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

Validation of the openMedicine cross-border identification model:

demonstration of concept tool from AEMPS

Expert Council Meeting, EMA.9th November 2016

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Background and opportunity

- **Preliminary results from openMedicine describe a few mechanisms that can be used in identification of products**

- **Analysis and conclusions are many, with many dependencies. This isn't simple to explain or validate**
  - Are the mechanisms complete?
  - What are the use cases supported, and...
  - ...how do these mechanisms work in practice?

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Goal / summary:

- **Present an approach to facilitate technical and conceptual discussions:**
  - Not to describe a full-fledged application
  - Not to start with the details
  - Data from multiple countries from Article 57, provided by EMA. Not all data used.

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Proposal: Share a Proof of Concept to Discuss, Validate & Explain openMedicine

- **Discuss** with internal and external partners
- **Validate** the concepts
- **Explain** the concepts and mechanics to public

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Proof of concept

- Simplified apps (not fully functional applications)
- Focused on identification of medicinal products
- Containing the data structures of IDMP
- Showing the conclusions from openMedicine
- Connected via “cross-border” datasets (e.g. Relevant part of epSOS dataset)

Prescribing app

Dispensing app

…

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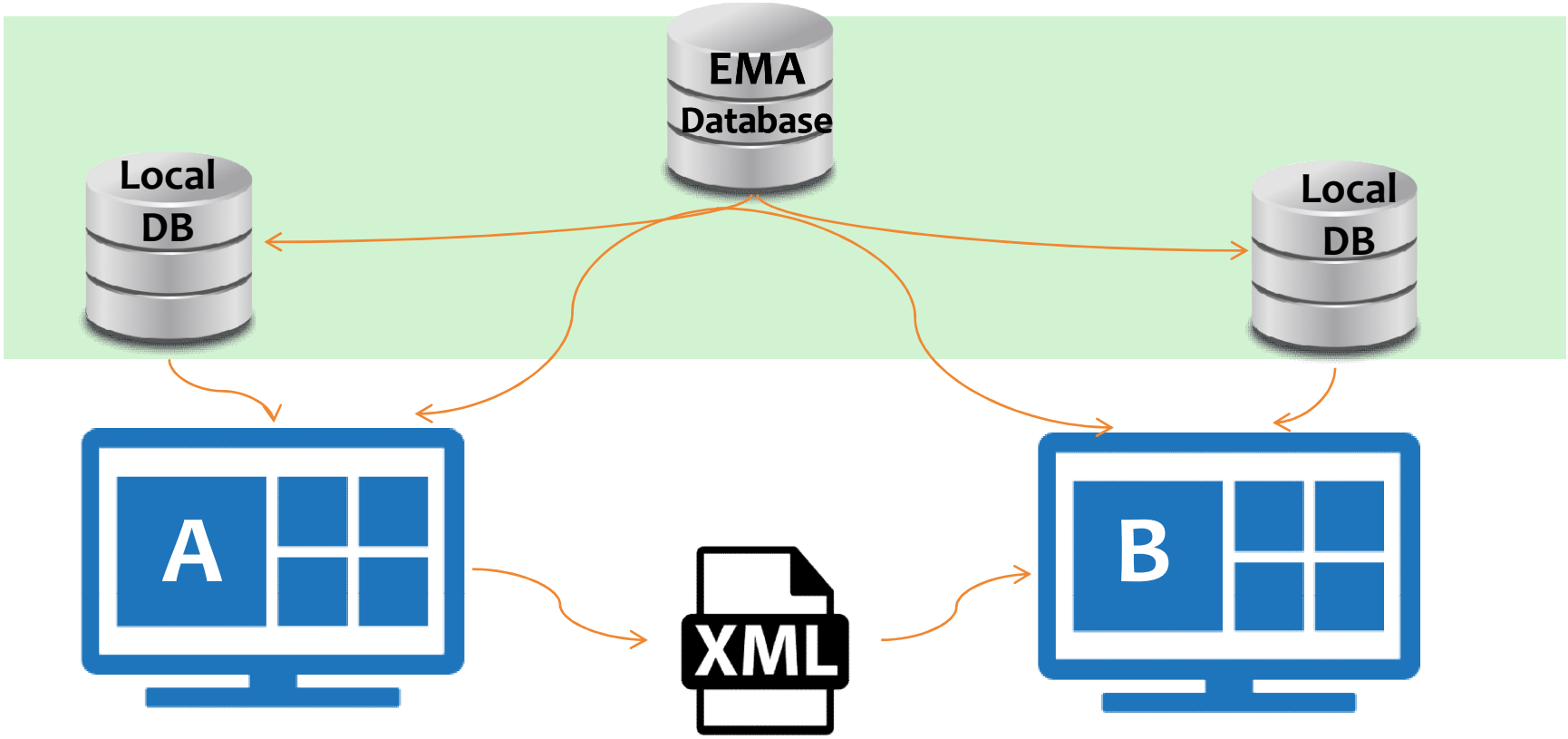
Goal: show, based on the EMA work on IDMP, how the EMA DB supports the openMedicine problems



- App in country A: Specify the product
- App in country B: Identify the specified product
- (XML) Clinical document transmits information
  - (example: ePrescription)

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STEP 1 CREATE PRESCRIPTION

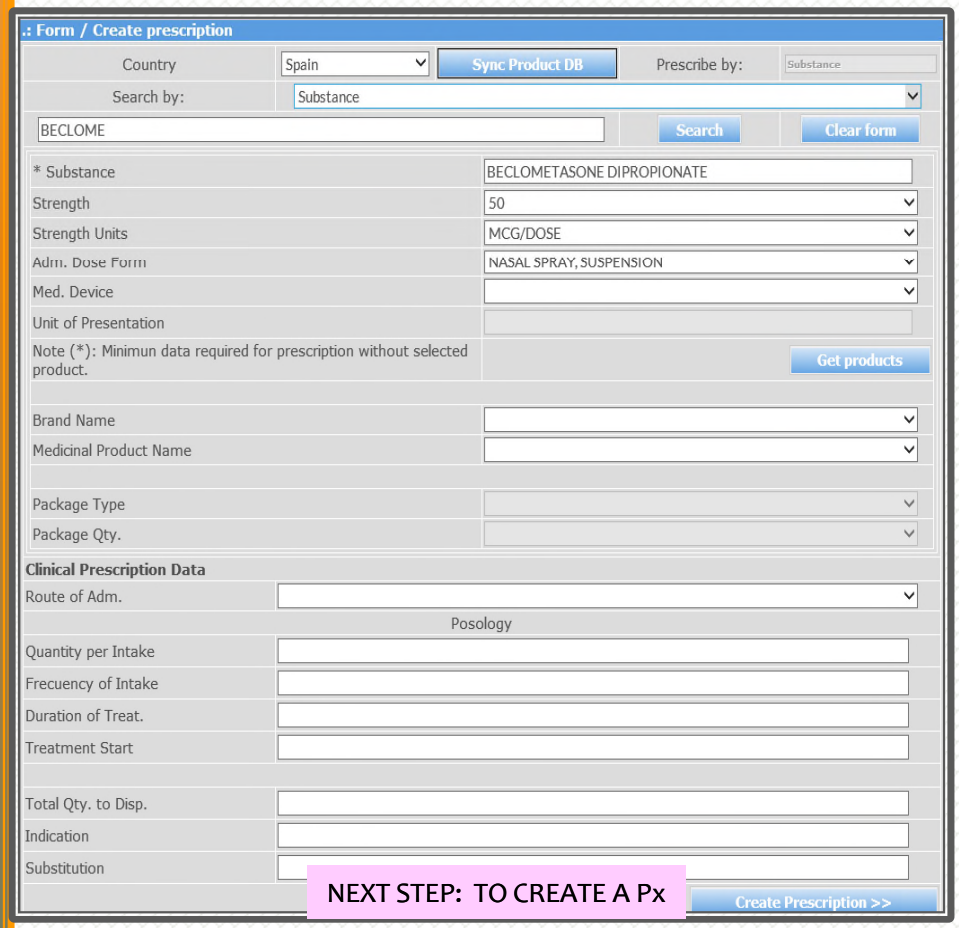
- Enter pharmaceutical product,medicinal product or the appropriate atributes

CLINICAL DATA

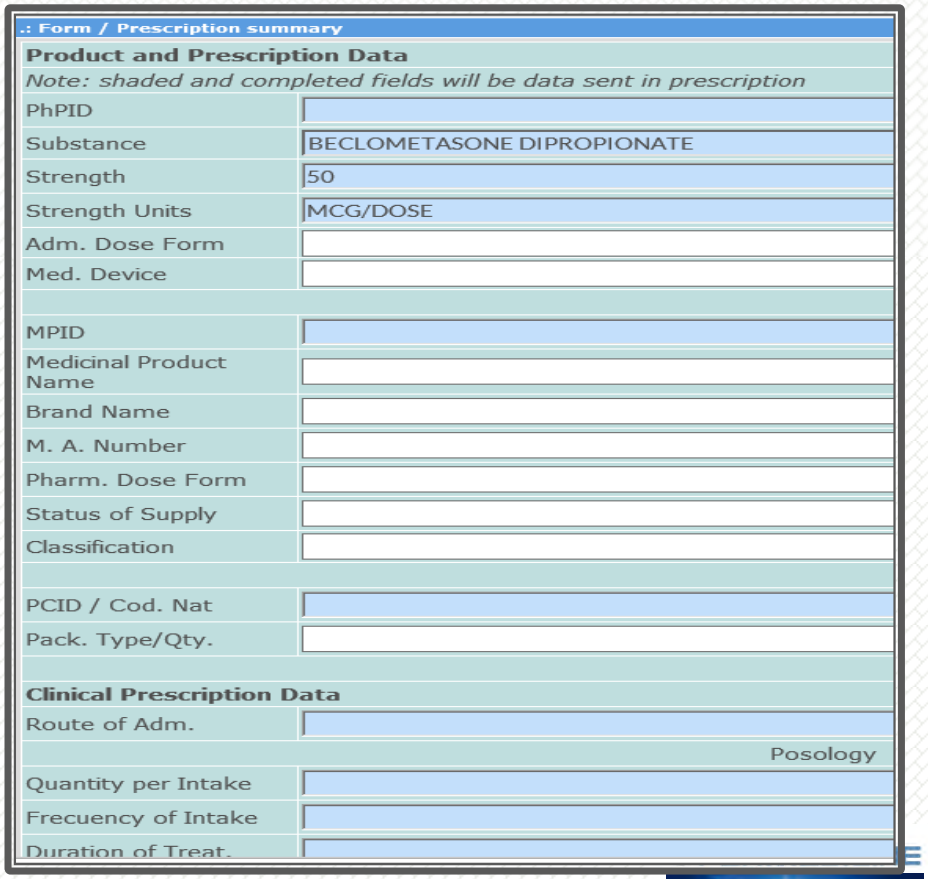
- Route of admin,Posology.....

PRESCRIPTION SUMMARY:

- Information "behind the sceenes"
- Fields in blue are the ones transmited when complete



NEXT STEP: TO CREATE A Px



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- **STEP 2: SEND THE PRESCRIPTION**
- **ISO IDMP openMedinine prescrition**
- **The information travels in the XML file, based on epSOS CDA, including new attributes like PhPID.**

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.: Form / Retrieve and decode prescription

Country	United Kingdom	Sync Product DB	Retrieve Prescription
Selected Product and Treatment Data			
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.			
Clinical Prescription Data			
Route of Adm.			
Posology			
Quantity per Intake			
Frecuency of Intake			
Duration of Treat			

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