openMedicine and cross border eHealth services – options for the univocal identification of medicinal products

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Meeting the global challenge of unique identification of medicinal products

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- Implementation by EMA of ISO IDMP standards through SPOR master data
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Meeting the global challenge of unique identification of medicinal products

Project objectives

➢ Univocal identification of a medicinal product for human use across Europe in
  ✓ ePrescriptions
  ✓ eDispensation reports
  ✓ Electronic Patient Summaries

➢ Evidence on substitution
Identification & patient safety challenges

- Due to different marketing authorisation procedures
  - Not every medicinal product is available in each member state
  - The same product may have different names across MSs
  - The same name may identify a different product in another MS

- Regularly substitution is necessary to dispense a foreign ePrescription

- Analysis of identification problems in
  - Regulatory context (pharmacovigilance; marketing authorisation)
  - Clinical records and documents
Standardised attributes for medicinal and pharmaceutical products

- The ISO IDMP (ID of medicinal products) suite of standards defines a set of attributes and their relations to identify different levels of medicines
- It harmonizes the concepts and the data elements (attributes)
- EMA & FDA will adopt it and maintain codes
- Pharmaceutical manufacturers will implement it (summary of product characteristics [SmPC]; pharmacovigilance)
- ePrescriptions may identify a package, a medicinal product, or an active substance plus further attributes as needed
xBorder ePrescription & dispensation

Common level is usually pharmaceutical product, i.e. substitution or selection

Product is specified at any of the IDMP levels in an ePrescription

Product is further specified, thanks to standardised attributes

Identifier = PhPID
Phar. Product

Identifier = MPID
Medicinal Product

Identifier = MPID
MP

Identifier = PCID
Package

Identifier = PCID
Package

Same medicinal product (if available)

Product is specified at any of the IDMP levels in an ePrescription
Implementation of ISO IDMP standards through SPOR master data

**SPOR data management services:** Delivering quality data management services on Substances, Products, Organisations and Referentials to power EU regulatory activities

21 November 2016
Francisco Penaranda, Head of Business Data and Analytics Department
Currently the submission of data on medicines by Marketing Authorisation Holders is a legal requirement introduced by Article 57(2) of Regulation (EC) No 726/2004 as amended.

Pharmaceutical companies that hold marketing authorisations for medicinal products for human use in the EU and the EEA are required to:

- Submit information to the EMA using the format referred to as Article 57 format or eXtended EudraVigilance Product Report Message (XEVPRM) format.

- Maintain the medicinal product information and notify the EMA of any newly authorised medicines or any variation to the terms of the marketing authorisations using the XEVPRM format.
• **Privacy, security and accountability:** the pharmaceutical industry is required to register with the EudraVigilance system prior to the electronic submission

• **Data validation:** a ‘technical validation’ and a systematic ‘Business validation’ of the content of each product record, based on the provided Summary of Product Characteristics (SmPC), is performed by the EMA to support Pharmacovigilance activities

• **Communication and training:** the Agency provides face-to-face and e-learning training as well as set of guidance documentation
• Article 57 initial data submission was required by 2 July 2012

• Article 57 database contains around 500,000 medicinal product records with a valid MA from around 4,100 Marketing Authorisation Holders (MAHs)

• From 16 June 2014, MAHs are required to complete previously submitted information with additional information (to support new regulatory obligations placed on the Agency), bring information up-to-date, and improve the data quality

• Since January 2015, MAH are required to maintain Article 57 data
Article 57 Database – Points to note

• **Data quality:** The review of the quality and integrity of the medicinal product information submitted is performed via a systematic validation of the medicinal product structured data received against the information written in the provided Summary of Product Characteristics (SmPCs) by EMA
  - The validation performed at the moment is suitable to support Pharmacovigilance activities
  - The validation performed at the moment is not suitable to support ePrescription/eDispensing
  - NCAs are not involved in the current validation process

• **Data completeness:** Close collaboration with the EU Network to monitor compliancy and introduce corrective actions. Results from 5 NCAs showed in May 2015 that the completion rate was ~92%; provisional results of the same exercise now is showing an increase of the compliance rate
Future evolution of Article 57

- Future target operating model to involve NCAs for the validation and to ensure data completeness
- Article 57/XEVPRM data format will be moved into the ISO IDMP format
- ISO IDMP standards are considered to be about master data: **data that can be re-used for multiple purposes**
- The approach to implement IDMP standards will be through 4 domains of master data
  - **Substance**
  - **Products**
  - **Organisations**
  - **Referentials**
- Four projects known as SPOR will implement services to **centralise** the **management** of each of the domains of **master data**
- Implementation will be phased
- Backward compatibility between Article 57/XEVPRM and new solution will be maintained (length to be determined)
Benefits:
- Efficiency
- Transparency

Business Cases

Foundation

ISO IDMP through SPOR
(Substance, Product, Organisation, Referentials)

SPOR master data will deliver the foundation for business processes through the provision of timely, accurate and re-usable master data.
High level programme timeline

- ISO IDMP through SPOR is a multi-year Programme
- The focus for 2016 is to deliver Referentials MS and Organisations MS
- RMS and OMS will lay the foundation for the delivery of PMS and SMS
- This will also provide the foundation for the future integration of SPOR with Telematics projects or programmes

- 2016
  - Implementation of Terms to support ISO IDMP 11239 and 11240 standards
  - Implementation of Organisations data to support ISO IDMP 11615 and 11238 standards

- 2017
  - RMS and OMS go-live

- 2018
  - Integration with CESSP (Telematics programme)

- ...
Thank you for your attention

Further information

Please send any queries regarding the IDMP/SPOR to:
SPOR-Change-Liaisons@ema.europa.eu

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

Draft Recommendations

eHealth Network

21-11-2016
Identifiers of medicines: 1st recommendation

A medicine should be identified by its attributes, or specified by at least one of the identifiers as defined in the IDMP standards (i.e. Pharmaceutical product(s) – PhPID(s), medicinal product - MPID, package - PCID)

All IDMP identifiers for a product and the respective identifying attributes should be electronically accessible to all parties.

The active substance (or set of active substances) with the required strength(s) and dose form that the Health Professional (HP) prescribes define the Pharmaceutical Product(s). The Pharmaceutical Product(s) selected by the HP will be automatically and univocally translated into the PhPID code(s).

When the health professional wants to specify a specific Medicinal Product, or a specific packaged Medicinal Product, the respective originator or generic brand name plus identifying attributes including quantity, or the MPID or PCID(s) will need to be used. For every MPID or PCID there is a unequivocal correspondence to globally unique PhPID(s).
First Recommendation - facilitators

- **Pre-requisite**
  - Availability of product dictionaries that include the IDMP identifiers

- **Vehicle**
  - ePrescription, eDispensation & electronic Patient Summary specifications

- **Role of stakeholders**
  - eHealth Network: adopt Guidelines taking into account IDMP
  - eHealth/NCAs: adapt national DBs to IDMP requirements
  - EMA, FDA: implement IDMP; assign PhPID; provide open access to authentic source of data and codes
  - National & international drug database providers: integrate IDMP data
  - EHR/clinical/pharmaceutical information system providers: adapt software to IDMP data needs
  - Health professionals: become aware of IDMP benefits and requirements

- **Timing**
  - Start adoption/adaptation as early as possible
  - At the latest before end of introductory phase of EMA IDMP data
Pharmaceutical Product ID: 2\textsuperscript{nd} recommendation

Each ePrescription, eDispensation, or medication record in an ePatient Summary should contain (an automatically added) pharmaceutical product identifier, preferably the global PhPID assigned by EMA, once available. An authorised mapping to the PhPID should be available in case of using proprietary identifiers.

Each ePrescription, eDispensation or medication record in an ePatient Summary may contain additional IDMP compatible identifiers.

The PhPID is globally unique, independent of national regulation, language, originator or generic product brand name; it reflects the core attributes of the medicine. Therefore it ideally facilitates expected as well as unexpected cross border searches for medicinal products equivalent to the prescribed one, or identifying, e.g., active medications in an electronic Patient Summary.
Cross-border exchange of medicinal and pharmaceutical product information – the short term: 3rd recommendation

In the short term, to improve the likelihood that a medicine specified in a cross-border ePrescription can indeed be fully identified and dispensed (or substituted), it should be considered to use for the time being the presently implemented and publicly available EMA substances data base and code system as an additional value set of the Master ValueSet Catalogue.

Considering that the global PhPID will become available only in the longer term, we present Recommendation 3. In order to bridge towards the future full implementation of ISO IDMP, Member States, through the task already assigned to eHMSEG-Semantic to revise MVC 2.0, may want to consider adopting the EMA substances data base and codes as an additional value set (VS) of the Master Valueset Catalogue (MVC), to be used both for ePrescriptions and electronic Patient Summaries. This may require MSs, based on their national medicinal products data base, to transcode national values into this VS, or to use, after validation, the contents of Art.57 data base. On the European road towards full implementation of IDMP, this process would allow to adopt a compatible short term solution already for CEF Wave 1.
Cross-border exchange of medicinal and pharmaceutical product information – the medium term: 4\textsuperscript{th} recommendation

As a further step towards IDMP implementation, MSs involved in CEF may want to assess and validate the suitability, efforts and risks involved in mapping the data elements needed for ePrescription and electronic Patient Summary, and for creating a PhPID from the presently available EMA Art. 57 data base

Considering that the global PhPID will become available only in the longer term, we present Recommendation 4 as a potential further step which may be considered by those member states which are involved in relevant CEF applications. Here it should be reflected that the Art. 57 data base was initially developed for pharmacovigilance purposes.
Identifying and reporting medicines across health service domains: 5\textsuperscript{th} recommendation

When recording medicines (identified as in the first recommendation) in care process documents (prescribing, dispensing, administration/billing, reports...) both in electronic systems and when sharing that information, the structures used for supporting information (e.g. for dosage instructions) should have standardised definitions/codes and be populated with globally recognised controlled terminologies like EDQM codes (European Directorate for the Quality of Medicines).

Agreement on terminology standards is required, e.g., for pharmaceutical forms, inner and outer container, route of administration, etc... EMA SPOR master data, through the Referentials Management Services, (RMS) will provide for such a repository. Considering that medication use related information should be documented in a comparable, consistent and reliably reusable way across the Union and globally, considering that important stakeholders and services are operating globally, we formulated the fifth recommendation.
Identification of other substances (adjuvants and excipients): 6th recommendation

Further work should be done to identify in a cross-border context adjuvants and excipients of pharmaceutical or medicinal products which may cause allergic reactions or intolerances.

Considering that pharmaceutical and medicinal products may contain adjuvants (substances that may increase the efficacy or potency of the active substance) as well as excipients (inert or inactive substances) that can cause allergic reactions or to which a patient may be intolerant, we present a sixth recommendation.
Identical PhPID throughout the complete lifecycle of a medicine: 7th Recommendation

The ISO IDMP suite of standards should be usable and used throughout the complete lifecycle of a medicine. This requires assigning a globally unique PhPID to each pharmaceutical product already at the development stage.

It has been mandated by the “Commission Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities” to use the ISO IDMP suite of standards and terminologies for pharmacovigilance purposes; the NCAs and EMA decided to adopt the ISO IDMP suite of standards and terminologies also in any other process of the medicinal product lifecycle. Considering the entire lifecycle of the data related to medicines as one continuum across the regulatory and clinical domains, considering that using different (terminology) standards for each or several of these domains hampers reuse and sharing of medication-related data, considering that no major problems have been identified during the openMedicine project in applying this also to clinical care, for pharmaco-epidemiology etc., we present a seventh recommendation.
Harmonisation of terms & concepts: 8th recommendation

Standard Development organisations (SDOs) and other stakeholders should update the terms and their definitions (concepts) used with respect to identifying, describing and recording medicines in order to harmonise them.

Considering that different definitions of the same terms in domain specific standards, guidelines, and European directives are used, and considering normal evolution over time, we present our eighth recommendation
Clinical applications & drug databases: 9\textsuperscript{th} recommendation

Medicinal Product Dictionaries (MPD) as well as clinical applications for recording and processing medicinal information should meet a set of quality criteria like correctly coded, compliance of structure and content with EMA and national specifics, and completeness and persistence of information regarding meanwhile withdrawn medicines. Completeness encompasses every product that can be prescribed, e.g. other not-to-be authorised products.

Considering the important role of drug databases providing at the point of prescription and at dispensing factual national as well as universal qualitative data and services, we formulate a ninth recommendation
Unique medicinal product names: 10\textsuperscript{th} recommendation

Newly marketed medicinal products should have a distinct name that differs from any other medicinal product name in the Union.

Considering that different medicinal products should have different names to avoid confusion which may potentially harm a patient, considering that in fact the same medicinal product name has been used for different medicinal products in different member states, we present this tenth recommendation.
Sustainability of authoritative source data: 11th recommendation

Sufficient resources should be allocated to make available in a timely fashion the IDMP compatible central European Medicines Database for cross-border health services. Its long-term maintenance needs to be assured.

The availability of a single, authoritative source of data about medicines across the Union is crucial for patient safety in cross border services and for many other applications. It requires a significant amount of human and financial resources considering that the database must to be fully structured and as much as possible coded, with translation of terms into all EU languages and alphabets.
Substitution: 12th recommendation

National rules on substitution of medicinal products at the point of dispensation, when specified in a cross-border prescription, should be harmonised.

Because patients presenting a foreign prescription have to pay for the medicinal product at the point of dispensation, local substitution rules based on cost containment considerations do not necessarily apply. Nevertheless, dispensing of a specific medicinal product prescribed in a foreign prescription will regularly necessitate substituting it by a product locally available (even if it is exactly the same product, but carries a different name). Considering that substitution rules are defined by the Member States, in order to maximise the likelihood that a medicinal product can indeed be dispensed abroad, we present the twelfth recommendation.