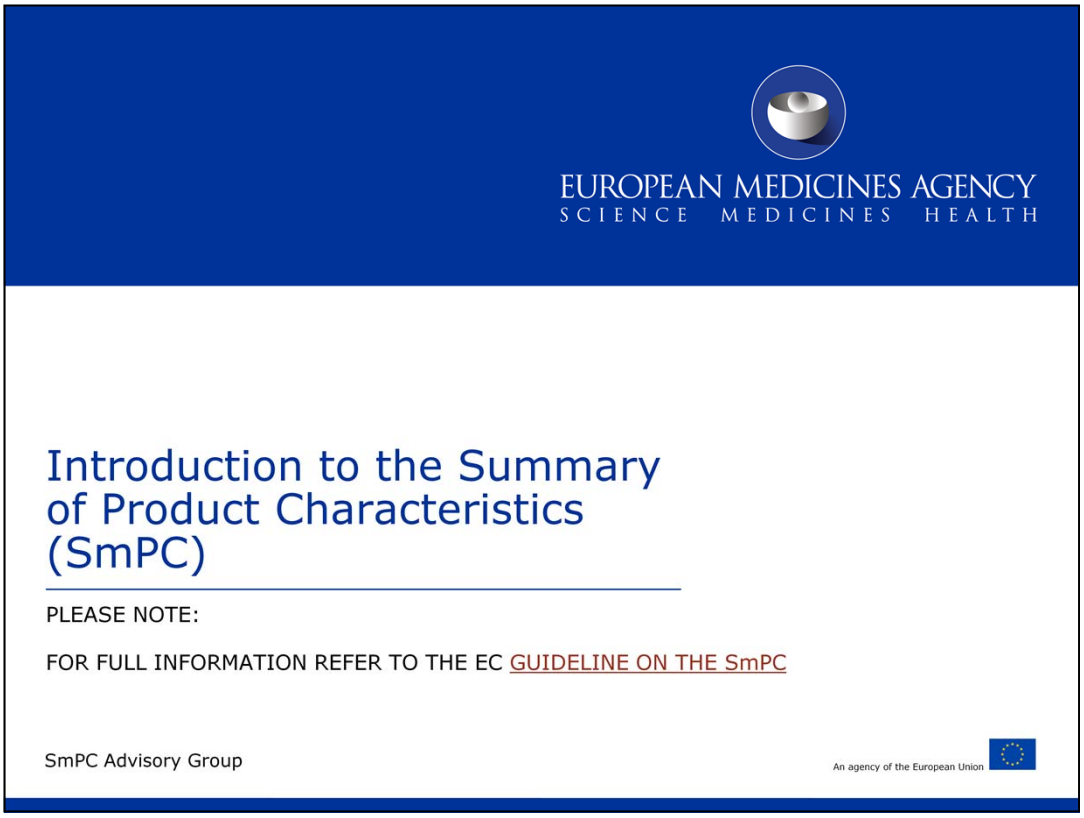
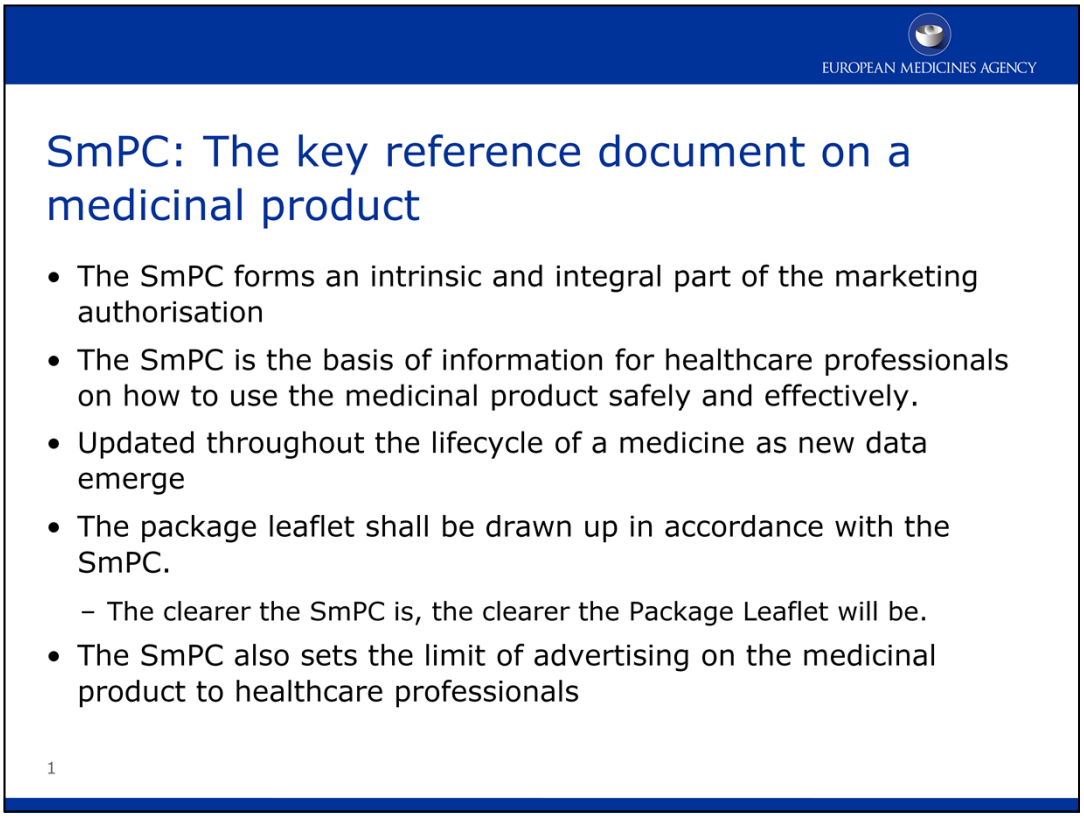


This video has been prepared by the SmPC AG and consists in a general introduction to the Summary of Product Characteristics



The Summary of Product Characteristics (or SmPC) is the most important regulatory document on a medicinal product in the European Union because it is part of the marketing authorisation of a medicinal product and represents the basis of information for healthcare professionals on how to use the medicinal product safely and effectively. For this purpose, it is a living document, updated throughout the lifecycle of the medicinal product as new efficacy or safety data emerge. The SmPC is also the reference document for preparing the package leaflet and therefore represent a key step in the provision of information to patients.

Finally, it sets the limit of advertising on the medicinal product to healthcare professionals.

It is therefore of utmost importance to ensure that information presented in SmPC are of high quality.

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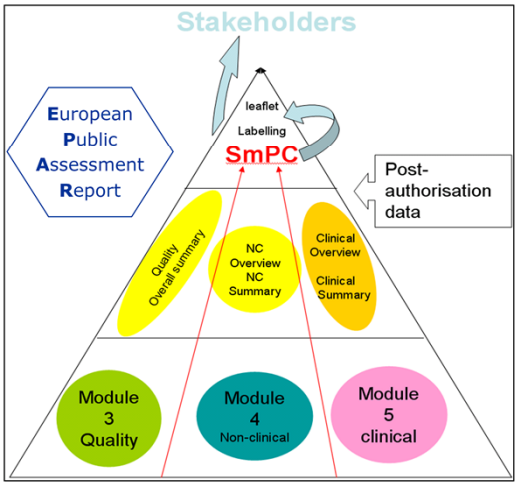
SmPC: The cornerstone between assessment and information

- The scientific assessment should evaluate how the SmPC will optimise the benefits and manage the risks.
- The SmPC is the agreed position on the medicinal product, as distilled during the course of the assessment process, before (and after) marketing authorisation.
- Detailed information and benefit-risk assessment is provided in public assessment report



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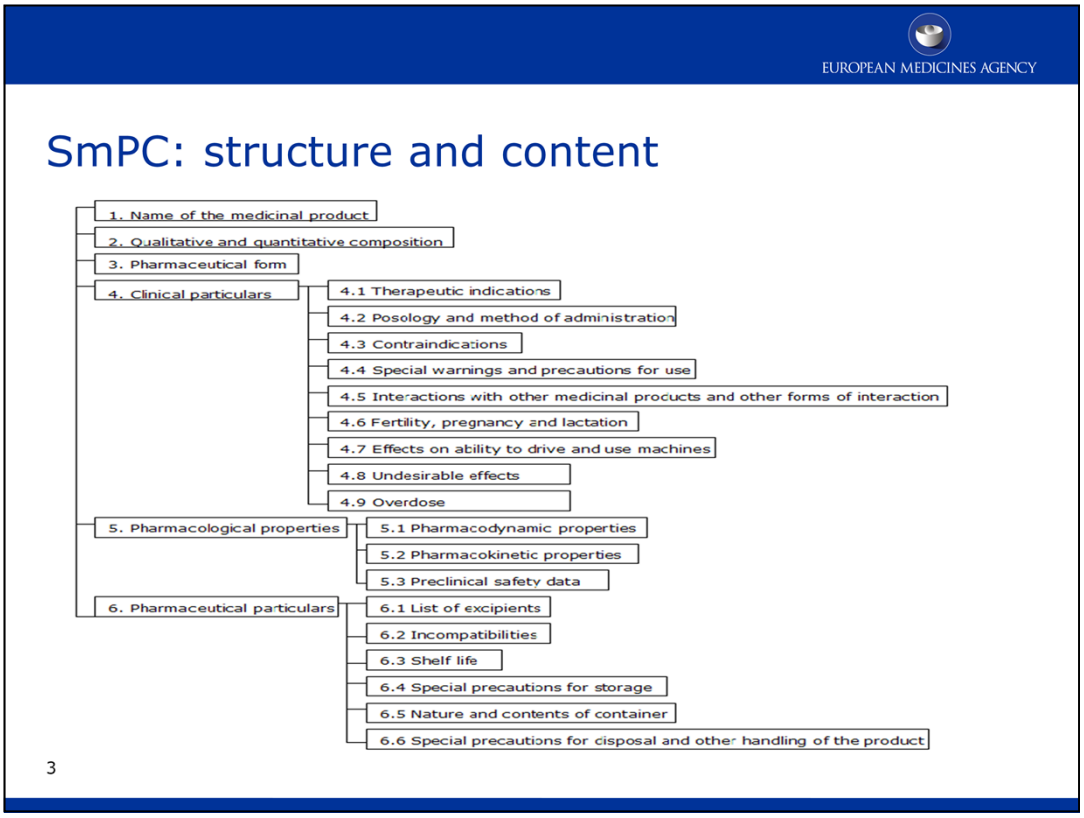
The SmPC is initially drafted by the applicant based on the results of the studies performed to support a marketing authorisation. The applicant should explain in its application how the SmPC will optimise the benefits and manage the risks. Competent Authorities will review the proposal during the assessment process before adopting it as part of the marketing authorisation. This assessment of the SmPC is reflected in the public assessment report of marketing authorisation application together with detailed information on studies performed during the development and the overall benefit risk assessment of the medicinal product. Because of its clinical orientation, the SmPC should be brief and concise, and it is recommended to end it with a link to the website of the competent authority having granted the authorisation for faciliating healthcare professionals' access to the detailed information of the public assessment report when necessary.

During the assessment, competent authorities will also ensure that the information of the SmPC has been appropriately translated into lay language for the patient in the package leaflet.

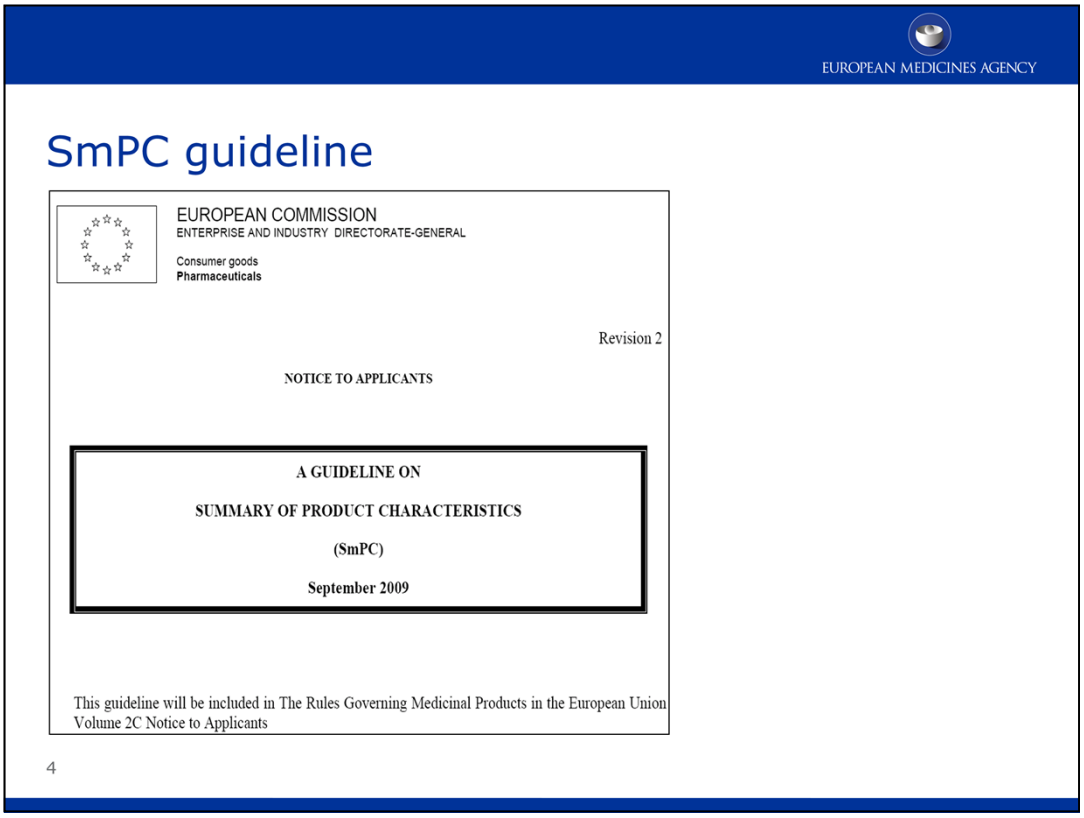
After authorisation, the SmPC should be kept updated as data emerge.

The SmPC is therefore the regulatory cornerstone to provide users with evidence-based information on a medicinal product.



The structure and content of the SmPC is defined by the European pharmaceutical legislation which allows to provide healthcare professional with a standard and harmonised format of information for all medicinal products authorised in the EU. The first sections provide brief information on the name, composition and pharmaceutical form of the product. The clinical particulars present the therapeutic indications, the dosage recommendations and safety information. They are complemented with information on the pharmacological properties of the medicine, which are relevant to health-care professionals, taking into account the approved therapeutic indication(s) and the potential adverse drug reactions. Finally, the pharmaceutical particulars are presented before few sections on regulatory information such as the name of the marketing authorisation holder.

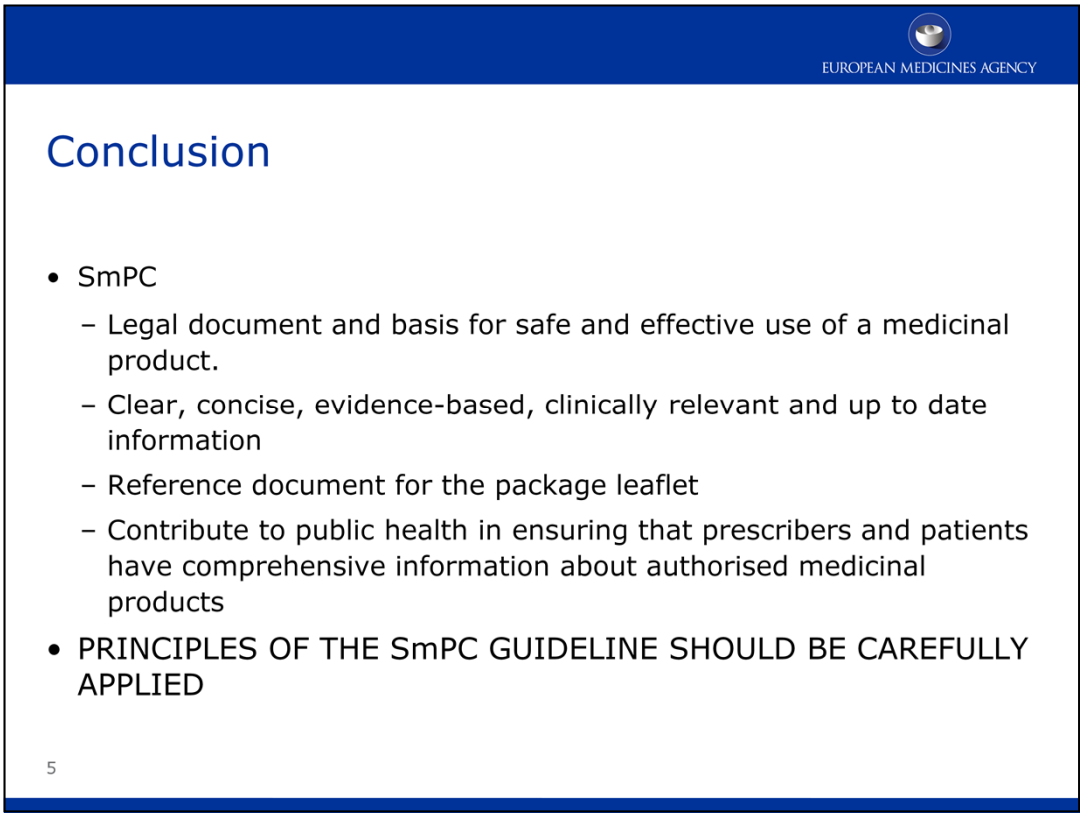
To facilitate the search of information, the integrity of each section of the document should be maintained by only including information which is relevant to the section heading. Sometimes, certain information could be suitable for several sections, in such cases, best use of cross-references should be made to avoid repetitive information.



SmPC should be drafted by applicant and reviewed by competent authorities according to the European Commission guideline on summary of product characteristics.

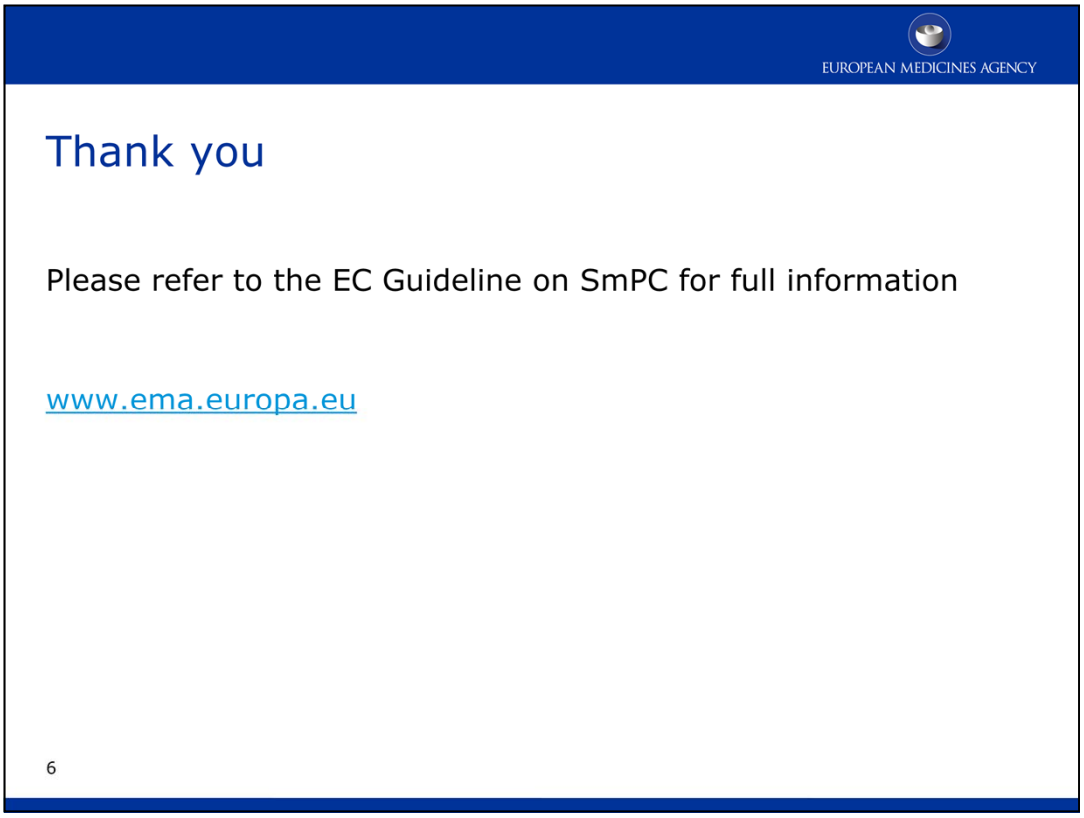
This guideline provides advice on the principles of presenting information in the SmPC. Compliance with the guideline is of utmost importance to ensure readability of the SmPC in order that SmPC fulfills its objective to be the basis for safe and effective use of the medicinal product. On top of specific recommendation for each section, the guideline present key direction to ensure for the whole SmPC, in particular:

- Information should be product specific and it is not in the remit of the SmPC to give general advice on the treatment of particular medical conditions.
- The SmPC should be worded in clear and concise language, using consistent terminology throughout the document.
- Each section of the SmPC should first deal with those issues that apply to the core population for whom the medicine is indicated followed - when necessary – by specific information for any relevant special population (e.g. children or elderly).



To conclude, the SmPC is a key legal document, and basis for the safe and effective use of a medicinal product. The information is aimed at healthcare professionals in their daily practice, it is therefore essential for the information to be clear, concise, evidence-based, clinically relevant and up to date to ensure optimal use of the medicine. It is also used to prepare information addressed to patients. The SmPC is therefore a key document contribute to public health through provision of information on the benefits and the risks of a medicinal product.

To ensure that the SmPC meet the needs of healthcare professionals and facilitate preparation of information addressed to patients in the package leaflet, the principles of the SmPC guideline should be carefully applied.



Thank you for viewing this video.

For full information on how to present information in the SmPC, please refer to the European Commission guideline on Summary of product characteristics.

This guideline may be found on the European Medicines Agency website together with further training material prepared by the SmPC AG.