Assessment report under article 59(4) of Directive 2001/83/EC on the current shortcomings in the SmPC and PL

78th Pharmaceutical Committee
27 March 2017

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

- Summary of Product Characteristics (SmPC)
  - **Article 11 of Directive 2001/83/EC**
- Package Leaflet (PL)
  - **Article 59 of Directive 2001/83/EC**
- Marketing authorisation
  - **Article 8(3)(j) of Directive 2001/83/EC**
  - **Article 6(1) of Regulation (EC) 726/2004**

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SmPC Guideline

- The substance of information **for health care professionals**
- PL is drafted in accordance with SmPC
- To provide advice on **principles of presenting information** in the SmPC
- To read in combination with other related guidance documents (e.g. antibiotics, vaccines or plasma-derived medicinal products etc)

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- **Quality Review of Documents** (QRD) group - advice on SmPC and develops templates

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Packaging Information Guideline

- To implement the provisions of the Directive 2001/83/EC in particular:
  - **Article 57** - requirements regarding labelling (pricing, reimbursement, the legal status for the supply to patient, authenticity and identification)
  - **Article 62 -** requirements regarding additional items included in the labelling (inclusion of symbols or pictograms on the outer packaging and the package leaflet)
- To ensure that these are in conformity with the legislative provisions and are correctly presented

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Readability Guideline

- Published in accordance with **Art 65(c) of Directive 2001/83/EC**
- To ensure that the **information is accessible** and **understandable** by those who receive it and **safe** and **appropriate** use of medicine
- To advice on the **content, design** and **layout concepts** of the labelling and package leaflet
- To set requirements for **Braille** and **formats** suitable for the blind and partially sighted patients
- To apply to all marketing authorisation procedures and to all medicinal products
- To define and recommend:

  type size and font, design and layout of the information, headings, print colour, syntax, style, paper and use of symbols and pictograms etc.

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EC's assessment report


EUROPEAN
COMMISSION

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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)

- Report from the Commission to the European Parliament and the Council on the SmPC and PL for medicinal products for human use
- On 22 March 2017 adopted
- Number of **recommendations** identified on how to improve and better meet the needs of patients and healthcare professionals
- Scope for improvement, but **within the boundaries on existing legislation**

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1. Room for improvement of PL rather than of SmPC

- Improve patient's comprehension and **readability** of the PL
- Issues related with **language complexity**, the **design** and **lay-out** of the PL identified in all patient groups
- Less problems identified in the SmPC
- Healthcare professionals agrees that the current information of the **SmPC is reasonable** and **valuable**
- Space for readability improvement of SmPC

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2. Amendments of Guidelines and QRD templates to enhance readability of PL

- Consider revise the existing guidelines in particular on **content** and **layout** related issues
- Improve **good information design** – content and layout should be jointly considered
- **Language** improvements would help to ensure that PL is "clearly legible" - required by legislation
- Consider more **flexibility** among different medicines in **QRD template**
- Consider introduction of guidance on translations in the existing guidelines

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3. Improving patient input in developing and testing of PLs

- Further improve the **input from patient** and methodology of testing
- Consider to make **user testing** process more **iterative**
- Ensure sufficiently **developed version** of the PL is **user-tested**
- Process coordinated by authorities in parallel to the assessment avoiding disruption of marketing authorisation
- To **focus on the content** rather than on the format and layout
- Consider potential amendments of the Readability Guideline
- Take into account the use of structured benefit-risk approaches

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4. Promotion and exchange of best practice

- Promote **user-tested** best examples of PL design
- Availability for industry on a regularly updated **platform**
- Examples should include, where possible, information on the **process of development**
- Examples should be **evidence based**

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5. Electronic SmPC and PL formats

- Explore the use of **electronic media** in the SmPC and PL
- e-PL **complementary to paper PL** - required by the legislation
- Explore e-PL as an integrated **part of care process**
- Consider as a **tool to inform patients** and **health care professionals** on changes in the SmPC and PL
- Future developments based on existing EMA work
- Multistakeholder approach

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6. Potential "key information" section in the SmPC and PL

- Not specifically envisaged in the existing EU legislation
- More **experience** and **evidence** needs to be gathered
- Testing can be considered as a means to further determine the **potential usefulness**
- The planed testing of adding such section to the *European Public Assessment Report* (EPAR) summary could be used for this purpose
- Possibility to use *Quick Response* (QR) codes

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Summary

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e-News
22/03/2017

Health and Food Safety Directorate General

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Public Health

Commission report recommends improvements to package leaflets

The medicines we buy in the EU contain a package leaflet which should provide us - the user, with clear information on the medicines we are taking – name of the product and the manufacturer, therapeutic indications, dosage, shelf life, adverse reactions, and more. EU rules in place since 2001 ensure this.

Today, the Commission publishes a report to the European Parliament and the Council on current shortcomings in the summary of product characteristics and the package leaflets, and puts forward recommendations on how they could be improved to better meet the needs of patients and healthcare professionals.

Assessment Report

- ✓ Adopted on 22 March 2017
- ✓ Published on the Commission website *https://ec.europa.eu/health/sites/health/files/files/documents/2017_03_report_smpc-pl_en.pdf*
- ✓ Transmitted to the European Parliament and the Council
- ✓ Next steps:
  - the Commission will work on implementation of recommendations with EMA and close collaboration with stakeholders

More information

- ***"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*

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Thank you!

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Public Health information:

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

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