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Economic actors in MDR/IVDR - definitions

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Outline

- Actors in MDR versus MDD
- How to understand the definitions
- Actions that define actors
- Defining actors
- Application dates (briefly!)

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Actors in MDR versus MDD

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Present, soon to be past…

- In MDD the only actors described was the manufacturers and its authorized representative
- The other actors were to be covered, where applicable, by the Quality Management System (QMS) and the Post Market Surveillance system (PMS) of the manufacturer
- Where the devices were intended to be used by laymen (i.e. consumers, patients) the General Product Safety Directive (GPSD) was also applicable to all economic actors in areas where MDD did not have requirements

Future, soon to be present…

- In MDR the entire supply chain between manufacturer and the end user are economic actors with defined responsibilites for each role.
- The set of responsibilities are adapted to the factors where the actors are able to check and have influence over
- The economic actor are:
  - *Manufacturer (will not be discussed further in this session)*
  - Authorized representative (AR)
  - Importer
  - Distributor
- This set of economic actors are common for several product safety legislations according to the ”new approach” in the EU

How to understand the definitions

Proceed with caution!

- In order to properly understand how the actor roles are defined and assigned, a few precautions are needed
  - The legal definition of the terms that are used does not necessarily correspond to the meaning in everyday use or how they are used in the business context
  - Each definition may seem simple(-ish) and somehow intuitive – but they are often ”nested” and layered
  - The actor role is defined by the activity a natural or a legal person takes with a certain device – hence, it’s better to think that the said person **acts as** a certain actor role than that a person **is** a certain actor
  - In the bigger picture, a natural or legal person can act as all actor roles - but only one actor role for a certain action for a certain device
  - The word ”device” in the legislation means one (1) specimen
- It is recommended to study ”The Blue Guide” for an overview of the intentions of the legislation – see
  - EN: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726(02)
  - SV: https://eur-lex.europa.eu/legal-content/SV/TXT/PDF/?uri=CELEX:52016XC0726(02)

Underlying conditions

- While *end user*/*final user* does not have a legal definition, they do influence the definitions of the actions and actor roles
- The *end user*/*final user* does not have a defined legal obligation in their use of the device – however, the *manufacturer* may presume that the intended use as stated in labelling/IFU is adhered to
  - The *manufacturer* shall also consider the reasonably foreseeable (mis)use of the device, and include it in the risk assessment
- The *intended purpose* – which also defines the *end user/final user* – will also influence the said definitions

Actions that define actors

Actions that define the actor roles

- Making available on the market (art 2.27 MDR, art 2.20 IVDR)
- Placing on the market (art 2.28 MDR, art 2.21 IVDR)
- Putting into service (art 2.29 MDR, art 2.22 IVDR)

Making available on the market I

- *'making available on the market' means **any supply of a device** […] for **distribution, consumption or use** on the Union market in the course of a commercial activity, whether in return for payment or free of charge*
- The wording highlighted with bold text means that many actors are affected
- Covers any transfer of ownership, possession or any other right between natural and/or legal persons until the end user
- It does not necessary require a physical transfer of products
  - An agreement (written or otherwise) to transfer certain device(s) is considered a supply
  - Includes and offer of said supply
- Also includes loan, leasing and hire

- Read more in section 2.2 in Blue Guide

Making available on the market II

- *'making available on the market' means any supply of a device […] for distribution, consumption or use on the Union market in the course of a **commercial activity**, whether in return for **payment or free of charge***
- *Commercial activity* means, in practice, that the supply is repeated/continuous and/or of non-negligible extent
- One also have to consider fairness – there shouldn't be a difference of responsibilities due to different types of owners/principals of said actors*
- Payment is not the determining factor

- Purpose: The legislation should enable accountability and traceability in the supply chain!

- Read more in section 2.2 in Blue Guide

* Health care providers – acting as such in the certain situation – may be covered by other legislation

Placing on the market

- *'placing on the market' means the first **making available** of a device […] on the Union market*
- A special case of *making available on the market*
- Performed as the roles *manufacturer* (mfr within the EU) and *importer* (mfr outside the EU)
- **Not** performed as the role *authorized representative* (AR) – but a natural or legal person that acts as AR may also act as an *importer* (probably common)
- **Remember:** *a device* refers to one (1) specimen – hence, each and every specimen is placed on the market by a *manufacturer* or an *importer*
- **Therefore:** *placing on the market* does **not** refer to launch of a product model/type (SKU)

- Read more: Section 2.3 in Blue Guide and a separate document: https://ec.europa.eu/docsroom/documents/10265/attachments/1/translations

Putting into service

- *'putting into service' means the stage at which a device […] has been **made available** to the **final user** as being ready for use on the Union market for the first time for its **intended purpose***
- Device ready for use or final assembly by the *final user* within the intended purpose: At the supply of the device (*e.g.* bandages, syringe/needle)
- Device requiring assembly not intended for the end user: At the completion of assembly by the party intended by the manufacturer (*e.g.* X-ray equipment)

Defining actors

Actor roles

- Authorized representative (AR) (art 2.32 MDR, art 2.25 IVDR)
- Importer (art 2.33 MDR, art 2.26 IVDR)
- Distributor (art 2.34 MDR, art 2.27 IVDR)

Authorized representative (AR)

- *'authorised representative' means 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*
- Only one (1) AR within the EU
- Not defined by the aforementioned actions
- Not necessarily the "holder of exclusive rights for the EU" in a business sense
- Often acts as importer as well

- Read more in section 3.2 in Blue Guide

Not to be taken lightly!

Importer

- *'importer' means any natural or legal person established within the Union that places a device from a third country on the Union market*
- Not exclusive, may be any number of *importers* for a certain device model
- A certain device (specimen) has only one *importer*
- Any actor who gets device(s) supplied to them from a party located outside the EU and supplies them further is an *importer*

- A *final user* that imports a device and *puts it into service* (health care providers, aesthetic treatments) has an equal responsibility to ensure that the device is in comformity

- Read more in section 3.3 in Blue Guide

Distributor

- *'distributor' means **any natural or legal person in** the supply chain, other than the manufacturer or the importer, that **makes a device available on the market**, up until the **point of putting into service***
- As hinted in the section on *making available,* the definition of *distributor* is more or less all-embracing for those who at all are involved in the supply of devices
- Huge variation in size and extent (from convenience stores to huge distribution centers)
- Many natural or legal persons may "happen" to act in this role as a side business

- Read more in section 3.4 in Blue Guide

Distributor – examples that *may* act as such

- Wholesalers
- Local sales offices of major corporations
- Retailers of electronics
- Kiosks
- Pharmacies
- Hjälpmedelscentraler
- Hjälpmedelsbutiker
- Grocery stores
- Distribution centres for pharmacies and health care providers

Application dates

Application dates – Placing on the market MDR

Category	Date
All devices of a type/model that has *not* been placed on the market under the MDD (”New devices”) (Art 123.2)	26 May 2020 (or earlier, see art 120.5)
All devices in class I according to the MDR (Art 123.2)	26 May 2020
Devices in class I according to the MDD, but class Ir, IIa, IIb or III acroding to the MDR (”Upclassed produkter”) (Art 120.3, with conditions)	26 May 2024

Application dates – Placing on the market MDR

Category	Date
Devices in class Is, Im, IIa, IIb or III according to the MDD, with a valid certificate according to the MDD (Art 120.2-3, with conditions) (Certificate according to annex bilaga 4 to the MDD: 26 maj 2022 at the latest)	Expiry date of the certificate, 26 May 2024 at the latest

Conditions in artikel 120.3: *”[…]provided that from the date of application of this Regulation it continues to* ***comply with either of those Directives****, and provided there are* ***no significant changes*** *in the design and intended purpose.”*

Application dates – Placing on the market IVDR

Category	Date
All devices of a type/model that has *not* been placed on the market under the IVDD (”New devices”) (Art 113.2)	26 May 2022 (or earlier, see art 110.5)
All devices that have not previously been assessed by a notified body according to the IVDD (including devices in class B or higher according to the IVDR) (Art 113.2)	26 May 2022
All devices that have been assessed by a notified body (List A and B and self tests) with a valid certificate according to the IVDD (Art 110.3, with the aforementioned conditions)	Expiry date of the certificate, 26 May 2024 at the latest

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Latest date making available on the market of devices according to MDD/IVDD

Kategori	Datum
All devices that have legally been placed on the market before 26 May 2020 (MDR Art 120.4) and 26 maj 2022 (IVDR Art 110.4) respectively	26 May 2025
All devices that hav been placed on the market from 26 May 2020 (MDR) and 26 maj 2022 (IVDR), respectively, according to the transitional provisions in Art 120.3 (MDR)/110.3 (IVDR) (Art 120.4 (MDR)/110.4 (IVDR))	26 May 2025

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Actor responsibilities = Day 1

- Even though some devices may be placed on the market and may be made available on the market after the 26 May 2020 while conforming to the requirements in MDD, they are on the market subject to the MDR
- **Main principle: Responsibilities of actors according to the MDR are in effect from 26 May 2020** unless specified otherwise.

Messages to take home

- It is unlikely that you do not have a role as an economic actor if you at all handle transfer of device – most of the time distributor
- Be sure to understand what actor role you act as in a certain situation
- **You** need to familiarise yourself with the legislation
- Do not accept a role until you fully understand it

- The application dates are complicated – however, you need to have them in mind

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MDR for economic operators

- Manufacturers
- Authorized representatives
- Importers
- Distributors

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The Authorised agent

- Non-EU Manufacturers outpost in EU

- Shared responsibility with manufacturer
- Must have Access to complete technical documentation
  - Must be in an EU official language
- Insurance must cover the liabilities you take on

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The Authorised agent

- Non-EU Manufacturers outpost in EU

- You need to have a strategy to ensure compliance
  - Contracts
  - Audits
  - Review of files

- Authorities will come to you since you must have all relevant information

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Importer

- New responsibilities

- Can be inspected by authorities

- Quality system not mandatory but You must show that you have done what you are obligated to do

- Might need registration

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Importer requirements

- If you get a direct shipment from outside EU you are importer
- Be aware of rerouted shippments can make you the importer

Importer must verify that….. (Article 13)

- Devices are CE marked
- Declaration of Conformity exist
- Labels and IFU exist
- Importers name exist on device or IFU
- The product is registered in EUDAMED database
- Storage and transportation meets manufacturers requirements
- Products marked with UDI (if applicable)

- Keep register of recall, complaints, non conforming products
- Traceability of to whom you have provided devices

Challenges for importers

- How do you control items that are direct shipped to customer
- Systems in place to ensure compliance

- Adding your name and contact data

If you always import a specific product, outsourcing the controls to the manufacturer might be one way

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Distributor requirements

- If you sell a product in EU you are a distributor
- This is regardless if the product is imported or not
- Applies to all parts of the distributor chain

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Distributor must verify that…. (Article 14)

- Device is CE marked
- DoC exist for the products you distribute
- The labels and IFU have right language(s)
- Importers name exist on device or IFU
- Secure storage and transportation meets manufacturers requirements
- Keep register of recall, complaints, non-conforming products
- Traceability of to whom you have provided devices

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What will it mean in practice for you?

- Regulations do not specific request a quality system, but:
  - Indirect needed to meet requirements
  - You need to ensure your processes take care of this

- How to handle MDD vs MDR products since transition timelines will differ between products

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Challenges for distributor

- How do you control items that are direct shipped to customer
- Systems in place to ensure compliance

- Language of IFU now also your responsibility

If you always distribute a specific product, outsourcing the controls to the importer/manufacturer might be one way

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Labeling and promotion

- Must promote devices in line with manufacturers CE marking

- Translation must be done in the manufacturers process otherwise you need a Notified Body

- You cannot create your own short version of IFU!

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Distributor vs manufacturer Article 16

- When a distributor or importer becomes a manufacturer.

- Label product with there own name
- Change intended use
- Modifies a device in the field deviating to much from original

- Translating user manuals requires registration. Check your contracts

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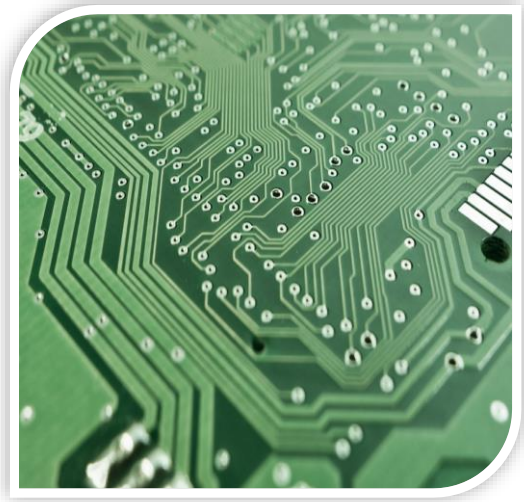
Spareparts Article 23

- Parts components and evidence for replacing them

- If it change safety and performance sparepart manufacturer are responsible for the whole product



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Guidance and resources

CAMD Overall responsible for implementation lead by Helena Dosiz Swedish MPA

https://www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf

EU comission guidance:
https://ec.europa.eu/docsroom/documents/33862/attachments/1/translations/en/renditions/native

Irish authority:
https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/ia-g0004-guide-for-distributors-of-medical-devices-v1.pdf?sfvrsn=13

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Summary

- You need to add or change way of working in several areas
  - Logistics and warehouse
  - Incoming inspections
  - Traceability
  - Promotion
  - Flexibility might be less than today
- Do you have the competence?

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Key take aways:

- Time to think through what you must do
- This is not that simple
- Know your distributing channels

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Registration and market surveillance

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Registration according to MDR/IVDR

Eudamed (common for EU)

NOTE! Delayed. Replaced by national measures for approximately 2 years.

- Authorised representatives
- Importers
- Manufacturers

National registration/notification

- Distributors (subject to national legislation)
- Actors performing translation/repackaging (art 16.2 , mandatory notification)
- Actors assembling systems/procedure packs (art 22, mandatory notification)
- Manufacturers of custom-made devices (subject to national legislation)

Purpose of registration

- Having a foundation to plan and perform market surveillance
- Enabling a way to establish the responsible actors for devices (and other products)
- Part of the ”agreement” of the ”new approach” family of product safety legislations where there are no pre-approvals

Swedish national legislation

- Not in place, formally
- A public consultation until 14th April 2020

- Main direction **at this time**: No requirement on registration for distributors at the time of application of MDR
- It may be introduced at a later date if the Swedish authorities (Läkemedelsverket etc) considers it necessary to maintain a safe market for the end users (patients, health care professionals, consumers)
- Fees for importers and distributors may also be introduced at a later time
- Fees for manufacturers and authorized representatives will be introduced sooner

Market surveillance - principles

- The market surveillance activities of the MPA should be
  - Prioritized and performed with a risk-based approach
  - Prioritized and performed to be as efficient and effective as possible
  - Proportional to the risk and severity of the non-conformities
  - Objective and according the rule of law
- The introduction of all levels of economic actors will provide a more versatile toolbox to enforce necessary measures to eliminate unacceptable risks and other non-conformities

Remember: Risk = Hazard x Exposure

Market surveillance - practice

- Both screening and based on signals (*e.g.* incident reports and other information)
- Läkemedelsverket are not bound to perform market surveillance from all incoming information – but will assess any and all signals
- Both administrative controls and physical inspections
- Aim
  1. To find proof to establish that actors and devices are in conformity
  2. Rectify non-conformities

  […]

  99. Punish/impose sanctions
- Possible sanctions include (proportionality important):
  - Läkemedelsverket: Injunction (föreläggande) or prohibition (förbud) – may be combined with a conditional fine (vite)
  - Läkemedelsverket: Fine (sanktionsavgift)
  - Court: Fine (böter) or imprisonment (fängelse)

Questions!

- You will have them, hence the exclamation mark!

- Preferrably via e-mail to: registrator@lakemedelsverket.se
- There is a phone service on Mon, Tue and Fri at 9-11 and 13-15 and Thu at 9-11. It is reached through the switchboard at 018-17 46 00