



Meeting the challenge of open access to medicinal products across the Union

*openMedicine approach:*  
A brief demonstration  
illustrating the core concepts.  
Proof of concept

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Slide credits to: Christian Hay (CEN TC251/GS1), Jose Teixeira (HL7)

Use Cases: Isabel Lazaro (AEMPS)



# Proof of concept perscribing and dispensing app

## Purpose:

- Discuss, validate and explain openMedicine
- to demonstrate the problem of medicinal product identification is a cross-member state setting

## Disclaimer - Constraints and limitations:

- Simplified apps' (not fully functional applications)
- Focused on identification of medicinal products
- Containing IDMP data structures & identifiers
- Showing the conclusions from openMedicine
- Connected via “cross-border” datasets (e.g. Relevant part of epSOS dataset)
- PhPID can be “simulated” while it does not exist

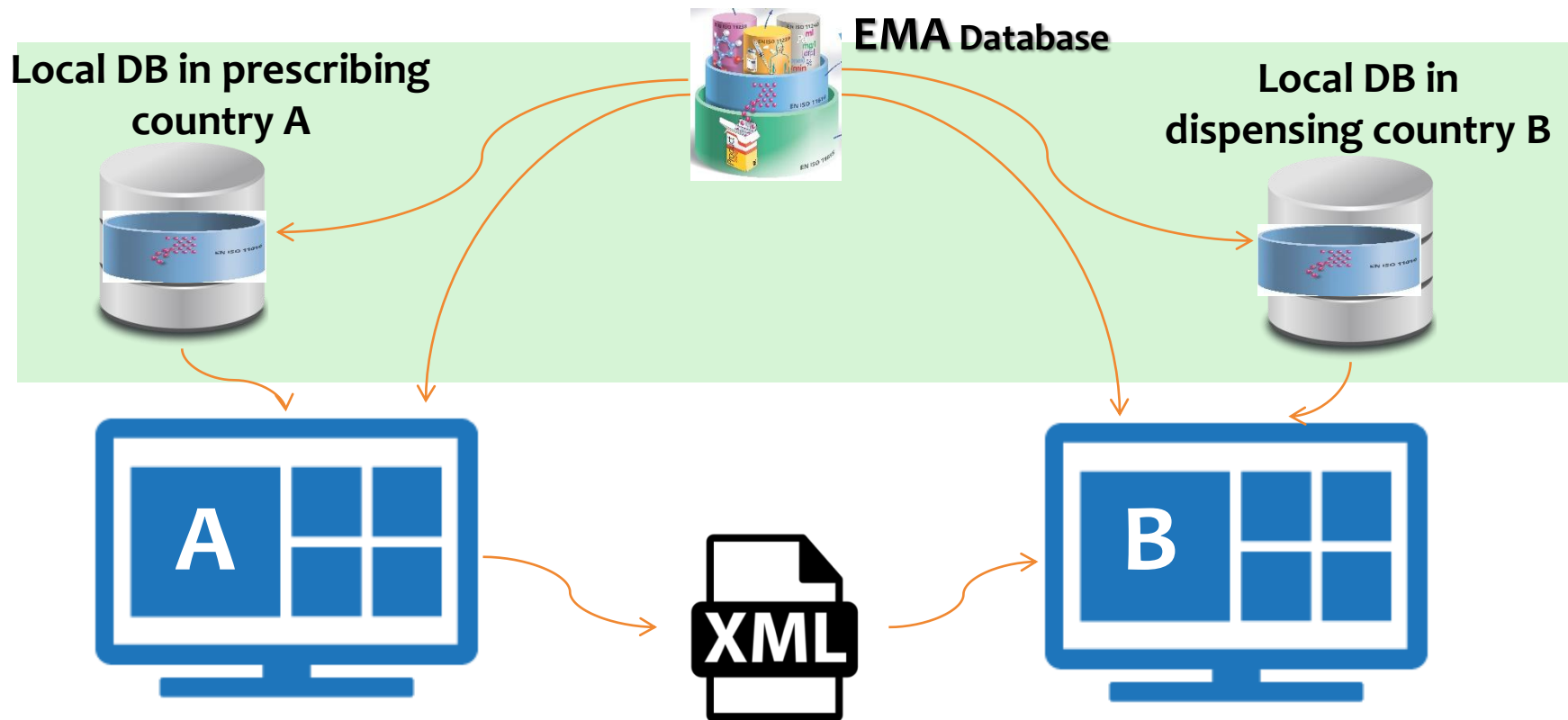
## Idea origin/credits:

- Jose Teixeira (HL7), Jose Simarro (AEMPS), Isabel Lazaro (AEMPS)

# Clinical Attributes in IDMP

		Attribute Name	Scope	Vocabulary	
Prescription	Product	<b>Preparation / compound product</b>			
		<b>Preparation ID</b>			
		<b>Preparation Name</b>			
		<b>Preparation Instructions</b>			
		<b>Components</b>			
		Component identification	Component ->Identification		
		Identifier	Component ->Identification->ID	Local / Xborder	Several - Details in D2.2, section 8
		Identifier type (OID, etc.)	Component ->Identification->Codeset	Local / Xborder	Several - Details in D2.2, section 8
		Component Name	Component ->Name	Local / Xborder	Several - Details in D2.2, section 8
		Component Role	Component ->Role	Local / Xborder	
	Component Strength	Component ->Strength	Local / Xborder	Several - Details in D2.2, section 8	
	Component Pharmaceutical Dose Form	Component -> PharmDoseForm			
	<b>Pharmaceutical Dose Form</b>	PharmDoseForm	Local / Xborder	Several - Details in D2.2, section 9	
	Treatment	Posology		Treatment->Posology	
		Quantity to administer per intake	Treatment->Posology->QtyPerEvent	Xborder	(numeric)
		Frequency of intakes	Treatment->Posology->Frequency	Xborder	UCUM
		Duration of treatment	Treatment->Posology->Duration	Xborder	UCUM
		Treatment Start	Treatment->Posology-TreatmentStart	Xborder	(date)
Total Quantity to administer		Treatment->QtyToAdminister	Local / Xborder	None	
Indication		Treatment->Indication	Local / Xborder	ICD9; ICD10: ICPC2; SNOMED; others..	
Route		Treatment->Route	Local / Xborder	EDQM- Std.Terms; Pharmacopoeia; ISO11239,...	
Substitution handling	Treatment->SubstHandling	Local / Xborder	See WP5		
Patient Summary	Product	Same as Prescription Product in this table			
	Treatment	Number of units per intake	Treatment->UnitsPerintake	Local / Xborder (numeric)	
		Frequency of intakes	Treatment->Frequency	Local / Xborder HL7	
		Duration of treatment	Treatment->TreatmentDuration	Local / Xborder HL7	
		Treatment Start	Treatment->TreatmentStart	Local / Xborder (date)	

# Goal: show how IDMP supports the openMedicine problems



- App in prescribing country A: Specify the product
- App in dispensing country B: Identify the specified product
- (XML) Clinical document transmits information
  - (example: ePrescription, e.g. HL7 CDA document in eHDSI)

Modified from: Christian Hay

# STEP 1 CREATE PRESCRIPTION

- Enter pharmaceutical product, medicinal product or the appropriate attributes



## CLINICAL DATA

- Route of admin, Posology....

## PRESCRIPTION SUMMARY:

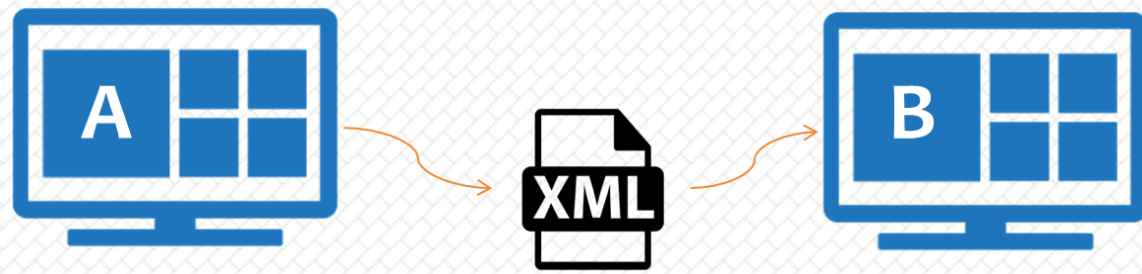
- Information “behind the scenes”
- Fields in blue are the ones transmitted when complete

NEXT STEP: TO CREATE A Px

: Form / Prescription summary	
<b>Product and Prescription Data</b>	
<i>Note: shaded and completed fields will be data sent in prescription</i>	
PhPID	
Substance	BECLOMETASONE DIPROPIONATE
Strength	50
Strength Units	MCG/DOSE
Adm. Dose Form	
Med. Device	
MPID	
Medicinal Product Name	
Brand Name	
M. A. Number	
Pharm. Dose Form	
Status of Supply	
Classification	
PCID / Cod. Nat	
Pack. Type/Qty.	
<b>Clinical Prescription Data</b>	
Route of Adm.	
	Posology
Quantity per Intake	
Frecuency of Intake	
Duration of Treat.	

## STEP 2: SEND THE PRESCRIPTION

- ISO IDMP openMedicine prescription
- The information travels in the XML file, based on epSOS CDA, including new attributes like PhPID.



**OpenMedicine**

.: Form / Retrieve and decode prescription

Country	United Kingdom	<input type="button" value="Sync Product DB"/>	<input type="button" value="Retrieve Prescription"/>
<b>Selected Product and Treatment Data</b>			
PhPID	PHPID_001		
Substance			
Strength			
Strength Units			
Adm. Dose Form			
Med. Device			
MPID	MPID_016		
Medicinal Product Name			
Brand Name			
M. A. Number			
Pharm. Dose Form			
Status of Supply			
Classification			
PCID			
Pack. Type/Qty.			
<b>Clinical Prescription Data</b>			
Route of Adm.	Posology		
Quantity per Intake			
Frecuency of Intake			
Duration of Treat			

# STEP 3: TO RETRIEVE THE PRESCRIPTION IN COUNTRY B, FROM COUNTRY A:

- Codes or coded attributes (in blue)
- Clinical data (free text)



:: Form / Equivalent products

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



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# Use Cases for the Proof of concept

Screenshots from the openMedicine demo app'



# Use case #1: MPID ,PhPID and PCID match

## INSULINE GLARGINE

- *centralized procedure*
- From Spain to UK
- PhPID and MPID transmitted
- MPID is recognised (MPID match and PCID match).
- Both decoded locally
- Equivalent: PhPID, MPID match (PCID?)

# Use case 1: MPID match

Concept		Created prescription	Transmitted in prescription	Decoded by the pharmacist	Equivalent result	
Product Attributes	Pharmaceutical Product	Column1	Column2			
		PhPID	PhP0000000001	PhP0000000001	PhP0000000001	PhP0000000001
		Substance(s)	Insuline glargine		Insuline glargine	Insuline glargine
		Administrable Dose Form	Solution for injection		Solution for injection	Solution for injection
		Strength				
		Quantity	100		100	100
	Units	units / ml		units / ml	units / ml	
	Medical Device					
	Unit of Presentation	Pre-filled pen		Pre-filled pen	Pre-filled pen	
	MPID	MP0000000001	MP0000000001	MP0000000001	MP0000000001	
	Medicinal Product Name	ABASAGLAR		ABASAGLAR	ABASAGLAR	
	Marketing Authorization					
	Country	SPAIN		UK	UK	
	Holder	Eli Lilly Regional Operations GmbH		Eli Lilly Regional Operations GmbH	Eli Lilly Regional Operations GmbH	
	Number	EU/1/14/944/007		EU/1/14/944/007	EU/1/14/944/007	
Procedure ID						
Indication						
Legal Status of Supply						
Classification	A10AE04 (ATC)		A10AE04 (ATC)	A10AE04 (ATC)		
Package	PCID	PCID				
		Package Item Container				
		Type	pre-filled pens		pre-filled pens	pre-filled pens
Quantity	5		5	5		
Treatment	Treatment	Posology				
		Quantity to administer per intake				
		Frequency of intakes				
		Duration of treatment				
		Treatment Start				
		Quantity to administer	14	14	14	14
Indication						
Route of administration	subcutaneous	subcutaneous	subcutaneous	subcutaneous		
Substitution handling						

# Use case #2: MPID not recognised, PhPID used

## MONTELUKAST SODIUM

- National Procedure (*paralel import*)
- From UK to Ireland
- PhPID, MPID transmitted.
- MPID not recognised, PhPID is taken.
- Decoded locally
- Equiva: 1 PhPID with several MPID ,but same Brand-Name (parallel import)

# Use case 2: no MPID match, but PhPID

Concept		Created prescription	Transmitted in prescription	Decoded by the pharmacist	Equivalent result		
Product Attributes	Pharmaceutical Product	Column1	Column2				
		PhPID	PhPID002	PhPID002	PhPID002	PhPID002	
		PhP Stratum					
		Substance(s)	Montelukast sodium		Montelukast sodium	Montelukast sodium	
		Administrable Dose Form	Oral, tablet		Oral, tablet	Oral, tablet	
		Strength					
		Quantity	10		10	10	
		Units	mg		mg	mg	
	Medical Device	NA					
	Unit of Presentation	tablet		tablet	tablet		
	Medicinal Product	MPID	MPID	MP002	MP002	(MPID not existing)	Several MPID's to choose from
			Medicinal Product Name	SINGLAIR			
			Marketing Authorization				
			Country	UK		IR	IR
			Holder	Accord Healthcare Limited			
			Number	PL20075/0182			
			Procedure ID	WWXX			
Indication							
Legal Status of Supply							
Classification	R03DC03						
Package	PCID	PCID					
		Package Item Container					
		Type	Box		Box	Box	
		Quantity	28		28	28	
Treatment	Treatment	Posology					
		Quantity to administer per intake	1	1	1	1	
		Frequency of intakes	1/day	1/day	1/day	1/day	
		Duration of treatment	30	30	30	30	
		Treatment Start					
		Quantity to administer					
		Indication					
		Route of administration	Oral	Oral	Oral	Oral	
Substitution handling							

# Use case #3: Attributes prescribed matching PhPID

## BECLOMETASONE DIPROPIONATE

- *National Procedure*
- From Spain to France
- No decoding
- PhPID found which matches several products with different MPIDs and MP names (nationally authorized)

# Use case 3: prescribed attributes match PhPID

Concept		Created prescription	Transmitted in prescription	Decoded by the pharmacist	Equivalent result		
Product Attributes	Pharmaceutical Product	Column1 ▾ Column2 ▾					
		PhPID			PhP003	PhP003	
		PhP Stratum					
		Substance(s)	beclometasona dipropionato		Dipropionate de béclométhasone	Dipropionate de béclométhasone	
		Administrable Dose Form	Nasal spray		Nasal	Nasal	
		Strength			pulverisation nasal	pulverisation nasal	
		Quantity	50		50	50	
		Units	mcg/puff		mcg/puff	mcg/puff	
		Medical Device					
	Unit of Presentation	Puff		Puff	Puff		
	Medicinal Product	MPID	MPID			Several MPID's found with same PhP	
			Medicinal Product Name				
			Marketing Authorization				
			Country	SPAIN		FR	FR
			Holder				
			Number				
			Procedure ID				
	Package	PCID	PCID				
Package Item Container							
Type							
Treatment	Posology	Quantity to administer per intake					
		Frequency of intakes					
		Duration of treatment					
		Treatment Start					
		Quantity to administer	1 bottle		1 bottle	1 bottle	
		Indication					
		Route of administration					
Substitution handling							

# Use case #4: MPID, PhPID, national ID's

## OMEPRAZOL

- *Mutual Recognition Procedure*
- From Italy to Spain
- PhPID, MPID, Nat ID transmitted
- Decode internationally
- Same PhPID, different MPID, Same Procedure number, different Invented names

# Use case 4: prescription with PhPID, MPID and national ID – all matching. But substitution.

Concept		Created prescription	Transmitted in prescription	Decoded by the pharmacist	Equivalent result	
Product Attributes	Pharmaceutical Product	Column1	Column2			
		PhPID	PhPID04	PhPID04	PhPID04	
		PhP Stratum				
		Substance(s)	Omeprazole		Omeprazole	
		Administrable Dose Form	Hard Gastro-Resistant capsule		Hard Gastro-Resistant capsule	
		Strength	20		20	
		Quantity	mg		mg	
	Units					
	Medical Device					
	Unit of Presentation	Hard Gastro-Resistant capsule		Hard Gastro-Resistant capsule		
	Medicinal Product	MPID	MPID	MPID04	MPID04	MPID05
			Medicinal Product Name	ANTRA		ANTRA
			Marketing Authorization			
			Country	ITALY		ITALY
			Holder	AstraZaneca		AstraZaneca
			Number	28245090		28245090
			Procedure ID	NL/H/2081/002		NL/H/2081/002
			Indication			
	Legal Status of Supply					
	Classification					
Package	PCID	PCID	NatID 001	NatID 001	NatID 001	
		Package Item Container				
		Type				
Treatment	Treatment	Quantity	28		28	
		Posology				
		Quantity to administer per intake				
		Frequency of intakes				
		Duration of treatment				
		Treatment Start				
		Quantity to administer				
		Indication				
Route of administration						
Substitution handling						





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**Thank you!**

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