Mapping EU initiatives on electronic product information

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HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY

Background

- Dec 2015, Strategy for EU Medicines Network to 2020
- Feb 2016, HMA Multi-annual Work Plan
- Feb 2017, HMA Support for better use for medicines
- Mar 2017, EC report to improve the EU product information
- Nov 2017, EMA action plan related to product information
- Dec 2017, merging HMA/EMA work on product information

HMA Support for better use for medicines

- Co-chaired by Spain and Norway
- Member States participating in the Group: the Netherlands, United Kingdom, Iceland, Norway, Spain and Germany (since April 2018). Also the chair of CMDh, EMA (since DEC/17) and European Commission (since APR/18). Some other MS have expressed their interest in joining.
- Nine teleconferences since FEB/17

Support for better use: relevant themes

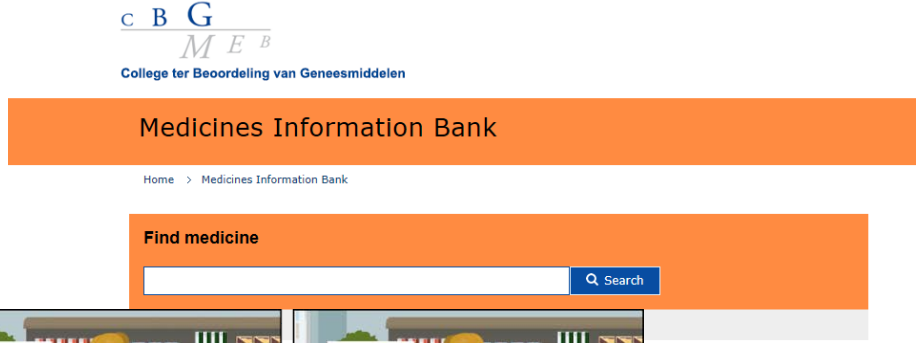
- Revisiting the content of information on medicinal products currently provided to patients and healthcare professionals
- Analysis of new contents of information on medicinal products that could be provided to patients and healthcare professionals in a clearer and more educational format
- To explore solutions to integrate the information contents analyzed in work streams 1 and 2 into current process of assessment and approval of medicines

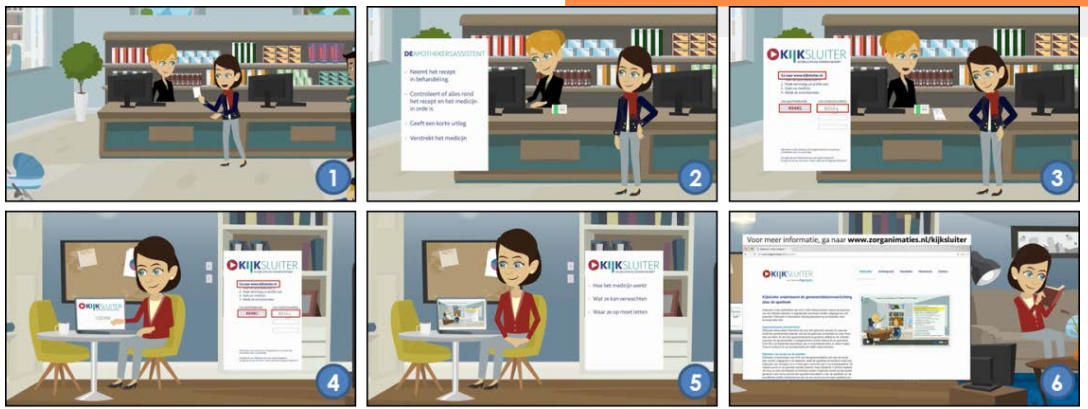
Some initiatives of HMA's Better Use Group

- Provide HMA with a Position Paper on Statutory Medicines Information
- Gather information from MS through two surveys circulated through the QRD group members
- Discussion of different initiatives ongoing in Member States
- Implementing recommendations of Work Package 6 (Risk Communication) of SCOPE (Strengthening Collaboration for Operating Pharmacovigilance in Europe)

The Netherlands: Program on support for better use of medicines

- Collaboration Watchyourmeds (product content explained in small movies)
- Medicines information Bank





Norway: «Quick-guide» for patients

- Information aid for doctors, pharmacist and patients
- Summary of information in simplified and accessible format
- Core information (indication, dosage, contra-indications, interactions), practical use (meals, alcohol, missed dose, seek help, signs of relevant serious side-effects, etc)
- Where to find more information

Penicillin

- fenoksymetylpenicillin

Statens legemiddelverk
Norwegian Medicines Agency

HVA BRUKES MEDISINEN TIL: Penicillin brukes i **behandlingen av infeksjoner** forårsaket av bakterier. Den virker ved å drepe eller hindre veksten av bakterier.

Denne medisinen er til deg. Ikke del den med andre.

Viktig informasjon om denne medisinen

Vær oppmerksom på:

- Kontakt lege dersom du ikke blir bedre eller tilstanden forverres
- Stopp behandlingen dersom du får en allergisk reaksjon (utslett, kløe, elveblest, hovner opp i lepper og tunge)
  - det er ikke farlig å stoppe brått med behandlingen
  - kontakt lege dersom du avbryter behandlingen for å bestemme ny behandling

Riktig bruk

- Fullfør kuren selv om du føler deg bedre
- Følg legens dose som står på pakkens etikett
- Ta neste dose som normalt dersom du glemmer å ta medisinen
  - ikke ta dobbel dose

Reseptfrie legemidler/kosttilskudd

- Kan kombineres med reseptfrie legemidler og kosttillskudd

Mat og drikke
Bør tas sammen med mat.

Alkohol
Moderat bruk.

Å kjøre bil
Påvirker ikke evnen til å kjøre bil.

Seksualfunksjon
Bruk av penicillin kan gi sopp i skjeden.

Graviditet
Kan brukes under graviditet.

Amming
Du kan amme selv om du tar penicillin.

Be fastlegen om en liste over alle medisiner du bruker. En medisinliste kan være livsviktig i en akutt situasjon, og gir god hjelp ved medisinbytte i apotek og når du henter e-resept.

Mer informasjon: • Se pakningsvedlegget • Kontakt apotek eller lege • www.helsenorge.no

Medisinråd – utarbeidet av Statens legemiddelverk

Spain: structured product information

▼Este medicamento está sujeto a seguimiento adicional, lo que agilizará la detección de nueva información sobre su seguridad. Se invita a los profesionales sanitarios a notificar las sospechas de reacciones adversas. Ver la sección 4.8, en la que se incluye información sobre cómo notificarlas.

1. NOMBRE DEL MEDICAMENTO

Senshio 60 mg comprimidos recubiertos con película

2. COMPOSICIÓN CUALITATIVA Y CUANTITATIVA

Cada comprimido recubierto con película contiene 60 mg de ospemifeno.
Excipiente con efecto conocido: Cada comprimido recubierto con película contiene 1,82 mg de lactosa en forma de monohidrato.

Para consultar la lista completa de excipientes, ver sección 6.1.

3. FORMA FARMACÉUTICA

Comprimido recubierto con película (comprimido).
Comprimidos recubiertos con película ovalados biconvexos, blancos o blanquecinos, de 12 mm x 6,45 mm, grabados con "60" por una cara.

FICHA TECNICA SENSHIO 60mg comprimidos recubiertos con película

Pulse aquí (Vínculo EMA) para ver el documento en formato PDF

ADVERTENCIA TRIÁNGULO NEGRO

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4. DATOS CLÍNICOS

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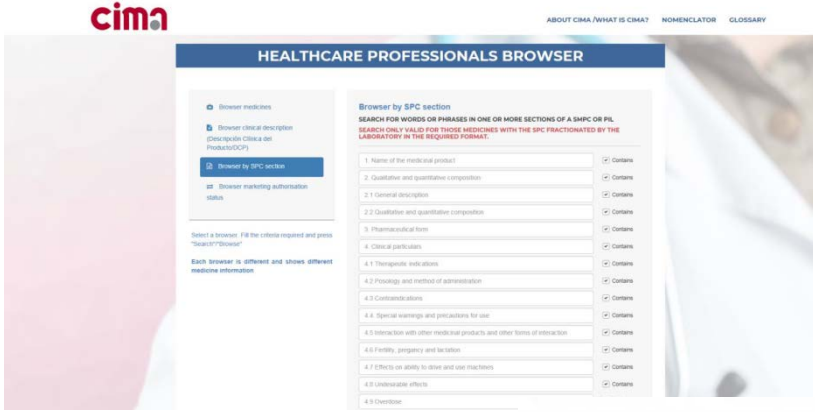
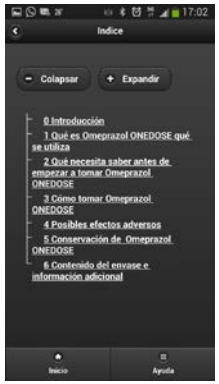
1. NOMBRE DEL MEDICAMENTO
2. COMPOSICIÓN CUALITATIVA Y CUANTITATIVA
3. FORMA FARMACÉUTICA
4. DATOS CLÍNICOS
5. PROPIEDADES FARMACOLÓGICAS
6. DATOS FARMACÉUTICOS
7. TITULAR DE LA AUTORIZACIÓN DE COMERCIALIZACIÓN
8. NÚMERO(S) DE AUTORIZACIÓN DE COMERCIALIZACIÓN
9. FECHA DE LA PRIMERA AUTORIZACIÓN/ RENOVACIÓN DE LA AUTORIZACIÓN
10. FECHA DE LA REVISIÓN DEL TEXTO

Spain: structured product information





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4. DATOS CLÍNICOS

4.1. Indicaciones terapéuticas

Senshio está indicado para el tratamiento de la atrofia vulvovaginal sintomática (AVV) de moderada a grave en mujeres postmenopáusicas que no cumplen los requisitos para recibir un tratamiento vaginal con estrógenos locales (ver sección 5.1).

4.2. Posología y forma de administración

Posología

La dosis recomendada es un comprimido de 60 mg una vez al día tomado con alimentos a la misma hora cada día.

Si se omite una dosis, el comprimido se debe tomar con alimentos tan pronto como se acuerde la paciente. No se debe tomar una dosis doble en el mismo día.

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1. NOMBRE DEL MEDICAMENTO
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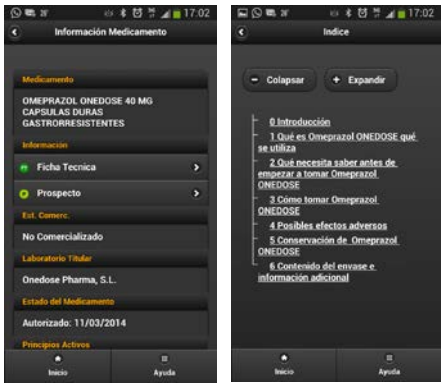


- Texts information fragmented by sections (no word and/or only pdf anymore)
- Easy search and navigation
- Links with other info formats (video)
- Possibility to offer information for handicapped
- Possibility to offer information relevant for subpopulations (children, elderly, by gender, by disease…)
- … and imagine what else…

MS questionnaire (through QRD members) I*

- Questionnaire answered by PL, IS, HR, UK, IT, HU, SE*, FI*, EE*, AT, NL, FR, ES, SK, NO, and BE (13 complete responses)
- Questions regarding e-PI (ongoing projects with structured data), views on electronic PIL and Quick Guides/Highlights on PILs

* Results from the 2nd questionnaire circulated to QRD members

MS questionnaire (through QRD members) II

- Ongoing projects and experience with structured data in NL, ES (already implemented) and NO. BE mentioned some private initiatives.
- MAHs should upload PI into a tool offered by NCAs
- Not considered a work overload but a efficient approach
- The use of an international standard for e-PI is required to help ensure consistency

MS questionnaire (through QRD members) III

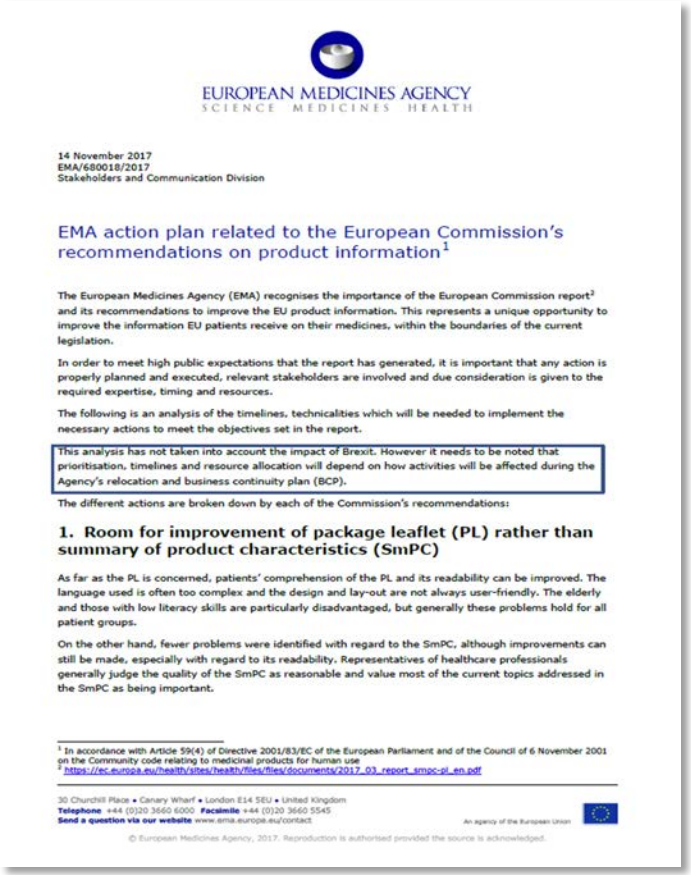
- Online availability of PILs as relevant and important but digital PILs cannot (yet) replace paper PILs
- Most MS positive towards replacing paper PILs by e-PILs for products administered by HCP (some pilots ongoing)
- A transition to the “digital first model” needed
- NO has conducted a pilot on quick-guides. Some experience in UK, NL, HU and, to a lesser extent, IT and AT

EC report to improve the EU PI

- Unique opportunity to improve the information EU patients receive on their medicines, within the boundaries of the current legislation

EMA Action Plan

- Involving all stakeholders (patients, consumers, healthcare professionals, industry, academics) and in collaboration with EU Member States and EC



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 November 2017
EMA/680018/2017
Stakeholders and Communication Division

EMA action plan related to the European Commission's recommendations on product information[1]

The European Medicines Agency (EMA) recognises the importance of the European Commission report[2] and its recommendations to improve the EU product information. This represents a unique opportunity to improve the information EU patients receive on their medicines, within the boundaries of the current legislation.

In order to meet high public expectations that the report has generated, it is important that any action is properly planned and executed, relevant stakeholders are involved and due consideration is given to the required expertise, timing and resources.

The following is an analysis of the timelines, technicalities which will be needed to implement the necessary actions to meet the objectives set in the report.

This analysis has not taken into account the impact of Brexit. However it needs to be noted that prioritisation, timelines and resource allocation will depend on how activities will be affected during the Agency's relocation and business continuity plan (BCP).

The different actions are broken down by each of the Commission's recommendations:

1. Room for improvement of package leaflet (PL) rather than summary of product characteristics (SmPC)

As far as the PL is concerned, patients' comprehension of the PL and its readability can be improved. The language used is often too complex and the design and lay-out are not always user-friendly. The elderly and those with low literacy skills are particularly disadvantaged, but generally these problems hold for all patient groups.

On the other hand, fewer problems were identified with regard to the SmPC, although improvements can still be made, especially with regard to its readability. Representatives of healthcare professionals generally judge the quality of the SmPC as reasonable and value most of the current topics addressed in the SmPC as being important.

[1] In accordance with Article 59(4) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use
[2] https://ec.europa.eu/health/sites/health/files/files/documents/2017_03_report_smpc-pl_en.pdf

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EC Report Recommendations

1 - Room for improvement of PL rather than of SmPC

2 - Amendments of Guidelines and QRD templates to enhance readability of PL

3 - Improving patient input in developing and testing of PLs

4 - Promotion and exchanges of best practice

5 - Electronic SmPC/PL formats (highest priority in EMA Action Plan: work started in 2017)

6 - Potential introduction of key information section in the SmPC and PL

Joint Industry Initiative & its Objectives

- AESGP, EFPIA and Medicines for Europe have created a joint Industry Task Force –

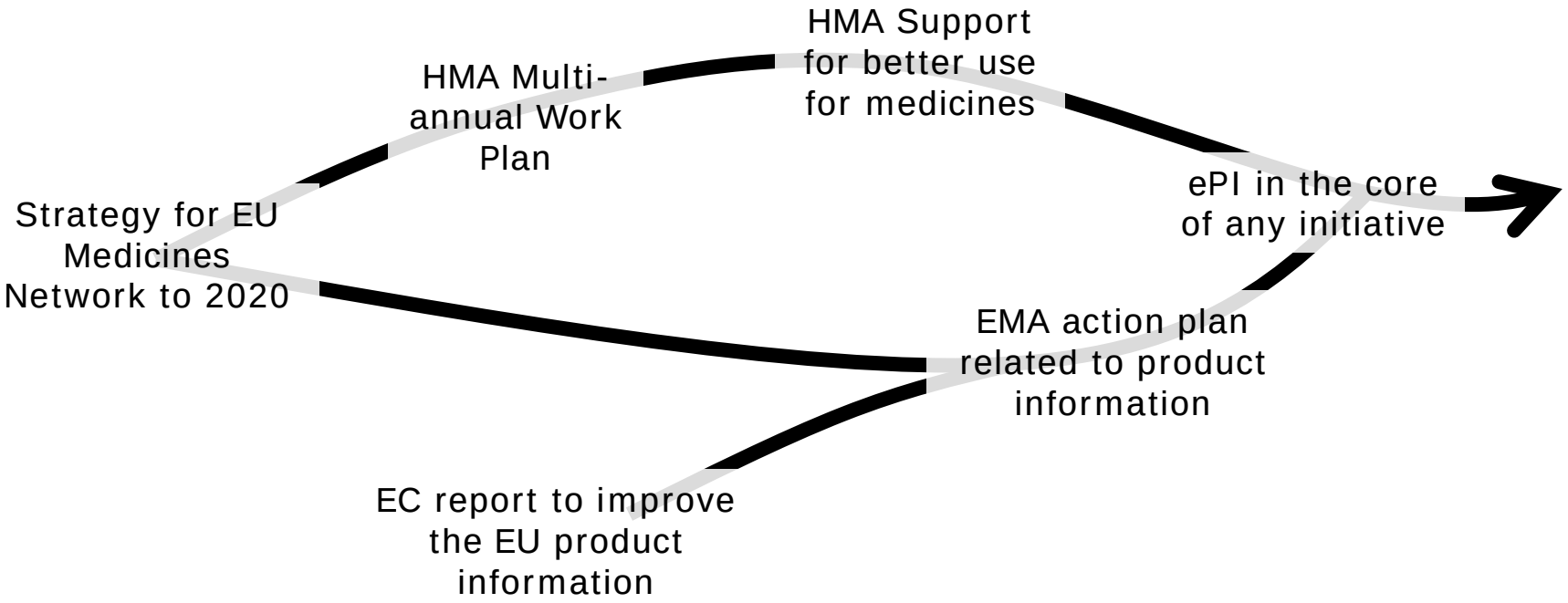
  Inter-Association Task Force eProduct Information

- This Task Force aims to partner with stakeholders to focus on:
  - Creating proposals for improved product information content, layout and readability within current legislation
  - Applying (digital) health literacy principles
  - Developing electronic product information formats concurrently
  - Enabling a single trusted portal to facilitate dissemination of electronic product information

medicines for europe
better access. better health.

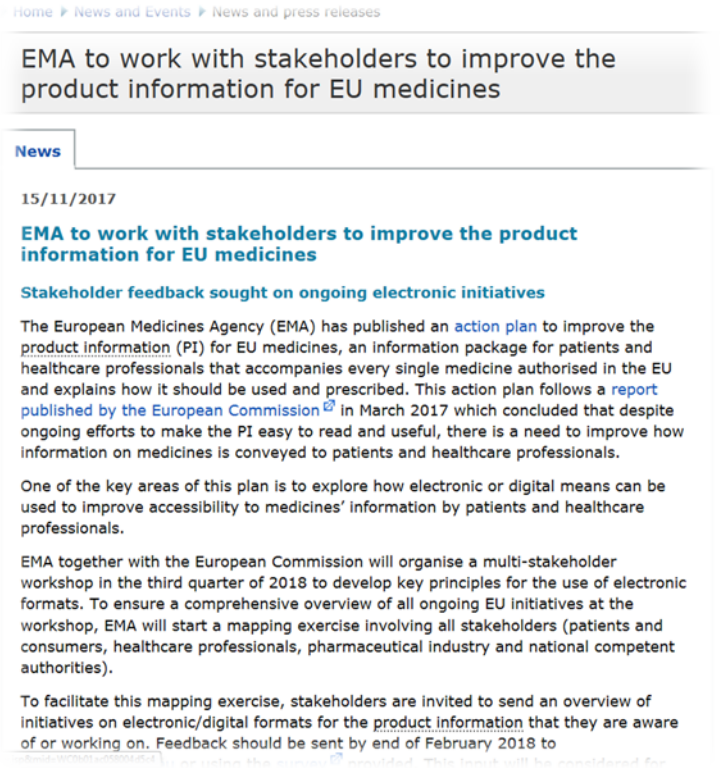
efpia
European Federation of Pharmaceutical Industries and Associations

AESGP


Strategy for EU Medicines Network to 2020
HMA Multi-annual Work Plan
HMA Support for better use for medicines
ePI in the core of any initiative
EMA action plan related to product information
EC report to improve the EU product information

EMA survey on ‘electronic PI’ initiatives

- Launched on EMA website Nov 2017 – Feb 2018
- Targeted dissemination to EMA’s stakeholders and EU partners



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EMA to work with stakeholders to improve the product information for EU medicines

News

15/11/2017

EMA to work with stakeholders to improve the product information for EU medicines

Stakeholder feedback sought on ongoing electronic initiatives

The European Medicines Agency (EMA) has published an action plan to improve the product information (PI) for EU medicines, an information package for patients and healthcare professionals that accompanies every single medicine authorised in the EU and explains how it should be used and prescribed. This action plan follows a report published by the European Commission in March 2017 which concluded that despite ongoing efforts to make the PI easy to read and useful, there is a need to improve how information on medicines is conveyed to patients and healthcare professionals.

One of the key areas of this plan is to explore how electronic or digital means can be used to improve accessibility to medicines’ information by patients and healthcare professionals.

EMA together with the European Commission will organise a multi-stakeholder workshop in the third quarter of 2018 to develop key principles for the use of electronic formats. To ensure a comprehensive overview of all ongoing EU initiatives at the workshop, EMA will start a mapping exercise involving all stakeholders (patients and consumers, healthcare professionals, pharmaceutical industry and national competent authorities).

To facilitate this mapping exercise, stakeholders are invited to send an overview of initiatives on electronic/digital formats for the product information that they are aware of or working on. Feedback should be sent by end of February 2018 to

Responders to EMA's survey

- 11 NCAs (BU, HR, DE, HU, IE, MT, NL, ES, SE, UK, NO)
- 6 HCP organisations
- 7 Patient organisations
- 1 Academia
- 1 Health-related media/advocacy
- 15 Pharma industry (including innovative, generic, OTC)
- 11 Consultants / tech developers

Conclusions

- Electronic Product Information is in the core of any initiative
- High impact on regulatory business
- High impact on the way the industry works
- High impact in clinical practice
- More important, is the most relevant way to progress on how medicines information is provided to health care professionals and patients

Next steps

- May-June.- Analysis of responses and mapping of EU and selected non-EU initiatives by the EMA and HMA group
- July 3rd.- F2F meeting in Madrid, to analyze current work. finalise the mapping and prepare the agenda for the EC/EMA/HMA workshop (stakeholder participation?)
- November 28-29.- EC-EMA-HMA **multi-stakeholder workshop** at EMA aimed at establishing key principles for the use of electronic SmPC/PL