Distribution under the MDR

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Agenda

1. MDR and distribution
2. Economic operators
3. Distributor
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5. MDR and distribution agreements
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1. MDR and distribution

- New chapter on economic operators (ch. II)
- Obligations introduced for importer and distributor
- The authorised representative

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2. The economic operators - overview

Manufacturer
A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark

Authorised representative
Any natural or legal person established within the Union who has **received** and accepted a written **mandate** from a manufacturer, located outside the Union, to **act on the manufacturer's behalf** in relation to specified tasks with regard to the latter's obligations under this Regulation

Importer
Any natural or legal person established within the Union that **places a device from a third country on the Union market.**

Distributor
Any natural or legal **person in the supply chain, other than the manufacturer or the importer,** who makes a device available on the market up until the point of putting into service.

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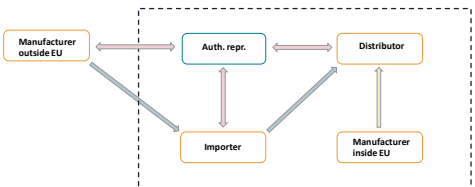
2. The economic operators - overview



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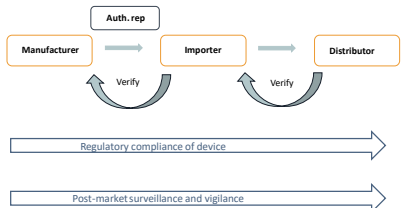
2. Economic operators – regulatory obligations



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2. Economic operators - regulatory obligations

		Auth. repr.	Importer	Distributor
Ensure/verify	Device is CE marked	√	√	√
	EU declaration of conformity and technical documentation exist	√	√	√
	Correct conformity assessment procedure has been performed	√		
	Labelling and accompanying information (IFU)		√	√
	Manufacturer has assigned UDI		√	√
	Importer has included name and contact details		√	√
	Manufacturer is identified and authorised representative has been assigned		√	
Other obl.	Appoint person responsible for regulatory compliance	√		
	Storage and transportation requirements fulfilled		√	√
	Keep a register of complaints	√	√	√
	Inform manufacturer if device gives rise to a serious risk or is not in conformity	√	√	√
	Eudamed registration obligations	√	√	√
	Reporting to competent authority re. serious incidents/serious risk	√	√	√
	Cooperation with competent authorities re preventative/corrective action	√	√	√
	Store UDI for Class III implantable devices	√	√	√
	Identification within the supply chain	√	√	√

2. Economic operators - the authorised representative

- A requirement for non-EU manufacturers

  Art. 11 (1): "Where a Manufacturer is not established in a Member State the device may only be placed on the EU market if the manufacturer designates a sole authorised representative."

- Legal liability

  *Art. 11 (5): "… where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10, the authorised representative shall be **legally liable** for defective devices on the same basis as, **jointly and severally** with, the manufacturer."*

3. Distributor – overview

A distributor's main obligations under the MDR may be summarized as follows:

- Verify compliance of device.
- Report of non-conformity of device.
- Cooperate in corrective actions.

3. Distributors – before making device available

Verify conformity

- Distributors shall:
  a) verify that device is **CE marked** (and has a declaration of conformity in the local language(s));
  b) verify that the devices is accompanied by a **label** and **information leaflet** in the local language(s);
  c) verify that an **UDI** has been assigned to the devices by the manufacturer;
  d) verify that the device has **information about the importer**; and
  e) ensure that **storage and transport conditions** reflect conditions set by the manufacturer.
- A distributor that consider a device to be non-conforming shall **inform manufacturer** (and any AR), and distributor shall then only make the device available once it is conforming. Distributor shall **also inform competent authority** if a device is considered (i) to presents a serious risk or (ii) to be falsified device.

3. Distributors – after making device available

Product traceability

- The UDI of class III implantable devices
- Identify/maintain register of (i) all economic operator "customers" and "supplier" and (ii) all health institution/healthcare professional customers

Market surveillance and reporting

- Inform the manufacturer of *non-conforming devices* (plus AR and importer if applicable) and cooperate re. corrective actions. Inform the competent authority if the device presents a *serious risk*.
- Keep a register of complaints, of non-conforming devices and of recalls/withdrawals.
- Immediately forward complaints/reports from healthcare professionals/patients/users to manufacturer (plus AR and importer if applicable).

Corrective action

- Take appropriate corrective actions when a competent authority identifies an *unacceptable risk* for health or safety.
- Cooperate with competent authorities to eliminate or mitigate the risks posed by devices on the market.
- Cooperate with the competent authorities when the latter carry out an evaluation of the device, including providing free samples of or access to device.

4. Quality management

- No specific requirement distributors (or importers) to implement a quality management system (compare art. 10 for manufacturers); however:

  "In order to meet the legislative requirements and to ensure that only medical devices that comply with the legislation are made available for supply, it is recommended that distributors have a quality system in place. … There are various established standards for quality systems, with ISO 13485 being the most commonly used …" (HPRA, Guide for Distributors of Medical Devices, 2018)

- Some tasks that call for quality systems type procedures:
  - "… ensure that…storage and transport conditions do not jeopardies its compliance with general safety and performance requirements."
  - "… keep a registry of complaints, non-conforming devices …"
  - "… co-operate … to ensure that the necessary corrective action … is taken …"

5. MDR and distribution agreements

- Where the distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also **inform the competent authority of the Member State** in which it is established. (art. 14-2)

  ❑ Agreement on obligation to consult and coordinate any communication with Manufacturer (plus carve-out from confidentiality clause)

- Distributors shall ensure that, while the device is under their responsibility, **storage or transport conditions** comply with the conditions set by the manufacturer. (art. 14-3)

  ❑ Agreement on storage and transport conditions.

- Distributors shall **co-operate** with the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer, and with competent authorities to ensure that the **necessary corrective action** to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken. (art. 14-2)

  ❑ Agreement to co-operate with and assist Manufacturer (and preferably, on procedure).
  ❑ Agreement on allocation/compensation for costs relating to corrective action/recall.

5. MDR and distribution agreements (cont.)

- Distributors that have received **complaints** or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall **immediately forward** this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. They shall **keep a register** of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.

  ❑ Agreement on complaint reporting and register keeping in addition to regulatory obligation (and preferably, also on procedure and systems to use).
  ❑ Agreement on allocation/compensation for costs relating to corrective action/recall.

- Distributors shall, upon request by a **competent authority**, provide it with **all the information and documentation** that is at their disposal and is necessary to demonstrate the conformity of a device.

  ❑ Agreement on obligation to consult and coordinate any communication with Manufacturer (plus carve-out from confidentiality clause)

- Distributors shall **cooperate with competent authorities**, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall **provide free samples of the device** or, where that is impracticable, grant access to the device.

  ❑ Agreement on procedure in connection with meetings/audits by authorities (for example, right for manufacturer to attend).
  ❑ Agreement on allocation/compensation for costs.

5. MDR and distribution agreements - confidentiality

Example

15.1 **DISTRIBUTOR shall treat as strictly confidential** any CONFIDENTIAL INFORMATION and shall use it solely for the purpose of and in accordance with this AGREEMENT. It shall not make any CONFIDENTIAL INFORMATION available to any third party **except to competent government agencies as required under law** and in this case (a) strictly to the extent requested by said agencies, (b) only upon exercise of its best efforts to cause said agencies to maintain confidentiality thereof and (c) in accordance with section 15.2.

15.2 **Prior to** making any CONFIDENTIAL INFORMATION available to a competent government agency pursuant to section 15.1 above, **DISTRIBUTOR shall consult with MANUFACTURER** and submit to MANUFACTURER the proposed disclosure at least five (5) days prior to the submission thereof. The purposes for such prior submission are: (i) to provide MANUFACTURER with the **opportunity to review and comment** on the contents of the proposed disclosure, and all MANUFACTURER's reasonable comments shall be accepted by DISTRIBUTOR; and (ii) to **identify any CONFIDENTIAL INFORMATION not required** to be disclosed considering the scope and purpose of the submission to the competent government agency and duly acknowledging the commercial interests of the MANUFACTURER, and any CONFIDENTIAL INFORMATION not being required to be disclosed shall be redacted.

5. MDR and distribution agreements - recalls

Example

MANUFACTURER shall be responsible for **initiating and/or implementing** all Product **recalls required by controlling regulatory agencies** and for **all voluntary Product market withdrawals** in the Territory. MANUFACTURER shall handle such matters in a timely, prudent and skillful manner, in compliance with all applicable laws, rules, policies, regulations and regulatory requirements, and in accord with MANUFACTURER's **standard operating procedures**. DISTRIBUTOR shall keep MANUFACTURER informed in a timely manner with respect to any matters relating to any suspected or actual recall and market withdrawal of a Product. **All costs incurred** in responding to recalls and market withdrawals shall be borne by MANUFACTURER, except to the extent such recall is due to the fault, negligence or wrong-doing of the Distributor. In the event of a Product recall **DISTRIBUTOR shall assist** promptly and efficiently in executing the Product recall as directed by MANUFACTURER.

Take aways!

- Ensure that agreements are not only compliant but also optimized for the new regulatory environment.
- Explore the need/benefits of a quality management system at the distributor level.