SWISS MEDTECH

Reliance on US – A way out?

11 March 2024 | Swiss Medtech Webinar: The development of the regulatory landscape in Switzerland

Sandra Rickenbacher-Läuchli, Member of the Executive Board, Swiss Medtech

Supply of medical devices

Current situation in Switzerland

CE

CE XXXX

- **Dependent on imports**
  Switzerland – like many other countries – is not able to independently produce the full range of medical devices it requires.

- **CE-marking required**
  In Switzerland, only medical devices that comply with the European Regulation may be used.

The mandate by the Swiss Parliament of 28 November 2022

Content of the parliamentary mandate

The Swiss Parliament instructs the Swiss government (Federal Council) based on motion 20.3211 to adapt the national legal basis so that in future – in addition to medical devices complying with European Medical Device Regulation (MDR, CE-marking) – medical devices of non-European regulations may also be used in Switzerland to supply the Swiss population.

Motion 20.3211 by Mr. Damian Müller, Member of the Council of States

«For more room for manoeuvre in the procurement of medical devices to supply the Swiss population»

Supply of medical devices

Situation in Switzerland in the future

CE

CE xxxx

+ FDA AUTHORIZED + ...

Why are FDA approved/cleared medical devices important for Switzerland?

1

To guarantee the sufficient supply of high-quality medical devices to the Swiss population.

2

To ensure that the Swiss population has access to the latest innovative medical devices.

3

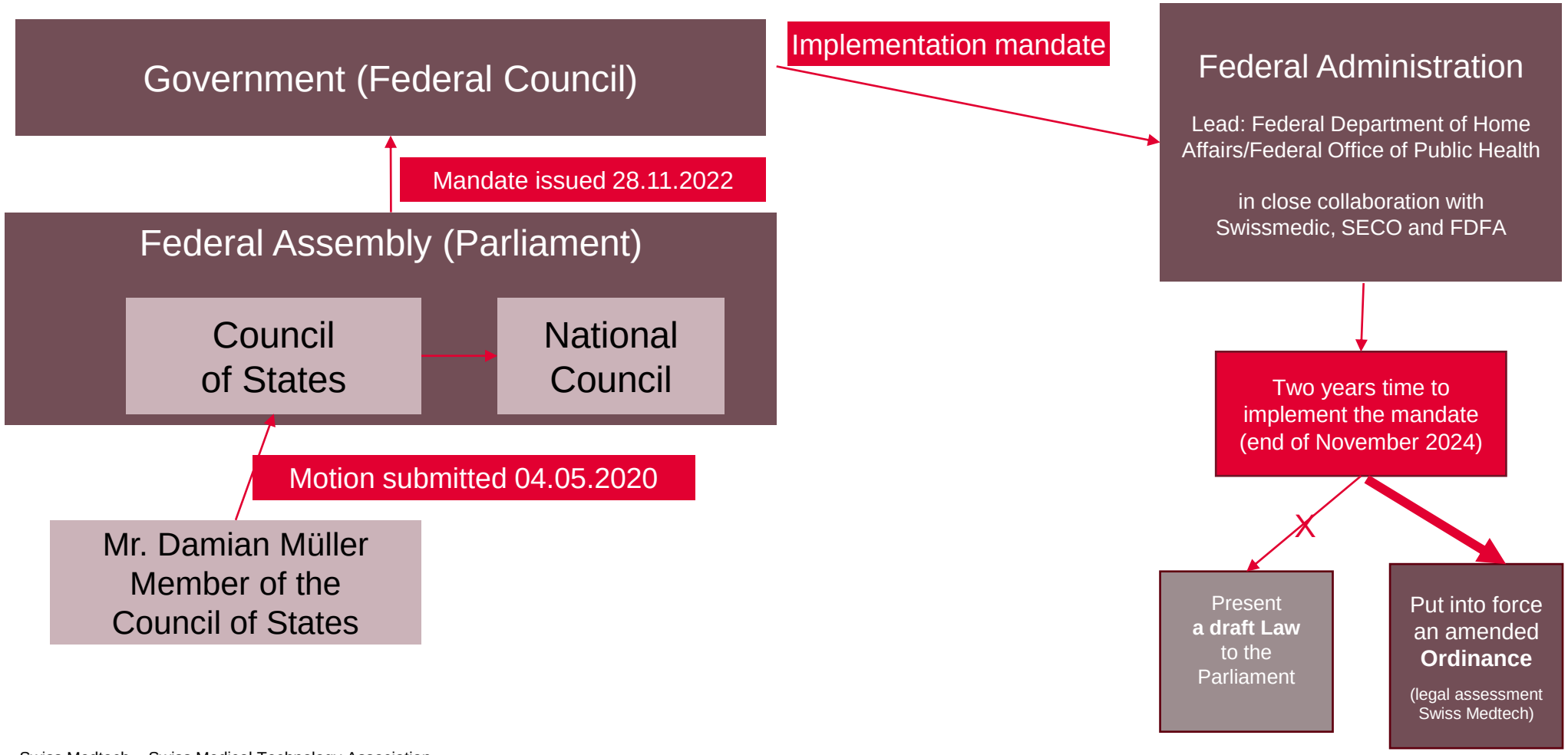
To strengthen the innovative power and competitiveness of the Swiss medical technology industry and Switzerland as such.

Essential to note

- **Parallel recognition:** The parliamentary mandate does not aim to abandon CE-marked medical devices but allows for parallel recognition of medical devices from non-European regulatory systems and, FDA approved medical devices in particular.

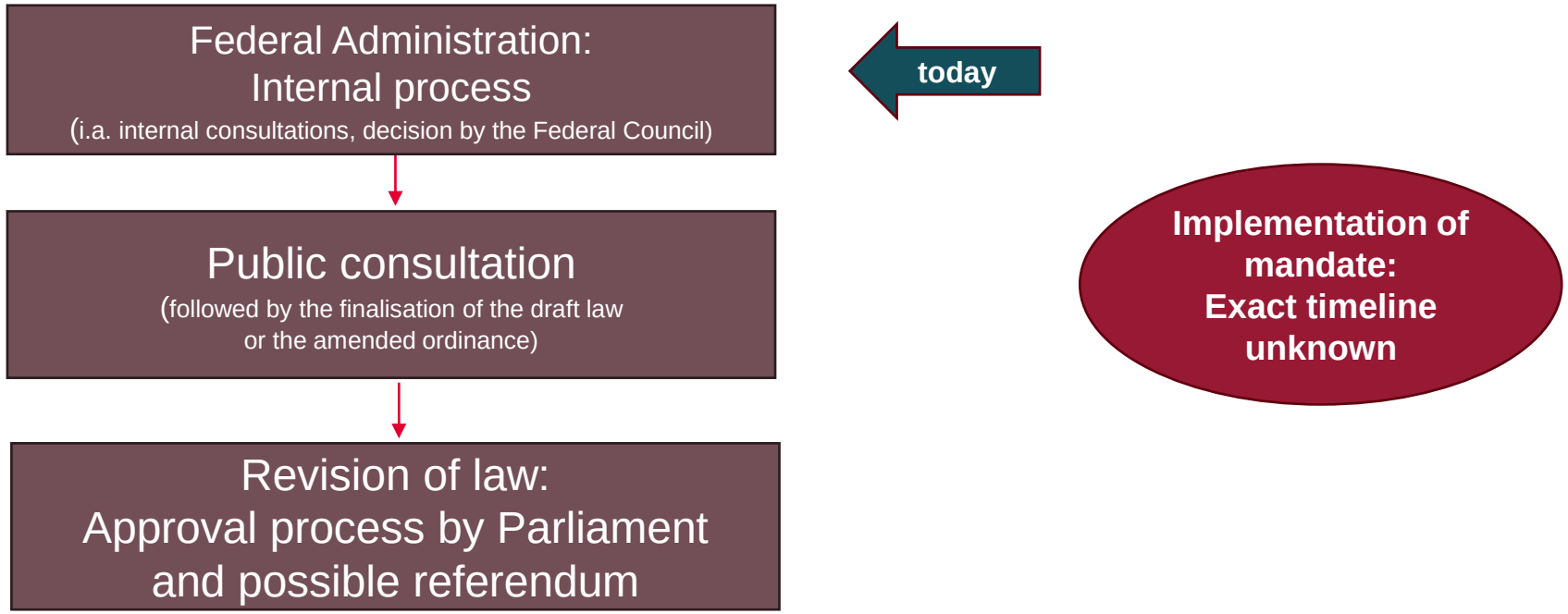
- **Not yet a reality:** FDA approved medical devices are not yet permitted in Switzerland.
- **Mandate issued – implementation to follow:** National legal basis must be adapted first. Only then, medical devices approved by the FDA may be imported into Switzerland.
- **Two years time**: The Federal Administration (lead: Federal Department of Home Affairs, Federal Office of Public Health) has two years time to implement the mandate.

The political process and the implementation mandate



Implementation of the parliamentary mandate

Status of implementation by the Federal Administration one and a half years after the adoption of motion 20.3211



Implementation of the parliamentary mandate

Policy to guide implementation (point of view Swiss Medtech)

- **Regulatory reliance:** Trust in a regulatory system with comparable standards.

What for a patient in a country with comparable standards (US) is good enough, is good enough for a patient in another country (CH).

- **No creation of hurdles** that would result in no FDA-cleared products being available on the Swiss market.
- Use of a **specific checklist** by the Swiss authorised representative as part of the onboarding of FDA-cleared products.

Implementation of the parliamentary mandate

What did Swiss Medtech do?

- **Expert Report** «Comparison of regulatory systems regarding safety of medical devices from the USA and EU» by Johner Institut

  1. Medical devices under both regulatory jurisdictions are developed, manufactured, and monitored according to comparably high standards.
  2. From today's perspective, medical devices approved for the U.S. by the FDA are, in principle, at least equally safe as CE-marked medical devices complying with EU regulations.

- **Legal Assessment** «Is a revision of the Therapeutic Products Act necessary to implement Motion 20.3211?» by Prof. Dr.iur. Tomas Poledna and Dr.iur. Remus Muresan

  Revision of the Therapeutic Products Act not necessary, revision of the Medical Device Ordinance is sufficient.

- Swiss Medtech in the process of elaborating **a draft version of the revised Medical Device Ordinance**

Implementation of the parliamentary mandate

Conclusions

- Swiss Medtech will continue to emphazise the interests of the medical technology sector towards the Swiss authorities.
- Swiss Medtech considers it important to know from the Federal Administration the timetable for the implementation of the mandate.
- The parliamentary mandate has to be implemented as soon as possible.

Do you have questions?

Sandra Rickenbacher-Läuchli
Head of Public Affairs & Legal Counsel
Member of the Executive Board
+41 31 330 97 75
+41 79 225 81 46

sandra.rickenbacher@swiss-medtech.ch

www.swiss-medtech.ch