EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Implementation plan of the Summary of Product Characteristics (SmPC) guideline

Adopted by CHMP February 2009

Introduction

The CHMP workplan 2008-2010 asks for revision and reinforcement of the implementation of the guideline on Summary of Product Characteristics (SmPC).

The main objectives of the revision, which was adopted by the CHMP in November 2008, were to reflect new requirements in relation to the paediatric regulation and to clarify guidance for some sections e.g. section 4.8 on undesirable effects.

In parallel to the revision, it has been observed that in practice SmPCs of medicinal products may present some divergences with the principles of the guideline. For example, the CHMP and the Pharmacovigilance Working Party has noted the complexity of information in section 4.8 of some antiretroviral products and vaccines, and, also expressed concerns on the consequential effects on the package leaflet.

The external consultation of the draft revision of the guideline has confirmed that stakeholders consider the guideline of benefit for the healthcare community and patients, and, look for a realistic implementation, in particular for already authorised medicinal products.

The present plan has been prepared to facilitate a harmonised and timely implementation of the SmPC guideline.

Implementation plan

The objectives of the implementation plan are to increase awareness and harmonised application of the SmPC guideline by all involved parties, including assessors, scientific administrators, Committees and working parties' members, and, pharmaceutical industry.

The implementation plan encompasses communication and training activities, measures to ensure compliance with the SmPC guideline and supportive tools.

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Communication an training activities

The SmPC guideline should be published and actively distributed to all relevant parties (see details in action plan).

Trainings should be organised to assessors and scientific administrators.

Training materials should be made available for long term use.

Organisation of workshop or web-based training with organisations such as DIA or TOPRA should also be explored as part of communication on the guideline to pharmaceutical industry.

Measures to ensure compliance

To ensure a consistent application of guidelines and to facilitate communication between applicants and regulators, the scientific and linguistic reviews of product information should be combined by the product team leader in a single set of comments *(already performed with PIM)* for agreement by the Rapporteur before adoption by the CHMP. QRD comments should be addressed to the attention of the product team leader.

Compliance with the SmPC guideline should be ensured prospectively for new marketing authorisations. For existing marketing authorisation, update of SmPCs should be undertaken in a pragmatic way keeping in mind the key objective of the SmPC, i.e. to ensure safe and effective use of medicines. Compliance with the SmPC guideline should be reviewed in case of application for extensions of indications or for renewal of marketing authorisations. However, it should not substitute for the marketing authorisation holder's obligation to update marketing authorisation throughout the life of the product by variation procedure as data emerge. Compliance should also be considered in case of variations based on new efficacy or safety data (in particular from paediatric clinical studies or in relation with a risk management plan) are submitted. The CHMP may at any time ask the marketing authorisation holder to update the SmPC if considered necessary to ensure safe and effective use of the medicine.

Supportive tools

Product team members or (co-) rapporteur's team member may at any time seek support from a *"virtual" SmPC advisory group*. The group will be responsible for promoting and facilitating the SmPC guideline implementation plan. It be composed of one representative from CHMP, PhVWP, PDCO, QRD, EMEA project managers together with the Chair of the Ad-Hoc SmPC group. CMD(h) is also welcomed to be represented. The main tasks of the group will be to provide advice on any matter related to the implementation of the SmPC guideline (e.g. need of or timing for updating SmPC, cross-product harmonisation, specific query on the text of an SmPC) and to prepare a report on the activities related to the implementation after 2 years of experience. In addition, the group may be invited to participate in training activities. The EMA Medical Information Sector (MIS) will coordinate and support the activities of the group. The group will communicate by email or teleconference/Vitero **only**.

Communication and dissemination of information related to the SmPC guideline and its implementation plan will be provided through a *Eudra SmPC webpage*, maintained by MIS and accessible to EMEA and National Competent Authorities. It will provide access to all related information, including:

- The SmPC guideline and its implementation plan;
- Training material such as a presentation summarising main changes and key aspects of the SmPC guideline, and/or e.g. video recording of training session(s);

- A list of other guidance documents providing recommendations on product information (e.g. core SmPC or relevant WP's guideline)*;*
- Links to other reference documents on product information (e.g. QRD templates).

The Eudra SmPC webpage will also be used as communication tool to ask advice to the SmPC advisory group. For example, a contact form will be available. Upon receipt of the query, MIS will prepare a draft answer for agreement by the coordination group. The final answer should be given within 5 working days. The webpage will provide an historical record of the advices given.

Action Plan

Activity	Deadline
Training	
- Preparation of training material	2Q2009
- List of guideline documents providing additional recommendations on SmPC	3Q2009
- Presentation of the SmPC guideline to assessor training	*date tbc*
- Presentation on specific aspect of the SmPC guideline at ad-hoc trainings upon WP's request	from 3/4Q2009
- Presentation of the SmPC guideline to EMEA scientific administrator	3/4Q2009
- To explore the organisation of workshop or web-based training with organisations such as DIA or TOPRA	3/4Q2009 – 2010
Process activities	
- Composition of SmPC advisory group	2Q2009
- Revision of the PIPIT procedure (to combine linguistic and scientific reviews of product information)	2/3Q2009
- Launch of Eudra SmPC webpage	4Q2009
Communication	
- Communication to Head of Agency informing on the implementation plan, the proposed training and the Eudra SmPC webpage	3Q2009
- Public announcement in CHMP press-release of the implementation plan, in particular the timelines for application to medicinal products.	*at the time of the publication of the revision of the guideline but no later than 3Q2009*
- EMEA publication and dissemination to all relevant parties (CxMPs, WPs, NCAs, EMEA) of the revision of the SmPC guideline.	*upon publication of the revision of the SmPC guideline by EC.*
Report	2011