EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Mandate, Objectives and Rules of Procedure for the EMA/CAT and Medical Devices' Notified Body (EMA/CAT-NB) Collaboration Group (CG)

1. General considerations

The primary objective of the European Medicine Agency (EMA) Committee for Advanced Therapies (CAT) - Notified Body (NB) Collaboration Group is to facilitate the implementation of the aspects of Regulation (EC) No. 1394/2007 relating to Advanced Therapy Medicinal Products (ATMP) when combined with Medical Devices (MD), in particular the provisions of Article 9 of that Regulation and Article 16 of the CAT implementing Rules of Procedures (EMEA/CAT/ EMEA/454446/2008).
The EMA/CAT-NB collaboration group is set up in line with Article 17 of the CAT's Rules of Procedures as a temporary ad hoc specialised advisory group of the CAT.

2. Mandate and objectives

The tasks of the EMA/CAT-NB Collaboration Group include:

1. The overview, coordination and the need for any update of any **process and guidance for consultation of a notified body** for medical devices during an assessment undertaken by the CAT of a combined ATMP/MD;
2. At the request of the CAT, coordinate of the development of **guidance on the standard information** to be exchanged relating to the assessment of the NB for the CAT's assessment of a combined ATMP/MD;
3. The coordination of the development of a **process and guidance relating to post-authorisation activities** for combined ATMPs/MD relating to variations/modifications to the combination and pharmacovigilance-vigilance legal provisions.

The EMA/CAT-NB Collaboration Group will report its activities, discussions and any draft proposal documents to the CAT for adoption. The documents drafted by the group and associated drafting groups will be tabled at the CAT meeting for adoption, and the Committee for Human Medicinal Products (CHMP), if appropriate.

The topics identified for discussion and development at the collaboration group will be outlined in its yearly working plan and included in the CAT Work programme in accordance with Article 17(1) of the CAT's Rules of Procedures, as appropriate.

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3. Composition and rules of participation

The EMA/CAT-NB Collaboration Group is intended to represent the regulatory stakeholders for ATMP and medical devices. To this end, the composition of the EMA/CAT-NB Collaboration Group includes up to:

- Four representatives from the CAT,
- Two representatives from the NB-MED working group,
- Two representatives from the Notified Body Operations Group (NBOG), and
- Two representatives from the European Medicines Agency (EMA).

Relevant EMA secretariat support will be provided as needed.

Representatives of the European Commission may participate to the EMA/CAT-NB CG and will have a status of observer.

Members of the EMA/CAT-NB CG will be nominated for a term of 3 years, after which the membership can be renewed (this should be read in conjunction with section 5).

Members of the EMA/CAT-NB CG may nominate an alternate representative to participate in those exceptional cases where the official representative is unable to attend a meeting.

As members will represent their organisation, it is their responsibility to liaise with their organisation as necessary in order to provide the position of the organisation on the topics to be addressed. It is also their responsibility to inform their organisation about the activities of the group.

Membership of the EMA/CAT-NB CG implies a commitment to participate actively in the work of the collaboration group and to attend the meetings of the collaboration group regularly.

Members who want to bring additional participants with relevant experience for a specific topic should notify the EMEA Secretariat in advance of the meeting. Participation will be subject to the agreement of the Chairpersons.

Meeting documentation will be distributed to the participants.

The composition of the EMA/CAT-NB collaboration group will be made publicly available on EMA Website.

4. Meeting frequency and dates

As agreed on the CAT Work programme, the EMA/CAT-NB Collaboration group will held up to three meetings/teleconferences *per* year.

Every effort should be used to employ electronic communication mechanisms including teleconferencing and electronic document conferencing systems when possible.

It may become necessary, in order to achieve the tasks identified that additional meetings and/or teleconferences of the collaboration group are arranged.

5. Duration of activity

The duration of the EMA/CAT-NB collaboration group will be assessed and decided on by the EMA/CAT.

6. Rules of procedures

6.1. Responsibilities of chairpersons

The EMA/CAT-NB CG will have a Chairperson and a Co-Chairperson. The Co-Chairperson(s) are responsible for the efficient conduct of the business of the EMA/CAT-NB collaboration group and shall in particular:

- Plan the work of the EMA/CAT-NB collaboration group meetings together with the EMA Secretariat;
- Monitor, together with the EMA Secretariat, that the rules of procedure are respected;
- Ensure the fulfilment of the mandate of the EMA/CAT-NB collaboration group;
- Ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the GC;
- Aim to achieve consensus on issues discussed by the EMA/CAT-NB Collaboration group;
- Ensure, together with EMA/CAT-NB CG and the EMA secretariat, the compliance with legal/regulatory framework;
- Co-ordinate together with the EMA secretariat the work of the EMA/CAT-NB collaboration group with that of the Committees and Working parties of the Agency as appropriate;
- The (Co-)Chairpersons are responsible for the conduct and running of the meetings i.e.:
    - To ensure that the all topics of the agenda are discussed;
    - To ensure that all EMA/CAT-NB collaboration group members have the opportunity to express their views.
    - To summarise the conclusions of the EMA/CAT-NB collaboration group on each question raised during the meeting,
    - To provide feedback from the EMA/CAT-NB collaboration group discussions including divergent views to the CAT and as appropriate the CHMP or any other EMA Committees' plenary meeting, where requested;
    - To propose to the CAT to invite additional experts to a EMA/CAT-NB collaboration group or any ad hoc drafting group meeting as appropriate;

6.2. Election of chairpersons

One Chairperson will be nominated by the EMA, and the other one will be elected by the CAT.
Both will stand for a period of 3 years. This appointment may be renewed for another 3 years term.
This should be read in conjunction with section 5.

6.3. EMA secretariat

1. Under the authority of the Executive Director, the EMA secretariat shall provide technical, scientific and administrative support to the EMA/CAT- NB Collaboration group.
2. Prepare the minutes of the EMA/CAT- NB Collaboration group in consultation with the Chairpersons.
3. Prepare - in consultation with the chairpersons - the relevant documents to be conveyed to the EMA/CAT- NB Collaboration group Members.
4. Ensure scientific and regulatory consistency of the recommendations of the EMA/ CAT- NB Collaboration group in cooperation with the Chairpersons.

6.4. Organisation of meetings and reporting arrangements

1. The dates of meetings are decided on by the EMA in agreement with the CAT. The EMA/CAT-NB collaboration group shall meet mainly by Tele-/Video-teleconferences or at the Agency in accordance with the frequency outlined in section 4.

2. Comments on documents should be made on standard templates with reference to the page and line number to which the comment relates.
3. The meetings will be held and minuted in English.
4. 4. The draft agenda for every meeting shall be circulated, together with the relating documents, by the EMA Secretariat, in consultation with the chairpersons, in good time before the meeting i.e. 2 weeks prior to the next meeting to allow for sufficient time for review. When this is not possible, the group member with lead responsibility for the document will communicate this to group members.
5. Minutes of collaboration group will be recorded by the EMA Secretariat.
6. When a Member of the EMA/CAT-NB collaboration group is unable to participate to a meeting, part of meeting, or discussion of a topic due to conflict of interest, he/she must inform the EMA Secretariat in advance in writing.
7. In accordance with Article 17(8) of the CAT's Rules of Procedures, the EMA/CAT-NB collaboration Group shall review its work programme of at least annually and it will be made publicly available.

6.5. Guarantees of independence

1. The Members referred to above shall not have any direct interests in the pharmaceutical/medical device 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/medical device 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 attending the EMA/CAT-NB Collaboration group 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.
3. 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 Managements Board (EMEA/H/31653) are applicable to members of the EMA/CAT- NB Collaboration group and experts participating in the activities of the EMA/CAT- NB Collaboration group.
4. Existing conflicts of interest will be resolved in line with EMA policy.

6.6. Code of conduct

Experts participating in the EMA's activities shall abide by the principles set out in the EMA Code of Conduct.

6.7. Transparency

General EMA Transparency policy applies to the EMA/CAT-NB collaboration group.

Following each collaboration group meeting a public summary group report will be prepared by the EMA Secretariat in collaboration with the group chair. Such summary report will be included in the following CAT meeting monthly report and placed on the EMA website.

6.8. General provisions

The Members of the EMA/CAT- NB Collaboration group 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 CG, members shall ensure, the views expressed are those of the CG.

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