



Meeting the challenge of open access to medicinal products

Objectives, process, and outcomes: What can openMedicine learn from ANTILOPE?

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Goal of openMed project

- **Contribute towards and enhance the safety and continuity of cross-border (and also national level) healthcare through interoperable ePrescriptions**
- **Develop concrete solutions to: “The challenge in ePrescription is how medicines can be communicated in the cross border setting.”**
- **Whereas the epSOS project basically solved the electronic “communication” or message transfer problem, it encountered a serious “delivery” problem:**
 - **the univocal identification of a medicinal product dispensed in another country (initially across the Union, but eventually globally)**
 - **If and where substitution is permitted, dispensation of a similar product in line with national regulations**



Objectives

Concrete objectives and practical solutions sought are to identify, validate, and feed into practical deployment

- a **common data model** - based and expanding upon the standards used/extended by epSOS and by existing standards (e.g. the ISO/IDMP standards) - for the prescribed medicinal products
- a common **vocabulary for unambiguous definition**, description, and identification of medicinal/pharmaceutical products throughout Europe
- Solution options for the handling of different concepts and practices of therapeutic and economic **substitution** across Europe
- a **roadmap** for post-project actions and implementations
- Coordination of practical solutions developed as well as policy recommendations and roadmap with the **EU-USA road mapping process** in the context of the eHealth MoU (USA/DHHS and EU/EC)



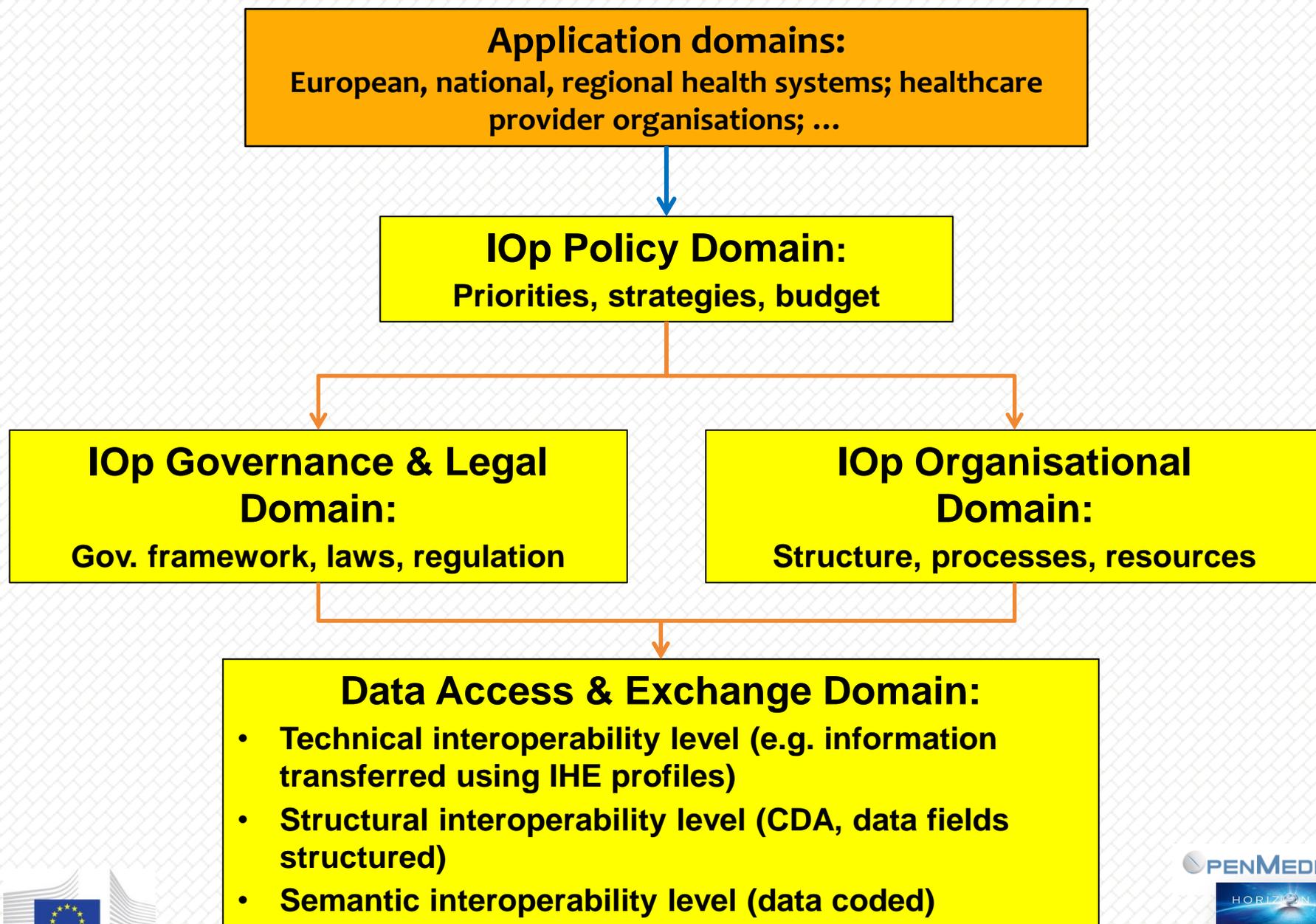
Conceptual approach - Unique identification and description of medicinal products

The overall concept to overcome the challenges identified is to develop concrete solutions in a European & global context:

- A **common data model** (to be intended as a set of coherent conceptual, logical and implementable data models) - based and expanding upon the ones used/developed by epSOS and existing standards (e.g. the ISO IDMP standards) - for the prescribed medicinal products
- A **common nomenclature** (a set of code and identification systems) for the unambiguous definition, description, and identification of medicinal/ pharmaceutical products throughout Europe and globally



Conceptual approach - Interoperability



First notes on proposed approach... & learning opportunities from Antilope

- Concentrate on and give priority to the concepts and data elements related to Medicinal Product Identification for ePrescribing and eDispensing (**Medication use case; cross-border**), and **additional use cases** (Pharmacovigilance, ...)
- Address the **process to validate medicinal descriptions**
- **Address process and architectural impacts of adopted solution on eHealth cross-border interoperability infrastructure** (NCPeH + National Infrastructures)
- The datasets related to administration (posology, instructions for preparation, instruction for the patients) will be only marginally considered in OpenMedicine

