European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

London, 25 June 2009
Doc Ref: EMEA/CHMP/125959/2008 Rev. 1

MANDATE, OBJECTIVES AND RULES OF PROCEDURE FOR THE CHMP PG WORKING PARTY

I. GENERAL CONSIDERATIONS

According to the CHMP rules of procedure, the Committee may consult its working parties on any scientific issue related to their specific fields of expertise. The Committee may also delegate certain tasks associated with the scientific evaluation of applications, or drafting of guidelines to the relevant working parties. The tasks identified by the Committee should be included in the work programme of each working party to be adopted by the CHMP.

Among the emerging technologies holding the promise to optimize drug development and use, Pharmacogenomics (PG) is one of those being integrated in the drug development strategy of major pharmaceutical companies. As the field is developed internationally and issues are common to all Regions and may impact on existing regional regulatory assessment practices and guidelines, there is a need to provide the CHMP with expert support for European and international cooperation on PG related matters.

The CHMP therefore in 2001 established a multidisciplinary expert group formalised in 2005 as the Pharmacogenetics Working Party, in accordance with the implementation of the Title IV of Regulation (EC) No 726/2004 of the European Parliament and of the Council, to provide recommendations to the Committee on all matters relating directly or indirectly to Pharmacogenetics and to perform the tasks described under section II. Following the adoption in 2008 of the ICH E-15 guideline on the definition of genomic biomarkers, the name of the working party is modified in to PG Working Party, the scientific remits and mandate extended accordingly to address the voluntary submissions of biomarkers addressing genomic biomarkers and expressed entities.

II. MANDATE AND OBJECTIVES

The PG Working Party is established to provide recommendations to the Committee on all matters relating directly or indirectly to PG including, but not limited to the tasks defined below:

- Provide for a technical multidisciplinary forum to the CHMP PG experts network and to Applicants; to host workshops and briefing meetings to share experience on issues arising from the integration of PG in drug development, assessment and information.
- Focus on and catalyse training for PG assessment.
- Prepare, review and update guidelines for the preparation and assessment of the PG parts of the regulatory submissions, in conjunction with other CHMP working parties.
- Support dossier evaluation to facilitate and maintain consistency in assessment.
- At the request of the CHMP or of the SAWP, contribute to scientific advice on general and product specific matters related to PG.
- Liaise with other Working parties (e.g. SAWP, SWP, EWP, PhVWP) on PG related matters on areas of mutual interest.
- Setting up of drafting groups including working party members and additional experts (see V. Rules of Procedure, point 4).

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- Advise, through the CHMP, the European Commission on PG related issues: this includes but is not limited to DG Enterprise, DG Research, DG Sanco.
- Liaise with interested parties (e.g. European Commission services, Industry associations including PG EFPIA Expert Group, EBE, learned societies including ESHG, EPPOSI and patients organisations). (See V. Rules of procedure point]
- Provide expert support to the CHMP for European and international cooperation on PG related matters.
- Contribute to PG related workshops and training.

III. COMPOSITION AND RULES OF PARTICIPATION

The PG Working Party is composed of experts selected from the European experts list according to their specific expertise.

A representative of the European Commission may attend all meetings of the Working Party.

CHMP members are invited to nominate up to 15 experts in PG as core group of the working party, on the basis of their specific scientific expertise and/or regulatory experience on the subjects covered within the scope of the working party's mandate.

The core group includes one member representing EWP, one member representing SWP, one member representing the PhVWP and one expert specialised in genetic testing methods evaluation. Members of other working parties also may attend meetings of the PGWP.

From the 15 core members a chairperson and a vice-chairperson shall be appointed by the CHMP.

Additional experts selected from the network may be invited as appropriate to form drafting groups, with possible consultation of academia and pharmaceutical industry' scientists if appropriate, depending on specific activities to be undertaken within the working party remits.

The final composition of the core group and of the expert network shall be agreed by CHMP.

CHMP members are encouraged to take an active role in the activities of the Working Party and to ensure that information on the activities of the PGWP is disseminated at the national level.

Membership of a working party implies a commitment to participate actively in the work of that working party and to attend the meetings of the Working Party regularly. Failure to attend at least 60% of the whole plenary sessions would result in termination of the membership.

A member may nominate an alternate to participate in those exceptional cases where he or she is unable to attend a meeting. The names and qualifications of alternates should be made available to the CHMP. The core member shall inform the EMEA secretariat at the latest 1 week in advance of the meeting if she/he will be replaced by the alternate. Alternates are encouraged to attend the PGWP meetings.

Members who want to bring additional experts should notify the EMEA Secretariat in advance to the meeting, subject to the agreement of the chairperson.

Meeting documentation will be distributed to an agreed list of recipients drawn up by the EMEA with the agreement of the chairperson.

Observers from non-EEA countries may participate with the agreement of the chairperson and the EMEA.

Observers from accession countries and MRA partners may have standing invitations to participate at certain working parties.

Specific confidentiality rules will apply to observers.

Certain PG Working Party members may be designated as contact persons with other working parties and/or scientific advisory groups to ensure good communication in areas of common interests. The concerned working parties will agree on responsibilities of the contact person.

IV. MEETING FREQUENCY

The PG working party shall meet up to five times per year in accordance with the adopted Work Programme. The dates of the meetings shall be included in the work programme of the working party. Drafting Groups meeting might be convened in the margin of the plenary to complement the written procedure.

A Workshop involving PG Experts from the Network and interested parties will be organised once a year to monitor progress and need in the field.

V. RULES OF PROCEDURE

1. Responsibilities of Chairperson and Vice-Chairperson(s) (where appointed)

1. The Chairperson, and if appointed, in his absence the Vice-Chairperson, is responsible for the efficient conduct of the business of the working party and shall in particular:

- plan the work of the working party together with the EMEA Secretariat;
- monitor, together with the EMEA Secretariat, that the rules of procedure are respected;
- ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the Working Party;
- aim to achieve consensus on issues discussed by the Working Party
- decide in exceptional cases, when a vote is necessary;
- ensure, together with the Working Party and the Secretariat, the regulatory and scientific consistency of the Working Party's recommendations;
- co-ordinate together with the EMEA secretariat the work of this Working Party with that of the other relevant Working Parties of the Agency
- report on the activities of the Working Party to the CHMP.

2. The Vice-Chairperson will deputise for the Chairperson when the latter is unable to chair either all or part of the Working Party meeting. On such occasions the Chairperson will seek the agreement of the Vice-Chairperson as early as possible, prior to the meeting and the EMEA Secretariat shall be informed immediately.

2. Election of Chairperson and vice Chairperson(s)

The Chairperson of a working party shall be elected by the members of the CHMP for a term of the Committee, which may be renewed. A Committee member, an alternate or a member of the working party may be elected by the Committee to fulfil this responsibility. Regardless of the time of election of the Chairperson he/she shall be appointed for the term of the Committee. This appointment may be renewed.
A Vice-Chairperson(s) may be elected by the Committee if the working party and committee(s) considers it appropriate.

Nominations should be submitted in writing to the EMEA secretariat no later than the start of the Committee meeting at which election of working party chairpersons is to take place.

Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.

The election of the Chairperson and the Vice-Chairperson(s), where appropriate, shall follow the same procedure as that for the election of the chairperson of Committee as stated in Article 3, paragraphs 1 to 4, of the Rules of Procedure of the CHMP.

3. Organisation of meetings and reporting arrangements

1. The Working Party shall meet regularly at the Agency
2. The dates of meetings are decided on an annual basis in consultation with the Working Party and the relevant Committee.

3. The meetings will be held and minuted in English.

4. The EMEA Secretariat, in consultation with the chairperson, at least 14 calendar days before the meeting, shall circulate the draft agenda for every meeting, together with the relating documents.

5. When a Member of the Working Party is unable to participate to a meeting, part of meeting, or discussion topic due to conflict of interest, he/she must inform the Secretariat in advance in writing.

6. The working party may identify and propose topics for consideration by the working party. Any proposal for a guideline, providing adequate justification, shall be transmitted to the Committee for endorsement and shall be preceded by a concept paper to be endorsed by the Committee.

7. Any recommendation from the working party shall be transmitted to the relevant Committee for adoption

8. When considered appropriate by the Working Party, oral presentations by companies can be made during working party meetings on matters directly related to the activities of the working Party, following agreement of the Committee.

9. The working party shall prepare an annual work programme for adoption by the Committee that shall include topics identified in accordance with point 6 above and any specific tasks identified by the Committee. The work programme shall be regularly reviewed and updated as necessary with the agreement of the Committee.

10. Agenda, table of conclusions and minutes of the meetings of the working party should be circulated to the Committee.

11. Where the Chairperson is an alternate or a member of the working party, he/she will be invited to attend plenary Committee meetings to report on the activities on the working party and ensure liaison with the work of the Committee.

12. The Committee shall agree the mandate of the Working Party. It shall be reviewed, at least at the start of each new term of the committee.

13. The PG Working Party chairperson or its delegate and the EMEA secretary will participate, on regular basis, in the meeting of the BCG.

4. Drafting Groups

When further consideration is required in order to prepare proposals on specific topics the working party may convene drafting groups constituted of members of the working party or experts, as appropriate.

The drafting group will report to its Working Party in direct line.

5. Participation of Experts in meetings

1. When necessary, the working party may avail itself of the services of experts in specific scientific or technical fields. Such experts shall have proven experience in the assessment of medicinal products or in their field of expertise and be included in the European Experts list. Where appropriate members from patient organisations or health care professionals may act as experts.

2. The names of these experts shall be notified to the EMEA Secretariat before the meeting that they are due to attend.

6. Guarantees of independence

1. The members of the working party and experts referred to above 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, and shall make an annual declaration of their financial interests. All indirect interests, which could relate to the

pharmaceutical industry, shall be entered in a register held by the Agency which is accessible to the public, on request at the Agency's office.

2. Members of the working party and experts attending these meetings shall declare at the beginning of each meeting any specific interests, which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be made available to the public.

   The specific provisions for handling declaration of interests and confidentiality undertakings as defined in the EMEA Policy on the Handling of Conflicts of Interests for Committee Members and Experts, adopted by the Management Board (EMEA/H/31653) are applicable to members of the working party and experts participating in the activities of the working party.

7. Code of conduct

Members of the working party and experts participating in the EMEA's activities shall abide by the principles set out in the EMEA Code of Conduct.

8. EMEA Secretariat

1. Under the authority of the Executive Director, the EMEA secretariat shall provide technical, scientific and administrative support to the working party. This includes the following:

- provide technical and scientific support to Rapporteurs, and other members of the working party
- provide legal, regulatory and scientific support to the working party;
- prepare and co-ordinate the work of the working party in consultation with their chairpersons;
- ensure, if appropriate, that the periods laid down by Community legislation for the adoption of the opinions are complied with;
- organise meetings of the working party ensuring timely circulation of meeting documents;
- facilitate the necessary contacts between the working party, Committee and other concern working parties and/or scientific advisory groups;
- ensure adequate co-ordination of the work carried out within the working party, the scientific Committee and other concerned working parties and/or scientific advisory groups;
- contribute to the overall quality assurance and assurance of scientific and regulatory consistency of the documents / recommendations of the Working Party in co-operation with the Chairperson or Vice-Chairperson, as appropriate;
- prepare the minutes of the meetings of working party in consultation with the Chairpersons;
- communicate when necessary any CHMP recommendations relevant to the Working Party to interested parties;
- contribute to the identification of experts;

2. The Executive Director of the Agency and members of the EMEA secretariat may attend all meetings of the working party.

9. Contacts with Interested Parties

1. Where relevant, the working party will establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and health-care professionals' associations.

2. Pharmaceutical industry, health care professionals, patients/consumers or other interested parties have the opportunity to comment in writing on draft guidelines and general regulatory developments during the public consultation of the documents.

3. When considered appropriate by the Working Party, oral presentations by interested parties can be made during working party meetings in earlier stages of development of guidelines. The working parties may also meet with interested parties to discuss general matters or specific

scientific issues with the agreement of the CHMP and under specific conditions to be agreed by the CHMP.

4. In any case, the working party shall neither conduct any deliberations nor reach any formal decisions in the presence of members of interested parties.

5. Before any consultation session, interested party representatives and working party members will communicate to the EMEA Secretariat the points they would like to be discussed, so that an agenda of the session can be prepared for agreement by the Working party Chairperson and circulation by the EMEA secretariat.

10. General Provisions

The Members of the Working Party as well as observers and all experts 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 CHMP, members shall ensure the views expressed are those of the CHMP.

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