ISO Identification of Medicinal Products (IDMP) and HL7 Structured Product Labeling (SPL)

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Overview

• Introduction to the IDMP standards
• Main features of the five ISO IDMP standards
• Implementation of the ISO IDMP standards
  – HL7 Structured Product Labeling (SPL)
    • US FDA

The Identification of Medicinal Products (IDMP) Standards

An Introduction
The Five ISO IDMP Standards

IDMP includes five Health Informatics standards:

• Data elements and structures for unique identification and exchange of regulated medicinal product information – ISO prEN 11615

• Data elements and structures for unique identification and exchange of regulated pharmaceutical product information – ISO prEN 11616

• Data elements and structures for unique identification and exchange of regulated information on substances) – ISO prEN 11238

• Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation and routes of administration - ISO prEN 11239

• Data elements and structures for unique identification and exchange of units of measurement - ISO prEN 11240
ISO IDMP (1 of 3)

- Developed in response to a worldwide demand for internationally harmonized specifications for medicinal products
- Provide the basis for the unique identification of medicinal products
- Facilitate the activities of medicines regulatory agencies worldwide by jurisdiction for a variety of regulatory activities
  – Development, registration and life cycle management of medicinal products
  – Pharmacovigilance and risk management

ISO IDMP (2 of 3)

- Messaging specifications are included as an integral part of the IDMP standards
  – Describe and protect the integrity of the interactions for the submission of regulated medicinal product information in the context of the unique product identification
  – Acknowledgement of receipt including the validation of transmitted information
  – Health Level Seven (HL7) Message Exchange
    • Normative within the ISO IDMP Standard
ISO IDMP (3 of 3)

- Standards designed to allow unambiguous identification of products across regions to improve the robustness of pharmacovigilance and regulatory activities

- Can be also applied to Investigational Medicinal Products

ISO 11238: Substances/Specified Substances

- **Substance:**
  - Is defined based on its main, general characteristics
  - Can have different roles e.g. active, adjuvant, basis of strength, excipient

- **Specified Substance:**
  - More granular, specific description of a substance e.g. including manufacturing information, purity, grade
  - Allows for the specification of multiple substances ("Intermediate Products" e.g. AS03 - adjuvant composed of squalene (10.69 milligrams), DL-α-tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams))
ISO 11239-Dosage Forms/Routes of Administration/Units of Presentation

- Where regional terms have a **lower** level of granularity and detail, a regional term will often map to more than one central term.

<table>
<thead>
<tr>
<th>Region A regional term (lower granularity)</th>
<th>Maps to central terms (one maps to several)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection</td>
<td>Injection solution</td>
</tr>
<tr>
<td></td>
<td>Injection suspension</td>
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<tr>
<td></td>
<td>Infusion solution</td>
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</table>

<table>
<thead>
<tr>
<th>Region B regional terms (higher granularity)</th>
<th>Map to central term (several map to one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Granule-filled soft capsule</td>
<td>Oral soft capsule</td>
</tr>
<tr>
<td>Liquid-filled soft capsule</td>
<td></td>
</tr>
<tr>
<td>Powder-filled soft capsule</td>
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</tbody>
</table>

- Where regionals terms have a **higher** level of granularity and detail, more than one regional term will often map to a single central term.

ISO 11240: Units of Measurement

- Specify rules for the usage of units of measurement for IDMP
- Define requirements for traceability to metrological standards
- Establish reference code system for units
- Provide structures and rules for mapping between different unit vocabularies and language translations, linking to existing systems, dictionaries and repositories.
• Pharmaceutical Product Identification (PhPID) based on the following subset of elements that describe the pharmaceutical product:
  – Substance(s)/Specified Substance(s)
  – Strength(s) - Strength units (units of measurement and/or unit of presentation)
  – Reference Strengths
  – Administrable Dose Form
  – Medical device: when it is a component of a medicinal product

PhPIDs utilizes:
• IDMP substance (ISO prEN 11238)
• IDMP pharmaceutical dose form/units of presentation (ISO prEN 11239)
• IDMP units of measurement (ISO prEN 11240)
ISO 11615: Medicinal Product Identification

- Defines, characterizes and uniquely identifies regulated medicinal products for human use during their entire life cycle
  - Development, authorization, post-marketing and renewal or withdrawal from the market
- Establishes definitions and concepts
- Describes data elements and their structural relationships required for the detailed description and unique identification of medicinal products
- Use of other normative IDMP HL7 standards for messaging purposes

Primary Identification of Medicinal Products

- Country Code
- Unique Company/Applicant Identifier
- **MPID – Medicinal Product Identifier**
  - To reliably recognise, monitor and trace the use of medicinal products
- **PCID – Medicinal Product Package Identifier**
  - To reliably recognise and trace medicinal products as packaged for sale or supply
- **BAID_1 – Medicinal Product Batch Identifier**
  - To reliably recognise and trace a manufactured batch or lot in compliance with the requirements of the marketing authorisation
- **BAID_2 – Medicinal Product Package Batch Identifier**
  - To reliably recognise and trace a manufactured batch or lot in compliance with the requirements of the marketing authorisation
The ISO Identification of Medicinal Products (IDMP) Standards and HL7 Structured Product Labeling (SPL)

FDA Implementation (Pre-IDMP)

- **Content of Labeling (Prescribing Information)/ Electronic Establishment Registration and Product Listing**
  - Data Elements
  - Controlled Vocabulary
  - Unique Identifiers
  
  **Drug to manufacturer identification (validated process)**

- **Indexing**
  - Coding prescribing information
  - MedDRA and SnoMed

- **FDA Online Label Repository**
  - Comprehensive repository of regulated medicinal products
  - Available to public
  - Validation procedures by FDA
  - Goal: Provide the most current medicinal product data to consumers and HCPs
Message Exchange

• **Health Level Seven (HL7)**
  – Must be able to not only harmonize content but also standardize the exchange of medicinal product information
  – Normative in ISO IDMP Standard

– HL7 Messaging
  • Compatibility
  • Interoperability
  • Portability

**Exchange med product, adverse event, compliance information between regulators**

Paper Forms (obsolete)
Structured Product Labeling (SPL)

- Electronic labeling standard developed by Health Level 7 (HL7)
  - Utilizes eXtensible Markup Language (XML)
    - Machine readable tags to improve search functionality across systems
  - Usability across multiple database platforms
    - Interoperability
    - Compatibility
    - Portability
  - Promote electronic health information initiatives
    - Electronic health records
    - Electronic prescribing
  - Enhanced search capabilities
Validation

- **Automated**
  - ISO IDMP/ICH M5/regional (e.g., FDA, EMA) business rules

- **Downstream Third Party Utilization**

  **Goal:** Real time availability of comprehensive and validated information

Future Data Standards Development

- **Blood Establishment Registration and Listing**
  - Replace paper FDA Form 2830 [link to PDF]

- **Human Cell and Tissue Establishment Registration and Listing**
  - Replace paper FDA Form 3356
  - eList (Provenge and Carticel)
Future Data Standards Development

- Unique Device Identification (UDI)
  - Per FDAAA
    - Standardized and globally unique single device identification system
  - HL7 SPL Release 5
    - Extend the Structured Product Labeling (SPL) standard to the next release (R5) for the support of medical devices
    - SPL R5 to support FDA's Unique Device Identification (UDI) database
    - Backward compatible with SPL R4 that supports drugs and biologics

Harmonization of Medicinal Product Identification Activities

- Harmonisation or Harmonization?
  - Harmonisation

- ISO Technical Committee 215/Working Group 6: Health Informatics

- International Conference on Harmonisation (M5)

**Identify regional requirement commonalities (EMA/FDA/MHLW)**
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**Comparison of ISO/ICH Activities with US Implementation Efforts**

- **ISO 11615**: Medicinal Product ID (MPID)
  - National Drug Code (NDC)

- **ISO 11616**: Pharmaceutical Product ID (PhPID)
  - TBD

- **ISO 11238**: Substances/Specified Substances
  - FDA Substance Registration System Unique Ingredient Identifiers (UNII)

- **ISO 11240**: Units of measurement
  - Unified Code for Units of Measure (UCUM)

- **ISO 11239**: Dosage forms (mapping exercise)
  - Future activity: EDQM/FDA/Other Stakeholders
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• Questions?

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