Final Expert Council Meeting

at EMA – European Medicines Agency

30 Churchill Place, Canary Warf, London E14 5EU

9th and 10th of November 2016

Agenda

Background and project goal:

Enabling the delivery of safe and efficient cross-border healthcare is a policy priority of the European Union.

The openMedicine project contributes to this policy by solving a problem of portability of medication related information across Europe. The main issue was a problem of univocally identifying the medicinal products to be dispensed in case of a cross-border ePrescription. The same problem of identification occurs in cross-border processing of a Patient Summary.

The openMedicine project wants to discuss with you, as domain expert, a number of recommendations and a roadmap to realise full identification of any pharmaceutical or medicinal product in the electronic patient summary as well as cross-border ePrescriptions.

The openMedicine project addresses the different regulations regarding substitution considering that the pharmacist still has to comply with national rules.

The openMedicine project identified different ways of prescribing a medication item: by package, by medicinal product, by pharmaceutical product or by active substance.
A specific medicinal product can be *identified* in a prescription either by an **identifier** (package ID or medicinal product ID) and/or by a **set of identifying attributes.** Some member states also allow to not specify a specific product, but only an **active substance (plus further attributes)** and/or a **group** (set, class, cluster,..) of several medicinal products which was predefined by an authority.

The project aims *to reach a global consensus* in order to describe and to identify unambiguously a medicinal and a pharmaceutical product, resulting in the authorised delivery of the appropriate medicine in a cross-border context. In detail, this concerns developing

- common data models for prescribed medicinal products
- a common vocabulary for unambiguous definition, description, and identification of medicinal products
- recommendations regarding the structure and the content of ePrescriptions, the Patient Summary and the prescription drug databases
- rules to harmonise practices of substitution
- a global roadmap for post-project actions and implementations.

Meeting objectives and expected outcomes

The openMedicine consortium and the supporting partners want to take the opportunity of this Final Expert Council Meeting to discuss the options proposed as well as the deliverables

submitted. These deliverables are available on the web site of the project at http://www.open-medicine.eu/downloads.html

Building on the ISO IDMP suite of standards is the direction taken by the European Union, its member states as well as North American regulatory authorities. Trans-Atlantic consensus seems to exist to adopt and to implement these standards including the cooperatively agreed upon or developed coding systems for certain attributes.

The openMedicine consortium promotes the long term option of using the same suite of standards throughout the complete lifecycle of a medicine: innovative research, clinical studies, marketing authorisation, manufacturing, marketing, prescribing, dispensing, administering, post-authorisation procedures, pharmaco-vigilance, billing, marketing cessation

For the time being, the Article 57 (2) EMA EudraVigilance drug database will remain a reference database for national drug databases, to be used also for prescribing, dispensing and patient medication data in EHRs as well as patient summaries. The Article 57 (2) EMA database will be converted within three years into a structured and fully IDMP compatible database.

This " openMedicine Expert Council" meeting will

- ✓ critically review the openMedicine results and deliverables
- ✓ discuss pertinent issues brought forward by Expert Council Members
- ✓ validate the openMedicine recommendations
- ✓ validate the openMedicine roadmap
- ✓ debate the options put forward by openMedicine for standards and their impact on ePrescriptions, electronic patient summaries and drug databases
- ✓ contribute, if needed to better enable safe and secure cross-border dispensing of pharmaceutical prescriptions, suggestions to modify European Directives and Electronic Patient Summary and ePrescription Guidelines

The final outcome expected is to substantially contribute to the further improvement of final project outcomes such as to achieve results which will indeed eventually translate into daily practice in Member States and globally, thereby improving healthcare delivery and patient safety.

Wednesday November 9th, 2016

Chair: Paolo Alcini, EMA

08:30		**Registration (please bring an ID document) & coffee**	
		Welcome and introduction	
09:00	09:10	Welcome (Host, project)	Paolo Alcini
09:20	10:00	Roll Call – 2' per expert (max)	All
10:00	10:15	The European Policy context (via Webex)	Gerald Cultot
10:15	10:30	Project Status	Karl Stroetmann
10:30	10:45	**Break**	
Session 1: Key results of openMedicine			
10:45	11:05	openMedicine data model for cross-border identification of pre-packaged medicinal product	William Goossen, Robert Vander Stichele
11:05	11:20	Identification issues for other products	Anna Gawronska, Isabel Lazaro
11:20	11:35	Substitution and Selection	Karl Stroetmann
11:35	11:45	Identifiers in regulatory and in clinical care context	Jos Devlies
11:45	12:10	Validation of the openMedicine cross-border identification model : demonstration of concept tool from AEMPS Spain	Isabel Lazaro, Kevin Horan
12:10	12:40	Plenary discussion	Moderator Marcello Melgara
12:40	13:30	**Lunch**	

Chair: Karl Stroetmann

Session 2 IDMP realisation			
13:30	13:50	Implementation of the ISO IDMP standard within the European Medicines Regulatory Network: EMA SPOR Roadmap, iterations and target operating model for medicinal products and substances	Paolo Alcini
13:50	14:25	-The US approach in distributing IDMP compatible data and databases -Global PhPID Generation Update	Vada Perkins Chr. Joneciks
14:25	14:45	Terminologies and coding systems: SPOR	Kevin Horan

Chair: Kevin Horan

Session 3 IDMP compatible implementation			
14:45	15:00	The use of the PhPID in pharmaco-vigilance	WHO-Upsala
15:00	15:30	Adjusting to IDMP – access needs and business challenges of drug database providers	T.R. Bizzaro J.F. Forget Geert Deloof
15:30	16:00	Identification of medicines in an EHR (Medication record; prescription history; patient summary)	Jos Devlies W. Ed Hammond
16:00	16:30	Break	
16:30	17:30	Main conclusions of the Work Packages	WP,Leaders
17:30	18:00	Plenary discussion	Moderator W. Ed Hammond

Thursday November 10th, 2016

09:00	09:10	Welcome (Host, project)	Paolo Alcini

Chair: Christian Hay, CEN

Session 4 openMedicine recommendations			
09:10	10:00	openMedicine identifiers and identifying attributes. Proof of concept.	José Teixeira
10:00	10:25	Impact of openMedicine on ePrescription, eDispensation and Patient Summary structures	Giorgio Cangioli
10:25	11:00	Break	
11:00	11:30	Introducing the openMedicine recommendations	Jos Devlies
11:30	12:30	Discussing the recommendations	Moderator Catherine Chronaci
12:30	13:30	Lunch	

Chair Marcello Melgara

Session 5 Draft roadmap			
13:30	14:00	The European “Joint Action to support the eHealth Network - (JAseHN)” and its ePatientSummary and ePrescription Guidelines - review of the input from openMedicine	Jeremy Thorp
14:00	14:30	How to integrate EMA SPOR and OpenMedicines Roadmaps	Jos Devlies and Paolo Alcini
14:30	14:45	Debate and validation	All

Chair Karl Stroetmann

Session 6 The way forward			
14:45	15:00	Suggestions for further work	All
15:00	15:45	Final statements by involved stakeholders	Various experts
15:45	16:00	Thank You and Farewell	Paolo Alcini Jos Devlies Karl Stroetmann

Contact information

Expert council & meeting organiser	Local organiser
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Venue:

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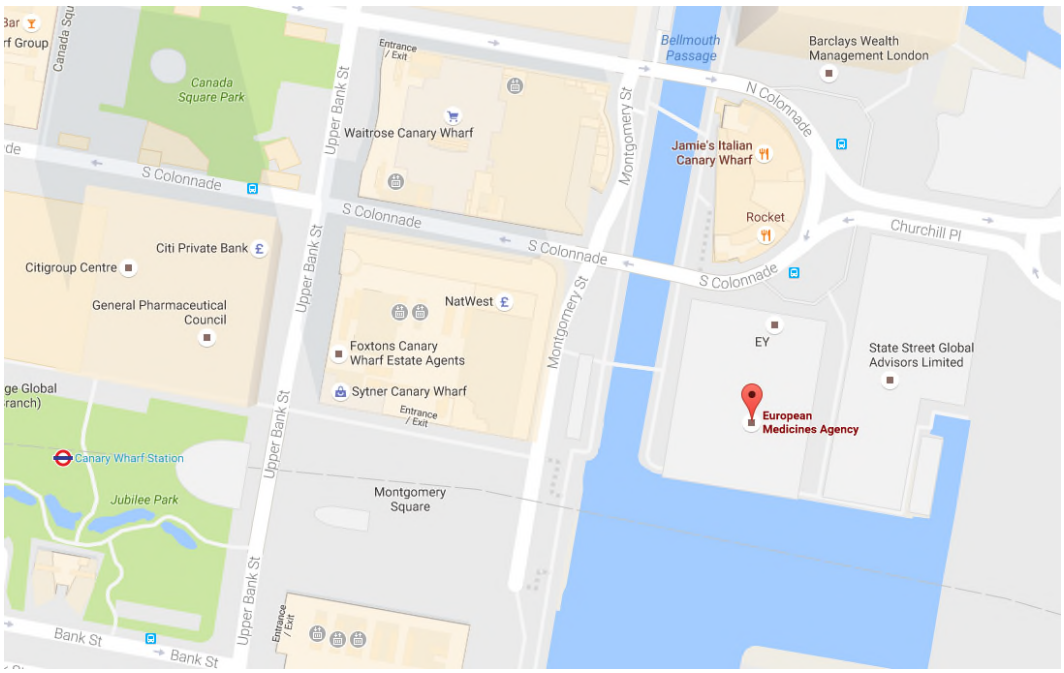
For location details, see
http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000129.jsp

Map of EMA location



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