

Meeting the Semantic Challenge of the Globally Unique Identification of Medicinal Products - The openMedicine Approach

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Abstract. To better enable cross-border healthcare delivery, particularly the exchange of ePrescriptions, this global undertaking advances the unique identification of medicinal products (MPs) and patient safety in cross-border settings. Major stakeholders harmonise their respective efforts to deliver

- common data models for prescribed MPs
- a common vocabulary for unambiguous definition, description, and identification of MPs
- rules to harmonise practices of therapeutic and economic substitution
- a global roadmap for post-project actions and implementations

Based on earlier activities of standard development organisations (SDOs), use case scenarios are developed, where the identification of an MP is an issue, including pharmacological and pharmacokinetic attributes, clinical indications, and risks to be considered. Next, the univocal identification of MPs is addressed, for standard pre-packed ones as well as for special cases like MPs with multi-components, biologics, or special packaging. Impacts will be considerable for global healthcare services and systems as well as – through simplifying and speeding up the registration of new products and afterwards pharmacovigilance - for national and international regulatory agencies, the MPs industry, and, in particular, patients.

Keywords. Medicine, pharmaceutical product, univocal identification, ePrescription, interoperability, therapeutic and economic substitution, cross-border healthcare, standard development organisations - SDO, World Health organisation, European Medicines Agency - EMA

Context

Information and communication technologies (ICT) applied to health (eHealth) can increase the efficiency, safety and quality of health services, and unlock innovation in health markets [1]. In the context of telehealth, i.e. the provision of health services at a distance [2], delivering safe and efficient cross-border healthcare poses a specific challenge in this context - the “delivery” problem of ePrescription: the univocal identification of the medicinal product (MP), which was noted in a prescription from a given country, by a pharmacist dispensing it in another country. S/He must be able to

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select from the pharmaceutical products available in that country the product that perfectly matches the prescribed pharmaceutical product for safe dispensation to the patient. Or, if and where substitution is permitted, the dispensation of a similar product in line with national regulation [3].

Global standard development organisations (World Health Organisation - WHO, Health Level 7 - HL7, International Organisation for Standardisation / European Committee for Standardisation [Centre Européen de Normalisation] - ISO/CEN, Global Standards 1 - GS1), the European Medicines Agency (EMA), EU Member State Competent and Regulatory Authorities, major stakeholders (industry, health professionals, patients) and partners in the USA will collaborate and harmonise their respective efforts to solve this problem.

1. Goal and Objectives

The overall goal is to enhance the safety and continuity of cross-border (and thereby also national level) treatment through interoperable ePrescriptions, and to develop concrete solutions to the challenges identified. Concrete objectives are to deliver:

- common data models for prescribed MPs
- a vocabulary for unambiguous description, and identification of MPs
- rules to harmonise practices of therapeutic and economic substitution
- a global roadmap for post-project actions and implementations.

2. Process and Activities

The work will benefit from earlier activities of regulatory agencies and global SDOs. The ISO 11615/11616/11238/11239/11240:2012 standards family on “Health informatics -- Identification of medicinal products [IDMP]” was created with the active engagement of regulatory agencies FDA and EMA, and intense debates in the ISO, HL7, CEN groups that engage in pharmacy standardisation. Meanwhile WHO, which maintains several coding systems including the Anatomical Therapeutic Chemical (ATC) Classification System, collaborates with the International Health Terminology Standards Development Organisation IHTSDO in various harmonization projects. There is need to bring these activities together, particularly also as EMA requires that medicinal product companies submit data using IDMP starting 2016. This is a big change both for EMA and the pharmaceutical industry. On the other hand, it is going to affect the information offered by the European Union Drug Regulating Authorities Pharmaceutical Database (EudraPharm), the database of medicinal products that EMA maintains. Also the experience of the European project to foster “Smart Open Services for European Patients - Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription” (epSOS) [3] has shown that, particularly on the issue of cross-border ePrescription/eDispensation, further standardisation activities are urgently needed.

The unique contribution of this initiative will be to develop upon this earlier work, identify differences and inconsistencies across already existing standards, and thereby harmonise global standardisation. As a first step, the project develops a concise

conceptual framework to guide its work, based on the interoperability domain framework as depicted in *Figure 1* and use case scenarios where the identification of an MP is an issue, including pharmacological and pharmacokinetic attributes, clinical indications and risks to be considered. Next, the identification and description of pharmaceutical products is addressed, not only for standard pre-packed medicinal products, but also for some special cases like MPs with multi-components, biologics, or special packaging as well as those cases where a prescription for a medicinal product only specifies a cluster or class of products. Furthermore, investigations are undertaken to clarify what attributes are needed for reverse identification of a medicinal product.

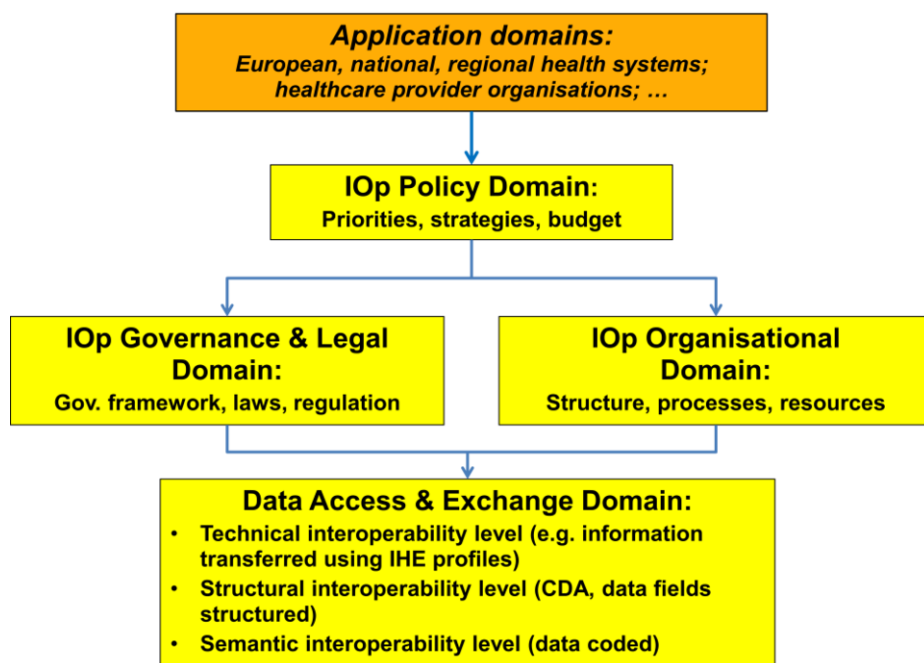


Figure 1. Interoperability domains

Substitution of medicinal products at the point of dispensation is a challenge in a cross-border setting due to widely divergent rules. Empirical evidence on the tension between maximising patient safety and maximising the probability that a cross-border prescription can indeed be adequately filled in another country is gathered and analysed to develop concrete solution proposals to overcome the challenges pinpointed.

3. Partner Organisations and Experts

The following organisations are core partners of this initiative:

- empirica Gesellschaft für Kommunikations- und Technologieforschung mbH, Germany

- Custodix NV, Belgium
- Health Products Regulatory Authority, Ireland
- Health Ministry of Regional Government Lombardia, Italy
- Health Level Seven International (Europe)
- Instytut Logistyki i Magazynowania (for GS1), Poland
- Nederlands Normalisatie Instituut (for ISO and CEN)
- Agencia Española de Medicamentos y Productos Sanitarios Parque Empresarial, Spain

In addition, to enable direct involvement of interested third parties which cannot or may not want to become a direct contractual partner in a project supported by the European Union, the initiative co-opted two international regulatory agencies: the European Medicines Agency (EMA), London, UK, and the World Health Organisation (WHO - Geneva, and the WHO Uppsala Monitoring Centre - UMC). Direct cooperation with the US Food and Drug Administration (FDA) has also been established.

Furthermore, to allow for the input and involvement of further (national) regulatory authorities, SDOs like the International Health Terminology Standards Development Organisation - IHTSDO, and major stakeholders (industry, health professionals, patients) the initiative will be supported and advised by an Expert Council and selected individual experts.

4. Outcomes

This project will deliver practical solutions ready to be taken over and eventually implemented by countries across the globe to solve two key issues of cross-border prescription services: the univocal identification of medicinal products, and clear rules of how to deal with substitution when presenting a prescription abroad. These solutions concern:

- Data models for prescribed medicinal products developed cooperatively by regulatory authorities and global SDOs, validated by experts and government representatives. They will be based on the groundwork already undertaken by EMA, FDA and SDOs. The data models will include ways of clustering medicines according to their bioequivalence, in view of substitution, and pharmacovigilance needs. This will include agreement on an international standard to represent multiple (active) ingredients in medications and a way to identify changes in that composition; agreement on the way to prescribe a class of pharmaceutical products or a cluster of medicinal products instead of a specified product.
- A common vocabulary for unambiguous definition, description, and identification of medicinal/pharmaceutical products which will be developed and validated in a similar fashion.
- Clear rules for the cross-border handling of different practices of therapeutic and economic substitution in Europe
- A roadmap for post-project implementation of the solutions elaborated, including a proposal for the future structures, processes and funding for a

(global) organisation to maintain, further develop and internationally coordinate technical and semantic interoperability assets, issues, and challenges.

Outlook

The impact on and benefits for patients, in particular those seeking healthcare services in another country, international travellers and those temporarily working and/or living abroad, will be considerable:

- Any patient can obtain seamlessly at least a medicine equivalent to the one prescript in another country
- Clinicians reviewing a foreign patient's summary understand fully the medicinal therapy information contained
- Pharmacists can fully identify what is the most appropriate medicinal product in his/her country that fulfils the therapeutic requirements of the product prescribed abroad, in accordance with his/her country laws and substitution rules
- Different actors [regulators (e.g. EMA, AIFA); national/regional/local information systems; pharmaceutical companies; sponsors of clinical trials] are enabled to meaningfully exchange MP data and share the same source of information.
- Identifiers can be used by any actor in any country for obtaining the product's "properties"

This work will also contribute towards fostering the innovation capacity of pharmaceutical companies by simplifying and speeding up the registration of new products and afterwards pharmacovigilance activities – innovations which contribute to patient safety and better healthcare.

Neither SDOs, national authorities, pharmaceutical companies or other stakeholders can solve the challenges identified on their own – we need global cooperation. It is anticipated that the cooperation initiated by this project will serve as the game changer to the situation of global MP identification.

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