European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

London, 16th April 2009
EMEA/99623/2009

COMMITTEE FOR ADVANCED THERAPY MEDICINAL PRODUCTS (CAT)

PROCEDURAL ADVICE ON THE PROVISION OF SCIENTIFIC RECOMMENDATION ON CLASSIFICATION OF ADVANCED THERAPY MEDICINAL PRODUCTS IN ACCORDANCE WITH ARTICLE 17 OF REGULATION (EC) NO 1394/2007

DISCUSSION AT CAT	January 2009
ADOPTION AT CAT	February 2009
RELEASE FOR EXTERNAL CONSULTATION	April 2009
ADOPTION BY CAT	

Comments should be provided by the 8th June 2009 using this template to: Monika.Katonova@emea.europa.eu

KEYWORDS	Scientific recommendation on classification, Advanced therapy medicinal products, Committee for Advanced Therapies, procedural guidance

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1. Introduction

This scientific recommendation on advanced therapy classification is an optional procedure for applicants, which involves the Committee for Advanced Therapies (CAT).

The purpose of this procedure is to determine whether a given product based on genes, cells or tissues meets the scientific criteria which define Advanced Therapy Medicinal Products (ATMPs), in order to address, as early as possible, questions of borderline with other areas such as cosmetics or medical devices, which may arise as science develops (Recital 24 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal product and amending Directive 2001/83/EC and Regulation (EC) No 726/2004).

This procedure is recommended to be done before scientific advice, Paediatric Investigation Plan (PIP), certification, orphan drug designation and submission of a Marketing Authorisation.

Within 60 calendar days following receipt of a valid request for scientific recommendation on classification, the CAT shall deliver its recommendation after consultation with the European Commission (EC). The EMEA shall also publish summaries of the recommendation, after deletion of all information of commercial confidential nature according to Article 17(1) and 17(2) of Regulation (EC) No 1394/2007.

This document describes the roles and responsibilities, the required documentation and the evaluation process for the scientific recommendation on classification of ATMPs. The publication of summaries of recommendations on the EMEA website is also presented.

2. Legal basis

- According to Recital 24 of Regulation (EC) No 1394/2007:

  "The Agency should be empowered to give scientific recommendations on whether a given product based on genes, cells or tissues meets the scientific criteria which define advanced therapy medicinal products, in order to address, as early as possible, questions of borderline with other areas such as cosmetics or medical devices, which may arise as science develops. The Committee for Advanced Therapies, with its unique expertise, should have a prominent role in the provision of such advice."

- According to Article 17 of Regulation (EC) No 1394/2007:

  "1. Any applicant developing a product based on genes, cells or tissues may request a scientific recommendation of the Agency with a view to determining whether the referred product falls, on scientific grounds, within the definition of an advanced therapy medicinal product. The Agency shall deliver this recommendation after consultation with the Commission and within 60 days after receipt of the request.

  2. The Agency shall publish summaries of the recommendations delivered in accordance with paragraph 1, after deletion of all information of commercial confidential nature."

3. Scope

The request for scientific recommendation on classification procedure is applicable only to products based on genes, cells or tissues, as starting material, active substance or finished product including when combined with medical devices, bio-materials, scaffolds or matrices, and for which there are doubts as to whether or not they fall with the definition of ATMP.

4. Roles and Responsibilities of all interested parties in the classification procedure

4.1 CAT:

The CAT is the committee responsible for the provision of scientific recommendations on classification.

4.2. CAT Secretariat

The CAT Secretariat is responsible for coordinating the procedure at the level of the CAT.

The CAT Secretariat is responsible for the consultation of the European Commission (EC).

4.3. CAT Coordinator(s)

The CAT Coordinator(s) are identified and nominated by the CAT according to the product request and the specific field of expertise.

The CAT Coordinator(s) supported by the EMEA Coordinator prepare and finalise the scientific recommendation on classification.

The CAT coordinator(s) supported by the EMEA coordinator identify whether a consultation of a Working parties and/or Notify Body[1] is needed. Those consultations are agreed at the CAT meeting.

4.4. EMEA Coordinator

The EMEA Coordinator is responsible for checking the adequacy of the request for scientific recommendation.

The EMEA Coordinator will be the contact point for the applicant once appointed.

The EMEA coordinator is responsible for supporting the CAT Coordinator(s) for the provision of scientific recommendations.

4.5. Innovation Task Force

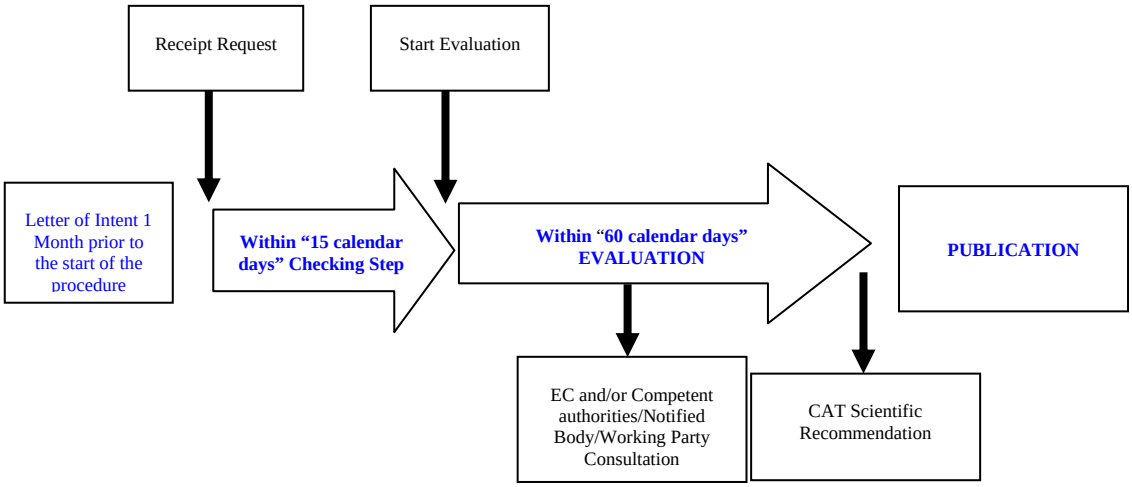
The Innovation Task Force provides peer-review (including scientific, regulatory and legal competences) of the draft scientific recommendation.

For more information regarding the ITF, please see the link enclosed: http://www.emea.europa.eu/htms/human/mes/itf.htm

[1] The consultation of a Notify Body is intended only in case of ATMP combined with Medical devices.

5. Procedure for the evaluation of a request for scientific recommendation on classification of ATMPs

Timetable for the evaluation



Day -30:

- A letter of intent is sent to the CAT Secretariat at least one month before the start of the procedure.
- An EMEA Coordinator is appointed.
- At the CAT meeting following the receipt of the letter of intent, the request is included in the agenda and the CAT Coordinator is nominated.

- **Checking Step:**

Day -15:

- The application for scientific recommendation on classification is received by the CAT Secretariat.
- The EMEA Coordinator checks the adequacy of the request.
- If major additional information is needed, the procedure is initiated at the next starting date, provided that the required information is made available.
- The EMEA Coordinator prepares a briefing note on the points for consideration by the CAT Coordinator (e.g. regulatory, legal and scientific issues, proposal to consult a Working Parties/Competent Authorities/Notified Body if needed).
- The procedure starts according to the list of submission dates.

- **Evaluation by CAT including EC consultation and Competent authorities/Notified body/Working party when needed:**

Day 0:

- Start of the procedure.
- The Timetable for the scientific recommendation is set up by the CAT Secretariat and presented to the CAT.
- The CAT Coordinator supported by the EMEA Coordinator prepares the draft scientific recommendation.

Day 15

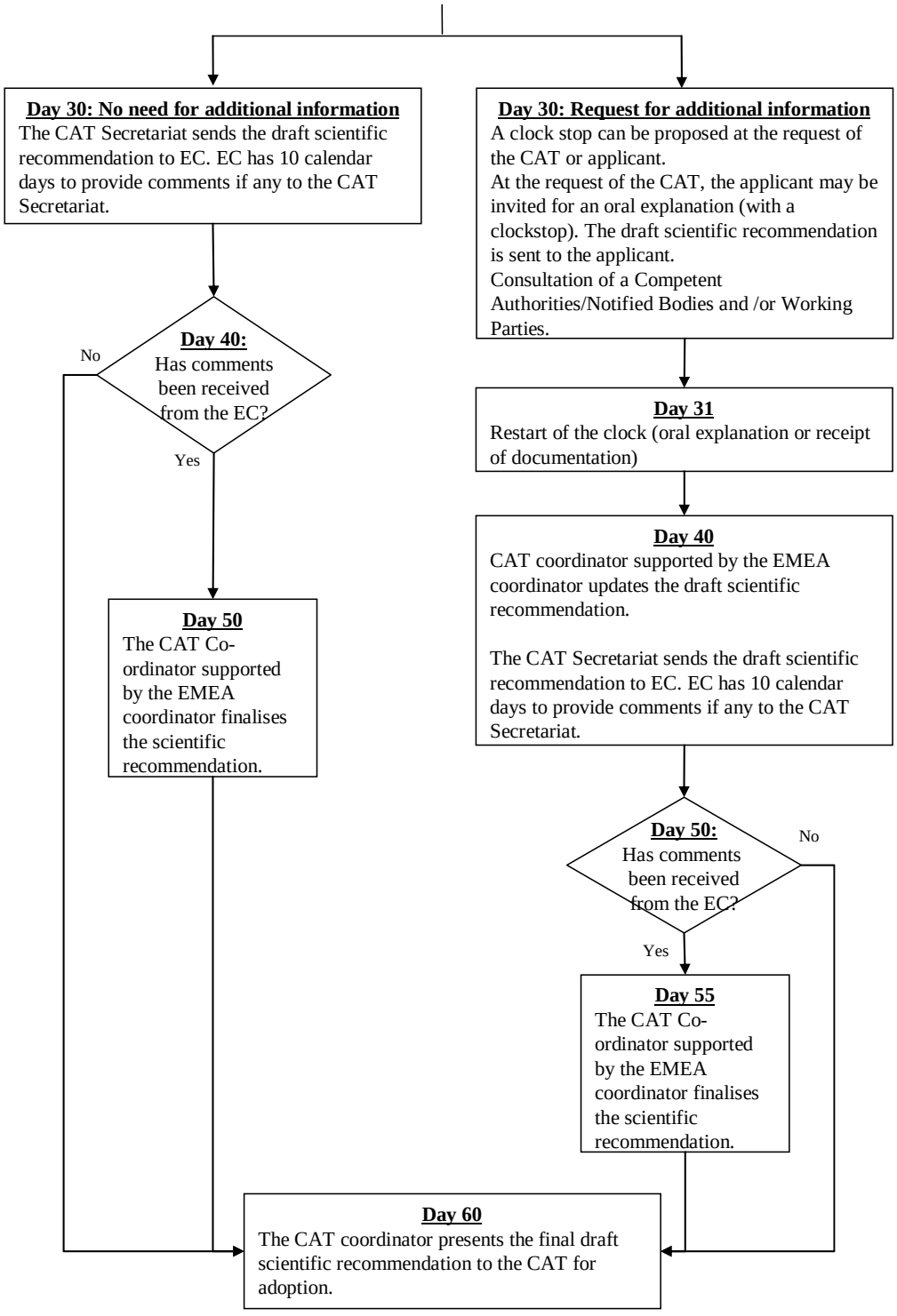
- The CAT Coordinator sends the draft scientific recommendation to the CAT and the ITF for comments within 7 days.

Day 27:

- The CAT Coordinator supported by the EMEA coordinator finalises the scientific recommendation for the next CAT meeting, identifies the need for clarification by the applicant (either written or via an oral explanation) and sends it to the CAT Secretariat.

Day 30: CAT meeting

- Presentation of the final draft scientific recommendation by CAT coordinator at CAT meeting;
- CAT discussion outcome: 2 Options



Day 60: Adoption by CAT of final scientific recommendation on ATMP classification

- Once adopted, the final CAT Scientific recommendation on classification of ATMP is sent to the company and represent the final position of the CAT.
- A summary of the scientific recommendation is published

6. Documentation required for scientific recommendation on classification of ATMPs

The scientific documentation supporting a request for scientific recommendation on classification is presented in the corresponding Request form Template .

7. Summaries for publication

According to Article 17(2), "(…) the Agency shall publish summaries of the recommendations delivered in accordance with paragraph 1, after deletion of all information of commercial confidential nature".

In the report on scientific recommendation on classification of ATMPs, a section initially proposed by the applicant and revised during the procedure by the EMEA Coordinator includes information for publication.

This section will consist of the following information:

- Product description
- Therapeutic area
- Outcome of the scientific recommendation
- Date

Within 7 days, the applicant can comment on this section of the report taking into account the principles of confidential information, as described on the EMEA document "Principles to be applied for the Deletion of Commercially Confidential Information for the Disclosure of EMEA Documents (EMEA/45422/06)".

This section will then be published after consideration by the CAT coordinator/EMEA coordinator of the applicant's comments.

ABBREVIATIONS

ATMPs: Advanced Therapy Medicinal Products

CAT: Committee for Advanced Therapy

EC: European Commission

EMEA: European Medicines Agency

ITF: Innovation Task Force

NB: Notified Body

WP: Working Party