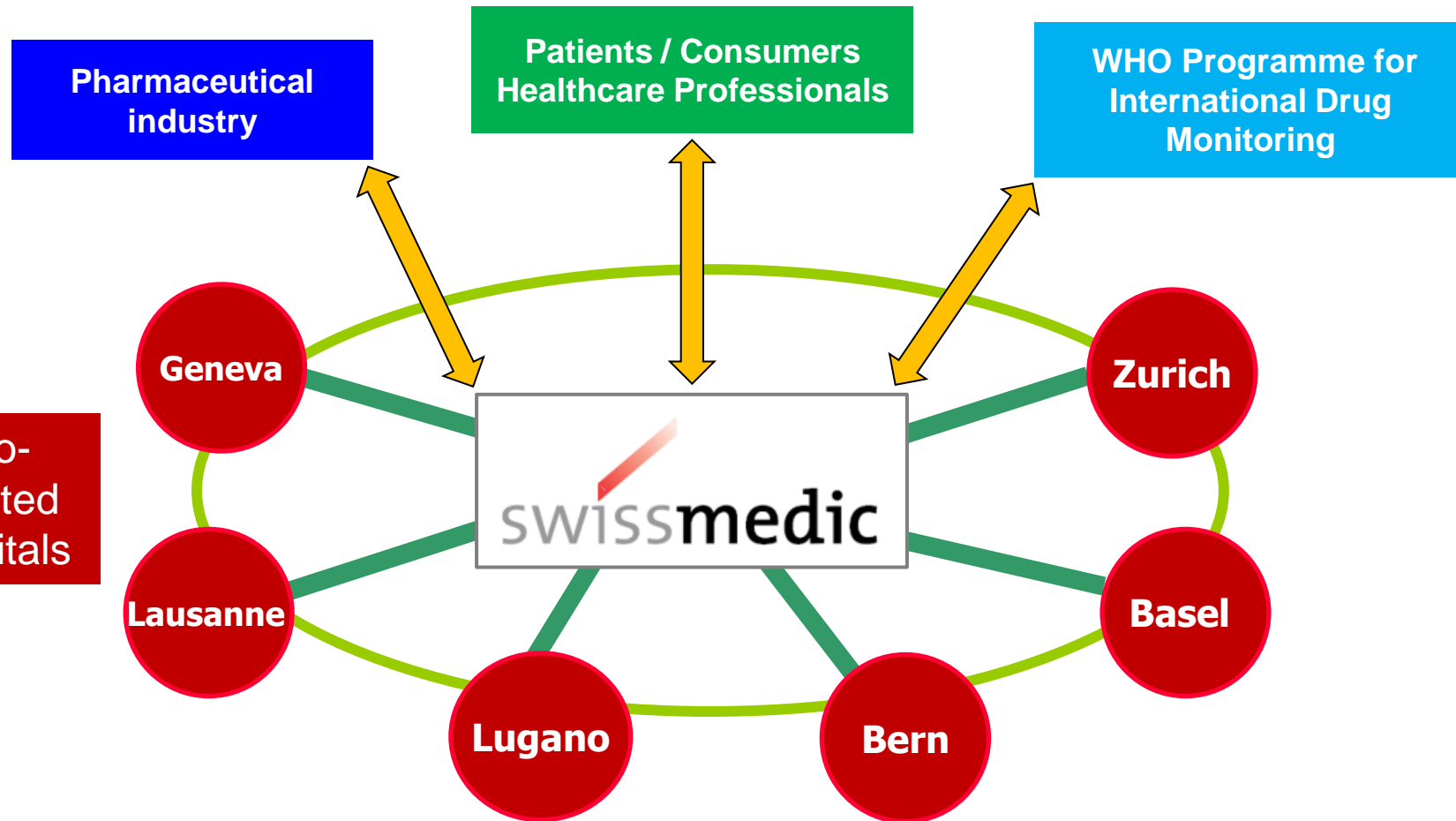
Exchange of spontaneous reports in Switzerland



Number of reports per year (incl. FUPs)



The Swiss Pharmacovigilance Network



Six regional pharmacovigilance centers located at the university hospitals

Collaboration between Swissmedic and Regional Pharmacovigilance Centers

- Regional centers are located at the Institutes for Clinical Pharmacology of the University hospitals
- In-depth evaluations of single-case reports on behalf of Swissmedic including comprehensive feedback letters for the primary reporters
- Pharmacological consultations: frequently identification of adverse reactions and submission to Swissmedic
- Education of physician, pharmacists, students (inpatient and outpatient care) in pharmacovigilance and medication safety
- Detection of adverse drug reactions / drug interactions in electronic healthcare records
- Publications on pharmacovigilance and medication safety topics

Vigilance News

Edition 28 – May 2022

Methotrexate

- Case report: Unexpected cause of aphthous ulcers, diarrhoea and thrombocytopenia in a patient with COVID-19 vaccine breakthrough infection

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• Successful re-exposure to COVID-19 mRNA vaccination at a reduced dosage in a patient with clinically suspected pericarditis/myocarditis after a first dose of COVID-19 vaccine	10
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Case report from Swissmedic Vigilance News: Unexpected cause of aphthous ulcers, diarrhoea and thrombocytopenia in a patient with COVID-19 vaccine breakthrough infection

Table 1: Data from the WHO pharmacovigilance database concerning methotrexate in Switzerland 2016-2021

	2016	2017	2018	2019	2020	2021
Number of ADR cases for MTX in Vigilyze in Switzerland per year	233	258	118	158	105	87
Of which fatal cases	12	11	4	7	3	9
Of which reported under PT Accidental exposure to product	66	35	9	5	1	0
Of which reported under PT Accidental overdose	6	1	2	6	1	1
Of which reported under PT Overdose	9	3	1	1	1	0
Of which reported under PT Product administration / prescribing error	12	5	0	9	0	0
Of which reported under PT Incorrect dose administered	4	1	0	1	2	2

Swissmedic Vigilance-News Edition 28 – May 2022

Case report of a delayed local reaction at the injection site ("COVID arm")



Photo 1
First reaction 7 days after vaccination: feeling of warmth, no pain



Photo 2
15 hours later: intensive feeling of warmth, pain



Photo 3
19 hours later: intake of antiallergic medication



Photo 4
34 hours later: less pain, less feeling of warmth



Photo 5
38 hours later: less pain, less feeling of warmth



Photo 6
44 hours later: only tenderness, less feeling of warmth



Photo 7
55 hours later: feeling of warmth and tenderness decreasing



Photo 8
67 hours later: no further feeling of warmth or tenderness

Swissmedic database of ICSRs 2012-2021 (n=92'953): SMQ Medication errors (n=3'884, 4.2%) Ranking of suspected / interacting medicines

Reported active ingredients (WHODrug)	S/I
AI: Methotrexate	202
AI: Fentanyl	94
AI: Paliperidone	79
AI: Acetylsalicylic acid	76
AI: Influenza vaccine	72
AI: Interferon beta-1a	72
AI: Iron	65
AI: Etonogestrel	58
AI: Teriparatide	55
AI: Tick-borne encephalitis vaccine	49
AI: Carbidopa;Levodopa	47

Swissmedic database of ICSRs 2012-2021 (n=92'953): SMQ Medication errors (n=3'884, 4.2%) Ranking of reported reactions

Reaction (MedDRA)	Count	Percentage
PT: Inappropriate schedule of product administration	475	12.2%
PT: Wrong technique in product usage process	379	9.8%
PT: Incorrect dose administered	370	9.5%
PT: Accidental overdose	356	9.2%
PT: Product administration error	308	7.9%
PT: Medication error	275	7.1%
PT: Product prescribing error	246	6.3%
PT: Incorrect route of product administration	240	6.2%
PT: Accidental exposure to product	231	5.9%
PT: Contraindicated product administered	167	4.3%
PT: Product storage error	159	4.1%

Visions with regard to medication safety

- Strengthening the collaboration with Swiss stakeholders, e.g. Patient Safety Foundation Switzerland
- Update of guidelines / recommendations for Marketing authorisation holders and Healthcare professionals on reporting medication errors
- Establishing one regional pharmacovigilance center with a focus on medication safety
- Information for HCPs regarding medication safety (publishing case reports from our database, Vigilance News)
- Strengthening the collaboration with International Medication Safety Network

Thank you for your attention!

thomas.stammschulte@swissmedic.ch

