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Actor roles according to MDR/IVDR – gentle reminder and clarifications

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Actor roles in MDR

- Brief recap of news in the MDR
  - **Importer** and **distributor** introduced as new roles in MDR with responsibilities laid down for the respective roles (Article 2.33. 2.34, 13, 14)
  - The responsibilities for the **authorized representatives** are clarified – a role not to be taken lightly! (Article 2.32, 11, 12)
  - Requirements on **traceability** in the supply chain are introduced (Article 25)
  - Rules on **marketing claims** are introduced (Article 7)
  - Provisions for **importers** and **distributors** to adapt devices to national legislation – strict requirements (*e.g.* QMS certified by NB, registration with the Swedish MPA) (Article 16)
  - **Anyone that assembles systems and procedure packs** and places them on the market are subject to new provisions and requirements (Article 22)
- ”Actor” is almost equivalent to the defined term ”economic operator” (article 2.35)

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Scope of application of the actor roles

- Different interpretation from what we presented last year
- The actor roles in MDR/IVDR, and the responsibilities that follows, are…
- …**applicable** for devices that are placed on the market according to MDR/IVDR
- …**not applicable** for devices already placed on the market before the date of application of MDR/IVDR (devices subject to the ”sell-off” provision)
- **…not applicable** for devices placed on the market subject to the transitional provisions (”legacy devices”) in MDR/IVDR

What role do I have?

- The actor role shall be decided from what you act as, *i.e.* what **you do** with **a certain device** in **a certain situation**
- Needs to be established on a case-by-case basis
- **A certain device = 1 piece**
- As a natural or legal person, you **cannot establish** that you **are** a certain actor **once and for all**
- As a natural or legal person, you may very well have to act in **several actor roles**
  - And hence assume the applicable responsibilites
- The above also apply for those that **also** act as health care providers
  - a hospital (or regional authority) may well **also** act as a manufacturer of medical devices
  - a unit for orthopaedic technology may **also** act as a manufacturer of custom-made devices

An importer…

- …is anyone that assumes ownership of devices from a party in a third country (*e g* UK, USA, China) and makes them available for distribution, consumption or use on the union market
- …may act in parallel with other importers for a device model or manufacturer
- …shall assume the responsibilities as detailed in article 13 in MDR/IVDR
- …needs to handle the said responsibilities in a structured manner
- …is subject to market surveillance by competent authorities

An importer… (cont'd)

- …needs to make sure that there is an Authorized Representative (AR, EC REP) present for any devices that are handled
  - Importing does not necessarily make you the AR
- …needs to identify themselves in information accompanying the devices
- …needs to register in EUDAMED, when fully functional
- …does not need to register with the Swedish MPA before EUDAMED

A distributor…

- …is anyone that assumes ownership of devices from an actor within the union market and makes them available for distribution, consumption or use on the union market
- …is an actor role that encompasses many natural or legal persons on all levels in the supply chain
- …shall assume the responsibilities as detailed in article 14 in MDR/IVDR
- …needs to handle the said responsibilities in a structured manner
- …does not need to register with EUDAMED
- …does not need to register with Swedish MPA
  - May be introduced at a later time if the need arises
- …is subject to market surveillance by competent authorities

In plain words

- Every link in the supply chain is an integral part to ensure the safety and performance of medical devices
- Each link have responsibilites that are adapted to the factors that are reasonable for the actor to check and have influence over
- Make sure any and all reports on incidents, complaints, suspicions of non-conformities etc is passed on to the manufacturer/AR.

- If in doubt if something is OK – DON'T DO IT!
- As any actor, YOU are expected to be vigilant
- As a manufacturer/AR, YOU are expected to enable other actors to submit information

Three sneaky articles!

- Not mentioned in article 13 and 14, but still apply to all economic operators
  - Article 7 – Marketing claims
  - Article 25 – Traceability
  - Article 27.8 – Storing UDI
- Highlights the need to have an overview of more than single articles in MDR

Article 7 – Marketing claims

- Each actor, or any other concerned party, is required to ensure that any and all claims that are made for a device are not in violation of article 7 in MDR/IVDR
- Implicitly required also before the MDR by
  - general legislation on marketing
  - MDD requirement that clinical evaluation shall support the safety and performance of the intended use
- *In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trade marks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:*
  - *ascribing functions and properties to the device which the device does not have;*
  - *creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have*
  - *failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose*
  - *suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.*

Article 25 - Traceability

- In MDD: Traceability needed to be ensured by the manufacturer in order to fulfil the requirements on materiovigilance – FSCAs, withdrawals and recalls
  - Not explicitly specified how in the legislation
- In MDR: Requirements on each link in the supply chain to be able to identify (*i.e.* keep records on)
  - *any economic operator to whom they have directly supplied a device*
  - *any economic operator who has directly supplied them with a device*
  - *any health institution or healthcare professional to which they have directly supplied a device*

  Note: Not a requirement to be able to identify individual customers apart from the above
- Each such link is needed to construct the chain

Article 27.8 – Storing UDI

- *Economic operators shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to:*
  - *class III implantable devices*
  - other devices, categories or groups of devices determined by the EU Commission and laid down in implementing acts