



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Resource management and better regulation
Finance, budget and controls

PUBLIC CALL FOR EXPRESSION OF INTEREST

**AS REPRESENTATIVES OF CLINICIANS TO THE
COMMITTEE FOR ADVANCED THERAPIES OF THE EUROPEAN MEDICINES AGENCY
(CAT/16/C)**

TEXT WITH CORRIGENDUM

Background

This public call for expressions of interest relates to the appointment by the European Commission of alternates representing 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".

The term of office of the previous members and alternates expired on 30 June 2016. On 23 July 2015 the European Commission launched a public call for expressions of interest to replace the outgoing members and alternates. Despite the fact that the original deadline for application was prolonged, the number of the applications received remained low. Hence, by its decision of 5 of July 2016 the Commission appointed the members and alternates representing patients' associations but only members representing clinicians.

This call should serve to fill the vacant positions of two alternates representing the clinicians. The members of the CAT are appointed for a renewable period of three years. The recently appointed members representing clinicians will end their mandate on 30

¹ OJ L324, 10.12.2007, p. 121.

June 2019. Their alternates appointed pursuant to this call will complete their mandate on the same date.

As this call should serve to appoint alternates for members appointed by the Commission Decision until 30 July 2019, consequently the alternates appointed at the conclusion of this call will complete their mandate at the same time as the members i.e: on 30 July 2019.

Workload and allowances

Appointees will be expected to attend the meetings of the CAT that meets for two days per month at EMA in London, UK. They should be prepared to actively contribute to scientific discussions, to examine documents and to make comments during meetings of the Committee.

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 language of the Committee is English.

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 recently tightened rules of EMA.³ Any detected current direct interest will lead to the exclusion from the appointment process.

² Cf. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017930.pdf

³ Cf. European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts', available online under the following link: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000178.jsp&mid=WC0b01ac0580029338

Assessment criteria

Assessment of expressions will be based on:

- Whether the proposed alternates represent clinicians.
- Whether the proposed alternates have experience relevant to the competencies of the CAT listed in Article 21(2) of the Regulation.
- Whether the proposed alternates 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:

http://ec.europa.eu/health/documents/public_call/call_index_en.htm

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

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), and (d) a CV.

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.

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 **30 September 2016**.

The complete application must be sent:

(a) either by electronic means not later than 30 September 2016 to the following address:

SANTE-CONSULT-A3@ec.europa.eu

The subject of the email should contain the reference number of the call for expression of interest: CAT/16/C

(b) or by post or by courier service not later than 30 September (date as postmarked or the date of the deposit slip) to the following address:

European Commission
DG Health and Food Safety
Unit SANTE A3
To the attention of Mr G.De Clercq
Call for expressions of interest CAT/16/C
Office B232 05/087
B-1049 Brussels
Belgium

For any further information on this call, please contact SANTE-CONSULT-A3@ec.europa.eu by referring in the subject of the email to the reference number of the call: CAT/16/C

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 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:

http://ec.europa.eu/health/documents/public_call/call_index_en.htm

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 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) (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.