



Identification of Medicinal Products (IDMP)

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Overview



- What is IDMP?
- Why is it important?
- ISO IDMP Global Harmonization
- International Adoption

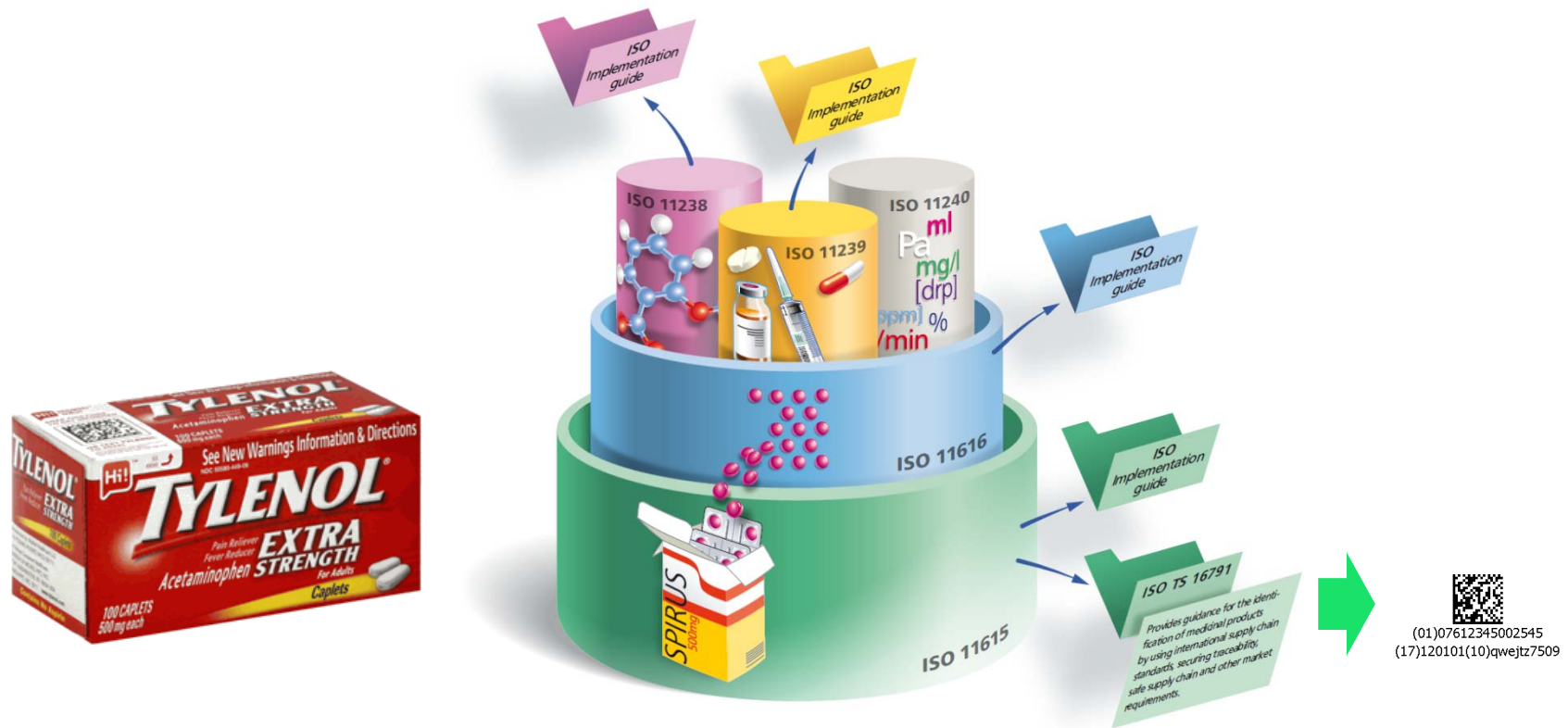


What is IDMP?

The Identification of Medicinal Product (IDMP) is a suite of five ISO standards that:

- Defines the data elements and structure to **uniquely** and **unambiguously** identifies medicinal product and substance (regionally or cross regions)
- Creates **common vocabulary** for improved people communication
- Creates **common messaging** standards for improved IT system communication

What is IDMP?



Units of Measurement



ISO 11240 - Data elements and structures for unique identification and exchange of **units of measurement**

Specifies rules for the usage and coded representation of units of measurement for the purpose of exchanging information about quantitative medicinal product characteristics (e.g. strength)

Dose Forms & Routes of Administration



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

- Specifies data elements and structure which uniquely and with certainty identify pharmaceutical dose forms, units of presentation and routes of administration related to medicinal product
- Specifies mechanism to associate the translation of a single concepts into multiple languages

Substance



ISO 11238 - Data elements and structures for unique identification and exchange of regulated information on **substances**

Provides an information model to define and identify substance within medicinal products or substances used for medicinal purposes.

- **Substance**: Defined based on its main, general characteristics
- **Specified Substance**: More granular, specific description of a substance

Pharmaceutical Product ID



ISO 11616 - Data elements and structures for unique identification and exchange of regulated **pharmaceutical product** information (**PhPID**)

- Provides specific levels of information relevant to the identification of a medicinal product or group of (*pharmaceutically equivalent*) medicinal products
- Derived ID based on the following subset of elements:
 - Substance(s)/Specified Substance(s)
 - Strength(s) – Strength units
 - Administrable Dose Form(s)

Medicinal Product Identification



ISO 11615 - Data elements and structures for unique identification and exchange of regulated **medicinal product** information

Establishes definitions and concepts and describes data elements and their structural relationships, which are required for the unique identification and the detailed description of Medicinal Products.



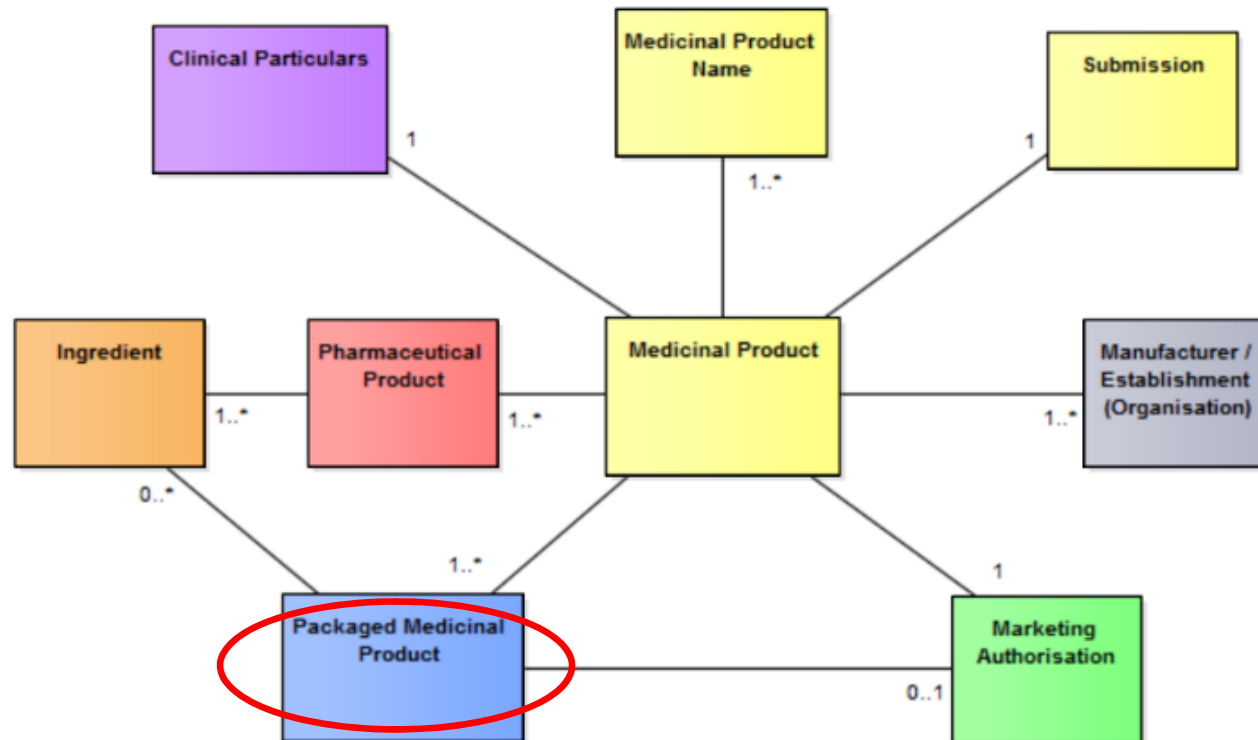
Medicinal Product Identification

Primary Identification of Medicinal Products

- **MPID** – Medicinal Product Identifier
 - **Country Code + Marketing Authorization Holder + Product Code**
- **PCID** – Medicinal Product Package Identifier
 - **MPID + Package Description Code** *NDC*
- **BAID_1** – Medicinal Product Batch Identifier (*Outer Packaging*)
 - **PCID + Batch Number + Expiration Date (ISO 8601 date format)**
- **BAID_2** - Medicinal Product Package Batch Identifier (*Immediate Packaging*)
 - **PCID + Batch Number + Expiration Date (ISO 8601 date format)**



IDMP Concept Model



Medicinal Product Identification




The Global Language of Business

Healthcare

Implementation Guideline:
Applying GS1 Standards for DSCSA and Traceability

Release 1.2, Nov 07 2016




4.1 Relationship between NDC – GTIN – SGTIN

The FDA National Drug Code (NDC) is a U.S. regulatory identifier used to identify pharmaceutical products for regulatory purposes. The GTIN is a supply chain identifier used to identify products for supply chain purposes. The SGTIN is a supply chain identifier used to identify individual instances of a product for supply chain purposes. There is a cohesive, hierarchical relationship between these identifiers. As illustrated in the figure below, NDCs can be embedded into GTINs so that identification of pharmaceutical products for supply chain purposes is consistent with identification of pharmaceutical products for regulatory purposes. GTINs can then be supplemented with serial numbers to identify individual instances of the pharmaceutical product.

Figure 4-1 Relationship of the NDC, GTIN and SGTIN




Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability

6.2.1 GTIN + Batch/Lot Number

6.2.1.1 EPC URI Format

The EPC URI format for a GTIN + batch/lot is the LGTIN EPC.

General syntax:
urn:epc:class:lgtin:CompanyPrefix.ItemRefAndIndicator.Lot

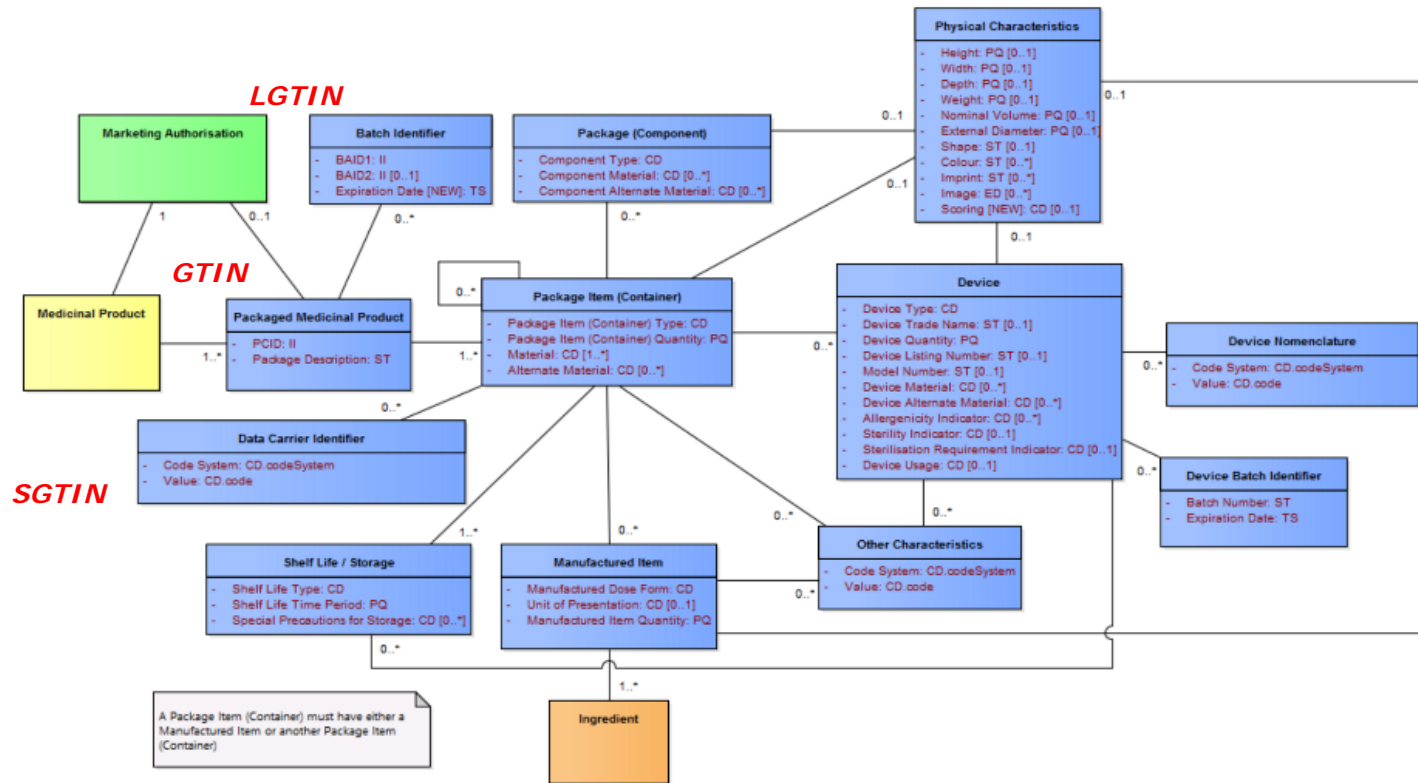
Example:
urn:epc:class:lgtin:030001.2123498.A1B2C3

The figure below depicts how the element string of a GTIN + batch/lot corresponds to the element string of a LGTIN EPC URI.

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Packaged Medicinal Product Detail Model

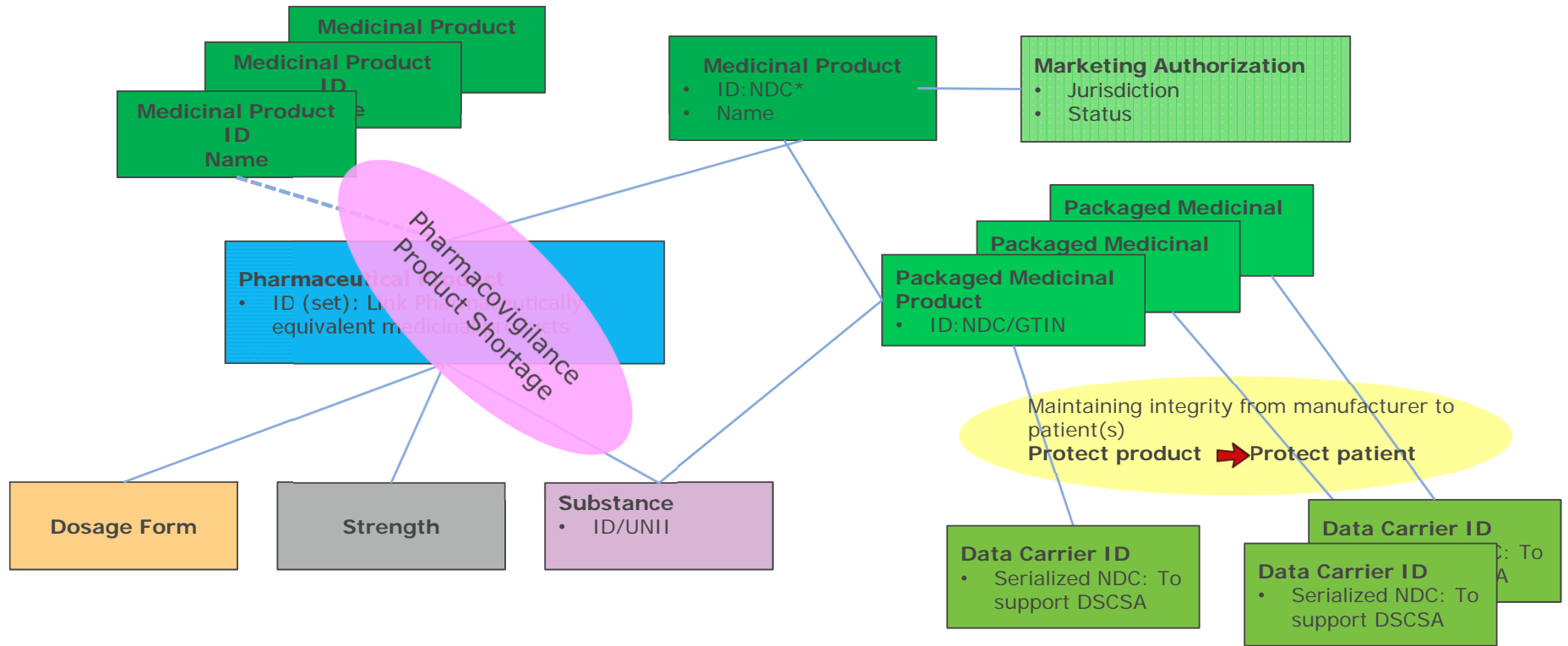




Why is it important?

- Data standards, like IDMP, creates common language that enables **INTEROPERABILITY**
 - regulator to regulator;
 - pharmaceutical company/clinical trial sponsor to regulator;
 - regulator to worldwide-maintained data sources.
- IDMP can improve **PATIENT SAFETY**
 - Is critical for pharmacovigilance & risk analytics - more specificity leads to more accuracy
 - Helps agencies authorize alternative products when there are shortages
- IDMP can improve **MONITORING OF THE GLOBAL SUPPLY CHAIN**
 - IDMP identifiers will be used to verify packages and batches, screen counterfeits
 - Improves the reporting & tracking of patient safety issues on an international level

Why is it important?





ISO IDMP Global Harmonization

- Medicinal Product ID (MPID) [Regional Identification \(NDC\)](#)
- Pharmaceutical Product ID (PhPID) [\(algorithm\)](#)
 - Based on core elements for identification of medicinal products
- Substances
 - Global Substance Registration System [\(GSRS\)](#)
- Dosage forms and Routes of Administration
 - European Directorate for the Quality of Medicines [\(EDQM\)](#)
- Units of measurement
 - Unified Code for Units of Measure [\(UCUM\)](#)

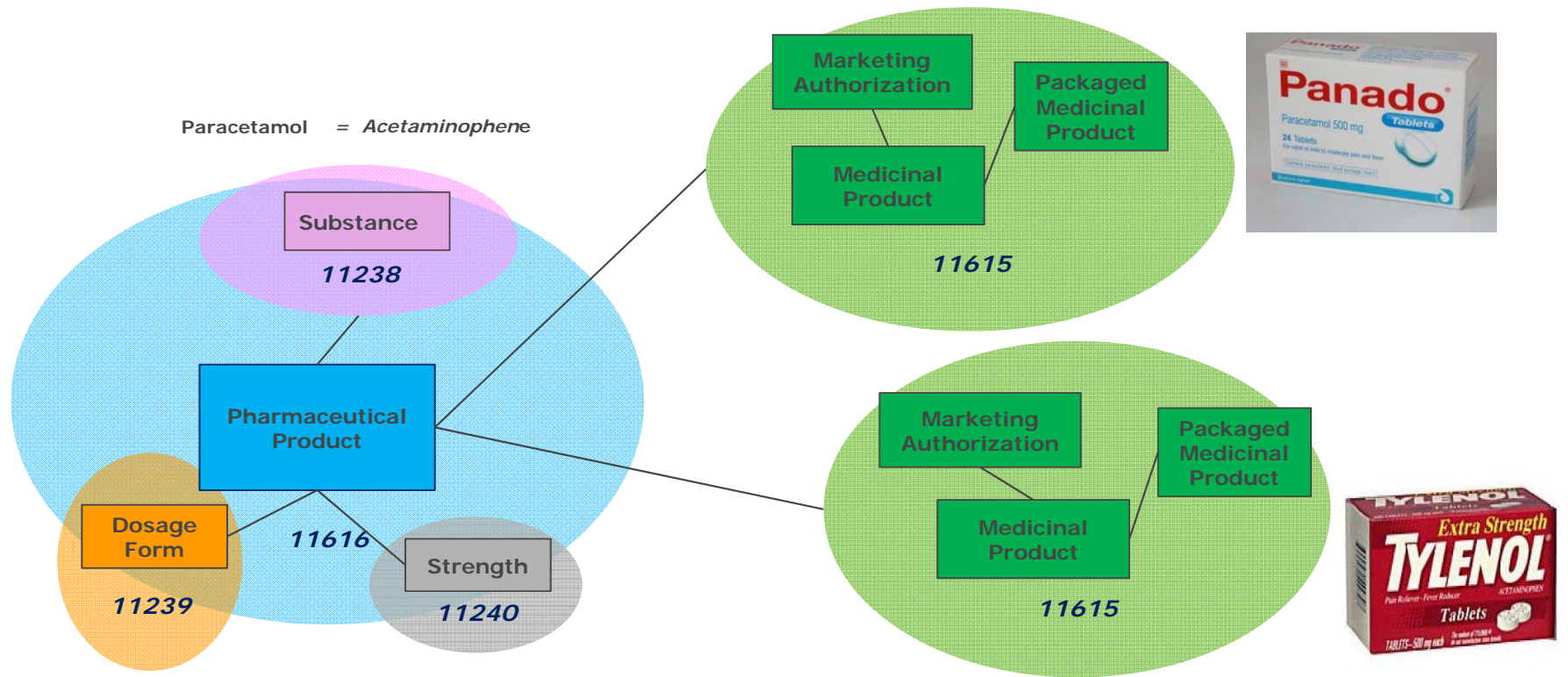
EDQM - The European Directorate for the Quality of Medicines & HealthCare

GSRS - Global Substance Registration System

UCUM - THE UNIFIED CODE FOR UNITS OF MEASURE by Regenstrief Institute



Pharmaceutically Equivalent Product



ISO IDMP International Adoption



- EMA/FDA Collaboration
- I.P.R.F. (International Pharmaceutical Regulators Forum)
 - EU, Netherland, Switzerland, Canada, Mexico, US, Brazil, Cuba, Japan, Korea, Malaysia, Singapore, Taiwan, South Africa, Thailand, WHO
- ACSS
 - Australia, Canada, Singapore, and Switzerland
- WHO
 - Can make PhPID adoption easier
- USP



Discussion Question? Comments?



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