Invitation to OpenMedicine Day:

Implementing ISO standards for the univocal identification of medicinal products (IDMP) in Europe

- The impact on EU member states: focus on Spain

23rd May 2016 (pm)

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

C/ Campezo number 1 –Edificio (building) 8 - Sala B

28022 Madrid

Context :

Enabling the delivery of safe cross-border healthcare is a policy priority of the European Union. The recently finished epSOS project (Smart Open Services for European Patients; 25 countries participated) developed cross-border services providing physicians access to basic medical data (patient summary, including medication record) when treating patients living temporarily abroad or travelling across Europe, and enabling patients to use a community pharmacy abroad to obtain their prescription medicines ("ePrescription"). It turned out that dispensing a pharmaceutical prescription poses a specific challenge in this context - the “delivery” problem of ePrescription. This concerns the univocal identification of the medicinal product (MP), which is noted in a prescription from a given country, by a pharmacist dispensing it in another country.

A prescribed medicinal product can be identified by its attributes in different ways, at least partially depending on its status (authorised, registered, free available,..), by its commercial name, package identifier, substance name, composition, or also by its grouping (pharmaceutical class, cluster,..).

Dispensing the product may also depend on national regulatory aspects allowing different levels of substitution by the dispensing pharmacist.

openMedicine aims to reach a global consensus in order to identify unambiguously medicinal and ipharmaceutical product(s). This will facilitate information exchange in a wide variety of applications, like pharmacovigilance, clinical record keeping, prescribing and decision support systems, registration and market authorisation of medicinal products, and pharmaceutical data bases including dictionaries. openMedicine closely cooperates with the European Medicines Regulatory Network, the European Medicines Agency (EMA), the US Federal Drug Agency (FDA), and standards development organisations. The work of openMedicine validates the implementation of the ISO IDMP suite of standards (11615/16, 11238-40) for the Identification of medicinal products in Europe in different use cases extending beyond regulatory purposes.

Objectives and expected outcomes

Each member state has a medicinal product database that is released regularly. For smooth cross border services we need structured and coded data and identification of medicinal products using IDMP attributes captured in the PhID and/or MpID.

With this background openMedicine wants to reach out to EU member states, their health ministries, national agencies and stakeholders to increase awareness of globally ongoing activities in this domain, and invites them to discuss further steps needed. A particular focus will be on whether the implementation of openMedicine results will be feasible, realistic and useful at the national level. The workshop will:

- provide a overview of ongoing developments
- review the implications and potential impact for specific use cases at the national and regional level of implementing global standards for the univocal identification of medicinal products (IDMP) at the European level,
- examine the expected added value for public health, clinical record keeping and decision support, pharmacovigilance, and industry
- identify opportunities, challenges, and costs of the pending roll-out of ISO/IDMP components in EU member states
- explore further steps and activities necessary to fully exploit the benefits foreseen in the workshop.

Meeting format

This expert meeting is intended as a transnational, pragmatic workshop serving as a venue for interested experts and health system stakeholders. It will provide a considerable exchange of expectations, experiences and opinions, and should also lead to constructive proposals for further joint activities.

It is envisaged that considerable time will be allocated to intensive discussions. Presentations should facilitate such discussions, e.g. by identifying issues and challenges of particular relevance and urgency in the overall context of the workshop.

	May 23rd, 2016	
Part 1: Setting the stage		
	Chair: José Manuel Simarro	
15.00	**Welcome** **Brief introduction of participants**	Belén Crespo Sánchez-Eznarriaga
15.10	**openMedicine – The business case for the univocal identification of medicines across Europe.**	K Stroetmann
15:25	**European Regulatory Network Vision for ISO IDMP**	Kevin Horan, ERN
15.35	**Regulatory framework and roadmap for national conformance to EU legislation** • EU regulatory framework • structure and process of the information flowing from EMA to national drug agencies, to clinical and pharmacy dispensing systems. • status and road plan of the national authorities	JM Simarro
16.05	**Health policy vision for ePrescription/eMedication services** • Vision of the Ministry of Health on digital health services for ePrescription/eMedication • Services and tools to be offered to regions, health agencies and the industry to implement for univocal medical product identification to: ✓ address patient safety ✓ fuel innovation and creativity in eHealth applications.	A Romero
16:25	**Global collaborative standards development: the case of ISO/IDMP** • Standards Development organisations (SDOs) cooperation on IDMP – the experience, lessons learned • Involvement of international and national regulatory authorities • Integrating activities and processes across the standards lifecycle.	C Chronaki
16.35	**Coffee break**	
Part 2: ePrescription in Healthcare delivery: national and European perspectives		
16.50	**Spanish experience on ePrescription and Patient Summary at regional, national, cross-border level:** • Status quo and perspective for ePrescription • challenges and problems of scaling up and sustaining deployment • epSOS/cross-border experience and needs • challenges or gaps in consistent use of value sets and codes	Luz Fidalgo
17.10	**Portuguese experience on ePrescription at national & cross-border level** • Status quo and plans for ePrescription • challenges and problems of scaling up and sustaining deployment • challenges or gaps in consistent use of value sets and codes	Tiago Suarez, A Alexander
17:30	**Vision of the Irish Regulatory Agency**	Kevin Horan HPRA
Part 3: Implementation challenges of the openMedicine approach		
17.50	**openMedicine approach:** a brief demonstration illustrating the core concepts of openMedicine relevant for implementation at the national level	I. Lázaro Salcedo

18.10	**Stakeholder Round Table: Can ISO/IDMP bridge the cross-border and national levels?** After a short introduction by Jos Devlies illustrating the added value of implementing ISO/IDMP components for univocal medicinal product identification the related opportunities, challenges, costs, and timeline will be discussed. Participants from national level authorities, health professionals, industry and standards development organizations will critically review and explore • the expected added value for public health, clinical decision support, pharmacovigilance, pharmacies, and others • implementation challenges and costs of the pending roll-out • further steps (structures and processes) necessary to fully exploit the benefits foreseen	J. Devlies & JM Simarro
18.45	**Summary and closing**	Rapporteurs: J. Devlies & JM Simarro
19:00	**End of the workshop**	

We kindly ask for confirmation of attendance to the following email address:
Ilazaro_externo@aemps.es

Logistics information

Contact Numbers:

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The easiest way to get from the Airport to the Agencia *Española de Medicamentos y Productos Sanitarios* is by taxi (more information below), they are close to each other but the communication is not easy if you are not familiar with it.

-From Terminal 1, 2, 3 it is around 18-22 Euros
-From Terminal 4 is an additional 5 Euros.

ALWAYS ASK for the Receipt.

How to get from the Airport to the City Centre.

The Airport has 4 Terminals (1,2,3 are together and T4 is a bit further away from the city) but there are free buses connecting them, they are about 10 min away.

1. **Taxi** http://www.aena-aeropuertos.es/csee/Satellite/Aeropuerto-Madrid-Barajas/en/Page/1237554330997/

   A flat fare of 30 Euros will apply for all journeys between the airport and the city centre (if inside the ring road M-30).

2. **Buses**. http://www.aena.es/csee/Satellite/Aeropuerto-Madrid-Barajas/en/InfoPractica_FP/1237554358266/1237554326802/
   -Aeropuerto-Atocha Renfe (203): **Runs every 15-20 minutes during the day and every 35 at night**

   From all airport terminals to Plaza de Cibeles or Atocha Renfe (Last stop).
   The ticket can be bought inside the bus and the price is 5 euros. The journey takes approx. 40 min, operating 24 h during 365 days.
   The stop at Atocha-RENFE is not used from 23:30 to 6:00. During this period the departure point is in Plaza de la Cibeles, where there are connections for all the Municipal Transport (EMT) night buses, known as "búhos" (owls).
   -Avenida de America-Airpotrt (Route 200):
   A single ticket costs €1.50 and is valid for one journey. You can only buy this on board.

3. **Cercanías Train** http://www.renfe.com/viajeros/cercanias/madrid/index.html

   C1 line local trains (Cercanías): operates **only from T4 terminal** airport to Principe Pío, stop in Atocha Renfe, walking distance to the Ministry of Health.
   They run every 30 minutes aprox and it takes approx. 25 min to Atocha. The ticket can be adquired at ticket machines and the price of a single ticket is 2.60.

4. **Metro** Stations (underground): http://www.metromadrid.es/en/index.html
   Atocha (L1), Antón Martín (L1) and Banco de España (L2). These stations are 10-15 min. walking distance from the meeting venue.
   You can Buy 10 trip tickets (the tickets can be used in metro and bus) or

   The Tourist Card: personal and non-transferable. When used, an official document must be presented (National Identity Document, Passport, etc) accrediting the identity, and the number noted in the coupon. There are five types, depending on validity: for 1, 2, 3, 5 and 7 calendar days. http://www.metromadrid.es/en/viaja_en_metro/Tarifasybilletes/abonos/contenido02.html