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SCIENCE MEDICINES HEALTH

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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Why do we need standardisation?

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Standardised data will…

Pharmacovigilance	**…improve signal detection and speed of response for authorised products, thus improving protection of public health in EU**
ePrescription	**…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**
Falsified medicines	…**support the mechanism for controlling authenticity of medicines**
Shortages	**…allow substances and products to be identified across countries enabling faster response to address shortages**
Batch recalls	**…allow substances and products to be identified across countries enabling faster identification and withdrawal**
Inspections	…**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
Regulatory activities	…**facilitate process efficiencies in regulatory activities** e.g. submission of regulatory application and Variations

ISO IDMP will introduce standardisation

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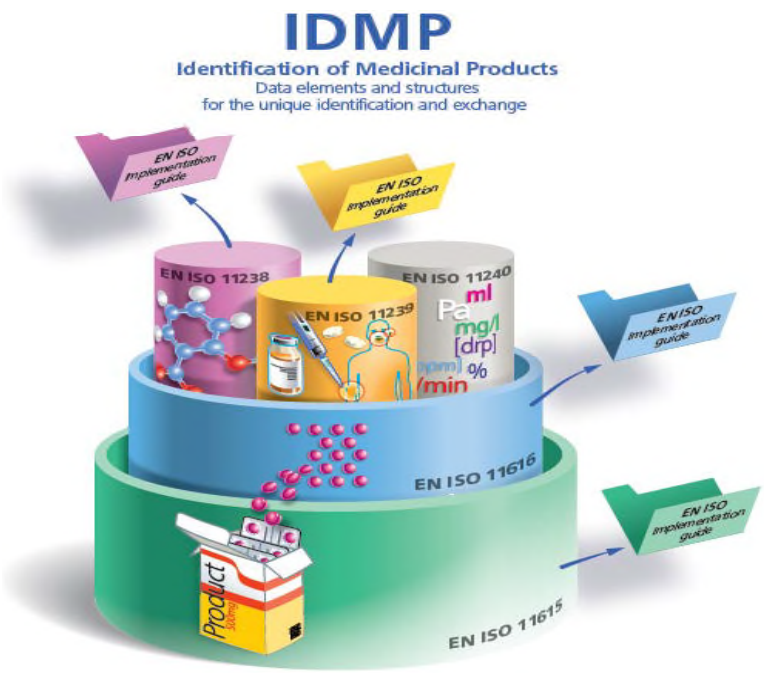
The ISO IDMP standards establish definitions and concepts and describe data elements and their structural relationships.

This enables the the **unique identification** of:



Source: ISO TC 215, Working Group 6 (Pharmacy and Medicines Business), December 2014

- 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

Current process to submit data on medicines in EU

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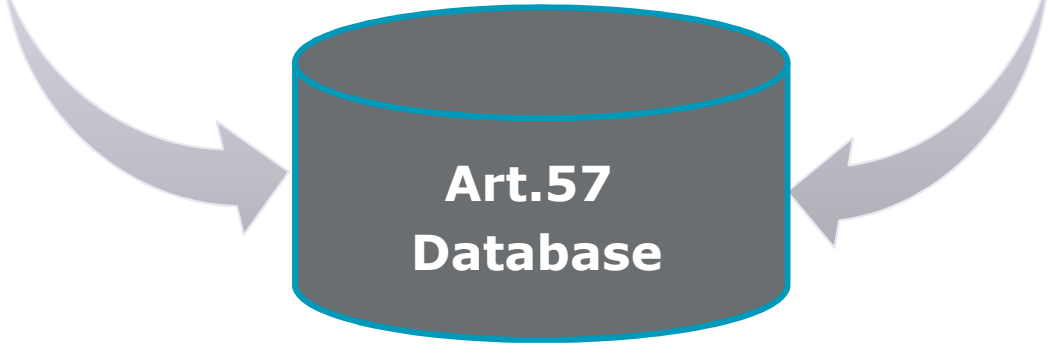
- Currently the submission of data on medicines by Marketing Authorisation Holders is a legal requirement introduced by Article 57(2) of Regulation (EC) No 726/2004 as amended
- Pharmaceutical companies that hold marketing authorisations for medicinal products for human use in the EU and the EEA are 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

Article 57 Database – governance (1)

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

Article 57 Database – governance (2)

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- **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 Database – content

- 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 – data format

- 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

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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

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**

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