EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Electronic product information

Update on ongoing work

Presented by Alexios Skarlatos, 25 September 2018
PCWP/HCPWP joint meeting

Joint HMA-EMA-EC collaboration on electronic product information

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European Commission report on improvements to the EU product information

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

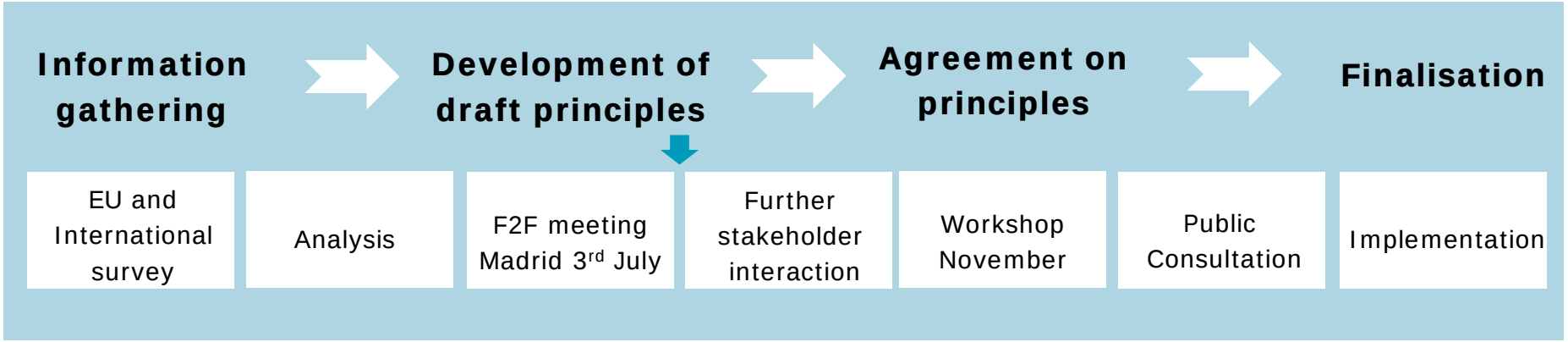
Draft EU definition of electronic PI

Authorised product information (PL, SmPC and labelling) in a format structured and adapted for electronic handling. **This will allow wider use of regulator-validated medicines information and its dissemination via print, web and various e-formats and platforms**

Exploring electronic formats prioritised - Why?

- Public health priority
- Need for coordination of multiple ongoing initiatives in the EU
- Maintain the role of regulatory authorities in providing information to patients

Methodology



Right timing to progress towards EU ePI

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Key findings from EU mapping

- **81** responses – including **19** NCAs
- **38** projects underway in the EU, mainly from industry or NCAs
- Spain and France (ePI already available)
- Projects at different stages of development, **14 out of 38** are well established
- **11** initiatives to increase the accessibility of PI ongoing:
  - ✓ **e.g. audible formats for visually impaired; videos for low health literacy**
- Where mentioned, **XML** is the electronic standard mostly used

Current international landscape

- Mapping of main international landscape ongoing
- Other organisations (e.g. Bill & Melinda Gates Foundation) with interest in the EU initiative
  - ✓ **considering use of electronic PI to address low health literacy and patients' needs in Low Income Countries (LICs)**

Outcome of the HMA-EMA-EC Face-to-Face Meeting

Madrid, 3rd July 2018

Presented to HMA

by Belén Crespo (AEMPS) and Juan García Burgos (EMA)

Vienna, 12 July 2018

Key outcomes

	Points for discussion	Draft principles
	Access to information	• Developing 'ePI' formats is a **public health priority**: ✓ Immediate **safety alerts** ✓ **Up-to-date** information ✓ Reinforcing the role of **regulators as authoritative source** of electronic information
	Special patients' needs	• Electronic PI should facilitate the development of **e-formats and platforms which address special patients' needs**, e.g.: ✓ audible formats for visually impaired citizens ✓ formats to address low health literacy

Points for discussion	Draft principles
Paper package leaflet *vs* ePI	• Electronic PI is **not a substitute for the paper package leaflet**, but a complement – support paper limitations • Paper PL has to be provided with all EU medicines, as required by the pharmaceutical legislation (Art. 58 of Dir 2001/83)
Electronic PI to contain only regulatory-approved information	• Use of electronic tools **does not change the content** of the PI approved by regulators • **The EU legislation has** safeguards in place (Title VIII of Dir 2001/83) to protect citizens from promotional material on medicines

Points for discussion	Draft principles
 Common EU electronic standard	• Progress towards ePI in the EU requires agreement on a **common EU electronic standard** • Any such standard should allow for **interoperability** with current and future EU systems **e.g. EU Telematics projects and cross-border prescription** • **Flexible implementation** by Member States and EMA is proposed • This will contribute to **harmonised access** to information on all medicines in the EU, whether **nationally or centrally authorised**
 Catering for the EU multilingual context	• The electronic standard agreed should be **able to deliver ePI in all EU languages** and according to national requirements

Points for discussion	Draft principles
Interdependency with EC's eHealth strategy	• The agreed electronic format should be **interoperable** in the future with existing national healthcare systems and future implementation of eHealth deliverables **e-prescription, cross-border prescription and e-health records**
New legislation on accessibility of websites and mobile applications of public sector bodies	• Implementation of **ePI should not impact nor delay Member States' compliance** with Dir. 2016/2102/EU • Although the requirements of this Directive are not legally binding for the Agency, **EMA aims to bring its standards in line** with them
Interdependency with other projects and legislation **Ongoing analysis**	• EU Telematics projects involving exchange of data across MSs and EMA – e.g. **SPOR, European Medicines Web Portal** • New veterinary legislation / Falsified Medicines Directive

Conclusions from the F2F meeting

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- Needs and concerns from all stakeholders well captured
- **Starting point** – need to agree on a common EU electronic standard (interoperable)
- Flexible implementation – but agreement on key principles is required to ensure coordination
- Simple/pragmatic approach
- ePI is not a substitute for the paper package leaflet
- Need for unbiased information coming directly from the authorities
- Discussion on governance and process for implementation will be needed at a later stage

Next steps

- **Further collaboration** with stakeholders
- **EC/EMA/HMA multi-stakeholder workshop** on electronic Product Information on 28 - 29 November 2018:
  - **Outcome - EU 'Key Principles'**
  - **Public consultation**
- *All actions to be considered under EMA's Business Continuity Planning due to relocation*

Participants

- Patients, consumers, healthcare professionals, national competent authorities, European Institutions, NGOs, academia, industry, third party information providers, EU Telematics Board members

Next steps

Further collaboration with stakeholders

- **Preparatory technical discussions** on features of common standard for electronic Product Information

  Outcome - Describe use cases and features for ePI to cover emerging key principles

  - Explore points for consideration in November meeting on standards for semi-structured ePI data

Participants

- Technical experts from EMA, NCAs, industry
- Call for participation of patient and HCP representative who would:
  - Be available for review of proposed features and use cases related to patient/HCP
  - Optionally participate in technical group TCs

Thank you for your attention