

Background information on the openMedicine project Benefits expected from the globally univocal identification of medicinal products

The challenge

The European Union (EU) funded openMedicine project explores the globally unique identification of medicinal products (MPs). It will deliver respectively contribute towards

- common data models for the identification and description of medicinal products
- a common vocabulary for their unambiguous description
- rules to guarantee safe identification of medicinal products
 - ✓ in prescriptions for cross-border dispensing
 - ✓ in case substitution is required
 - ✓ in patient summaries as well as adverse event reporting for pharmacovigilance
- a global roadmap for post-project actions and implementation.

Based on earlier activities of standard development organisations (SDOs), use case scenarios were developed, where the univocal identification of a medicinal product (and, where applicable, the pharmaceutical products contained therein) is a key factor. The univocal identification of MPs is addressed for standard pre-packed ones with one or several active ingredients, as well as for special cases like MPs prepared in the pharmacy, containing several pharmaceutical products, packed together with a medical device, for biologics, etc.

This is in response to, amongst others, the challenge to univocally identify a medicinal product specified in an (electronic) prescription in the context of cross-border or international healthcare. Whereas e.g. stating the *GTIN* (Global Trade Item Number) of a package of a medicinal product (MP) in a country's prescription univocally identifies the MP with all its descriptive attributes, including the quantity contained in the package, in other countries the *name* of an original/innovative or a generic MP as produced by a specific pharmaceutical company, together with the quantity to be dispensed, plus perhaps additional attributes like pharmaceutical dose form, strength, route of administration and further identifying items may appear.

Due to differences in the market authorisation procedures for medicinal products across countries (through their national agencies) or for all of the European Union (through the European Medicines Agency – EMA) and their naming rules, the 'same' MP may carry a different "given" name (for innovative products) or "common" name (for generic products) in other countries. And the *same* name may identify across countries *different* products (and different active substances contained therein), or products available in one country may not be authorised in another one – but a more or less identical generic medicinal product may be available.

And the *same active ingredient* or substance may carry several different names across the globe, and be contained in hundreds of differently branded generic MPs.

Furthermore, an MP may consist of two or more pharmaceutical products (like a package of contraceptive pills, or a medicinal product for treatment of coronary heart disease containing two active ingredients), or a pharmaceutical product may be packaged with a medical device – combinations which may not be available in another country.

Next to this, the legal way to specify a medicine to be dispensed in prescriptions varies across countries: it may be the generic or "given" name, for innovative ones the "invented" name, or only a code which may refer to a specific package, an active ingredient, or a national code that identifies a set of medicinal products only, i.e. it "clusters" several of them into a group from which the pharmacist has to select the one to be dispensed.

The solution

The openMedicine project supports the ongoing global consensus process to describe and identify unambiguously medicinal and pharmaceutical products, resulting in the authorised delivery of the appropriate medicine and its identification throughout clinical processes. It closely cooperates with the European Medicines Agency (EMA) in London, WHO, ISO, CEN, GS1, HL7 and other standardisation organisations. For many years already, EMA and the USA Federal Drug Agency (FDA) have been cooperating and exchanging expertise on this same goal, and these activities and their results are also reflected and integrated into open-Medicine work, e.g. through three focused expert workshops, two at EMA and one at FDA premises.

Core identification concepts revolve around globally unique codes for the

- ID of a package of a medicinal product (PCID)
- ID of a medicinal product (MPID)
- ID of a pharmaceutical product (PhPID)
- ID of the (active) substance (SubID)

It is expected that by mid 2018 these IDs will be generated and maintained centrally by the European Medicines Agency (in cooperation with FDA and others to assure global uniqueness) for medicinal products authorised to be marketed across the European Union. These four IDs will form the core identifiers for openMedicine, and they will allow mapping from one level of specification (e.g. substance ID), to another level.

Furthermore, all descriptive and other attributes of medicinal products deemed relevant for regulatory and clinical purposes will be standardised and, as far as possible, assigned coded vocabularies, measures, etc. The maintenance and update of such codes will be assigned to appropriate agencies and organisations.

It will take additional time for integrating the EMA central database and the national drug databases, and to make all of this information available to end-users via their IT systems.

All of this work is based on and aligned with the ISO 11615/11616/11238/11239/11240:2012 standards family on "Health informatics -- Identification of medicinal products (IDMP)".

These key aspects (attributes and vocabulary) are being mapped to the different interacting systems - as the regulators define the appropriate data, it is important that such data can be used in systems for prescribing, dispensing, etc. The project is eliciting recommendations for practical implementation, including adoption of standards, changes and implementation guidance for standards (e.g. ePrescription), or use in medicinal product dictionaries.

The benefits

The direct and indirect impact on safety and quality of care for patients, like those seeking healthcare services in another country, international travellers, or those temporarily working and/or living abroad, but also for those in a diverse national healthcare market, and for other stakeholders will be considerable:

- Any patient can obtain seamlessly at least a medicine equivalent to the one prescribed in another country (in line with respective local regulations)
- Clinicians reviewing a patient's summary, electronic health record or other documents containing information on medications prescribed and dispensed understand fully the medicinal therapy information contained
- An individual patient's medication records from diverse sources can easily be integrated, validated, and used as input to computerised physician order entry (CPOE), clinical decision support and other (software) systems
- Community pharmacists can fully identify what is the most appropriate medicinal product in their country that meets the specification and fulfils the therapeutic requirements of the product prescribed abroad, in accordance with their country's laws and substitution rules
- Different actors [regulators (e.g. EMA, national agencies); healthcare professionals, national/regional/local medicinal product information systems; pharmaceutical companies; sponsors of clinical trials, medical researchers] are enabled to meaningfully exchange MP data globally and share the same sources of information

- The pharmacovigilance cycle is closed, by ensuring that from marketing authorisation to adverse event reporting and product discontinuation the products are univocally identified, even if they are specified in different ways by clinical actors during this cycle
- The quality of data and evidence for pharmacovigilance and pharmacoeconomics will become greatly enhanced, their integration as well as their analysis for public health policy decision making facilitated
- Identifiers or descriptive attributes can be used by any actor, also patients, in any country for obtaining the product's "properties", e.g. in an emergency for the reverse identification of a medicinal product.

This 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,
- supporting the digital economy by providing a standard approach to identifying products across clinical and regulatory systems, as well as production and logistic processes
- enabling patients by simplifying product identification in patient-empowering systems,

All of this will foster innovations which fundamentally contribute to patient safety and better healthcare.

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