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e-Product Information Initiative

February 2018

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

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Task Force's General Principles

- Pharmaceutical industry fully supports the provision of PI text which is:
  - comprehensive
  - accurate
  - up-to-date
  - trusted (regulator-approved information)
- Such information must be
  - easily accessible
  - understandable & relevant for the target audience and
  - allowing the patients/HCPs to obtain, identify and use the information necessary to meet their individual needs.
- Patients' role in their own health care is changing from patient compliance to patient engagement.
- **Increasing importance of improved access along with content, readability and layout of product information, which are considered key pillars for correct and appropriate use.**

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Readability, Layout and Content of the Product Information

- In order to be effective, product information has to be noticed, read, understood, trusted and remembered
- These shortcomings may lead to inappropriate consequences, such as
  - patients are not adhering to treatment
  - patients may become confused or worried
  - reduced treatment benefits, symptom control and disease management

Importance of Health Literacy

"Health Literacy is linked to literacy and entails people's **knowledge, motivation and competences to access, understand, appraise and apply health information** to make judgements and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life course."

Ref: European Health Literacy Consortium (2012)

- Limited health literacy is very common
- 47% of all respondents have inadequate or problematic health literacy

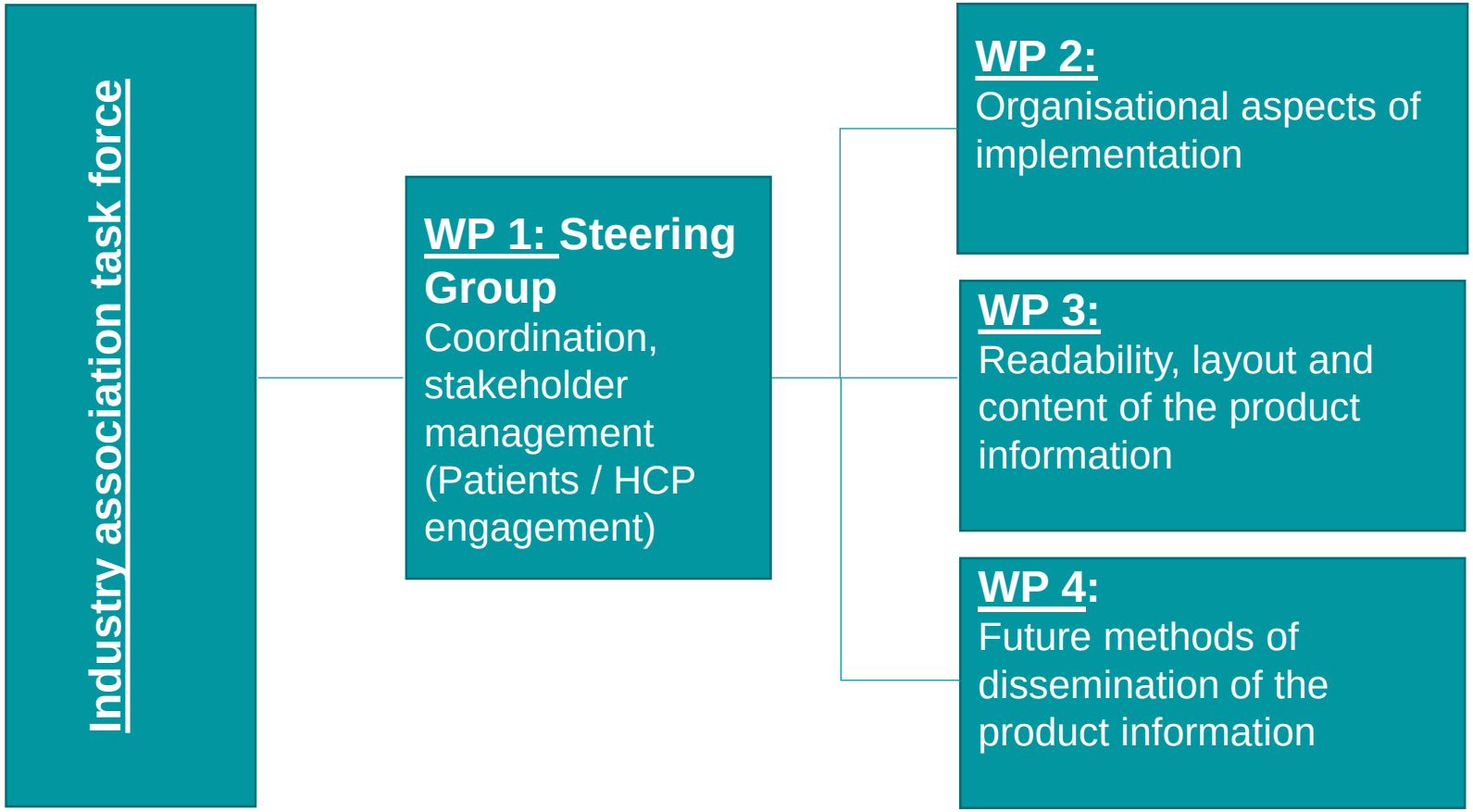
Advantages of e-Dissemination

- Use of existing and evolving **technologies** allows **immediate access** to regulator-approved ‘real-time’ PI, rather than relying on potentially out of date paper copies or electronic information from non-trusted sources.
- Allowing enhanced **device-related instructions** for the application of medicines (e.g. video instructions for asthma sprays, pre-filled syringes)
- Addressing **needs of people with disabilities**
- **Most importantly**, enabling **rapid availability of new efficacy & safety** information to patients and HCPs (in contrast to paper PL, where the introduction of changes takes often several months)
- Allows rapid and simple **implementation of changes** to the PL;
  - Helping to facilitate continuous supply of product to the market
  - Reducing environmental impact (paper and production)

Advantages of e-Dissemination cont.

- Electronic dissemination of PL and SmPC addresses the shortcomings of paper based system by:
  - Allowing for flexibility in **font size and line spacing**
  - Enabling patients to **search for information in a tailored fashion** to meet their own needs
  - Flexibility to provide **enhanced, tailored information and interactive features** (e.g. interactions based on concomitant medications).
  - Addressing the issues associated with **multi-language packs**
  - **Easing access** to medications **for small markets** and/or small patient populations
  - Supporting information management in professional environments such as **hospital settings**

Industry Task Force structure



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Industry Task Force view on implementation of eProduct Information

- Electronic PI should be introduced in a **stepwise approach in the EU**, over a period of time that allows for a **smooth transition from paper**.
- The focus should be on developing the electronic version as THE definitive source for most patients with **paper gradually becoming only a 'back up'** for those who cannot or do not want to use the electronic version. This could be achieved by building experience and trust amongst stakeholders.
- For those patients who cannot access their PI electronically, it has to be ascertained that they can get the corresponding most recent regulator-approved **PI printed in the pharmacy, at the point of sale**
- **Specific situation for non-prescription medicinal products**: as patients may have no or little interaction with a HCP, information provided directly with the pack will continue to be required. It could be complemented by a more user-friendly electronic information.

Diverse landscape of Member States initiatives - established collaboration between regulators & industry

Italy

- Companies to provide updated PI to a database within 30 days after approval
- The patient receives up-to-date information (onsite printing @pharmacies)
- NEW: under discussion that information about database sufficient
- Tailored and faster dissemination of new info
- Decreased risk of drug shortages
- Less destruction costs or recalls

PI accessible via smartphone

The Netherlands

- PI content explained in small movies

Belgium - Hospital pilot project: cooperation between industry, pharmacists and authorities. Testing of hospital packs e-only info without paper leaflet

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Concurrently: German Pilot Study (proof-of-concept for IATF-proposals)

- Gain experience in real-life environment & complete the picture and connect the dots
- Create an electronic database to provide up-to-date PI to patients in various formats
- Allow simplified access via an integrated system (apps, web page, print-out in pharmacies)
- Exploring synergies with the development of a more flexible QRD Template (e.g. additional function as style sheet for easier transformation into various output formats)

In cooperation with all relevant stakeholders including:

- Patient representatives
- Pharmacists representives
- National competent authority representatives

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Change challenges into opportunities: cooperation of all stakeholders is needed

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EMA Reflection Paper on Web Portal

- EU Telematics Strategy and Implementation Roadmap 2015 – 2017

"The EU Medicines Web portal for human medicinal products will be a free, unbiased, scientifically-valid source of medicinal product information on the internet."

- Oct 2016 EMA Reflection paper: Development of the European medicines web portal
  - Enhanced cooperation and visibility within the EU regulatory & re-use and data sharing

European Commission's report/recommendations

Room for improvement of PL rather than of SmPC

- Patient's comprehension and PL readability can be improved.
- Language often too complex and design / lay-out not always user-friendly.
- The elderly and those with low literate skills are particularly disadvantaged, generally true for all patient groups.

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Criteria

Work towards two main goals:

- **To support EMA's vision of a single European information system on medicinal products which is accessible to the public and speedily available everywhere across Europe**
- **Regulator-approved Product Information up-to-date and in an adaptive format**

The Vision is to be part of e-health and to link into the digital care of patients

Inter-association task force e-Product Information
– a joint effort to answer current challenges

We appreciate your feedback and offer our expertise to contribute to further improvements of patient information.