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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

81th Pharmaceutical Committee
23 October 2018

Health and Food Safety

European Commission

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

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European Commission's report on Product Information (SmPC, PL and labelling)

EUROPEAN
COMMISSION

Brussels, 22.3.2017
COM(2017) 135 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

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

(Text with EEA relevance)

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

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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

Drug Package Insert (FDA 115)

EMA action plan

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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:

- 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

Joint EC-EMA-HMA collaboration on electronic Product Information

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		
08:30	*Registration and reimbursement arrangements*	
09:00	• Welcome, health and safety information and workshop objectives	Melanie Carr (EMA) Commissioner Vytenis Andriukaitis (EC) European Parliament
Session 1: Setting the scene – Why ePI? *Chaired by Olga Solomon (EC) and Alexios Skarlatos (EMA)*		
09:20	• Towards digital transformation of health and care	• Kristina Kurgonaitė (EC)
09:30	• Opportunities for expanding access to product information for medicines: stakeholders' needs and challenges	• Nanneke Hendricks (MEB) • Kaisa Immonen (EPF) • Consumers speaker (BEUC) • HCPs speaker (PGEU) • Gesine Bejeuhr (Industry's Inter-Association Task Force - IATF)
10:30	Questions and answers	
10:40	*Coffee*	

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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)*		
11:00	• Overview of initiatives from the EMA-HMA mapping	EMA
11:15	• Initiatives from national competent authorities	• Spain • France • BE-LUX Pilot • Nordic initiatives • Sweden
12:15	Questions and answers	
12:30	*Lunch*	
13:30	• Initiatives from stakeholders	• FASS (Sweden) • eMC (UK) • Gebrauchsinformation 4.0 (Germany) • Research initiatives (tbc)
14:20	Questions and answers	
14:30	*Coffee*	

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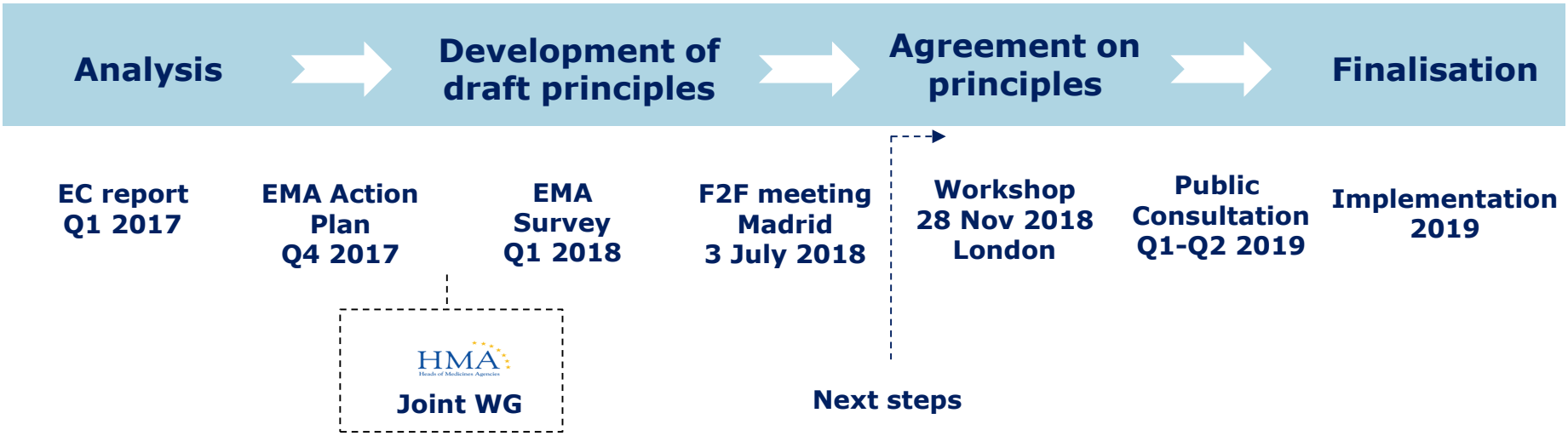
Session 3: Towards an EU ePI *Chaired by Zaide Frias (EMA) and Melanie Carr (EMA)*		
14:50	• Common electronic standard: potential features and use cases	EMA
15:15	• Analysis and discussion on proposed key principles for ePI: • Definition of ePI • Expanding access to medicines information • Complementing 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		
17:30	• Concluding remarks and next steps	EMA
18:00	*End of meeting*	

Timeline & Next steps



Thank you

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

European Medicines Agency

https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information-requirements