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Human Medicines Development and Evaluation

Mandate, objectives and rules of procedure for the CHMP Geriatric Expert Group (GEG)

1. General considerations

In accordance with its 2011-2013 work programme, and the EMA Roadmap to 2015, the CHMP has adopted the EMA Geriatric Medicines Strategy (Doc. Ref. EMA/CHMP/137793/2011) on 17 February 2011.

The Geriatric Expert Group (GEG) has been established to assist in the implementation of the Strategy. It is a "virtual" expert group which communicates by email or teleconference only.

This document will be reviewed on a regular basis to reflect on the experience gained by the group. The first review will take place after one year.

2. Objectives and mandate

The CHMP GEG is established in order to provide CHMP members and assessors, as well as the European Medicines Agency scientific administrators with high-level scientific advice on the following matters relating to geriatric medicines and gerontology, upon CHMP request:

- Input on geriatric aspects of guidelines under drafting or revision, at Working Party stage.
- Specific geriatric aspects of medicines development, assessment of products or pharmacovigilance issues.
- Participation or requests for ad-hoc input to the undertakings of SAG or other EMA meetings, if geriatric expertise is needed depending on the questions raised.
- Participating in other activities of the Geriatric implementation plan on an ad-hoc voluntary basis (e.g. training activities).

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The answers to queries are of an advisory nature and the final decision on the question submitted will remain under the responsibility of the concerned scientific committee.

3. Composition and rules of procedure

3.1. Nomination of members

The CHMP GEG is initially composed of 9 members, plus the EMA secretariat, as agreed by CHMP. The CHMP may change at any time the number of members and/or their expertise.

In principle the CHMP GEG activity will be focused on clinical and methodological issues. However, its composition could be adapted to the need to review other issues (i.e. quality, biological, non-clinical, pharmacovigilance) if geriatric aspects are considered of relevance in the discussion.

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

The core members of the Expert group are experts from National competent authorities, European Medicines Agency scientific administrators, and other selected from the European experts list according to their specific expertise. Due to the multidisciplinary approach required by the care of the geriatric patients, such experts will include not only physicians with experience of treating geriatric patients, clinical pharmacologist with an interest in the elderly, physicians and regulators, but also independent experts from other fields, as needed.

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

If needed, the GEG 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 (EMEA/483439/2008 rev. 1).As foreseen by these Rules, Patients/consumers or healthcare professionals will be invited as individual experts, and therefore will not represent their organisation.

The nominations for the CHMP GEG will be adopted by the CHMP following proposals from CHMP members and EMA. No time limit is proposed for the term of CHMP GEG members, however (re)nominations should take place at the time of CHMP (re)nomination. Its composition can be reviewed by the CHMP at any time and at least when the CHMP is (re)nominated.

3.2. Nomination of chairperson

The Chairperson will be nominated by the CHMP, chosen from the members of the group.
The nomination will be for one term corresponding to the CHMP term and may be renewed once.

3.3. Meeting frequency

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

Membership of the CHMP GEG 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.

3.4. Queries and answer process

Queries, within the scope of the mandate, should be triggered by CHMP members or European Medicines Agency product team members in coordination with the (co-) Rapporteur's.

Requests for advice or for participation to a meeting can also be triggered on behalf of a committee or a working party by its Chair or secretariat.

The EMA Secretariat will prepare the background documentation to the query within 5 days of it being raised, and email it to the GEG, together with a timetable for the answers.

The expert group may ask for clarifications prior to providing advice.

Each member of the Group will produce comments within 15 working days from the request, unless a different timeframe is specified.

These comments will be collated by the EMA secretariat, and a teleconference will be organised within 20 working days from the request to draft the GEG answer.

The CHMP/WP member(s) who raised the issue could also be involved in the GEG discussions. If there are major discrepancies between the CHMP and the GEG position, a presentation to the CHMP will be carried out by the Chairperson of the CHMP GEG.

The EMA will be responsible for sending back the final answer to CHMP.

The EMA will record the queries and their answers on the EMA Geriatric database.

Minutes of the teleconferences will be drafted by EMA Secretariat and circulated for comments before they are forwarded to CHMP. The EMA Secretariat will present minutes and conclusions to CHMP or ORGAM, as appropriate.

3.5. Responsibilities of chairperson

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

- Plan the work of the CHMP GEG 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
- Present to CHMP the outcome of the discussion, in case of discrepancy with the CHMP position

4. Code of conduct and Guarantees of Independence

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

Members of CHMP GEG 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 GEG teleconferences shall declare at the beginning any specific interest, which could be considered to be prejudicial to their independence with respect to the points of the agenda.

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

5. Agency secretariat

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

- Prepare and co-ordinate the work in consultation with the Chairperson
- Organise the TC ensuring timely circulation of meeting documents.
- Facilitate the necessary contacts between the CHMP GEG and the Committees, WPs/DGs and other groups such as the Clinical Trial facilitation group.
- Prepare the agenda and minutes of the TC in consultation with the Chairperson
- 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 the TC of the CHMP GEG.