Implementation of ISO IDMP standards within the European Medicines Regulatory Network

EMA SPOR Roadmap, iterations and target operating model for medicinal products and substances

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Paolo Alcini, Head of Data Standardisation and Analytics
### Why do we need standardisation?

**Standardised data will...**

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Pharmacovigilance</td>
<td>Improve signal detection and speed of response for authorised products, thus improving protection of public health in EU</td>
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<tr>
<td>ePrescription</td>
<td>Support cross-border electronic prescriptions of medicines in EU enabling patients to obtain the right products when outside their home country based on standardised data</td>
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<td>Falsified medicines</td>
<td>Support the mechanism for controlling authenticity of medicines</td>
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<td>Shortages</td>
<td>Allow substances and products to be identified across countries enabling faster response to address shortages</td>
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<tr>
<td>Batch recalls</td>
<td>Allow substances and products to be identified across countries enabling faster identification and withdrawal</td>
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<tr>
<td>Inspections</td>
<td>Improve the link between the Supply Chain and the regulatory dossier since inspectors will have better records available to support their findings on Manufacturing sites</td>
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<tr>
<td>Regulatory activities</td>
<td>Facilitate process efficiencies in regulatory activities e.g. submission of regulatory application and Variations</td>
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ISO IDMP will introduce standardisation

The ISO IDMP standards establish definitions and concepts and describe data elements and their structural relationships.

This enables the unique identification of:

- Medicinal product information (MPID/PCID) - ISO 11615 and DTS 20443
  - co-leaders: Vada Perkins and Paolo Alcini
- Pharmaceutical product information (PhPID) - ISO 11616 and DTS 20451
  - co-leaders: Vada Perkins and Paolo Alcini
- Substances (Substance ID/Specified Substance ID) - ISO 11238 and DTS 19844
  - co-leaders: Lawrence Callahan and Herman Diederik
- Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239 and DTS 20440
  - Leader: Christopher Jarvis
- Units of measurement (UCUM) - ISO 11240
  - Co-leaders: Aniello Santoro and Christof Gessner
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 as to 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.
NCAs & EC grant/amend Marketing Authorisations (MA) of Medicinal Products following **evaluation** and **approval** of product information

15 calendar days from the date of authorisation

No later than 30 calendar days from the date the amendments of MA have been authorised

**Article 57 database contains regulated information on Medicinal Products in Europe**
• **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.

• **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
• Most of the information available in the Article 57 database is encoded based on a set of controlled terminologies (i.e. vocabularies)

• Substance terminology provides codification for substance names in English and EU languages for both Active ingredient(s), excipient(s) and adjuvant(s)

• The Article 57 database handles information in both Latin and non-Latin characters (e.g. Greek and Cyrillic)
Feasibility on data and format

**Structured Medicinal Product Information:**
- P1: MAH (Legal Entity)
- P2: QPPV
- P3: PhV Enquiries
- P4: PSMF
- P5: Authorisation country code
- P6: Authorisation procedure
- P7: Authorisation status
- P8: Authorisation number
- P9: Authorisation date
- P10: MRP/DCP/EU number
- P11: Date of withdrawal/revocation/suspension
- P12: Package description
- P13: Orphan drug designation
- P14: Comments (e.g. paediatric use)
- P15: Medicinal product name
- P16: Medicinal product invented name
- P17: Product generic name
- P18: Product company name
- P19: Product strength name
- P20: Product form name
- P21: Pharmaceutical Form
- P22: Route of administration(s)
- P23: Active ingredient(s), Adjuvant(s)
- P24: Excipients
- P25: Medical device(s)
- P26: Strength of active ingredient(s)/adjuvant(s)
- P27: Therapeutic Indication(s)
- P28: ATC code
- P29: Medicinal Product type/Legal Basis
- P30: Summary of Medicinal Product Characteristics

**Substance Information:**
- S1: Substance names
- S2: Substance Translations
- S3: Substance synonyms
- S4: Substance class
- S5: Reference source
- S6: International Codes

**Reference Terminology:**
- R1: Pharmaceutical form
- R2: Route of Administration
- R3: ATC codes
- R4: Units of Measurement
- R5: Units of presentation
- R6: Reference source

**Organisation information:**
- O1: MAH (Legal Entity) details
- O2: QPPV
- O3: PhV Enquiries
- O4: PhV System Master File

- Data elements required by ePrescription guidance
- Data elements EMA recommends for use in the ePrescription Business Case