Summary of Product Characteristics

What is it and what does it contain?

Magdalena Hurkacz

Department of Clinical Pharmacology, Wrocław Medical University

Based on: SmPC Advisory Group, European Medicines Agency

What is the summary of product characteristics (SmPC)?

- The SmPC is a legal document approved as part of the marketing authorization of each medicine.
- The SmPC is the basis of information for healthcare professionals on how to use the medicine.
- Its information is updated throughout the life-cycle of the product as new data emerge.

SmPC: The cornerstone between assessment and information

- The SmPC is the result of the agreed position on the medicinal product, as distilled during the course of the assessment process, before and after marketing authorization.
- The SmPC is the basis of information for healthcare professionals on how to use the medicine.
- Its information is updated throughout the life-cycle of the product as new data emerge.

SmPC: The cornerstones between assessment and information

- Factors which may influence a benefit or a risk in an individual should be clearly described.
- The SmPC has to be updated throughout the life of the product as data emerge.

SmPC and SmPC guideline

- Article 11 of Directive 2001/83/EC defines the content and the order of the SmPC.
- The SmPC guideline advises on the principles of presenting information in the SmPC:
  - Product specific information;
  - Clear and concise language (Public Assessment Report provides detailed information);
  - Advice for use in the core population for whom the medicine is indicated followed – when necessary – by specific information for any relevant special population.

Where SmPC information can be found?

The holder of the marketing authorization shall forthwith supply any new information which might entail the variation of the marketing authorization including the SmPC (EC/726/2004).
Where SmPC information can be found?

- Competent authorities' websites European Medicines Agency
- National Competent Authorities
- Medicines compendia or dictionary
- SmPCs are the main source of information of: Medical and pharmaceutical references
- Electronic prescribing support tools
- All parts of advertising must comply with the SmPC
- The package leaflets are based from SmPC information

Which information can be found in the SmPC?

- Essential information for the use of a medicine

Which information can be found in the SmPC?

- Qualitative and quantitative information on the benefits and the risks
  - Information for individualised care paediatric and elderly population
  - Organ impairment, concomitant disease
  - Interaction with other medicines
  - Genomic factors
  - Pregnancy, lactation and fertility
  - Composition of the medicine: prevention of hypersensitivity and excipients with known effects
  - Information on specific situations
- Pharmaceutical information

Structure of the information within the SmPC

- Information is presented according to a predefined structure

- Certain information is suitable in different sections but cross-references are made to avoid repetitive information

How to use SmPC in practice?

- Information is presented according to a predefined structure
- Information for individualised care paediatric and elderly population
- Certain information is suitable in different sections but cross-references are made to avoid repetitive information

- Pregnant, lactation and fertility
- Composition of the medicine: prevention of hypersensitivity and excipients with known effects
- Information on specific situations
- Pharmaceutical information
The **therapeutic indication(s)** of the medicine is given in section 4.1, in defining the target disease and the population to benefit from the medicine.

The **dose** is specified in section 4.2 "**Posology and method of administration**" for each indication(s) and each relevant subpopulation (e.g. depending on age, concomitant disease):

- With information on frequency of intake, influence of food, duration of treatment,
- Advice on dose adjustment (e.g. to optimise the benefits according to patient's response or to limit the risk e.g. in relation to drug interactions),
- Additional information on dosing as necessary (e.g. need for dose titration or tapering off, maximum recommended dose, action to be taken if an intake is missed)

Section 4.2 also informs on the **method of administration**, which information can be complemented with special instructions for handling the medicine in section 6.6.

The situations where the medicine **must not be used for safety reasons** are outlined in section 4.3 "**Contraindications**. They define the **patient populations** who must not take the medicine.

Section 4.4 on "**Special warnings and precautions for use**" provides information on:

- Risks requiring a precaution for use prior or during treatment (e.g. monitoring);
- Special patient groups that are at increased risk;
- Risks to which healthcare professionals need to be alerted to prevent or handle occurrence.

Information for individualized care

The information in the SmPC first addresses the recommendations that apply to the general population for whom the medicine is indicated.

- Because the characteristics of some subpopulations e.g. age, concomitant disease, genomic factors, ... may demand specificity in the use of the medicine, the SmPC provides dedicated information for these groups of patients when information is available.
- Such information is usually presented under specific subheading within each relevant section of the SmPC.
Samples

**Elderly population**
- Similarly, information in the elderly population may be presented in subsections when clinically relevant differences are known e.g. need for dose adjustment, specific risks, metabolism,...

**Paediatric population:**
- Children are a specific subpopulation and a difference in the use of the medicine is common for this group or some subsets. Therefore, the SmPC requires mandatory information in several section of the SmPC e.g. sections 4.2, 4.4, 4.5, 5.1,... to address the appropriate use in children.

**Interaction with other medicinal products**
- Related special warnings or precautions for use are presented under subheading in section 4.4.
- Information on possible dose adjustment required are provided in section 4.2 and contraindications in section 4.3

**Organ impairment, concomitant diseases**
- Hepatic and renal impairment
  - Patients with hepatic or renal impairment may be subject to dose adjustment due to potentially altered drug metabolism or excretion.
  - Information on possible dose adjustment required are provided in section 4.2 and the differences in pharmacokinetic profile in section 5.2

**Concomitant diseases**
- Related special warnings or precautions for use are presented under subheading in section 4.4.
- Information on possible dose adjustment required are provided in section 4.2 and contraindications in section 4.3

**Interaction with other medicinal products and other forms of interaction (section 4.5)**
- Interactions with other medicines are presented in section 4.5 and recommendations on posology adjustment, precautions for use or contraindications are also reflected in sections 4.2, 4.4 or 4.3 respectively;
Samples

Genomic factors

- Pharmacogenomics (PGx) is defined as the study of variations of DNA and RNA characteristics as related to drug response. The knowledge in this field is ever increasing with the potential to improve the discovery, development and use of medicines.
- When available and clinically relevant, information regarding specificity due to pharmacogenomics are presented in the SmPC e.g. indication or posology, dose adjustment, contraindication, safety information.

Pregnancy, lactation and fertility (section 4.6)

- Pregnancy and lactation
  - Section 4.6 provides available information regarding the use of the drug during pregnancy and recommendations on the use or not of the medicine during pregnancy. Recommendation on the need to stop or continue breastfeeding while on the medicine is also provided.

Pregnancy, lactation and fertility (section 4.6)

- Need for contraception
  - In case of a need of contraception during and/or after treatment, the information will be provided along with the rationale behind the recommendation
- Fertility
  - When there is a possible effect of the drug on male and female fertility, clinical data if available as well as relevant conclusions are provided

How is the information prepared?

What is not included in the SmPC?

- Detailed information on the scientific development which is available in the public assessment report
  - Information in non-approved indication
    - Because the MAH has not claimed the indication
    - An indication has been claimed but data did not demonstrate a positive benefit risk of the medicine; withdrawal or refusal AR provide available data.
    - Exception in the paediatric group; the Paediatric Regulation aims to improve the information regarding this subgroup by providing all information on clinically relevant trials

What is not included in the SmPC?

- Detailed information on the scientific development which is available in the public assessment report
  - Specific issue for which data is lacking;
  - General advice on the treatment of particular medical conditions.
How can you help maintain the best quality of information?

- The SmPC is a living document that requires update when new relevant information emerges e.g.:
  - New adverse reactions observed after marketing of the product reported to the national competent authorities or the company;
  - Following safety communication updates.

How can you help maintain the best quality of information?

- The new European pharmacovigilance legislation encourages participation of patients and healthcare professionals in reporting suspected adverse reaction.

Where to find more information?

- European Medicines Agency
- EudraSmPC
  - http://eudrasmpc.eudra.org/
  - SmPC guideline
  - Information on benefit-risk of medicines: patients’, consumers’ and healthcare professionals’ expectations
- Ask EMA

Annex: Summary of the scope of the 2009 update of the SmPC guideline

- Reinforcement of principles for presenting clear and concise information
- Some other changes:
  - Guidance on the presentation of pharmacogenomic data
  - 2: excipients listed should be stated qualitatively and quantitatively
  - 4.2: divided into two subsections, “Posology” and “Method of administration”
  - 4.6: update according to CHMP/SWP guideline on human reproduction and lactation
  - 4.7: Distinction introduced between “minor influence” and “moderate influence”
  - 4.9: clearer recommendation for information on monitoring
  - 5.1: specific standard statement for biosimilar medicinal product
  - 5.3: Environmental Risk Assessment (ERA)
  - 6.1: “Authentication factor”