DELIVERABLE

Grant Agreement number: 643796
Project Title: openMedicine

D6.4 Second annual report on the activities of the Expert Council

Status: Final after ATR

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<table>
<thead>
<tr>
<th>Jos Devlies</th>
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<tbody>
<tr>
<td>Members of Expert Council</td>
<td>Comments</td>
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<tr>
<td>Consortium partners</td>
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## Revision history, status, abstract, keywords, originality

### Revision History

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<td>Status</td>
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### Abstract (for dissemination)

This document presents the strategy and the results of involving a large number of external stakeholders as structural partner or as member of the expert council.

### Keywords

Review, report, council meeting, experts

### Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.
# Table of content

Revision history, status, abstract, keywords, originality ............................................. 2

1 Executive summary ........................................................................................................ 4
   1.1 Overview and context ................................................................................................. 4
   1.2 Different roles of the experts ................................................................................... 5
   1.3 Represented stakeholders ......................................................................................... 6
   1.4 List of openMedicine experts and affiliation .......................................................... 8

2 Second openMedicine Expert Council ......................................................................... 10
   2.1 Invitation .................................................................................................................... 10
   2.2 Agenda – Final ........................................................................................................... 12
   2.3 Presentations – Summary ........................................................................................ 16
   2.4 Minutes – Summary of discussions and Conclusions .............................................. 35
   2.5 openMedicine presentations .................................................................................... 38

3 EU-US openMedicine Workshop ................................................................................. 40
   3.1 Invitation .................................................................................................................... 40
   3.2 Attendees ................................................................................................................... 46
   3.3 Summary of the presentations: Day 1 ..................................................................... 48
   3.4 Presentations available – day one ............................................................................ 60
   3.5 Agenda - Day 2 .......................................................................................................... 61
   3.6 Summary of the presentations – day 2 ..................................................................... 63
   3.7 Presentations available – day 2 ................................................................................ 69
   3.8 Minutes – Summary of discussions and conclusions .............................................. 69

4 Final Expert Council Meeting ...................................................................................... 71
   4.1 Invitation .................................................................................................................... 71
   4.2 Final Agenda .............................................................................................................. 73
   4.3 Attendees ................................................................................................................... 76
   4.4 Presentations ............................................................................................................. 77
   4.5 Minutes – Summary of discussions and conclusions .............................................. 82

5 Expert Reviewers and Contributors ............................................................................ 84
1 Executive summary

1.1 Overview and context

openMedicine is a "coordination and support action" project addressing issues of identification of medicinal products in different use cases on top of the problems identified by the ePSOS project. This report covers the activities undertaken in the context of the Expert Council during year two of the Action.

The production, prescribing, dispensing and usage of medicines is a highly regulated domain, nationally as well as at European level, and involving the patient as well as a large range of stakeholders.

The whole process of producing, marketing, prescribing, dispensing and administering medicinal products is up to a certain level similar in most of the Member States, nevertheless building mostly on national rules, authorisations and content of the drug databases in use. National public stakeholders are mainly the national drug agencies, the ministries of health, the social security/health insurances.

Problems occur when medicinal product related information and/or documents like prescriptions and medication related patient information cross (some of) the borders. These problems are due to missing links regarding standards for medication related information and cross border identification of the products.

Standardisation bodies (IT as well as domain specific), drug database editors, domain experts and regulatory authorities are essential in solving those two main hurdles in cross border portability and interoperability of medicinal product related services. EMA (European Medicines Agency) is essential as central / European marketing authorisation body.

openMedicine decided to go for a large representation of domain specialists, in a transatlantic approach, as Members of the Expert Council. EMA accepted presidency of the Expert Council meeting.

openMedicine encouraged participation of interested experts in the activities of the project at work package level. Other experts were nominated as reviewers of individual deliverables. The reviewing activities are reported in deliverable D6.2 Validation.

The openMedicine consortium organised "Inaugural openMedicine Expert Council" took place at EMA, June 26, 2015, chaired by Paolo Alcini, EMA. The Minutes of the meeting are included in this deliverable. The presentations given are available on the web site and on Dropbox.

Some of the attendees made interesting comments and provided, as requested, 3 "statements" addressing for them important issues regarding the openMedicine project.

The "second openMedicine Expert Council" meeting was hosted by CEN/CENELEC in Brussels, January 21-22, 2016.

The third and final "openMedicine Expert Council" was hosted again at EMA on November 9 and 10, 2016.

On June 20 and 21, a Workshop was held at the FDA offices, Silver Springs, Washington DC, USA.

The openMedicine project is a "coordination and support action" addressing very specific problems related to the cross border exchange of medication related data, mainly part of cross border ePrescriptions.

The openMedicine consortium contains IT as well as medicines related expertise, enough to define solutions for the enumerated problems. Defining solutions is not enough. These solutions need to be acceptable to and accepted by the decision makers.
The consortium finally agreed on recommendations with an initial set of experts, representing most of the "decision makers".

The list of experts did not change much. We accepted some additional experts. Most of them joined the openMedicine expert team when attending the US/EU workshop. They are added in Italic to the list of experts.

1.2 Different roles of the experts

An invitation letter was sent to the experts and/or their affiliated companies or organisations. Candidate experts were at the same time requested to express their preferred role within the project.

As explained in the invitation letter, four different roles were defined:

- Structural partners
- Supporting individual experts, at work package or task level
- Members of the Expert Council
- Reviewers

The input from the supporting partners was important and constructive, building towards consensus between the different domains.

Hereby briefly we repeat the role of the different "partners":

**Structural partnership** is subject of approval by the Board and only possible for international organisations, active in “medicines” standardisation, databases, e.g. EMA, WHO etc… They can attend any meeting they are interested in, GA (General Assembly) excepted. They don't have voting rights. Refunding of out-of-the-pocket expenses is possible.

**Supporting individual experts** are subject of approval by the WP Leader (s) of the work packet they candidate. The number of F2F meetings will be limited. They only attend the WP meetings and only contribute to the WPs for which they have been accepted. See list of work packages and work package leaders for inclusion in the work package team.

Individual experts may request to be involved in more than one of the Work Packages. No more than 5 experts per work package will be accepted.

**Members of the Expert Council** are nominated by the Board. They are considered as expert in at least one of the two1 tracks in the project. A grant will be assigned for work done and costs reimbursed. This grant does not apply for public agents. The Expert Council meets 3 times during the lifetime of the project: M6 (June 2015), M11 (November 2015) and M23 (November 2016). They are not involved in the day-to-day activities of the project, structural partners. Considering the costs and travel requirements transatlantic experts will preferably be nominated as member of the expert council. The expert council will be limited to 20 external experts.

**Reviewers** are involved in a process of external validation. They are 'nominated' by the WP Leader. Reviewer should indicate which deliverable they may review. A fee and reimbursement of costs are foreseen. They can't review a deliverable to which they contributed significantly. Transatlantic experts can be nominated as reviewers.

They are listed in 1.2.

Partners added since the previous report are in italic.

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1 Medicinal product identification and substitution
1.3 Represented stakeholders
In the following, "affiliated" organisations across Europe and Transatlantic are listed.

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<thead>
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<th>Table 1  Affiliated European organisations</th>
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<tr>
<td>Organisation</td>
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<td>WHO-UMC</td>
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<td>WHO-Geneva</td>
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<td>Health and Social Care Information Centre – NHS</td>
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<td>Pharmaceutical Group of the European Union</td>
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<td>AUTH – Informatics and Information Security Laboratory</td>
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<td>Belgian Federal Drug Agency</td>
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<td>Heralampos Karanikas</td>
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<td>Vidal – Drug Database</td>
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<td>Joint Action to support the eHealth Network (JAs eHN)</td>
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<td>Clinical Pharmacology – K.U.L. Catholic University of Leuven</td>
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Note: 'X' indicates affiliation.
Table 2 Transatlantic associated stakeholders

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<td>Struct Council Review WP1 WP2 WP3 WP4 WP5 WP6</td>
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</table>
### 1.4 List of openMedicine experts and affiliation

Each associated stakeholder is represented by up to three “experts”, resulting in the following list of openMedicine experts.

**Table 3 List of openMedicine experts and their affiliation**

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Country</th>
<th>Representative</th>
<th>e-Mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Medicines Agency</td>
<td>UK</td>
<td>Paolo Alcini</td>
<td><a href="mailto:paolo.alcini@ema.europa.eu">paolo.alcini@ema.europa.eu</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Panagiotis Telonis</td>
<td><a href="mailto:Panagiotis.Telonis@ema.europa.eu">Panagiotis.Telonis@ema.europa.eu</a></td>
</tr>
<tr>
<td>IHTSDO</td>
<td>DK</td>
<td>Anna Adelof</td>
<td><a href="mailto:aad@ihtsdo.org">aad@ihtsdo.org</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Jane Millar</td>
<td><a href="mailto:jmi@ihtsdo.org">jmi@ihtsdo.org</a></td>
</tr>
<tr>
<td>WHO-UMC</td>
<td>S</td>
<td>Ola Strandberg</td>
<td><a href="mailto:Ola.Strandberg@who-umc.org">Ola.Strandberg@who-umc.org</a></td>
</tr>
<tr>
<td></td>
<td>S</td>
<td>Marie Lindquist</td>
<td><a href="mailto:Marie.Lindquist@who-umc.org">Marie.Lindquist@who-umc.org</a></td>
</tr>
<tr>
<td></td>
<td>S</td>
<td>Malin Jakobsson</td>
<td><a href="mailto:Malin.Jakobsson@umc-products.com">Malin.Jakobsson@umc-products.com</a></td>
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<tr>
<td>WHO-Geneva</td>
<td>CH</td>
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<td>Danish National eHealth Agency</td>
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<td>Croatian Medicines Agency</td>
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<td>Novartis – EFPIA</td>
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<td>AUTH – Informatics and Information Security Laboratory</td>
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<td>Georges Pangalos</td>
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<tr>
<td>Intelligent Law &amp; Internet Applications</td>
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<td>Sebastian Reilos</td>
<td><a href="mailto:office@ilia.ch">office@ilia.ch</a></td>
</tr>
<tr>
<td>National Institute for Health and Welfare (THL)</td>
<td>FI</td>
<td>Viveca Bergman</td>
<td><a href="mailto:viveca.bergman@thl.fi">viveca.bergman@thl.fi</a></td>
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<tr>
<td></td>
<td>FI</td>
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<td>Belgian Federal Drug Agency</td>
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<td>Vanessa Binamé</td>
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<tr>
<td>Haralampous Karanikas</td>
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<tr>
<td>Vidal Editions</td>
<td>B</td>
<td>Annemieke Vergauwe</td>
<td><a href="mailto:Annemieke.vergauwe@medibridge.be">Annemieke.vergauwe@medibridge.be</a></td>
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<tr>
<td>Office for Registration of Medicinal Products</td>
<td>PL</td>
<td>Grzegorz Cessak</td>
<td><a href="mailto:prezes@urpl.gov.pl">prezes@urpl.gov.pl</a></td>
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<td>Dirk Broeckx</td>
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<tr>
<td>Faculty of Pharmacy, K.U.L</td>
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<td>NLM – National Library of Medicine</td>
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2 Second openMedicine Expert Council

The Second openMedicine Expert Council was hosted by CEN/CENELEC at their offices in Brussels, January 21st & 22nd, 2016

2.1 Invitation

An initial announcement was sent to all the experts at the end of October 2015. Below, a full copy of that letter is shown.

Dear Expert Council Member

The openMedicine consortium and the supporting organisations are pleased to invite you to attend the Second openMedicine Expert Council, scheduled January 21st and 22nd, 2016 in Brussels, Belgium.

The openMedicine Expert Council meeting will be held at the offices of CEN/CENELEC, Avenue de Marnix 17, BRUSSELS, Belgium. Attached to this mail you find a flyer 'Directions to CEN', also including a limited list of Hotels, nearby the CEN Offices. CEN/CENELEC does not have special rates agreed with these hotels. The CEN Offices and these hotels are nearby the internal ring road and thus quite centrally located.

The meeting will start at 10:00 on day 1 and end on day 2, not later than 16:00, enabling most European attendees to fly in or to arrive by train on the 21st and to leave on the 22nd.

The focus of the meeting will be on the submitted deliverables and an initial set of recommendations. A detailed agenda will be send to you within two weeks from now, after being approved by the Project Executive Board meeting of the 10th and 11th November 2015 in Milan, Italy.

The project progressed quite well. Five work packages delivered yet one or more deliverables, as listed in an addendum to this mail and available on the openMed Dropbox. Some additional deliverables will be available before the Expert Council Meeting, more especially for Work Packages 2 (pre-packed medicinal products), 5 (substitution) and 6 (initial set of recommendations).

The material is available on the openMed Dropbox in the map "material for expert council meeting". The access rights will be assigned by Louisa Reck from the coordinator's team (empirica).

The material is also available on the openMedicine web site www.open-medicine.eu, go to the Login Section:

Username: OpenMed_RE
Password; Grant#643796
The Minutes of the previous Expert Council Meeting will be included in the first version of Deliverable 6.1, reporting on "Experts activities".

May we remind you on a request made after the first openMedicine expert council meeting in London? We asked each of you to provide 3 "statements", reflecting issues that you consider as important, related to identification of medicinal products in an ePrescription domain. Some of you did send their statements promptly… new statements are very welcome. They may address issues related to identification of medicinal products in general, to use cases related to the electronic prescription as well as related to standards or even drug databases.

Please confirm your presence at the Second Expert Council by returning a completed form to Mrs. Louisa Reck, louisa.reck@empirica.com.

Problems, remarks and suggestions are welcome at jos.devlies@custodix.com

Kind greetings

Jos Devlies
Medical Director Custodix
2.2 Agenda – Final

Second Expert Council Meeting

at CEN – CENELEC Management Centre
17 Avenue Marnix, Brussels
21st & 22nd of January 2016

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 ePrescriptions across Europe. The main challenge is the univocal identification of medicinal products to be dispensed by a community pharmacist in case of a cross-border ePrescription. Towards this end, the project will formulate a number of recommendations and a roadmap, also to realise the full identification of any pharmaceutical or medicinal product in the patient summary.

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

A prescribed medicinal product can be *identified* by its attributes in different ways, at least partially depending on its status (authorised, registered, freely available...), by its (brand) name, package identifier, substance name, composition, set of descriptive attributes and also by its grouping (pharmaceutical class, cluster...).

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 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 content of ePrescriptions, the Patient Summary and the prescription drug databases
- rules to harmonise practices of therapeutic and economic 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 mid-term Expert Council Meeting to discuss the initial solutions identified as well as the first deliverables submitted. These deliverables are available on the web site of the project www.open-medicine.eu.

Building on the ISO IDMP suite of standards (11615/16, 11238-40 - Identification of medicinal products) is the main option identified so far. Global consensus seems to exist amongst regulatory authorities to further develop, adopt and implement this suite of standards once it is ready.

The so-called Article 57 (2) drug database of the European Medicines Agency (EMA) – an element of its EudraVigilance (European Union Drug Regulating Authorities Pharmacovigilance) data processing network and management system - will be available as source me-
dicinal product database for prescription (national databases) and dispensation, as well as for patient medication data in EHRs and patient summaries.

This "Second openMedicine Expert Council" meeting will
- discuss issues brought forward by the Expert Council Members and related to the first deliverables
- debate openMedicine options for standards and their impact on prescriptions, patient summaries and drug databases
- elicit your suggestions on defining ultimately a set of recommendations and a roadmap on how to reach a cross border identification of medicines wherever needed

The final outcome expected is how to improve and streamline the further project process such as to optimise work and achieve results which will indeed eventually translate into daily practice in Member States and globally, thereby improving healthcare delivery and patient safety.

Thursday January 21st, 2016

Chair: Paolo Alcini, EMA

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>09:30</td>
<td>Welcome (Host, project)</td>
<td>Christian Hay, CEN</td>
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<td></td>
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<td>Karl Stroetmann</td>
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<tr>
<td>09:50</td>
<td>Roll Call – 3’ per expert (max)</td>
<td>All</td>
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<tr>
<td>10:20</td>
<td>openMedicine, the main issues</td>
<td>Karl Stroetmann</td>
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<td>10:35</td>
<td>Break</td>
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EMA – Article 57(2) European Regulatory Drug Database

<table>
<thead>
<tr>
<th>Time</th>
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<th>Speaker</th>
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<tbody>
<tr>
<td>11:00</td>
<td>Introduction</td>
<td>Jos Devlies</td>
</tr>
<tr>
<td>11:15</td>
<td>Demo of the Art. 57 (2) Dug Database</td>
<td>Kevin Horan</td>
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<tr>
<td>11:35</td>
<td>Plenary Discussion</td>
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<td>12:00</td>
<td>Medicinal Product Identifying Attributes in Art 57 (2) compared to the epSOS prescription</td>
<td>Marcello Melgara</td>
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<td>12:20</td>
<td>Article 57 (2) database converted to the EMA IDMP drug database: comprehensive set of descriptive and/or identifying attributes as needed for prescription and patient summary</td>
<td>José Teixeira</td>
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<td>12:40</td>
<td>Lunch</td>
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Chair: Karl Stroetmann, project coordinator

EMA – Article 57(2) European Regulatory Drug Database

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<tbody>
<tr>
<td>13:45</td>
<td>IDMP compatible Article 57 (2) drug database as source for national prescription databases: how and when?</td>
<td>Paolo Alcini</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Kevin Horan</td>
</tr>
<tr>
<td>14:05</td>
<td>prEN_ISO/DTS 19256 (Requirements for medicinal product dictionary systems for health care) and requirements for commercial prescription drug databases</td>
<td>Jean-François For-</td>
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</table>

Page 13 of 84 30/06/2017
One attendee from the US and one attendee from Canada attended the meeting by teleconference.

The attendees are listed in Table 4.

<table>
<thead>
<tr>
<th>Name</th>
<th>organisation represented</th>
<th>email address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Karl Stroetmann</td>
<td>GE empirica</td>
<td><a href="mailto:karl.stroetmann@empirica.com">karl.stroetmann@empirica.com</a></td>
</tr>
<tr>
<td>Jos Devlies</td>
<td>BE Custodix</td>
<td><a href="mailto:jos.devlies@eurorec.org">jos.devlies@eurorec.org</a></td>
</tr>
<tr>
<td>Alan Reilly</td>
<td>IE PGEU</td>
<td><a href="mailto:alan.reilly@ipu.ie">alan.reilly@ipu.ie</a></td>
</tr>
<tr>
<td>Jamie Wilkinson</td>
<td>EU PGEU</td>
<td><a href="mailto:j.wilkinson@pgeu.eu">j.wilkinson@pgeu.eu</a></td>
</tr>
<tr>
<td>Judith Jones</td>
<td>USA The Degge Group, Ltd.</td>
<td><a href="mailto:jkjones@deggegroup.com">jkjones@deggegroup.com</a></td>
</tr>
<tr>
<td>Isabel Lazaro</td>
<td>E AEMPS</td>
<td><a href="mailto:ilazaro.externo@aemps.es">ilazaro.externo@aemps.es</a></td>
</tr>
<tr>
<td>Malin Jakobsson</td>
<td>S WHO-UMC Upsala</td>
<td><a href="mailto:Malin.Jakobsson@umc-products.com">Malin.Jakobsson@umc-products.com</a></td>
</tr>
<tr>
<td>Jeremy Thorp</td>
<td>UK HSCIC</td>
<td><a href="mailto:jeremy.thorp@hscic.gov.uk">jeremy.thorp@hscic.gov.uk</a></td>
</tr>
<tr>
<td>Dipak Kalra</td>
<td>N EuroRec</td>
<td><a href="mailto:dipak.kalra@eurorec.org">dipak.kalra@eurorec.org</a></td>
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<tr>
<td>Vada Perkins</td>
<td>USA FDA</td>
<td><a href="mailto:Vada.Perkins@fda.hhs.gov">Vada.Perkins@fda.hhs.gov</a></td>
</tr>
<tr>
<td>Robert Vander Stichele</td>
<td>BE University of Ghent</td>
<td><a href="mailto:Robert.VanderStichele@UGent.be">Robert.VanderStichele@UGent.be</a></td>
</tr>
<tr>
<td>Ian Green</td>
<td>UK IHTSDO</td>
<td><a href="mailto:igr@ihtsdo.org">igr@ihtsdo.org</a></td>
</tr>
<tr>
<td>Michèle Thonnet</td>
<td>FR Ministry oh health, France</td>
<td><a href="mailto:Michele.THONNET@sg.social.gouv.fr">Michele.THONNET@sg.social.gouv.fr</a></td>
</tr>
<tr>
<td>Catherine Chronaki</td>
<td>GR HL7 foundation</td>
<td><a href="mailto:chronaki@gmail.com">chronaki@gmail.com</a></td>
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<tr>
<td>15</td>
<td>José Costa Teixeira</td>
<td>PT</td>
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<tr>
<td>16</td>
<td>Paolo Alcini</td>
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<td>17</td>
<td>José Simarro Escribano</td>
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<td>18</td>
<td>Jean-Francois Forget</td>
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<td>19</td>
<td>William Goossen</td>
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<td>Shirin Golyardi</td>
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<td>Shelly Spiro</td>
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<td>23</td>
<td>Julie James</td>
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<td>Sprenger Michiel</td>
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<td>25</td>
<td>Anna-Gawronska-Blaszczyk</td>
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<td>26</td>
<td>Marcello Melgara</td>
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<td>27</td>
<td>Tammy Powell</td>
<td>USA</td>
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<tr>
<td>28</td>
<td>Gerald Cultot</td>
<td>EU</td>
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<tr>
<td>29</td>
<td>Christian Hay</td>
<td>NL</td>
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<td>30</td>
<td>Klaus Gritschneider</td>
<td>GE</td>
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2.3 **Presentations – Summary**

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<tr>
<td>1</td>
<td>Christian Hay: CEN – “Welcome”</td>
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</table>

**Our vision regarding standards and openMedicine**

- By close collaboration with ISO TC 215, we believe that global standards are beneficial for patient safety and interoperability.
- openMedicine plays a pivotal role in the use of existing standards.
- openMedicine is essential for influencing new standards.
- Because of Europe’s multicultural, multilingual and multijurisdictional aspects.
- We expect openMedicine to deliver directions to stakeholders for implementing IDMP and IDMP-derived standards in the clinical world.
  - As end goal (mid term)
  - With possible transition path (short term)

---

**IDMP impact on other standards**

- IDMP impacts existing and new standards, since the vision is to dispose of coherent data for medicinal products:
  - CEN ISO TS 19236 (requirements for medicinal product dictionary for health care)
  - CEN ISO TS 17251 (business requirements for the exchange of structured dose instructions for medicinal products)
  - CEN ISO TS 16791 (requirements for International machine-readable coding of medicinal product package identifiers)
  - prEN ISO FDIS 17523 (requirements for electronic prescriptions)
  - pr EN ISO DIS 19293 (requirements for the record of Dispense Medicinal Products)
  - And... what users need

---

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<tbody>
<tr>
<td>2</td>
<td>Karl Stroetmann: “<em>openMedicine and cross border eHealth services – core challenges</em>”</td>
</tr>
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</table>
Goals

- Univocal identification of a medicinal product for human use across Europe
- Substitution

The Solution

Standardisation (ISO-IDMP suite; EMA Art. 57 (2) DB, European & global assets)

Key messages

- openMedicine is key to deliver success
- European Commission supports this work
  - Univocal identification of medicinal products: ePrescription
  - Full identification of any pharmaceutical or medicinal product: Patient Summary
- openMedicine & EMA working together
- JAseHN involved in the process
- CEN awareness raised through the ICT Roll-
Conclusions D 1.3

- Appropriate identifiers come from ISO EN IDMP series
- Enable use of IDMP & terminologies in epSOS, etc.
- Draft DCM Medicinal Product => core for classes, terminologies, systems, processes, and communications
- Standards framework => various contexts & issues identified and made manageable
- Finalization requirements for D 2.3 DCM

WP3 conclusion

Validations and/or extension of the WP3 model with reference to "other medicinal products"

Country A
- Substance
- Strength
- Form
-...
- Identifier
- WHO
- WPI
-...
- Packagings
- GTIN
-...

Country B
- Substance
- Strength
- Form
-...
- Identifier
- WHO
- WPI
-...
- Packagings
- GTIN
-...

Isabel Lázaro: “WP4- Clusters and Reverse Identification”
CLUSTER - definition

“Group of medicinal products which have been preselected by a Regulatory Agency or by the Health Ministry or other similar organization, following predefined criteria”.

This predefined criteria selected could be:
- Regulatory
- Pharmacological- Same class or group of ingredients
- Economic
- Context: hospital, community pharmacy
- National (or International, Art 57 database)

REVERSE IDENTIFICATION

The options which enable identification of a medicine starting from the product unit description.
- Attributes from WP2-combinations which will allow identification
- Other attributes
- How they will help identify: Use cases D1.2
  - In an emergency context-unaware use
  - Product traceability...
| 7 | Karl Stroetmann: “WP5 - Substitution and selection – core challenges” |

**Definitions of substitution**

- **Oxford Dictionary:**
  “The action of replacing someone or something with another person or thing.”

- **Economic theory:***
  Many products may be used as substitutes for others such as margarine for butter, or tea for coffee. Substitute goods are “different goods that, at least partly, satisfy the same needs of the consumers and, therefore, can be used to replace one another.”

|  |  |

**Substitution versus selection of a medicinal product**

- **Substitution** takes place when, at the point of dispensation in a community pharmacy, not the medicinal product specified in the prescription is dispensed, but rather another medicinal product, in line with national law and/or regulations.

- **Selection** takes place when, at the point of dispensation in a community pharmacy, the pharmacist has to select a specific medicinal product which meets the selection criteria (e.g. active ingredient; member of a predefined set of MPs, ...) specified in a prescription, in line with national law and/or regulations (Cf. WP 4)
Catherine Chronaki – Jos Devlies:
“Towards safe optimal eprescription – dispensation - cure
A wallet of identifiers – Initial Recommendations”

What does safe optimal eprescription imply?

● Just imagine the Star Wars moment of ePrescription in
10 years or 100 years..
  ● selecting the best prescription given the circumstances
    including the substances available
  ● taking into account the medical history of the patient – their
    preferences – their allergies – their illness trajectory
  ● negotiating the dosage – monitoring the reaction
  ● noting clinical effectiveness –
  ● requesting consent to participate in a trial – contribute a case
    for study.

Initial Recommendations

● **Recommendation #1:**
  ● Advance understanding and wide use of identifiers Pharmaceutical
    ID and optionally also Medicinal production ID).

● **Recommendation #2:**
  ● Advance use of the attributes selected by openMedicine in the daily
    practice.

● **Recommendation #3: (to be discussed)**
  ● EMA: serve citizens/doctors answering the question:
    ● Does my prescription work in Member State x

***PhPID top ISO IDMP level/ MPID second level***
Jos Devlies: “Importance of medicinal product databases”

Comparing epSOS to openMedicine

- epSOS requires direct/indirect interaction with prescribers national drug database:
  - not evident
  - not always good quality
  - translation issue
- the information needed to search an equivalent product at dispensing site is part of/ included in the electronic prescription
- openMedicine only for ePrescription
- openMedicine independent from national database in country B

What does openMedicine (now) says?
Medications in Cross-Border eHealth

- **ePrescription**: purchase order for a medication, with the goal of maximising patient safety, effectiveness, probability of dispensing
- **eDispensation**: detailed description of what was dispensed, to be recorded in the Country of Affiliation
- **Medication Summary of the Patient Summary**:
  - List of prescribed medications -> same info as eP
  - List of dispensed medications -> same info as eD
  - List of current medications
  - List of relevant medications

Conclusion

The adoption of the EMA Article 57 database is **feasible** taking in mind the following considerations:

- The Art 57 dictionary was created to support pharmacovigilance (PhV) activities even if its use is now being extended to fulfill additional business cases. The EMA is making great efforts to ensure the highest level of quality and completeness as possible but it is not possible to guarantee 100% correctness of the data. The overall implementation of ePrescription should put in place risk minimisation measure to reduce or avoid possibilities of errors due to incorrect/missing data.
- It is important because also with ISO IDMP implementation and input by MSs, the data quality will not be guaranteed 100%. Therefore, we suggest starting using Art. 57 instead of waiting for IDMP.
- For the implementation of the Option 2), it may be necessary for the EMA to develop additional services for allowing access to the data; however, the EMA cannot currently commit to develop such IT services because this will require budget, time and resources to perform business requirements gathering, requirement analysis and implementation. EC should contact EMA to explain the importance of having these services implemented to support ePrescription.
- The EMA is now developing the new version of the Art57 database that will be based on ISO IDMP standard. Therefore MSs should think about the pros/cons of integrating now with the current Art57 dictionary or wait 2018 when the new dictionary will be available.

José Teixeira: “Comprehensive set of descriptive and/or identifying attributes as needed for prescription and patient summary”
Conclusions in D2.2

- This analysis confirms the power of EMA as a central hub for product information.
  - Art 57 (IDMP-compliant part)
  - IDMP database

- Need a standard mechanism to transport product information to national regulatory and clinical systems
  - Content standard exists – ISO 19356
  - Transport standards needed – action initiated (HL7 and IHE)

- Need to confirm whether/how standards can transport all attributes in the wallet
  - Implementation guidance needed
Paolo Alcini: “The implementation of ISO IDMP for identification of medicinal products”

Summary and recommendations

- Plan long term programme (not project)
- IDMP has a big impact on your organisation but also brings a lot of potential benefits
- Start “now”, if not initiated, to reap the benefits and avoid non-compliance
- Address people, process and technology. It is not only about IT!
- Find out what you have and what you don’t have (gap analysis)
  - A significant number of structured data is expected to be submitted
  - A high percentage of the data need transformation, manual extraction (e.g. labelling, SPC, documents, module 3) or a new process for data collection
- Implement the programme depending on your organisation and EU roadmap
- Keep evolving and build scalable solutions (change is the only constant)

Jean-François Forget: “MPD Systems”

*The MPD-system does not exist on its own. It is a component of a larger clinical and/or pharmacy information system*

Adapted from: “ISO TS 19256”
Conclusion

- **DISs requires computable semantic interoperability and the use of global standards, at drug level and at disease level.**

- **Mapping global standard with local formularies (medicinal products and packaging) is the “cornerstone” for usability in health informatics.**

- **MPD is a subset of DISs which has to be fully shared (interoperability and security).**

- **One of the challenges to IDMP implementation will be to support the EMA’s pharmacovigilance database (Article 57), and the computer-generated e-prescription interoperability needs in primary or secondary care. This could be a win-win situation.**
Background & Perspectives-1

- Experience (since 1979) in identifying and profiling international population databases for
  - Regulatory purposes
  - Public health
  - Medical product epidemiology research
    - Utilization & patterns
    - Effects of medical products
    - Outcomes & costs

JK Jones 21-1-2016

Background & Perspectives-2

- Conduct of multiple studies in different country databases for comparison

- Brief past experience in developing EMR for GPs

- Serving on CIOMS MedDRA Std Med Queries (SMQ) Committee

- Serving on USAN (linking AMA US generic naming to INN names)

JK Jones 21-1-2016
Potential Contribution to the Open Medicine Effort

- Bridge to Data (www.BridgeToData.org). Degge’s nonprofit affiliate, is mapping ~72+ variables for international population databases (currently at >30 countries).
- Definitions of exposure are mapped for all described databases, but in the future efforts by Open Medicine can enhance this resource.
- Categories of data can be broadened (as they are currently being done for genetic data).

Tammy Powell: “RxNorm Overview”

Wrap-up

- RxNorm is a set of names and codes for E-prescribing, formulary management, medication history.
- RxNorm content determined by the data we receive from our sources.
- RxNorm organized by ‘TTY’; SCD is the center of the universe, SBD, GPCK, BPCK.
<table>
<thead>
<tr>
<th>17</th>
<th>Robert Vander Stichele: “Granularity in identifying medicinal product (packages) and drug groups”</th>
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<tbody>
<tr>
<td></td>
<td>Differences in granularity needed in the identification of a medicinal product (package)</td>
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<td>For computerized decision support systems</td>
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<td>For Drug Dictionaries</td>
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<td>For physician prescribing (specification of choice and use) and for pharmacist selection and dispensing (identification of what the patient took)</td>
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<td>For data on drugs utilisation</td>
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<td>(measuring exposure of medicines to populations)</td>
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<td>Looking at granularity using the IDMP family of identifiers</td>
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<td>• unique identifiers</td>
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Tammy Powell: “RxNorm Prescribable Substance Names (PSN)”

Why Prescribable Names?

- Normalized Names Don’t match what prescriber and dispenser are used to seeing
- Work with NCPDP

## Context for the guidelines

(b) draw up guidelines on:

(i) a non-exhaustive list of data that are to be included in patients’ summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders; and

(ii) effective methods for enabling the use of medical information for public health and research

Article 11 (2-b) of the Directive, which defines the need for "guidelines supporting the Member States in developing the interoperability of ePrescriptions".

## What is a guideline?

- There does not appear to be a formal or legal definition of what “guideline” means in the context of European acts or documents
- The weight and meaning of guidelines vary considerably across European Commission Directorates
- From a legal perspective, given the limited EU competences in the field of health, the term "guidelines" should be interpreted in a legally non-binding way, as there is no legal base for harmonisation in this field
- These guidelines shall be "supportive", so that they can be formulated only as recommendations
- Hence the guidelines are non-binding
Next Steps

eHealth Network Joint Action is committed to updates to the Guidelines
  • Patient Summary 2016
  • ePrescription 2016
  • Patient Registries 2017

CEF call for initial ehealth services (PS and eP)
  - issued in November 2015
  - For response by March 2016
  - Go live? End 2016

Possible Input from Open Medicine

Potential outputs from Open Medicine to help review of the eP guidelines
  • Specifications
  • Standards
  • Distribution and maintenance
  • Conformance tests
  • Guidance

20 Malin Jakobson: “Reflections on OpenMedicine project from a global perspective”
<table>
<thead>
<tr>
<th>Page</th>
<th>Ian Green: “IHTSDO – SNOMED CT drug content update”</th>
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<tbody>
<tr>
<td></td>
<td><strong>Drug content in the SNOMED CT International Release</strong></td>
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<tr>
<td></td>
<td>• Drug content in SNOMED CT International Release at generic level with dose form</td>
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<tr>
<td></td>
<td>• Provide a level of commonality globally</td>
</tr>
<tr>
<td></td>
<td>• No intention to go beyond this level at National level</td>
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<tr>
<td></td>
<td>• Provide hooks for members to link in their national pharmacy extensions</td>
</tr>
<tr>
<td></td>
<td>• IHTSDO Members involved with development and testing</td>
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<tr>
<td></td>
<td>• Initial work completed for January 2016 International Release, with further refinement for July 2016 release</td>
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Alignment with International Standards

- Aim is to align the drug content in the International SNOMED CT release (within the scope of content coverage) with international drug standards
- Collaborations
  - GS1
  - ISO
  - Discussions with MedDRA
- Incorporated WHO Essential medicines list in the International release
- Defining editorial guidance on the presentation of drugs in the International release
- Developing default drug model for use in member countries — more extensive detail than covered in the International release, aligned with International Standards

22

Julie James: “openMedicine
Can the vision become reality?”

Unique and unambiguous identification of medicinal products

- To allow information about medicinal products to flow WHEREVER it is needed
2.4 Minutes – Summary of discussions and Conclusions

The excerpts presented above in the preceding section already constitute a succinct summary of the ideas, concepts and issues discussed. Therefore we here address only the following further issues:

1. Lessons learned during the Council meeting regarding
   - The openMedicine mandate
   - The article 57 (2) database
   - The conversion and roadmap towards an IDMP compatible database

2. The need to deliver

3. The need that what’s delivered is used

4. The role of National / International databases

5. The role of different groups or organisations in facilitating the realisation of the openMedicine challenge.

6. The options when also making use of SNOMED-IHTSDO terminology and mapping and/or approaching the multi-coding challenge

7. The trans-Atlantic cooperation

8. A better understanding of the concepts "cluster" and "substitution"

A discussion summary point per point is as follows:

1. **Lessons learned during the Council meeting regarding**
   - The openMedicine mandate
   - The article 57 (2) database
• The conversion and roadmap towards an IDMP compatible database

Considering the options taken by both, EMA and the FDA, when implementing ISO IDMP, the Council confirmed the preliminary decision taken by openMedicine earlier to go the same direction, more especially to use a globally univocal PhPID (pharmaceutical product ID) to each combination of quantity of substance per product unit, dosage form, and route of administration. This PhPID solves the core issue of the cross-border identification of equivalent medicinal products, provided that this information is made available in the prescription at the point of care and at the point of dispensing, and provided substitution to be allowed at the appropriate level.

We agreed to follow the EN ISO IDMP series standards for this identifier.

EMA on the other hand collects and centralises market authorisation information into the Article 57 (2) pharmacovigilance database, promoting that database also as source data for other medication related services.

The Article 57 (2) is not yet complete – it presently covers about 98% of all medicinal products available across the Union - nor is the information provided by the industry fully validated by their national drug agencies. The (partially structured) data elements should be extended to at least 92 data elements as defined in ISO IDMP and by the deliverables from WPs 2 and 3 of openMedicine. The description of these 92 data elements is, e.g., part of D 2.2.

The new EMA IDMP compatible database is expected to be EN ISO IDMP compatible in 2018.

Validation against the use cases will also be required.

2. The need to deliver

It seemed difficult for the representatives of the European Commission to accept that nothing definite related to the cross-border identification of medicinal products should be available at the normal closing time of the project. The IDMP compatible EMA drug database will indeed become available at the earliest per 2018.

The question which therefore was discussed was: do we need to have a complete drug database in order to illustrate that including the PhPID into the ePrescription enables to identify equivalent medicinal products cross border?

The answer was a clear NO on proof of concept basis.

The FDA (V. Perkins) accepted to assign – based on the common FDA/EMA algorithm – a PhPID to a number of products of a country A and of a country B (epSOS) approach. This would enable to demonstrate the correctness of the openMedicine options.

3. The need that what’s delivered is used

Including the PhPID into the electronic prescription should not require any effort of the prescriber. It should be a feature of the prescribing application software, based on an accordingly adapted EC guideline. Given that the initial ePrescription indeed contains all the necessary attributes univocally identifying a single medicinal product (or a package, but also for INN prescriptions identifying a subset of products), then the software (having access to an IDMP database) will be able to automatically, i.e. without additional efforts by the prescriber when compared with the status-quo situation, add for cross-border purposes the additional information (like the PhPID) needed.
But industry representatives attending noted that commercial activities make only sense from their business case point of view once indeed an IDMP data base is available for commercial applications.

4. **The role of the national / international databases**

The identifiers should be available at the point of prescription and at the point of dispensing a medicinal product. This highlights the important role of the national drug databases, including the global PhPID for each of the products. Of course the multiple ePrescribing software should all be able to produce such a prescription. This will require connections, access or linkages, from national public databases produced or made available for national purposes to the European database produced and made available by EMA.

5. **The role of different groups or organisations in facilitating the realisation of the openMedicine challenge**

The national competent health authorities (national and European) have an important role in facilitating the realisation of the openMedicine options. This was underlined in the discussions; even so certain reluctance was signalled with respect to time and resource constraints to be accounted for.

But the potential health added value, particularly with respect to patient safety, but also for health system efficiency and industry benefits, was regarded as so important that hardly a reason may exist why to postpone such adaptations and adjusting the EC guideline accordingly. The same should already apply to presently planned CEF eHealth activities.

6. **The IHTSDO option and possible mapping and/or approaching the multi-coding challenge**

Questions concerning terminology led to a discussion of the IHTSDO (SNOMED) option. It turned out that IHTSDO has indeed some parallel developments in the semantic field, but it is considering cooperation with EMA and FDA to “align” these developments. A concrete example might be regarding the substances, both parties setting up a new coding system. A maximal mapping can only be profitable for all parties. It was also discussed briefly to fully align such efforts in order to avoid waste of resources.

Another way of cooperation might be through the concept of multi-coding (sets of identifiers), storing competing codes based on as complete as possible validated mappings. But no definite solution on this was forthcoming.

In the implementation specifications that were used for epSOS, this could be assured through the “translate” tag in the HL7 v3 Clinical Document or message.

7. **The transatlantic cooperation**

The transatlantic approach, based on the cooperation between EMA and the FDA as well as on the partnership within openMedicine, was highly acclaimed and strongly supported. It fits perfectly in the Commission's strategy as made concrete in the Memorandum of Understanding and in the Trillium Bridge conclusions.

The FDA (V. Perkins) committed to organise a US based openMedicine meeting, to highlight the cooperation and to promote the global approach of the openMedicine partners and supporting parties.
8. **A better understanding of the concepts "cluster" and "substitution"**

The concepts "cluster" and "substitution" were heavily discussed. A kind of consensus was finally found around the following definitions:

- A cluster is any subset of two or more medicinal products identified as belonging to a subset, be it defined by a code (like in some countries) or a description of a group of medicinal products by generic identifying attributes (e.g. INN prescriptions).

- Substitution is when a specific medicinal product has been identified in a ePrescription, but at the point of dispensing an equivalent (same PhPID) but different medicinal product (by name e.g.) than what has been prescribed is delivered to the patient.

Rapporteur: Dr. Jos Devlies, Custodix

2.5 **openMedicine presentations**

Presentations are available on the openMedicine Dropbox as well as on the website.

See \openMed\Meetings\Brussels January 2016 2nd Exp Council meeting\Presentations

The material is also available on the openMedicine web site www.open-medicine.eu, go to the Login Section:

Username: OpenMed_RE

Password: Grant#643796

In total 21 presentations were given or made available. Their full list is provided on the next page.
3 EU-US openMedicine Workshop

The Food and Drug Administration (FDA) invited the openMedicine project team for a joint workshop at their offices in Silver Spring, MD, June 21-22, 2016.

3.1 Invitation

Towards a trans-Atlantic solution to univocally identify medicinal products

USA-EU Workshop

FDA White Oak Campus, 10903 New Hampshire Av., Silver Spring, MD, June 20-21, 2016

Background

The European Commission's Directorate General for Communications Networks, Content and Technology (DG CONNECT) and the United States Department of Health and Human Services (DHHS) have agreed on a roadmap to strengthen trans-Atlantic cooperation in eHealth and health information technologies (IT). This builds on a Memorandum of Understanding (MoU) on this topic, signed in 2010 under the auspices of the Transatlantic Economic Council. A high priority area is standards development. The goal is to advance the development and use of internationally recognized standards which support transnational interoperability of electronic health information and communication technology. A medium-term objective is to identify common vocabularies, message structures and tools suitable for the international exchange of electronic health record data.

This meets with the European Union (EU) policy priority of enabling the delivery of safe and efficient cross-border healthcare.

The openMedicine project (http://www.open-medicine.eu/home) contributes to this policy by solving a problem of portability of ePrescriptions across Europe and globally. The main challenge is the univocal identification of medicinal products for human use to be dispensed by a community pharmacist in another country (cross-border ePrescription). Towards this end, the project will furthermore formulate a number of recommendations and a roadmap for implementation and sustainability. This will also support the full identification of any pharmaceutical or medicinal product in the patient summary and other documents.

---

The openMedicine project also addresses the different regulations regarding substitution, considering that a dispensing pharmacist has to comply with the respective national rules.

The project aims to reach a global consensus in order to describe and to identify unambiguously medicinal and pharmaceutical products, resulting in the authorised delivery of the appropriate medicine. It closely cooperates with the European Medicines Agency (EMA) in London, WHO, ISO, CEN, GS1, HL7 and other standardisation organisations.

For many years already, EMA and FDA have been closely cooperating and exchanging expertise on this same goal. This workshop will bring together these different activity strands, provide an overview of ongoing and planned activities, and deliver suggestions to further improve and intensify trans-Atlantic cooperation.

**Objectives**

It is against this background that in the context of the openMedicine project, its Expert Council activities and long-standing cooperation between FDA and EMA a specific EU/USA cooperation event is arranged. The specific objectives are to

Present, discuss and further develop concrete, actionable results of the openMedicine project with respect to

- a common data model for medicinal products (MPs)
- a common vocabulary for the unambiguous identification and description of MPs
- recommendations regarding the content of ePrescriptions, the Patient Summary and prescription drug databases
- rules to harmonise practices of substitution at the point of dispensation
- a global roadmap for post-project actions and implementations

Present similar and complementary activities and results from USA/FDA

Obtain reactions from trans-Atlantic stakeholders on the options discussed/foreseen in the European Union and its member states as well as in the USA and Canada

Inform each other on European and North-American implementations of ePrescription, eDispensation, ePatient Summary etc.

Explore global cooperation opportunities in these domains with standards development organisations (SDOs)

Identify communalities, gaps, discrepancies and opportunities for closer cooperation and exchange, next steps.
Meeting format

The workshop is intended as a translational, pragmatic workshop serving as a collective venue for invited experts. It is to provide an overview of ongoing and planned activities, how to connect and intertwine all relevant activity strings of the authorities and other organisations involved. It will provide for a constructive exchange of opinions how to reach global consensus, and should lead to initial roadmap recommendations and proposals for further 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.

Topics

Core challenges to be considered gyrate around the univocal identification and description of medicinal products, including the wider issues related to this, and the consistent and cooperative implementation of corresponding data bases for the various stakeholders.

Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>08:00</td>
<td>Registration &amp; coffee</td>
<td>USA</td>
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<tr>
<td>08:40</td>
<td>Welcome</td>
<td>FDA</td>
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<td>Brief introduction of participants</td>
<td>All</td>
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<tr>
<td>09:00</td>
<td>The European Union (EU) policy challenge: univocal identification of</td>
<td>Karl Stroetmann, openMedicine</td>
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<td>medicinal products (MPs) and substitution in cross-border healthcare</td>
<td>Dipak Kalra, European Institute for Health Records (EuroRec)</td>
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<td>settings</td>
<td>Karl A. Stroetmann, openMedicine</td>
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<td>Identification of medicines and the regulatory context</td>
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<td>EU xBorder Healthcare Directive</td>
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<td>Exchange of patient data: electronic patient summary</td>
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<td>(incl. medication record), ePrescription</td>
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<td>Member State cooperation, and ePrescription Guidelines</td>
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<td>OpenMedicine challenges</td>
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<td>Business case</td>
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<td>Roadmap</td>
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<td>09:30</td>
<td>Coffee Break</td>
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<tr>
<td>Time</td>
<td>Session</td>
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| 10:00 | The US policy context: univocal identification of medicines and the use of standards throughout the product lifecycle.  
- Clinical Trials  
- Assessment and Marketing Authorization  
- ePrescription and eDispensing  
- Pharmacovigilance                                                                 | Vada Perkins, FDA  
Tammy Powell, National Library of Medicine (NLM)  
John Klimek, National Council for Prescription Drug Programs (NCPDP)  
Tom Bizzaro, First Databank |
| 11:00 | Trans-Atlantic regulatory cooperation and harmonisation - focus on IDMP  
History and achievements  
Next steps                                                                 | Joan Blair, FDA  
Paolo Alcini, EMA |
| 11:30 | Plenum discussion                                                                               | All                                                                                           |
| 11:50 | Summary of the morning                                                                          | Vik Srivastava, Health Canada, rapporteur                                                    |
| 12:00 | Lunch                                                                                            |                                                                                                |

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<tr>
<th>Time</th>
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<th>Providers</th>
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| 13:00 | Identification and description of branded medicinal products – the openMedicine approach       | Christian Hay, openMedicine  
William Goossen, openMedicine  
José Teixeira, openMedicine |
|       | ISO developments                                                                                  |                                                                                                |
|       | Consensus standards evolution                                                                     |                                                                                                |
|       | ISO-IDMP suite                                                                                    |                                                                                                |
|       | openMedicine framework                                                                            |                                                                                                |
|       | Needs from complementary use cases                                                                |                                                                                                |
|       | Gap analysis                                                                                      |                                                                                                |
|       | Framework                                                                                        |                                                                                                |
|       | OpenMedicine standards based identification and description enabling dispensing equivalent medicinal products |                                                                                                |
|       | Identifiers                                                                                       |                                                                                                |
|       | Identifying attributes set                                                                         |                                                                                                |
|       | Descriptive attributes                                                                            |                                                                                                |
| 13:50 | EU and USA harmonisation of content and message exchange for IDMP implementation                  | Kevin Horan, openMedicine/ Health Products Regulatory Authority, Ireland  
Vada Perkins, FDA, USA |
<p>|       | • SMS, RMS and OMS: common terminology for enabling the generation of PHPID, MPID, PCID in EU and beyond |                                                                                                |
|       | • HL7 Structured Product Labelling (SPL) specification as enabler of EU-US exchange of medicinal product information |                                                                                                |</p>
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<tr>
<th>Time</th>
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<tr>
<td>14:30</td>
<td>Coffee break</td>
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| 15:00 | Implementing IDMP: The pivotal role of the PhPID (Pharmaceutical product identification) | Paolo Alcini, EMA  
Vada Perkins, FDA |
| 15:40 | Validating, Implementing & Distributing ISO IDMP | Kevin Horan, openMedicine/Health Products Regulatory Authority, Ireland  
Vada Perkins, FDA |
| 16:40 | Added value of using IDMP in other domains | Gordy Schiff, Harvard Medical School |
| 17:00 | Plenum discussion | All |
| 17:20 | Summary of the afternoon | Jos Devlies, openMedicine |
| 17:30 | End of the afternoon | |
| 19:00 | Dinner | |

**Location**
At FDA White Oak Campus, 10903 New Hampshire Avenue, Silver Spring, MD 20993 (near Washington, DC)
Workshop facilities are provided by FDA.

**Participation**
Participation is by invitation only. Participation should be confirmed not later than June 6 to
- Judith Badoo for US participants: judith.badoo@fda.hhs.gov
- Jos Devlies for European participants: jos.devlies@custodix.be
European participants must submit the Foreign Visitor Data Request Form by May 20 to judith.badoo@fda.hhs.gov
Contacts

Local organisation:

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Foreign Regulatory Communications Coordinator
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Agenda:

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3.2 Attendees

Up to 28 attended the workshop. Local experts from the FDA did not all sign the attendee sheet.
The majority of the attendees were US or Canadian citizens representing most of the organisations involved in eHealth. They were invited by the FDA.
### 3.3 Summary of the presentations: Day 1

|   | Karl Stroetmann: “The European Union (EU) policy challenge”. |

**The vision for eHealth interoperability**

- The eHealth Digital Services Infrastructure (DSI) to be implemented by Member States under the Connecting Europe Facility (CEF) 2015 work programme
- Initial incentive funding by the European Commission will support the implementation of the cross border ePatient Summary and the ePrescription services
- The CEF-supported services will also establish the basic infrastructure, governance and interoperability framework needed to enable the exchange of health data based on a clear legal basis, and within a secure and trusted environment

|   | Karl Stroetmann: “Medicinal products (MPs) ID and substitution in cross-border healthcare settings”. |

**The Solution**

**Standardisation (ISO-IDMP suite; EMA Art. 57 (2) DB, European & global assets)**
### The US policy context:
**Tammy Powell, John Klimek, Tom Bizzaro, Vada Perkins**

This part of the session addressed the US context of identifying, prescribing and assessing medicinal treatments in the US.

<table>
<thead>
<tr>
<th>Page</th>
<th>Tammy Powell: “RxNorm Overview”</th>
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</table>

**What is RxNorm?**

- A set of names and codes used to represent drugs in electronic medical records used for:
  - E-prescribing
  - Formulary
  - Medication History

- Two sets of names:
  - Drug compendia names
  - RxNorm authorized names

- RxNorm Releases, Browser & API
  - New web-based RxNAV Summer 2016

---

**How do I access RxNorm data?**


- Monthly zip file*
  - Weekly updates for newly added FDA drug labels
- Current Prescribable Content subset zip file
- APIs – RxNorm, prescribable subset

*Requires a (free) UMLS license to access

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<table>
<thead>
<tr>
<th>Page</th>
<th>John Klimek R.Ph.: “openMedicine project/FDA Workshop”</th>
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</table>
The NCPDP has an important role regarding standards, best practice definition. It calls itself “a problem-solving forum for healthcare.

The NCPDP has an important role regarding standards, best practice definition. It calls itself “a problem-solving forum for healthcare.

The main drug database provider in the US endorsed immediately the concept of “pharmaceutical product ID” as identifier for interoperability services not only across borders but also related to knowledge.

The Trans-Atlantic regulatory cooperation and harmonisation – focus on IDMP
John Blair, Paolo Alcini

Joan Wilmarth Blair: “Trans-Atlantic Regulatory Coopera-
tion and Harmonisation on IDMP – Historical Perspective”.
Goal of Presentation

Provide an appreciation of the complex history of the Identification of Medical Product (IDMP) standards while noting the ongoing engagement of FDA, EMA and several EU MS’s

- Multiple threads of activity interwoven over time
- FDA, EMA and MS’s have been involved in all of these threads throughout that history
- Separate from, and simultaneously to, these threads, FDA and EMA have had a close working relationship to progress the standards and their regulatory implementation, endorsed at leadership level

Both speakers of this slot are active in the regulator business.

Both EMA and FDA have an impressive track record of cooperation.

Adopting the validated set of substances is crucial. They form the starting point for building the IDMP identifier.

Conclusion

- Development of IDMP has been multi-dimensional
- Both technically and politically complex
- Many naysayers along the way – has required tenacity
- Throughout this history, FDA/EMA/EU dialogue and collaboration has been continual
  - Have provided leadership and direction to progressing the development and uptake of these standards
- Herculean undertaking: all involved can be proud

Paolo Alcini: “Trans-Atlantic regulatory cooperation and harmonisation
Focus on IDMP: next steps”.

N
G-SRS Business Process & Technical Specifications

- Establishment of a bilateral framework (e.g., MOU, Cooperative Agreement) to support a joint governance process for substance registration and maintenance.
- EU Network/FDA will establish agreements with each other for substance registration & maintenance which includes an overarching scientific and technical* governance process.
- Registration & maintenance between EU-Network and FDA for substance terms and unique IDs.
- Resource for EU-Network/FDA Substance ID that maps to other regional IDs (harmonization).

*Technical refers to G-SRS software and core DMF compliant system requirements

Thank you

Identification and description of branded medicinal products – the openMedicine approach.

8 Christian Hay; “openMedicine ISO developments”.
Christian Hay reported on the IDMP suite of standards.

Why ISO? Some possible answers:

- ISO has a defined, recognised, process for the development of international standards
- ISO involves a very large experts community in the standard development / assessment
  - Not only National Mirror Bodies, but a number of Liaison organisations
- ISO standards are recognised in the international community for their value as reference
  (e.g. requirement of ISO standards is not a technical barrier to free trade)

W. Goossen illustrated the "central position" of the pharmaceutical product in the medication data model.

Overall goal and objectives of D 1.3

- initial multi-standards framework
- solutions to issues identified in epSOS
- attention to factors related to multiple contexts
- univocal identification of medicinal products:
  - identifiers
  - and descriptive attributes
- application context: ePrescription, eDispense, record keeping
José Costa Teixeira: “Practical impact of standards on cross-border medication”.

Unified approach

- One consistent way to address all cases

- Prescription is an example
  - There are other use cases, also working the same way

- Using MPID or PhPID in prescription is an example
  - Other use cases can exist, following the same rules.

- Branded products are the foremost example
  - Also supporting other products and constraints

The “unified” approach in addressing the issue of the cross-border identification of a pharmaceutical product is the most promising conclusion out of this workshop.
EU and USA harmonisation of content and message exchange for IDMP implementation.

1

Kevin Horan: “SMS, RMS and OMS: Common Terminologies for enabling ISO IDMP”.
Kevin Horal documented the SPOR project of EMA getting the possible values for the concepts: substance, product, organisation and referentials.

RMS & OMS roadmaps

- The focus for 2016 is on implementation of Referential and Organisations

1  2  Vada A. Perkins: “EU and USA Harmonisation of Content and Message Exchange for IDMP Implementation”.

In Summary

- FDA is working to implement IDMP internally
- Pathways exist for recommending or requiring standardized electronic submission of IDMP data
- If FDA determines that the best path is to require standardized electronic submissions, that requirement would be a minimum of 24 months after final guidance is issued.
Paolo Alcini: “PHPID and its enabler role for identification of medicines for e-prescription”.

Paolo Alcini explained why the PHPID plays a pivotal role in the identification of medicinal products.

Kevin Horan: “EU ISO IDMP Roadmap to enable ePrescription cross-borders”.

The solution (…continue):

How does this work?

- Common data structure
- Centralized data values
- Use of common data values across borders
- When an identifier is specified in one place, it can be mapped to the common structure in any other country.

Notes:
- Country Of Home Country
- Country Of Foreign Country
- The prescribed package ID (PKID) can be identified in country B, but the package/product is not available there. However, it can be mapped to the underlying PHPID, which in turn can be mapped to medicinal products available.
Kevin Horan and Vada Perkins addressed – as an introduction on the topic, the validation of the PhPID and the way to get this distributed, implemented …

1 Malin Jakobson: “Global harmonisation versus national regulatory considerations”.

Forum for international collaboration

• EMA and FDA already started on joint projects
• Suggested to move into IPRF (International Pharmaceutical Regulators Forum)

Pharmacovigilance being at the origin of structuring medication related data (the Art. 57 database), it’s migration to IDMP is supported by UMC

1 Gordon Schiff: Pill Identification. Where do We Stand/Sit/Rest?
Physically identifying artefact e.g. by means of an imprint is still a valid method for identification of a pharmaceutical / medicinal product. Specific catalogues are available on the market and used?

### Background

- **Longstanding issues indentifying pills**
  - Handkerchiefs, pill organizers, other countries/languages
  - Primary care, poison control centers, police, patients themselves
    - >500,000 calls/year to Poison Control Centers for pill ID

- **Akin to everyone choosing own license plate number**

- **USP Standardized Imprint Code Resolutions (+ WHO)**
  - 1990 and 2000 urging development of universal coding system.
  - Also interest by WHO for international standards

- **USP Task force**
  - Key players
  - Made good progress in moving toward consensus
  - Ultimately stalled by industry concerns
3.4 Presentations available – day one

The presentations are available on the Dropbox of the openMedicine project

See `openMed\Meetings`

The material is also available on the openMedicine website www.open-medicine.eu, go to the Login Section:

Username: OpenMed_RE
Password: Grant#643796

- Christian_Hay_openMed.Washington_V2.pptx  1 718 kB
- Gordon_Schiff_Solid_Oral_Dosage_Indentification_Open..  1 534 kB
- IDMP history of coop final_Joan Blair.pptx  1 079 kB
- John_Klimesk_OpenMedicine FDA Meeting FINAL.pptx  4 041 kB
- Jose.Teixeira_Presentation_for_publication_OpenMedWS..  301 kB
- Karl.S_Dipak.K_openMed_WS_EU_Policies_Intro09.00_V0..  1 349 kB
- Karl_Stroetmann_openMed_WS_Intro09.15_V01.pptx  167 kB
- Kevin_Horan_EU_ISO_IDMP_Roadmap_to_enable_epresc..  367 kB
- Kevin_Horan_SOR_common_terminology_for_enabling_LIS..  359 kB
- Malin.Jackobson_Global_harmonisation_vs_national_reg..  988 kB
- Paolo.Alcini_PHPID_and_its_enabler_role_for_identificati..  992 kB
- Paolo.Alcini_Trans-Atlantic_regulatory_cooperation_har..  730 kB
- Tammy.Powell_OpenMedicine_June2016RxNormSlides.p..  712 kB
- Thomas_Bizzaro_OpenMedicine_June20-21Washington....  3 529 kB
- Vada_Perkins_OpenMedWS_IDMP_Activity_Update_June...  4 589 kB
- W.Goossen_openMedicine_WP1_D2.3GoossenWashington...

`openMed\Meetings\FDA Workshop June 2016\OpenMedWS_June20Day1_WashingtonUS
Presentations of Day 1`
### 3.5 Agenda - Day 2

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>08:30</td>
<td>Breakfast</td>
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<tr>
<td></td>
<td>Chair (morning): Paolo Alcini</td>
<td>EMA</td>
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<tr>
<td>09:00</td>
<td>Summary of day 1 and introduction to day 2</td>
<td>Jos Devlies, openMedicine</td>
</tr>
<tr>
<td>09:10</td>
<td>Implementing IDMP in Canada – a progress report</td>
<td>Vik Srivastava, Health Canada</td>
</tr>
<tr>
<td>09:40</td>
<td>Added value of using IDMP in other domains</td>
<td>Dipak Kalra, European Institute for Health Records, Devlies Jos, openMedicine, John Klimek, NCPDP</td>
</tr>
<tr>
<td>10:50</td>
<td>Coffee Break</td>
<td></td>
</tr>
<tr>
<td>11:20</td>
<td>Round Table: Cooperation and impact on SDOs / global standardisation endeavours</td>
<td>Christian Hay (Chair)</td>
</tr>
<tr>
<td></td>
<td>“Whilst ISO standards are becoming mature, implementers work to meet IDMP as regulatory requirements, what does your SDO undertake to leverage these standards?”</td>
<td>John Klimek</td>
</tr>
<tr>
<td></td>
<td>• National Council for Prescription Drug Programs (NCPDP)</td>
<td>Giorgio Cangioli</td>
</tr>
<tr>
<td></td>
<td>• HL7</td>
<td>William Goossen</td>
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<tr>
<td></td>
<td>• ISO/CEN</td>
<td>Bron Kisler</td>
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<td></td>
<td>• CDISC</td>
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</tr>
<tr>
<td>12:20</td>
<td>Summary of the morning</td>
<td>Karl Stroetmann</td>
</tr>
<tr>
<td>12:30</td>
<td>LUNCH</td>
<td></td>
</tr>
</tbody>
</table>
### 13:30
**Chair (afternoon): Kevin Horan**

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>13:30</td>
<td><strong>Practical applications of implementing IDMP</strong></td>
<td>Jeremy Thorp, EU eHealth Network; NHS England Kevin Horan, Irish Health Products Regulatory Authority (HPRA) Isabel Lazaro, Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)</td>
</tr>
<tr>
<td></td>
<td>- EU ePrescription Guidelines, linking to EMA Art. 57 (2) data base, and IDMP</td>
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<tr>
<td></td>
<td>- Regulator view: update, harmonisation needs and expected benefits across the EU regulatory network – a view from a small national agency</td>
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<tr>
<td></td>
<td>- Practical use case demonstration - Benefits / challenges</td>
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</tbody>
</table>

### 14:30
**Trans-Atlantic validation, roadmap, and implementation planning**

- openMed recommendations and roadmap

### 15:00
**Coffee Break**

### 15:20
**Vision, next steps for cooperation, global outreach**

- ISO IDMP global implementation: IPRF
- Considerations for the development and maintenance of global PHPIDs

### 16:10
**Plenum discussion**

### 16:30
**Summary of the afternoon, and overall workshop results**

### 16:45
**Third Expert Council Meeting, October 27, 2016 at EMA, London**

**Thanks, farewell**

### 17:00
**End of day 2**
## 3.6 Summary of the presentations – day 2

|---|---|

**Why is it important to Health Canada?**

- Data standards, like IDMP, creates common language that enables INTEROPERABILITY – Regulator to regulator; – Pharmaceutical company to regulator; – Clinical trial sponsor to regulator; – Regulator to healthcare institutions (Provinces/Territories)
- IDMP helps improve PATIENT SAFETY – Is critical for pharmacovigilance & risk analytics - more specificity leads to more accuracy – Improves the reporting & tracking of patient safety issues on an international level
- IDMP improves MONITORING OF THE GLOBAL SUPPLY CHAIN – IDMP identifiers will be used to verify packages and batches, screen counterfeits – Helps agencies authorize alternative products when there are shortages
- IDMP foundational to ICMRA priorities on pharmacovigilance and global supply chain
- IDMP helps improve TRANSPARENCY AND OPENNESS – Improves enabling Health Canada’s Regulatory Transparency and Openness Framework
- The International Pharmaceutical Regulators Forum is proposing global WG on IDMP implementation

Health Canada investigated IDMP and identified numerous advantages to implement it in Canada

<table>
<thead>
<tr>
<th></th>
<th>IDMP - Health Canada Status:</th>
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<tbody>
<tr>
<td></td>
<td>Health Canada has not yet formally declared its intentions on IDMP</td>
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<tr>
<td></td>
<td>There are significant benefits to adoption but also significant challenges</td>
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<td></td>
<td>A policy decision on the adoption of IDMP needs to be developed</td>
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<td></td>
<td>HPFB participation on the IPRF WG regarding IDMP Implementation</td>
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<td></td>
<td>Need to decide on HPFB IP investments – start preparing new systems and tools for IDMP or continue with status quo DIN</td>
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<td></td>
<td>Decide on HPFB support on e-prescribing</td>
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</tbody>
</table>
### Next Steps:
- Obtain feedback on the need for Health Canada to adopt & implement IDMP
- BEC Decision on HC participation on the International Pharmaceutical Regulators Forum’s WG on IDMP implementation
- Policy analysis and decision on IDMP adoption & implementation
- Proceed with function and non-functional pilot –Structured Product Monograph

<table>
<thead>
<tr>
<th>2</th>
<th>Dipak Kalra, Julie James: “Medication data in patient summaries”.</th>
</tr>
</thead>
</table>

#### Conclusions

- Health summaries (not one standard summary!) can play important roles in cross-border and within-border care co-ordination
- Standardised representations of (most of) the summary content are vital to enable EHR systems support (care pathway tracking, decision support, trends etc.) and wider uses of the health data
- Harmonising the unplanned care summary (~ International Patient Summary) is an important first step
- Since medication information vitally underpins continuity and safety of care, globally robust medicinal product identification is also an important step
- However we next need urgently to standardise on a trustworthy Medication Profile (= structure + content + workflows + policies)

| 3 | Jos Devlies: “Medication in Patient Summaries”. |
Scope of “the” patient summary

- **Scope defines the content**

- **Different summaries possible in parallel**
  - *Emergency or unexpected care*
  - *Sharing of data for cooperating practices*
  - *Pathology specific patient dossier: multidisciplinary diabetes dossier*
  - *Patient Migration File....*

- **eHealth network defined a “basic and extended Patient Summary dataset”**
  - *Basic Dataset: “minimum required”*
  - *Extended Dataset*

---

**Principles**

- **Concise**

- **Only what’s needed to provide unexpected care**

- **One and only one patient summary**
  - *Cacaphony*
  - *Ideally the GP, record holder*

- **Duration**
  - Until “next”
  - *archived in case of being consulted*

- **Confidentiality**
Exploitation / Management issues

- Complementary services needed
  - Patient Consent
  - Safe “data boxes”
  - Locator services
    - Regional HUBs
    - Central Metahub
  - Access management
  - Therapeutic link

- Hit Rate
- Quality issue

---

John Klimek: “openMedicine project/FDA Workshop”.

EHR Systems / Medication Lists

- ONC Meaningful Use Requirements
  - EHR Confidentiality
  - Maintain active medication list
  - Unique patients seen by the EP (eligible provide) have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data
  - The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation

The medication related information is an important section in a patient summary. IDMP will favour its cross border accessibility.
Isabel Lázaro Salcedo: "openMedicine approach: A brief demonstration illustrating the core concepts. Proof of concept."

**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  
...

Jos Devlies: “Recommendations & Roadmap”.

**What do we need?**

- **an identifier, globally unique**  
  - language independent  
  - country independent  
  - medicinal product name independent  
  - authorisation independent  
  - authorisation holder independent

- **or a set of identifying attributes**  
  - (active) substance(s)  
  - Strength  
  - dosage form  
  - route of administration

- **expressed by using “using standards”**
Recommendations regarding ePrescription

- **Functional integration of the PhPID in ePrescribing**
  - Either effective integration into the prescription message
  - Or through centralised mappings services

- **Drug databases**
  - Make the PhPID available at the point of prescription
  - Make other ID’s available too

- **HL7, IHE and analogues**
  - Enable more than one identifier in a prescription message

- **EHR applications**
  - Enable storage of several identifiers
  - Include at least the PhPID in a patient summary

---

7  
Joan Wilmarth Blair: “Vision: Next Steps and Global Outreach”.

---

Global Regulatory Outreach

- **International Pharmaceutical Regulators**  
  Forum (IPRF): June 2016 agreed to establish IDMP Working Group
  - IPRF participation has included: Brazil, Canada, China, EMA/EVC, India, Japan, Korea, Mexico, Russia, Switzerland, Taiwan but WG’s have broader participation (an open forum)
  - Also Regional Harmonization Initiatives: APEC, ASEAN, EAC, GCC, PANDRH, SADC
  - Provides venue for regulatory discussions to facilitate uptake
3.7 Presentations available – day 2

- Dipak_Kalra_Medication_data_in_patient_summary_2018.pdf: 2,885 kB
- Future_vision_final_Joan_Blair.pptx: 941 kB
- Isable_Lazaro_Proof_of_concept_for_openMedicine.pdf: 663 kB
- Jos_Devlies_guidelines_patient_summary_en.pdf: 2,142 kB
- Jos_Devlies_OpenMedicine_Washington20160621.pdf: 224 kB
- Jos_Devlies_Recommendations.pptx: 302 kB
- Karl_Stroetmann_OpenMedicine_SilverSpring2018.pdf: 253 kB
- Srivastava_Presentation_OpenMedicinesWS_June2018.pdf: 1,057 kB

/openMed/Meetings/FDA_Workshop_June_2016/OpenMedWS_June21Day2_WashingtonUS

3.8 Minutes – Summary of discussions and conclusions

The third meeting of the openMedicine consortium was organised as an EU-US workshop. The excerpts presented above in the preceding section already constitute a succinct summary of the ideas, concepts and issues discussed. Therefore we here address only the following further issues:

The first openMedicine expert council meeting in London focused on defining and delimiting the issues to be addressed by the project. The invited experts where expected to explain – within their domain of expertise – how the identification issue is addressed, while suggesting a "global solution".

The second openMedicine expert council meeting focused on the first results of the project (Is IDMP fit to solve the issue of the cross-border identification of a prescribed medicine, being it a brand medicinal product (innovator or generic product) or a substance based prescription).

This EU-US workshop had a different scope: If we want an openMedicine based identification of medicines we better take the option of a global solution, a "global identifier". Considering the 2010 Transatlantic Memorandum of Understanding, an invitational workshop was organised in order to assess feasibility and to evaluate usability and possible success factors in both the US and Europe. This, against the background that the international, even more the transatlantic cooperation of the regulatory authorities is the man driving force behind the development and introduction of the IDMP suite of standards.

At the start of the workshop, the European Union (EU) policy challenge: univocal identification of medicinal products (MPs) and substitution in cross-border healthcare settings was presented to allow US participants to better understand and put into focus the European perspective. This was very helpful in assisting later discussions, but the core cross-border issues are not of that much relevance in the more closed US market environment.

On the other hand, it turned out that also in the US policy context the univocal identification of medicines and the use of standards throughout the product lifecycle has gained policy prominence and high priority in recent years. But the drivers are more patient
safety/pharmacovigilance and economic efficiency in applying for marketing authorisation for new products by industry.

As was reconfirmed by the representatives of national and European authorities, all of this has led to a complementary situation of interests and expected benefits – the topic of trans-Atlantic regulatory cooperation and harmonisation. For already many years, EMA and FDA, together with SDOs have been cooperating in further defining and translating ISO IDMP into applications, particularly on challenges like PhPID, substance database and other standardising and coding challenges, including the semantic dimensions.

When the openMedicine approach towards identification and description of branded medicinal products was discussed, it turned out that it fully meets with US perspectives and vision, and was fully supported. It was even the case that US representatives from commercial companies were very supportive and interested in further developments, noting that the workshop provided also for them new and highly relevant insights, but that real business activities can only be expected once it is sure that an IDMP compatible drug database will indeed become available and accessible with certainty about timing and contents.

Against this background, EU and USA harmonisation of content and message exchange for IDMP implementation met with full approval without major discussions.

As already noted at the prior Brussels meeting, the pivotal role of the PhPID (Pharmaceutical product identification) introduction was confirmed, and the process leading to its realisation discussed in some detail, as later reflected in the recommendations in D 6.3. Also, the fundamental need for USA/Canada and EU to work together on this was underlined.

Implementing IDMP in Canada – a progress report – was a highly interesting presentation on processes taking place in Canada, a message confirming the trans-Atlantic approach pursued by EMA and FDA. Informally, Canada seems to go along the same road (map).

With great interest were the presentations on the added value of using IDMP in other domains embraced. Also for North-American participants this provided new insights into the clinical and wider relevance of IDMP implementation and the additional aspects and needs resulting in a reform. It was agreed that this is a domain needed considerable further attention.

On the practical aspects of implementing IDMP followed a more fundamental note and discussion contributed by Mr. Jeremy Thorp (UK). He also addressed issues related to the distribution, the maintenance and the financing capacities needed – all against the planned revision of the EU ePrescription Guideline. These challenges, as discussed at the workshop, have been addressed in Deliverable D 6.3.

The issues and challenges of trans-Atlantic validation, roadmap, and implementation planning as well as the ideas presented for a vision, the next steps needed for continued cooperation, and an eventual global outreach met with full approval, the workshop attendees all underlining the urgent need to continue the discussions started or continued by this workshop. These discussions also heavily contributed towards adapting, improving and extending the issues already identified for the final recommendations to be delivered by openMedicine, as well as for core items and steps to be reflected in the roadmap.

Rapporteur: Karl Stroetmann, empirica
4 Final Expert Council Meeting

The Final openMedicine Expert Council was hosted by EMA at their offices in London, November 9th & 10th, 2016.

4.1 Invitation

Final Expert Council Meeting

at EMA – European Medicines Agency
30 Churchill Place, Canary Warf, London E14 5EU
9th and 10th of November 2016

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.openmedicine.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, pharmacovigilance, 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.
### 4.2 Final Agenda

**Wednesday November 9th, 2016**

Chair: Paolo Alcini, EMA

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30</td>
<td>Registration (please bring an ID document) &amp; coffee</td>
<td></td>
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<tr>
<td></td>
<td>Welcome and introduction</td>
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</tr>
<tr>
<td>09:00</td>
<td>Welcome (Host, project)</td>
<td>Paolo Alcini</td>
</tr>
<tr>
<td>09:20</td>
<td>Roll Call – 2’ per expert (max)</td>
<td>All</td>
</tr>
<tr>
<td>10:00</td>
<td>The European Policy context</td>
<td>Gerald Cultot</td>
</tr>
<tr>
<td>10:15</td>
<td>Project Status</td>
<td>Karl Stroetmann</td>
</tr>
<tr>
<td>10:30</td>
<td>Break</td>
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</tr>
<tr>
<td></td>
<td><strong>Session 1: Key results of openMedicine</strong></td>
<td></td>
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<tr>
<td>11:00</td>
<td>openMedicine data model for cross-border identification of pre-packaged medicinal product</td>
<td>William Goossen, Robert Vander Stichele</td>
</tr>
<tr>
<td>11:15</td>
<td>Identification issues for other products</td>
<td>Anna Gawronska-Blaszczyk, Isabel Lazaro</td>
</tr>
<tr>
<td>11:30</td>
<td>Substitution and Selection</td>
<td>Karl Stroetmann</td>
</tr>
<tr>
<td>11:45</td>
<td>Identifiers in regulatory and in clinical care context</td>
<td>Jos Devlies</td>
</tr>
<tr>
<td>11:55</td>
<td>Validation of the openMedicine cross-border identification model</td>
<td>Isabel Lazaro, Kevin Horan</td>
</tr>
<tr>
<td>12:10</td>
<td>Plenary discussion</td>
<td>Moderator Marcello Melgara</td>
</tr>
<tr>
<td>12:45</td>
<td>Lunch</td>
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Chair: Karl Stroetmann

**Session 2  IDMP realisation**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>13:45</td>
<td>National drug agencies: what remains national? Role in IDMP implemented world</td>
<td>Kevin Horan</td>
</tr>
<tr>
<td>14:00</td>
<td>Progress IDMP database and encountered problems</td>
<td>Kevin Horan</td>
</tr>
<tr>
<td>14:15</td>
<td>The US approach in distributing IDMP compatible data and databases</td>
<td>Vada Perkins Chr. Joneciks</td>
</tr>
<tr>
<td></td>
<td>-Global PhPID Generation Update</td>
<td></td>
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<tr>
<td>14:35</td>
<td>The use of the PhPID in pharmacovigilance</td>
<td>WHO-Uppsala</td>
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<tr>
<td>14:50</td>
<td>Terminologies and coding systems: SPOR</td>
<td>TBD</td>
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</table>
D6.4 Second annual report on the activities of the Expert Council

Chair: Kevin Horan

Session 3  IDMP compatible implementation

<table>
<thead>
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<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15:30</td>
<td>EMA and FDA Drug Databases as authentic source for public and private database providers</td>
<td>Paolo Alcini / Kevin Horan</td>
</tr>
<tr>
<td>15:45</td>
<td>Adjusting to IDMP – access needs and business challenges of drug database providers</td>
<td>T.R. Bizzaro, J.F. Forget, Geert Deloof</td>
</tr>
<tr>
<td>16:15</td>
<td>Identification of medicines in an EHR (Medication record; prescription history; patient summary)</td>
<td>Jos Devlies, W. Ed Hammond</td>
</tr>
<tr>
<td>16:45</td>
<td>Plenary discussion</td>
<td>Moderator W. Ed Hammond</td>
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Thursday November 10th, 2016

Chair: Christian Hay, CEN

Session 4  openMedicine recommendations

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>09:10</td>
<td>Draft openMedicine recommendations - Overview</td>
<td>Jos Devlies</td>
</tr>
<tr>
<td>09:35</td>
<td>Recommendations on identifiers and identifying attributes</td>
<td>José Teixeira</td>
</tr>
<tr>
<td>10:00</td>
<td>Impact of IDMP and the recommendations on 'standard messaging' (HL7).</td>
<td>Giorgio Cangioli</td>
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<tr>
<td>10:25</td>
<td>Break</td>
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<tr>
<td>11:00</td>
<td>Discussing the recommendations</td>
<td>Moderator Catherine Chronaki</td>
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<td>12:15</td>
<td>Lunch</td>
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Chair Marcello Melgara

Session 5  Draft roadmap

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<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>13:30</td>
<td>The European “Joint Action to support the eHealth Network - (JAseHN)” and its ePatient Summary and ePrescription Guidelines - review of the input from openMedicine</td>
<td>Jeremy Thorp</td>
</tr>
<tr>
<td>14:00</td>
<td>Presentation of the openMedicine Roadmap</td>
<td>Paolo Alcini, Jos Devlies</td>
</tr>
<tr>
<td>14:30</td>
<td>Debate and validation</td>
<td>All</td>
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Chair Karl Stroetmann
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<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>14:45</td>
<td>Introduction</td>
<td>Gerald Cultot, Karl Stroetmann</td>
<td>EMA – FDA</td>
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<td></td>
<td>WHO</td>
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<td>15:00</td>
<td>Final statements by involved stakeholders</td>
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<td>CEN</td>
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<td>EU</td>
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<tr>
<td>15:45</td>
<td>Outlook and Farewell</td>
<td>Paolo Alcini, Jos Devlies,</td>
<td>Karl Stroetmann</td>
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4.3 Attendees

31 experts attended the meeting

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<thead>
<tr>
<th>Attendee</th>
<th>Company / Organization</th>
<th>Country</th>
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<tbody>
<tr>
<td>Gerald Cultot</td>
<td>DGConnect</td>
<td>EU</td>
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<tr>
<td>Bizzaro Tom</td>
<td>First Data Bank</td>
<td>US</td>
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<td>Jacqueline Surugue</td>
<td>EAHPIFR</td>
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<td>Perkins Vada</td>
<td>IDGlobaly US</td>
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<tr>
<td>Dilks Tony</td>
<td>FDB Europe UK</td>
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<tr>
<td>Judith Jones</td>
<td>Degge Group US</td>
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<td>Ed Hammond</td>
<td>DCHI US</td>
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<td>Jarvis Christopher</td>
<td>EDQM FR</td>
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<tr>
<td>Jean-Francois Forget</td>
<td>VIDAL FR</td>
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<td>Geert Deloof</td>
<td>BCFI BE</td>
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<tr>
<td>Robert Vanderstichele</td>
<td>Uni. Of Ghent BE</td>
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<tr>
<td>José Teixeira</td>
<td>IHE PT</td>
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<tr>
<td>Jeremy Thorp</td>
<td>NHS Digital UK</td>
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<tr>
<td>Julie James</td>
<td>BlueWaveInform UK</td>
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<td>Franck Gener</td>
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<td>Jamie Wilkinson</td>
<td>PGEU BE</td>
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<td>Nurmi Harri</td>
<td>THL FI</td>
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<td>Dipak Kalra</td>
<td>EuroRec UK</td>
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<tr>
<td>Ian Green</td>
<td>IHTSDO DK</td>
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<tr>
<td>Paul Houston</td>
<td>CDISK UK</td>
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<tr>
<td>Paolo Alcini</td>
<td>EMA IT</td>
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<tr>
<td>Karl A Stroetmann</td>
<td>empirica DE</td>
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<tr>
<td>Marcello Melgara</td>
<td>LIspa It</td>
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<tr>
<td>Kevin Horan</td>
<td>IRL</td>
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<tr>
<td>William Goossen</td>
<td>Results4Care NL</td>
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<tr>
<td>Anna Gawronska-Blaszczyk</td>
<td>GS1:iliim PL</td>
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<td>Paulina Mlodawska</td>
<td>GS1/ILIM PL</td>
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<tr>
<td>Izabel Lazaro</td>
<td>AEMPS ES</td>
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<tr>
<td>Catherine Chronaki</td>
<td>HL7 GR</td>
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<tr>
<td>Jos Devlies</td>
<td>Custodix BE</td>
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<tr>
<td>Giorgio Cangioli</td>
<td>HL7 IT</td>
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4.4 **Presentations**

The presentations are available on Dropbox
\openMed\Meetings\London November 9-10 2016\Presentations

![List of presentations](image.png)
<table>
<thead>
<tr>
<th></th>
<th><strong>Prof. Dr. Karl Stroetmann:</strong> “openMedicine and cross border eHealth services – status and meeting objectives.”</th>
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<tbody>
<tr>
<td></td>
<td>Focus on implementable results:</td>
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<tr>
<td></td>
<td>- Buy-in from EMA, FDA, national competent authorities</td>
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<tr>
<td></td>
<td>- International SDOs like ISO(IDMP), WHO, HL7 and others leverage our work</td>
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<tr>
<td></td>
<td>- EMA IDMP database (Migration from Art.57 DB) will become a core service for member state health systems</td>
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<td>- Cooperation facilitates reaching unambiguous, practical results.</td>
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<tr>
<th></th>
<th><strong>Robert Vander Stichele:</strong> “Identifying medicinal products suitable for an INN Prescription”</th>
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<tr>
<td></td>
<td>Requirements:</td>
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<tr>
<td></td>
<td>- A European database of VMP-groups</td>
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<td></td>
<td>- Estimated number of records to be maintained (between 3,000 and 9,000)</td>
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<td>- Standards for substance (at two levels), codification of the EURD list in the PSUR project, an ontology for substances</td>
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<td>- Standardized Measures of strength, administration units, pharmaceutical form, route of administration</td>
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<td>- An ontology for form/routes</td>
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<tr>
<th></th>
<th><strong>Anna Gawrońska:</strong> “Identification and description other medicinal products”</th>
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<td></td>
<td>Other medicinal products:</td>
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<td></td>
<td>Non-pre-packaged medicinal products</td>
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<tr>
<td></td>
<td>- magistral formula</td>
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<td></td>
<td>- officinal formula</td>
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<tr>
<td></td>
<td>- radionuclides in the form of sealed sources</td>
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<td></td>
<td>- advanced therapy MP prepared on a non-routine basis</td>
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<td></td>
<td>Pre-packaged medicinal products</td>
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<td>- advanced therapy medicinal products</td>
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<td>- foods for special medical purposes (enteral)</td>
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<td>- homoeopathic medicines</td>
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<td>- herbal medicinal products</td>
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<td>- orphan medicinal products</td>
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<td>- medicinal products for paediatric use</td>
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<td>nanotechnology medicinal products</td>
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<td>4</td>
<td><strong>Prof. Dr. Karl Stroetmann: “Dispensation of medical products in cross-border healthcare – the substitution challenge –”</strong></td>
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<tr>
<td>Based on an European study (25 member states) on “Type of prescriptions” and “Prescription options” he made the following definition on “Substitution”: “The action of replacing a medicinal product, univocally specified in a prescription, including the quantity to be dispensed, by another medicinal product which differs with regard to one or several of the attributes identifying precisely the one the prescriber noted for dispensation”.</td>
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<tr>
<th>5</th>
<th><strong>Jos Devlies “Identifiers in regulatory and in clinical care”</strong></th>
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<tr>
<td>A product can be identified by an identifier (a code or a name) or by a sufficient set of descriptive attributes) A distinction should be made between the concepts &quot;medication line&quot; and prescription line.</td>
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<tr>
<th>6</th>
<th><strong>Kevin Horan &amp; Isabel Lázaro Salcedo: “Validation of the openMedicine cross-border identification model: demonstration of concept tool from AEMPS”</strong></th>
</tr>
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<tbody>
<tr>
<td>Proof of concept:</td>
<td></td>
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<tr>
<td>- Simplified apps(not fully functional applications)</td>
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<tr>
<td>- Focused on identification of medicinal products</td>
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<tr>
<td>- Containing the data structures of IDMP</td>
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<tr>
<td>- Showing the conclusions from openMedicine</td>
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<tr>
<td>- Connected via “cross-border” datasets (e.g. Relevant part of epSOS dataset)</td>
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<table>
<thead>
<tr>
<th>7</th>
<th><strong>Paolo Alcini: “Implementation of ISO IDMP standards within the European Medicines Regulatory Network”</strong></th>
</tr>
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<tbody>
<tr>
<td>- Currently the submission of data on medicines by Marketing Authorisation Holders is a legal requirement introduced by Article 57(2) of Regulation (EC) No 726/2004 as amended</td>
<td></td>
</tr>
<tr>
<td>- Pharmaceutical companies that hold marketing authorisations for medicinal products for human use in the EU and the EEA are required to:</td>
<td></td>
</tr>
<tr>
<td>Submit information to the EMA using the format referred as to Article 57 format or eXtended EudraVigilance Product Report Message (XEVPRM) format.</td>
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</tr>
<tr>
<td>Maintain the medicinal product information and notify the EMA of any newly authorised medicines or any variation to the terms of the marketing authorisations using the XEVPRM format</td>
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</tbody>
</table>
| 8 | **Jean-François Forget:** “Adjusting to IDMP”.

Conclusions:
- Mapping with local formularies (PhP<->MP<->packaging) is the “cornerstone” for usability in health informatics
- IDMP and article 57 database is a huge opportunity to fix it at a global level
- The major question for us is: will a unique set of MpID and PhPID be published as a global repository for all healthcare providers...and when?
- If the answer is yes, in the short/middle term, strong communication could motivate the market to be prepared to adopt one global repository in some years....and not promote new local or specific solutions |

| 9 | **Geert De Loof:** “The role of drug database providers in the implementation of the IDMP Standard. Access needs and business challenges of drug database providers.”

Belgian Centre for Pharmacotherapeutic Information (BCPI):
The BCPI is a:
- not for profit,
- non-governmental organization
- providing independent information on drugs and promoting Rational Prescribing,
- intended for health professionals

The BCPI is one of the partners of SAM (Source Authentique des Médicaments- Authentic Source of Medicines in Belgium) |

| 10 | **W. Ed Hammond:** “Identifications of medicines in an EHR”

What do we need?
- Within the EHR, we need to know the drug and its prescribing components
- We need to know management or administration details
- External to the EHR we need to know additional attributes of the drug
- The EHR System needs to provide a set of functionalities to support the medication process. |

| 11 | **Giorgio Cangioli:** “Impact of IDMP and the recommendations for standards (HL7)”

“The HL7 Version3 messaging standard shall be utilized for the exchange of medicinal product information emphasizing the importance of having a standardized method of exchanging medicinal product information in support of regulatory and pharmacovigilance activities” |
<table>
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<th>Page</th>
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| 12   | **EMA European Medicines Agency: Terminologies and Coding Systems SPOR**  
SPOR – Referentials:  
In the case of the regulated EU pharmaceutical industry, there are four domains of master data:  
Master data is any non-transactional information that is considered to play a key role in the core operation of a business and re-used for multiple purposes  
1 Substances: Harmonised data and definitions to uniquely identify the ingredients and materials that constitute medicinal product  
2 Products: Harmonised data and definitions to uniquely identify medicinal product based on regulated information (e.g. marketing authorisation, packaging and medicinal information)  
3 Organisations: Data that comprises of organisation name and location address data for organisations such as MAH, sponsors, regulatory authority, manufacturers  
4 Referentials: Lists of terms (controlled vocabularies) used to describe attributes of products e.g. lists of dosage forms, units of measurement, routes of administration |
| 13   | **Paul Houston: “CDISC B2E, beginning to End”**  
Stage 1: CDISC & IDMP Harmonization  
Stage 2: Clinical Trial Registration & Results 2 CDISC PROTOCOL |
| 14   | **Julie James: “From Vision to Reality: Regulatory agency information as source for Medicinal Product Terminology for ePrescribing: The story from Canada.”**  
Partnership between – Health Canada, Drugs and Health Products Department, part of the Health Products and Food Branch (the “regulatory agency”) and – Canada Health Infoway, an organisation responsible to the federal, provincial/territorial governments, whose mission is to “help to improve the health of Canadians by working with partners to accelerate the development, adoption and effective use of digital health across Canada” |
4.5 Minutes – Summary of discussions and conclusions

Here again, the above excerpts from presentations given in section “4.4 Presentations” provide a first insight into what was discussed at that meeting.

Based on these substantial contributions, the Final Expert Council Meeting assessed the options proposed against the research and insights presented in the deliverables, which had been made available to all attendees. (These deliverables are available on the web site of the project at http://www.open-medicine.eu/downloads.html). Furthermore, the recommendations submitted by WP 6 were discussed in great detail sometimes, whereas others were so obvious that they were just accepted and endorsed.

There was strong agreement that building on the ISO IDMP suite of standards is indeed the direction to go by the European Union, as presented by EMA as its central competent authority and by the national competent authorities as well. This all the more because the strong trans-Atlantic cooperation initiated many years ago on this, particularly by EMA and FDA, but also reflected in the ground-building work undertaken together in the standardisation/ISO context, was strongly re-confirmed by the experts and regarded as a fundamental base on which to continue to further develop not only the concepts and standards, but particularly also to proceed and even to accelerate the practical implementation. So it was confirmed that trans-Atlantic consensus indeed exists to adopt and implement IDMP as fast as possible.

Similarly, there was strong support for continuous and even more deep cooperation on the coding systems for given attributes of medicinal products. EDQM and UCUM standards, for example, will become integrated, and the global substance data base, a pivotal element in all these activities, will be finalised by EMA and FDA as soon as possible. These are some of the core components without which final implementation will not succeed.

The results of openMedicine, like the openMedicine data model for cross-border identification of pre-packaged medicinal products, were also discussed in some detail, with full endorsement of the detailed clinical model presented. The need for a reliable identification also for other products was underlined, but did not meet with the same priority, because its relevance in cross-border healthcare provision may be rather limited.

On the other hand, the final results concerning substitution and selection of medicinal products at the point of dispensation did not only meet with great interest, but were also discussed with considerable controversy. This clearly is a hot topic where opinions and also professional interests play a major role. So agreement on the basic concepts is possible, but there are divergent views on the implications, particularly as to whether member states should be requested to undertake first steps towards harmonisation of basic substitution rules or not. A point here is that it is not widely known that in a cross-border submission of an ePrescription the patient has to fully pay for the drugs at the point of dispensation, i.e. he/she is serviced like a private patient, and therefore the usual substitution rules based on reimbursement regulations do not apply. Another point to note is that the rules and implications around cluster prescribing are new and not widely known even to the attending experts – here also further discussions seem warranted.

On the other hand, the message that medicinal product identifiers should be defined and standardised such that they can be used both in regulatory and in clinical care contexts was just acknowledged and fully endorsed. In this context, the presentations on identification of medicines in an EHR (Medication record; prescription history; patient summary) were regarded as path-setting. Here some aspects related to IDMP were discussed in more detail, especially regarding their use in clinical care:

Route of administration and dosage form are handled as ONE attribute in Art. 57 database. This is not the way clinical systems are structured. This may require a revision of the standard.
The substances – as defined in Article 57 database and/or extracted within the EMA – SPOR DB and coding system - may not (yet) fully fit the needs of the management of medication and for prescription purposes. Here the RxNorm presentation documented the concept of PSN = Prescribable Substance Name, which may indicate a way forward on this challenge by reducing the number of substance names to the healthcare professional and meeting his/her needs, a concept also to be discussed in Europe.

The role of the public and private drug database providers was discussed. They have an important role to bring the definite data on the desk of the prescriber and of the dispenser.

On the implementation side, the validation concept, approach and mock-up of the openMedicine cross-border identification model as presented in a real life, online situation met with great interest and as a valid proof of the concepts developed.

Furthermore, the openMedicine suggestion to strongly promote 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, pharmacovigilance, billing, marketing cessation) was also endorsed and further discussed with this intention, also be support on the other side of the Atlantic.

It was heavily discussed and confirmed that the present Article 57 (2) EMA database needs to be converted as fast as possible into a structured and fully IDMP compatible data-base to allow further progress also at the national level to advance towards better patient safety, pharmacovigilance and efficiency in meeting industry and market needs. In this context, validation and completeness of the Art.57 DB urgently needs to be improved first.

This observation resulted in a proposal to create two complementary recommendations, taking into account the urgent need by the CEF eHealth services initiative, which has to make soon a first decision on what to use as a base for cross-border medicinal product identification. This issue was then later addressed by an "editorial group" meeting on the 10th after the actual meeting and on the 11th of November.

This openMedicine Expert Council meeting then reviewed and sometimes just acknowledged, but often also discussed in some detail the draft openMedicine recommendations submitted. Results of these discussions have been reflected in D 6.3 and are implemented there.

The submitted initial openMedicine roadmap was briefly discussed, but in the end it was left to the consortium to further develop it into a more coherent roadmap.

In summary, this final meeting indeed substantially contributed to the further improvement of 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.

Rapporteur: Karl Stroetmann, empirica
5 Expert Reviewers and Contributors

Some experts preferred to be reviewer of one or more deliverables. They are listed in chapter 1.2.

The Work Package leader selected one of them to review the respective deliverables.

The reviewers could express whatever opinion they had or whatever suggestion they wanted to make. Remarks and suggestions were then circulated within a work package group. It was strongly recommended that the author of the commented deliverable integrated remarks and suggestions or to argue why s/he can't accept one or more of remarks and suggestions.

Mediation by the PEB (Project Executive Board) was foreseen in case of disagreement between the reviewer expert and the author. But this was never the case.

Some external experts were asked by a task or a work package leader to contribute/critically review one or more sections of a deliverable, being considered as a specialist regarding certain topics.