UDI - Tracing & Reporting

EAHP

Gothenburg, Sweden

22 & 23.03.2018

famhp
federal agency for medicines and health products

Valérie Nys
Program Manager

.be

DISCLOSURE

Conflict of Interest : nothing to disclose

Self –Assessment questions

Answer yes or no

1. **Does the basic UDI has a traceability purpose ?**

2. **Is the application date for UDI registration in Eudamed the same for all risk class devices ?**

3. **In Belgium, is the traceability project applicable for all medical devices ?**

UDI :
the Forever Project
or
the neverending project ?

Back to the beginning

Starting point in 2008

Post Market Surveillance of products

- a challenge for manufacturers, users and authorities
- in case of corrective actions good track and trace systems are necessary for appropriate reactions
- there are different voluntary machine readable device identification system available (e.g. GS-1,HIBIC). Main purpose of these systems is the economical and logistical optimisation.
- However supply chain and healthcare sector infrastructure don't use the same or an uniform device identification system

Idea: Making the use of auto-identification technologies mandatory

- could increase the safety of medical devices
- could reduce costs
- could optimise the processes in the public healthcare service
- could be a model for an efficient global medical devices surveillance system

5

UDI System & Objectives

UDI assigned to all devices unless excepted	**Clearly identify the device**
Create and maintain UDI Database	**UDI Database as authoritative source for key identification attributes**
Integrate UDI into electronic health information	**Use UDI data to improve device evaluation and patient, clinical and regulatory decision-making**
DI & Basic UDI as key to unlock device identification data	

UDI in new regulation MDR / IVDR

7

What is MDR / IVDR ?

- Major European Union Medical Device Regulatory Reform
- Move from 3 Directives to 2 Regulations (direct effect)
  - Medical Devices Regulation (MDR) 2017/745
  - In Vitro Diagnostics Regulation (IVDR) 2017/746
- Key Point : Restore confidence across the industry
  - Reinforced conformity assessment
  - Clearer obligations for economic operators
  - Greater emphasis on supply chain traceability – Introduction of UDI
  - Enhanced market surveillance by authorities

UDI - MDR / IVDR timeline

UDI must be placed on the Label and reported to EUDAMED within 1 to 5 years after the Date of Application according to the device class

Device Class	UDI in Eudamed *	UDI on label	UDI Direct Mark on Reusable
MD Class III & Implantables	26 May 2020	26 May 2021	26 May 2023
MD Class IIa & IIb	26 May 2020	26 May 2023	26 May 2025
MD Class I	26 May 2020	26 May 2025	26 May 2027
IVD Class D	26 May 2022	26 May 2023	26 May 2023
IVD Class B & C	26 May 2022	26 May 2025	26 May 2025
IVD Class A	26 May 2022	26 May 2027	26 May 2027

* report to Eudamed before placing on the market

MDR / IVDR UDI Requirements

Label

- Add UDI (Device Id + Production Id) on Device Label & Package
- Present UDI in human-readable plain-text and Automatic Id and Data Capture (AIDC) technology

Direct Marking (DM)

- Permanently mark UDI on reusable devices

EU UDI Database (EUDAMED)

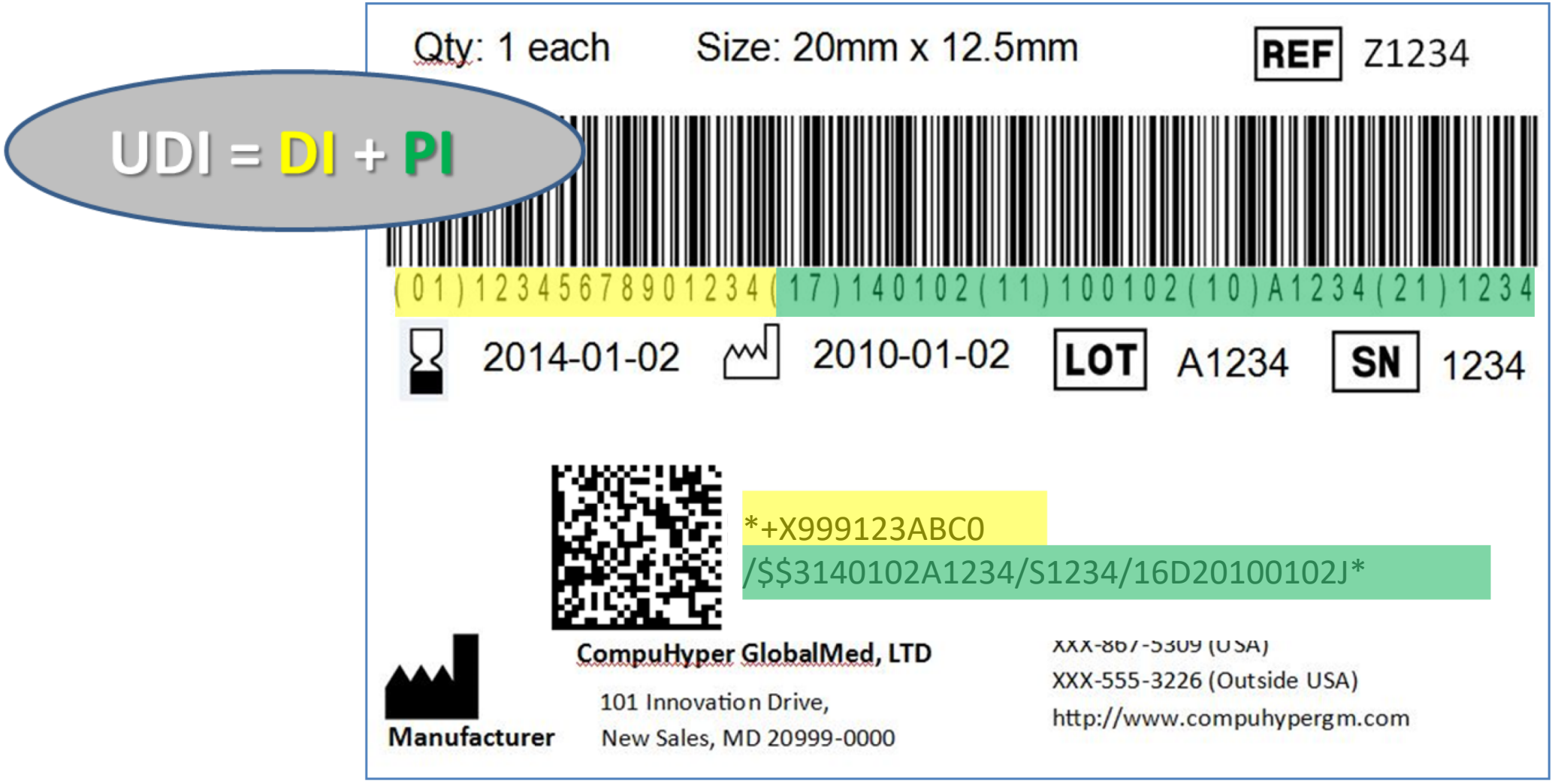
- Submit DI, Basic UDI and device attributes to **EUDAMED before placing on the market**
- Basic UDI – Key to Eudamed / Way to regroup UDI

Reporting

- Include UDI in Annual Reports, Post Marketing Surveillance, Incident report

Traceability

- Storage of UDI for class III implantable devices by economic operator, Health Institution and Healthcare professionals by electronic means
- Member states shall encourage and may require Healthcare professionals to store and keep preferably by electronic means the UDI of the devices they have been supplied with
- Implant card for the patient



Basic UDI – Not on Label / only in Eudamed

Implementation of Traceability in Belgium

12

Context

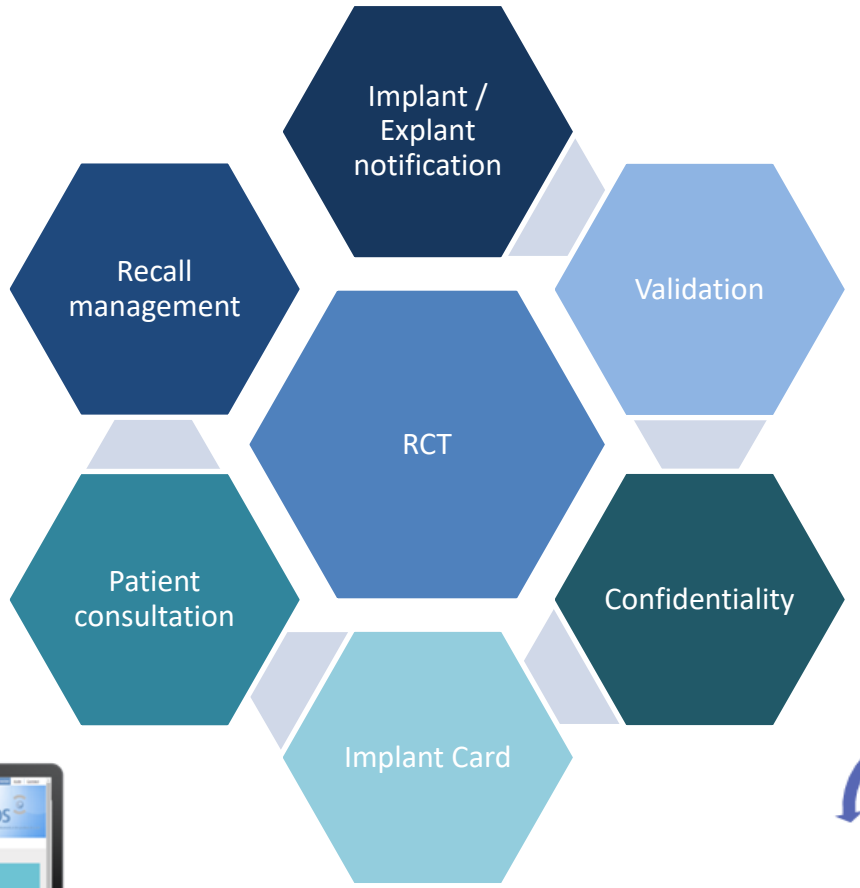
PIP Scandal

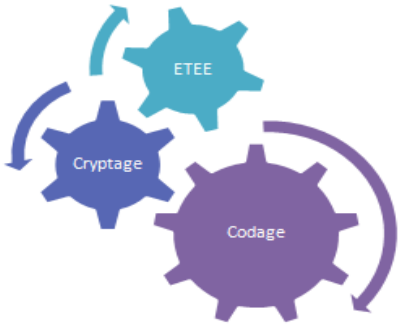
- Plan for improvement in the Medical device sector in Belgium
- Build a traceability system
- Ensure more transparency to the patient

Start of the RCT & TDMI Projects

13

RCT: Traceability Register





RCT: Major Functionalities

Implant notification

Consultation

Get implant card

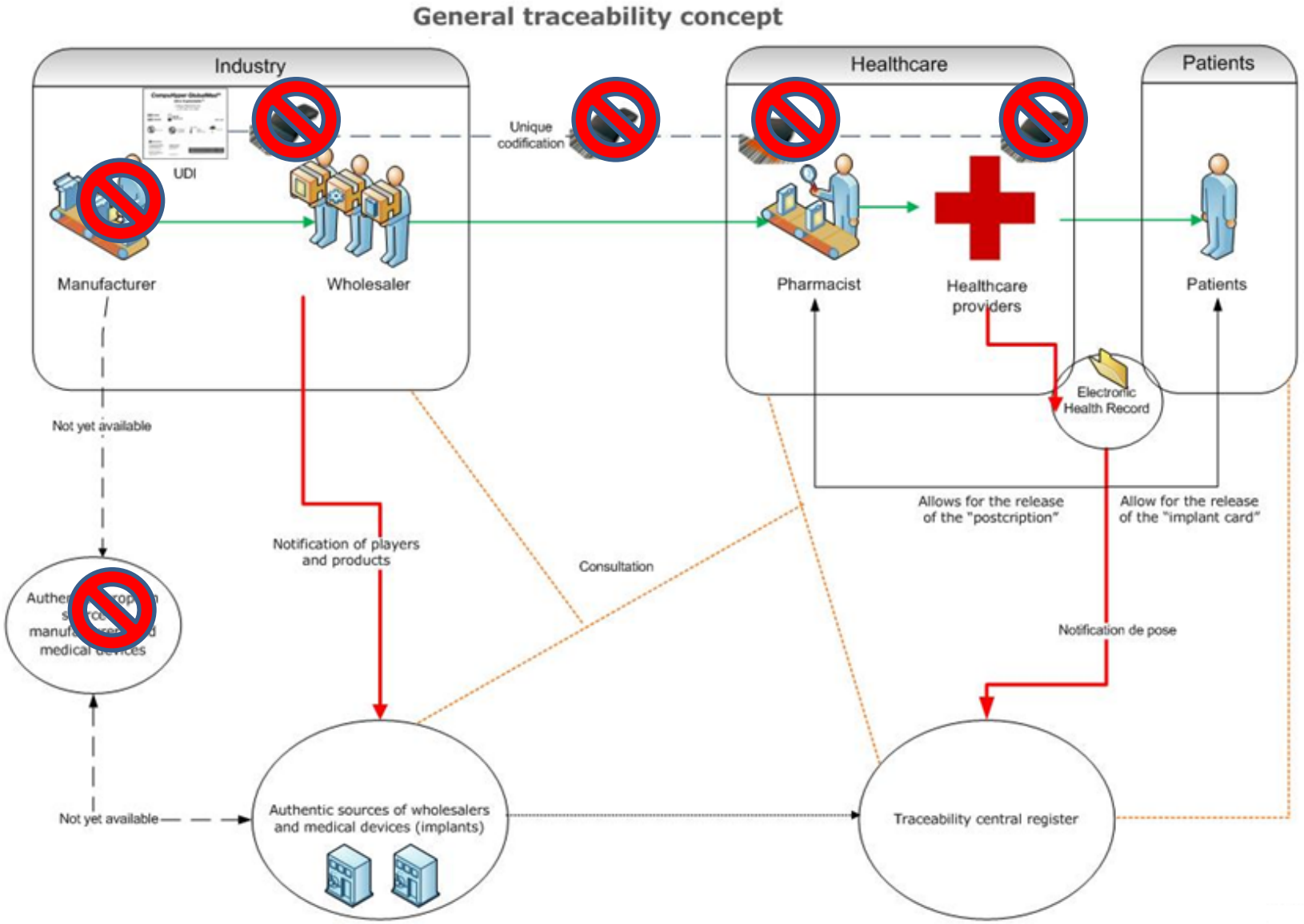
Data warehouse (anonymization)

Consultation Rapid Alert – recall

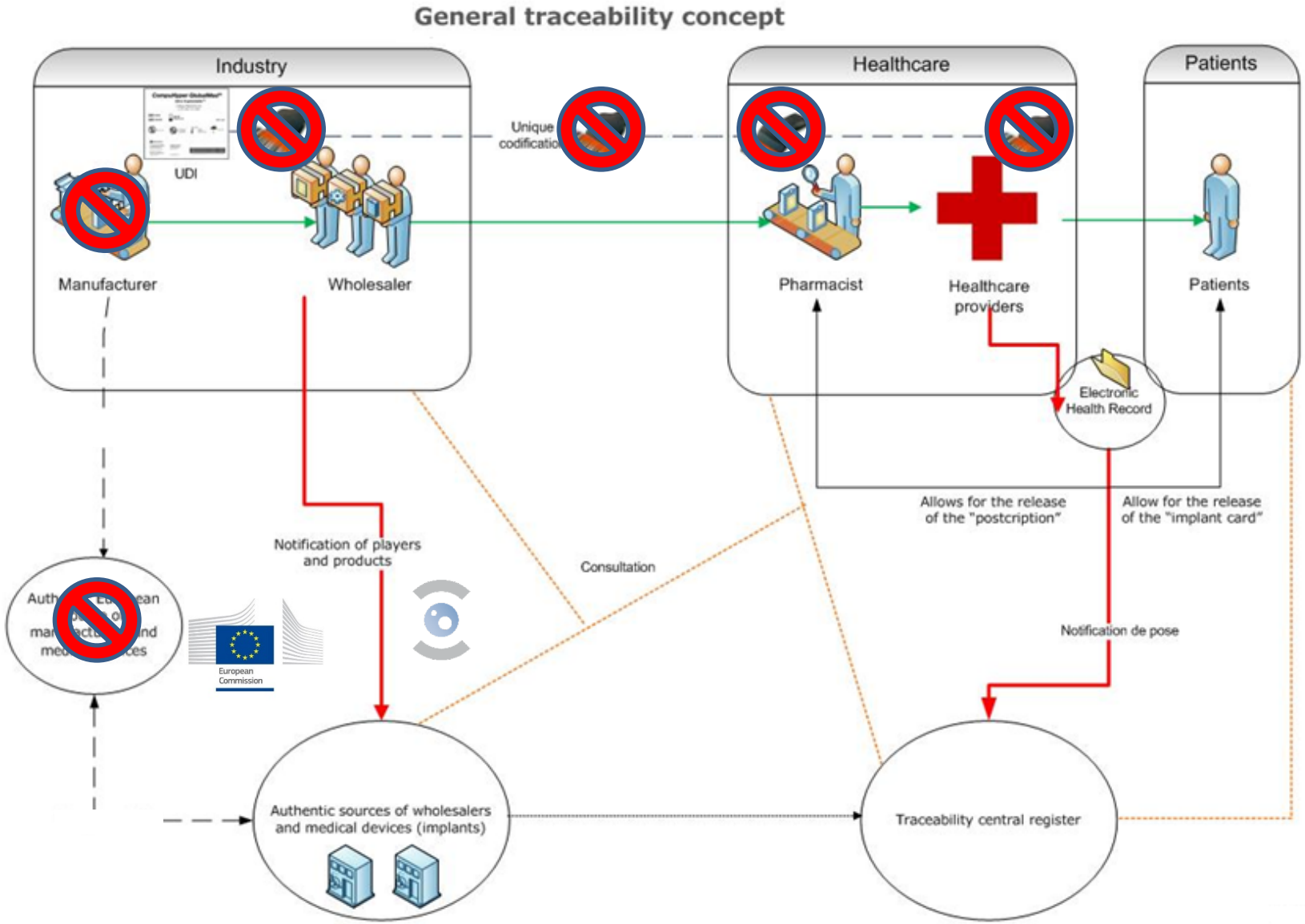
Consultation of notifications

Implant Card

TDMI: Traceability of Medical devices



TDMI: Traceability of Medical devices



Next steps short term

Pilot phase running

- Scope: 10 implants family
- Mandatory Use second half 2018 ?

Stent	Esthetics of reconstructive implant
Neuro stimulator	Electrode and biosensor
Cochlear implant	Mechanics heart implant
Hydrocephalus shunt	Electronics and electrics heart implant
Orthopedics implant	ophthalmic implant

Next steps mid-term

- **Integration with Eudamed**
  - change in validation process / Integration UDI
  - scope : class III devices and implants

What’s in it for me ?

20

Expected Outcomes UDI & traceability

More rapid and accurate device data capture at the point of care

More accurate detection of safety events

More effectively manage medical device recalls

A more secure global, supply chain, helping to address counterfeiting and diversion and prepare for medical emergencies

Self –Assessment questions

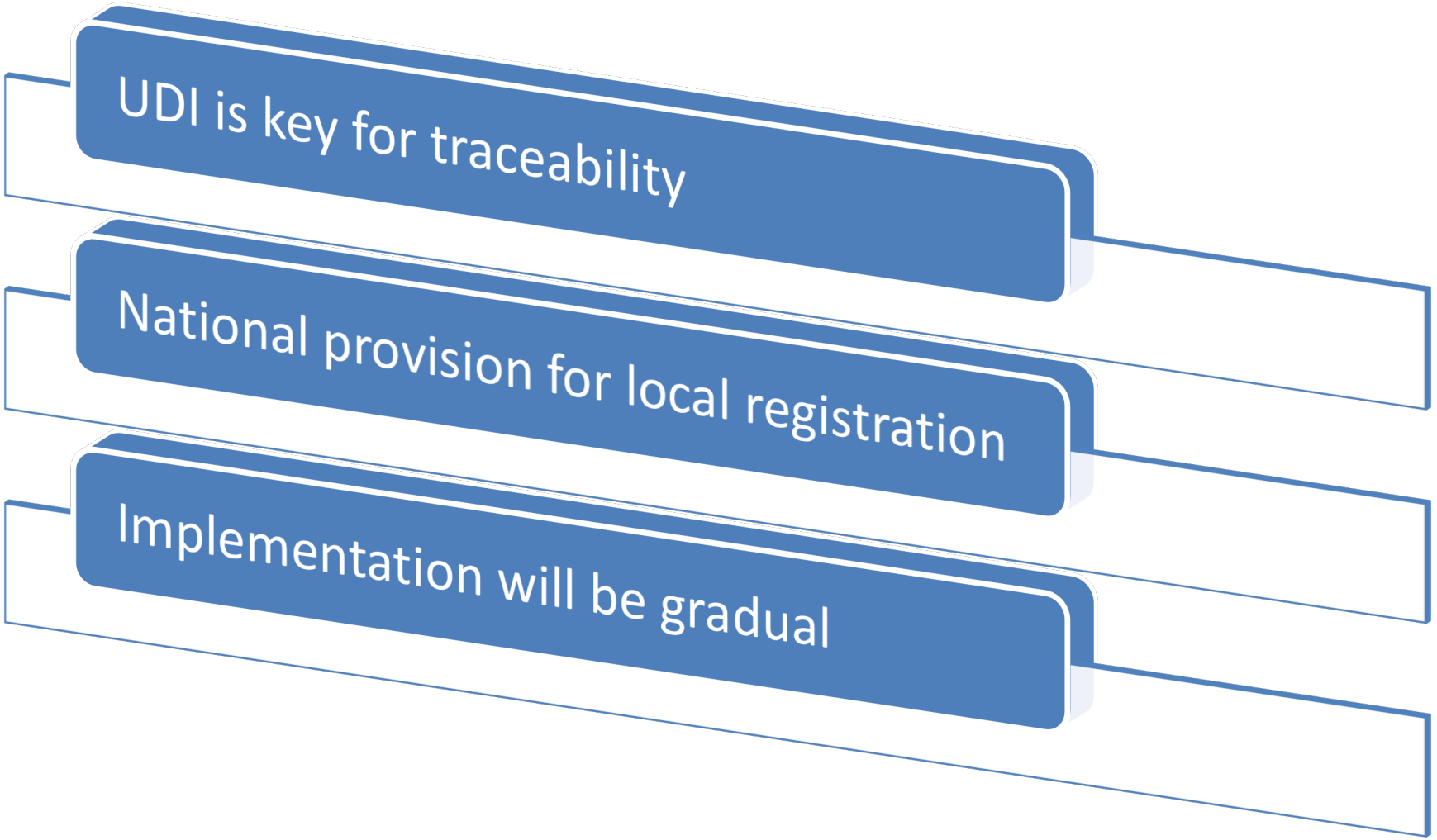
Answer yes or no

1. **Does the basic UDI has a traceability purpose ?** **No**

2. **Is the application date for UDI registration in Eudamed the same for all risk class devices ?** **Yes**

3. **In Belgium, is the traceability project is applicable for all medical devices ?** **No**

Take Away messages



Contact

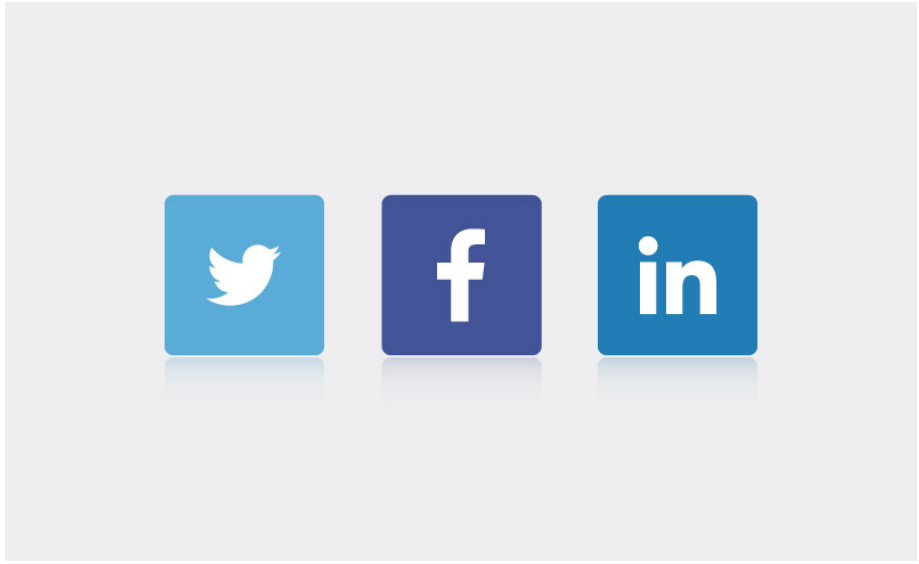
Federal Agency for Medicines and Health Products – FAMHP

Place Victor Horta 40/40
1060 BRUXELLES

tel. + 32 2 528 40 00
fax + 32 2 528 40 01
e-mail meddev@fagg-afmps.be

www.afmps.be – www.fagg.be

Follow the FAMHP on Facebook, Twitter and LinkedIn



Your medicines and health products, our concern

famhp

.be