OPENMEDICINE

Meeting the challenge of open access to medicinal products across the Union

OPENMEDICINE *addresses drug identification and substitution challenges of safely dispensing prescriptions to people no matter where these prescriptions are issued, bridging national, European, transatlantic, and global borders.*

Objectives of the project

Identification and substitution of medicinal products

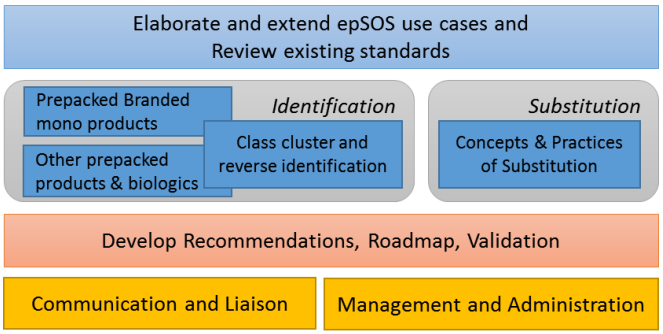
Large scale eHealth implementations of the patient summary and ePrescription services are a policy priority of the eHealth Network of European Union Member State representatives. This requires scalable and sustainable solution of two problems:

First, how can medicinal products be identified so that they are safely dispensed across border in another Member State and globally?

Second, if substitution of medicinal products for therapeutic and/or economic reasons is permitted in a Member State, how are the relevant medicinal products identified when the original prescription comes from another Member State?

OPENMEDICINE advances the unique identification of medicinal products and the safety of cross-border health care through focused actions to deliver:

- a **common data model** for prescribed medication based on global standards
- an **unambiguous vocabulary** for description and identification of medicinal and pharmaceutical products
- robust rules to regulate and gradually harmonize **concepts and practices** of therapeutic and economic substitution
- a **global implementation roadmap** to realise interoperable and safe eHealth services across local, state, and International borders
- coordination of OPENMEDICINE **practical solutions** and policy recommendations with the **EU/US roadmap process** for eHealth cooperation.



Project Description

Pushing the envelope for interoperable ePrescription

Towards a European Medicinal Product Database for reliable and safe border-proof

OPENMEDICINE addresses the reliable selection/prescription and the safe dispensation of medicines. Accurate identification of medicinal products is critical when the country of prescription differs from the country of dispensing, as in the epSOS ePrescription use cases. Substitution for economic or therapeutic concerns is a related challenge when it is allowed to dispense a different medicinal product than the one prescribed. Substitution is common practice in some countries, but also a reality in emergencies or "on duty" dispensing.

OPENMEDICINE activities reflect these considerations starting with extending the epSOS cross-border ePrescription use cases (WP1). Work on identification issues (WP2, 3, 4) and substitution (WP5) proceeds in parallel. Recommendations, Roadmap, Validation (WP6) engage external experts and stakeholders. Communication & liaison (WP7) focuses mainly on national drug agencies, stakeholders in production, prescription and dispensing of medicinal products, but also patients and other players as health IT industry.

***CASE STUDY**: Paolo a retired businessman, technology suave, suffers from hypertension, likes traveling for recreation, and feels safe while abroad as he is actively involved in managing his health using online tools and gadgets. He works closely with his personal physician, who adjusts Paolo's medication and dosage to keep his hypertension under control. Paolo meticulously monitors his BP noting symptoms and adverse events online in his personal health record that supports the European Patient Summary Guideline. While on travel in Poland, Paolo lost the bag with his new prescription medication package, and needs a new one. The patient has a patient summary uploaded and consults a local physician to get a prescription. The local physician identifies the local equivalent medicinal product using appropriate services. The pharmacist dispenses the medicinal product based on that prescription. They are thankful to European policy supporting the European Medicinal Products Database.*

Expected Benefits and Societal Impact

The **impact and benefits** of OPENMEDICINE for patients, clinicians, pharmacists, regulators and the pharma industry will be significant:

- Patients will obtain seamlessly medicine equivalent to that prescribed to them in another country
- Clinicians reviewing the patient summary of a foreign patient will fully understand the medication section.
- Pharmacists can safely identify appropriate medicinal products that fulfil the therapeutic requirements of the medicine prescribed abroad, in accordance with local laws and substitution rules
- Medical trials spanning multiple countries can meaningfully exchange data and care information on medicinal products

Have you ever needed to get some medication or a prescription whilst abroad but the healthcare professionals were not able to identify the right medicine or provide it? **Support OPENMEDICINE!**

Identifiers of medicinal products help access "properties" of a medicinal product anywhere, creating opportunities for services supporting patients today and tomorrow:

- Cost of maintaining up-to-date medication lists is reduced
- Bridges between pharma and health care are reinforced
- Registration of new products is more efficient
- Recruitment for clinical trials involving patients in multiple countries will be easier
- Pharmacovigilance activities are more effective, advancing patient safety and improving health care.

Work in this domain started in 2008, when **Standards development organisations** (SDOs) cooperated globally to develop the identification of Medicinal Product (IDMP) and the adverse event reporting standards (ICSR). Here EMA, the US FDA and other regulators, together with global manufacturers represented through the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) worked together, driven by collaborative spirit and a shared vision. Advancing this work and **streamlining implementation based on a validated roadmap is an opportunity for immense global impact.**

Moving forward, an effective **Governance and regulatory framework** adopted by European and national regulatory agencies is essential. It should be translated into the daily practice of feeding and maintaining the data of the common data model, including updates along the life cycle of medicinal products.

The ambition of OPENMEDICINE is to push the envelope for open access to medicinal product identification and directly impact safety and quality of care, enabling innovation and supporting economic substitution where appropriate.

www.open-medicine.eu

OPENMEDICINE

Meeting the challenge of open Access to Medicinal Products across the Union

Project co-ordinator:
empirica Gesellschaft für Kommunikations- und Technologieforschung mbH (DE)

Contact person:
Coordination
Prof. Dr. Karl A. Stroetmann
empirica Communication & Technology Research
Oxfordstr. 2, DE-53111 Bonn, Germany
Tel: +49 (2 28) 9 85 30-0/-52
Email: karl.stroetmann@empirica.com

Co-operation, expert Council & roadmap
Dr. Jos Devlies
Custodix NV
Kortrijkse steenweg 214 bus 2
BE 9830 Sint Martens Latem - Belgium
Phone: +32 (9) 2 10 11 63
Mobile: +32 (4 75) 26 61 48
Email: jos.devlies@custodix.com

Project Website:
www.open-medicine.eu

Partners:

- empirica mbH (D)
- Custodix NV (B)
- Health Products Regulatory Authority (IE)
- Health Ministry of Regional Government Lombardy (I)
- HL7 International Foundation (B)
- Instytut Logistyki i Magazynowania (PL)
- Nederlands Normalisatie Instituut (NEN for European Standards CEN) (NL)
- Agencia Española de Medicamentos y Productos Sanitarios Parque Empresarial (E)

Selected Experts / Advisory Council

- European Medicine Agency (UK) [Chair]
- International Health Terminology Standards Development Organization (DK)
- World Health Organization,Upsala Monitoring Center (S)
- World Health Organization (CH)
- NHS Health & Social Care Information Center (UK)
- Danish National eHealth Agency (DK)
- Croatian Medicines Agency (HR)
- Novartis for European Federation of Pharmaceutical Industries and Associations (EFPIA, CH)
- European Generic Medicines Association (B)
- Pharmaceutical Group of the European Union (PGEU, B)
- Centre of eHealth and Innovation UNIBIT (BG)
- AUTH –Informatics and Information Security Lab (GR)
- Blue Wave Informatics Ltd (UK)
- Intelligent Law & Internet Applications (A)
- Belgian Federal Drug Agency (B)
- Office of Registration of Medicinal Products (PL)
- National Institute for Health and Welfare (FIN)
- The Degge Group (United States)
- Food and Drug Administration (USA)
- Clinical Data Interchange Standards Consortium (USA)

Timetable: from 12/2014 to 12/2016
Total cost: €997,938.00
EC funding: €997,938.00
Instrument: Coordination and Support Action
Project Officer: Eduardo GONZALEZ OTERO
Project Identifier: H2020-PHC-2014-single-stage-project N°643796

Keywords: Medicinal product identification, substitution, standards, eHealth interoperability, Cross-border eHealth services, EU-US cooperation