EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Development and Evaluation

Mandate, objectives and rules of procedure for the CHMP guidelines consistency group

1. General considerations

In accordance with Article 56 (2) of EC Regulation 726/2004 as amended, the CHMP may establish standing and temporary working parties. The "Reflection Paper on Working Parties (WP) CHMP/EMA group analysis and proposals" document adopted by the CHMP in May 2010 has foreseen the creation of the Guidelines Consistency Group (CHMP GCG).

The document will be reviewed on a regular basis to reflect on the experience gained by this group.

2. Objectives and mandate

The CHMP GCG has been created in order to provide high-level scientific and regulatory peer review of concept papers, draft guidelines and reflection papers (thereafter referred to as "papers") before they are adopted by the CHMP. It is not expected that the CHMP GCG carry out detailed revision of the text of the documents nor editorial checks.

The CHMP GCG objective is to ensure that all clinical and methodological guidelines follow regulatory and scientific consistency. The term consistency refers to a lack of contradiction and in the context of papers it refers to reaching accordance with recent scientific advice and other scientific opinions of the CHMP as well as with other guidelines, assuming that when a deviation is detected it is duly justified.

In principle the CHMP GCG will be focused on clinical and methodological papers and those where non-clinical and/or in vitro data are considered as the main part to demonstrate therapeutic equivalence or benefit. However, its composition could be adapted to the need of reviewing other papers (i.e. quality, biological, non-clinical, pharmacovigilance) as agreed by the CHMP and other relevant EMA Committees. The CHMP GCG will ensure that aspects related to paediatric and elderly populations are well integrated in the papers as appropriate. When a mention to the SPC is included the consistency will be checked with the SPC guideline.

The composition of the GCG can be reviewed by the CHMP at any time, but at least every three years.

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3. Composition and rules of participation

The CHMP GCG is initially composed of 4 members, at least one of them a CHMP member, a Chairperson plus EMA Secretariat. The CHMP may change at any time the number of members and/or their expertise.

The members should have extensive clinical and methodological experience on the relevant scientific and regulatory matters.

The nominations for the CHMP GCG will be adopted by the CHMP following proposals from CHMP members and EMA. No time limit is proposed for the term of CHMP GCG members, however (re)nominations should take place every three years. Membership of the CHMP GCG implies a commitment to participate actively in the work and to attend the teleconferences (TC) regularly.

If a member does not participate in three consecutive TC without reasonable justification, EMA Secretariat may ask CHMP, in consultation with the CHMP GCG Chairperson, to reconfirm his/her membership or to nominate a new one.

When a WP/DG adopts a final draft paper (including a concept paper) before consultation and before final adoption, EMA will circulate it to the CHMP GCG. A predefined time for review is 1 month. Each member of CHMP GCG will produce comments, if any, and they should be accompanied by a clear proposal regarding alternative text or deletion. A TC of CHMP GCG members will be organised before EMA Secretariat forwards comments from CHMP GCG to WP/DG Chairperson and the guideline's rapporteur. The CHMP GCG may discuss directly with the WP/DG Chair and the guideline's Rapporteur and they could also be involved in the WP/DG discussions. If there are no major issues, and the comments made by the CHMP GCG are introduced, the paper will be submitted to the CHMP for release for consultation or for adoption. If there are major discrepancies between CHMP GCG and WP/DG, a presentation to the CHMP will be carried out by a member of the CHMP GCG and the chair of WP/DG or by the guideline's rapporteur.

In principle no face to face CHMP GCG meetings are planned and TC will be arranged on an ad hoc basis by the EMA Secretariat with the agreement of the Chairperson.

Minutes will be drafted by EMA Secretariat and circulated for comments before they are forwarded to CHMP. EMA Secretariat will present minutes and conclusions to CHMP/ORGAM.

4. Nomination of chairperson

The Chairperson will be nominated by the CHMP for three years and may be renewed once.

5. Responsibilities of chairperson

The Chairperson is responsible for efficient conduct of the business of the CHMP GCG and shall in particular:

- Plan the work of the CHMP GCG together with the EMA Secretariat
- Ensure, together with the EMA Secretariat, that objectives are fulfilled and rules of procedure respected
- Ensure that at the beginning of each meeting any potential conflict of interest is declared

- Ensure, together with the EMA Secretariat, consistency of the recommendations and decisions

6. Guarantees of independence

The members of CHMP GCG shall not have any direct interests in the pharmaceutical industry, which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. The specific provisions for handling declaration of interests and confidentiality undertakings as defined in the current version of the EMA Policy on the Handling of Conflicts of Interests for Committee Members and Experts, adopted by the Management Board.

All attendees of CHMP GCG TC shall declare at the beginning specific interest, which could be considered to be prejudicial to their independence with respect to the points of the agenda. In particular, in case that CHMP GCG members are also members of the WP/DG producing the paper under review, they will be excluded of the CHMP GCG review, discussions and conclusions with regard to that/those particular paper/s.

7. Code of conduct

Members of the CHMP GCG shall abide by the principles set out in the Agency Code of Conduct.

8. Agency secretariat

Under the authority of the Executive Director, the EMA secretariat shall provide technical, scientific and administrative support to the CHMP GCG. This includes the following:

- Prepare and co-ordinate the work in consultation with the Chairperson
- Organise TC ensuring timely circulation of meeting documents
- Facilitate the necessary contacts between the CHMP GCG and the Committees and WPs/DGs and other groups
- Prepare the agenda and minutes of the TC in consultation with the Chairperson
- Ensure that Regulatory Affairs and Legal provide appropriate advice when needed.
- Facilitate the necessary contacts and co-ordination with the Coordination Group

The Executive Director of the Agency and members of the EMA secretariat may attend TC of the CHMP GCG.

9. General provisions

The Members of the CHMP GCG shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by individual professional secrecy.

When participating in international or other fora on behalf of the EMA/CHMP, members shall ensure that the views expressed are those of the EMA/CHMP.

When participating in international or other fora not specifically on behalf of the EMA/CHMP, members shall make clear that the views expressed are their own views and not those of the EMA/CHMP.