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Challenges Ahead for INFARMED I.P. Codification and Traceability Systems

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Summary

- Falsified Medicines Directive:
  - Safety features
- Codification Projects
  - Reimbursement
  - Medical Devices
- Next Steps

Directive 2011/62/EU published 1 Jul 2011
FMD: *Falsified Medicines Directive*

- Amending Directive 2001/83/EC relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products

- Entry into force: 2 January 2013

- Safety Features: 36 months after Delegated Act

Safety Features: Art.54.º-A

- Introduces obligatory 'safety features' to allow verification of the authenticity of medicinal products ('unique identifier')

- Delegated act to be adopted by the Commission setting out the details relating to the unique identifier

- Consultation period from 18 November 2011 to 27 April 2012
  - contributions published on European Commission website

Delegated Act: Safety Features

- the characteristics and technical specifications of the unique identifier;
- the modalities for verification of the safety features;
- the provisions on the establishment, management and accessibility of the repositories
- system in which information on the safety features is to be contained;
- the lists containing the medicinal products or product categories which, in the case of prescription medicines do not have to bear the safety features, and in the case of nonprescription medicines must bear the safety features;
- the procedures for the notification of medicinal products by the national competent authorities to the Commission, as regards medicinal products at risk of falsification or not at risk of falsification.

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UI - Unique Identifier

- Authentication of package through *Unique Identifier holding a serialisation number*

- Serialisation number to contain, as a minimum, a manufacturer product code and the pack number

- Aditionally it may contain batch number, expiry date and eventually reimbursement code

UI Characteristics & Technical Specifications

- Harmonization of technical specifications of UI (as guarantee of system interoperability)

- 2D barcode as a data carrier for the unique identifier:

  - Allows the storage of a large amount of information and is suitable for small packs

  - Considered a more reliable and affordable carrier

Modalities for Verification

- *End-to-end verification:* Product registered by manufacturer and checked out when dispensed

- Additionally to end-to-end:
  - Systematic check by the wholesaler/distributor:
    - High financial and logistical costs
    - Delays in distribution

- Risk-based assessment verification (random checks) when:
  - the product is not obtained by the wholesaler from the manufacturing authorization holder or the marketing authorization holder;
  - the product is returned to the wholesaler from another wholesaler or person authorized to sell medicines to the public.

Repository System

Options:

- **Stakeholders governance**
  - Viewed as the most cost/effective option by most stakeholders
  - Necessary to establish adequate means of access to information by EMs and data protection
- **EU governance**
  - Harmonized system
  - Protection of commercial confidential information
  - Complex and Costly
- **National governance**
  - Independance of the system
  - Protection of commercial confidential information
  - 27 separate systems: greater complexity and costs
- **Hybrid Sistem**
  - Stakeholders: Implementation and managemet
  - EU or MSs: Control and acessibility

Next Steps

- Follow on going discussion on delegated act
- Meetings with national stakeholders to agree on national strategy
- Transpose legislation into national medicines act
- Regulatory scientific advice if needed

Codification of medicinal products

Codification of medicinal products Registry Number

- For medicinal products with MA in Portugal
- Unique Code for each medicinal product
- Included data:
  - Active substance/INN
  - Pharmaceutical form
  - Dosage
  - Presentation
  - Brand name
  - MAH
- Also used in monitoring medicines use linking several databases
  - National Health Service (SNS)
  - Total market
  - Sales declaration in the scope of commercialization fee.

Advantages

- Access to national market data
- Use monitoring
- Access to information on commercialization and dispensing of medicines
  - Also from hospital market through national hospital medicines code
- Data cross-check gives room for improvement

Codification of Medicines for Hospital Use

Until 2007:

- Different codes and descriptions for each hospital
- Impossible to exchange information between hospital and NHS bodies
- No monitoring of hospital usage

Necessity to codify

Hospital Medicines National Code – CHNM

CHNM:

- Identifies unequivocally a set of features for medicinal products
- Applies to all medicines with MA in Portugal
- Established to manage medicines in hospitals: prescription, dispensing, purchasing and use monitoring
- For all hospitals and NHS bodies

CHNM

CHNM description:

- INN
- Pharmaceutical Form
- Dosage
- Route of administration
- Packaging

Aditional Information for each CHNM

- CFT and ATC classification
- Classification for dispensing
- MA status
- Information on special pathologies
- Information on pricing and reimbursement
- If included in the national hospital formulary
- Brand name
- SPCs and FIs
- MAHs

Advantages

- Continuous update of hospital databases
  - Infarmed has a monthly list of all medicines
- Flexibility of purchasing procedures by hospitals through SPMS catalogue
- Establishing a consumption monitoring system in hospitals
- The consumption monitoring system provides:
  - Reliable and comparable information
  - Periodic information - monthly upload of hospital consumption in INFARMED's database
  - Timely Information – publication of monthly reports
  - Data in value and volume for active substances, dosage , pharmaceutical form

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Codification of Medical Devices

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European Database EUDAMED

Centralized Registry of Medical Devices

Constraints:

- No guarantee of unique identification of medical devices
- Non compulsory registry of all medical devices

UDI (Unique Device Identification)

- International Codification Project
- Main Objective: traceability of medical devices to protect public health
- Code composed of fixed part (Device Identifier) and *variable* part (Production Identifier);
- Guarantees the unique identification of medical devices up to production level (batch/serial number)

National Codification Project

Objectives:

- Traceability for vigilance purposes
- Tool to support NHS allowing for quantification, valorisation, communication

Code concept

- Symbol representing the identification and features of the medical device
- Unique identification obtained only through combination of manufacturer/reference

National Codification Project

Data origin:

Online registry of medical devices at INFARMED portal

- 2003 - 2011 – registry of medical devices families
- 2011 onwards – ramification of references and data update

National Codification Project

Code characteristics

- Sequential/non-intelligent

Features:

- Manufacturer
- Reference given by the manufacturer
- Brand
- Model
- NPDM Classification

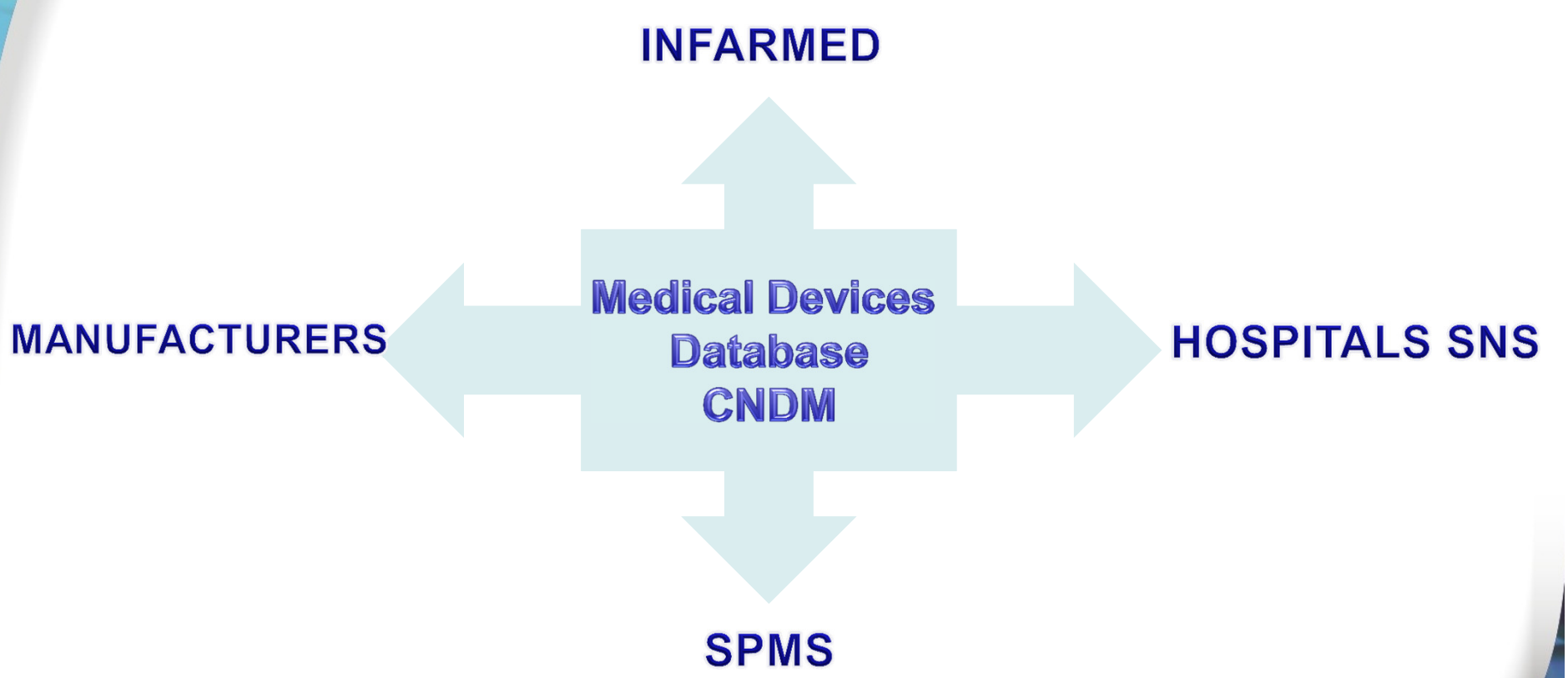
National Codification Project

NPDM Classification

- Medical Devices names
- Grouping of Devices: use/technological specifications/anatomical location
- Harmonization in description associated to unique code

Measure 3.65

Finalize the codification system and a common registry for supplying medical material to be established by INFARMED and SPMS based on international experience. Update the record periodically.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MANUFACTURERS
Medical Devices
Database
CNDM
HOSPITALS SNS
SPMS

Room for improvement…

- financial sustainability of the National Healthcare Service
- participation of different stakeholders across the Healthcare's supply chain
- 100% traceability is fundamental for patient safety

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Thank You!

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