EC/HMA/EMA workshop on electronic Product Information (ePI)

Session 1: Setting the scene – Why ePI?

Towards digital transformation of health and care

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Why ePI?

Article 59(4) Directive 2001/83/EC

> By 1 January 2013, the Commission shall present to the European Parliament and the Council an assessment report on current short-comings 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. The Commission shall, if appropriate, and on the basis of the report, and consultation with appropriate stakeholders, present proposals in order to improve the readability, layout and content of these documents.

"[…] *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

1. *"PIL-S study" – current shortcomings in the leaflets of medicinal products for human use*
2. *"PILS-BOX study" - feasibility and value of a possible insertion of "key information section"*

Consultation of Member States

- Summarised in the background document
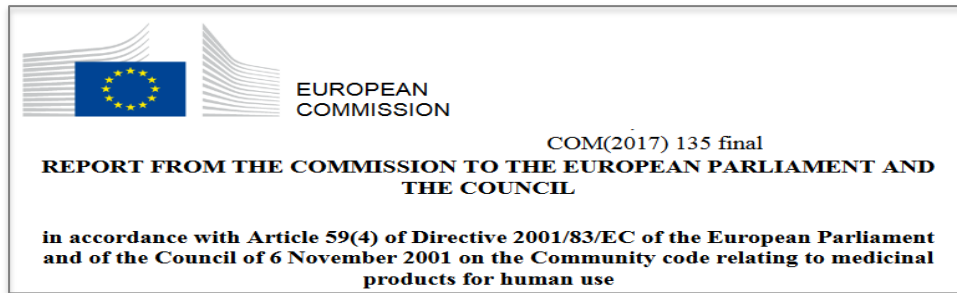- Published on the Commission website, together with the external study reports

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Why ePI? – EU initiatives on PI

EC report on PI

- Adopted and published on 22 March 2017

- Number of recommendations identified

- Scope for improvement within the boundaries of existing legislation

EMA action plan

- Developed and adopted in Q4 2017

- Identified concrete deliverables and timelines

- ePI was given the highest priority (implementation started in 2017)

EUROPEAN COMMISSION

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

ePI formats:

- e-formats bring new opportunities

- Potential **benefits in developing key principles** […] to provide the information to individual EU citizens

- e-formats **should be complementary to paper PL** […] to ensure availability of the information **to all patients**

EC/EMA/HMA joint collaboration:

- Mapping current digital initiatives in EU

- Multi-stakeholder workshop on ePI

- Develop key principles for the use of ePI

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Why ePI? - moving towards digital transformation of health and care

Exploring electronic formats – 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
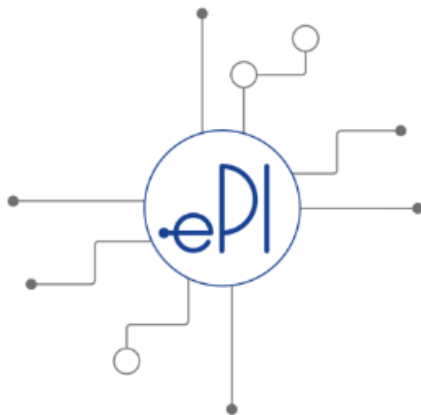
Digital transformation – Why?

- Digitalisation is a priority in the EU
  - Digital Single Market Strategy (2015)
  - Communication on Digital Health & Care (2018)
- Right timing moving towards ePI

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Health Priorities in the Digital Single Market Strategy

European Commission

Give citizens **better access** to their **health data**, everywhere in the EU

Use **digital** services for citizen empowerment and person-centred care

Connect and **share** health data for research, faster diagnosis and better health outcomes

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Source: Commission Mid-Term Review of the Digital Single Market Strategy, May 2017

Commission Communication on
Digital Transformation of Health and Care
COM(2018)233

Secure access and exchange of health data

Data sharing for better reseach and personalised healthcare
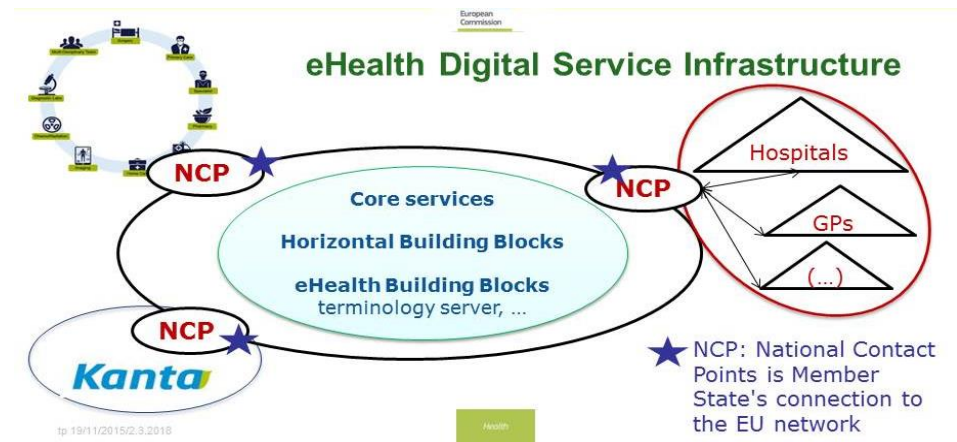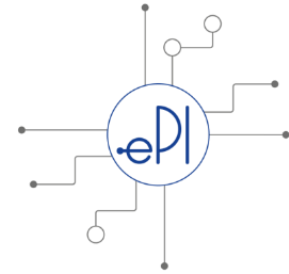
Empowering patients with digital tools
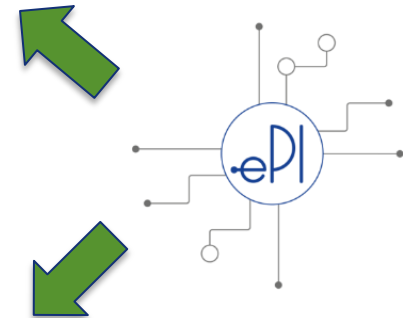
eHealth Digital Service Infrastructure for cross-border exchange of health data

- **ePrescriptions**

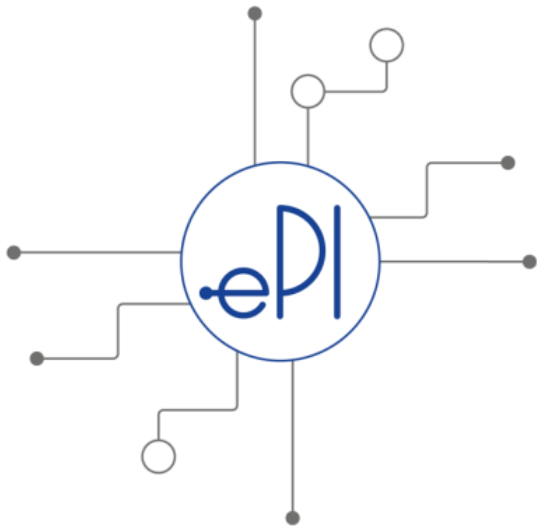- **Patient Summary**

Any questions?

Further information

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

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See websites for contact details

European Medicines Agency www.ema.europa.eu
Heads of Medicines Agencies www.hma.eu
European Commission www.ec.europa.eu

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