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Human medicines development and evaluation

Mandate, objectives and rules of procedure for the coordination group

1. General consideration

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 foreseen the creation of the Coordination Group (CG).

The current Bio-Coordination Group (BCG) functions are taken over by the CG.

The document will be reviewed on a regular basis to take account of experience with the working of this group.

2. Objectives and mandate

The CG is created in order to integrate all related Committees and WPs and Drafting Groups (DGs).

The Coordination Group has functional objectives, such as coordination of activities among the respective WP/DG, avoiding overlapping and ensuring horizontal activities (i.e. ICH), training of assessors and relationship with stakeholders. Furthermore, CHMP can delegate to this group some of its functions with regard to WP/DG operations.

its mandate is to cover the following:

- Discuss and agree WPs and DGs work programmes to ensure consistency between the documents and to clearly define roles and strategy for dealing with topics
- Sharing agendas of WPs/DGs meeting (face to face or by tele/videoconference)
- Be informed on additional assessors, experts and observers to be invited to meetings
- Ensuring WPs activities stick to their mandate and rules of procedure and discussing deviations
- Ensure adequate training activities for assessors
- Identifying and solving overlapping activities of different WPs/DGs
- Identifying and discussion of potential gaps in the functioning of WPs and DGs

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- Coordinate activities with stakeholders including agreement for direct interaction with WPs/DGs
- Coordinate and adopt WP members participation in Briefing Meetings organised by ITF
- Coordinate Guidelines planning
- Enhance, in a flexible manner, the horizontal (between WPs) and vertical (to CHMP) transmission of information
- Be accountable to CHMP for the work of the CG and WP

3. Composition and rules of participation

The CG will be composed by CHMP, CAT and PDCO Chairs, WPs Chairs (or their back-ups) and the respective EMA secretariats. Drafting Groups can be represented either by the Chair or by the EMA Secretariat. It is not expected that experts participate in the CG.

The CG will be chaired by the CHMP Chairperson.

The CG members will represent and will act as the official spokesperson of his/her Committee/WP/DG at the CG. He/She will provide feedback from the CG discussions to his/her WP/DG.

A monthly teleconference (TC) before the CHMP week will be arranged and in principle no face to face meetings are planned.

The TC will have a common agenda, but differentiating three parts: matters specific for Biological WPs (BWP, BPWP, VWP, BMWP and CAT and its WPs if any), general matters and Therapeutic WPs matters (SWP, CV, CNS, any other existing therapeutic WPs and Drafting Groups, Biostatistics WP and PKWP). QWP and SAWP will also participate.

The monthly TC of the CG will be open to all CHMP members.

Meeting documentation will be distributed with the agreement of the Chairperson 1 week before the TC.

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

It is not expected that the CG carry out detailed and lengthy discussions/presentations from WPs chairs and it should not enter in the scientific acceptance of guidelines.

4. Responsibilities of chairperson

The Chairperson, in his absence his back up, is responsible for efficient conduct of the business of the CG and shall in particular:

- Plan the work of the CG 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

5. Guarantees of independence

The members of CG 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 EMA Policy on the Handling of Conflicts of Interests for Committee Members and Experts, adopted by the Management Board (in its current version).

All attendees of CG 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.

6. Code of conduct

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

7. Agency secretariat

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

- Prepare and co-ordinate the work in consultation with its chairperson
- Organise meetings ensuring timely circulation of meeting documents
- Facilitate the necessary contacts between the CG and the Committees and WPs/DGs and other groups
- Prepare the agenda and minutes of the meetings in consultation with the Chairpersons
- Provide legal, regulatory and scientific support.
- Responsible for the coordination of Committees, WP/DG with regard to planning and producing guidelines
- Facilitate the necessary contacts and co-ordination with the Consistency Group

The Executive Director of the Agency and members of the EMA secretariat may attend all meetings.

8. General provisions

The Members of the CG 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.