HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Medical Device Regulation 2017/745

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Health Services Executive Webinar

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Health Products Regulatory Authority

Introduction

How Does This Impact Me?

Overview

- Part 1: Obligations Specific to Health Institutions
  - In-House Manufacturing
  - Reprocessing of Single Use Medical Devices
  - Implant Cards
  - Clinical Investigations

- Part 2: Roles & Responsibilities Within the Supply Chain
  - The Device Supply Chain
  - Importers
  - Distributors

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Part 1: Obligations Specific to Health Institutions

In-House Manufacturing (Article 5.5)

- In-House Manufactured Devices Conditions:
  a) the devices are not transferred to another legal entity;
  b) manufacture and use of the devices occur under appropriate quality management systems;
  c) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market,
  d) the health institution provides information upon request on the use of such devices to its competent authority (i.e. the HPRA), which shall include a justification of their manufacturing, modification and use;

In-House Manufacturing (Article 5.5)

- In-House Manufactured Devices Conditions:

e) the health institution draws up a declaration which it shall make publicly available, including:

i. The name and address of the manufacturing health institution;

ii. The details necessary to identify the devices;

iii. A declaration that the devices meet the general safety and performance requirements set out in Annex I of the MDR and, where applicable, the information on which requirements are not fully met with a reasoned justification therefor;

In-House Manufacturing (Article 5.5)

- In-House Manufactured Devices Conditions:

f) the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority (i.e. the HPRA) to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met;

g) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (f), and;

h) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions;

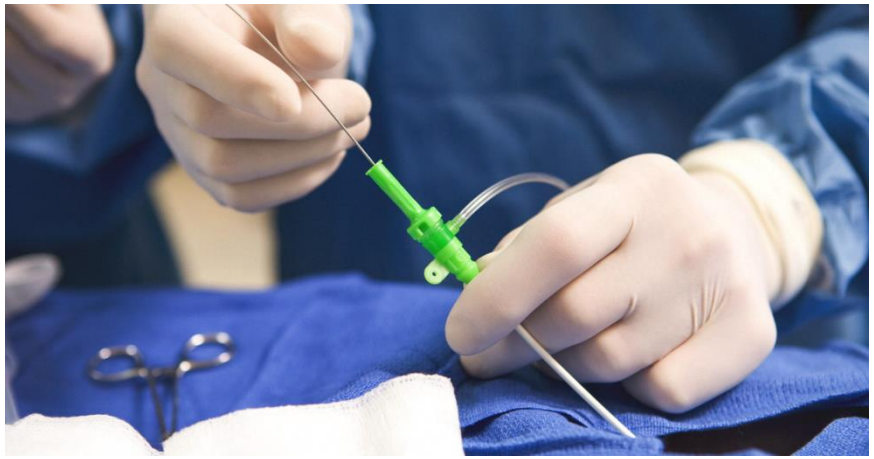
In-House Manufacturing (Article 5.5)

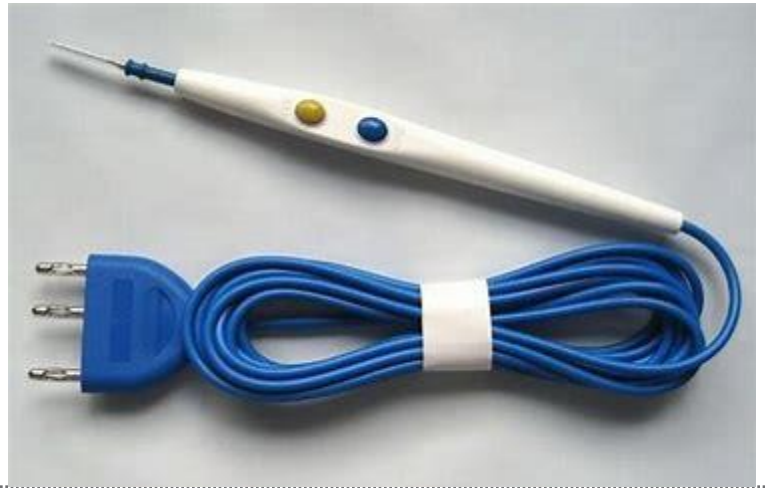
- In-House Manufactured Devices Conditions:
  - They should be registered with the HPRA;
  - They should not be manufactured on an industrial scale.

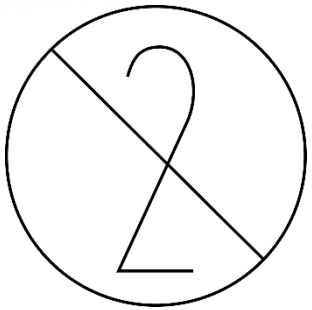
In-House Manufacturing

- Questions?
  - Are there devices which you manufacturer or modify in-house?
  - Is there an appropriate quality management system in place for these?
  - Can this target populations specific needs be met at an appropriate level by an equivalent device on the market?

Single-Use Devices & Their Reprocessing







Definitions

- ‘single-use device’ means a device that is **intended** to be used on **one** individual during a **single** procedure;

- ‘reprocessing’ means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device;

Article 17 – Single-Use Devices & Their Reprocessing.

- Only applies to devices indicated as ‘single-use’ by their original manufacturer

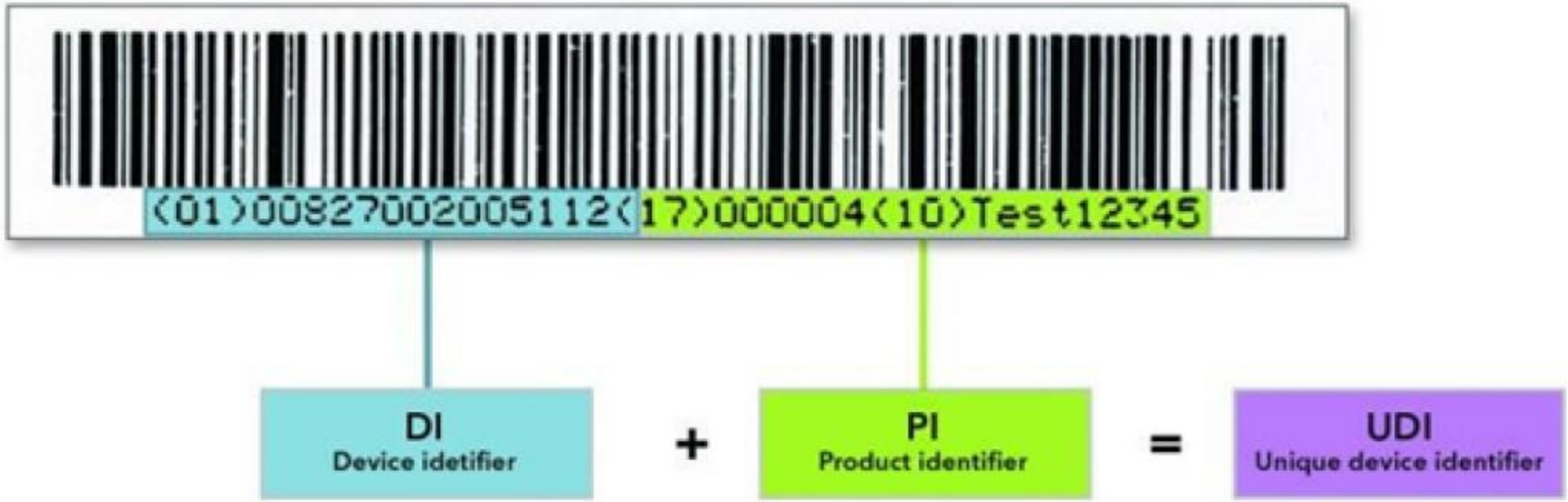
- Whether a device is single-use or not is dependent on the manufacturers labelling and instructions. Devices may have sterilisation/re-sterilisation instructions in the instructions for use (IFU), and these should be followed to avoid off-label use or undertaken the legal responsibilities of the manufacturer.

- Any reprocessing activities conducted outside of the original manufacturer’s directions/ instructions is considered reprocessing in accordance with Article 17. Any entities engaged in such reprocessing activities of single-use devices considered to be the legal manufacturer of the device for the purposes of the MDR.

Article 17 – Single-Use Devices & Their Reprocessing.

- Questions?
  - Are there SUDs which are currently being reprocessed within your practice?
  - Are you sterilising devices in accordance with their instructions for use?
  - Are your external reprocesses (commercial reprocessors) compliant with Article 17(2) and fulfilling their requirements as a legal manufacturer?

Traceability & UDIs



Traceability & UDIs

- UDIs are Unique Device Identifiers.

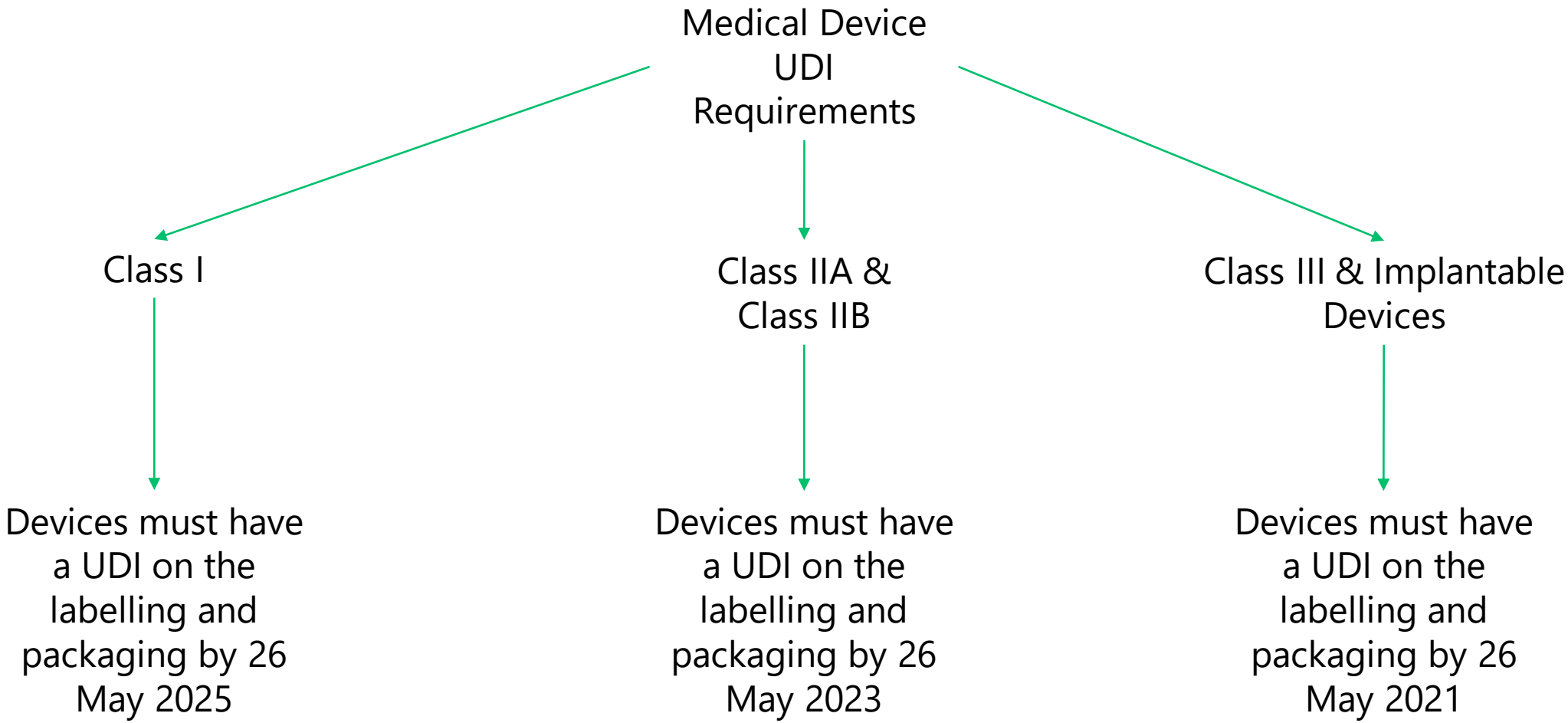
- The UDI system aims to:
  - facilitate easier traceability of medical devices;
  - significantly enhance the effectiveness of the post-market safety-related activities for devices;
  - allow for better monitoring by competent authorities;
  - help to reduce medical errors and to fight against falsified devices;
  - improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators.

Traceability & UDIs

- Health Institutions shall store and keep (preferably by electronic means) the UDI of Class III implantable devices which they have supplied or with which they have been supplied. – Article 27(9)

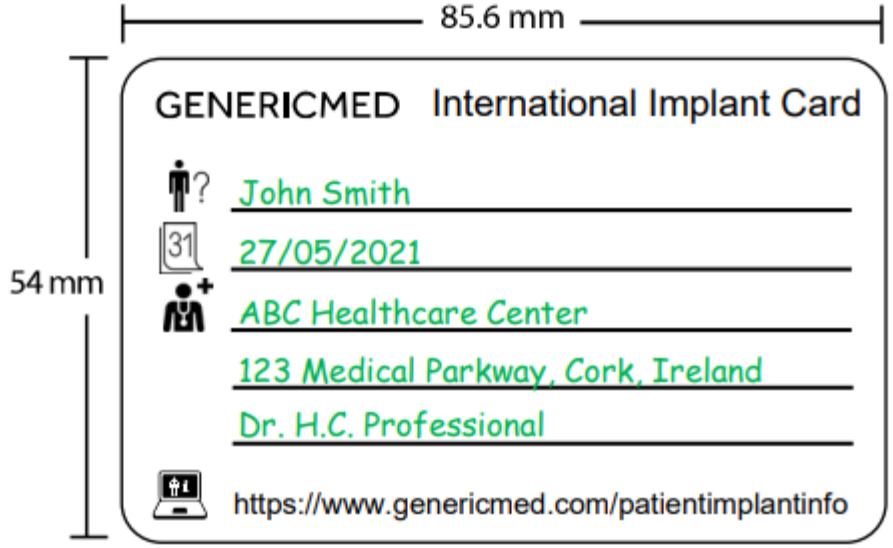
- Health Institutions and healthcare professionals may be encouraged to keep the UDIs of all devices with which they have been supplied, but must keep the UDIs of class III implantable devices at a minimum.

Traceability & UDIs



Implant Cards

Front – Not to scale (handwritten text on pre-printed content)



Back – Not to scale (blank – serial printed content in production)

Handwritten text

Content Printed on manufacturing line

Pre-printed Text (from supplier)

Implant Cards

- Implant cards
  - Aim to enable patients to access to all the relevant information concerning the devices with which they have been implanted.
  - Aim to enable patients to identify themselves as persons requiring special care in certain situations, such as during security checks, and inform emergency clinical staff or first responders about their special care/needs.

- Health Institutions are required under Article 18 to make the information on the implant card available by any means that allows rapid access to that information to any patients who have been implanted with the device.

- Health Institution also must supply patients with the implant cards where applicable.

Traceability, UDIs & Implant Cards

- Questions?
  - Are manufacturers of class III implantable devices providing you with implant cards?
  - Are you providing implant cards to all our patients?
  - Do you have systems and processes in place that will allow patients to rapidly access the information on the implant card?
  - Do you have system and processes in place for recording the UDIs of our class III implantable devices? Can we expand this to other devices if needed?

Clinical Investigations

‘Clinical Investigation’ (CI) is defined in the MDR as any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device.

Clinical Investigations

Types of Clinical Investigations:

- **Pre-market clinical investigations** (i.e. devices without a CE mark) (see Article 62 of the MDR).
- **Post-market clinical investigations** (i.e. post-market clinical follow-up (PMCF) investigations) (see Article 74 of the MDR).
- Clinical Investigations undertaken for purposes other than those listed in **Article 62** of the MDR (see Article 82 of the MDR and the additional requirements laid out in S.I. No. 261 of 2021).
- Clinical investigations of medical devices without an intended medical purpose (see **Annex XVI** of MDR).

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Part 2: Roles & Responsibilities Within the Supply Chain

Roles & Responsibilities Within the Supply Chain

- ‘importer’ means any natural or legal person established within the Union that places a device from a third country on the Union market;
  - See Article 13 for general obligations

- ‘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;
  - See Article 14 for general obligations

- Strongly linked to the legal/financial transfer of ownership and whether devices are made available to others on the union market.

Supply Chain

EU-Based Manufacturer

Distributor

End Users

Supply Chain

Non EU-Based Manufacturer

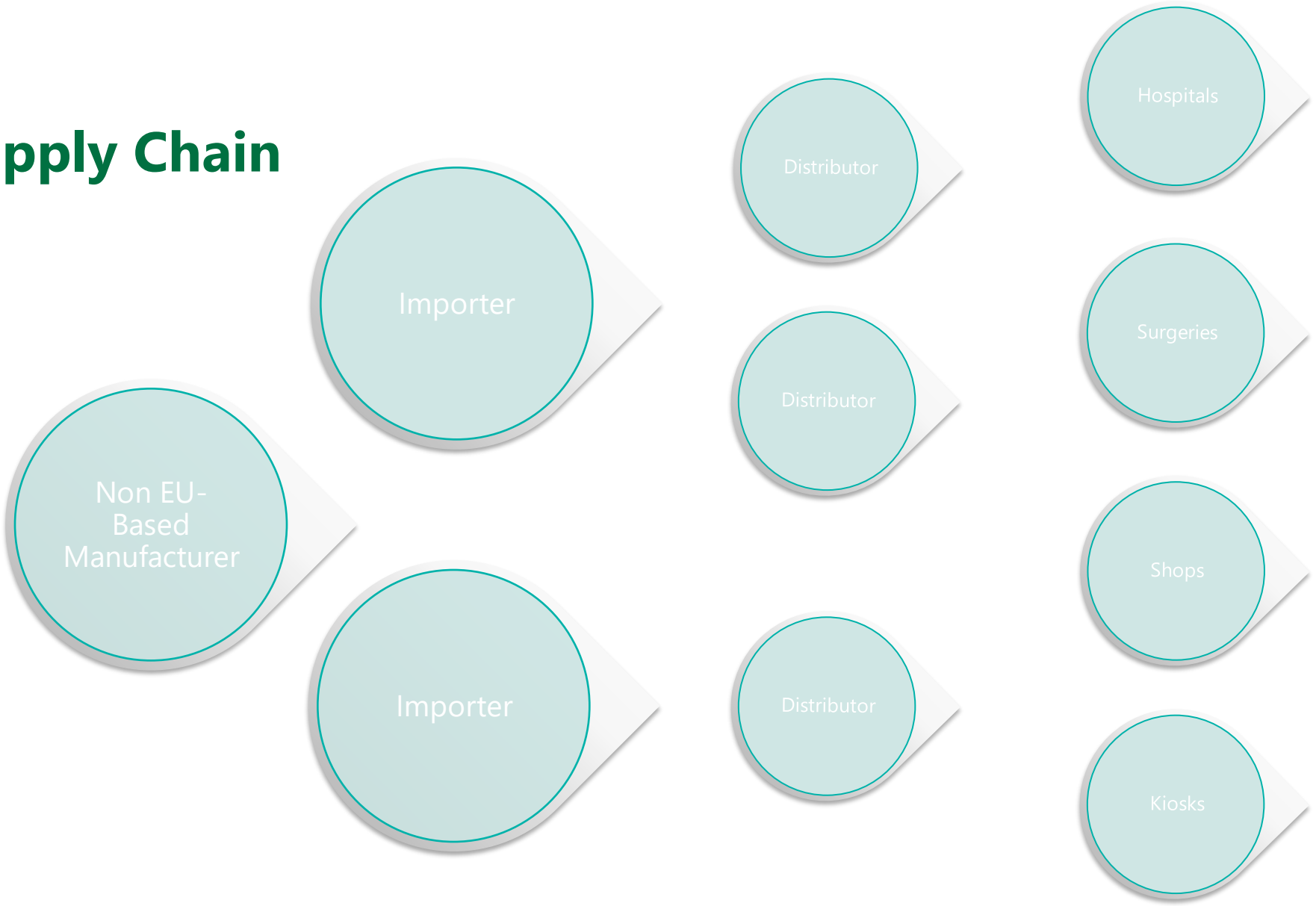
Importer

Distributor

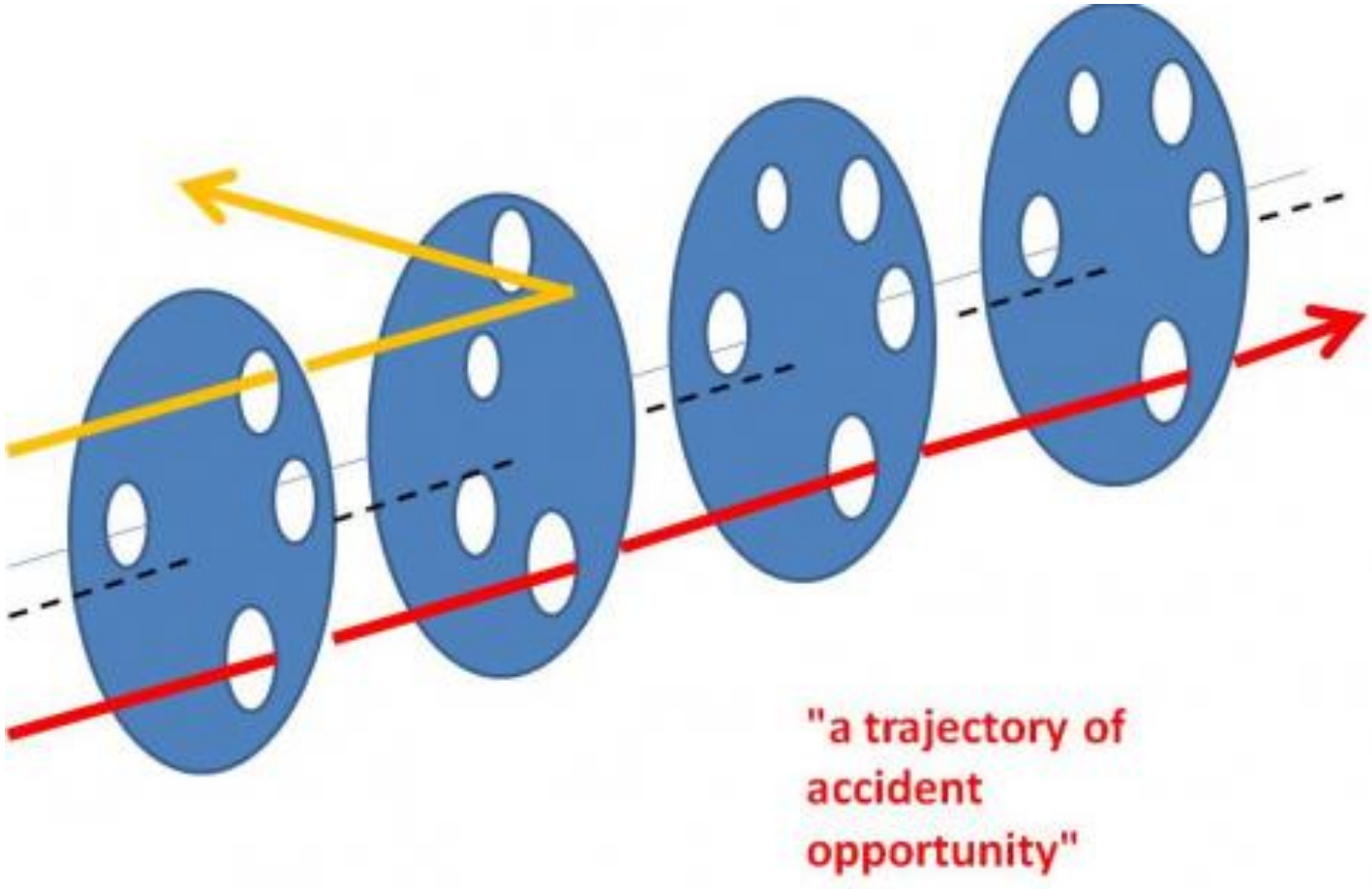
End Users

EU-Based Authorised Representative

Supply Chain



Reason's Swiss Cheese Model



Roles & Responsibilities Within the Supply Chain

- Each EO has their own set of obligations, and must comply with the MDR in full.
- Each EO must complete their own checks and validation.
- It is not possible to delegate legal responsibilities to another EO.

Roles & Responsibilities Within the Supply Chain

- Questions
  - Am I meeting the definition of an importer or a distributor?
  - What are my obligations? Do we need to review our processes to ensure we conduct the required checks or record the necessary information?
  - Where can I learn more on these requirements so that I can better plan our MDR implementation and ensure compliance?

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Further Information & Guidance

Further Information & Guidance

Fact-sheets, infographics and guidance are available on the HPRA's website:

http://www.hpra.ie/homepage/medical-devices/regulatory-information/new-eu-device-regulations/useful-documents

A detailed HPRA webinar on the medical device supply chain and economic operator obligations is also available on the HPRA's website :

http://www.hpra.ie/homepage/medical-devices/regulatory-information/new-eu-device-regulations/webinars-implementation-of-mdr-and-ivdr

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Thank You!