How to facilitate the cross-borders cross-domains identification of products

(HL7 and IDMP)

openMedicine in a Nutshell

- ***What*: Univocal identification of "medicinal products"**
- ***Why*:** Assuring patient safety and continuity of care for **cross-border services** (e.g. ePrescription; Patient Summary)
- ***How*: *common data models, common vocabulary, rules and a global roadmap for the identification and description of "medicinal products".***
- ***Who*:** *National Regulatory Agencies (Ireland, Spain) ; Regions (Lombardy) ; SDOs (GS1; ISO/CEN; HL7); SMEs (Custodix, Empirica). Expert Council (EMA, FDA,WHO; IHTSDO; several national agencies; …)*
- ***When*:** *January 2015 – January 2017*

Not only Europe…
…not only regulators

- **International experts**, not limited to the regulatory domain, have been involved in the projects through three experts meetings (the final one planned for November in London)

- An **USA-EU Workshop** *("Towards a Trans-atlantic Solution To Univocally Identify Medicinal Products")* extended to Canada, was held in June at the FDA venue

The choice…

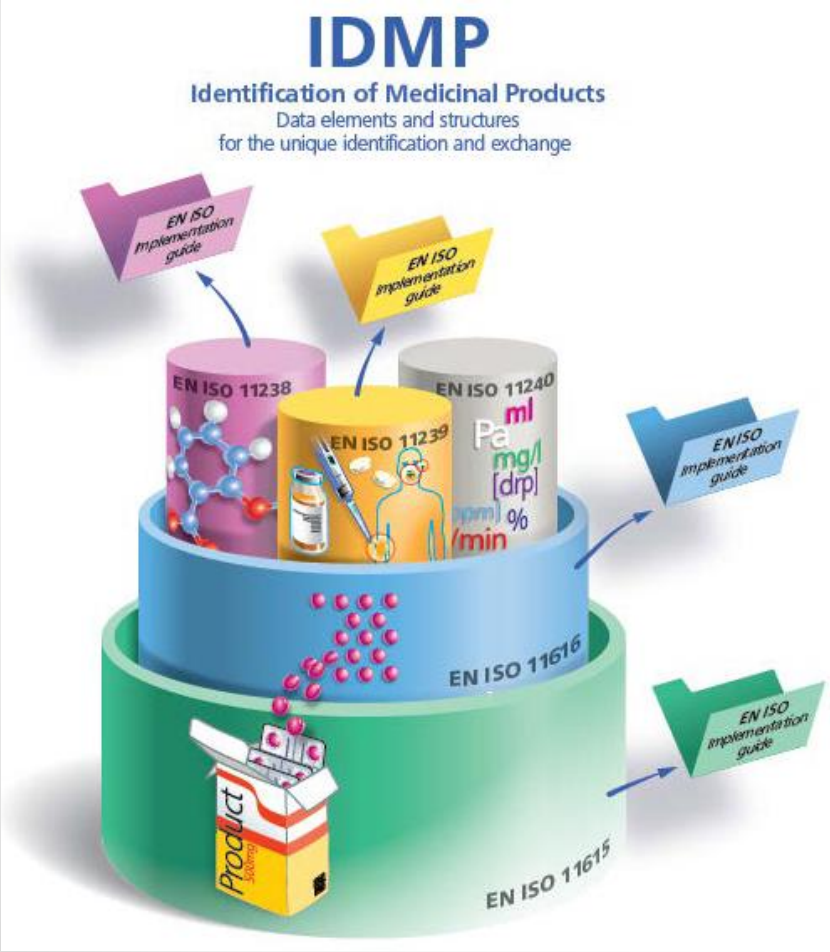
ISO Identification of Medicinal Products (IDMP) Standards

Why IDMP

- IDMP is out and its adoption is expected to be global.
- European (EMA), American (FDA), Canadian (Health Canada) etc. have on-going processes for implementing in their registration (SPL) and pharmacovigilance (ICSR) processes
  - IDMP Implementation Guide to be released, IDMP revision on going
  - Global identification of substances (G-SRS, GINAS)
  - FDA is working for algorithm for unique identification of Pharmaceutical Product (EN ISO 11615), WHO Uppsala proposed to act as global registry for PhPID
  - European SPOR* services expected by 2018
  - …
- …need of **unique identification and description of medicines across jurisdictions and domains**

*SPOR: substance, product, organisation and referential data

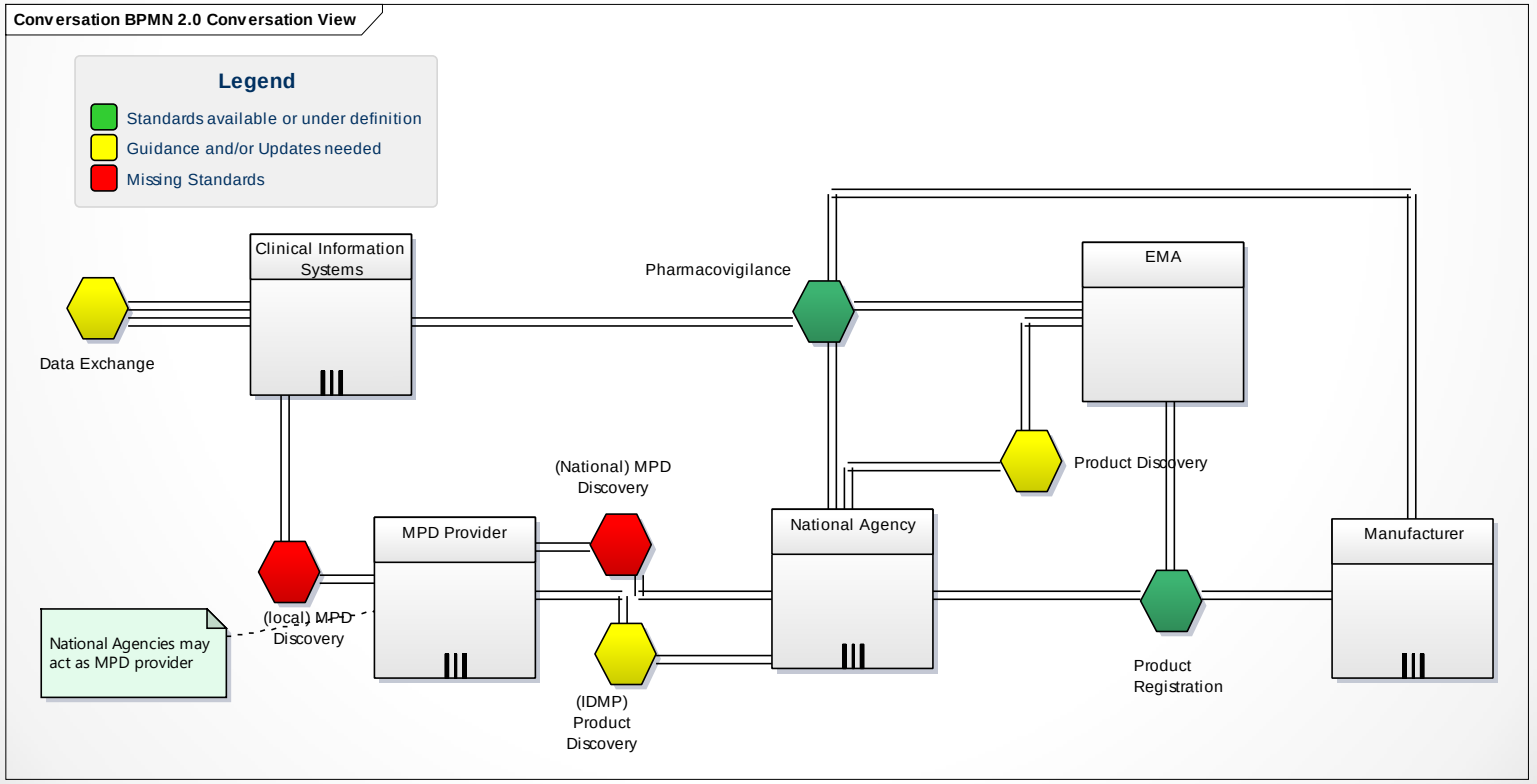
What is IDMP



- The ISO IDMP standards establish **definitions and concepts and describe data elements** and their structural relationships that are required for the **unique identification** of:
  - **Medicinal product information (MPID/PCID) - ISO 11615**
  - Pharmaceutical product information (PHPID) – EN ISO 11616
  - Substances (Substance ID) – EN ISO 11238
  - Pharmaceutical dose forms, units of presentation, routes of administration and packaging - EN ISO 11239
  - Units of measurement (UCUM) – EN ISO 11240
- ISO IDMP standards apply to both authorised and developmental medicinal products for Human use (EMA extends IDMP to animal health medicinal products)
- ISO IDMP standards support the activities of **medicines regulatory agencies** worldwide by jurisdiction

openMedicine findings

- IDMP attributes and identifiers have to be timely available to "end users" systems



openMedicine findings

- Current (HL7) standards partially cover the IDMP model :
  - HL7 SPL (i.e. CPM) is the way IDMP is supposed to be implemented, but the forward model mapping from the IDMP to the CPM is not always so straightforward…
  - Not all the HL7 V3 / CDA based conversations use the CPM…
  - What is the best way to transmit IDMP attributes and identifiers using V2 messaging ? (..if actually needed…)
  - What about FHIR ?
    - The closest resource is the Medication resource , but it seems not aligned with the IDMP concepts

So what ?

- PSSs with RCRIM and Pharmacy to work on communication about products between Agency / MPD provider and Clinical Systems has been proposed.
- FHIR presents a great opportunity
  - Regulators are defining their roadmaps and technical mechanisms
  - FHIR is a standard for Trial Use
  - **Good time to bring IDMP into FHIR**
- Guidance and update on HL7 standards for the implementation of the IDMP / MPD concepts are needed

Questions to TSC

- How the unique identification and description of medicines across jurisdictions and domains can be helped ?

- How can be promoted the implementation of the ISO IDMP model (structure, identifiers and attributes) my means of the HL7 products ?