

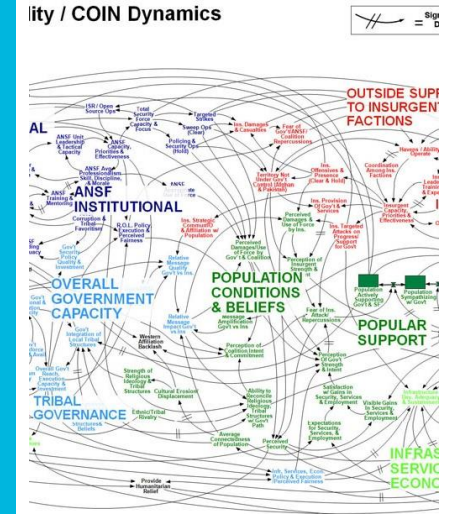


Brief overview on IDMP

October 2018

Christian Hay, Sr consultant healthcare, GS1 Global Office

ality / COIN Dynamics



Page 22

Overview of IDMP



- You can also visit www.isotc215-wg6.team

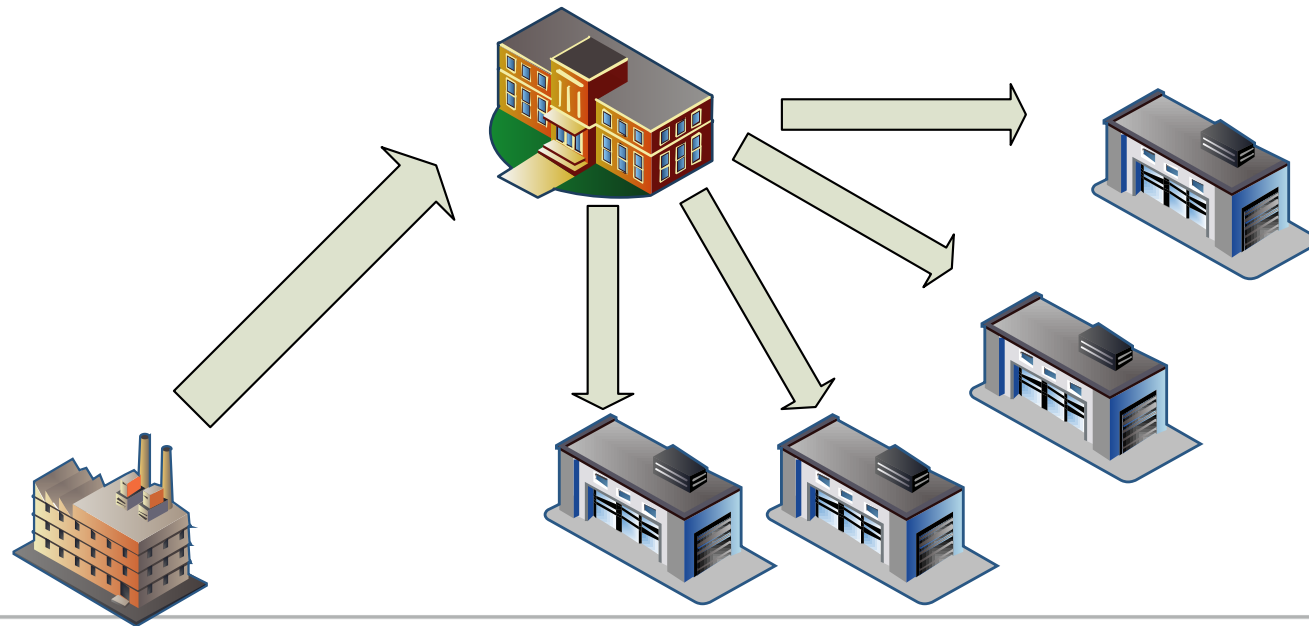
IDMP to support adverse event reporting



The identification, compilation and central management of pharmaceutical master data will support compliance with ISO standards and respond to the need for standardisation

The 5 ISO IDMP standards are all about **master data**

Master data is any non-transactional information that is considered to play a key role in the core operation of a business and is re-used for multiple purposes

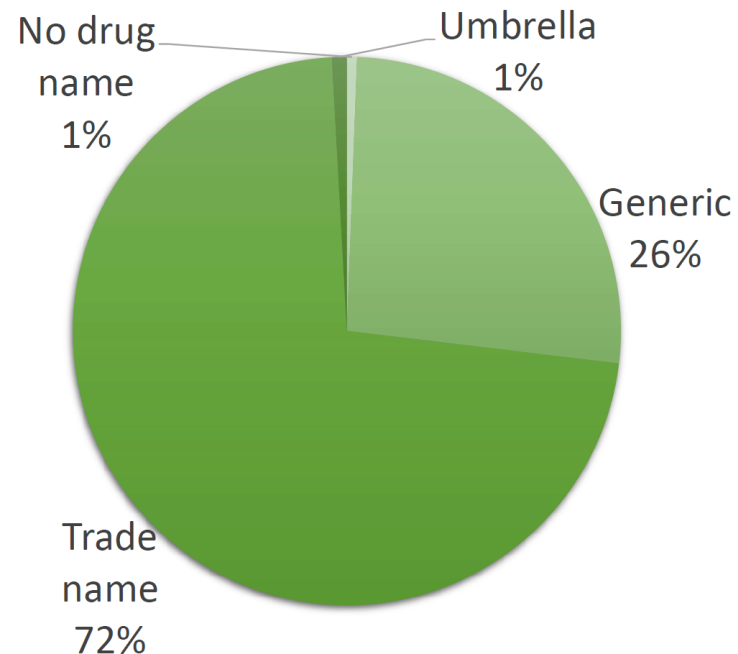


Adverse events: how are medicines identified to now?



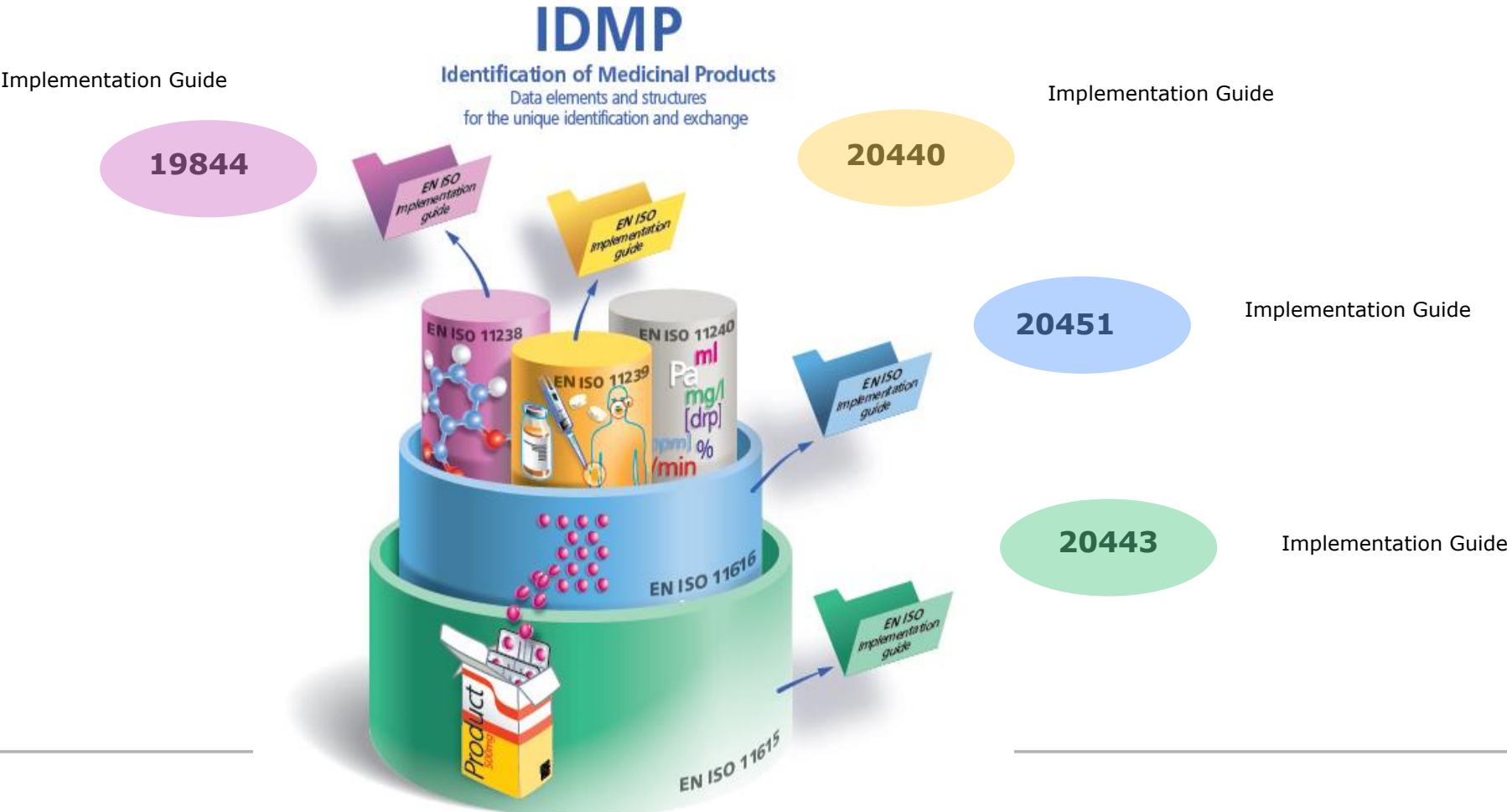
Identification of drug on ICSRs

Drug names on VigiBase ICSRs

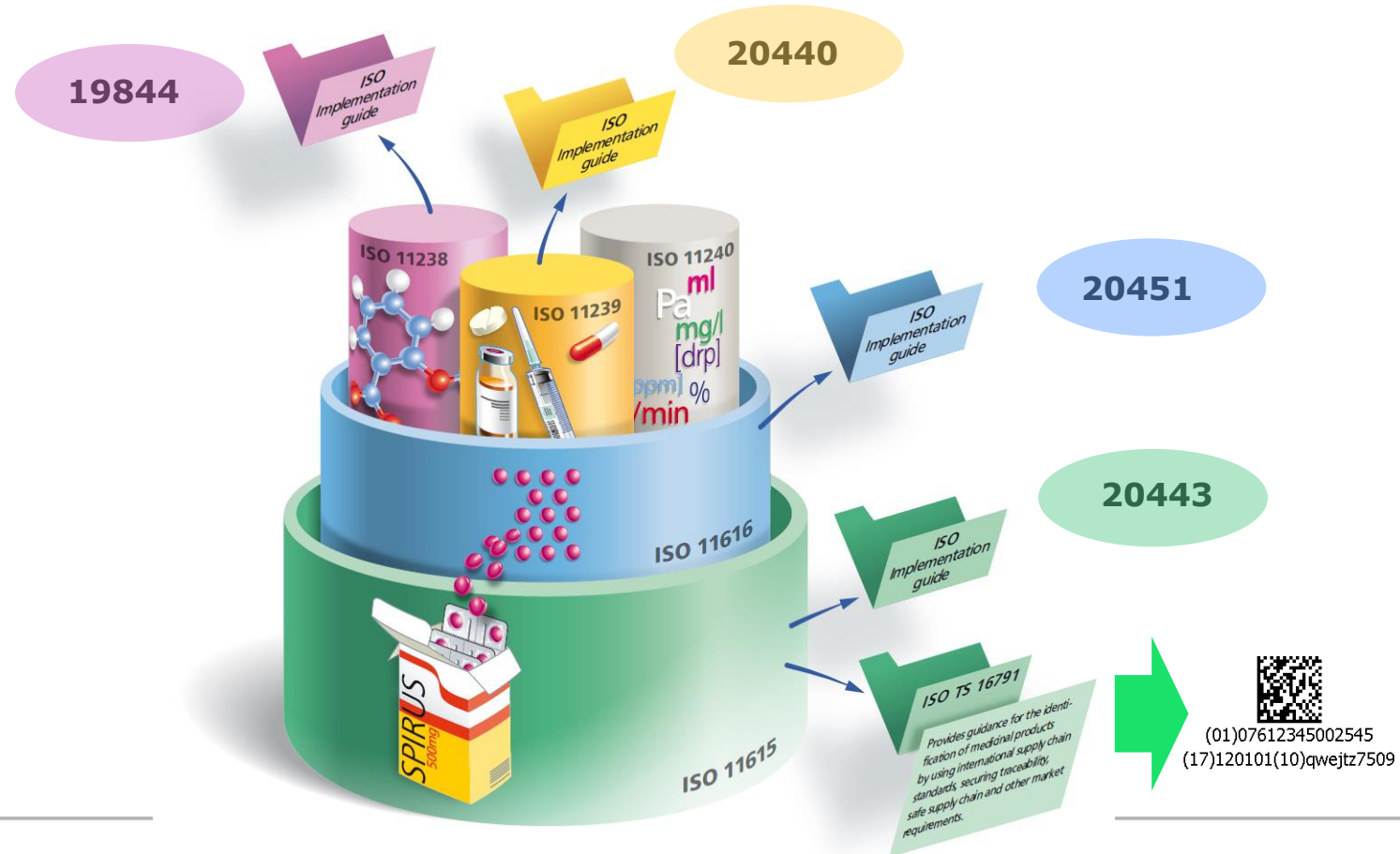


Source:
M. Jakobsson,
IDMP workshop
November 2017,
Liverpool

IDMP in a graphical representation



IDMP – the link to Supply Chain



DataMatrix, the supply chain preferred carrier



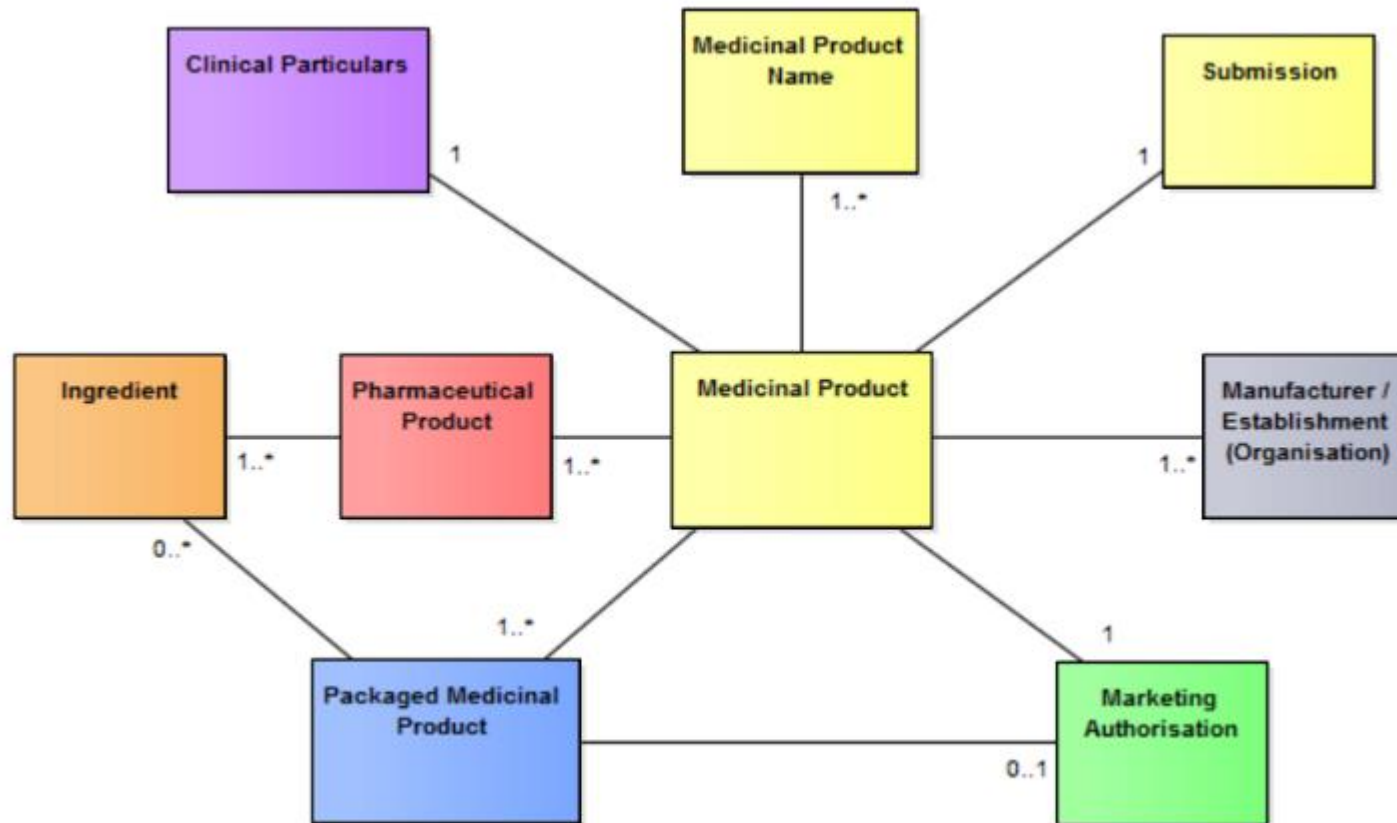
Product identifier (GTIN)

IDMP:
Packaged Item
Data Carrier Identifier
Code System* : 2.51.1.1
Value: 08699536160085

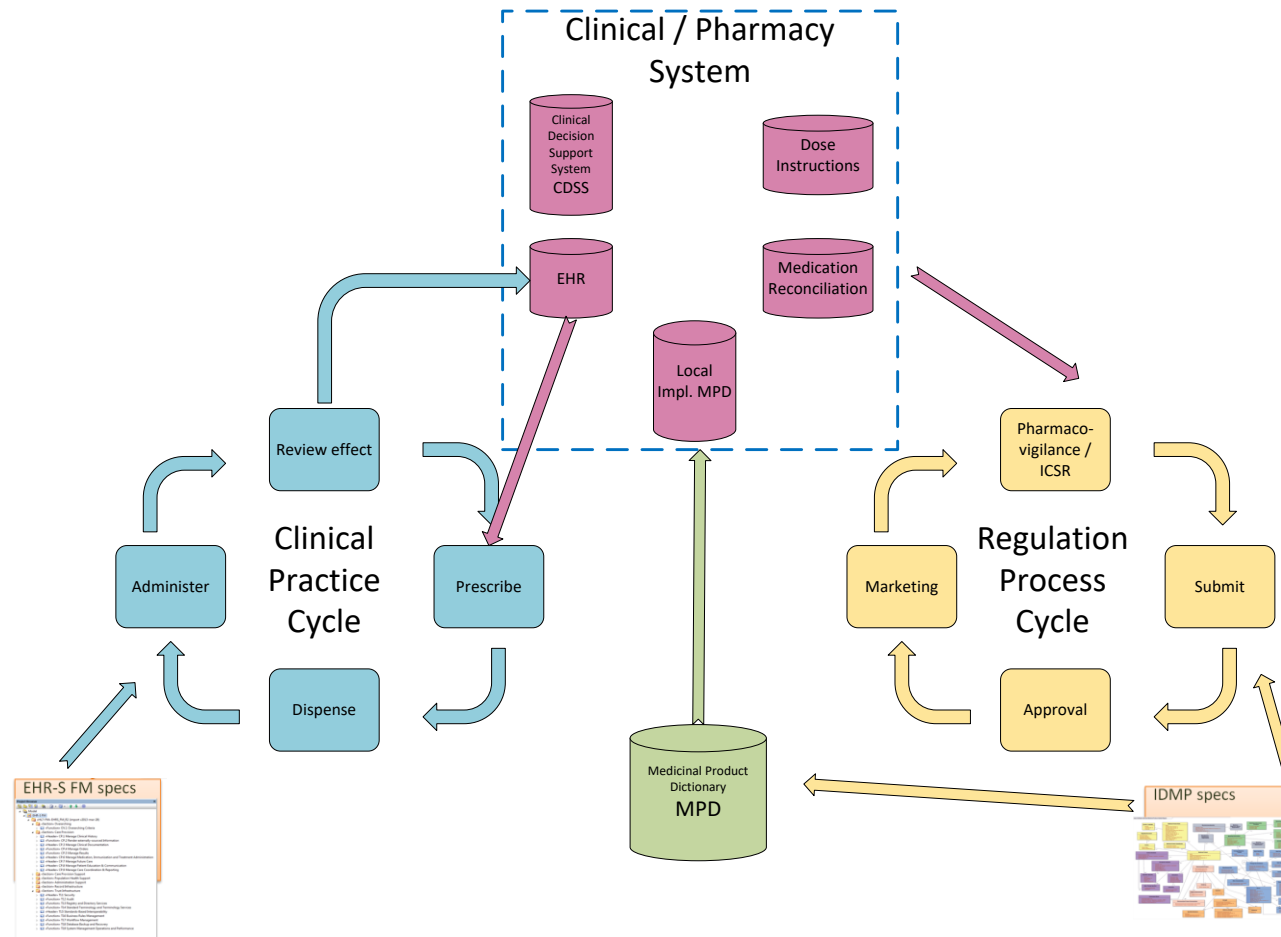
* OID for GS1 GTIN

Supply chain identifier has a data structure, addressed by IHE UBP

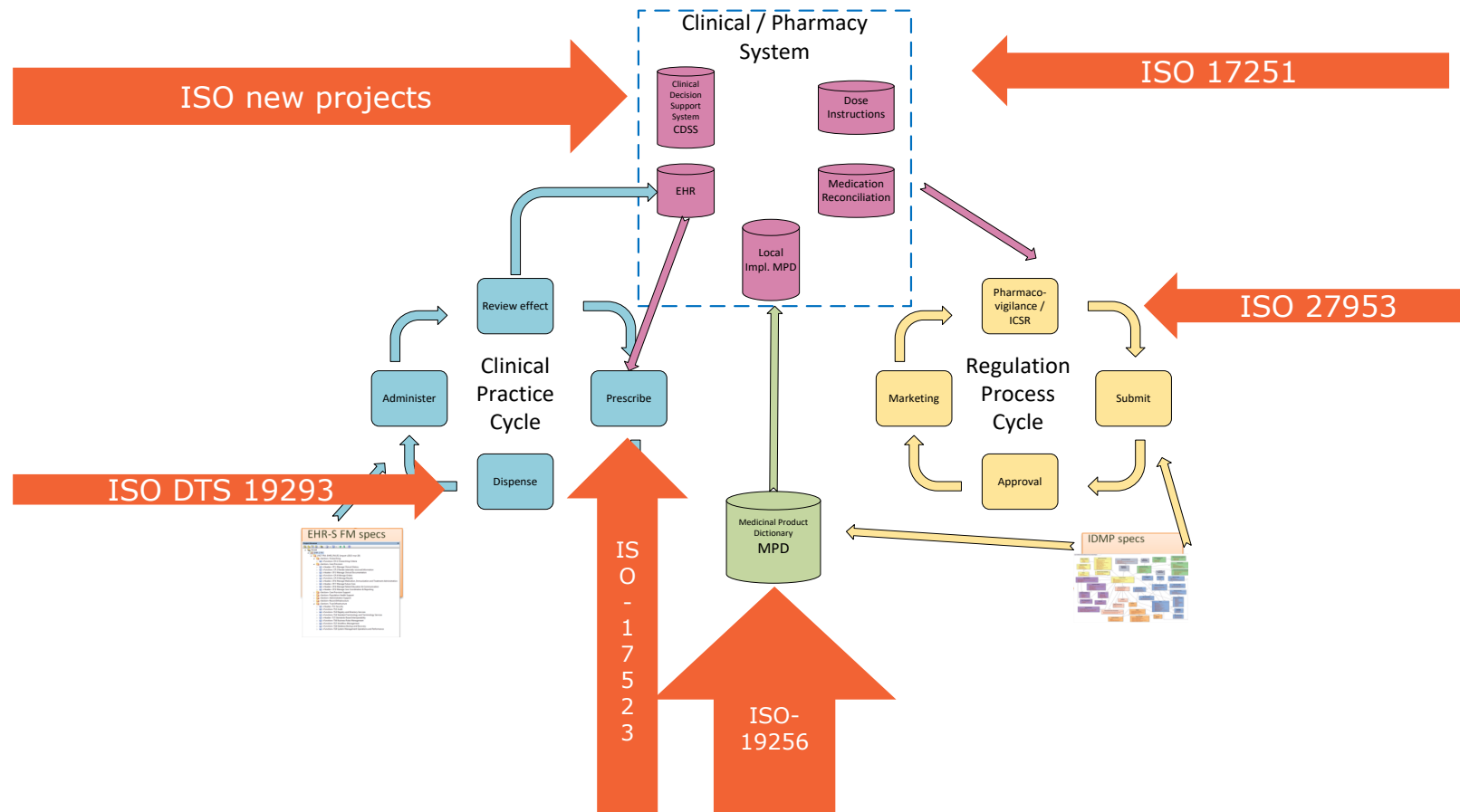
Medicinal Product overarching model



IDMP impact on Clinical Processes



IDMP impact on Clinical Processes (cont.)



Main IDMP identifiers



EUROPEAN MEDICINES AGENCY

ISO IDMP Global Harmonisation

Medicinal Product ID (MPID)

- [Regional Identification](#)

Pharmaceutical Product ID (PhPID) [\(algorithm\)](#)

- Based on core elements for identification of medicinal products

Substances

- Global Substance Registration System [\(G-SRS\)](#)

Dosage forms and Routes of Administration

- European Directorate for the Quality of Medicines [\(EDQM\)](#)

Units of measurement

- Unified Code for Units of Measure [\(UCUM\)](#)

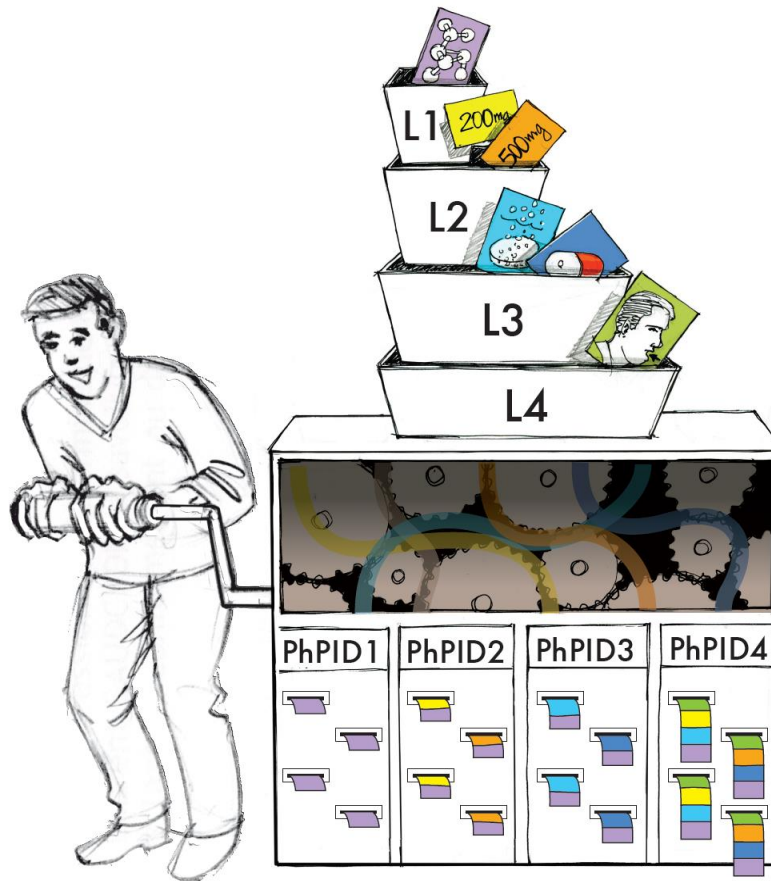
Why is substance (ID) important



Example: Paracetamol/Acetaminophen

- | | | |
|--|--|---|
| • PhPID_SUB_L1 →
paracetamol | • PhPID_SUB_L1 →
paracetamol | • PhPID_SUB_L1 →
paracetamol |
| • PhPID_SUB_L2 →
paracetamol, 500 mg | • PhPID_SUB_L2 →
paracetamol, 500 mg | • PhPID_SUB_L2 →
paracetamol, 500 mg |
| • PhPID_SUB_L3 →
paracetamol, tablet | • PhPID_SUB_L3 →
paracetamol, tablet | • PhPID_SUB_L3 →
paracetamol, capsule |
| • PhPID_SUB_L4 →
paracetamol, 500 mg,
tablet | • PhPID_SUB_L4 →
paracetamol, 500 mg,
tablet | • PhPID_SUB_L4 →
paracetamol, 500 mg,
capsule |

Substance ID as food for PhPID generation



- PhPID_SUB_L1 → paracetamol
- PhPID_SUB_L2 → paracetamol, 500 mg
- PhPID_SUB_L3 → paracetamol, tablet
- PhPID_SUB_L4 → paracetamol, 500 mg, tablet

Substance ID as food for PhPID generation

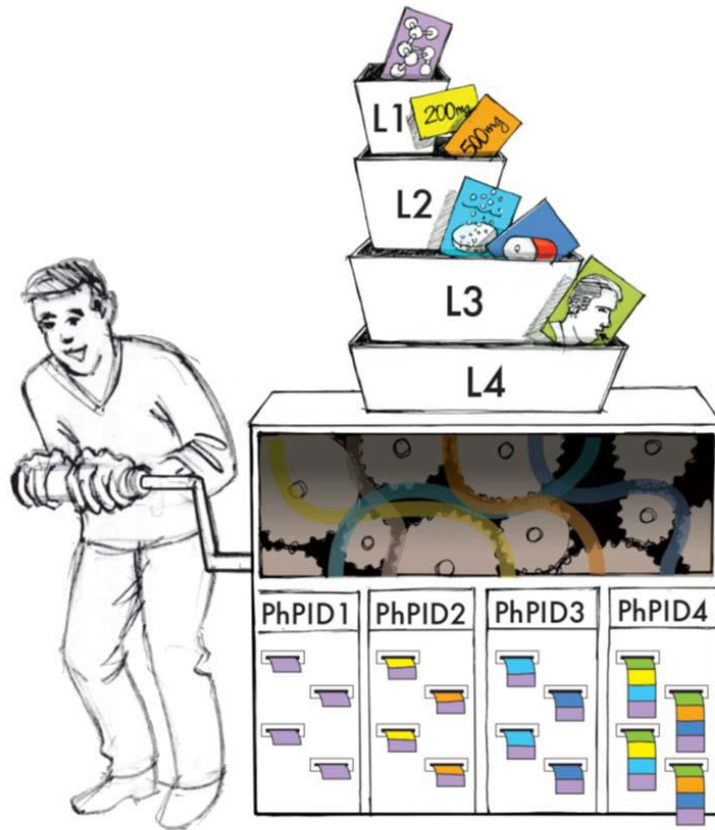


PhPID Substance Levels	PhPID_SUB_L1 → Substance(s) PhPID_SUB_L2 → Substance(s) + Strength + Reference Strength PhPID_SUB_L3 → Substance(s) + Administrable Dose Form PhPID_SUB_L4 → Substance(s) + Strength + Reference Strength + Administrable Dose Form
PhPID Specified Substance Levels	PhPID_SpSUB_L1 → Specified Substance(s) PhPID_SpSUB_L2 → Specified Substance(s) + Strength + Reference Strength PhPID_SpSUB_L3 → Specified Substance(s) + Administrable Dose Form PhPID_SpSUB_L4 → Specified Substance(s) + Strength + Reference Strength + Administrable Dose Form

Substance ID as food for PhPID generation (cont.)



Example 1: Solid oral



Invented brand name: LITHDRUG (lithium carbonate, pharmacopeia), prolonged-release tablets 300 mg, ISO IDMP Manufacturer Alpha

Components: 1

Strength/dosage form: 300 mg tablet

Active substances: lithium carbonate

Reference strength: lithium ion, 8.1 mmol
(represented inside brackets in the next two tables)

Substance ID as food for PhPID generation (cont.)

Description of PhPID Substance Stratum



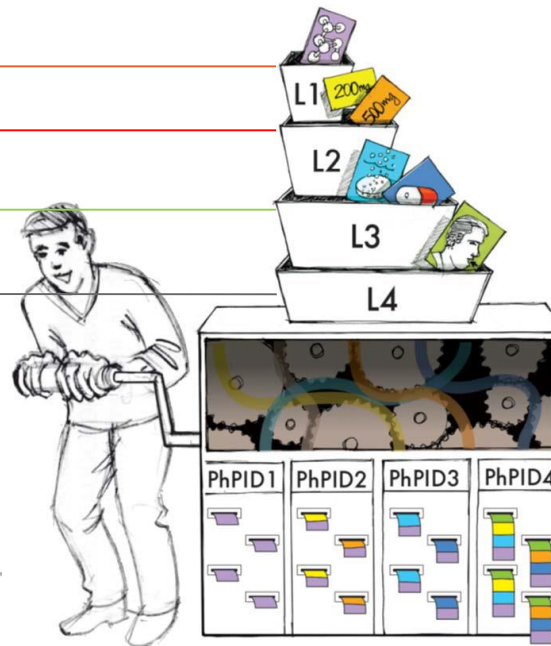
PhPID_SUB_L1 → lithium carbonate

PhPID_SUB_L2 → lithium carbonate 300 mg (lithium ion, 8,1 mmol)

PhPID_SUB_L3 → lithium carbonate, prolonged-release tablet

PhPID_SUB_L4 → lithium carbonate 300 mg (lithium ion, 8,1 mmol), prolonged-release tablet

Source: ISO 11616



PhPID algorithm as per ISO 11616 & ISO/TS 20451

PhPID codes

Substance ID as food for PhPID generation (cont.)



Example 2

Trimetoprim (AN164J8Y0X) 160 mg and Sulfamethoxazole (JE42381TNV) 800 mg tablet (C42998)



Dose form

Substance ID

Strength

Substance ID

Strength

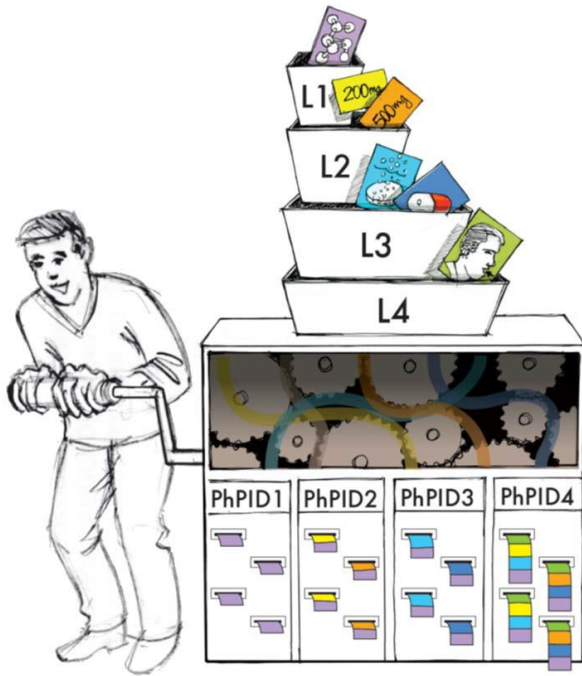
Input string Level 3:

C42998|AN164J8Y0X|160e-3 g|JE42381TNV|8.000e2 mg
code/Trimetoprim/160mg normalised/Sulfamethoxazole/800 mg normalised



PhPID algorithm as per ISO 11616 & ISO/TS 20451

MD5 Digest (or PHPID code): 8663a93b-5627-7466-306d-fd794b7d268a



IDMP benefits

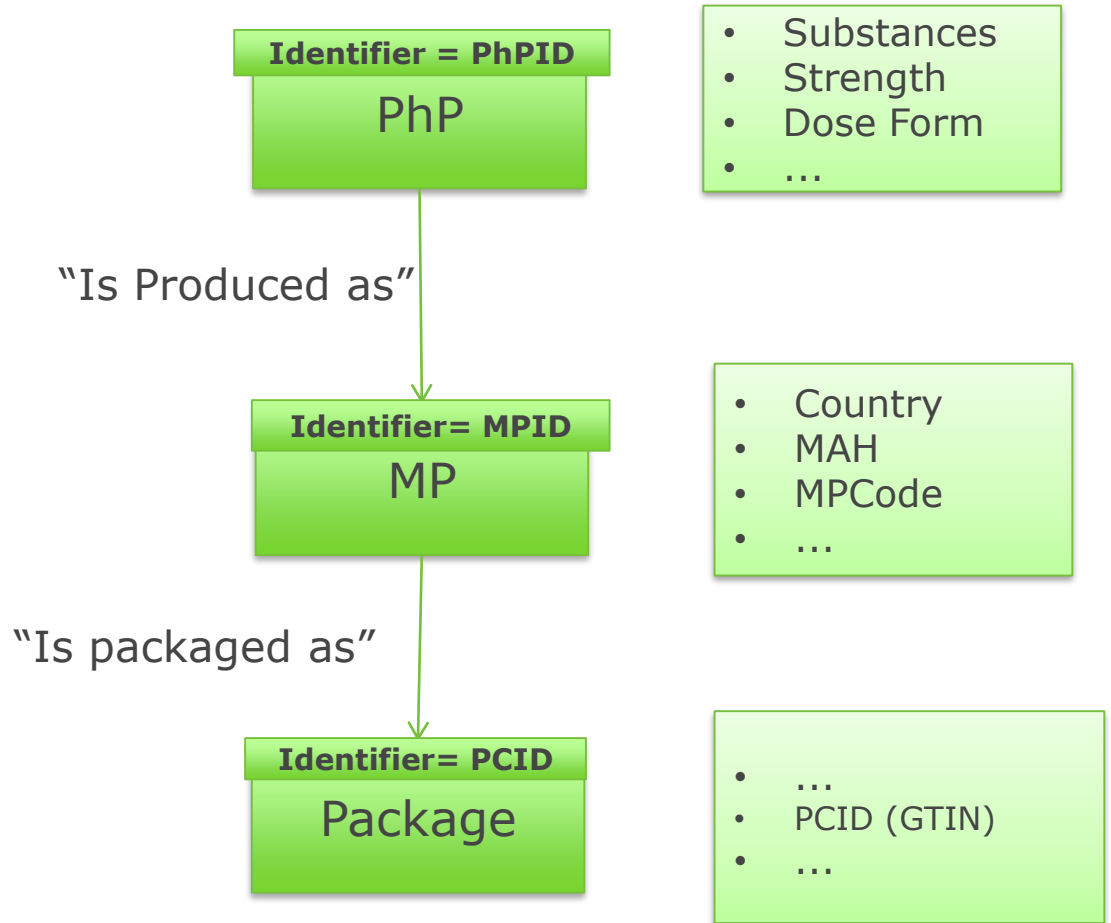


ISO IDMP defines a set of attributes and their relations to identify different levels of products.

It harmonizes the concepts and the data elements (attributes)

It is ready for adoption and manufacturers are adhering.

How does this help in cross-border identification?

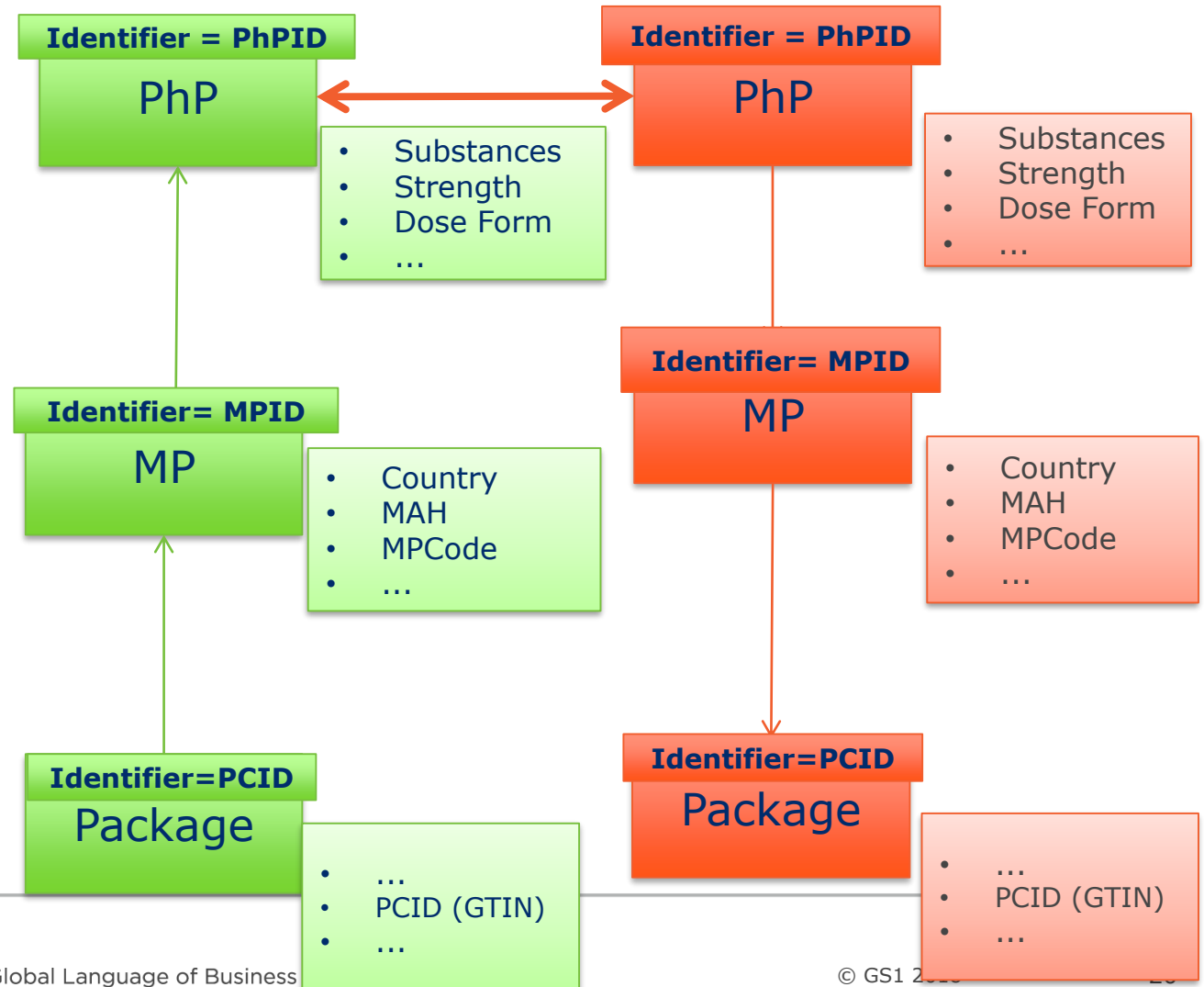


How does this work?



- Common data structure
- Centrally defined attribute values
- Use of common data values across borders:
- When an identifier is specified in one place, it can be mapped to the common structure in any other country.
- *The prescribed package ID (PCID) can be identified in country B, but the package/product is not available there. However, it can be mapped to the underlying PhPID, which in turn can be mapped to medicinal products available.*

Enable Safe and Informed dispensing



From ISO IDMP to ISO ePrescription



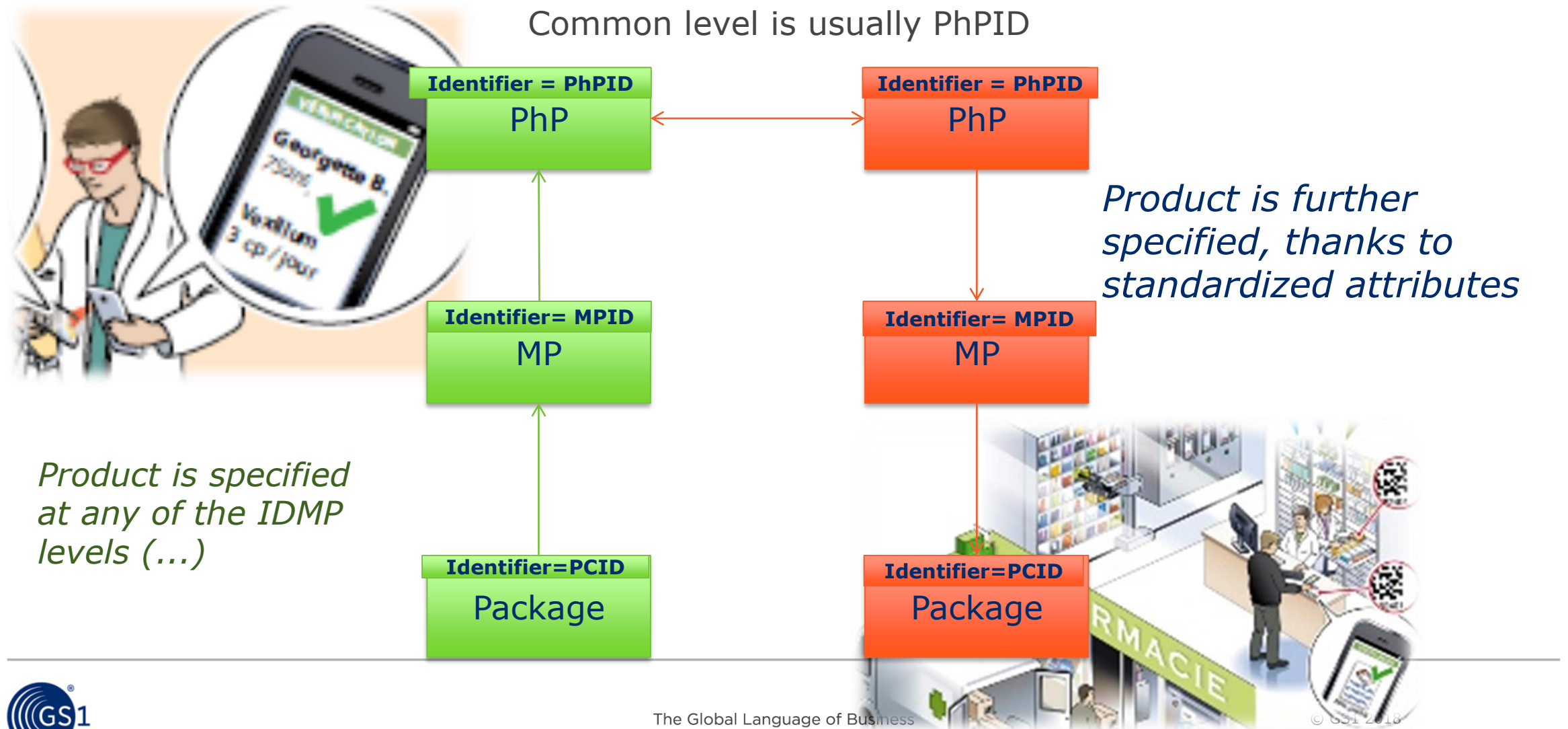
U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov

Use Case

- ISO (FDIS) 17523:Health Informatics-
Requirements for Electronic Prescriptions
 - Normative: Suite of ISO IDMP standards
- Supports unique identification of a
pharmaceutical product prescribed
electronically in different regions/jurisdictions

Example: Prescription





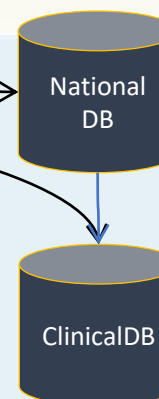
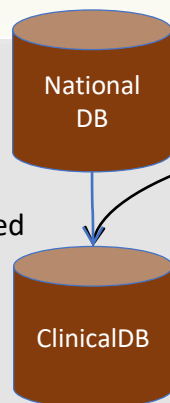
1. EMA governs the data structure and values

2. Each country has a DB in sync with EMA

EMA SPOR DB

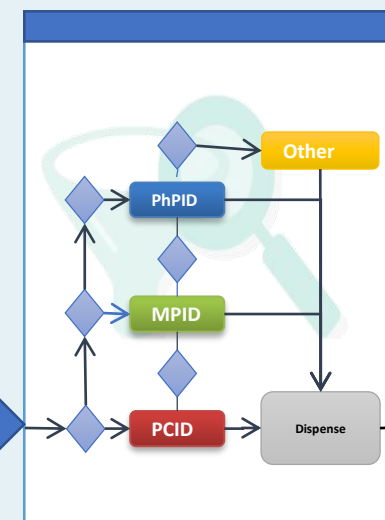
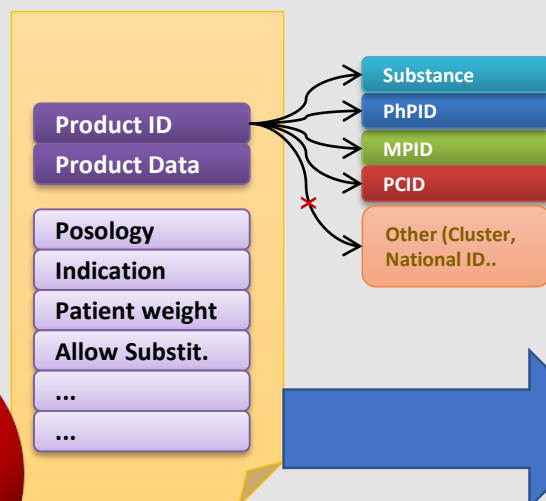
ID (PhPID)
Substance
Strength
Dose form
...
ID (MPID)
Brand Name
MAH Number
MAH Number
Indications
...
ID (PCID)
Qty / Pack
Presentation
...
...

3. Every clinical system
uses the centrally defined
values



7. finally, any ADE or information about use is also
compatible with IDMP and can be reused in clinical
settings or by the regulators

4. Every time a medication
is specified,
it is done according to the
IDMP attributes...



6. ...Because & assuming the other national and
Clinical DBs are in sync with the EMA SPOR DB

5. ...which allows the product attributes
and identifier to be recognized
anywhere...



From ISO IDMP to ISO “MPD”



MPD : CEN ISO TS 19256, Requirements for Medicinal Product Dictionaries for Clinical Use

IDMP

- Marketing authorization application
- Jurisdiction
- Indications
- Regulated documentation other than SPC/labelling

MPD-system

- substance
- dose form
- strength
- container type
- etc

Non IDMP components

- price/reimbursement
- Drops/ml, density
- Local legislation concerning opium, 'poison' etc
- Level of formulary (standardized, semi-standardized) for extemp. preparations
- Advice for PPP
- Selling time after withdrawal



Contact



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