EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Resource management and better regulation
Finance, budget and Controls

PUBLIC CALL FOR EXPRESSIONS OF INTEREST

FOR REPRESENTATIVES OF PATIENTS' ASSOCIATIONS AND CLINICIANS TO THE COMMITTEE FOR ADVANCED THERAPIES OF THE EUROPEAN MEDICINES AGENCY (CAT/24/PA) AND (CAT/24/C)

CORRIGENDUM 2 DATED 18/10/2024 – DEADLINE EXTENSION (SEE POINT 7 BELOW)

1. Background

This public call for expressions of interest relates to the appointment by the European Commission of members and alternates representing patients' associations and clinicians at the Committee for Advanced Therapies (CAT) of the European Medicines Agency (EMA).

Regulation (EC) No 1394/2007 of the European Parliament and of the Council on advanced therapy medicinal products ([1]) ("the Regulation") as updated ([2]) lays down specific rules concerning the authorisation, supervision and pharmacovigilance of advanced therapy medicinal products (gene therapy, somatic cell therapy and tissue engineering). Central to the operation of this Regulation is the Committee for Advanced Therapies (CAT) established as part of the EMA.

For ease of reference, the provisions of the Regulation directly relating to the CAT are outlined in the Annex to this document. Articles 21, 22 and 23 of the Regulation are of particular importance, as they provide for the composition and tasks of the CAT, as well as the requirements regarding conflicts of interest.

Subparagraph (c) of Article 21(1) lays down that the CAT shall include "two members and two alternates appointed by the Commission, on the basis of a public call for expressions of interest and after consulting the European Parliament, in order to represent clinicians".

Subparagraph (d) of Article 21(1) lays down that the CAT shall include "two members and two alternates appointed by the Commission, on the basis of a public call for expressions of interest and after consulting the European Parliament, in order to represent patients' associations".

The members of CAT are appointed for a renewable period of three years. The term of office of current members expires on 30 June 2025.

([1]) OJ L324, 10.12.2007, p. 121.

([2]) OJ L 87, 31.3.2009, p. 174.

2. Workload and allowances

Active and regular participation of the appointees in EMA Committee meetings is essential for the functioning of the Committee. Appointees will be expected to attend and actively participate to the meetings of the CAT, for their entire duration. They should be prepared to actively contribute to scientific discussions, to examine documents and to make comments during meetings of the Committee. Appointees will be involved in the committee's procedures in the same way as other members.

The Committee holds its meetings either physically at the EMA premises in Amsterdam, The Netherlands or in a fully remote setting, where all participants connect to the meeting remotely. In-person attendance for physical meetings is expected for the appointee in order to contribute to quorum and to voting on Committee opinions. The Committee meets each month for a maximum of three consecutive days ([3]).

Appointees should be prepared to actively participate and contribute to the meeting discussions, review documents and make comments during the Committee meetings, with a specific focus on the target group they represent (patients or clinicians) ([4]). Appointees will be involved in the Committee's procedures in the same way as other members, as relevant. They should respect the procedural and legal timelines.

Applicants should take into account that meetings involve preparatory work. They should also be prepared to work with electronic methods for the management and exchange of documents. The working documents are drafted in English and the meetings are also conducted in English. Therefore, a good command of English is essential.

For physical meetings, travel, accommodation and subsistence costs for members of the Committee will be met by EMA according to its reimbursement rules for delegates. ([5])

3. Transparency

The activities of the committees shall be carried by observing principles of transparency. EMA shall publish all relevant documents on a dedicated website. In particular, it shall make available to the public, without undue delay: — the names of the members of the committee; — the members' curriculum vitae and declarations of interests; — the committee rules of procedure; — certain opinions adopted by the committee in accordance with the relevant legislation; - the agenda and minutes of committee meetings, including a list of participants.

4. Duty of confidentiality

Article 76 of Regulation (EC) No 726/2004 ([6]) sets out a duty of confidentiality for members of scientific Committees. They must treat information on EMA's work with the utmost discretion and confidentiality and must not disclose information of the kind covered by the obligation of professional secrecy, even after their duties have ceased.

([3]) Meetings dates are published at this link.

([4]) More information about the role of patients' associations and clinicians in EMA scientific committees is available at: Committee for Advanced Therapies (CAT) | European Medicines Agency (europa.eu)

([5]) Cf. Rules for reimbursement of expenses for delegates and experts attending meetings.

([6]) *OJ L 136, 30.4.2004, p. 1.*

5. Independence – Conflict of interest

Members of the CAT shall neither have financial or other interests in the pharmaceutical industry nor in the biotechnology sector and medical device sector (including medical devices, or tissues/cells sector) 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 or as soon as their interests change. Members are required to provide declarations of any specific interests at each meeting, which might be considered prejudicial to their independence in relation to the items on the agenda.

For this purpose, it is essential that applicants submit, together with their application, a duly completed declaration of interest form (as explained below). All applicants will be subject to a pre-screening of any potential competing interests in line with EMA policy on handling of competing interests. ([7])

Any detected current direct interest will lead to the exclusion from the appointment process.

6. Assessment criteria

Assessment of expressions of interest of representatives of patients' associations (**CAT/24/PA**) will be based on:

- Whether the candidates represent patients' associations. Representing associations active at European level would be an asset. Ability and experience in representing associations, and the characteristics of the associations represented will be assessed (i.e. representing the interests and perspectives of those directly affected by regulatory decisions). *
- Whether the candidates have the scientific qualification or experience relevant to the competencies of the CAT listed in Article 21(2) of the Regulation.
- Whether the candidates have competences and experience relevant to the tasks of the CAT listed in Article 23 of the Regulation.

* The documents adopted by the European Medicines Agency on the criteria to be fulfilled by patients' and health professionals' organisations will be considered in the assessment process with regard to the association that the candidate is representing. ([8])

Assessment of expressions of interest of representatives of clinicians (**CAT/24/C**) will be based on:

- Whether the candidates represent clinicians, (i.e. having general scientific/medical expertise (including clinical practice)).

([7]) Cf. European Medicines Agency policy on the handling of competing interests, available online under the following link: https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees-members-and-experts_en.pdf

([8]) Criteria to be fulfilled by patients' and consumers' organisations or by healthcare professionals' organisations involved in European Medicines Agency (EMA) activities.
and Assessment of patient, consumer and healthcare professional organisations' compliance with EMA eligibility criteria

- Whether the candidates have the scientific qualification or experience relevant to the competencies of the CAT listed in Article 21(2) of the Regulation.
- Whether the candidates have competences and experience relevant to the tasks of the CAT listed in Article 23 of the Regulation.

7. Application procedure and closing date

Interested persons must comply with the requirements below, otherwise their applications will not be taken into consideration.

Interested persons must complete, print, sign and date the application and the declaration of interests forms, which are available on the Health and Food Safety Directorate-General's website:

https://ec.europa.eu/health/documents/public_call/call_index_en

The application must include:

a) the completed application form (signed),
b) the completed form on declaration of interests (signed),
c) a CV,
d) a recommendation letter from the association that the applicant wishes to represent (mandatory for patients associations representatives, not mandatory for clinicians).

The Commission reserves the right to ask for further supporting documents at a later stage, if deemed necessary.

Applications must be completed in one of the official languages of the European Union including the necessary documentation. It would, however, be appreciated, without it being a requirement, if at least a summary of experience and other pertinent information in English could be provided in order to facilitate the selection procedure.

For the representatives of clinicians (**CAT/24/C**): The appointment is nominal for individual natural persons.
For representatives of patients' associations (**CAT/24/PA**): The appointment is nominal for individual natural persons. However, these individuals are appointed with the purpose of representing interested parties via associations at the European level. Therefore, applications to this Call need to be submitted in agreement with the associations which the applicant desires to represent. **This agreement should be demonstrated in the recommendation letter – attachment (d) for the application**. Associations can put forward (i.e. support by a recommendation letter) more than one candidate.

In submitting an application, applicants accept the procedures and conditions as described in this Call and in the documents to which it refers. In compiling their application, applicants may under no circumstances refer to any documents submitted in prior applications (example: photocopies of previous applications will not be accepted). Any

misrepresentation in supplying the required information may lead to exclusion from the present Call.

The **deadline** for submission of applications is **04.11.2024, 11:59 pm**, Brussels time.

The complete application must be sent:

by electronic means not later than **04 November 2024**, **11:59 p.m**, **Brussels time**, to the following address:

SANTE-CALL-AGENCIES@ec.europa.eu

The subject of the email should contain the reference number of the Call for expressions of interest: **CAT/24/C or CAT/24/PA**, as appropriate.

For any further information on this call, please contact SANTE-CALLAGENCIES@ec.europa.eu by referring in the subject of the email to the reference number of the call: **CAT/24/C or CAT/24/PA**, as appropriate.

8. Appointment process

Candidates applying to this call for expressions of interest will be informed of the outcome of the selection process. The European Parliament will be consulted prior to the appointment. Individuals who are not appointed may be invited to constitute a reserve list to be used in the event of the need to replace members or alternates who are unable to complete their mandate.

9. Protection of personal data

The Commission will ensure that candidates' personal data are processed as required by Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data (OJ L 295, 21.11.2018, p. 39–98). This applies in particular to the confidentiality and security of such data. For more detailed information on the scope, purposes and means of the processing of their personal data in the context of this Call, candidates are invited to consult the specific privacy statement published on the Call webpage at the following address:

https://ec.europa.eu/health/documents/public_call/call_index_en

ANNEX

Provisions directly relating to the Committee for Advanced Therapies of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004

Article 20

Committee for Advanced Therapies

1. A Committee for Advanced Therapies shall be established within the Agency.

2. Save where otherwise provided in this Regulation, Regulation (EC) No 726/2004 shall apply to the Committee for Advanced Therapies.

3. The Executive Director of the Agency shall ensure appropriate coordination between the Committee for Advanced Therapies and the other Committees of the Agency, in particular the Committee for Medicinal Products for Human Use, the Pharmacovigilance Risk Assessment Committee and the Committee for Orphan Medicinal Products, their working parties and any other scientific advisory groups.

Article 21

Composition of the Committee for Advanced Therapies

1. The Committee for Advanced Therapies shall be composed of the following members:

(a) five members or co-opted members of the Committee for Medicinal Products for Human Use from five Member States, with alternates either proposed by their respective Member State or, in the case of co-opted members of the Committee for Medicinal Products for Human Use, identified by the latter on the advice of the corresponding co-opted member. These five members with their alternates shall be appointed by the Committee for Medicinal Products for Human Use;

(b) one member and one alternate appointed by each Member State whose national competent authority is not represented among the members and alternates appointed by the Committee for Medicinal Products for Human Use;

(c) two members and two alternates appointed by the Commission, on the basis of a public call for expressions of interest and after consulting the European Parliament, in order to represent clinicians;

(d) two members and two alternates appointed by the Commission, on the basis of a public call for expressions of interest and after consulting the European Parliament, in order to represent patients' associations.

The alternates shall represent and vote for the members in their absence.

2. All members of the Committee for Advanced Therapies shall be chosen for their scientific qualification or experience in respect of advanced therapy medicinal products. For the purposes of paragraph 1(b), the Member States shall cooperate, under the coordination of the Executive Director of the Agency, in order to ensure that the final

composition of the Committee for Advanced Therapies provides appropriate and balanced coverage of the scientific areas relevant to advanced therapies, including medical devices, tissue engineering, gene therapy, cell therapy, biotechnology, surgery, pharmacovigilance, risk management and ethics.

At least two members and two alternates of the Committee for Advanced Therapies shall have scientific expertise in medical devices.

3. The members of the Committee for Advanced Therapies shall be appointed for a renewable period of three years. At meetings of the Committee for Advanced Therapies, they may be accompanied by experts.

4. The Committee for Advanced Therapies shall elect its Chairman from among its members for a term of three years, renewable once.

5. The names and scientific qualifications of all members shall be made public by the Agency, in particular on the Agency's website.

Article 22

Conflicts of interest

In addition to the requirements laid down in Article 63 of Regulation (EC) No 726/2004, members and alternates of the Committee for Advanced Therapies shall have no financial or other interests in the biotechnology sector and medical device sector that could affect their impartiality. All indirect interests that could relate to these sectors shall be entered in the register referred to in Article 63(2) of Regulation (EC) No 726/2004.

Article 23

Tasks of the Committee for Advanced Therapies

The Committee for Advanced Therapies shall have the following tasks:

(a) to formulate a draft opinion on the quality, safety and efficacy of an advanced therapy medicinal product for final approval by the Committee for Medicinal Products for Human Use and to advise the latter on any data generated in the development of such a product;

(b) to provide advice, pursuant to Article 17, on whether a product falls within the definition of an advanced therapy medicinal product;

(c) at the request of the Committee for Medicinal Products for Human Use, to advise on any medicinal product which may require, for the evaluation of its quality, safety or efficacy, expertise in one of the scientific areas referred to in Article 21(2);

(d) to provide advice on any question related to advanced therapy medicinal products, at the request of the Executive Director of the Agency or the Commission;

(e) to assist scientifically in the elaboration of any documents related to the fulfilment of the objectives of this Regulation;

(f) at the Commission's request, to provide scientific expertise and advice for any Community initiative related to the development of innovative medicines and

therapies which requires expertise in one of the scientific areas referred to in Article 21(2);

(g) to contribute to the scientific advice procedures referred to in Article 16 of this Regulation and in Article 57(1)(n) of Regulation (EC) No 726/2004.