Medicinal Product Data Standardisation – Prerequisite for Efficient Data Exchange Between Stakeholders and Impact on the (Inter)National Health Systems

Medicinal Product Data Standardisation in the Agency for Medicinal Products and Medical Devices (HALMED)

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IARIA

Maja Fatiga

- Maja Fatiga received the master’s degree in informatics from the University of Zagreb, Faculty of Organization and Informatics in Varaždin, Croatia
- She is currently a doctoral student, enrolled in the doctoral study at Faculty of Organization and Informatics in Varaždin, Croatia
- Currently, she works in HALMED as an advisor for software solution

Sanja Grčić Plečko

- Sanja Grčić Plečko received the master's degree in electrical engineering from the University of Zagreb, Faculty of Electrical Engineering and Computing, Croatia, in 1989.
- She is currently a doctoral student, enrolled in the doctoral study programme Information Society on Faculty of Information Studies in Novo Mesto, Slovenia
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- Currently, she works in HALMED and acts as Project Coordinating Committee (PCC) representative for HALMED on UNICOM project

Dubravka Sudić

- Dubravka Sudić received the master's degree in mathematics and informatics from the University of Zagreb, Faculty of Science, Croatia
- She works in HALMED as Head of IT department

Medicinal products identification

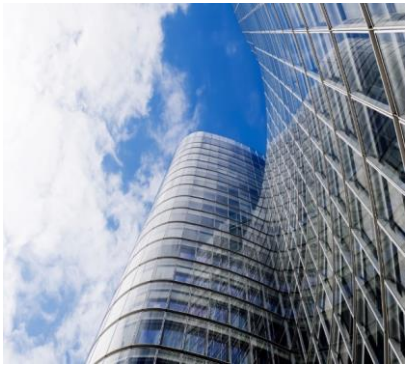
- Global challenge: healthcare stakeholders at each medicinal product life-cycle stage are capturing in their information systems different sets of data, using different codebooks, different languages, and even different abbreviations
- Example:
  - Drug dispensation in foreign country
  - Covid-19 pandemic
- How to share and exchange data when the data is incompatible

ISO IDMP (International Organization for Standardization, Identification of Medicinal Products)

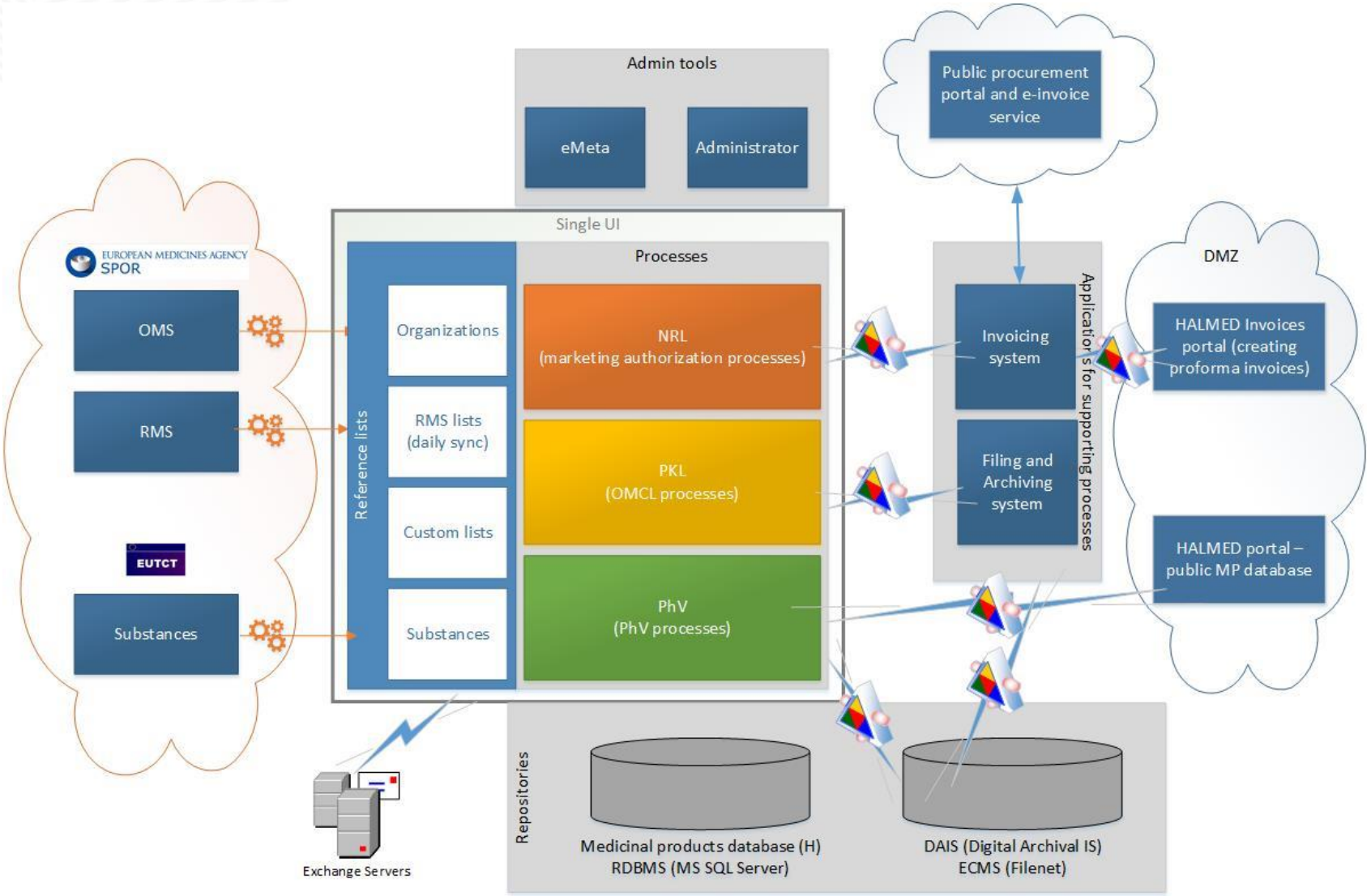
- Consists of **five** *Health Informatics – Identification of Medicinal Products* standards:
  1. ISO 11615 — Data elements and structures for the unique identification and exchange of regulated **medicinal product** information
  2. ISO 11616 — Data elements and structures for the unique identification and exchange of regulated **pharmaceutical product** information
  3. ISO 11238 — Data elements and structures for the unique identification and exchange of regulated information on **substances**
  4. ISO 11239 — Data elements and structures for the unique identification and exchange of regulated information on **pharmaceutical dose forms**, **units of presentation, routes of administration** and **packaging**
  5. ISO 11240 — Data elements and structures for the unique identification and exchange of **units of measurement**

Agency for Medicinal Products and Medical Devices (HALMED)

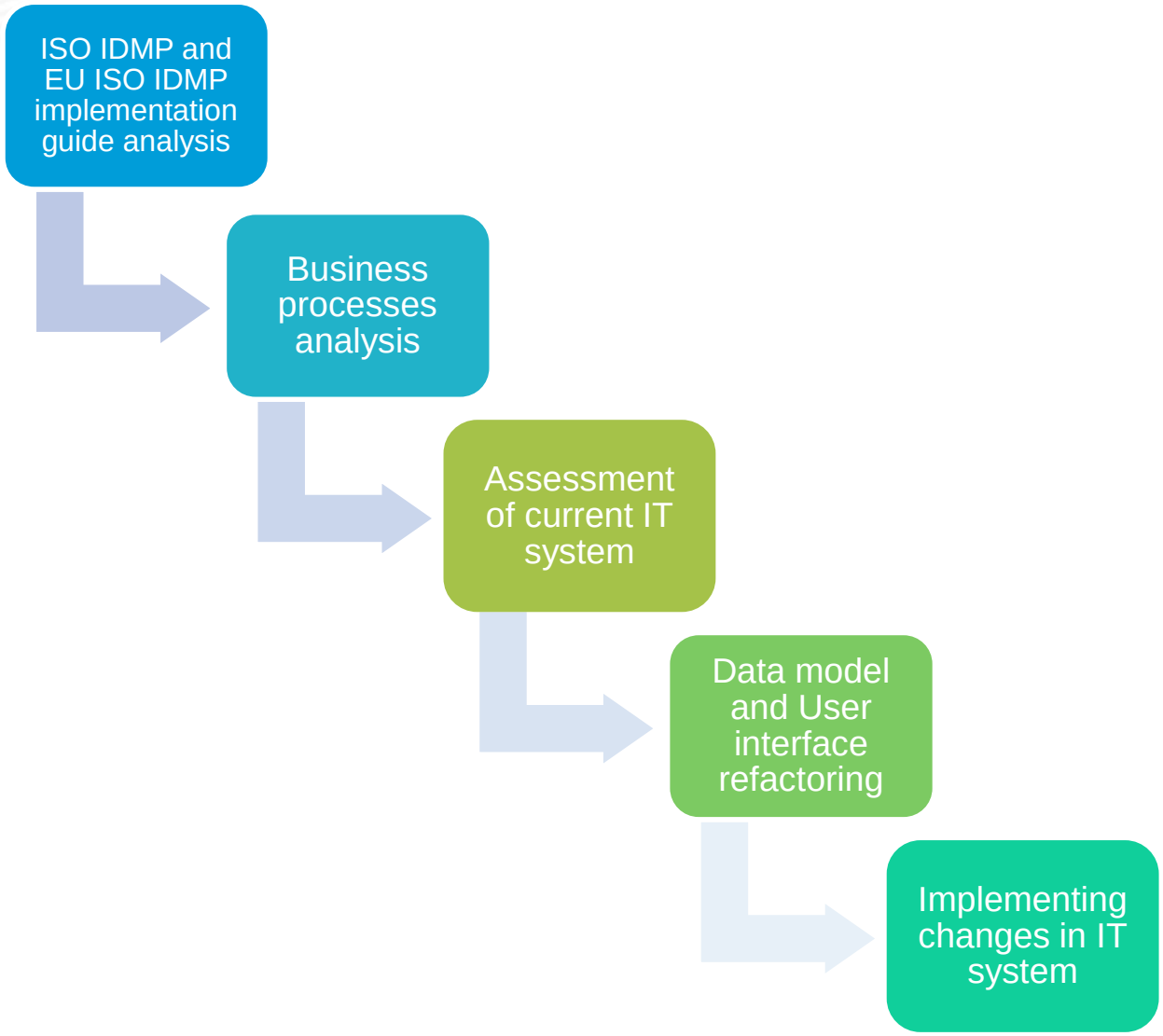
- Croatian competent authority in the field of human medicines and medical devices
  - Established on 1 October 2003
  - Location: Zagreb – 3 different locations
  - Self-financing
  - Joined the EU on 1 July 2013
  - 230 employees
  - 7550 medicinal products in database (5964 authorised nationally (2463 active) and 1.586 through MRP/DCP procedures (1313 active))



HALMED's current IT system



The methodology of refactoring internal IT system and medicinal product database in order to comply with ISO IDMP standards



The methodology of refactoring internal IT system and medicinal product database in order to comply with ISO IDMP standards (1)

ISO IDMP and EU ISO IDMP implementation guide analysis

- Analysis of ISO IDMP data model
- Assessment of required data described in EU ISO IDMP implementation guide prepared by EMA

The methodology of refactoring internal IT system and medicinal product database in order to comply with ISO IDMP standards (2)

Business processes analysis

- Analysis of all the processes in the organization that use medicinal product data
- Analysis of external stakeholder's dataset
- Defining master data set

The methodology of refactoring internal IT system and medicinal product database in order to comply with ISO IDMP standards (3)

Assessment of current IT system

- Assessment of current IT system with medicinal products database
- Detecting gaps vs. ISO IDMP data model and defining what parts of data model should be reconstructed, what entities and attributes should be introduced and what are the areas that need some adjustments
- Decision if an entirely new system will be implemented or the old system can be refactored

The methodology of refactoring internal IT system and medicinal product database in order to comply with ISO IDMP standards (4)

Data model and User interface refactoring

- Proposition of refactored medicinal product database data model
- Proposition of User interface reconstruction through UI mock-ups
- Detection of the new RMS lists that should be introduced
- Testing of the data model and UI reconstruction on different medicinal products (especially those with complex packaging and composition)

The methodology of refactoring internal IT system and medicinal product database in order to comply with ISO IDMP standards (5)

Implementing changes in IT system

- Refactoring of medicinal product database data model
- Introduction of all SPOR RMS lists that should be used for attributes of new entities in data model
- User interface reconstruction
- Update of API services to other connected systems and preparing FHIR messages for SPOR PMS
- Migrating data to new data model

The methodology of refactoring internal IT system and medicinal product database in order to comply with ISO IDMP standards

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Further work

Refactoring of HALMED IT system in order to comply with ISO IDMP

Data migration to new data model, data cleansing and data mapping with SPOR list terms

National database based on ISO IDMP data model built as part of project *eLijekovi* (*eMedicine*)

Medicinal product data sent from HALMED's database to *eLijekovi* (*eMedicine*) database and reused in Croatian healthcare systems

Medicinal product data from Croatian healthcare systems exchanged with other EU systems

Conclusion

- Immense complexity of the processes related to the marketing authorisation of medicinal products and to the production of reliable medicinal product data
- The possibility of uniquely identifying medicinal products globally is becoming top priority
- Solution: ISO IDMP set of standards
- Goal: share medicinal products data world widely
- The implementation process is very demanding for the industry, the healthcare organisations and/or the regulators
- We are at the beginning!

Acknowledgment

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Thank you for your attention!

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