swissmedic
20 Jahre 2002 - 2022

New regulation on in vitro diagnostic medical devices (IVDs)

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Market Surveillance

What is an IVD?

- Medical device
- What does **in vitro** mean?
  - **“In glass”** (from Latin vitrum = glass).

  - Organisms and structures are <u>not</u> investigated in their natural environment / in the body, but...
  - under **experimental conditions** instead

- **Intended** for the in vitro examination of **specimens**, including blood and tissue donations, obtained from the human body
- For **clinical diagnosis** only (not for research use)

What is an "in-house IVD"?

- **Medical devices** that are **manufactured and used solely within healthcare institutions**.
- With the exception of devices for performance studies, they **are deemed to have been put into service** (i.e. they are not placed on the market).
- These devices are also subject to the relevant **general safety and performance requirements** (Annex I EU-IVDR)

Status: EU-CH Mutual Recognition Agreement (MRA) for IVDs

Ref. Ares(2022)3889385 - 24/05/2022

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
DIRECTORATE-GENERAL FOR TRADE

The Directors-General

Brussels May 2022

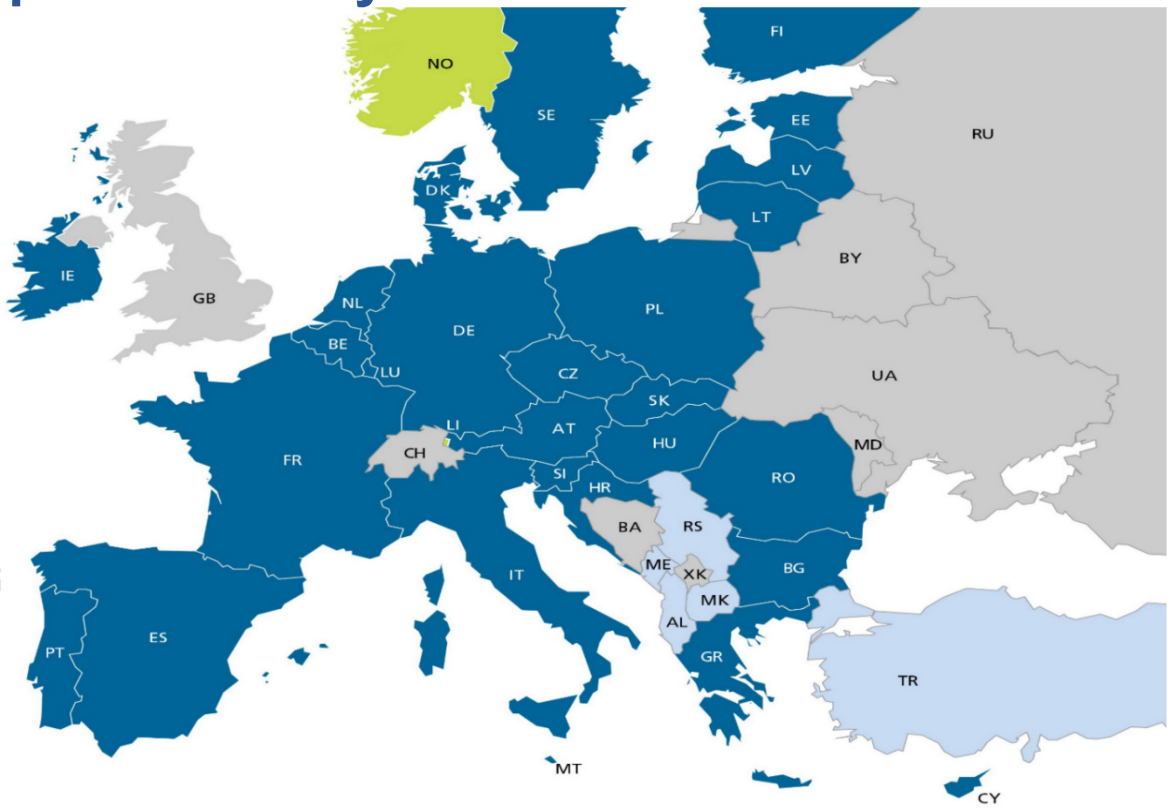
NOTICE TO STAKEHOLDERS: STATUS OF THE EU-SWITZERLAND MUTUAL RECOGNITION AGREEMENT (MRA) FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES

The new Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices becomes applicable on 26 May 2022[1], replacing Directive 98/79/EC. In the absence of an update of the MRA to include Regulation (EU) 2017/746, the part of the MRA chapter covering *in vitro* diagnostic medical devices ceases to apply as of 26 May 2022[2].

As a result, the trade facilitating effects of the MRA for *in vitro* diagnostic medical devices, including the mutual recognition of conformity assessment results, the absence of the need for an authorised representative and the alignment of technical regulations, cease to apply as of that date.

Situation since 26 May 2021 or, for IVDs, since 26 May 2022

- / **regulation in force and applicable with the following main aims:**
  - To improve device safety and therefore **patient safety**
  - To increase **transparency**



- **MRA is not updated**
  - becomes "third country"
  - equates breakdown of negotiations

  on InstA with Brexit decision

Switzerland is a "third country" - Significance for Swissmedic

since 2002 **up to 26 May 2021** **…after the "Notice to Stakeholders"**

Joint market surveillance

Close cooperation in EU

- **Work sharing**: Sharing of safety reports
  Work sharing vigilance – Exchanging information, joint declaration of **safety risks**
- Efficient processes for administrative actions
- Access to **shared database**
- Developing expertise thanks to joint working groups

ACCESS DENIED

- Work sharing ceases - monitoring requires more resources
- Lack of access to EU information and data sharing platform (only "public access")
- Exclusion from MDCG and CAMD Working Groups
- Data sharing ceases - Limited safety information available from EU partner authorities
  => potentially negative effect on patient safety
  => supportive measures required
- Negative effects on market attractiveness
- Potentially negative effects on supply

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How are medical devices regulated in Switzerland?

New, completely revised legal framework for the **market access** and **market surveillance** of medical devices and IVDs in 🇨🇭!

Federal Assembly

- Therapeutic Products Act (TPA) 812.21
- Human Research Act (HRA) 810.30

Federal Council

- Medical Devices Ordinance (MedDO) **812.213**
- Ordinance on In vitro Diagnostic Medical Devices (IvDO) **812.219**
- Ordinance on Clinical Trials with Medical Devices (ClinO-MD) 810.306

Regulation of IVDs before 26.05.2022

Regulation of IVDs from 26.05.2022

Mitigating measures in the IvDO due to the lack of an updated MRA 1/2

- Certificates issued by EU/EEA-CABs are recognised **unilaterally** [**Security of supply**]
- **Registration of economic operators with Swissmedic** ("CHRN") [**Transparency and implementability**]

- Validated summary report on the device must be published by the manufacturer [**Transparency**]
- *Device registration incl. UDI requirement incl. information to SMC*

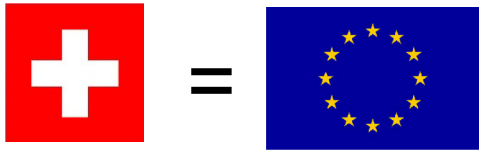
Mitigating measures in the IvDO due to the lack of an updated MRA 2/2

- Incidents and FSCAs must still be reported to Swissmedic
- **Appointment of authorised representatives** CH REP for manufacturers from EU/EEA for devices that are placed on the market after 26.05.2022 with **mandatory requirements** (incl. product information) **and transitional periods**
- Notification obligations for IVDs of all risk classes continue to apply (for the time being)
- Relaxation of requirements for devices that are not intended for lay use: Details of the CH REP may, until 31 March 2025, appear on a document accompanying the device

⇒ **Aim:** Responsibility for safety measures and the fulfilment of liability obligations with domicile in  is ensured.

Implementation challenges due to the lack of an updated MRA

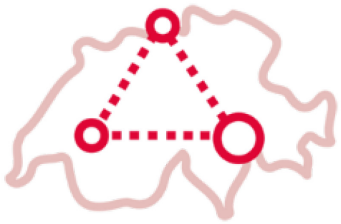
- Remit of Federal Council: Implement CH regulation **equivalent to the EU**



- **Volatile environment and short-term nature**
- **EU not ready**: certain documents relating to implementation still missing – work ongoing
- Numerous references in CH law to IVDR (incl. dynamic references) and parallel MRA no longer apply => **legal interpretation required in some cases**
- **Thousands of questions** from economic operators
- Implementation **without an updated MRA** entails **additional workload**!

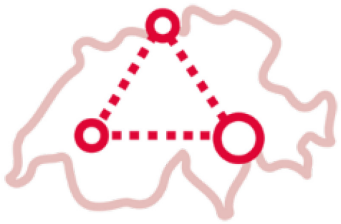
Round Table on Medical Technology (RTMT) - Background

- Swissmedic has organised the RTMT **since May 2019**
- **Platform for the exchange of views with stakeholders** on all aspects relating to **medical devices regulation**.
- These meetings are designed to enable the parties **to exchange information** and **raise issues** in order to be able to respond promptly and appropriately to **regulatory** or **technical developments** as necessary.
- The **direct exchange** with association representatives has since **proven its value**.
- **Exchanging views** on regulatory, process-related and technical issues

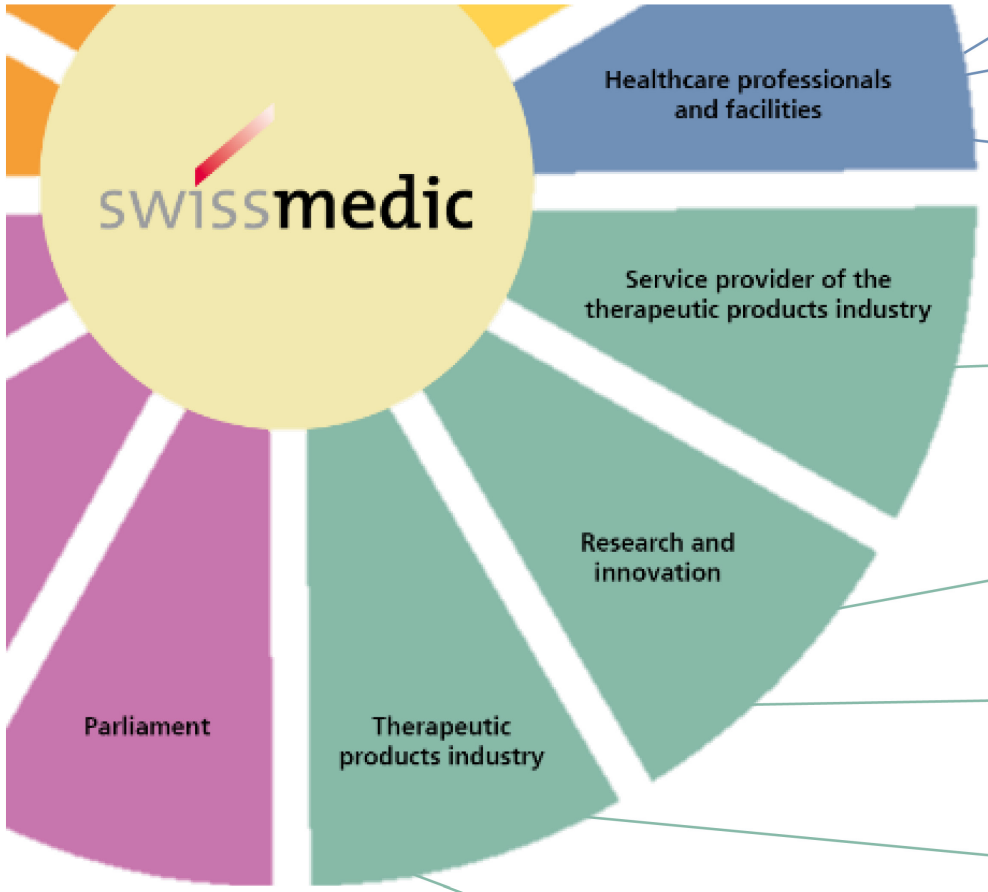


RTMT - Purpose

- **Strengthen** and **improve the implementation of the regulation** of medical devices and in vitro diagnostic medical devices **in Switzerland**
- Stakeholders are **informed** about relevant **new developments** or changes in implementation practice and are given the opportunity to review these for practicality and operational feasibility.
- The RTMT serves as a **multiplier for conveying information** about new or upcoming technical, process-related and regulatory changes.
- **Targeted involvement of members** in order to support the implementation of new and modified requirements of medical devices regulation.



RTMT - Composition



- SULM – Swiss Union of Laboratory Medicine
- QC - Quality Cyrcle of healthcare institutions
- SGMK - Swiss Society for Medical Cosmetics
- RAPS Switzerland Chapter (RAPS)
- SCTO - Swiss Clinical Trial Organisation
- Health Tech Cluster Switzerland, HTCS
- SMT - Swiss Medtech
- SVDI - Swiss Diagnostics Industry Association

Take-home messages

Aims of the mitigating measures in the IvDO:

- Achieve original aims of the revision of the regulations also for
- Maintain an **orderly supply** of **safe** medical devices
- Maintain nearest equivalent implementation (**safety standard similar to**)
- Swissmedic receives **safety-related information** despite its exclusion from the EU network and the lack of access to EU databases

=> Ensure patient safety and healthcare provision

Take-home messages

Round Table on Medical Technology (RTMT) / Questions

- Check the **Swissmedic website** incl. the **frequently asked questions**, where you may be able to find what you're looking for.

- Forward your **questions to your association**. The associations **cluster** and **prioritise** questions and address these to the RTMT.

- Spaces are still available: As an association/organisation you can submit a **nomination form** for admission to the **RTMT**.

Laws, ordinances, agreements, etc. mentioned in the presentation

TPA: Therapeutic Products Act - SR 812.21
HRA: Human Research Act SR 810.30
MedDO: Medical Devices Ordinance SR 812.213
ClinO-MD: Ordinance on Clinical Trials with Medical Devices SR 810.306
IvDO: Ordinance on In Vitro Diagnostic Medical Devices (SR 812.219)

MDR: Regulation (EU) on Medical Devices 2017/745
IVDR: Regulation (EU) on In vitro Diagnostic Medical Devices

MRA-2017: SR 0.946.526.81
Notice to stakeholders: https://health.ec.europa.eu/latest-updates/notice-stakeholders-status-eu-switzerland-mutual-recognition-agreement-mra-vitro-diagnostic-medical-2022-05-24_en
EUDAMED3: EUDAMED database - EUDAMED (europa.eu)

Useful links

Explanatory report: Ordinance on In Vitro Diagnostic Medical Devices and amendment of the Ordinance on Clinical Trials with Medical Devices:
https://www.bag.admin.ch/dam/bag/de/dokumente/biomed/heilmittel/meprrevision/BRB-mai2022/10_erlaeuterungen_ivdv_klinv-mep.pdf.download.pdf/10_erlaeuterungen_ivdv_klinv-mep_de.pdf

Swissmedic Newsletter: NEW > Registration form for Swissmedic News Services (mailxpert.ch)

Round Table on Medical Technology: Round Table on Medical Technology (RTMT) (swissmedic.ch)

Frequently Asked Questions: Q&A