OpenMedicine Day:

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

The impact on EU member states: South - Eastern Europe

25th October, 2016

Athens Megaron, Greece

Context

Enabling the delivery of safe cross-border healthcare is a policy priority of the European Union. The 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 local 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, etc.), by its commercial name, package identifier, substance name, composition, and 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 and to describe a medicine in its different presentation forms. This will facilitate information exchange in a wide variety of applications, like pharmacovigilance, clinical record keeping, prescribing, dispensation, and decision support systems, registration and market authorisation of new products, pharmaceutical data bases. openMedicine closely cooperates with the European Medicines Agency (EMA), the US Federal Drug Agency (FDA), and standards development organisations. The work develops upon and extends the presently available ISO IDMP suite (11615/16, 11238-40) - Identification of medicinal products. An implementation of this suite is now on going by EMA and will be in the short term the reference MP database at EU level for regulatory purposes.

Objectives

It is against this background that openMedicine reaches out to EU member states, their national agencies and stakeholders to increase awareness of the globally ongoing activities in the domain of medical product identification and discuss further steps needed. A particular focus should be on whether the implementation of openMedicine results will be feasible, realistic and useful at the national level. The workshop will

- provide a concise overview of ongoing developments
- explore the implications and potential impacts of implementing global standards for the univocal identification of medicinal products (IDMP) at the national level,
- explore the expected added value for medicinal care, public health, clinical decision support, pharmacoeconomics, pharmacovigilance
- identify challenges and costs of the pending roll-out in EU member states

- explore further steps and activities necessary to fully exploit the benefits foreseen.

Meeting format

This expert meeting is intended as a translational hands-on, pragmatic workshop serving as a venue for interested national experts and health system stakeholders in South Eastern Europe. It will provide for a considered exchange of expectations, experience and opinions, and should also lead to constructive proposals for further activities.

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.

	October 25th, 2016	
Part 1: Setting the stage		
	Chairs: Karl Stroetmann & Catherine Chronaki	
9:30	**Welcome Hellenic Ministry of Health and Social Solidarity / National Organization for Medicines** *Brief introduction of participants*	All
9:45	**openMedicine – The business case for the univocal identification of medicines across Europe**	K. Stroetmann
10:00	**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?	EMA IDMP Task Force, GS1, Christian Hay
10:15	**openMedicine approach:** a brief demonstration illustrating the core concepts of openMedicine relevant for implementation at the national level	Catherine Chronaki
10:30	**Q&A, Discussion**	
11:00	**Coffee break**	
eMedication in Healthcare delivery: national, regional, and European perspectives [Jos Devlies & Alex Berler (TBA)		
11:30	• **Health policy vision for ePrescription/eMedication services** Vision of the Ministry of Health on digital health services • Services and tools for health agencies and the industry to ✓ Enable openMedicine implementation ✓ address patient safety and • Fuel innovation and creativity in eHealth applications.	Greek Ministry of Health and Social Solidarity, Hellenic Drug Organization (TBA)
11:45	**Experience & Expectation on e-Prescription/ e-Dispensation at regional, national, cross-border level: moving towards digital eServices** • European e-Prescription Guidelines	**Tassos Tagaris (TBA), IDIKA**

	• Status quo and perspective for ePrescription / eDispensation • challenges and problems of scaling up and sustaining de-ployment • challenges or gaps in consistent use of value sets and codes	
12:00	**Member State Panel**[1]	
12:30	**Lunch**	
Stakeholder Feedback (Zoi Kolitsi (TBA) & Stephan Schug)		
13:30	**Industry and Professional View Points (Panel)** • Input from Pharmacies • Input from Pharmaceutical companies • Input from IT companies • Input from Drug dictionary and added value services • Input from Electronic Health Record System vendors • Input from Health Professionals • Input from the National School of Public Health	**Pharmacy Association, Physician Association, EHR vendors**
14.30	**Stakeholder Round Table: Can ISO/IDMP bridge the cross-border and national levels?** Participants from national level authorities, health professionals, industry and standards development organizations will critically re-view and explore • the expected added value for clinical care, 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 • Migration path for the European e-Prescription guidelines	**Rapporteurs (TBA)**
14:45	**Summary and closing**	Jos Devlies, Catherine Chronaki
15.00	**End of the workshop**	

Attendance by invitation only.

[1] EU member states in South Eastern Europe: Malta, Italy, Bulgaria, Slovenia, Romania, Greece, Cyprus, Croatia.

Logistics information

TBA