swissmedic
20 Jahre 2002 - 2022

# Swissmedic, Safety and industry monitoring authority for therapeutic products

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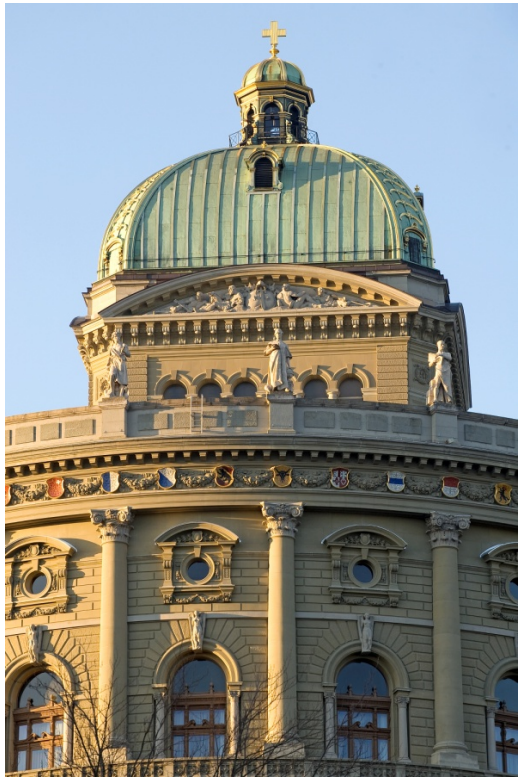
# Importance of Swissmedic – Governance



- **Therapeutic product safety – patient safety** (medicinal products and medical devices incl. IVDs)
- **Safety and industry oversight role**
- Regulator of systemically important sectors (pharma and medtech: approx. 8% of GDP)
- **Tasks performed independently** (governance and scientific expertise)
- Swissmedic – an outsourced unit
- Public corporate governance – associated with the FDHA (independent operational management)
- Managed by way of strategic goals **– independent budget and financing**
- **National policy-oriented and strategic view** (current situation without MRA)
  - **Independence at Swiss level** in respect of other regulatory areas;
  - Flexibility/room for manoeuvre in the existentially important health sector

# Legal mandate

**To safeguard**

- Quality
- Safety
- Efficacy / Conformity

} of medicinal products **and medical devices (incl. IVDs)** – full lifecycle

**Demarcation: *Not responsible*** for

- Setting prices / Costs of therapeutic products => FOPH (SL, MiGeL*)
- Supply => Cantons, FONES, FOPH
- Legislation: Acts and FC Ordinances => lead FOPH
- MRA negotiations and economic (export) issues => SECO

*List of medical supplies and devices (MiGeL)

# What does Swissmedic produce? - Product groups at Swissmedic

**Standards PG**
- Legal framework
- Technical standards

**Information PG**
- Informing the general public
- Informing the therapeutic products sector

**Market Access PG**
- Authorisation
- Licensing

**Market Surveillance PG**
- Medicinal products vigilance
- Market monitoring of medicinal products
- **Medical devices vigilance**
- **Market monitoring of medical devices**

**Penal Law PG**

**Medicinal products:** Authorisation, licensing and monitoring

**Medical devices: Focus on monitoring and information**

# Swissmedic – Bridge between therapeutic products industry and the public

# Official market surveillance (Art. 58 TPA)

- Swissmedic verifies:
  - … whether the manufacture, distribution, dispensing and maintenance of, and claims relating to, therapeutic products are lawful.
  - …the therapeutic products placed on the market. (Medicinal products: conformity with the marketing authorisation / Medical devices: conformity with legal requirements).
- [carry out]… announced and unannounced inspections.
- Swissmedic takes the necessary administrative measures…
- The Agency shall be responsible for **monitoring the safety of therapeutic products**.
- [Swissmedic] … may take samples, request essential information or documents, and ask for any help necessary for this purpose…

# Monitoring of medical devices

- Approval and monitoring of clinical trials with medical devices
- Hospital inspections in respect maintenance incl. reprocessing and reporting process
- Monitoring and designation of conformity assessment bodies (CABs)
- Vigilance and international coordination of signals, FSCA
- Checks on the market in respect of conformity
- Market surveillance: key actions for medical devices and operators incl. inspections

→ Risk-based investigation and prioritisation of monitoring

→ Aim of intervention: protection of patients and users – ensuring/ restoring legal status

# Challenges in 2021/2022 – Focus on medical devices

## COVID-19 pandemic – Reports concerning Sars-CoV-2 rapid tests

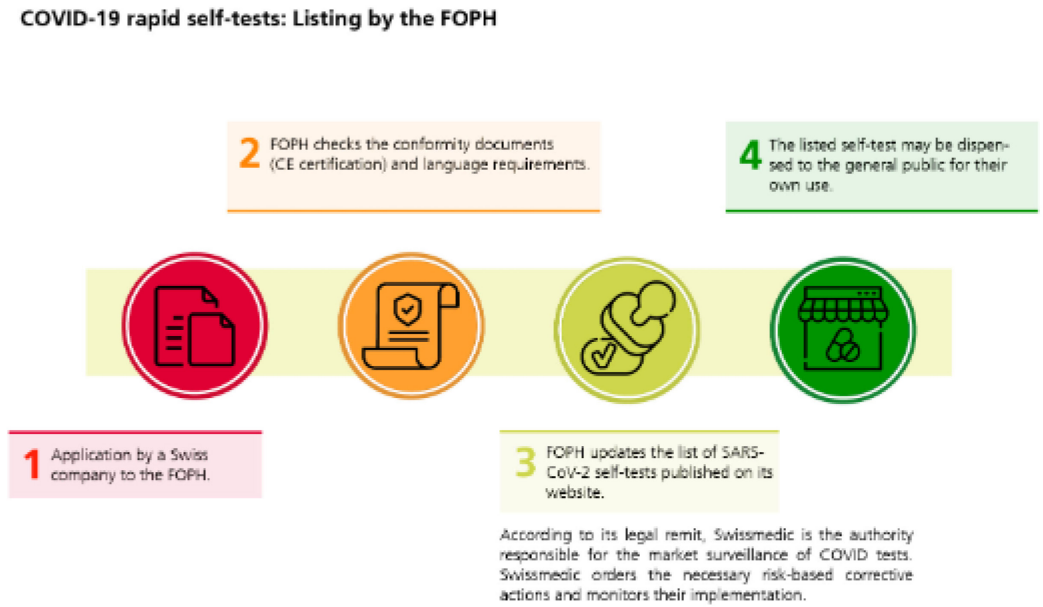
### Swissmedic takes action against dispensing of non-compliant rapid tests by Swiss online shops

23.09.2021

**The Medical Devices Ordinance (MedDO) prohibits the dispensing to the general public of in vitro diagnostic medical devices for the diagnosis of transmissible human diseases. Exemptions for Sars-CoV-2 self-tests were specified in COVID-19 Ordinance 3 and have been in effect since 7 April 2021.**

Swissmedic received a total of 51 reports concerning Sars-CoV-2 rapid tests between February and June 2021. This corresponds to around one-quarter of the total annual reports received concerning medical devices prior to the pandemic. Reports were largely made by market players (37%), private individuals (20%), federal authorities excluding Swissmedic (18%) and cantonal authorities (12%).

Swissmedic examined reports of suspicious activity concerning dispensing of Sars-CoV-2 rapid tests, reviewed claims and product information in online shops and carried out test purchases from suppliers in Switzerland. In 15 cases (29%), administrative proceedings were initiated and dispensing of the tests prohibited by an official decision. Two market players voluntarily ceased




Source: exception-certain-sars-cov-2-rapid-self-tests

# Challenges in 2021/2022 – Focus on medical devices

## Integration within the European monitoring system

The Mutual Recognition Agreement with the EU Member States on conformity assessments for medical devices was not updated with effect from 26 May 2021. As a direct consequence, Switzerland ceased to be a closely integrated part of the European system. In concrete terms, this means not only that Switzerland no longer benefits from simplified administrative assistance and participation in market monitoring activities, it has also lost access to EUDAMED, the new shared database and information system.

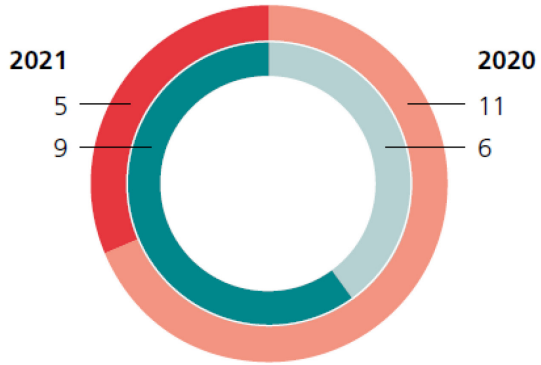
=> No longer apply due to lack of MRA…….

**Activities:**

Once again, the number of reports of suspected non-conforming medical devices declined year-on-year, although the number of reports received is still above the average for recent years. A large number of reports concerned masks and COVID-19 tests. Swissmedic ordered corrective action in 95 cases. It also carried out nine on-the-spot inspections of Swiss companies.

**Inspections**

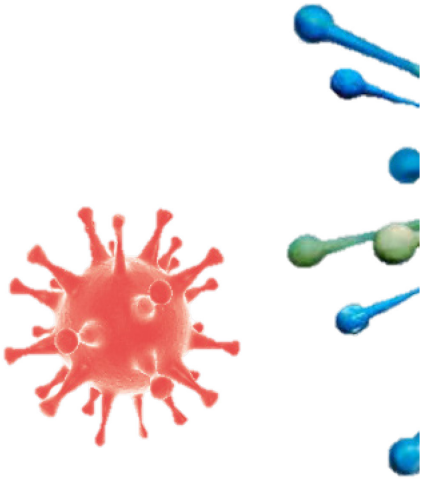
Inspections by foreign authorities (including accompanying inspectors on site if needed)
Inspections of market controls




**Hospital inspections**


Source: Swissmedic Annual Report 2021

# Examples from market surveillance 2021/2022



**Urgent Field Notice**

**Incorrect patient swabs contained in ID NOW COVID-19 Test Kits**

**FSCA-identifier: 2021 10**
**Device Correction**

October 27, 2021

**Urgent Field Safety Notice**

**Products:** **TaqPath™ COVID-19 CE-IVD RT-PCR Kit , 1000 reactions (Catalog #A48067)**
**TaqPath™ COVID-19 CE-IVD RT-PCR Kit, 100 reactions (Catalog #A51738)**

**Urgent Field Safety Notice**

NeuMoDx™ Cartridge (REF 100100)
LOT 106629, 106630, 106631, and 106632

Dear QIAGEN Customer,

This Urgent Field Safety Notice is to inform you that QIAGEN has identified an increased rate of potential false-positive results for the SARS-CoV-2 target obtained with cartridges in LOT 106629, 106630, 106631, and 106632 of the NeuMoDx Cartridge (REF 100100).

Date: 13.08.2021

**Dringende Field Safety Notice (FSN)**
**Saliva Ersatz Kit Disposan**

Zu Händen von *:

Käufern und Anwendern von Speichel-Kits für das wiederholte Pool-Testprogramm auf SARS-CoV-2 mit PCR.

Source: https://fsca.swissmedic.ch/mep/

# Aims and key elements of the event

# Aims and key elements

- Tasks of Swissmedic as a safety and industry monitoring authority
- Current legal basis for medical devices / IVDs in Switzerland
- Additions on performance studies with IVDs and requirements of in-house IVDs
- Specific information on **vigilance and market surveillance** to enable **economic operators to act on their own initiative in conformity with the law**
- Registration obligations
- Answers to frequently asked questions

**The following are not being addressed today**

- Private-sector contractual issues, such as liability questions
- Anti-trust issues
- Design, implementation in relation to specific medical devices or IVDS