European Medicines Agency
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PRESS RELEASE
EMEA holds first meeting of Committee for Advanced Therapies (CAT)

On 15 and 16 January, the European Medicines Agency (EMEA) held the first meeting of the new Committee for Advanced Therapies (CAT). The CAT is a multidisciplinary committee, gathering together some of the best available experts in Europe to assess the quality, safety and efficacy of advanced therapy medicinal products (ATMPs) and to follow scientific developments in the field. It was established in accordance with Regulation (EC) No 1394/2007 on advanced therapy medicinal products.

ATMPs are medicinal products for human use, and are based on gene therapy, somatic cell therapy or tissue engineering. They offer groundbreaking new treatment opportunities for diseases and injuries of the human body. The regulatory framework established by the new legislation on ATMPs is designed to ensure the free movement of these medicines within the European Union (EU), to facilitate their access to the EU market, and to foster the competitiveness of European pharmaceutical companies in the field, while guaranteeing the highest level of health protection for patients.

Welcoming the Committee members, EMEA Executive Director Thomas Lönngren said, "The establishment of the CAT, the sixth scientific committee here at the EMEA, is a milestone in the history of pharmaceutical regulation in Europe. Some of the best experts in the field of advanced therapies will be working together so that patients suffering from serious diseases and injuries across the EU can safely benefit from revolutionary new treatments. Their work will help pharmaceutical companies, in particular small and medium-sized ones, to unleash their innovative potential and bring new medicines to the market."

Responsibilities of the CAT
The CAT has a pivotal role in fulfilling the objectives of the legislation. One of its main tasks is to prepare a draft opinion on each ATMP application before the Committee for Medicinal Products for Human Use (CHMP) adopts a final opinion on the granting, variation, suspension or revocation of a marketing authorisation for the medicine concerned.

Other responsibilities of the CAT include:
- evaluation and certification of quality and non-clinical data of ATMPs under development by small and medium-sized enterprises;
- provision of scientific recommendations on the classification of ATMPs;
- contribution to the provision of scientific advice, including advice on the conduct of pharmacovigilance and risk-management systems of ATMPs, as well as on measures to monitor the continuing effectiveness of these medicines, in liaison with the Scientific Advice Working Party (SAWP);
- provision, at the request of the European Commission, of scientific expertise and advice as part of any Community initiative related to the development of innovative medicines and therapies that requires expertise on ATMPs.

Composition
The Committee is composed of:
- five members of the CHMP appointed by the CHMP itself;
- one member appointed by each EU Member State whose national competent authority is not represented among the members and alternates appointed by the CHMP;

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- two members appointed by the European Commission to represent clinicians;
- two members appointed by the European Commission to represent patients' associations.

Each member of the CAT has one appointed alternate who replaces the member in their absence. All members and their alternates are appointed for a renewable period of three years. The Chair and Vice-chair of the CAT will be elected from among its members for a three-year term during the next meeting, on 12 and 13 February 2009.

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Notes:

1. A question-and-answer document on the regulation of advanced therapy medicinal products is available here: http://www.emea.europa.eu/pdfs/human/cat/Q&A_1432709en.pdf
2. An overview of the role and responsibilities, membership and other details about the Committee for Advanced Therapies is available here: http://www.emea.europa.eu/htms/general/contacts/CAT/CAT.html
3. Regulation (EC) No 1394/2007 on advanced therapy medicinal products is available here: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_2007_1394/reg_2007_1394_en.pdf
4. Information from the European Commission on advanced therapies is available here: http://ec.europa.eu/enterprise/pharmaceuticals/advtherapies/advanced_en.htm
5. More information on the work of the EMEA in the area of advanced therapies is available here: http://www.emea.europa.eu/htms/human/mes/advancedtherapies.htm
6. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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