Defining Economic Operators

Economic Operators as a Supplier

Obligations to the Manufacturer

Person Responsible

Economic Operators in the MDR

Economic Operators

Economic Operators

- One important element in the new regulations is the role of the Economic Operator

- *Economic operator* means the manufacturer, the authorized representative, the importer, and the distributor.

- In the MDR, economic operator also includes:
  - An organization that assembles systems or procedure packs
  - An organization that sterilizes systems or procedure packs

Definitions

- *Manufacturer* means the 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 his name or trademark.

- *Authorized 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 European Union, to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation

- *Importer* means any natural or legal person established within the Union who places a device from a third country on the Union market

- *Distributor* means 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

Identification Within The Supply Chain

- Economic operators shall be able to identify the following to the competent authority, for 10 years in general and 15 years for implantable devices:

  (a) any economic operator to whom they have directly supplied a device;

  (b) any economic operator who has directly supplied them with a device;

  (c) any health institution or healthcare professional to whom they have directly supplied a device.

MDR Article 25

Economic Operators

Registration

- Before placing a device on the market any manufacturer, authorized representative, and importer must register in the European Databank

- The Competent Authority obtains a single registration number (SRN) and provides it to the manufacturer, authorized representative, or importer

- The manufacturer uses the single registration number when applying to a Notified Body for certification

- The manufacturer uses the single registration number for entering the electronic system on UDI

MDR Article 31

Manufacturer

- The manufacturer has many obligations under Article 10 including
- Setting up systems for quality management, risk management, post-market surveillance and unique device identification
- Registering in EudaMed with a Single Registration Number
- Creating Technical Document required by Annex II and Annex III
- Drawing up a Declaration of Conformity
- Ensure financial coverage for product liability
- Establish relationships contracts, etc. with other economic operators (authorized representative, importers, and distributors)

Obligations of the Economic Operators to the Manufacturer

Service

- The manufacturer will establish EN ISO 13485:2017
  - The EU will publish its version of ISO 13485:2016 to show the linkage to the MDR. I predict it will appear this year.
- The manufacturer receives a service from the other economic operators
- The manufacturer must evaluate, select, and re-evaluate them under 7.4.1 Purchasing Process
- The manufacture must provide information under 7.4.2 Purchasing Information
- Since the manufacturer is outsourcing a process, then the controls must include a written quality agreements under 4.1.5

Authorized Representative

- Where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorized representative.

- The manufacturer and the authorized representative agree, in writing, on a mandate that requires the authorized representative to:
  - Verify the declaration of conformity and technical documentation
  - Keep a copy of the technical documentation, the declaration of conformity and a copy of the relevant certificates
  - Register and verify that the manufacturer has registered
  - Immediately inform the manufacturer about complaints and reports from healthcare professionals, patients, and users about suspected incidents related to the device
- The authorized representative is legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.

Importer

- Importers shall place on the Union market only devices that are in conformity with the MDR
- The importer verifies:
  - The product has a CE Mark and a Declaration of Conformity
  - The manufacturer is identified and the authorized representative is identified
  - The device is labeled and has instructions for use
  - The manufacturer assigned a UDI
  - The device is registered in EudaMed – the importer adds information
- The importer adds information to the device: their name, registered trade name or registered trade mark, registered place of business, and the address at which they can be contacted
- Importers who receive complaints or reports from healthcare professionals, patients, or users immediately forward this information to the manufacturer and its authorized representative

Distributor

- The distributor verifies:
  - The product has a CE Mark and a Declaration of Conformity
  - The device is labeled and has instructions for use
  - The importer added the required information
  - The manufacturer assigned a UDI

- Distributors ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer

- Distributors who receive complaints or reports from healthcare professionals, patients, or users immediately forward this information to the manufacturer, the manufacturer's authorized representative, and the importer

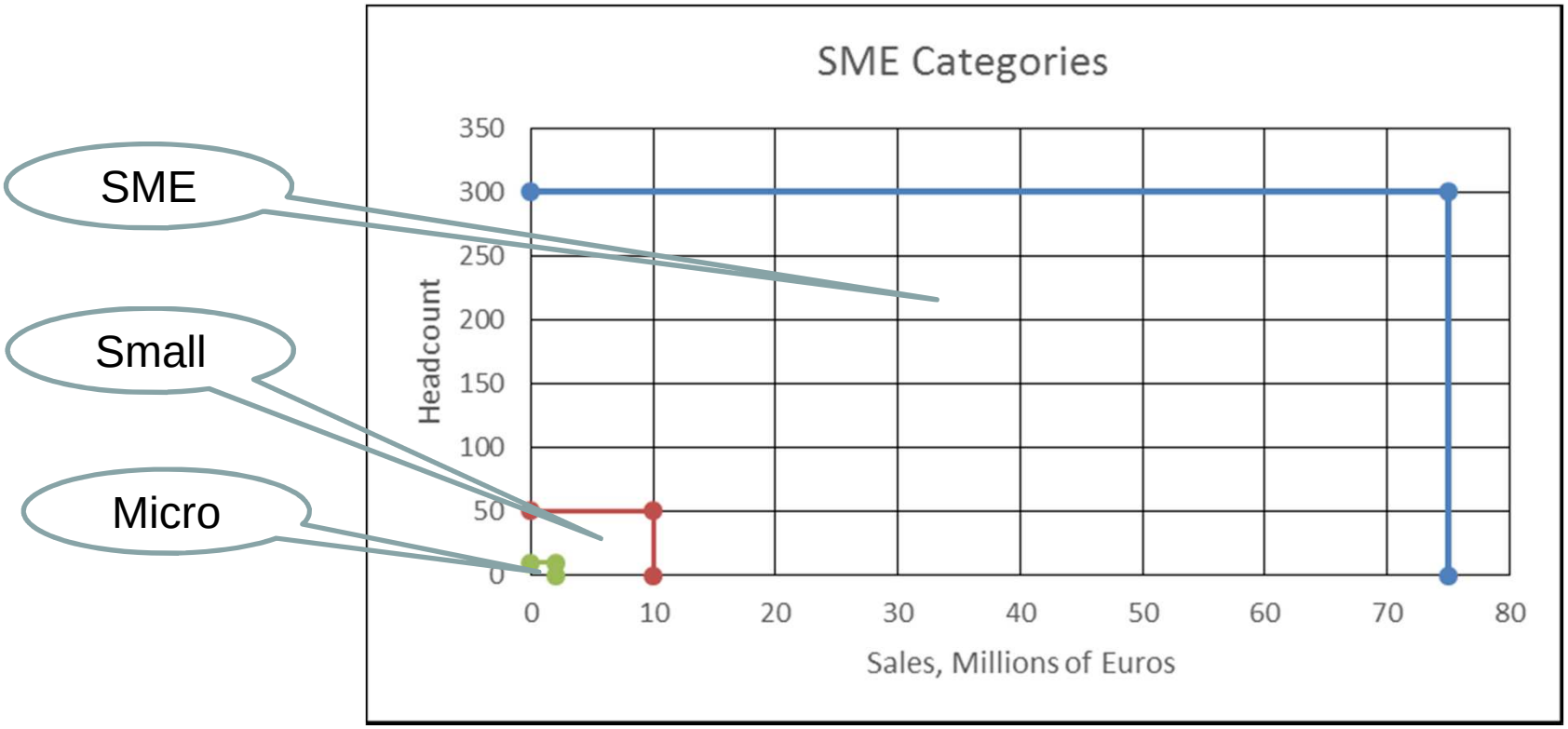
Person Responsible for Regulatory Compliance

Person Responsible – Qualification

- Manufacturers have at least person in the organization responsible from regulatory compliance
  - Micro and small enterprises only need a person permanently and continuously at their disposal

- The requisite expertise shall be demonstrated by either of the following qualifications:
  - a diploma, certificate, or other evidence of formal qualification, awarded on completion of a university degree or an equivalent course of study in law, medicine, pharmacy, engineering, or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices
  - four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

SME Categories



Person Responsible – Responsibilities

- The person responsible ensures:
  - Device conformity is checked before release
  - The technical documentation is up-to-date
  - The Declaration of Conformity is up-to-date
  - The company meets the PMS requirements
  - The company meets the reporting requirements:
    - Serious incidents
    - Field safety corrective actions
    - Trend reporting
    - Analysis of serious incidents
    - Analysis of field safety corrective actions
    - Analysis of vigilance data

Person Responsible – Qualification

- Authorized representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union.

- The requisite expertise shall be demonstrated by either of the following qualifications:
  - a diploma, certificate, or other evidence of formal qualification, awarded on completion of a university degree or an equivalent course of study in law, medicine, pharmacy, engineering, or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices
  - four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Exercise

- This exercise provides an opportunity to understand roles in various regulatory systems