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Mission of Switzerland to the EU

Switzerland & the EU
Where are we heading?

11 March 2024

Agenda

- A new European Health Union

- EU Regulations on (in vitro) Medical Devices
  - Extensions of the transition period & Follow up
  - EU Bodies in the field of MedTech

- Swiss - EU Relations
  - State of play

Swiss Mission to the EU

"The Mission is Switzerland's diplomatic representation to the EU. It represents Switzerland's interests towards the EU, and facilitates contacts between Swiss and EU representatives".

A new European Health Union

Health Policies mainly in the competences of EU member states. Commission has mostly a coordinating role.

The **European Health Union** (a broader concept) was built during pandemic years with the aim to:

- better protect the health of citizens.
- equip the EU and its Member States to better prevent and address future pandemics.
- improve the resilience of Europe's health systems.

Content (linked to Medical Devices)

Reinforcement of the mandate of the **European Medicines Agency** (EMA)

- *Monitoring and mitigating shortages of medicines and medical devices caused by major events.*

Creation of **a Health Emergency Response Authority** (HERA)

- *Secure access to medicines and medical equipment for emergencies. Launching emergency procurements and emergency deployment of medical countermeasures.*

Creation of the **European Health Data Space**

- *Interplay with medical devices regulations and (high risk) AI systems; Secondary use of electronic health data (also from / for Medical Devices).*

European Health Data Space

- Regulation is currently discussed in the Council and European Parliament.
- Is a health specific framework that aims at:
  - empowering individuals through digital access and control of their electronic personal health data > **primary use of data**
  - providing health data for research, innovation, policy-making and regulatory activities > **secondary use of data**

…which promotes the development of innovative medical devices.

EU Regulations on (in vitro) Medical Devices

Adoption in April 2017 by the Council and the European Parliament.

Fully applicable since 26 May 2021/22.

Key objective: Enhancing competitiveness while ensuring the safety and quality of medical devices, as well as patient safety.

- Still big differences between EU Member States in regard to the implementation status.
- Different additional reasons led to a high risk that a large share of devices would not have been available to EU patients.

Extension of the transition period
(to prevent shortages)

- March 2023: Concil and the Parliament agreed on a regulation to extend the transition period for medical devices.

- November 2023: (EPSCO) Council decided to extend also the transition period for in vitro medical devices.
  23 January 2024: The Commission presented the draft text.
  21 February 2024: Compromise agreement between Council & Parliament.

  The text foresees:
  - *further extending of the transition period for certain IVDs (particularly those that are high-risk).*
  - *enabling a gradual roll-out of EUDAMED, the new electronic database.*
  - *requiring manufacturers to flag up potential shortages of critical medical devices and IVDs.*

But in the view of the European Commission:

- Extensions have also negative effects, as the number of submitted applications for medical devices have significantly decreased.

- Will continue to remind all actors to «do their job» and implement the regulations without delays:
  - Industry: to submit applications.
  - Member States: to create good conditions for the implementation.

Further work

European Commission (DG SANTE) is looking at

- facilitations within the regulations
- easier access, accelerated approvals, grant of certificates under certain conditions,…

Evaluation of the Regulations in 2027.

March 2023: Start and ongoing study to collect data and establish a kind of «impact assessment». First results: End 2024.

Main EU Bodies in the field of MedTech

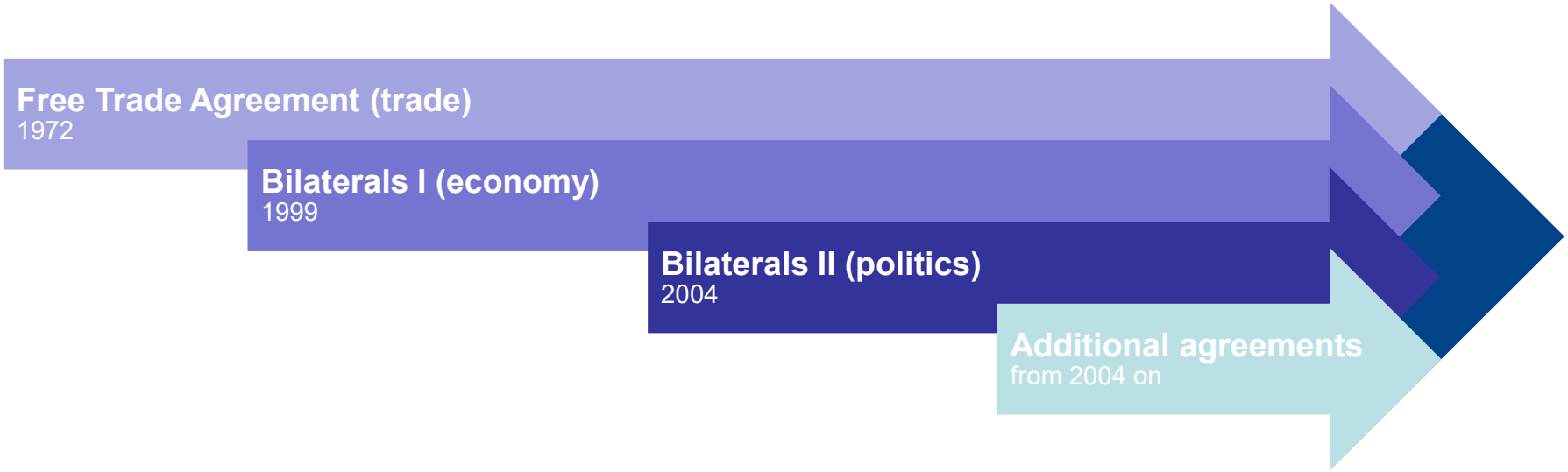
(not conclusive)

- DG SANTE: Medical Device Coordination Group (MDCG) with 10 sub-groups.
- DG SANTE + IE, DE + Industry: Task force on orphan medical devices (definition of orphan, security of the products,…).
- EMA Expert Panels – Scientific advice for orphan, break-through and novel devices.

- Frequent updates to the EU Health Minister meetings (EPSCO) and the European Parliament on the state of play of the implementation.

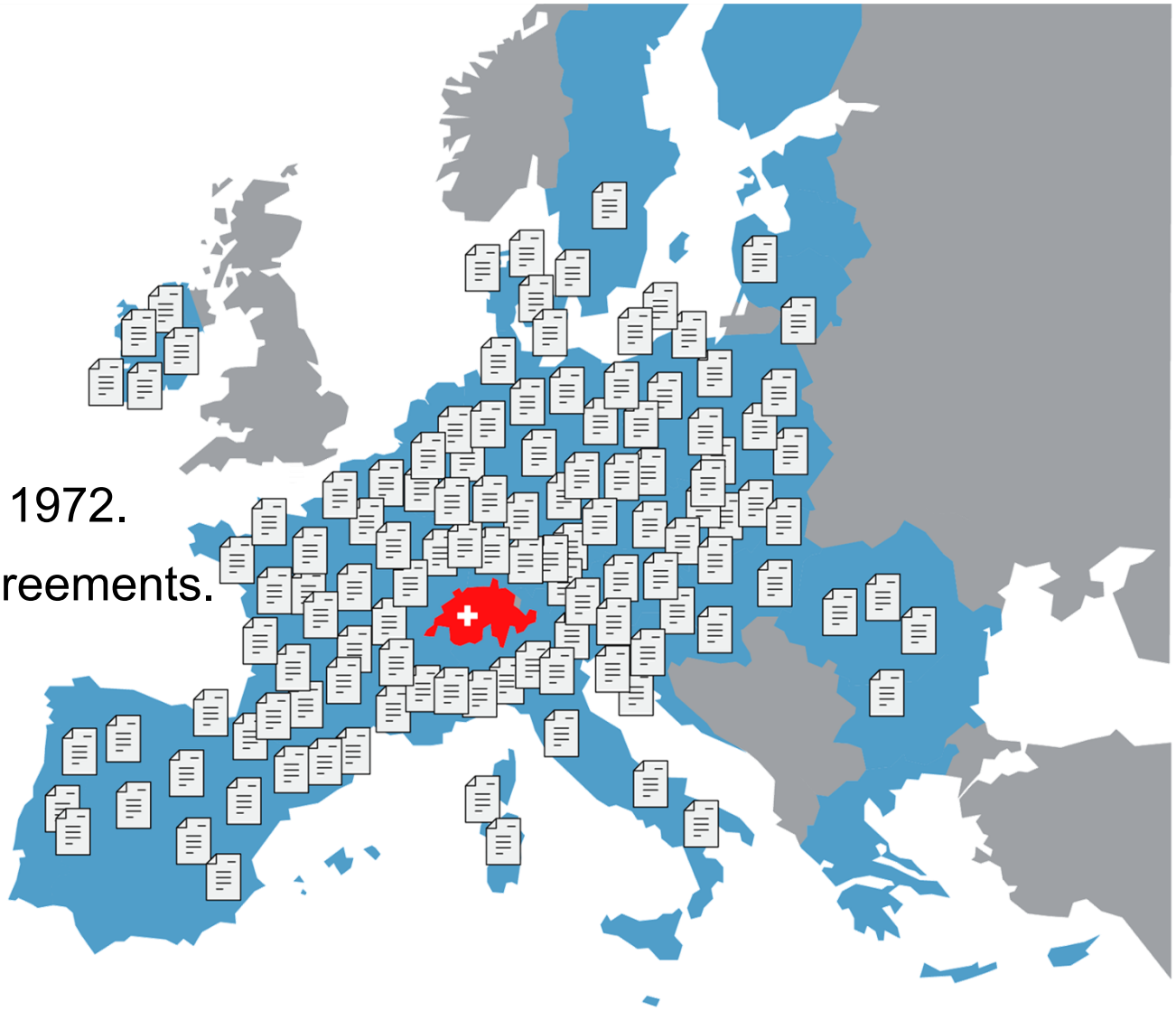
Swiss - EU Relations

Historical overview



Bilateral relations since 1972.

On the basis of >100 agreements.



Swiss-EU Relations: Medical Devices

Technical barriers to trade (MRA) Agreement: Bilaterals I
(Came into force 2002)

Ensures mutual recognition in relation to conformity assessment for the majority of industrial products (incl. Medical Devices).

- Same market access conditions for Swiss and EU manufacturers.
- Saves time and money in bringing new products to the market.

- 26 May 2021: Revised medical device regulations came into force and
- decision of the Federal Council not to sign the institutional agreement.

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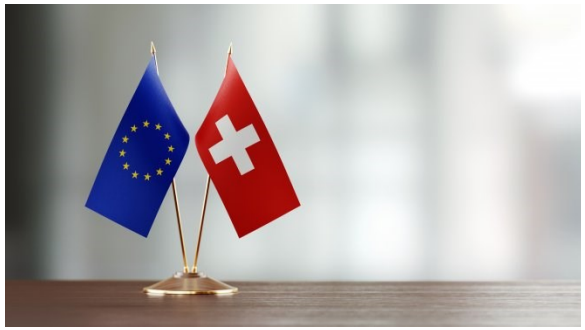
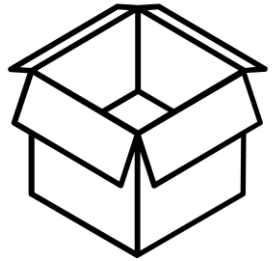
No further updates of the market access agreements (in particular MRA).

- Switzerland holds on equivalence with the EU provisions (revision of MedDO of 1 November 23).

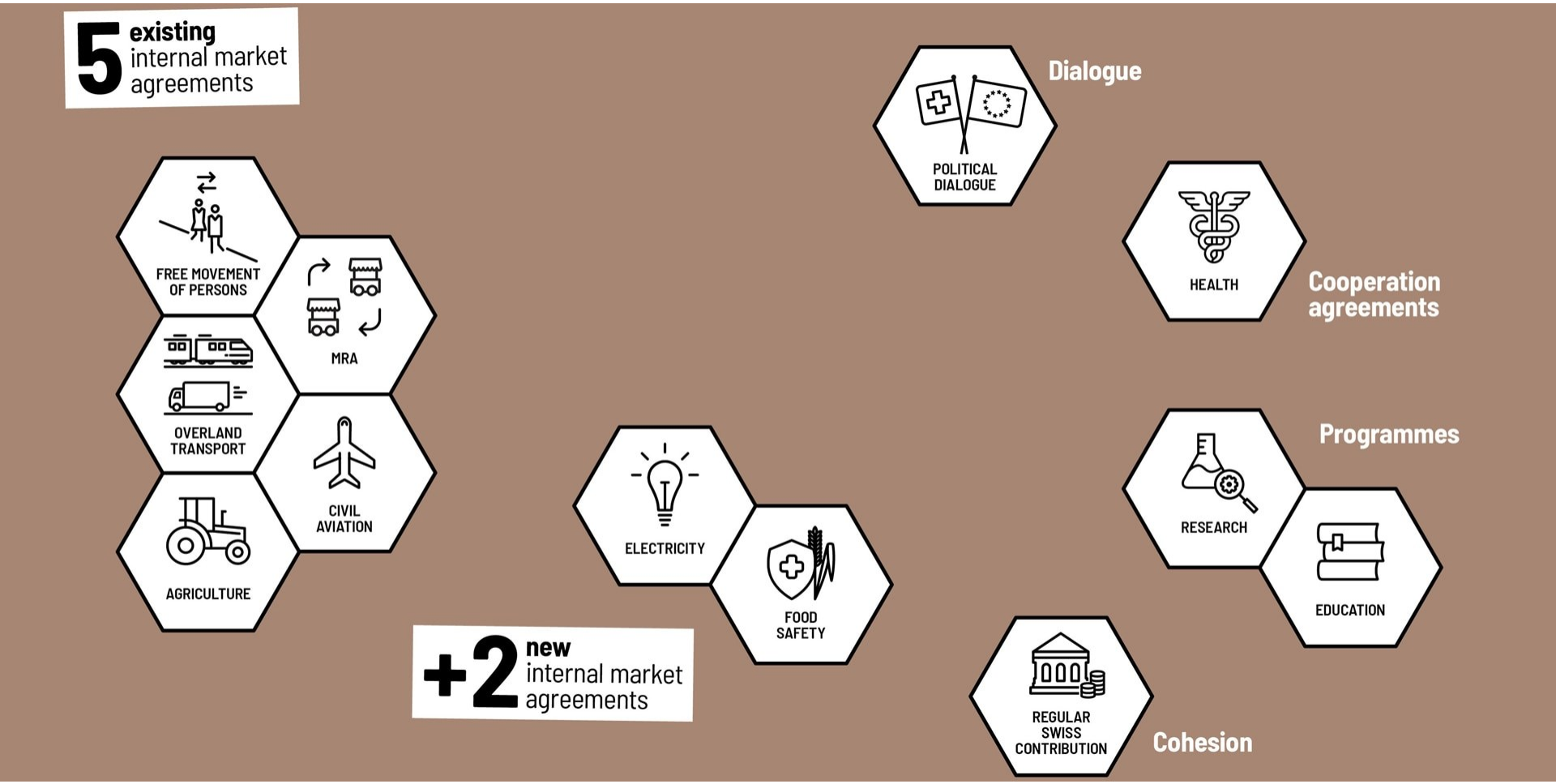


Further development of the bilateral approach – state of play

The Federal Council intends to stabilise and further develop the bilateral approach



- 25 February 2022: Federal Council set the direction for a comprehensive **negotiating package**.
- March 2022 till the end of 2023: Exploratory talks.
- 15 December 2023: Federal Council approved the draft negotiation mandate (sets out guidelines for negotiations)
- 8 March 2024: Adoption of a **negotiation mandate** (after Consultation of the parliament and the cantons. The social and economic partners were invited to comment).
  The EU mandate shall follow soon.


5 existing internal market agreements
FREE MOVEMENT OF PERSONS
MRA
OVERLAND TRANSPORT
CIVIL AVIATION
AGRICULTURE
+2 new internal market agreements
ELECTRICITY
FOOD SAFETY
Dialogue
POLITICAL DIALOGUE
HEALTH
Cooperation agreements
Programmes
RESEARCH
EDUCATION
REGULAR SWISS CONTRIBUTION
Cohesion

Thank you for your attention