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The Commission report on SmPC and package leaflet for medicinal products for human use

PCWP / HCPWP joint meeting

28 June 2017

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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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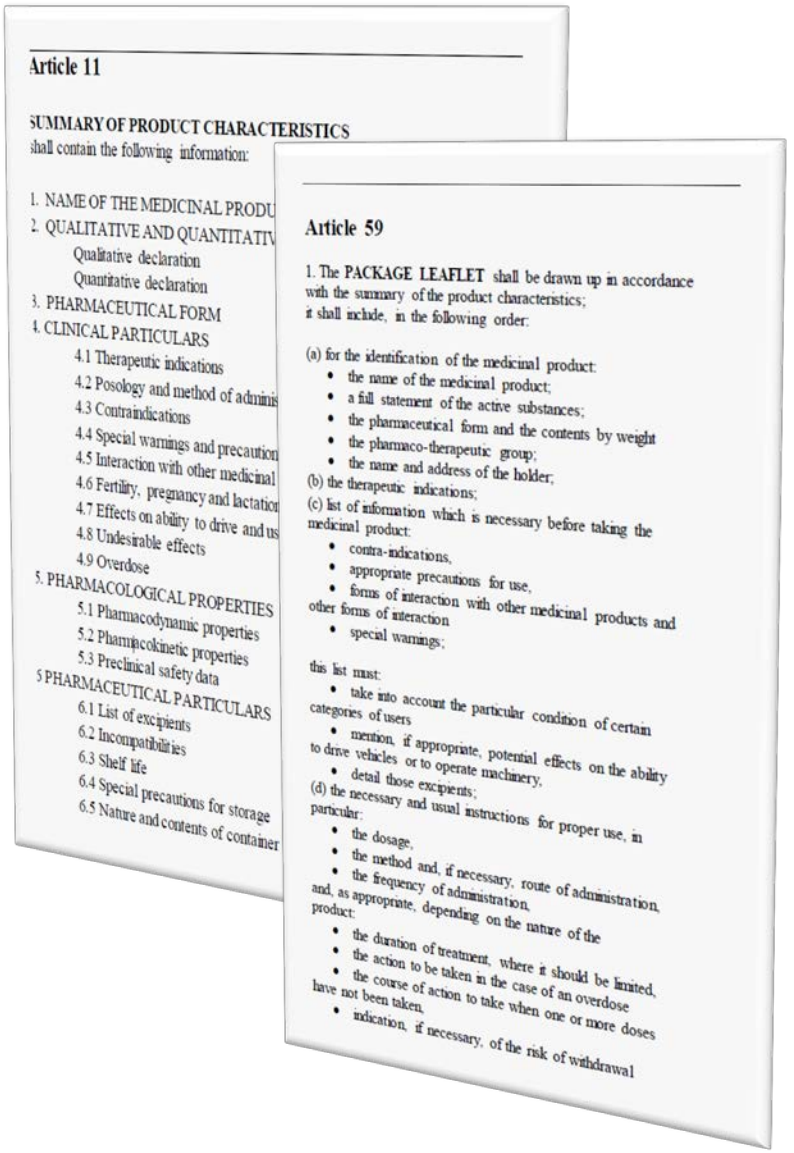
Regulatory Framework

- *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



Article 11

SUMMARY OF PRODUCT CHARACTERISTICS
shall contain the following information:

1. NAME OF THE MEDICINAL PRODU
2. QUALITATIVE AND QUANTITATIV
   - Qualitative declaration
   - Quantitative declaration
3. PHARMACEUTICAL FORM
4. CLINICAL PARTICULARS
   - 4.1 Therapeutic indications
   - 4.2 Posology and method of adminis
   - 4.3 Contraindications
   - 4.4 Special warnings and precaution
   - 4.5 Interaction with other medicinal
   - 4.6 Fertility, pregnancy and lactatio
   - 4.7 Effects on ability to drive and us
   - 4.8 Undesirable effects
   - 4.9 Overdose
5. PHARMACOLOGICAL PROPERTIES
   - 5.1 Pharmacodynamic properties
   - 5.2 Pharmacokinetic properties
   - 5.3 Preclinical safety data
5 PHARMACEUTICAL PARTICULARS
   - 6.1 List of excipients
   - 6.2 Incompatibilities
   - 6.3 Shelf life
   - 6.4 Special precautions for storage
   - 6.5 Nature and contents of container

Article 59

1. The **PACKAGE LEAFLET** shall be drawn up in accordance with the summary of the product characteristics; it shall include, in the following order:

(a) for the identification of the medicinal product:
- the name of the medicinal product;
- a full statement of the active substances;
- the pharmaceutical form and the contents by weight
- the pharmaco-therapeutic group;
- the name and address of the holder;

(b) the therapeutic indications;

(c) list of information which is necessary before taking the medicinal product:
- contra-indications,
- appropriate precautions for use,
- forms of interaction with other medicinal products and other forms of interaction
- special warnings;

this list must:
- take into account the particular condition of certain categories of users
- mention, if appropriate, potential effects on the ability to drive vehicles or to operate machinery,
- detail those excipients;

(d) the necessary and usual instructions for proper use, in particular:
- the dosage,
- the method and, if necessary, route of administration,
- the frequency of administration,

and, as appropriate, depending on the nature of the product:
- the duration of treatment, where it should be limited,
- the action to be taken in the case of an overdose
- the course of action to take when one or more doses have not been taken,
- indication, if necessary, of the risk of withdrawal

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EC's assessment report


EUROPEAN COMMISSION

Brussels, 22.3.2017
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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

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

- Consider revise the existing guidelines (e.g. readability, content and layout related issues)
- Consider more flexibility among different medicines in QRD template (in the framework of the existing legislation)
- 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 the related methodology
- Make user testing process more iterative
- Ensure sufficiently developed version is user-tested
- Process coordinated by authorities in parallel to the assessment avoiding disruption of marketing authorisation

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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
- The best examples 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 and as a tool to inform patients and health care professionals on changes in the SmPC and PL
- Future developments based on existing EMA work with 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
- Current testing can be considered as a means to further determine the potential usefulness
- 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 with EMA and NCA will work on implementation of recommendations in 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!

European Commission Public Health information:

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

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