



**COUNCIL OF
THE EUROPEAN UNION**



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Advanced therapy medicinal products*

The Council adopted a Regulation on advanced therapy medicinal products (PE-CONS 3627/07), accepting all the amendments suggested by the European Parliament at first reading on 25 April 2007.

Advanced therapy medicinal products offer new opportunities for the treatment of diseases and dysfunctions of the human body. The Regulation lays down specific rules concerning the authorisation, supervision and pharmacovigilance of advanced therapy medicinal products.

Its core objective is to create a single legal framework for three kinds of advanced therapies (gene therapy, somatic cell therapy and tissue-engineering) where development, due to scientific progress in cellular and molecular biotechnology, is very fast.

Developments in this field are of great importance for future treatment of illnesses. There is, consequently, a significant need to create Community rules in order to facilitate innovation, development and clinical use on an emerging market. Both European patients and the European pharmaceutical industry will benefit from rules ensuring, simultaneously, health, safety and equality in the access to the market.

P R E S S

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Because of the novelty and technical specificity of advanced therapy medicinal products, the Regulation introduces specially tailored and harmonised rules for the authorisation of these products that aim to secure high standards of safety and the free movement of those products within the Community.

This Regulation does not affect the application of national legislation prohibiting or restricting, on ethical grounds, the sale, supply or use of medicinal products containing, consisting of or derived from certain types of cells.

This Regulation builds on existing Community law and the products covered by it are also subject to the already existing requirements. Some of the aspects specifically ruled by the new piece of legislation are described below:

- In order to safeguard public health, all modern biotechnology medicinal products currently regulated at Community level are subject to a centralised authorisation procedure, involving a single scientific evaluation of the quality, safety and efficacy of the product, which is carried out to the highest possible standard by the European Medicines Agency (EMA). This procedure will also be compulsory for advanced therapy medicinal products. The evaluation of advanced therapy medicinal products often requires very specific expertise, which goes beyond the traditional pharmaceutical field and covers areas bordering on other sectors such as biotechnology and medical devices. For this reason, the Regulation creates, within the EMA, a **Committee for Advanced Therapies (CAT)**, which will be responsible for preparing draft opinions on the quality, safety and efficacy of each advanced therapy medicinal product for final approval by the EMA's Committee for Medicinal Products for Human Use. The CAT should gather the best available expertise on advanced therapy medicinal products in the Community. The composition of the CAT should ensure appropriate coverage of the scientific areas relevant to advanced therapies, including gene therapy, cell therapy, tissue engineering, medical devices, pharmacovigilance and ethics. Patient associations and clinicians should also be represented.

- The holder of a marketing authorisation for an advanced therapy medicinal product shall maintain a system ensuring that the individual product and its materials, including all substances coming into contact with the cells or tissues it may contain, can be **traced** through the sourcing, manufacturing, packaging, storage, transport and delivery to the hospital, institution or private practice where the product is used. The hospital, institution or private practice where the advanced therapy medicinal product is used shall establish and maintain a system for patient and product traceability. That system shall contain sufficient detail to allow linking of each product to the patient who received it and vice versa.