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Third Country Status: The Swiss Medtech Industry without Mutual Recognition Agreement (MRA)

Webinar MDR Readiness Q&A, 17./21.12.2020

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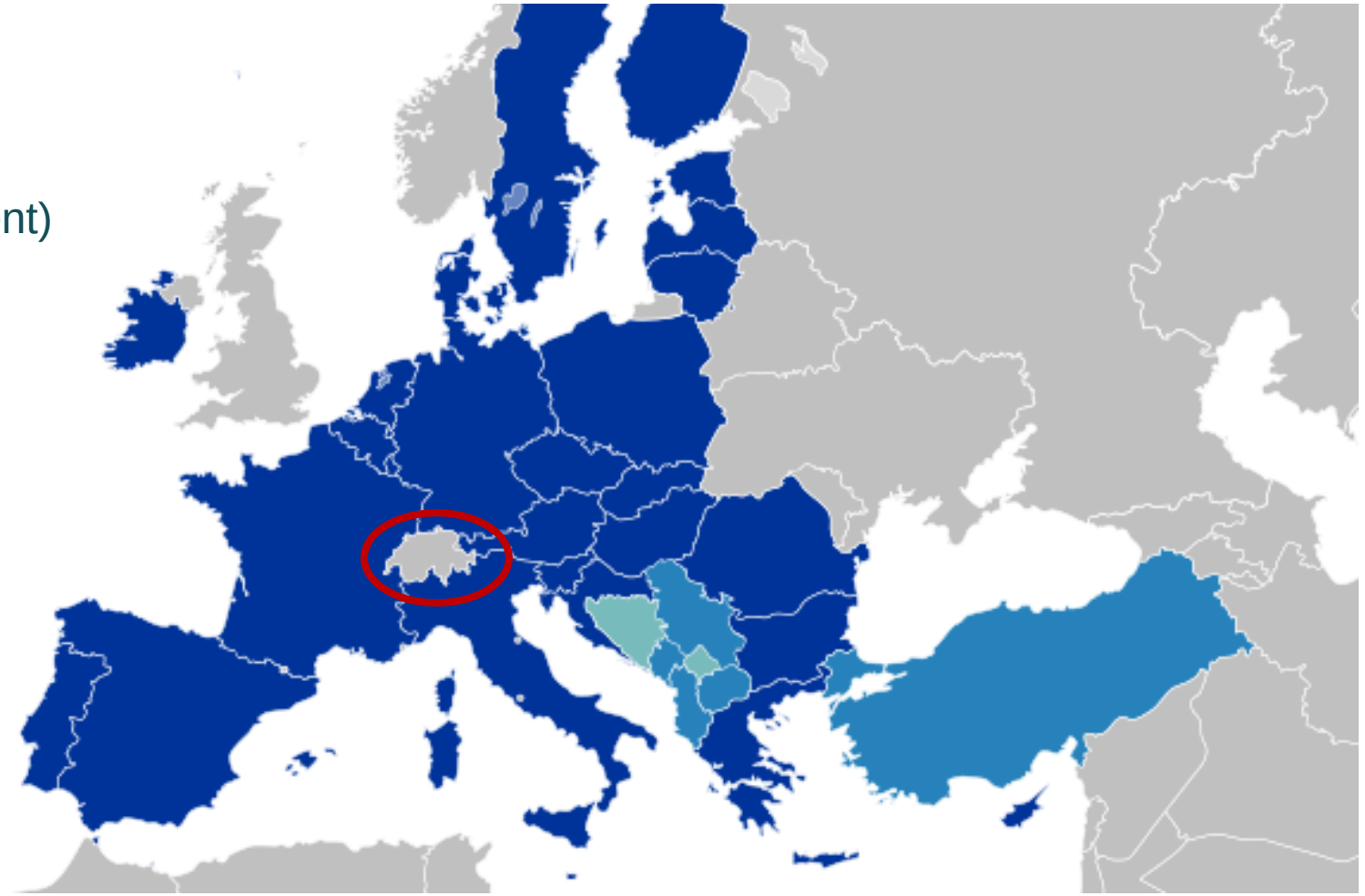
1. Regulation in Switzerland
   is NOT independent from EU
   (MDR, IVDR)

2. Rules of collaboration
   with EU covered in MRA
   (Mutual Recognition Agreement)

Agreement
between the European Community and the Swiss Confederation
on mutual recognition in relation to conformity assessment

(Text as of 22 December 2017)



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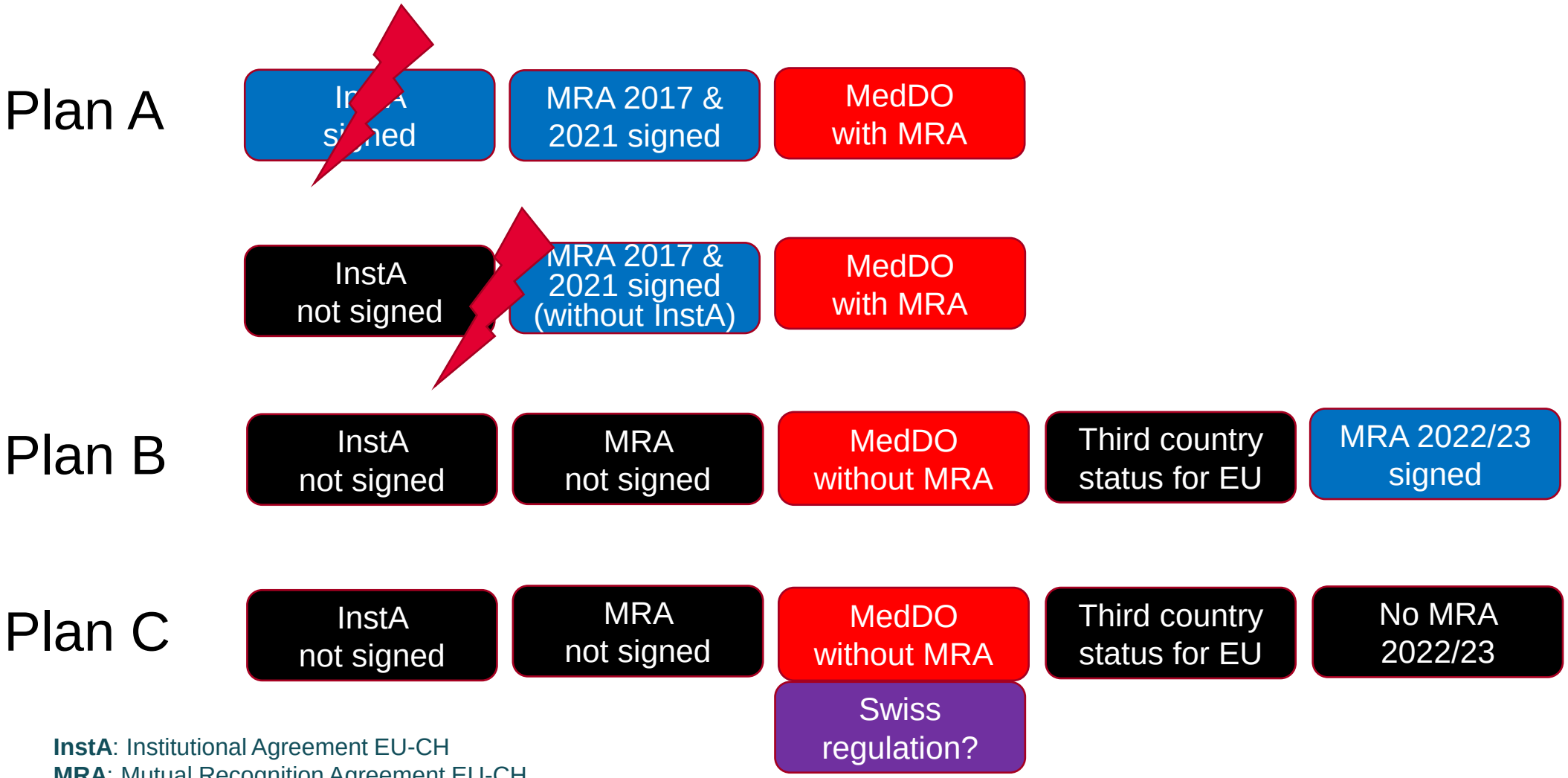
Scenarios EU-CH for Medtech Industry



InstA: Institutional Agreement EU-CH
MRA: Mutual Recognition Agreement EU-CH
MedDO: Swiss Medical Device Ordonnance

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Effect of Third Country Status

Swiss manufacturer

- **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 a location for the medtech industry
- Recommendation for action «As well as» by Swiss Medtech, April 2019

Swiss distributor & importer

- **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, 16.12.2020

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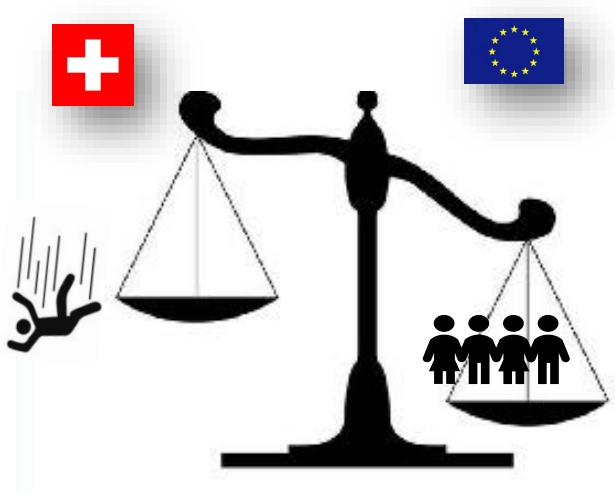
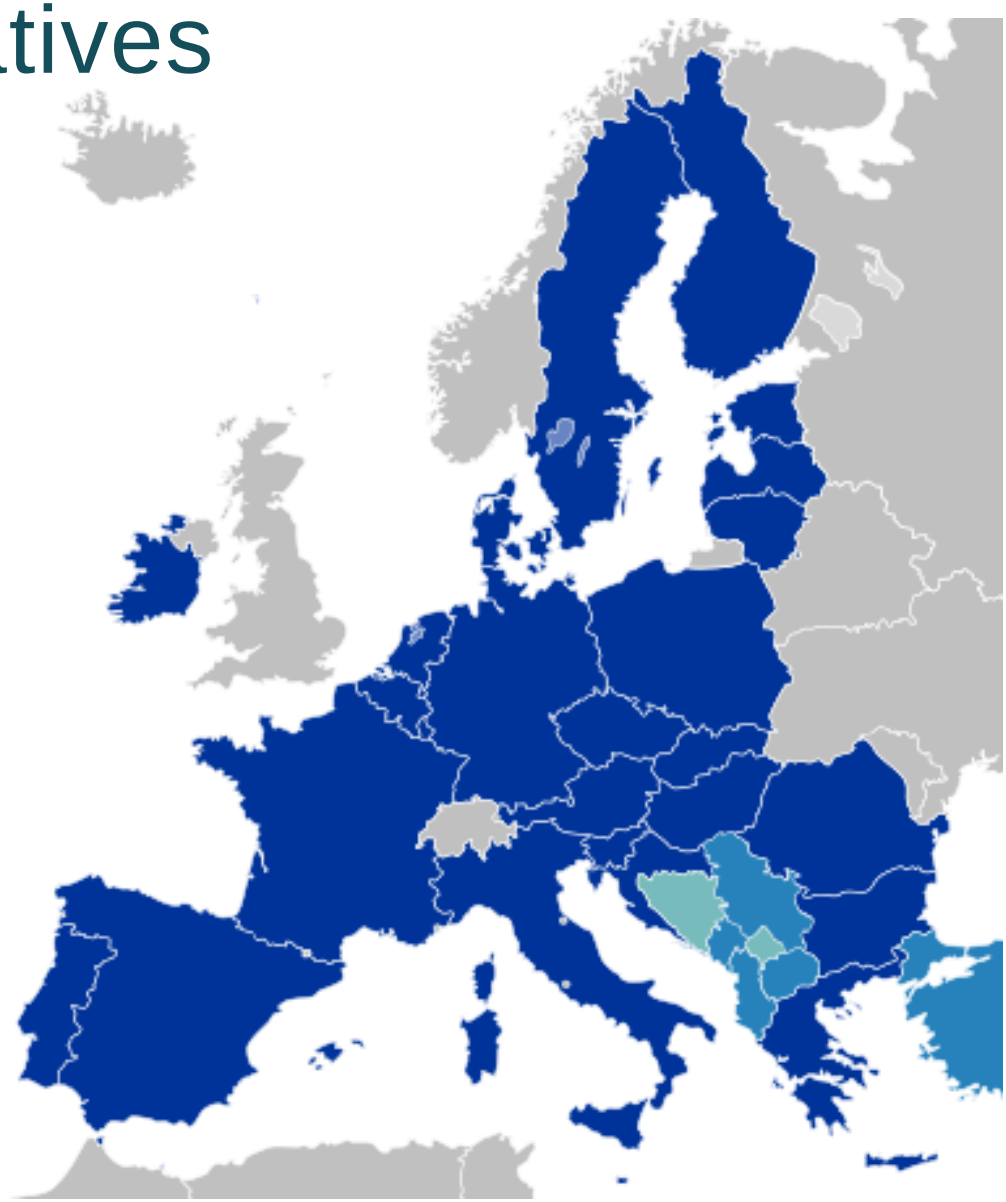
Import of MD using Representatives

- EU: EAR for 446 Mio. inhabitants (without UK & CH)
- UK: UKRP for 66 Mio. inhabitants (15% of EU)
- CH: Swiss AR for 8 Mio. inhabitants (2% of EU)

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





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The Representative in EU, UK, CH



	EAR	UKRP	Swiss AR
Company	Yes, in EU	Address in UK	Yes, in CH
Person	Yes, PRRC in EU	Yes, UKRP in UK	Yes, in CH
Registrierung der MP	Yes (EUDAMED)	Yes (MHRA)	Yes, to be defined
Labelling of representative	Yes, label	No (CE), Yes (UKCA)	Yes, to be defined
Reporting of vigilance cases	Yes	Yes (MHRA)	Yes (Swissmedic)
Communication with authorities	Yes	Yes	Yes
Access to TD of manufacturer	Yes	Yes	Yes, to be defined
Liability	Yes	To be defined	Yes, to be defined
Transition period	None (4 years lead time)	4,8,12 months (CE), 2.5 years (UKCA)	Yes, to be defined (MedDO today: none)

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Requirements for Swiss AR

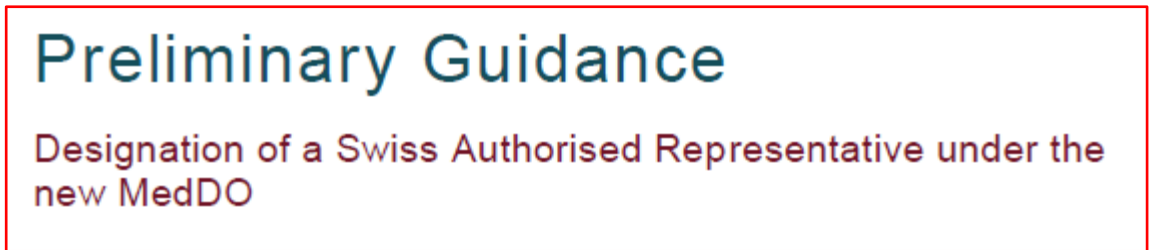
Based on MedDO, Version 01.07.2020, Art. 51.3:
Seine Rechte und Pflichten sowie der Umfang des Mandats richten sich nach Artikel 11 EU-MDR.

The tasks of a Swiss AR are analogous to those of an EU AR and include:

- Verification of compliance with registration requirements
- Guarantee access to a copy of the technical documentation
- Support of the authorities during audits and product tests
- Reporting of incidents and complaints (Vigilance Report)

Overview of MedDO articles addressing Swiss AR and references to the MDR

MedDO	Reference to MDR
– Art. 51 Duties (of the authorised representative)	– Art. 11 Authorised representative – Art. 12 Change of authorised representative
– Art. 52 Person responsible for regulatory compliance, referencing MedDO Article 49, Paragraphs 2 - 4	– Art. 15 Person responsible for regulatory compliance
– Art. 55 Registration of manufacturers, authorised representatives and importers	– Art. 30 Electronic system for registration of economic operators, Paragraph 3 – Art. 31 Registration of manufacturers, authorised representatives and importers
– Art. 16 Product information	– Annex I, chapter III



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SMT’s Demands on Adaptation of MedDO

1. No introduction of the revised MedDO without MRA
2. Tasks of Swiss AR can remain at EU company (legal manufacturer or EAR).

3. Sufficient **transition period**
4. Exemption for MD of **risk class I**
5. Requirments for **labelling**
6. Access on **technical documentation**

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Survey among Swiss Distributors (Nov. 2020)

Questionnaire and discussion with 20 representatively selected distributors: 27.7. – 20.11.2020

Feedback until 20.11.2020: 20 distributors (100% return)

• Initial set-up cost (in CHF)	50 Mio.
• Recurring cost (in CHF/y)	30 Mio.
• Possible supply gap for Swiss patients	up to 25% of all imported MD (1.5 Bio. CHF = 12% of all MD in CH)

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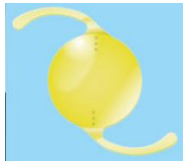
Which MD will be Missing?






- Cannot be predicted today!

- Depends on regulatory hurdle (Swiss AR)
- Depends on the willingness of Swiss companies
- Depends on business case of foreign companies
- Depends on negotiating skills
- Depends on willingness to pay higher remuneration

→ **Will become clearer within 4-6 months after initiation**
(after call of action re. Swiss AR)

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Can Swiss Manufacturers Produce the Missing MD ?

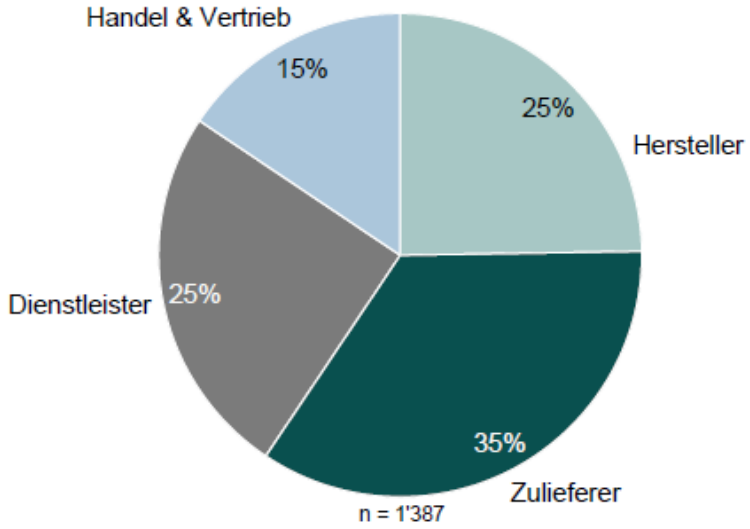
Missing imported MD:

- Worst case: 25% of 300’000 = 75’000 MD
- Best case: 12% of 300’000 = 36’000 MD

Swiss manufacturers: 350

→ Best case: Each manufacturer takes over 100 MP (development, production, clinical data, CE-approval)

→ **Impossible!** (Only possible for a few individual products)



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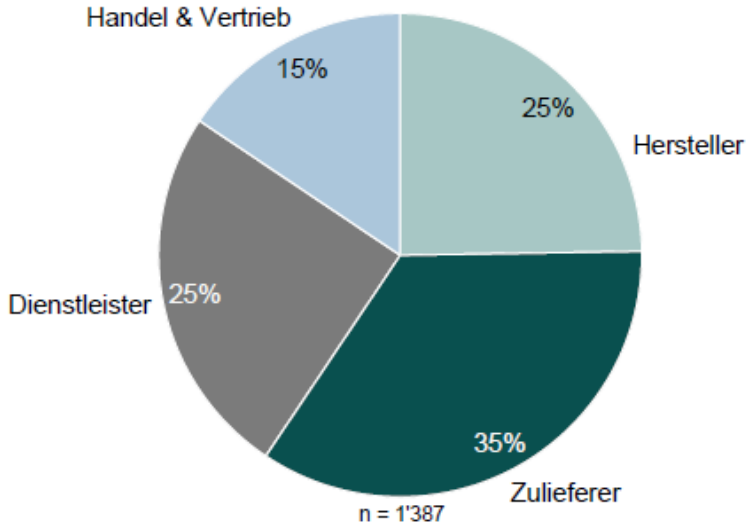
Can Swiss Distributors/Importers Procure the Missing MP elsewhere ?

Missing imported MD:

- Worst case: 25% of 300’000 = 75’000 MD
- Best case: 12% of 300’000 = 36’000 MD

Swiss distributors: 210

→ Best case: Each CH-distributor takes over 150 MP
(Search, contract, labelling, distribution, re-education)



→ **Difficult**. (Partially feasible if transition period is long enough, min. 18 months)

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How many Swiss AR are Needed?

Approx. 5’000 foreign manufacturers

→ In best case: 5’000 Swiss AR

→ Spread over 210 distributors: 24 mandates per distributor
→ Spread over 100 distributors and 100 consultants: 25 mandates per company

→ **Large effort for CH companies** (needs sufficiently long transition period)

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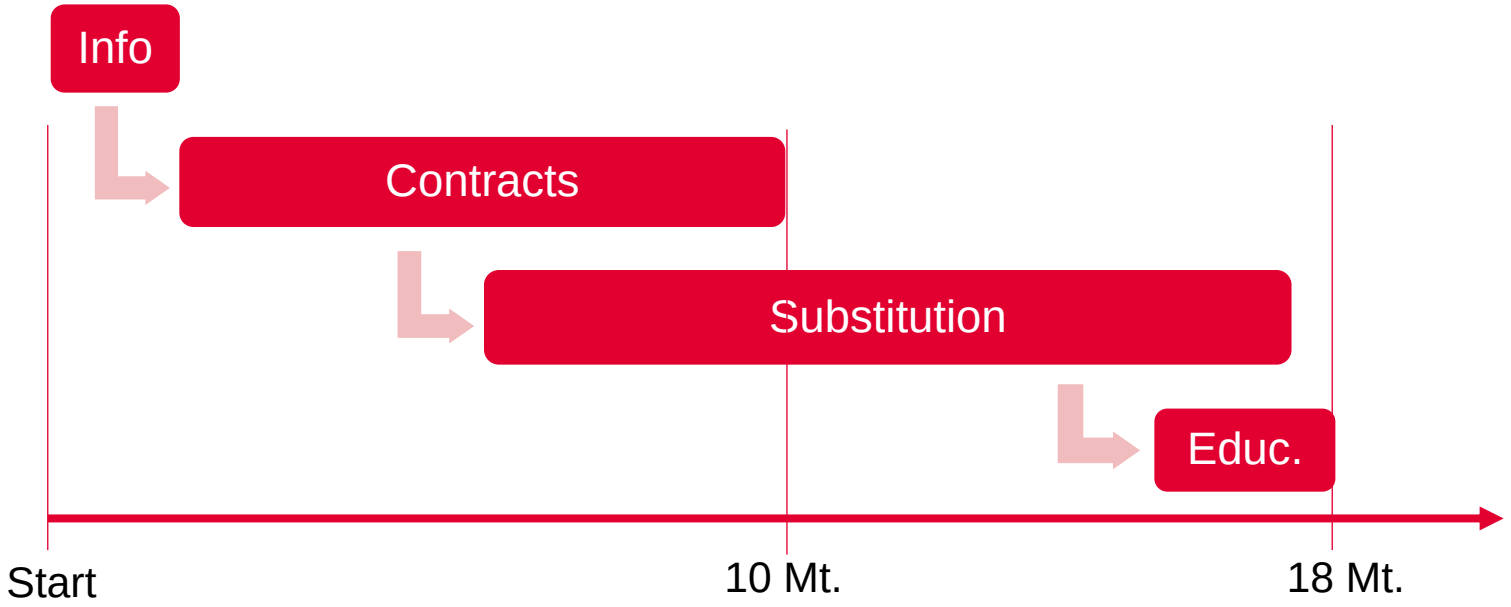
Establishment of the Swiss AR

Time required for establishment:

• Info to foreign manufacturers	2 (1-6) months
• Establishment of Swiss AR (contracts, logistics)	8 (2-12) months
• Search for substitute products (if possible)	12 (6-24) months
• Re-education of customers	3 (1-12) months
• *TOTAL (Average)*	*25 months*



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Conclusion for SMT and Authorities

- SMT: Introduce MedDO in such a way that there is only a **small impact on Swiss distributors and importers** and also only a **small supply gap for Swiss patients**.

- Authorities: **Weighing up of interests** must be ensured
    - Product safety
    - Enforceability
    - Equivalence to EU
    - Security of supply

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Recommendation for Action

1. Dilemma: The Swiss medtech sector must be informed in detail about the contingency planning so that it can start the clarifications!
   - Confidential consultation with the authorities:
     → Agreement with FOPH on communication re. “Eventual-MepV“
   - Public access to final text of revised MedDO:
     → ca. April 2021

2. **Recommendation for action** for Swiss distributors and importers

   Start planning now, but do not execute before final text of MedDO available

   - Rationale: no wasted effort, but organisational preparation, rapid identification of the missing medical products, start of the search for substitutes
   - Precondition: needs sufficient transition period after May 2021

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