



Meeting the global challenge of unique identification of medicinal products

Cross-border ePrescriptions in the EU – Towards a European approach to univocally identify medicinal products

:

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eHealth-Rahmenbedingungen im europäischen Vergleich:
Strategien, Gesetzgebung, Umsetzung

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in the context of



Goals

- Univocal identification of a**
 - prescribed medicinal product (MP)
 - for human use in
 - cross-border healthcare by a
 - dispensing community pharmacist
 - in another Member State than that in which the prescription was issued
- Substitution**

The Identification Problem

- Supply side -

- One active ingredient (INN – 5 languages)**
- Many generic names**
 - Metoprolol (beta blocker): 17**
 - Simeticone (antiflatulent): 12**
- Up to hundreds of brand names:**
 - Metoprolol: > 400**
 - Simeticone: > 300**

<http://www.drugs.com/international/metoprolol.html>

<http://www.drugs.com/international/simeticone.html>

The Identification Problem

- Demand side -

- **Prescriber (healthcare professional)**
- **Community Pharmacist**
- **Patient**
- **Third Party Payer (NHS, statutory insurance,...) (NOT in a cross-border situation?)**
- **Regulators**

The Identification Problem

- Substitution -

- **Definition**
- **Reasons** (availability, shortage, regulator...)
- **Types:**
 - *Same* medicinal product - MP (different names, perhaps quantity; [parallel] import)
 - *Generic* (same active ingredient, but differences of names, maybe of inert ingredients, salts...)
 - Substitution *not* allowed: dosage form, strength, route of administration, etc.
 - *Therapeutic* substitution is not an issue
- **Selection:** Only a *substance*, or a *set* of MPs in the prescription

Meeting the global challenge of unique identification of medicinal products

The Solution (I)

- Global cooperation (EMA, FDA, SDOs, EU member States...)
- Implementation of *ISO-IDMP suite of standards* and transfer of EMA “Art. 57 (2) Data Base” for pharmacovigilance
 - Substances (ISO 11238)
 - Pharmaceutical dose forms, units of presentation, routes of administration and packaging (ISO 11239)
 - Units of measurement (ISO 11240)
 - Regulated *pharmaceutical* product information (ISO 11616)
 - regulated *medicinal* product information (ISO 11615)
- European & global semantic assets (codes)
 - four domains of master data in pharmaceutical regulatory processes: **substance, product, organisation and referential (SPOR)** data.



ISO IDMP standards

- The **ISO IDMP standards** establish definitions and concepts, describe data elements and their structural relationships that are required for the unique identification of:

IDMP Identification of Medicinal Products Data elements and structures for the unique identification and exchange



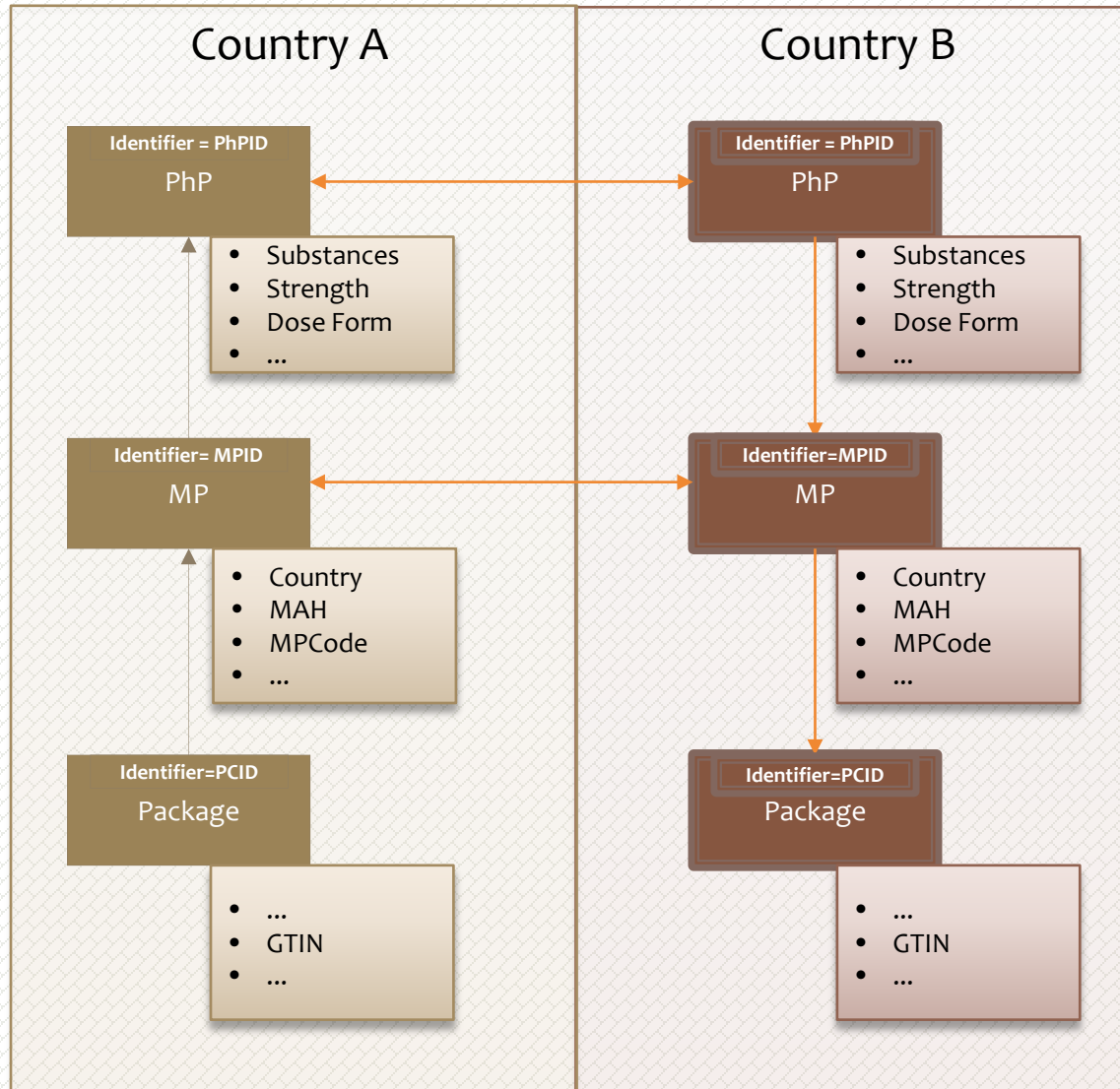
- Substances** (Substance ID) - ISO 11238
- Pharmaceutical** dose forms (EDQM), units of presentation, routes of administration and packaging - ISO 11239
- Units of measurement** (UCUM) - ISO 11240
- Pharmaceutical products** (PhPID) - ISO 11616
- Medicinal products** (MPID/PCID) - ISO 11615

- ISO IDMP standards apply to both authorised and developmental medicinal products for **human** use

The Solution (II)

- European & global semantic assets (codes) -
Four domains of master data in pharmaceutical regulatory processes: SPOR data on
 - Substance* data (describing the ingredients of a medicine)
 - Product* data (describing the marketing and medicinal information relating to a product)
 - Organisation* data (providing the contact details of organisations and individuals responsible for various aspects of a medicine [over its life cycle])
 - Referential* data (providing controlled vocabularies, e.g. dosage, pharmaceutical forms, country codes, package codes, weight codes)

Cross-country identification process



Business Case - Benefits

- Patients
- Clinicians
- Pharmacists
- Pharmacovigilance
- Pharma industry - registration of new medicinal products (MPs)
- Further actors [national & international regulators (e.g. EMA, FDA); national/ regional/local information systems; clinical trials]
- Identifiers can be used in any country for obtaining the product's "properties"

Longer-term Challenges


Implementation & diffusion of solutions


- National/regional agencies/authorities
- Medicinal products databases
- Clinical context:
 - ePrescription software
 - Pharmacy systems
 - eDispensation software
 - Medication decision-making (CDSS)
 - Patient data recording (EMR/EHR) systems
 - Computerised provider order entry (CPOE) systems
 - ...


Implementation – a Screen Mock-up


Entry mask for the prescriber

Prescribing
country:
Spain

Country 

Search 

Information 

Create Prescription 

Country	Spain	Sync Product DB	Prescribe by: Substance
Search by:	Substance		
insulin	Search	Clear form	
* Substance	INSULIN GLARGINE		
Strength	100		
Strength Units	UNITS/ML		
Adm. Dose Form	SOLUTION FOR INJECTION		
Med. Device	Pre-filled syringe		
Note (*): Minimun data required for prescription without selected product.	Get products		
Brand Name	ABASAGLAR		
Medicinal Product Name	ABASAGLAR 100 UNIDADES/ML SOLUCIÓ		
Package Type			
Package Qty.			
Clinical Prescription Data			
Route of Adm.	SUBCUTANEOUS USE		
Posology			
Quantity per Intake			
Frecuency of Intake			
Duration of Treat.			
Treatment Start	14		
Total Qty. to Disp.			
Indication	subcutaneous		
Substitution			
Create Prescription >>			



Implementation– a Screen Mock-up

Background processes

PhPID



MPID



PCID



Product and Prescription Data	
* PhPID	PHPID_001
Substance	INSULIN GLARGINE
Strength	100
Strength Units	UNITS/ML
Adm. Dose Form	SOLUTION FOR INJECTION
Med. Device	Pre-filled syringe
* MPID	MPID_016
Medicinal Product Name	ABASAGLAR 100 UNIDADES/ML SOLUCIÓN INYECTABLE EN PLUM
Brand Name	ABASAGLAR
M. A. Number	EU/1/14/944/007
Pharm. Dose Form	SOLUCIÓN INYECTABLE EN PLUMA PRECARGADA
Status of Supply	
Classification	A10AE04 - Insulina glargina
* PCID / Cod. Nat	
Pack. Type/Qty.	
Clinical Prescription Data	
Route of Adm.	SUBCUTANEOUS USE
Posology	
Quantity per Intake	
Frecuency of Intake	
Duration of Treat.	
Treatment Start	14
Total Qty. to Disp.	
Indication	subcutaneous
Substitution	
Send Prescription >>	

Prescribing
country :
Spain



Implementation – a Screen Mock-up

Country
PhPID

MPID

PCID

Form

Country: United Kingdom | Sync Product DB | Retrieve Prescription

Selected Product and Treatment Data

PhPID	PHPID_001
Substance	INSULIN GLARGINE
Strength	100
Strength Units	UNITS/ML
Adm. Dose Form	SOLUTION FOR INJECTION
Med. Device	Pre-filled syringe

MPID

MPID	MPID_016
Medicinal Product Name	ABASAGLAR 100 UNIDADES/ML SOLUCIÓN INYECTABLE EN PLUMA
Brand Name	ABASAGLAR
M. A. Number	EU/1/14/944/007
Pharm. Dose Form	SOLUCIÓN INYECTABLE EN PLUMA PRECARGADA
Status of Supply	
Classification	A10AE04 - Insulina glargina

PCID

PCID	
Pack. Type/Qty.	

Clinical Prescription Data

Route of Adm.	SUBCUTANEOUS USE
Posology	
Quantity per Intake	
Frecuency of Intake	
Duration of Treat.	
Treatment Start	14
Total Qty. to Disp.	
Indication	subcutaneous
Substitution	

Decode Locally | Decode Internationally

Dispensing
country:
UK



Implementation– a Screen Mock-up

National equivalents



All national equivalents will be displayed. Colour-coding identifies the level of accuracy of the matches displayed (according to the MPID/PhPID).

Medicinal products that matches with the received data		Equivalent
PhPID's Attributes	Medicinal Product Name	
INSULIN GLARGINE 100 UNITS/ML, SOLUTION FOR INJECTION, Pre-filled syringe	ABASAGLAR 100 UNITS/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN	
INSULIN GLARGINE 100 UNITS/ML, SOLUTION FOR INJECTION, Pre-filled syringe	ABASAGLAR 100 UNITS/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN	
INSULIN GLARGINE 100 UNITS/ML, SOLUTION FOR INJECTION, Pre-filled syringe	ABASAGLAR 100 UNITS/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN	
INSULIN GLARGINE 100 UNITS/ML, SOLUTION FOR INJECTION, Pre-filled syringe	ABASAGLAR 100 UNITS/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN	
INSULIN GLARGINE 100 UNITS/ML, SOLUTION FOR INJECTION, Pre-filled syringe	ABASAGLAR 100 UNITS/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN	
INSULIN GLARGINE 100 UNITS/ML, SOLUTION FOR INJECTION, Pre-filled syringe	ABASAGLAR 100 UNITS/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN	
INSULIN GLARGINE 100 UNITS/ML, SOLUTION FOR INJECTION, Pre-filled syringe	ABASAGLAR 100 UNITS/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN	
INSULIN GLARGINE 100 UNITS/ML, SOLUTION FOR INJECTION, Pre-filled syringe	ABASAGLAR 100 UNITS/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN	
INSULIN GLARGINE 100 UNITS/ML, SOLUTION FOR INJECTION, Pre-filled syringe	ABASAGLAR 100 UNITS/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN	
Color Key		
PhPID Match	MPID Match	PCID Match

Dispensing country:
UK



Clinical Relevance

- Active medication summary of electronic patient summary (ePS)
- Prescription history
- eDispensation report (up to 50% not dispensed)
- Reconciliation of medicines/contraindications
- Compliance (in DE 28% of dispensed MPs not taken)
- Global pharmacovigilance
- Patient information & empowerment
- Clinical research & studies
- Public health



Administrative benefits

- Integration with reimbursement systems
- Reduced risk of fraud and prescription falsification
- Avoidance of duplicate prescriptions to replace lost or misplaced ones
- Avoidance of early or double refills
- Improved medication stock management/logistics



A German perspective

- 20 years ago the eHealth working Group of the German Federal Government's Forum Info 2000:
A *Germany-wide ePrescription* (elektronisches Rezept) is THE core implementation ("Leuchtturm Projekt")
- Mentioned for implementation in the 2003 Statutory Health Insurance Modernisation Law:
"Der Spitzenverband Bund der Krankenkassen, ... schaffen die für die Einführung und Anwendung der elektronischen Gesundheitskarte, insbesondere des *elektronischen Rezeptes* und der elektronischen Patientenakte, erforderliche interoperable ... Telematikinfrastruktur"
- In view of the obvious multiple benefits, it seems timely to re-start such discussions in Germany



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