Follow-up to Commission's Report on Product Information Leaflets and related activities

81th Pharmaceutical Committee
23 October 2018
Introduction

• **Article 59(4) Directive 2001/83/EC**
  
  "an assessment report on current shortcomings in the summary of product characteristics and the package leaflet and how they could be improved in order to better meet the needs of patients and healthcare professionals"

• **Two external study reports - NIVEL and University of Leeds**
  
  • "PIL-S study" – current shortcomings in the leaflets of medicinal products for human use
  
  • "PILS-BOX study" - feasibility and value of a possible insertion of “key information section”

• **Consultation of Member States - Pharmaceutical Committee**
  
  • Summarised in the background document
  
  • Published on the Commission website, together with the external study reports
European Commission's report on Product Information (SmPC, PL and labelling)

- Adopted and published on 22 March 2017
- Number of recommendations identified
- Scope for improvement within the boundaries of existing legislation
European Commission's report recommendations

1. Room for improvement of PL rather than of SmPC
2. Amendments of Guidelines and Quality Review Documents templates
3. Improving patient input in developing and testing of PLs
4. Promotion and exchange of best practice
5. **Electronic SmPC and PL formats (paper PL not replaced)**
6. Potential "key information" section in the SmPC and PL
Developed and adopted in Q4 2017

- Identified concrete deliverables and timelines
- **ePI was given the highest priority** (implementation has started in 2017)
- Other actions will be initiated based on available resources

In the context of the Agency’s relocation, implementation of all recommendations can only be initiated once the Agency’s workforce is stable enough and above a certain limit of staff retention, which can guarantee the ability to go beyond essential core activities
Draft EU definition of electronic PI
Authorised product information (PL, SmPC and labelling) in a format structured and adapted for electronic handling. → wider use of regulator-validated medicines info 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
Madrid meeting July 2018: Conclusions of initial stakeholder consultation

- 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
EC-EMA-HMA multi-stakeholder workshop on electronic Product Information

• **28 November 2018, in London**

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

• Agree with all stakeholders on common EU key principles for the use of electronic SmPC and PL formats in the EU. This will involve consideration of:

  ✓ the possibilities offered by electronic formats to improve provision of PI, as well as stakeholder needs and concerns
  ✓ the main projects ongoing in the EU on electronic PI formats
  ✓ how ePI fits in with other EU and global initiatives

• Create a draft proposal of the key principles for public consultation
# Agenda Workshop

**28 November 2018**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presentations</th>
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<tbody>
<tr>
<td>08:30</td>
<td>Registration and reimbursement arrangements</td>
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<tr>
<td>09:00</td>
<td>Welcome, health and safety information and workshop objectives</td>
<td>Melanie Carr (EMA) Commissioner Vytenis Andriukaitis (EC) European Parliament</td>
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<tr>
<td>09:20</td>
<td>Towards digital transformation of health and care</td>
<td>Kristina Kurgonaitė (EC)</td>
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<td>09:30</td>
<td>Opportunities for expanding access to product information for medicines: stakeholders’ needs and challenges</td>
<td>Nanneke Hendricks (MEB) Kaisa Immonen (EPF) Consumers speaker (BEUC) HCPs speaker (PGEU) Gesine Bejeuhr (Industry’s Inter-Association Task Force - IATF)</td>
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<tr>
<td>10:30</td>
<td>Questions and answers</td>
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<td>10:40</td>
<td>Coffee</td>
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# Session 2: Current landscape – How does ePI fit in with other initiatives?

*Chaired by Maria Jesus Lamas Diaz (HMA/AEMPS) and Juan Garcia Burgos (EMA)*

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Content</th>
<th>EMA</th>
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<tbody>
<tr>
<td>11:00</td>
<td>Overview of initiatives from the EMA-HMA mapping</td>
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<tr>
<td>11:15</td>
<td>Initiatives from national competent authorities</td>
<td>• Spain</td>
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<td>• France</td>
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<td>• BE-LUX Pilot</td>
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<td>• Nordic initiatives</td>
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<td>• Sweden</td>
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<td>12:15</td>
<td>Questions and answers</td>
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<tr>
<td>12:30</td>
<td>Lunch</td>
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<tr>
<td>13:30</td>
<td>Initiatives from stakeholders</td>
<td>• FASS (Sweden)</td>
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<td>• eMC (UK)</td>
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<td>• Gebrauchsinformation 4.0 (Germany)</td>
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<td></td>
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<td>• Research initiatives (tbc)</td>
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<td>14:20</td>
<td>Questions and answers</td>
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<td>14:30</td>
<td>Coffee</td>
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### Session 3: Towards an EU ePI

*Chaired by Zaide Frias (EMA) and Melanie Carr (EMA)*

<table>
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<th>Time</th>
<th>Agenda Item</th>
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<tr>
<td>14:50</td>
<td>- Common electronic standard: potential features and use cases</td>
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| 15:15 | - Analysis and discussion on proposed key principles for ePI:  
  - Definition of ePI  
  - Expanding access to medicines information  
  - Complementing paper package leaflet  
  - Regulatory-approved information only  
  - EU multilingual context  
  - Common EU electronic standard  
  - Interdependency with EU and global initiatives  
  - Process governance | EMA/ HMA/EC – Facilitated discussion with participants aimed at consensus building |

#### Conclusions and next steps

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<tr>
<td>17:30</td>
<td>- Concluding remarks and next steps</td>
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<td>18:00</td>
<td><em>End of meeting</em></td>
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Timeline & Next steps

- **Analysis**
  - EC report Q1 2017
  - EMA Action Plan Q4 2017
  - EMA Survey Q1 2018

- **Development of draft principles**
  - F2F meeting Madrid 3 July 2018

- **Agreement on principles**
  - Workshop 28 Nov 2018 London

- **Finalisation**
  - Public Consultation Q1-Q2 2019
  - Implementation 2019

**Joint WG**

**Next steps**
Thank you

European Commission
http://ec.europa.eu/health/index_en.htm

European Medicines Agency