



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public webpage on summary of product characteristics (SmPC)

PCWP-HCP WG joint meeting, 28 February 2012

Laurent Brassart
Medical Information – Information Compliance and Consistency

An agency of the European Union





Background

- Information on benefit-risk of medicines: patients', consumers' and healthcare professionals' expectations (10/07/2009)
 - To optimise regulatory information
 - SmPC Guideline implementation plan
 - Revision of the template of package leaflet
 - EPAR usability project
 - To inform about the role of the regulatory authorities
(e.g. where to find information on benefits and risks, where data come from)
- Involvement of Patients and Healthcare Professionals Organisations in the review of SmPC and package leaflet



SmPC implementation plan



Welcome to EudraSmPC

This website helps you review SmPCs (Summary of Product Characteristics) – in line with the SmPC Guideline. You can get advice from the SmPC Advisory Group by submitting a query form or by searching the database. And you can access training presentations and useful links.

Key Documents

- SmPC Guideline
- Guideline on excipients
- Annex II advanced therapy regulation
- Scientific guidelines with SmPC recommendations:
 - Quality and Biologicals
 - Non-clinical
 - Clinical efficacy and safety

Links

- EudraLex
- QRD
- Herbal Medicinal Products
- Centrally authorised products
- European Medicines Agency
- HMA

SmPC Advisory Group

- Mandate and Rules of Procedure
- List of Members
- CHMP SmPC Implementation Plan

Training Presentations

Introduction to SmPC Guideline			
Presentation User Guide	1. Name of medicinal product	2. Qualitative and quantitative composition	3. Pharmaceutical form
4.1 Therapeutic indications	4.2 Posology & method of administration	4.3 Contraindications	4.4 Special warnings & precautions for use
4.5 Interactions	4.6 Fertility, Pregnancy and Lactation	4.7 Effects on ability to drive and use machines	4.8 Undesirable effects
4.9 Overdose	5.1 Pharmacodynamic Properties	5.2 Pharmacokinetic Properties	5.3 Preclinical safety data
6. Pharmaceutical particulars	Section 7-12	Paediatrics	Pharmacogenomics

SmPC Advisory Group Query and Search

Do you have a specific SmPC related query?

We will be pleased to advise you, within a short timeframe, on all matters relating to the SmPC Guideline (e.g. on the application of the guideline for a specific SmPC)

[click here](#)

Search database of previous advice

[click here](#)



A cost-effective tool to facilitate harmonised review of SmPC within the regulatory network



Why a public access to the webpage?

- Share training material with pharmaceutical industry
- Support Healthcare Professional or Patients Organisations' involvement in the review of SmPC or Package leaflet
- Increase HCPs' knowledge on SmPC
- Contribute to public awareness of regulatory information



Future public webpage

- Same content as EudraSmPC webpage except Query&Answer system which supports regulatory review process.
 - Update of training presentations + on-demand webinars
- New presentations:
 - “SmPC: what is it and what does it contain?”
 - A draft presentation is being circulated for your input
 - Future presentations
 - *Package Leaflet*
 - *Elderly population and SmPC information*
 - *Other suggestions?*