PUBLIC CALL FOR EXPRESSION OF INTEREST

AS REPRESENTATIVES OF PATIENTS' ASSOCIATIONS AND CLINICIANS TO THE
COMMITTEE FOR ADVANCED THERAPIES OF THE EUROPEAN MEDICINES AGENCY
AND (CAT/18/PA) AND (CAT/18/C)

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 products¹ ("the Regulation") 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. Of particular note, Articles 21, 22 and 23 of the Regulation 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 2019.

¹ OJ L324, 10.12.2007, p. 121.
**Workload and allowances**

Active and regular participation of the appointees is essential for the functioning of the Committee. Appointees will be expected to attend the meetings of the CAT that meets for two days per month at EMA premises. 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.

In this regard representatives of patients' associations and clinicians and are expected to have a specific focus on the target group they represent (advocacy). They should provide input based on the real-life experience of those affected by a disease and its current therapeutic environment. They are also expected to contribute by assessing the real-life implications of regulatory decisions.

Applicants should take into account that meetings in general involve preparatory work. They should also be willing to work with electronic methods for the management and exchange of documents. The working documents are in English and the meetings are also conducted in English. The very good command of English is therefore essential.

Travel, accommodation and subsistence costs for members of the Committee will be met by EMA according to its reimbursement rules for delegates.2

**Independence – Conflict of interest**

Members of the CAT shall neither have financial or other interests in the pharmaceutical industry nor in the biotechnology 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 asked to provide declarations at each meeting of any specific interests 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 declaration of interests form, as explained below, which is fully completed. All applicants will be subject to a pre-screening of any potential conflict of interest in line with EMA policy on handling of competing interests.3 Any detected current direct interest will lead to the exclusion from the appointment process.

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**Assessment criteria**

Assessment of expressions of representatives of patients' associations (CAT/18/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.*
- Whether the candidates have 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.

Assessment of expressions of representatives of clinicians (CAT/18/C) will be based on:

- Whether the candidates represent clinicians. General scientific/medical expertise (including clinical practice).
- Whether the candidates have 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.

**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 the application form and the form on declaration of interests, which can be downloaded for completion from the Health and Food Safety Directorate-General's web-site at:


After completion, the application form and the form on declaration of interests should be printed, signed and dated.

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The application must include:

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

If appropriate, supporting documents may be annexed. 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/18/C):
The appointment is nominal for individual natural persons.

For representatives of patients associations (CAT/18/PA):
The appointment is nominal for individual natural persons. However, these individuals are appointed with the purpose of representing interested parties via associations. 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 (e) for the application.

Associations can to 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 **18 July 2018. 11:59 pm, Brussels time.**

The complete application must be sent:

(a) either by electronic means not later than **18 July 2018, 11:59 pm, 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 expression of interest: CAT/18/C or CAT/18/PA;
(b) or by post or by courier service not later than **18 July 2018** (date as postmarked or the date of the deposit slip) to the following address:

European Commission  
Health and Food Safety Directorate-General  
Unit A3 “Finance, budget and controls”  
Call for interest (CAT/18/C) or Call for interest (CAT/18/PA)  
B232 05/101  
B-1049 Brussels

For any further information on this call, please contact SANTE-CALL-AGENCIES@ec.europa.eu by referring in the subject of the email to the reference number of the call: CAT/18/C or CAT/18/PA.

**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.

**Protection of personal data**

The Commission will ensure that candidates’ personal data are processed as required by Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Union institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1). 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:

ANNEX


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 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;
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.