swissmedic

Online event

Information on the new medical devices regulation

Thursday, 2 September 2021

Authorised representatives, importers and distributors

Obligations of economic operators in Switzerland

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Agenda

- Overview of the roles of economic operators
- Obligations of economic operators
  - Authorised representative: CH-REP
  - Importer
  - Distributor
- General requirement for all economic operators
  - Disclosure requirements
  - Traceability of devices
- Take-home message

Disclaimer

- *The applicable medical device provisions of the Therapeutic Products Act (TPA; SR 812.21) and the Medical Devices Ordinance (MedDO; SR 812.213) have been generalised for this presentation.*
- *The current legal provisions apply in all cases.*
- *Specific cases are not covered by this presentation.*

Making available - Placing on the market - Putting into service

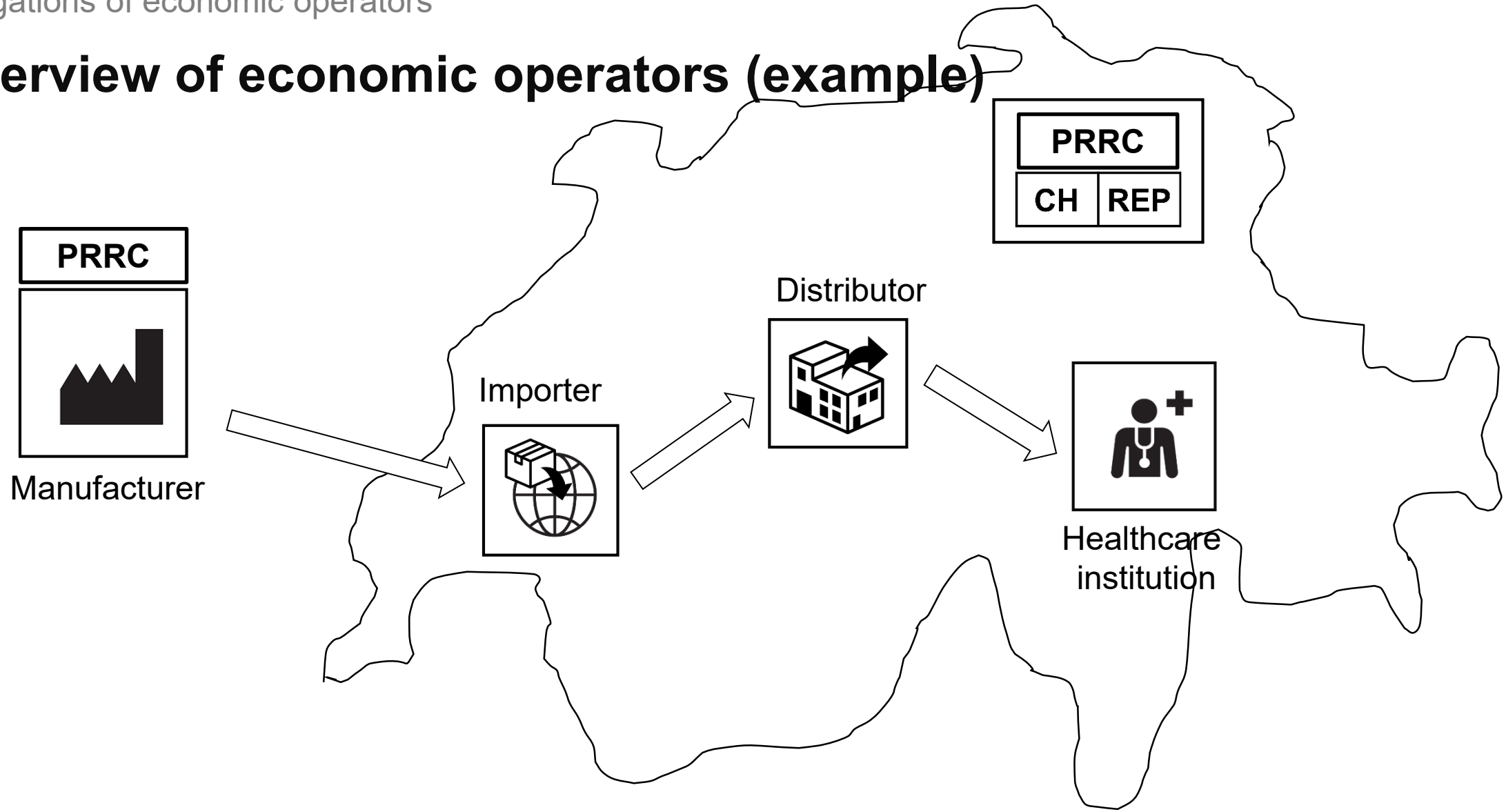
- Making available on the market

  eans any supply of a device, other than an investigational device, for distribution, consumption or use on the Swiss market in the course of a commercial activity, whether in return for payment or free of charge (Art. 4 para. 1 let. a MedDO)
- Placing on the market

  the first making available of a device on the Swiss market (Art. 4 para. 1 let. b MedDO)
  - the concept of placing on the market refers to each individual device, not to a type of device. Each individual device is placed on the market, even if devices of the same model or type are already on the market
- Putting into service

  the stage at which a device has been made available to the final user as being ready for use for the first time for its intended purpose (Art. 4 para. 1 let. c MedDO)

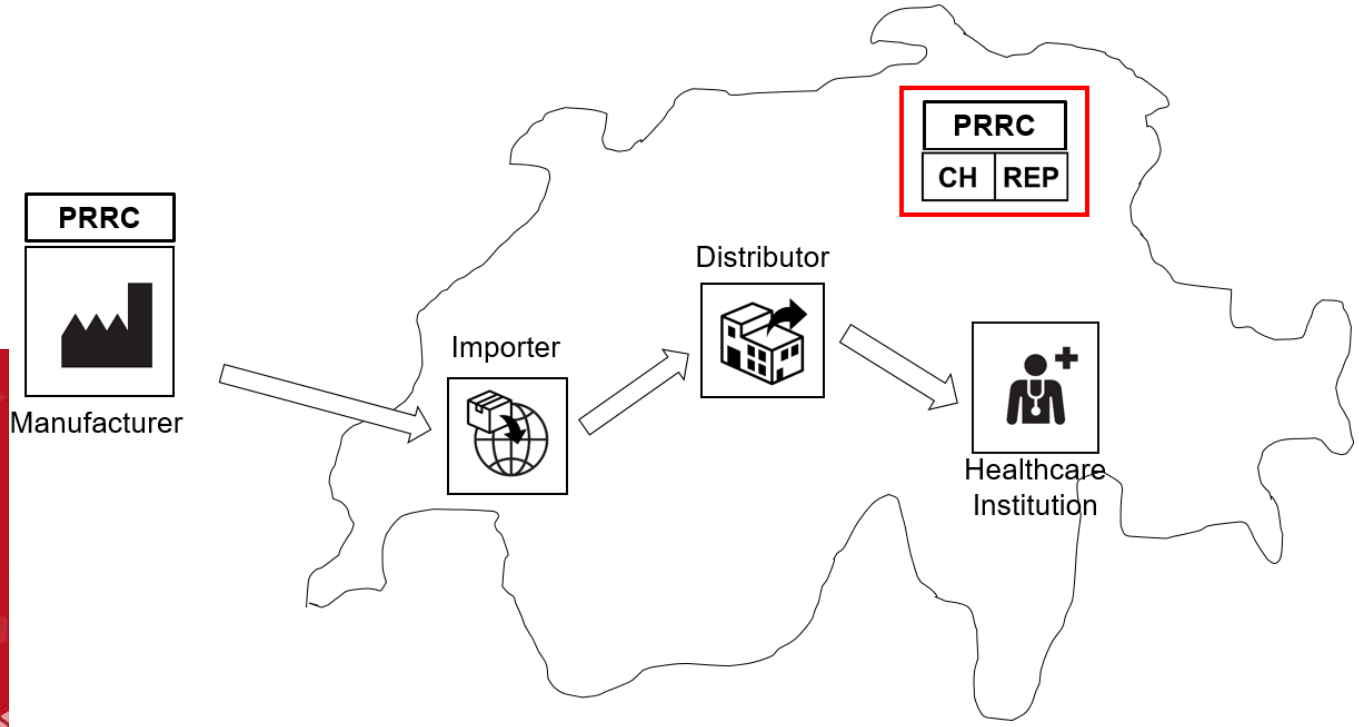
Overview of economic operators (example)



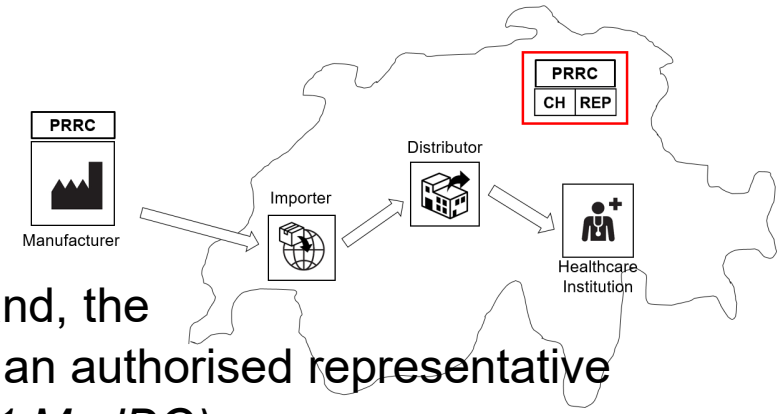
Authorised representative: CH-REP

- Any natural or legal person domiciled in Switzerland who has received and accepted **a written mandate** from a manufacturer located in another country to act on the manufacturer's behalf in relation to **specified tasks** with regard to the latter's obligation under this Ordinance

- *Definition: Art. 4 para. 1 let. g MedDO*
- *Obligations: Art. 51 and Art. 52 MedDO*



Authorised representative: Obligations 1

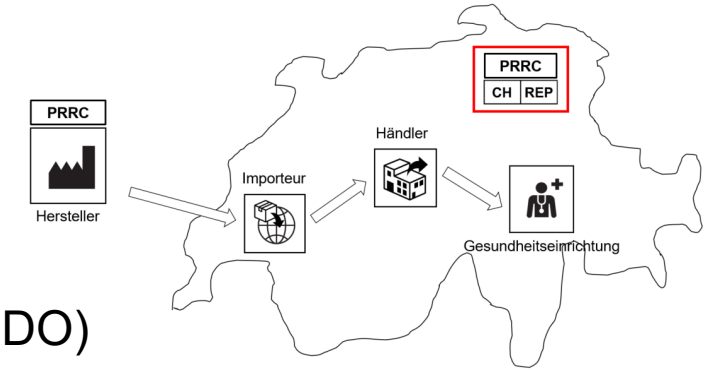


- Where the manufacturer of a medical device is not domiciled in Switzerland, the device may only be placed on the market if the manufacturer designates an authorised representative domiciled in Switzerland by means of a **written mandate**. *(Art. 51 para. 1 MedDO)*.

- The authorised representative is responsible for
  - the formal and safety-related aspects of placing the device on the market. (*Art. 51 para. 2 MedDO)*
  - keeping available the technical documentation or concluding a contract stipulating that the manufacturer shall, on request, submit the documentation directly to Swissmedic within 7 days. Art. 51 para. 3bis MedDO

- Further rights and obligations, as well as the scope, are based on Articles 11 and 12 MDR

Authorised representative: Obligations 2



- Authorised representatives must be registered with Swissmedic (Art. 55 MedDO)

- Authorised representatives must ensure that they have permanently and continuously at their disposal at least one PRRC (Art. 52 para. 1 MedDO)

  PRRC: Person Responsible for Regulatory Compliance

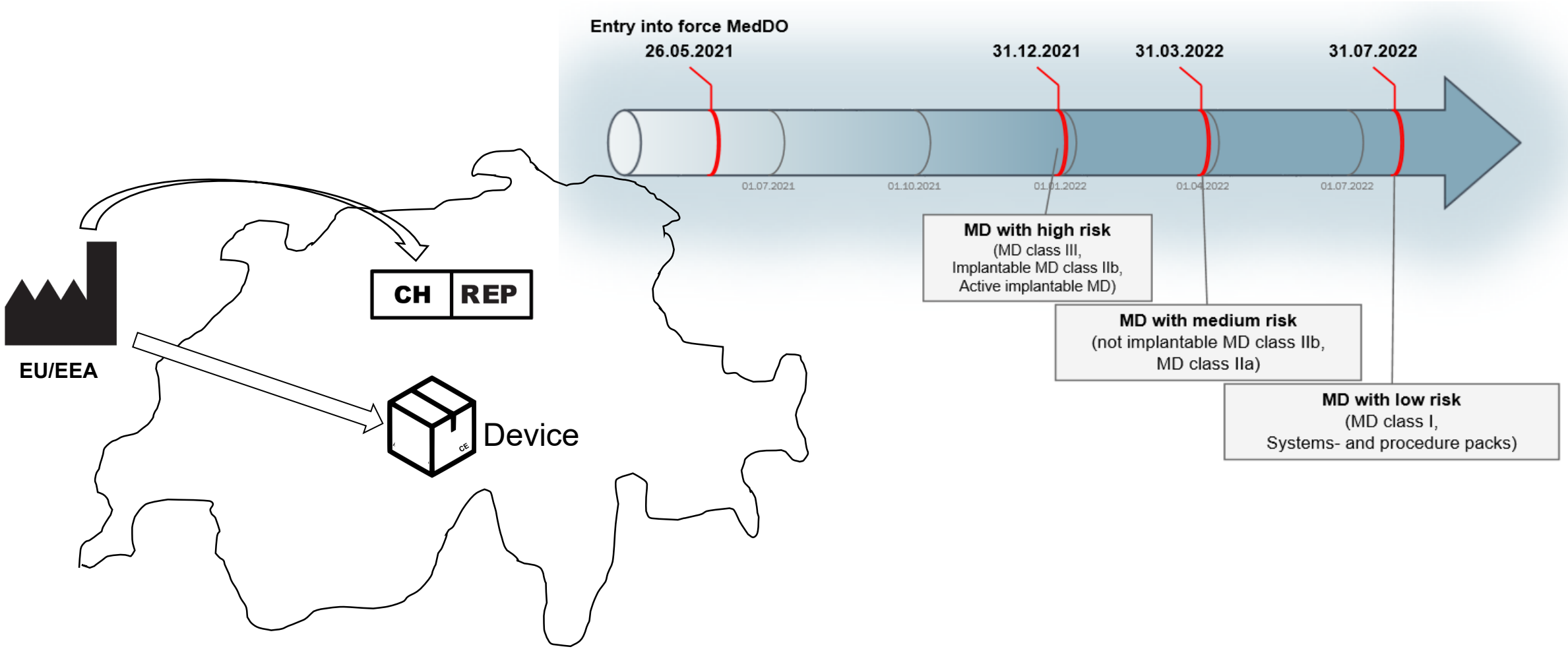
- PRRC requirements are defined in Art. 49, paras. 2-4 MedDO

- In the absence of the MRA (mutual recognition agreement), the obligation to designate an authorised representative now also applies to devices from EU/EEA countries

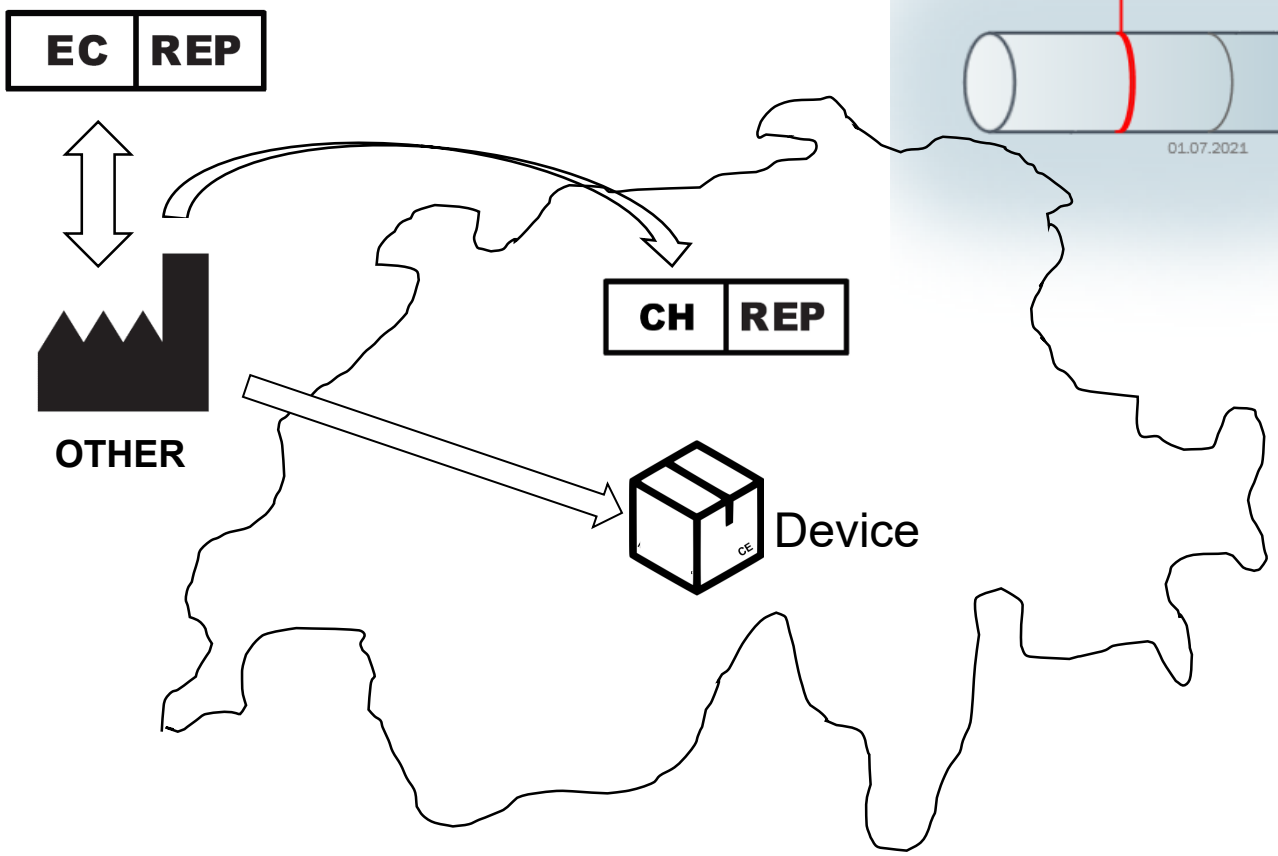
Appointment of an authorised representative

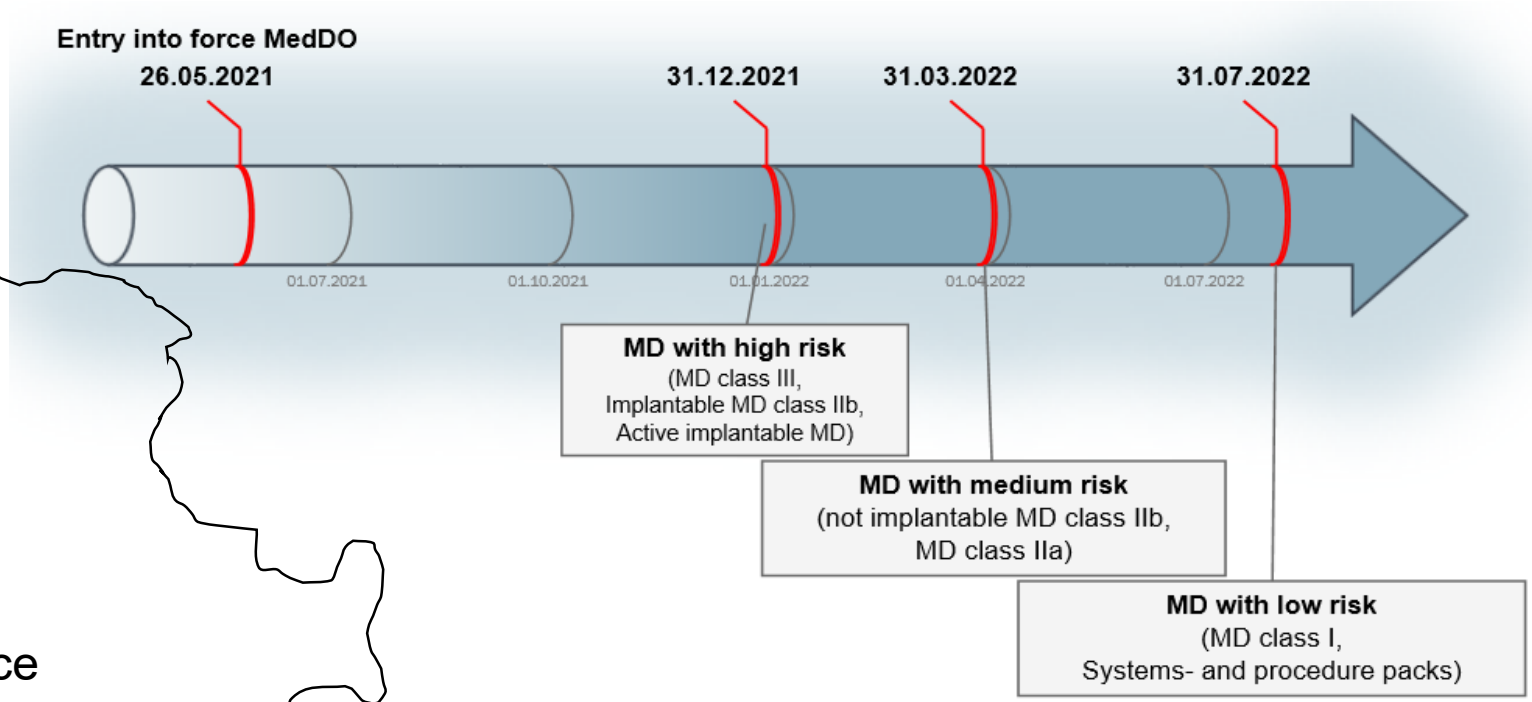
- CH-specific requirements for foreign manufacturers
  - Appointment of an authorised representative (CH-Rep; Art. 51 para. 1 and Art. 104a MedDO)
- A distinction is made between
  - Manufacturers in the EU/EEA
  - Manufacturers in a third country
    - With EC-Rep
    - Without EC-Rep
- Special case:
  - Manufacturers domiciled in Liechtenstein -> no CH-Rep (placing on the market within customs union)

Transitional periods for mandating a CH-Rep

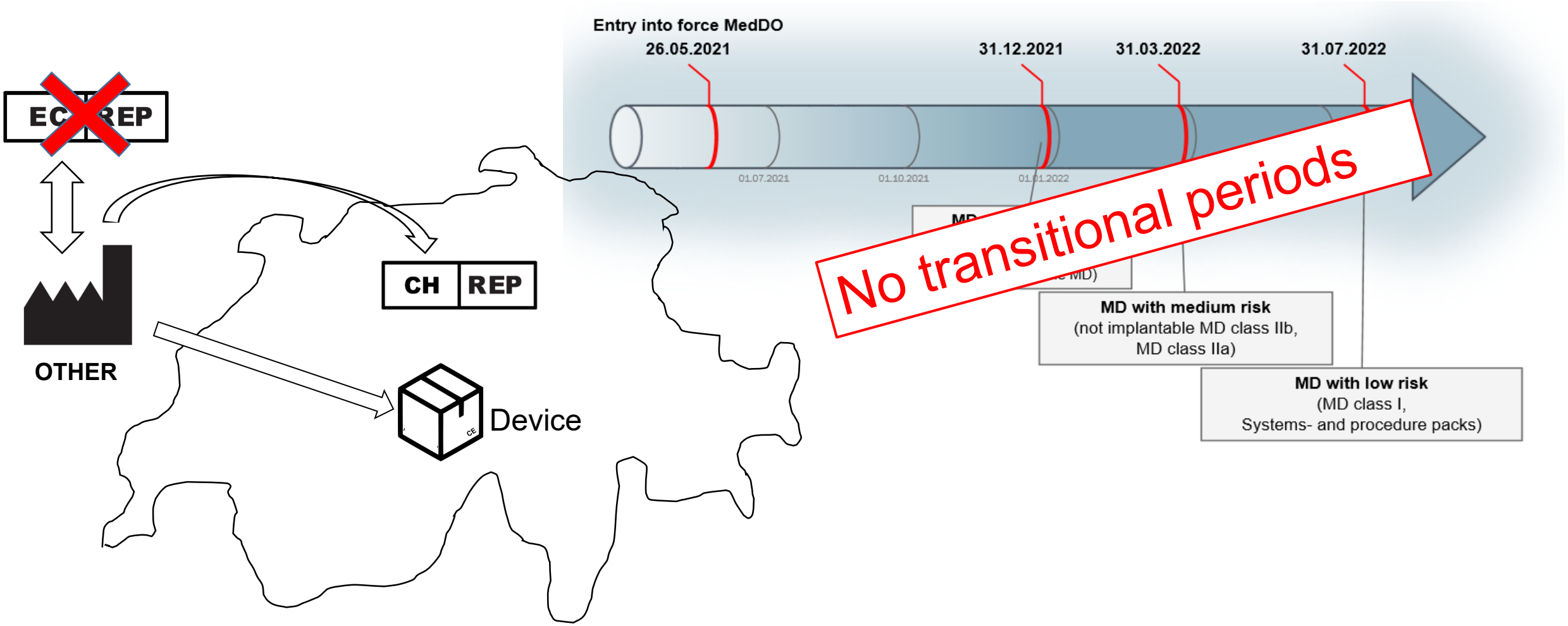


Transitional periods for mandating a CH-Rep

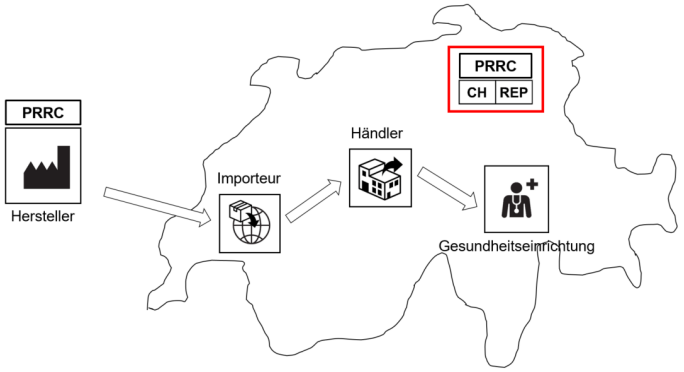




Transitional periods for mandating a CH-Rep



Authorised representative - FAQ



- **Can the manufacturer's PRRC also act for the authorised representative**
  - The MedDO does not specify any corresponding requirements, i.e. the possibility that the PRRC may also be the PRRC of an EC-REP or manufacturer is not ruled out.

- **Must the PRRC of the authorised representative be domiciled in Switzerland?**
  - The MedDO does not place any restrictions on the residence of the PRRC; the relevant factor here is that the tasks should be carried out regardless of any geographical distance

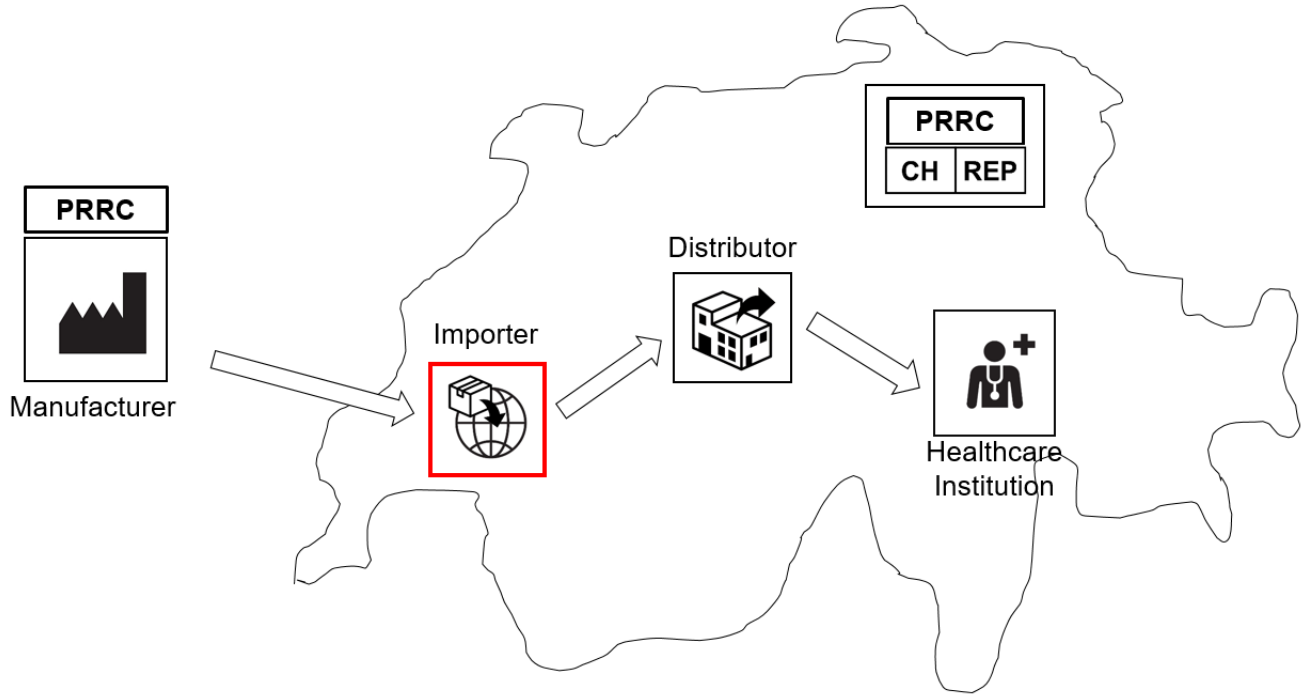
- **How will the authorised representatives be monitored?**
  - Swissmedic is responsible for monitoring the authorised representatives

Further information can be found in the information sheet on the Swiss authorised representative
https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/ch-rep.html

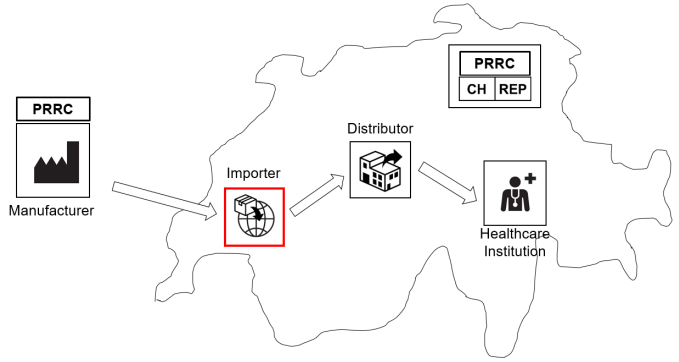
Importer

- Natural or legal person established within Switzerland that places a device from a foreign country on the Swiss market

- *Definition: Art. 4 para. 1 let. h MedDO*
- *Obligations: Art. 53 MedDO*



Importer: Obligations



- In the absence of the MRA, this role also applies to devices from the EU/EEA

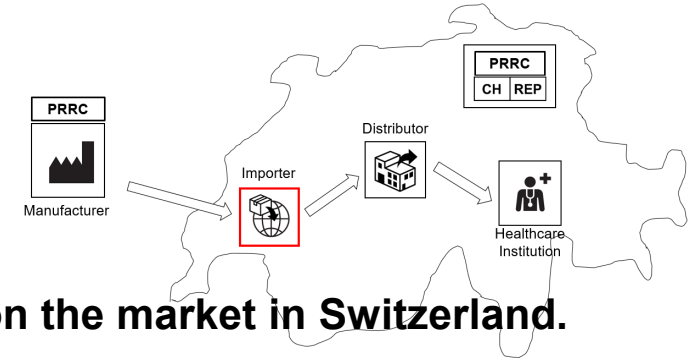
- Before placing a device on the market, the importer shall verify that (Art 53 MedDO)
  - The device carries the conformity marking
  - The declaration of conformity has been drawn up
  - The manufacturer is identified and that an authorised representative is designated
  - The product is labelled in accordance with this Ordinance and accompanied by instructions for use (3 languages)
  - Where required, a UDI is assigned

- The importer must print their name, place of business and contact address on the product, the product packaging or a document enclosed with the product (Art. 53 para. 2)

- If there is any doubt about conformity, the device must not be placed on the market (Art. 53 para. 3 MedDO)

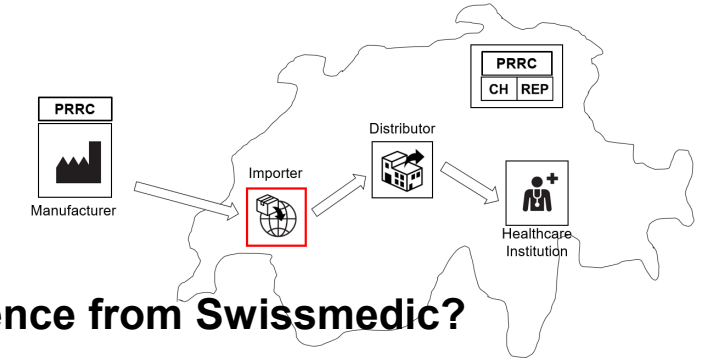
- Importers must be registered with Swissmedic (Art. 55 MedDO)

Importer - FAQ



- **Two companies import identical devices from another country and place these on the market in Switzerland. Which of the two companies is the importer?**
  - Both companies take on the role of the importer (*Art. 4 para. 1 let. h MedDO).* Both companies must comply with the corresponding obligations (*Art. 53 MedDO)*.
- **What are the obligations for importers and distributors in respect of MDD/AIMDD devices (legacy devices)?**
  - According to the transitional provisions specified in Art. 101 paras. 1 and 2 MedDO, MDD-compliant devices may be placed on the market after 26 May 2021 provided the following provisions of MDR are fulfilled:
    - post-market surveillance is ensured for these devices
    - their market monitoring is ensured
    - vigilance is ensured
    - economic operators are registered
    - the devices are registered (not yet available)
- **Can an importer be designated (e.g. contractually) to assume the responsibility of importer for all devices that are imported?**
  - No, there is no designated importer. An importer is any natural or legal person **in Switzerland** that places a **device from a foreign country on the Swiss market** (see Art. 4 para. 1 let. h MedDO).

Importer - FAQ



- **Do authorised representatives, importers and distributors of devices need a licence from Swissmedic?**
  - No
  - According to Article 55 MedDO, authorised representatives and importers must be registered with Swissmedic ("CHRN").

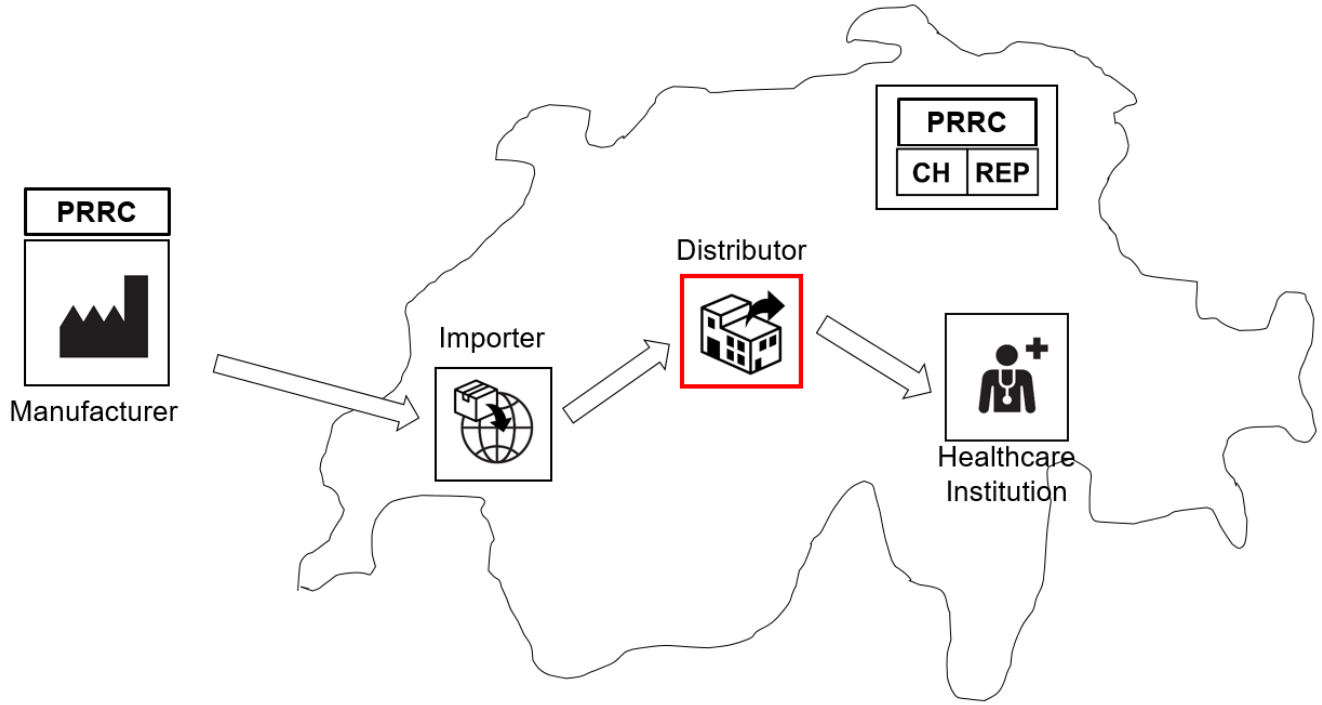
- **A company imports a device from a manufacturer in another country and places this on the market in Switzerland. The same company is mandated as a CH-REP by the manufacturer. What are the company's obligations?**
  - The company assumes the obligations of both the CH-REP and the importer.
  - It must be registered both as an importer and CH-REP and **receives two different CHRNs.**

- **How will the importers be monitored?**
  - Swissmedic is responsible for the monitoring of the importers.

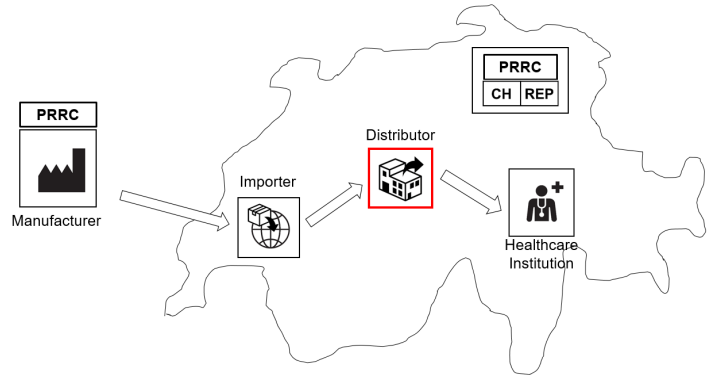
Distributor

- Any natural or legal person in the supply chain (other than the manufacturer or the importer) that makes a device available on the Swiss market, up until the point of putting into service.

- *Definition: Art. 4, para. 1 let. i MedDO*
- *Obligations: Art. 54 MedDO*

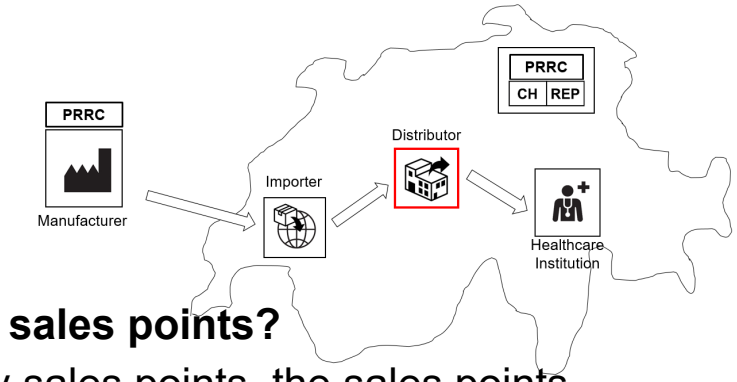


Distributor: Obligations



- Before making a device available on the market, the distributor must verify that
  - The device carries the conformity marking
  - The declaration of conformity has been drawn up
  - The device is accompanied by product information
  - Where devices have been imported, the importer’s name is stated
  - Where required, a UDI is assigned
- If there is any doubt about conformity, the device must not be placed on the market (Art. 54 para. 3 MedDO)
- Distributors must be not registered with Swissmedic

Distributor - FAQ



- **What are the obligations of pharmacies, supermarkets, online shops and other sales points?**
  - Devices imported from another country and placed on the market in Switzerland by sales points, the sales points are importers
  - Devices procured in Switzerland, the sales points assume the role of distributor
  - In both cases, compliance with the corresponding obligations must be ensured

- **As a healthcare institution, we dispense devices used for treating patients (e.g. dressing material for changing at home or support stockings). So are we importers / distributors?**
  - If the use/treatment also means putting into service (Art. 4 para. 1 let. c MedDO), the obligations for users/final users apply.
  - If trading activity exists (Art. 4 para. 1 let. i MedDO) and there is no direct relationship with the treatment/use, the obligations of the distributor (or the importer in the case of an import) must be observed.
  - In the case of a direct import from another country associated with direct use through a healthcare institution in Switzerland, Art. 70 MedDO should also be observed – the professional user assumes responsibility for the conformity of the device.
- **I am a retailer: Do I have to check all my medical devices?**
  - With the exception of the information on the importer, random sampling may be used for the purposes of verification. (Art. 54 para. 2 MedDO)

Other obligations

- Disclosure requirements
- Traceability of devices

Disclosure requirements for economic operators

- **The duty of disclosure (Art. 47c TPA) requires economic operators to disclose the following to Swissmedic on request:**
  - all economic operators from whom they have acquired a device;
  - all economic operators to whom they have supplied a device; and
  - all health institutions or health professionals to whom they have supplied a medical device.

- **What does this mean for data recording? What data am I, as an economic operator, obliged to record and keep?**
  - In order to satisfy the disclosure requirements, an economic operator must record, which devices it has acquired and forwarded (source or recipient of the devices, quantities, lot and serial numbers, dates of deliveries).
  - The data must be stored in such way, that the economic operator can provide the information stated in Art. 47c TPA without great effort (i.e. at very short notice if necessary), for example in connection with the official monitoring of field safety corrective actions or market surveillance procedures.
  - The duty of disclosure does not require each individual device to be traced (exception: class III implantable devices, see Art. 65 MedDO).

Traceability of devices

- Economic operators shall cooperate so as to achieve an appropriate level of traceability of devices (Art. 64 para. 1 MedDO)

- Economic operators shall disclose the following to Swissmedic on request:
  - all economic operators from whom they have acquired a device and
  - all economic operators, healthcare institutions and healthcare professionals to whom they have supplied a device.

- This duty of disclosure continues for at least 10 years (or for at least 15 years in the case of implants) after the last product covered by the declaration of conformity was placed on the market (Art. 47c TPA and Art. 64 para. 2 MedDO).

- Economic operators (and healthcare institutions) shall store and keep, preferably by electronic means, the UDI of the class III implantable devices which they have supplied, or with which they have been supplied (Art. 65 MedDO)

Take-home messages

- The specific role of every economic operator in Switzerland must be defined. Any organisation can have several roles. Only those who are aware of their specific role will be able to identify and fulfil this role

- Check the following for all your devices:
  - Do I know my role?
  - Do I know the obligations of this role and do I fulfil them?
  - Are my devices compliant and can I also prove this?

- In our establishment have we fulfilled the duty of disclosure and guaranteed the traceability of our devices?

- **Further information on our website and especially in the information sheets**
  - **about economic operators** https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/pflichten-bevollmaechtigte.html
  - **for healthcare institutions** https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reprocessing---maintenance/beschaffung.html
  - **about the authorised representative** https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/ch-rep.html

Thank you for your valued attention