EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

Advanced therapy medicinal products

and the Committee for Advanced Therapies

An agency of the European Union

Advanced therapy medicinal products legislation

Regulation (EC) No 1394/2007 established the legal and regulatory framework for advanced therapy medicinal products (ATMPs) in the European Union.

ATMPs are defined as gene- and cell-therapy and tissue-engineered medicinal products.

The regulation provides incentives to companies involved in developing ATMPs, including:

- fee reductions for scientific advice;
- scientific recommendations on ATMP classification;
- evaluation and certification of quality and non-clinical data.

Committee for Advanced Therapies (CAT)

The CAT, established by the ATMP Regulation, is the European Medicines Agency's main scientific committee for the evaluation of applications for marketing authorisation for ATMPs.

Other activities of the CAT include the scientific evaluation of quality and non-clinical data for certification procedures, contributing to scientific advice for ATMPs, and providing scientific recommendations on ATMP classification.

The CAT is also responsible for the preparation of scientific guidelines in the fields of gene- and cell-therapy and tissue-engineered products.

The Committee plays a prominent role in shaping the regulatory and scientific background for ATMPs and contributes to early discussions with ATMP developers (for example via ATMP classifications, scientific-advice requests and collaboration with the Agency's Innovation Task Force in briefing meetings with developers).

The CAT also offers a platform for ATMP-related discussions among national authorities of the European Union (EU), and engages with global regulatory authorities on international standardisation discussions.

The ATMP Regulation and the establishment of the CAT are a clear signal to patients in the EU that ATMPs, which offer potentially groundbreaking new treatments for disease and injuries to the human body, are on the horizon, and to ATMP developers that these novel products can be authorised.

ATMPs in the EU – overcoming the challenges to bring ATMPs to the patient

The number of ATMPs that have been submitted for marketing authorisation is still limited for the moment. However, a significant increase has been seen over the last years in the number of scientific advice and classification requests for ATMPs, indicating an active ATMP development. This is mirrored by the number of ATMPs in clinical trials.

EMA and CAT are aware of the many challenges that developers of ATMPs are facing. CAT is contributing towards creating an environment that encourages the development of ATMPs via the organisation of workshops and trainings, the development of scientific guidance to take stock of the fast evolution of science and adaptations of the regulatory requirements to the specificities of ATMPs, with the goal to have these medicines that offer novel treatment options available to patients as soon as feasible.

Early and repetitive interactions between the ATMP developers and the national authorities and the EMA / CAT are strongly encouraged. EMA / CAT will advise companies on the most appropriate regulatory and scientific route to be followed. This includes interactions with the EMA's Innovation Task Force and the SME office, orphan designation, ATMP classification and certification, scientific advice and PRIME.

CAT and the international regulators

ATMP development is becoming more and more global. Since its establishment, CAT has had regular contact with US-FDA to discuss ATMP related topics of common interest. ATMP cluster teleconference calls are organised every two months and the participation to the ATMP cluster has been extended to Health Canada and Pharmaceuticals and Medical Devices Agency (Japan).

CAT is also contributing to the work of the International Pharmaceutical Regulators Forum's (IPRF) Gene Therapy and Cell Therapy working groups. For more information on IPRF's role and composition, see: www.i-p-r-f.org

Information on the Agency's website

Human Regulatory > Advanced therapies and About us > Committees > CAT ATMP-CAT_

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