EU-MDR: What are the challenges for the „other“ Economic Operators –

EU Authorized Representative, Importer, Distributor

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MDR – Status of the legal effect

- MDR -- REGULATION (EU) 2017/745
- Entry into force May 2017
- Shall apply from 26 May 2020 (with certain transition scenarios for manufacturers)

- For Manufacturer: MDR = MDD (93/42/EWG) + MEDDEV + UDI
- For Distributor: MDR = *new*
- For Importer: MDR = *new*
- For EU-Auth. Repre.: MDD + *new* + *„liability regardless of fault“*

Responsibilities of the Distributors (Art. 14)

- Every distributor has to verify:
  - CE marking on the product
  - EU-Declaration of conformity *(Note: should be available in the language of the target country)*
  - Instructions for use in the language of the target country
  - Has the importer fulfilled required tasks?
  - UDI has been assigned *(Note: Transitional periods for labelling)*
- Proof on representative samples – incl. documentation

Responsibilities of the Distributors (Art. 14)

- The distributor shall ensure storage and transport conditions. *(Note: documentation)*
- If the product does not comply with the regulation =>>
  - Stop distribution
  - Inform Manufacturer (Auth.Repr.) and Importer (In the case of serious danger or falsified products, the Distributor shall inform the competent authority of the Member State in which he is established)
- When a product was placed on the market and did not comply with the Regulation
  - Inform Manufacturer (Auth.Repr.) and Importer
  - In case of serious danger, the distributor informs the competent authority of the countries in which it was made available

Responsibilities of the Distributors (Art. 14)

- Distributors shall, upon request, provide the competent authority with all information and documentation at their disposal which is necessary to demonstrate the conformity of a device.
- ….. Distributors shall, upon request, provide a competent authority with free samples of the product or, where this is impracticable, grant access to the device.

Importer (Art. 13)

- Verify:
  - CE marking on the product
  - EU-Declaration of conformity *(Note: should be available in the language of the target country)*
  - Instructions for use in the language of the target country
  - UDI has been assigned *(Note: Transitional periods for labelling)*
  - the Manufacturer is identified and the Authorized Representative has been appointed
  - Product labelling correct?
  - EudaMed Registration available? and add their part in accordance with Article 31

Importer (Art. 13)

- If the product does not comply with the regulation? =>>
  - May not place the product on the market
  - Information to manufacturers and Authorized representatives
  - In the case of "serious danger" or falsified products, he shall inform his competent authority
- Name and address of importer on product or packaging or document (e.g. IFU or similar) – shall not obscure the manufacturer's information
- The importer must ensure storage and transport conditions

  (Note: documentation)

Importer (Art. 13)

- Register for:
  - Complaints
  - Non-conforming devices (before and after placing on the market)
  - Recalls und Withdrawals
  - Making data available for Manufacturer and Auth. Repre.
- When a product was placed on the market and did not comply with the Regulation
  - Inform Manufacturer and Auth. Repre.
  - Support with corrective actions e.g. FSCA
  - In case of serious danger, the importer shall inform the competent authorities (Countries in which it was made available) and if involved the Notified Body,

Importer (Art. 13)

- Forwards “complaints” about suspected incidents immediately to the manufacturer and the Authorized Representative
- Maintain the EU-Declaration of Conformity and certificates of the manufacturer for 10/15 years
- … provide a competent authority, upon request, with free samples of the product or, where this is impracticable, grant access to the product

Authorised Representive (Art. 11)

- Minimum for all products in a generic product group
- Written mandate
- Check
  - DoC, tech. Doc.
  - EUDAMED (+ addition)
- Need to have available
  - tech. Doc.
  - Certificates of the Notified Body (10/15 years)

Authorised Representive (Art. 11)

- Cooperation with authorities
  - Check that an appropriate the conformity assessment has been carried out
  - Guarantee product or access to product for authorities
  - FSCA
- Forwarding of complaints to manufacturers

Authorised Representative (Art. 11)

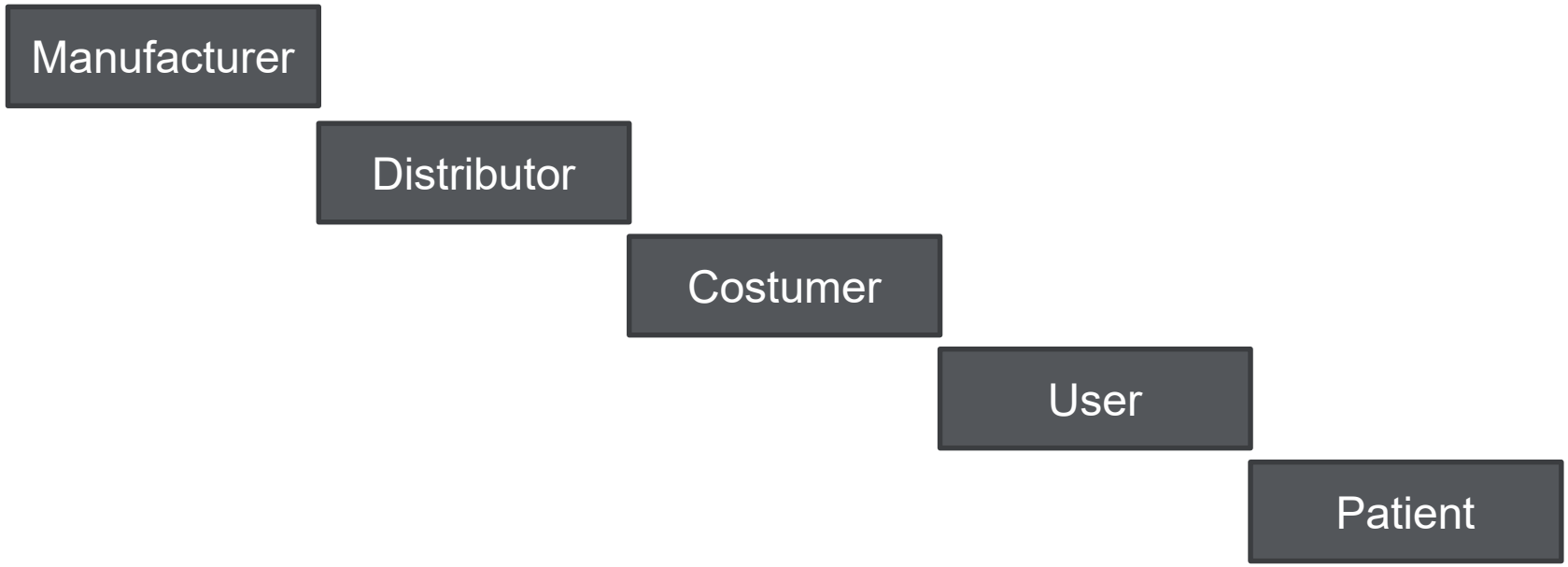
- **Termination of the mandate if the manufacturer does not comply with the regulation / violates it**
- Attention: in paragraph (4) clear definition of what the manufacturer may not delegate to the authorized representative

Authorised Representative (Art. 11)

- (5) If the manufacturer .... has not complied with his obligations under Article 10, the Authorized Representative .... shall be held jointly and severally **liable for defective products on the same basis as the manufacturer**.
- Article 15 Person responsible for regulatory compliance
  - (6) Authorized Representative shall have permanently and continuously access to such qualified person

other Econimic Operators

- Assemblers of systems and treatment units– Art. 22
- Independent Repackers / IFU translation / … – Art. 16 (not included in the definition)


Manufacturer
Distributor
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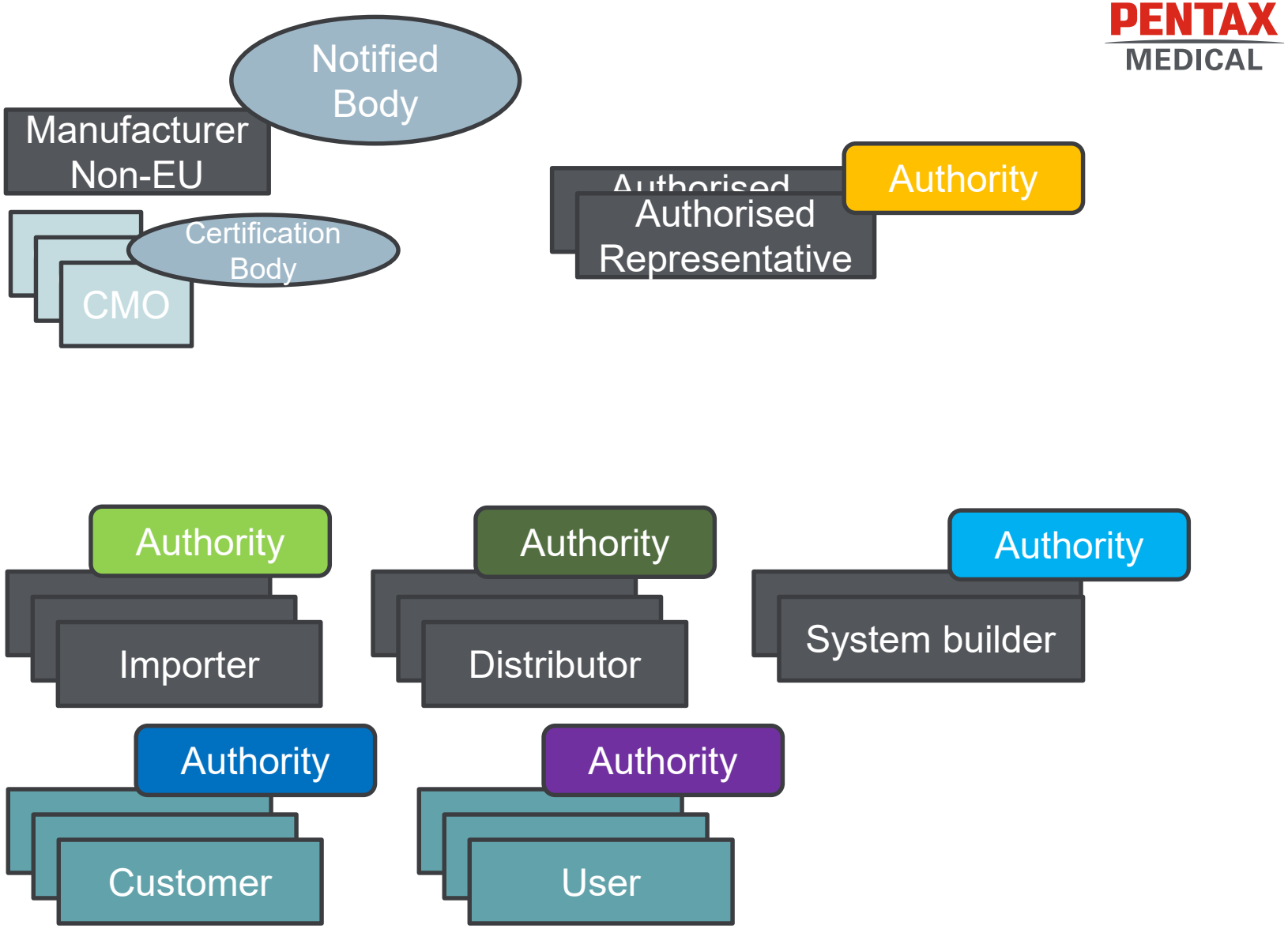
Notified Body
Manufacturer Non-EU
Certification Body
CMO
Authority
Authorised Representative
Authority
Importer
Authority
Distributor
Authority
System builder
Authority
Customer
Authority
User

Thank you!

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