Initiatives for electronic EU product information

The EMA, together with the European Commission, is working towards making product information for medicines available in electronic formats to patients and healthcare professionals in Europe. This survey aims to identify on-going initiatives in this field.
Thank you in advance for your valuable input.

Feedback form for stakeholders, partners and interested parties

What is your name?

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What is the name of your organisation?

AESGP - Association of the European Self-Medication Industry, EFPIA - European Federation of Pharmaceutical Industries and Associations, Medicines for Europe

What is your area of work?

- ○ Academia
- ○ Competent authority
- ○ Consultant/developer
- ○ Healthcare professional organisation
- ○ Other public bodies
- ○ Patient or consumer organisation/NGO
- ◉ Pharmaceutical industry
- ○ Other

Please describe your project and give the project name if applicable.

The Inter-Association Initiative eProduct Information developed a concept for electronic dissemination to allow easier and real-time access to information (regulator approved package leaflet texts) with improved content, layout and readability of product information to patients and healthcare providers.

What are the objectives of the project?

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 (with aim for making use of existing EU/Member State infrastructure) to facilitate timely dissemination of electronic product information

Such information must be
- easily accessible,
- relevant for the target audience and understandable
- reliable, regulatory authority approved and
- allow patients/HCPs to obtain, identify and use the information necessary to meet their individual needs in a timely manner, thus enhancing patient safety.

Are other stakeholders/parties also participating in the project? Please give details:

The IATF eProductInformation developed proposals for improvements of SmPCs and PLs based on the experience of pharmaceutical industry with e.g. readability tests. The IATF also consult and engage with other stakeholders, e.g.:
- EFPIA workshop in February 2014 with patients, pharmacists and health care professional representatives.
- exchange with the Health Literacy Coalition,
- exchange of views with PGEU (community pharmacists) and BEUC (consumers),
- engagement with regulators at several occasions, i.e. CMDh, TMB, DG SANTE
- discussions with national providers of electronic platforms for product information

What timelines do you plan for implementation of your project?

This initiative was officially launched in 2015 with an aim to complement the EC report and recommendations and also develop an EU-wide long-term strategy, bearing in mind many national-level initiatives / ideas. Since the initiative covers several aspects of the product information (dissemintation, readability, format...) the timelines vary and the next milestones are also linked to EC/EMA next steps and their planning. The initiative focuses on aspects that can be easiliy implemented within the current legislative framework. In addition, we are looking into future and look for solutions to move to a paper-less environment (with an optional print-out at the dispensing point), e.g. Art. 58 of Dir. 2001/83/EC interpretation.

Are you interested in collaborating with EMA, including potential participation in the EMA-EC workshop?

- (●) Yes
- ( ) No

Do you have any other information you would like to share with us?

The Inter-Association Initiative collected an overview of national activities concerning digital product information that is included in the attachment. The Inter-Association Initiative closely collaborates with the German project GI 4.0 and intends to collaborate with an IMI project for the development of electronic labelling systems. A two-stage IMI project is envisioned, first establishing the principles and standards behind e-labeling in line with the objectives of the EMA action, and secondly the identification, testing and optimisation of the foundational technologies that will underpin electronic delivery.

Please upload any prototype file, if available.

The maximum file size is 1 MB

94b13432-87cb-478b-a243-952ab95df5f1/eProduct_Information_feb_2018_reduced.pdf
371e84a3-9d78-435b-826a-3f919481349e/National_initiatives_incl_executive_summary.pdf

Who is the contact person for the project?

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What is the contact email address?

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By participating in this survey, your submission will be assessed by EMA. EMA collects and stores your personal data for the purpose of this survey and for contacting you in the future in the context of similar EMA activities.

Contact

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