OPENMEDICINE

Meeting the global challenge of unique identification of medicinal products

Meeting the cross-border challenge of unique identification of medicinal products

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ETSI eHealth Open Meeting on Health and the Internet of Things (HIT)

Sophia Antipolis, Nov. 20, 2015

ETSI

OPENMEDICINE is a project funded by the European Commission in the context of HORIZON 2020

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- **MBA** (Diplom-Kaufmann) Berlin, Free University – 1968
- **PhD** (International Finance, Business Administration, Economics) University of British Columbia, Vancouver, BC, Canada – 1974
- **eHealth projects** in Europe, trans-Atlantic and Africa

The business case

Have you ever visited a pharmacy in a foreign country presenting a prescription from your doctor at home and the pharmacist did not have a clue?

- What is needed:

- Univocal identification of a medicinal product (MP) prescribed in another country
- If the (identical) MP is not available, suitable regulation of substitution in the country of dispensation

- Why it is needed:

- Assuring patient safety of cross-border ePrescription/Dispensation
- Assuring continuity of care cross borders

European Union policy priorities

A Digital Single Market Strategy for Europe

- **Digital interoperability & standardisation in the health domain as a means to boost competitiveness:**

> *The Commission will launch an integrated standardisation plan to identify and define key priorities for standardisation with a focus on the technologies and domains that are deemed to be critical to the Digital Single Market, including essential sectoral interoperability and standards in areas such as health (telemedicine, m-health), transport (travel planning, e-freight), environment, and energy. The Commission will revise and extend the European Interoperability Framework.*

Source: COM(2015) 192 final; Brussels, 6.5.2015, p. 16

The solution

The overall concept to solve the problem is to develop concrete solutions in a global context:

- A common data model (a set of coherent conceptual, logical and implementable data models) - expanding upon the ones developed by epSOS[1] and facilitating adoption of the ISO IDMP set of standards[2]
- A common nomenclature (a set of code and identification systems) for the unambiguous definition, description, and identification of medicinal products, pharmaceutical products, and ingredients
- Global cooperation: European Medicines Agency (EMA), FDA, national drug agencies and health authorities, industry, other stakeholders

This will be complemented by

- a report on substitution
- a set of recommendations, as well as
- a roadmap for implementation

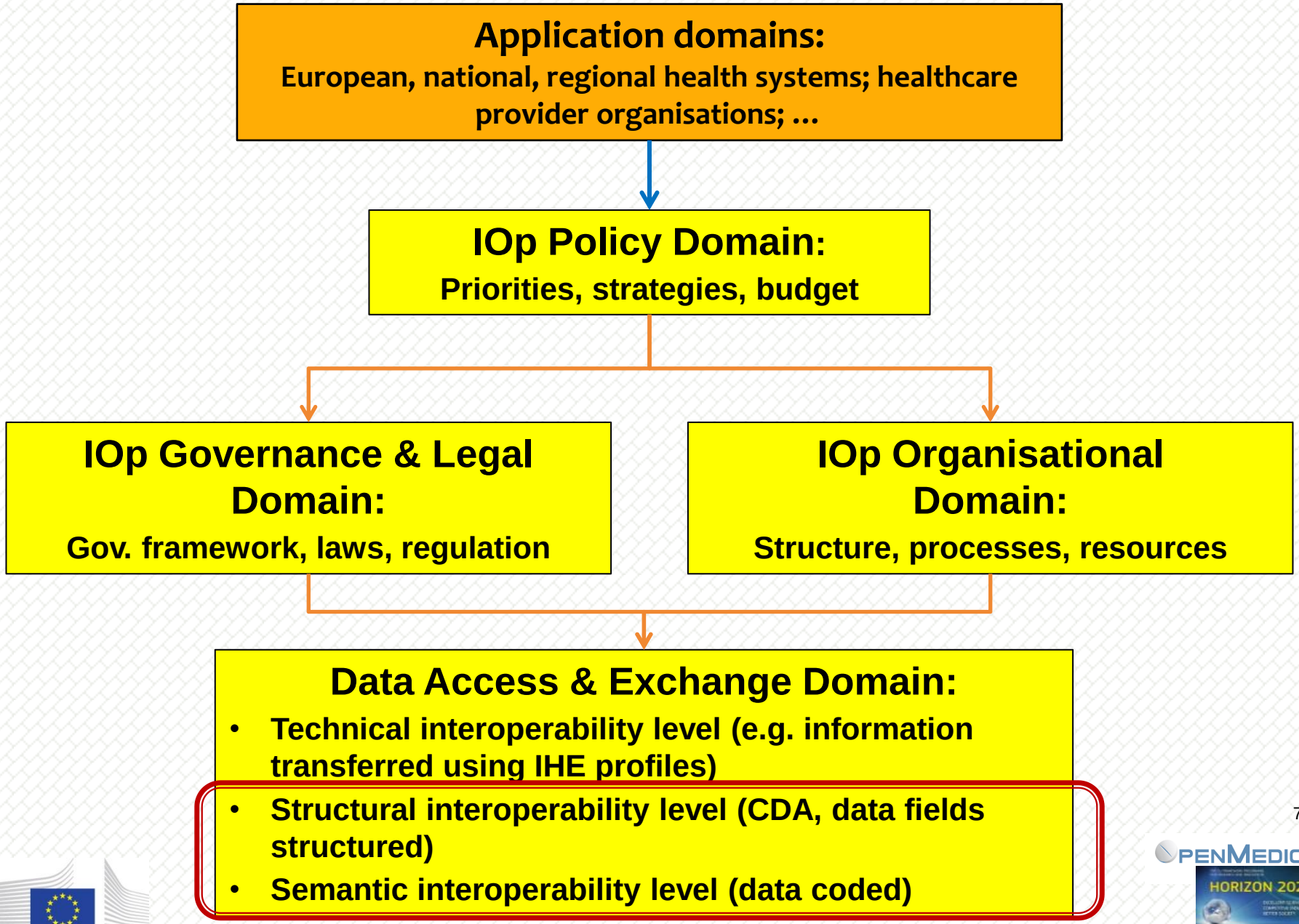
[1] epSOS - Smart Open Services for European Patients - Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription

[2] ISO IDMP suite (11615/16, 11238-40) - Identification of medicinal products

Identification

- Identification is more than assigning a code
- A code is one possible identifier
- Identification = defining the minimal set of descriptive attributes of a medicine
- Content of the set depends on the kind of medicine
- A core challenge is to define the different “sets of identifying attributes” required to identify a medicinal product or a pharmaceutical product in a given context / for a given application

Conceptual approach – Interoperability framework



Identification levels: from substance to cluster

- Cluster : no identifier << possible?
- Pharmaceutical or therapeutic class

- Medicinal Product Package
- Package identification NATIONAL
- Extended identification: each instance of a medicinal product package

- Medicinal Product
- Marketing authorisation holder
- NO / not always an identifier

- Pharmaceutical product
- Manufacturer => batch / Batchnumber
- **NO identifier. No name. Description of a composition**

- Manufacturer => batch => batch number
- Substance => Ingredient => active ingredient OR excipient
- Ingredient Identifier <= ATC or INN

The ISO IDMP suite (11615/16, 11238-40) is only a starting point

Related standards

- **No single standard is addressing the full identification issue**
- **ISO IDMP suite:**
  - 11615… for the unique identification and exchange of regulated *medicinal* product information
  - 11616… for the unique identification and exchange of regulated *pharmaceutical* product information
  - 11238… for the unique identification and exchange of regulated information on *substances*
  - 11239… for the unique identification and exchange of regulated information on pharmaceutical *dose forms, units of presentation, routes of administration and packaging*
  - 11240… for the unique identification and exchange of *units of measurement*

Envisaged solution: EMA Art. 57 DB on Medicinal Products and pharmacovigilance will adopt ISO IDMP standards

Substance Information:
- S1: Substance names
- S2: Substance Translations
- S3: Substance synonyms
- S4: Substance class
- S5: Reference source
- S6: International Codes

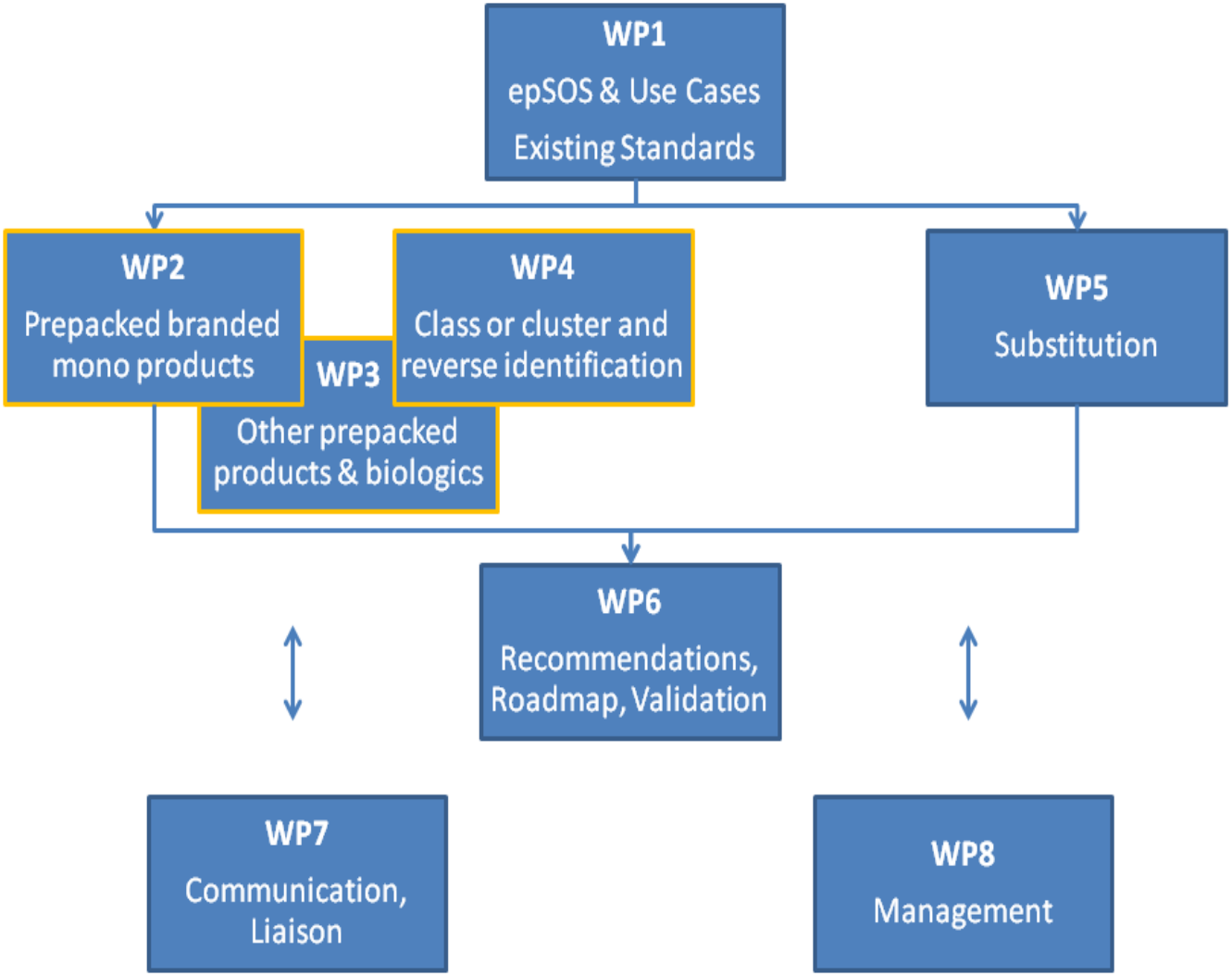
Reference Terminology:

-R1: Pharmaceutical form
-R2: Route of Administration
-R3: ATC codes
-R4: Units of Measurement
-R5: Units of presentation
-R6: Reference source

Organisation information:
-O1: MAH (Legal Entity) details
-O2: QPPV
-O3: PhV Enquiries
-O4: PhV System Master File

Structured Medicinal Product Information:
- P1: MAH (Legal Entity)
- P2: QPPV
- P3: PhV Enquiries
- P4: PSMF
- P5: Authorisation country code
- P6: Authorisation procedure
- P7: Authorisation status
- P8: Authorisation number
- P9: Authorisation date
- P10: MRP/DCP/EU number
- P11: Date of withdrawal/revocation/suspension
- P12: Package description
- P13: Orphan drug designation
- P14: Comments (e.g. paediatric use)
- P15: Medicinal product name
- P16: Medicinal product invented name
- P17: Product generic name
- P18: Product company name
- P19: Product strength name
- P20: Product form name
- P21: Pharmaceutical Form
- P22: Route of administration(s)
- P23: Active ingredient(s), Adjuvant(s)
- P24: Excipients
- P25: Medical device(s)
- P26: Strength of active ingredient(s)/adjuvant(s)
- P27: Therapeutic Indication(s)
- P28: ATC code
- P29: Medicinal Product type/Legal Basis
- P30: Summary of Medicinal Product Characteristics

The workflow



The benefits

- Safe dispensation to *patients* of a medicine at least equivalent to the one prescript in another country
- *Clinicians* understand better the medicinal therapy information contained in foreign patient summaries
- *Pharmacists* identify what is the most appropriate medicinal product that fulfils the requirements of the product prescribed abroad, in accordance with national substitution rules
- *Further actors* [national & international regulators (e.g. EMA, FDA); national/ regional/local information systems; pharmaceutical companies; sponsors of clinical trials] can meaningfully exchange MP data across countries and share the same source of information
- Identifiers can be used in any country for *obtaining the product's "properties"*
- Simplification and speeding up of the *registration of new MPs*
- Improved, easier *pharmacovigilance*

Coordination and partners

Project coordination & management	External co-operation, expert council
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Participant organisations	Country
empirica Gesellschaft für Kommunikations- und Technologieforschung mbH, Bonn	DE
Custodix NV, Ghent	BE
Health Products Regulatory Authority, Dublin	IE
Health Ministry of Regional Government Lombardia, Milano	IT
Health Level Seven International (Europe)	BE
Instytut Logistyki i Magazynowania, Poznań	PL
Nederlands Normalisatie Instituut (for European Committee for Standardization (CEN)), Amsterdam	NL
Agencia Española de Medicamentos y Productos Sanitarios Parque Empresarial, Madrid	ES
Co-opted international regulatory agencies	
European Medicines Agency (EMA), London, UK	
World Health Organisation (WHO), Geneva, & WHO Uppsala Monitoring Centre (UMC)	

Acknowledgements

- The ideas, insights and information presented are derived from the openMedicine Coordination & Support Action, which receives funding from the *European Commission Directorate General for Communications Networks, Content and Technology* under Grant Agreement No: 643796 - support which is gratefully acknowledged
- Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of the information presented. The views expressed are solely those of the author(s) and do not necessarily reflect those of the European Commission or any other organisation
- We are most grateful to colleagues at the participating organisations as well as external experts who contribute and critically review project work