EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 May 2010
EMA/CAT/450145/2009
Human medicines development and evaluation

Mandate, objectives and rules of procedure for the CAT Cell-based Products Temporary Working Party (CPWP)

Adopted

Interim proposal of mandate which is aligned with the CHMP draft proposal of a restructuring of working parties and follows the Committee for Advanced Therapies (CAT) need for support from a temporary working party on cell-based therapy issues. The current version of the mandate is subject to further modification depending of the outcome of the review and restructuring of working parties.

1. General considerations

The field of cell therapy, within the framework of Advanced Therapy Medicinal products is a rapidly developing field with a strong international orientation. With implementation of the Regulation on advanced therapies and the establishment of the CAT at the Agency, it is considered important to reorganise the European expertise gathered from member states' regulatory authorities and scientific institutions in order to better assist the CAT in their scientific tasks related to cell therapy (which includes somatic cell therapy medicinal products and tissue engineered products). It is proposed that the Working Party on Cell-based Products to be set up under the umbrella of the CAT.

According to the rules of procedure of the CAT, 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 CAT.

The Working Party on Cell-based Products (CPWP) will therefore act as a multidisciplinary working party of the CAT to provide recommendations to the CAT on all matters relating directly or indirectly to cell-based products and to perform the tasks described under section II. For coordination with the CHMP, other committees and working parties see the EMA policy on appropriate coordination between the scientific committees of the agency (Reference No. EMEA/124704/2005 Rev.1).

The CPWP shall be represented at the Working Party Coordination Group.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

2. Mandate and objectives

The CPWP is established to provide recommendations to the CAT on all matters relating directly or indirectly to cell-based therapy including the tasks defined below:

- Preparation, review and update of guidelines and other guidance documents (e.g. reflection papers), in conjunction with other appropriate working parties, to ensure that specific issues for cell-based products (somatic cell therapy medicinal products and tissue engineered products) are fully addressed. Scientific guidelines will be adopted jointly by the CAT and the CHMP; other guidance documents will be adopted by the CAT;
- Ensure that the CAT and, through the CAT, scientific committees or working parties are informed on scientific issues specific to cell-based therapy medicinal products and provide scientific reports on matters of public interest and emerging issues pertaining to cell-based therapy.

At the request of the CAT:

- Contribution to scientific advice, marketing authorisation evaluation, post-authorisation procedure evaluation, certification, paediatric investigation plan evaluation and orphan designation on general and product specific matters related to cell-based products;
- Contribution to briefing meetings related to cell therapies with external parties (pharmaceutical companies, academia, public/private partnership or patients' associations) through the participation of experts in close collaboration with the Innovation Task Force;
- Liaison with interested parties (e.g. learned societies, trade organisations, industry, academia, patient's organisations) in close collaboration with the CAT. (See VI. Rules of procedure);
- International cooperation on cell-based products related matters;
- Focus and catalyst for training for quality, preclinical and clinical assessment of cell-based products, as agreed or requested by the CAT and contribution to and organisation of external workshops and trainings related to cell-based products;
- Constitute a rapid-acting crisis group to take on board specific issues related to cell-based products with the objective of exchanging information on a European level and to co-ordinate responses to the public in a timely manner;
- Any other task delegated by the CAT for example liaison with the EC, other committees and working parties on matters relevant to cell-based therapy.

3. Composition and rules of participation

The CPWP is composed of experts proposed from the European experts list according to their specific expertise.

Up to 10 experts identified and nominated by the CAT 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, shall constitute the working party. One or more members of the working party shall have specific expertise in the development, evaluation or post marketing follow-up of medical devices.

The core group shall include at least:

- one person from the BWP,
- one person from the SWP,

- one person from the CAT

who have a background experience in cell-based therapy.

From the 10 CPWP members, a chair and a vice-chair shall be appointed by the CAT.

Depending on the topic of discussion, the scientific secretariat shall ensure consultation of the relevant therapeutic temporary working party and drafting group.

Depending on the topics included in the agenda, the Agency secretariat with the agreement of the Chair may propose additional experts for individual CPWP meetings (see section VI, point 5).

The list of additional experts shall be agreed by the CAT in advance of the CPWP meeting.

Members who want to bring additional participants to a CPWP plenary meeting should notify the Agency secretariat in advance of the meeting, subject to the agreement of the Chair.

Membership of a working party implies a commitment to participate actively in the work of that working party and to attend the entire meeting of the working party regularly. If a member does not participate in 3 consecutive meetings or does not contribute actively, the Chair of the WP will bring this to the attention of the CAT that may decide on a replacement.

A member may nominate a replacement to participate in those exceptional cases where he or she is unable to attend a meeting. The member shall inform the Agency secretariat at the latest 1 week in advance of the meeting if she/he will be replaced.

Observers from the European Commission, EDQM, WHO and other international and EU organisation may attend all meetings of the CPWP, if agreed with the CAT and Agency secretariat.

Members from other Committees and/or their working parties may participate with the agreement of the Chair and the Agency.

CPWP members that are also members of BWP, SWP, and/or the CAT will act as contact persons with other Working Parties and/or scientific advisory groups to ensure good communication in areas of common interest, and in particular to report on relevant activities to respective working parties.

CAT members are encouraged to take an active role in the activities of the CPWP and to ensure that relevant information is disseminated at national level.

4. Meeting frequency

The frequency of CPWP meetings shall be agreed by the CAT in accordance with the adopted Work Programme. The dates of the meetings shall be included in the work plan of the CPWP.

Separate drafting group meetings may be organised by teleconference or, where appropriate, face-to-face upon CAT agreement. The composition of separate drafting groups can be different from the composition of regular plenary CPWP meetings.

5. Duration of activity

The continuity of the CPWP will be confirmed once a year by the CAT.

6. Rules of procedure

6.1. Responsibilities of Chair and Vice-chair

6.1.1 The Chair, in his absence the Vice-chair, is responsible for the efficient conduct of the business of the CPWP, in conjunction with the Agency secretariat and shall in particular:

- Plan the work of the Working Party together with the Agency;
- Monitor, together with the Agency 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 Agency secretariat, the regulatory and scientific consistency of the Working Party's recommendations;
- Co-ordinate, together with the Agency secretariat, the work of this Working Party with that of the other relevant working parties of the Agency, in conjunction the Working Party Coordination Group;
- Report on the activities of the Working Party to the CAT or other working parties as appropriate, and the Agency.

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

6.2. Election of Chair and Vice-chair

The Chair and Vice-chair of the CPWP shall be elected by the members of the CAT for a three year term. This appointment may be renewed once.

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

Candidates shall submit a mission statement in support of their candidature at the time of the nomination.

The election of the chair and the vice-chair shall follow the same procedure as that for the election of the chair of Committee as stated in Article 3, paragraphs 1 to 4, of the Rules of Procedure of the CAT.

6.3. Organisation of meetings and reporting arrangements

6.3.1 The CPWP shall meet regularly at the Agency.

6.3.2 The dates of meetings are decided on an annual basis in consultation with the Working Party, the CAT and the Agency.

6.3.3 The meetings will be held and minuted in English.

6.3.4 The draft agenda for every meeting, as adopted by the CAT in consultation with the Chair, shall be circulated, together with the relating documents, by the Agency secretariat at least 7 calendar days before the meeting.

6.3.5 When a member of the CPWP is unable to participate in a meeting, part of meeting, or discussion topic due to conflict of interest, he/she must inform the secretariat in advance in writing.

6.3.6 The Working Party may identify and propose topics for its consideration. Any proposal for a guideline, providing adequate justification, shall be transmitted to the CAT and the endorsed by the Agency and shall be preceded by a concept paper to be endorsed by the CAT and the CHMP. Other guidance documents will be adopted by the CAT.

6.3.7 Any recommendation from the CPWP shall be transmitted to the CAT for adoption.

6.3.8 The CPWP shall prepare an annual work programme for adoption by the CAT which 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 CAT and the Working Party Coordination Group.

6.3.9 Table of conclusions / minutes of the meetings of the Working Party should be circulated to the CAT for information.

6.3.10 The Chair will be invited to attend plenary meetings of the CAT and where relevant the CHMP to report on the activities on the CPWP and ensure liaison with the work of the CAT.

6.3.11 The mandate of the CPWP shall be agreed by the CAT. It shall be reviewed at least every three years.

6.3.12 The CPWP Chair or its delegate and the Agency Secretary will participate, on a regular basis, in the meetings of the Working Party Coordination Group.

6.4. Drafting Groups

When further consideration is required in order to prepare proposals on specific topics the CPWP 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.

6.5. Participation of Experts in meetings

6.5.1 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, learned societies or other health care professionals may act as experts.

6.5.2 The names of these experts shall be notified to the Agency secretariat before the meeting that they are due to attend.

6.6. Guarantees of independence

6.6.1 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 that 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.

6.6.2 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.

6.6.3 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 (EMA/H/31653/03) are applicable to members of the Working Party and experts participating in the activities of the Working Party.

6.7. Code of conduct

Members of the Working Party and experts participating in the Agency's activities shall abide by the principles set out in the Agency Code of Conduct.

6.8. Agency secretariat

6.8.1 Under the authority of the Executive Director, the Agency secretariat shall provide technical, scientific and administrative support to the Working Party. This includes the following:

- Provide technical and scientific support to rapporteurs/co-ordinators, 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 chairs;
- 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, the Committees and other concerned working parties and/or scientific advisory groups;
- Ensure adequate co-ordination of the work carried out within the Working Party, the scientific Committee(s) 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 Chair or Vice-chair, as appropriate;
- Prepare the agenda, table of conclusions and minutes of the meetings of Working Party in consultation with the chairs;
- Communicate when necessary any CAT recommendations relevant to the Working Party to interested parties;
- Contribute to the identification of experts.

6.8.2 The Executive Director of the Agency and members of the Agency secretariat may attend all meetings of the Working Party.

6.9. Contacts with Interested Parties

6.9.1 As agreed with the CAT and where relevant, the Working Party will establish contacts, on an advisory basis, with parties concerned with the use of cell-based products, in particular patient organisations and health-care professionals' associations.

6.9.2 Draft guidelines and general regulatory developments will be subject to public consultation of all interested parties (industry, health care professionals, patients/consumers or other).

6.9.3 When considered appropriate by the Working Party and the CAT, 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 CAT and under specific conditions to be agreed by the CAT.

6.9.4 In any case, the Working Party shall neither conduct any deliberations nor reach any formal decisions in the presence of members of interested parties.

6.9.5 Before any consultation session, interested party representatives and Working Party members will communicate to the Agency 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 Chair and circulation by the Agency secretariat.

6.10. 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 CAT, members shall ensure that the views expressed are those of the Committee.

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