IDMP stands for “Identification of Medicinal Products”

The set of five EN/ISO international standards has been developed in response to a worldwide demand for internationally harmonized specifications for identification and description of medicinal products. IDMP provides the basis for the unique identification of medicinal products, which facilitates 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). They can also be applied to Investigational Medicinal Products.

Messaging specifications are included as an integral part of the IDMP standards. They describe and protect the integrity of the interactions for the submission of regulated medicinal product information in the context of the unique product identification; they include acknowledgement of receipt including the validation of transmitted information. Health Level Seven (HL7) Message Exchange are normative within the IDMP Standards.

IDMP standards are completed with Implementation Guides which are currently in development (2014), as well with TS 16791 (provides guidance for the identification of medicinal products by using international supply chain standards, securing traceability, safe supply chain and other market requirements) and TR 14872 (Requirements for the implementation of the standards for the identification of medicinal products for the exchange of regulated medicinal product information), the latter being in development.

The standards can be found in the ISO Standards catalogue at:
http://www.iso.org/iso/home/store/catalogue_tc/

Identification of Medicinal Products (IDMP)

A major collaborative development addressing the needs for global identification of regulated medicinal products

This document has been prepared by ISO TC 215, Working Group 6
(Pharmacy and Medicines Business), December 2014

IDMP

Identification of Medicinal Products

Data elements and structures
for the unique identification and exchange

EN ISO 11238

Substances

Regulated information on substances

Defines Substances by their main, general characteristics and Specified Substances (which are more granular, specific descriptions of a substance, e.g. including manufacturing information, purity, grade). Substances can have different roles in medicinal products (e.g. active, adjuvant, basis of strength, excipient). The standard also allows for the specification of multiple component substances ("Intermediate Products").

EN ISO 11239

Dose forms, etc.

Regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

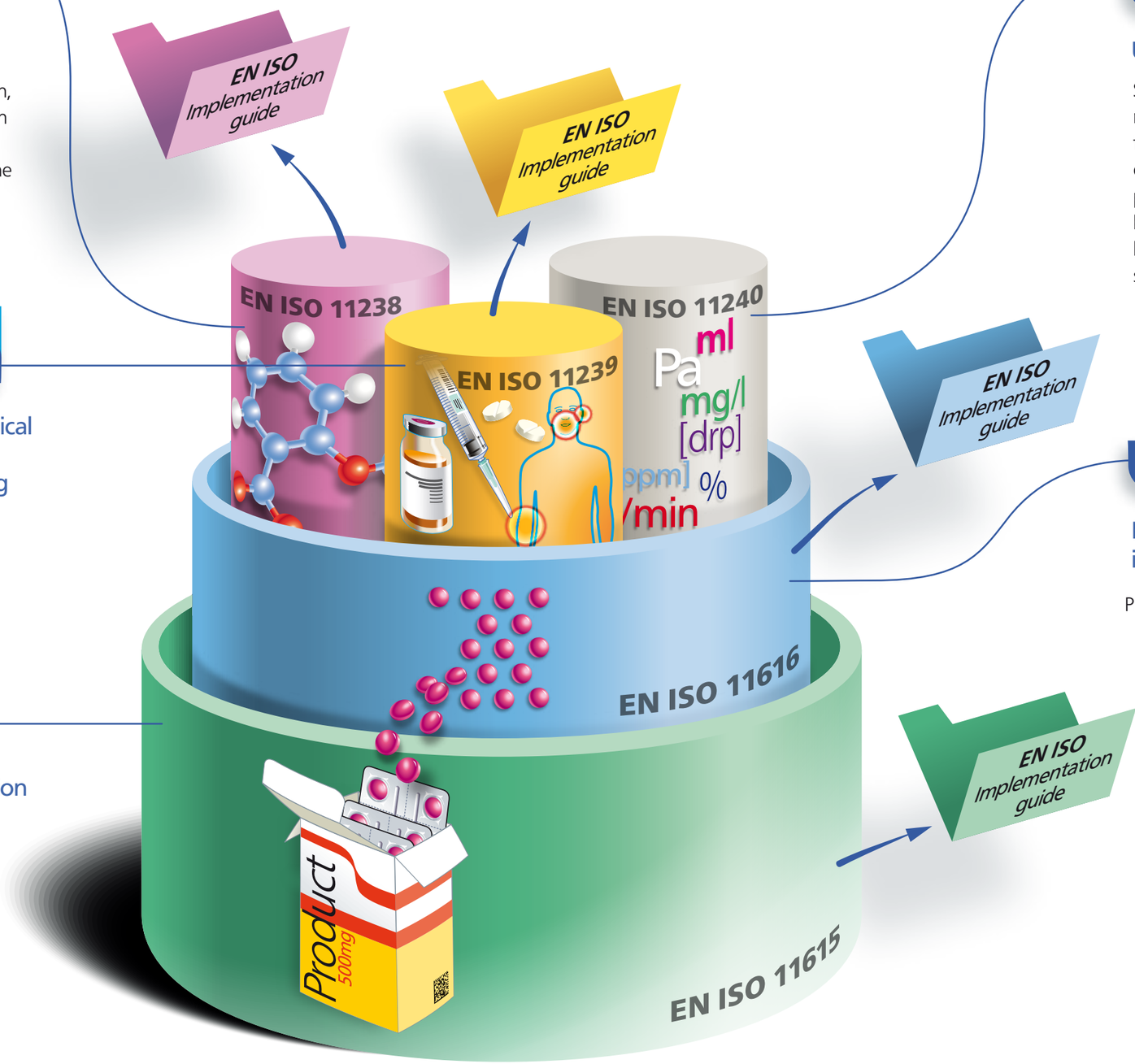
Identifies and defines concepts for each of the above. For example, in dose forms: "injection solution", "injection suspension" (or a less granular regional term linked to these)

EN ISO 11615

MPID

Regulated medicinal product information

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) by describing the detailed data elements and their structural relationships that uniquely identify a medicinal product.



EN ISO 11240

Units of measurement

Units of measurement

Specifies rules for the usage of units of measurement for IDMP; defines requirements for traceability to metrological standards; establishes reference code system for units; provides structures and rules for mapping between different unit vocabularies and language translations, linking to existing systems, dictionaries and repositories

EN ISO 11616

PhPID

Regulated pharmaceutical product information

Pharmaceutical Product Identification (PhPID) uniquely identifies a generic (pharmaceutical) representation of a medicinal product at various levels, based on the following subset of elements

- Substance(s)/Specified Substance(s)
- Strength(s) - Strength units (units of measurement and/or unit of presentation)
- Reference Strengths
- Administrable Dose Form