



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Summary of product characteristics (SmPC)

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What is it and what does it contain?





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## What is the summary of product characteristics (SmPC)?

- The SmPC is a legal document approved as part of the marketing authorisation 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



## 2. Where SmPC information can be found?

### I. Competent authorities' websites

- I. [European Medicines Agency](#)
- II. [National Competent Authorities](#)

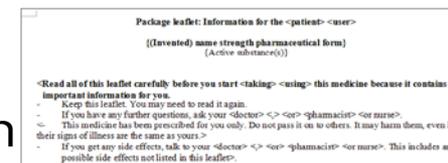
### II. Medicines compendia or dictionary

### III. SmPCs are the main source of information of:

- I. Medical and pharmaceutical references
- II. Electronic prescribing support tools

### IV. All parts of advertising must comply with the SmPC

### V. The package leaflets are based on SmPC information



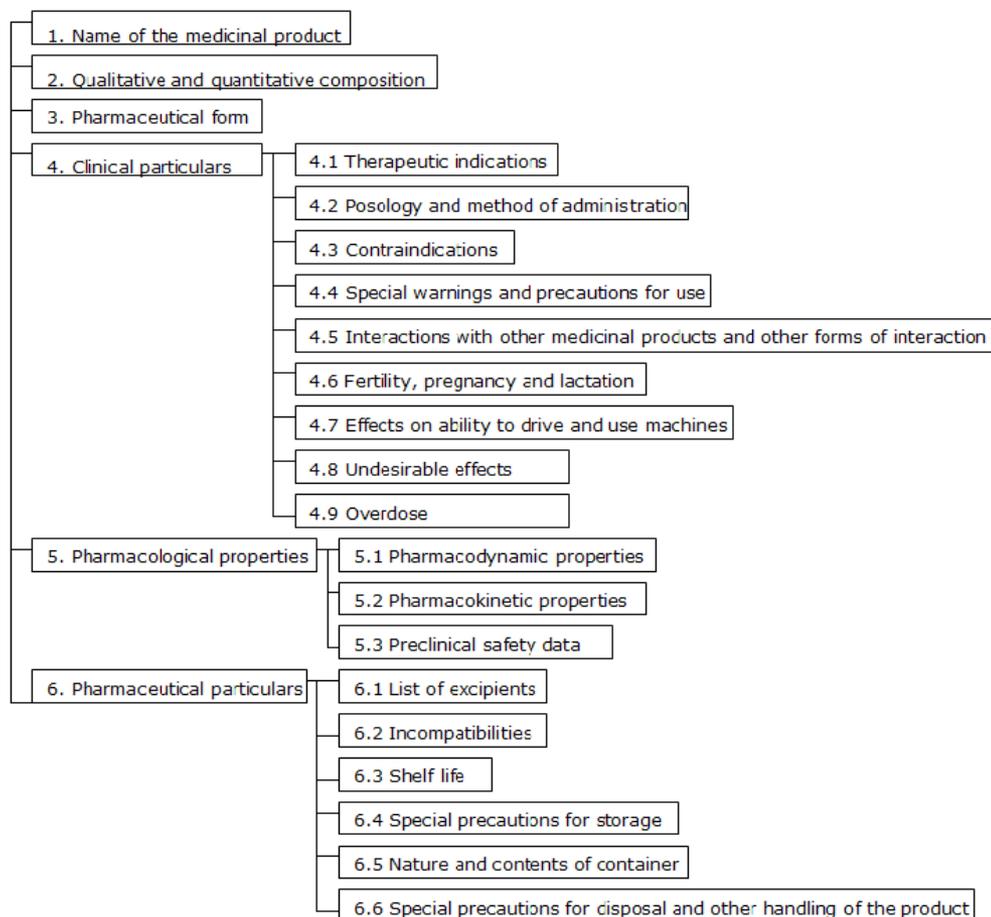


### 3. Which information can be found in the SmPC?

- Essential information for the use of a medicine
- 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



## 4. Structure of the information in the SmPC



Information is presented according to a predefined structure

Some information may be suitable in different sections but cross-references are made to avoid repetitive information



## 5. Essential information for the use of the medicine (1/2)

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 can be complemented with special instructions for handling the medicine in section 6.6



## 5. Essential information for the use of the medicine (2/2)

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



## 6. Information on the benefits of the medicine

Section 5.1 “**Pharmacodynamic properties**” summarises the benefits of the medicine in presenting:

- Its mechanism of action
- The main results of the clinical trials supporting the marketing authorisation
  - In giving the main characteristics of the patient population studied
  - And presenting the effects qualitatively and quantitatively
- Additional clinically relevant information in special populations:
  - In a balanced way (i.e. informing on uncertainties as appropriate)
  - Including study results in the paediatric population, even if the product is not (yet) indicated, to improve information available on the use of medicine in the various paediatric populations



## 7. Information on the risks of the medicine

- Section 4.8 “**Undesirable effects**” provides:
  - A summary of safety profile of the medicine informing on the most serious and/or most frequently occurring adverse reactions
  - A tabulated list of all adverse reactions with their respective frequency category, presented according to a standard system organ classification
  - Information characterising specific adverse reaction which may be useful to prevent, assess or manage the occurrence of an adverse reaction in clinical practice
  - Information on clinically relevant differences in special population
- Information on a specific risk is also reflected in section 4.4 “**Special warnings and precautions for use**” when the risk leads to a precaution for use or when healthcare professionals have to be warned of this risk



## 8. Information for individualised care (1/8)

- 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

*Information on the most frequent subpopulations is illustrated in the next slides*



# Paediatric and elderly population (2/8)

## 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 sections of the SmPC e.g. sections [4.2](#), [4.4](#), [4.5](#), [5.1](#), to address the appropriate use in children

## 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,...



# Organ impairment, concomitant diseases (3/8)

## 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) (4/8)

- 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, if any
- Information on the interaction with food and drinks is provided in section 4.5 as well as [4.2](#) if appropriate



## Genomic factors (5/8)

- 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) (6/8)

## Pregnancy

- 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

## 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



## Composition of the medicine: prevention of hypersensitivity and excipients with known effects (7/8)

Hypersensitivity reactions due to the content of the medicine are handled in the SmPC by:

- Explicitly listing the composition of the medicine i.e. active ingredients and all excipients in section [6.1](#)
- Highlighting the excipients with known effects in sections [2](#) and [4.4](#) with a description of their risk
- Providing information on possible residues that could be present in the medicine in sections [2](#), [4.3](#), [4.4](#) and [4.8](#) with the appropriate related information



## Information on specific situations (8/8)

### Effects on ability to drive and use machines (section 4.7)

- Based on the safety profile of the drug, information on the influence of the medicine on the ability to drive and use machine is provided and depending on the level of influence, appropriate warnings for use will also be provided in section 4.4

### Overdose (section 4.9)

- In case of overdose, section 4.9 provides information on the symptoms and description of the management



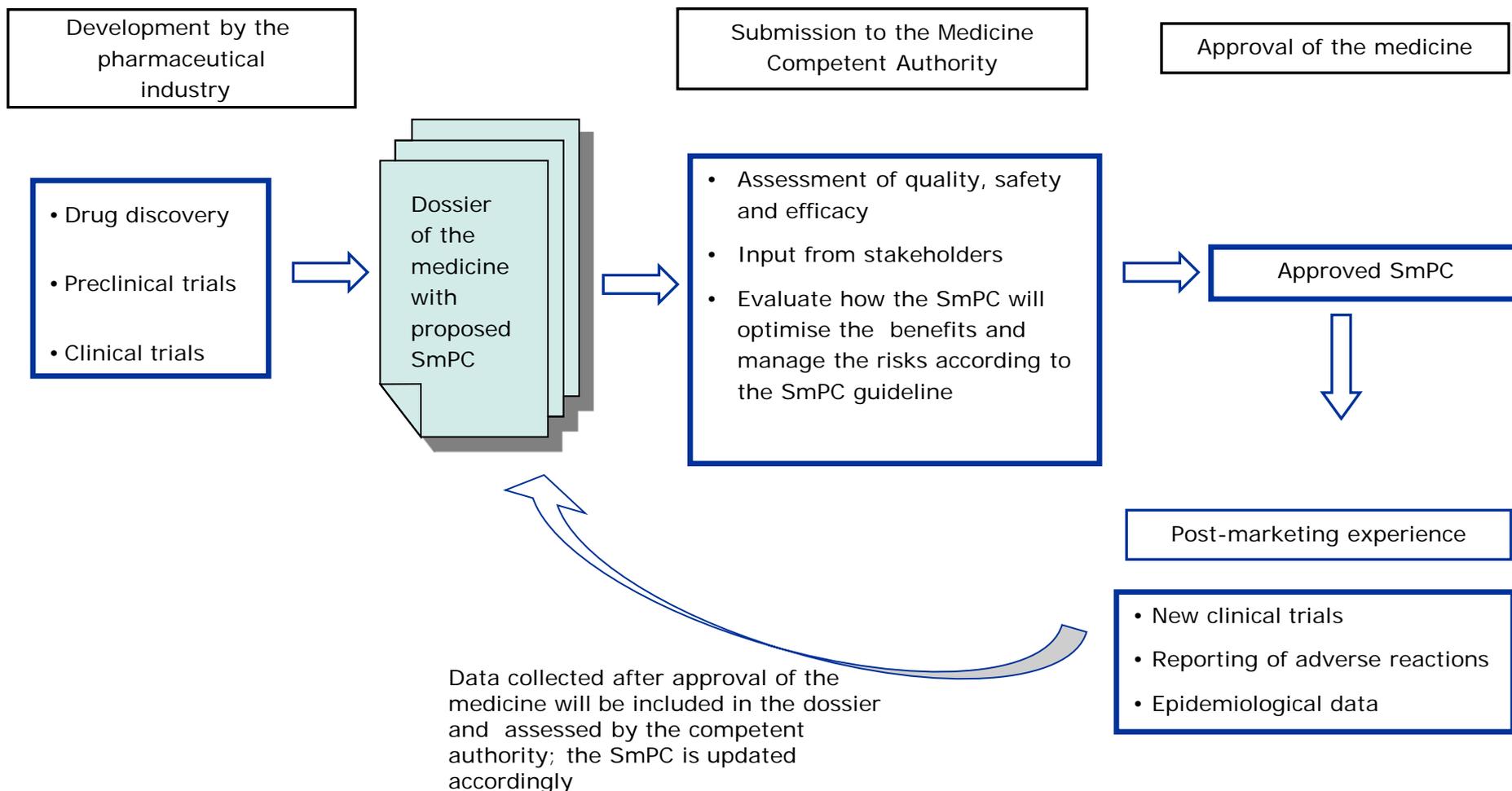
## 9. Pharmaceutical information

In addition to the clinical and pharmacological information, the SmPC also provides pharmaceutical information:

- Incompatibilities, section 6.2
  - Provides information on physical and chemical incompatibilities of the medicine and the products with which the medicine is likely to be co-administered with
- Shelf life, section 6.3
  - Information on shelf life as packaged and if appropriate, information on shelf life after reconstitution is given
- Precautions for storage, disposal and handling, section 6.4 and 6.6 respectively
  - Brief explanation on the recommended storage conditions and the measures to take in regards to the disposal or handling of the medicine e.g. reconstitution



# 10. How is the information prepared?





## 11. 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
- Specific issue for which data is lacking
- General advice on the treatment of particular medical conditions



## 12. 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
- The new European pharmacovigilance legislation encourages participation of patients and healthcare professionals in reporting suspected adverse reactions





## 13. Test your knowledge on the SmPC click on the right box

Why is the SmPC an essential source of information on a medicine?

- It is an integral part of the marketing authorisation
- The information provided in the SmPC is validated by competent authorities
- Information kept up to date
- Basis for the preparation of the package leaflet and advertisement
- Evidence-based scientific information
- Legal document



## 13. Test your knowledge on the SmPC click on the right box

Where can you find information on the composition of the medicine?

- Section 1 "Name of the medicinal product"
- Section 2 "Qualitative and quantitative composition"
- Section 3 "Pharmaceutical form"
- Section 4.4 "Special warnings and precautions for use"
- Section 6.1 "List of excipients"



## 13. Test your knowledge on the SmPC click on the right box

Where can you find information on the appearance of the medicine?

- Section 1 "Name of the medicinal product"
- Section 2 "Qualitative and quantitative composition"
- Section 3 "Pharmaceutical form"
- Section 4.2 "Posology and method of administration"
- Section 6.6 "Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product"



## 13. Test your knowledge on the SmPC click on the right box

Where to find efficacy information?

- Section 4.1 "Therapeutic indications"
- Section 4.7 "Effects on the ability to drive and use machines"
- Section 4.8 "Undesirable effects"
- Section 5.1 "Pharmacodynamic properties"



## 13. Test your knowledge on the SmPC click on the right box

Which type of safety information can be found in the SmPC?

- Information on situations where the product must not be used for safety reasons are given in Section 4.3 “Contraindications”
- Information on specific risks are given in Section 4.4 “Special warnings and precautions for use”
- Information on interactions are provided in Section 4.5 “Interactions with medicinal products”
- Information on safety information regarding the use of the medicine during pregnancy are stated in Section 4.6 “Pregnancy, fertility and lactation”
- Adverse reactions of the medicines are given in Section 4.8 “Undesirable effects”



## 13. Test your knowledge on the SmPC click on the right box

Where may information on safety monitoring be found?

- Section 4.1 "Therapeutic indications"
- Section 4.2 "Posology and method of administration"
- Section 4.3 "Contraindications"
- Section 4.4 "Special warnings and precautions for use"
- Section 4.5 "Interaction with other medicinal products and other forms of interaction"



## 13. Test your knowledge on the SmPC click on the right box

Where to find dose recommendation for an individual patient (e.g. a patient with renal impairment)?

- Section 4.1 "Therapeutic indications"
- Section 4.2 "Posology and method of administration"
- Section 4.3 "Contraindications"
- Section 5.2 "Pharmacokinetics properties"



## 14. Where to find more information?

- European Medicines Agency: <http://www.ema.europa.eu>
- [SmPC guideline](#)
- [Information on benefit-risk of medicines: patients', consumers' and healthcare professionals' expectations](#)
- [Ask EMA](#)



Thank you for consulting this  
training presentation

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SmPC Advisory Group