SWISS MEDTECH

Welcome to MDR@noon

«Import of Medical Devices without MRA»

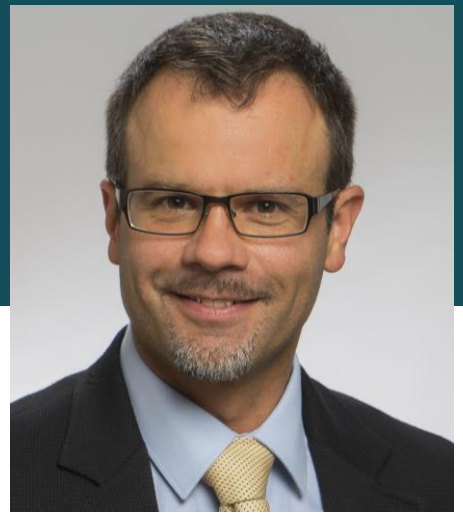
19 May 2021

SWISS MEDTECH

MDR@noon

«Import of Medical Devices without MRA»

Deepa Rajagopalan
(The Tao of Excellence)



Markus Wipf
(Axxos)

Michael Maier (Medidee)

MDR@noon Rules

Participants on mute

Camera off

Questions via chat

Session recorded

Host: Daniel Delfosse, Head of RA

Supported by Solothurn Economic Development Agency

CANTON OF solothurn
Economic development

Pdf and recording available on homepage: https://www.swiss-medtech.ch/

SWISS MEDTECH

Status Medtech Switzerland: Quo vadis?

May 2021

Daniel Delfosse, Dr.sc.techn., Head of RA, Swiss Medtech

daniel.delfosse@swiss-medtech.ch

The Federal Council › EAER › SECO

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

State Secretariat for Economic Affairs
SECO

Bundesrat will die Versorgung mit sicheren Medizinprodukten gewährleisten

Breaking News

Bern, 19.05.2021 - Dank des Abkommens mit der Europäischen Union (EU) über die gegenseitige Anerkennung von Konformitätsbewertungen (MRA) nimmt die Schweiz am Binnenmarktes der EU für Medizinprodukte teil. Eine Aktualisierung dieses Abkommens ist aufgrund einer Totalrevision der Gesetzgebung in der Schweiz sowie in der EU per 26. Mai 2021 nötig. Diese Aktualisierung wird von der EU an Fortschritte beim institutionellen Abkommen geknüpft und konnte bisher nicht abgeschlossen werden. Ohne die Aktualisierung entstehen erhebliche Hemmnisse in den Lieferketten von Medizinprodukten zwischen der Schweiz und der EU, die Zusammenarbeit in der Marktüberwachung ist eingeschränkt und die Sicherstellung der Patientensicherheit geschwächt. Der Bundesrat hat deshalb an seiner Sitzung vom 19. Mai 2021 Massnahmen beschlossen, um sowohl die Versorgung der Schweiz mit sicheren Medizinprodukten als auch die Marktüberwachung künftig zu gewährleisten.

https://www.seco.admin.ch/seco/de/home/seco/nsb-news.msg-id-83581.html

Situation MRA - Swiss Medtech Industry

1. No update of the MRA without InstA
2. Without update of the MRA, Switzerland will become a third country for the EU from 26 May 2021.
3. As a third country, the privileged exchange of medical devices CH-EU will be lost.

Glossary
InstA: Institutional Agreement EU-CH
MRA: Mutual Recognition Agreement EU-CH
MDR: Medical Device Regulation
MedDO: Swiss Medical Device Ordonnance
AR: Authorised Representative
SMT: Swiss Medtech

Glossary
MDR products: MD with MDR certificate and all remaining class I devices
MDD products: MD with a MDD certificate (legacy devices) and upclassified devices (class I to Ix or Iia)
TP: Transition period

Effect of Third Country Status (no MRA)

Swiss Manufacturers

- **Export** of MD to EU only with EAR (EU Authorised Representative)
- Set-up costs CHF 110 Mio., recurring costs CHF 75 Mio./year
- **Loss of attractiveness** of Switzerland as location for the medtech industry (Start-ups, SME, Multi.nationals)
- Recommendation for action «As well as» by Swiss Medtech, April 2019

Swiss Importers & Distributors

- **Import** of MD into CH only with Swiss AR (Swiss Authorised Representative)
- Set-up costs CHF >50 Mio., recurring costs CHF >30 Mio./year
- **Supply gap for Swiss patients**, as many foreign manufacturers not willing to install Swiss AR
- Recommendation for action «Plan now» by Swiss Medtech, Dec. 2020

SWISS MEDTECH

Status MRA & MedDO

MRA:

- Offer for amendment by EU commission
- Negotiations ongoing
- To be finalised after 26 May 2021

MedDO (amendment):

- Text sent to Federal Council
- Planned adoption of MedDO on 19.05.2021
- Publication to follow shortly

From : DG SANTE B6 Medical Devices & DG TRADE **31 March 2021**

The Commission services would like to inform that, to mitigate the risk of possible disruptions of supply of medical devices on the EU market, and to provide legal certainty to companies, the European Union will propose to Switzerland a limited modification to the current Mutual Recognition Agreement. An amendment is currently under preparation, aimed at granting certificates already issued in Switzerland for existing medical devices under the Swiss legislation equivalent to existing EU Directives the same transitional validity as the new EU Medical Devices Regulation grants to certificates issued in the EU.

Modifications in MedDO

Transition period for establishement of Swiss AR (including product labeling):

- **Until 31.12.2021:** For MD class III, implantable MD class IIb and active implantable devices
- **Until 31.03.2022:** For MD class IIa
- **Until 31.07.2022:** For MD class I

Why are ARs needed?

MRA (Mutual Recognition Agreement)

- MRA (last update on Dec. 2017) does not cover MDR and IVDR

→ For medical products under MDR/IVDR, Switzerland becomes third country to EU

- Access to EU-database and mutual assistance of authorities suspended

→ Need for authorised representative in EU

Swiss Authorities: Weighing up of interests must be ensured

- Product safety
- Enforceability
- Equivalence to EU
- Security of supply

→ Need for authorised representative in CH

Problem: Import of MD to CH

Market attractivity (market size, price level)

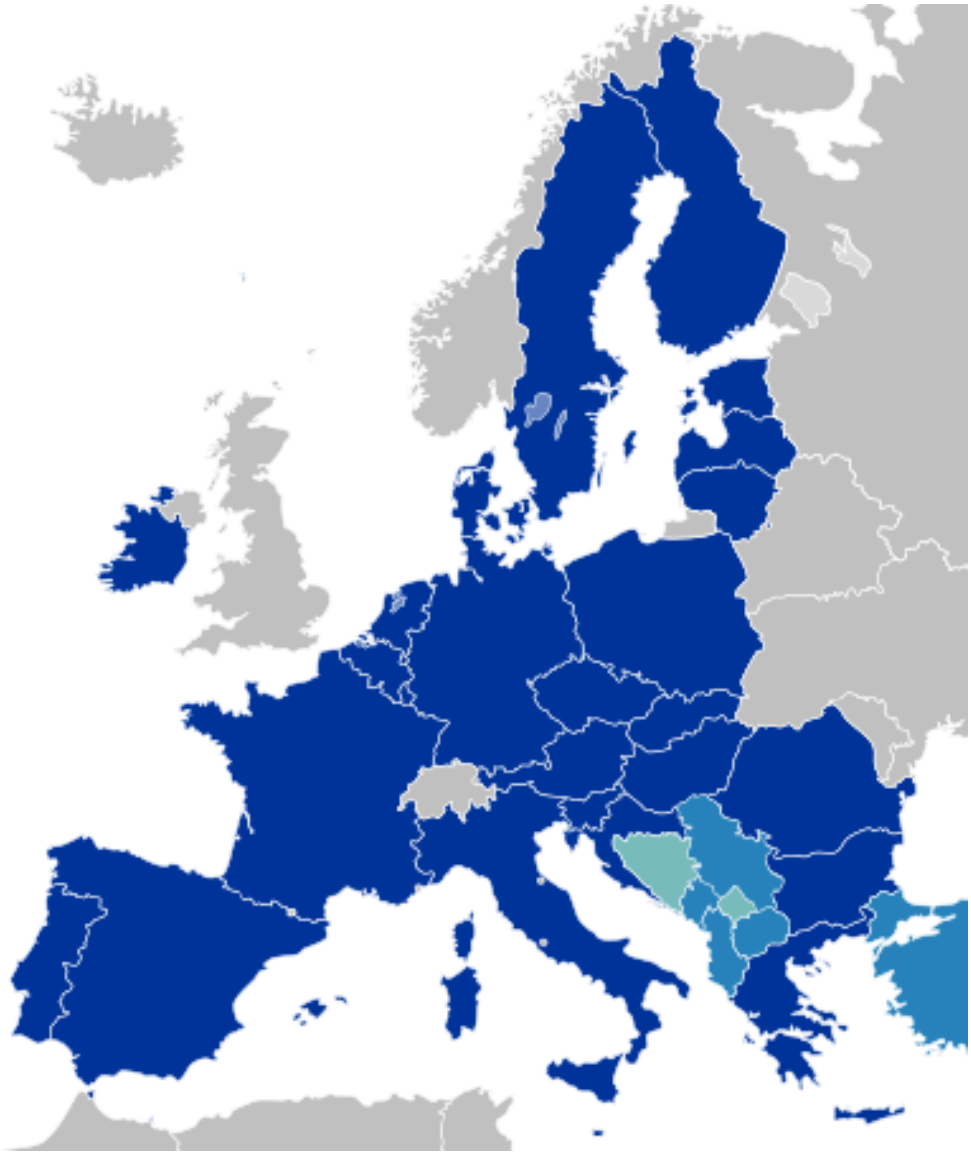
- EU: 446 Mio. inhabitants (without UK & CH)
- UK: 66 Mio. inhabitants (15% of EU)
- CH: 8 Mio. inhabitants (2% of EU)

Business decision of foreign manufacturer to place product on markets or not.

Goal A: Regulatory environment remains attractive for Swiss medtech companies

Goal B: The supply of Swiss patients with medical devices remains at the current level

→ Regulatory environment remains attractive for foreign medtech companies (from EU and RoW)



How many Swiss AR are needed?

Approx. 5'000 foreign manufacturers (300’000 medical devices)

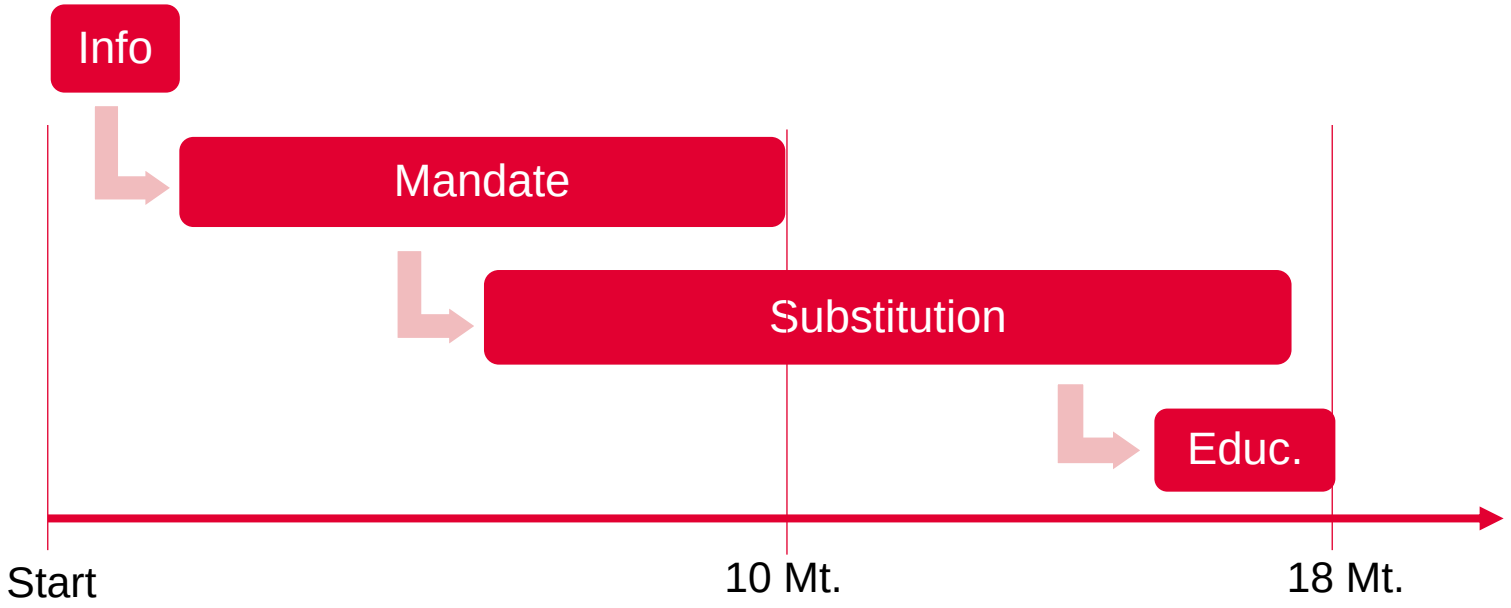
→ In best case: 5’000 Swiss AR
→ Divided among 100 importers/distributors and 20 consultant companies:
>40 mandates per company

Hurdles:
Contract negotiation for written mandate, joint liability, access to TD, responsibilities
→ Needs sufficient number of Swiss AR and sufficiently long transition period

Time needed to establish a Swiss AR

Time needed for establishment:

• Information to foreign legal manufacturer	2 (1-6) months
• Setting-up Swiss AR (mandate, liability coverage, logistics)	8 (2-12) months
• Search for substitue products (if available)	12 (6-24) months
• Re-education of user	3 (1-12) months
• *TOTAL (average)*	*25 months*



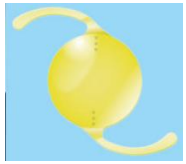
SWISS MEDTECH

Which MD will be missing?

- Up to 25% of all importied MD (12% of all MD in use today)
- Which ones? Cannot be predicted today!

Depends on:
- Regulatory requirements (TP for Swiss AR)
- Willingness of Swiss companies (Swiss AR)
- Willingness of foreign companies (business case)
- Willingness to pay higher remuneration (Swiss patients)

→ **Will become clearer in Q4/2021**
(List of missing products to be established by SMT)



Support by Swiss Medtech

1. Information for Swiss manufacturers
   - Guidance for CH manufacturers re. EAR
   - Webinars and Q&A sessions

2. Information for Swiss importers & distributors
   - Guidance for CH distributors and importers re. Swiss rep.
   - 1-pager as information for foreign suppliers
   - Model contract for the appointment of a CH authorised representative
   - Webinars and Q&A sessions

https://www.swiss-medtech.ch/news/mdr-portal

Balancing of Goods: at what Cost?

Equivalency to EU Law

Safety of Medical Device

Third country status

Enforceability

Security of Supply

+ 8% cost of MD due to MDR

[Source: SMTI, Sept. 2020]

+ 2% cost for exported MD (EAR)

+ 2-10% cost for imported MD (Swiss AR)

[Source: SMT surveys from March 2020 and Nov. 2020]

+ x% cost for substitution MD (Swiss AR)

Cost of medical devices: 12B CHF (14% of total health cost of 85B CHF)
Cost increase of medical devices by 10% → Increase in total costs by 1.4%

Scenarios

1. Worst case (situation today)
   - No update of MRA, MedDO enters in force on 26 May 2021

   → Swiss AR & importer in CH necessary for all imported MDD & MDR products after TP of MedDO (Jan-Aug 2022)

2. Medium case (not before June 2021)
   - Small update of MRA with defined TP (3 years ?), MedDO amended again

   → Swiss AR & importer in CH necessary for imported MDR products after TP of MedDO (Jan-Aug 2022), for imported MDD products after TP of MRA (probably May 2024)

3. Best case (after signing of InstA or similar agreement)
   - Full update of MRA (incl. MDR & IVDR), MedDO amended again

   → Swiss AR necessary, but can be done by EU company (legal manufacturer or EAR)