Assessment of current shortcomings in the summary of product characteristics (SmPC) and the package leaflet (PIL)

8 March 2016

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*
  - **Readability of PIL/SmPC and possible 'key information' section**
  - **Literature search and stakeholder surveys**
- *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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External studies

- *Carried out by NIVEL (Netherlands institute for health services research) together with University of Leeds*
- *Two studies:*
  - **(1) Study on the PL and SmPC of Medicinal Products for Human use ("PIL-S study")**
  - **(2) Feasibility and value of a possible "key information section" in PL and SmPC of medicinal products for human use ("PILS-BOX study")**

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(1) "PIL-S study"

- *Objectives:*
  - **Assessment of readability and comprehensibility of the PL and the SmPC as sources of information on prescription and non-prescription medicines for patients and health care professionals;**
  - **Assessment of the causes and (potential) consequences of identified shortcomings, and**
  - **Recommendations for improvement of PILs and SmPCs of prescription and non-prescription medicines based on this assessment.**

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(1) "PIL-S study"

- *Methodology:*
  - **Extensive literature research**
  - **European-wide stakeholder survey**
  - **Online discussion forums**

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(1) "PIL-S study" - Outline of recommendations

- *Focus on improvement of PL (language, design, lay-out)*
- *Consider reformulation of guidelines*
  - **good information design**
  - **more flexibility between medicines (information in QRD template)**
  - **consider guideline on translation**
- *Strengthen input from patients*
  - **Iterative user-testing: test changes**
- *Consider best-practice examples of leaflet design (anonymised)*
- *Examine the potential of electronic media*
  - **Explore e-PIL for: highlight relevant information, design, multilingual leaflets**
  - **PIL as part of care process: role of healthcare professionals**
  - **Alerts for changes in PIL to long-term users**

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(2) "PILS-BOX study"

- *Objectives:*
  - **Collect existing evidence on the potential impact of adding a key information section on the safety and efficacy of medicines' use;**
  - **Assess the feasibility of adding a key information section in the context of the European Union legislation;**
  - **Assess the potential cost/efficacy of adding key information in the context of the EU legislation.**

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(2) "PILS-BOX study"

- *Methodology:*
  - **Literature search**
  - **European-wide stakeholders consultation**
  - **An analysis to evaluate the Strengths, Weaknesses, Opportunities and Threats (SWOT analysis)**

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(2) "PILS-BOX study" - Outline of recommendations

- *No mandatory introduction of the Key Information Section (lack of evidence)*
- *Gather further evidence on existing examples*
- *User-testing and wider research*
- *Develop criteria for inclusion of the information in these sections*

Summary of Member States' comments

- *General support for main conclusions and recommendations*
  - **Relevance of topics regardless of some limitations of the studies**
  - **Focus on PL: general support, but some comments point also to areas of improvement of SmPC identified in the study**

- *No need for legislative change*
  - **No mandatory introduction of *key information section***
    - Lack of evidence on methodology and on effects
    - Very challenging to harmonise
      - different products / patient needs / cultures
    - Longer leaflet = potentially less readable leaflet

  - **Enhancement of statutory information to support safe and effective use: considered possible within current legislative framework (article 56 of Directive 2001/83)**
      - 'easily legible' and 'clearly comprehensible'

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Summary of comments *(cont'd)*

- **Keep 'legal function' of 'full disclosure' of undesirable effects and enhance 'communication function'**
  - e.g. work on improvement of communication of risk quantification / frequency categories
  - e.g. explore 'good communication design' within the QRD[1] group
  - keep in mind harmonisation of the template / harmonisation of market
    - but recognise that justified deviations are possible: role of the assessment phase
  - use of electronic formats as structured information (also relevant for SmPC)
    - but keep paper leaflet (inequalities: estimate of 10-15 % not using Internet)

[1]The Working Group on Quality Review of Documents (QRD) provides assistance to the European Medicines Agency's scientific committees and to companies on linguistic aspects of the product information for medicines. This includes summaries of product characteristics, labelling and package leaflets.

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Summary of comments *(cont'd)*

- **Information on benefits: cautious approach**
  - *'compatible with the SmPC', 'useful to the patient'* and *'to the exclusion of any element of a promotional nature'* (art. 62 of Directive 2001/83)
  - a possibility and not requirement
    - cf. QRD guideline: sub-heading *'How X works'*
  - benefit = indication ?
  - to be confirmed by further research

- **User-testing**
  - Supported; emphasis on updates and linguistic versions

- **Best-practice examples**
  - 'Why not?'
  - Consult stakeholders
  - Base selection on evidence

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Publication

- *"PIL-S study": http://ec.europa.eu/health/files/committee/75meeting/pil_s.pdf*
- *"PILS-BOX study": http://ec.europa.eu/health/files/committee/75meeting/pilbx.pdf*
- *Summary of Member States' comments: http://ec.europa.eu/health/files/committee/75meeting/pharm699_6a_pil_and_smpc_doc.pdf*

Thank you!

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Public Health information:
http://ec.europa.eu/health/index_en.htm

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