EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Mandate, objectives and rules of procedure for the Summary of Product Characteristics (SmPC) Advisory Group

Adopted by CHMP March 2010

1. General considerations

In accordance with its 2008-2010 workplan, the CHMP has adopted an implementation plan of the SmPC guideline (Doc. Ref. EMA/655980/2008) on 19 February 2009.

The SmPC Advisory Group has been established to promote and facilitate the application of the SmPC guideline.

It is a "virtual" group which communicates by email or teleconference/vitero only. All activities of the group are made accessible to the European Medicines Agency and National Competent Authorities through the Eudra network.

The European Medicines Agency Medical Information Sector (Information Compliance and Consistency Team) will coordinate and support the activities of the group.

2. Mandate and objectives

The SmPC Advisory Group is established to provide CHMP and CMD(h) members and assessors, as well as the European Medicines Agency scientific administrators with advice on all matters relating to the SmPC guideline.

The European Medicines Agency Medical Information Sector will prepare all related documents for review and approval by the SmPC Advisory Group. This will include:

- Training materials on the SmPC guideline;
- Answers to queries on the application of the SmPC guideline e.g. for product related procedures (see section 5.2);
- The provision of other recommendation on product information via the Eudra SmPC webpage;
- A report on the activities related to the SmPC implementation plan after 1 year of experience.

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It should be noted that answers to queries are of advisory nature and that the final decision on product information will remain under the responsibility of the concerned scientific committee, when adopting the product information as part of the opinion.

The activities of the group are independent and complementary to the assistance to the European Medicines Agency scientific committees on linguistic aspects of the product information provided by the Working Group on Quality Review of Documents (QRD).

3. Composition and rules of participation

The SmPC Advisory group is composed of representatives from CHMP, CMD(h), PhVWP, PDCO, QRD, European Medicines Agency scientific administrators, the Chair of the Ad-Hoc SmPC guideline group and the European Medicines Agency MIS coordinator. The experts are selected from the European experts list according to their specific expertise.

The final composition shall be agreed by CHMP.

Other expert from National Competent Authorities or the European Medicines Agency may be consulted on a case-by-case basis e.g. the chairs of the CHMP working parties.

In case specific expertise is needed, the Advisory group could also consult other experts in accordance with relevant European Medicines Agency/CHMP policies such as the rules of involvement of members of patients'/consumers' and healthcare professionals' organisations in committees related activities.

4. Meeting frequency

Not applicable: the group will communicate by email or teleconference/Vitero only.

5. Rules of procedure

5.1. Responsibilities of the SmPC Advisory Group members

The group will be responsible for:

- Promoting and providing support to the activities of the group within scientific committees, working parties, or other setting of the European regulatory network;
- Aiming to achieve consensus on issues considered;
- Ensuring the scientific and regulatory consistency of the recommendations of the group;
- Participating in other activities of the SmPC implementation plan on a voluntary basis (e.g. training activities);
- Contributing to the preparation of a report on the SmPC implementation plan after 1 year of experience, considering its impact on product information and related regulatory guidance and processes.

In addition to the above the Agency's Medical Information Sector (Information Compliance and Consistency Team) will:

- Coordinate and support the activities of the group;
- Prepare all related documents for review and approval by the SmPC Advisory Group;
- Prepare and manage of the Eudra SmPC webpage.

5.2. Query and answer process

5.2.1. Scope of queries

Queries should concern any matter related to the SmPC guideline and its implementation (e.g. need of or timing for updating SmPC, cross-product harmonisation, specific query on the text of a SmPC) in relation to:

- Centrally authorised products;
- Products referred to the CHMP;
- Other products or class of products being discussed by scientific committees or working parties, in particular the PhVWP and the CMD(h).

In the case of products being assessed by the CHMP, advice could be triggered by CHMP members, (co-) Rapporteur's assessors, QRD members or European Medicines Agency product team members.

For other products, advice should be triggered on behalf of a committee or a working party by its Chair, secretariat or representative in the SmPC Advisory Group.

5.2.2. Processing of queries

- Queries should be submitted to the Agency's Medical Information Sector using a query form available on the Eudra SmPC webpage.
- MIS will prepare an answer to the query within 5 working days according to the following principles:
    - Linguistic or template-related queries will be transmitted to the QRD secretariat for consideration;
    - Query identical to a previous query will be directly answered by MIS;
    - Within 2 working days, the MIS will draft the answer to the query on the basis of the SmPC guideline and other relevant approved guidance. If necessary, for specific issues (e.g. on quality or non-clinical aspect) the MIS may first consult a CHMP expert in the concerned field (e.g. the chair of a WP);
    - The draft answer will be circulated to all the members of the advisory group for a 2-day consultation.
- The group should aim to achieve consensus on issues raised through the use of available guidance, experience and a pragmatic approach.
- The advisory group may ask for clarifications on the conclusion of scientific assessment prior to providing advice.
- In case different opinions are expressed, a teleconference (or Vitero) may be organised to find a consensus, which may result in a prolongation of the time to answer.
- In case specific expertise is needed, MIS will consider the optimal timing for answering with the enquirer.
- MIS will be responsible for sending back the final answer.

5.2.3. Recording of queries and answers

MIS will record the queries and their answers on the Eudra SmPC webpage.