Identification of Medicinal Products (IDMP)

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Overview

- ICH background
- ICH Milestones
- ISO Identification of Medicinal Products
- Next steps in the ICH process

ICH Background

- In November 2003 the ICH Steering Committee (SC) approved a Concept Paper for the development of a new tripartite guideline:
  - *Data Elements and Standards for Drug Dictionaries*
- Objectives:
  - Support the identification of medicinal products in all ICH regions
    - Individual Case Safety Reports (ICSRs) and adverse reaction reporting in pharmacovigilance and clinical trials
    - Case evaluation and signal detection
    - Earlier detection of potential safety issues
    - Protection of public health

ICH Milestones

- In May 2005 the ICH M5 guideline was released for consultation at step 2 of the ICH process
  - List of Routes of Administration and Units and Measurements
- In June 2006 the ICH Steering Committee agreed that ICH M5 electronic standards would be developed with SDOs
- In February 2007 the M5 EWG finalised:
  - ICH M5 business requirements for five 'New Work Item Proposals' (NWIPs) for the *ISO Identification of Medicinal Products (IDMP) project*
  - The revised M5 guideline taking into account the comments received during public consultation as a supporting document for the NWIPs
- Maintenance requirements to be defined by ISO

ISO Identification of Medicinal Products

1. Health informatics – Identification of Medicinal Products – Data Elements and Structures for the Exchange of Regulated *Medicinal Product* Information for Drug Dictionaries *(MPID)* (prEN ISO 11615)

2. Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for *Ingredients (Substances)* (prEN ISO 11238)

3. Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for *Pharmaceutical Product Identifiers (PhPIDs)* (prEN ISO 11616)

ISO Identification of Medicinal Products

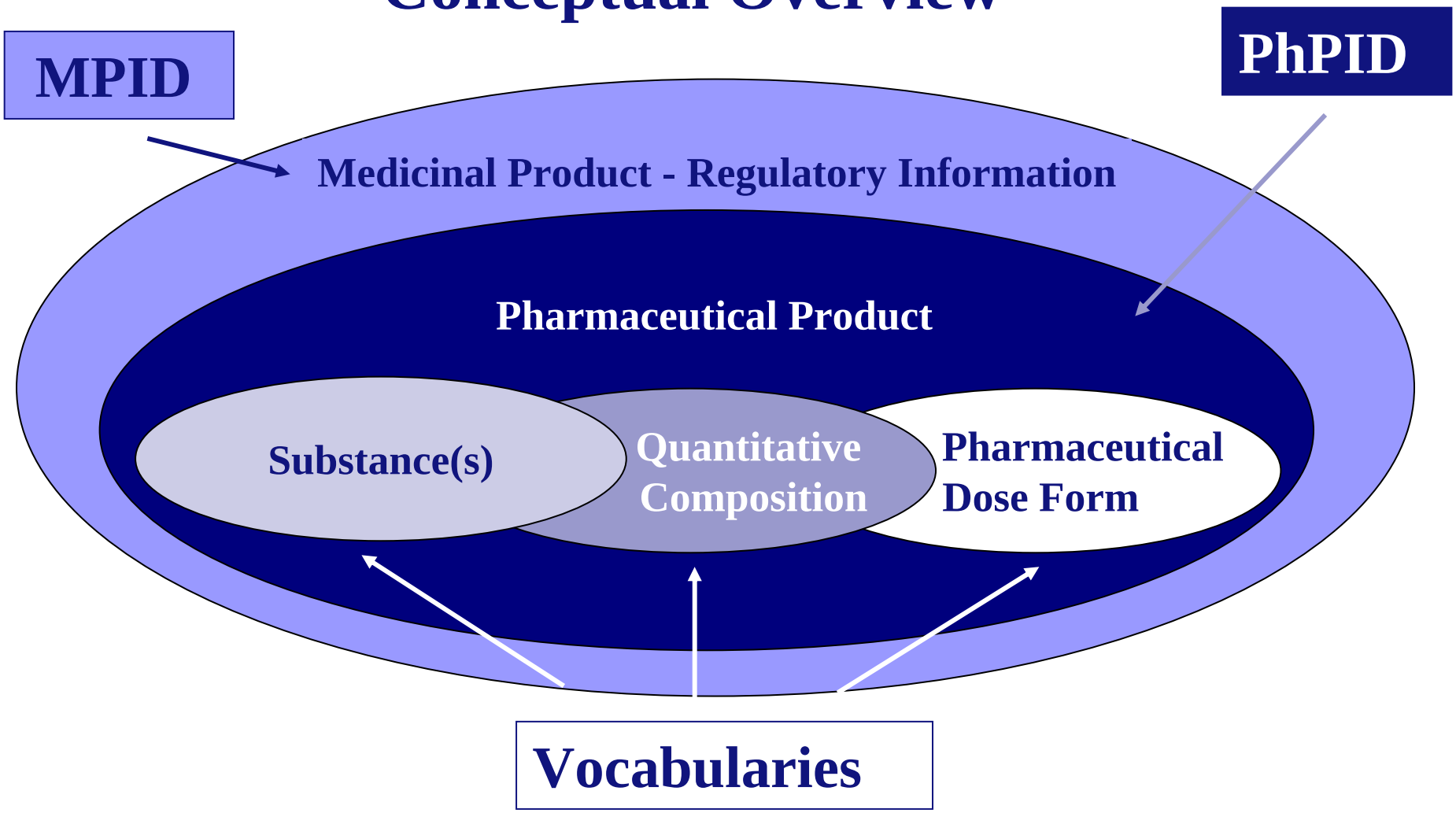
4. Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for *Pharmaceutical Dose Forms, Units of Presentation and Routes of Administration* (prEN ISO 11239)

5. Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for *Units of Measurement* (prEN ISO 11240)

6. Health informatics – Structures and Controlled Vocabularies for *Laboratory Test Units* for the Reporting of Laboratory Results (prEN ISO 11595)

Maintenance of vocabularies

Conceptual Overview



Next Steps in the ICH Process

- Prepare for ICH Step 2 for Testing Plan
- Prepare step 2 ICH M5 Implementation Guide
- Conduct Step 2 for Testing to provide ICH input into the standard development process
- Finalise step 4 ICH M5 Implementation Guide

Thank you

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