

Commission Vice-President Verheugen welcomes Parliament vote on Advanced Therapies

Today, the European Parliament voted on a Commission proposal to regulate new medical products based on genes, cells and tissues. These advanced therapies herald revolutionary treatments of a number of diseases or injuries, such as skin in burn victims, Alzheimer, cancer or muscular dystrophy. But harmonised EU rules are urgently needed to ensure uniform patients' access to treatments and support the development of this emerging biotechnology industry. Today the Parliament endorsed the Commission intention to address all advanced therapies within a single European framework, and introduced a compromise package of amendments designed to further improve the text without altering its fundamental elements. The compromise package is fully acceptable to the Commission, and will now be examined by the Council of Member States.

Commission Vice President Günter Verheugen stated: *"I am very pleased that the European Parliament approved the compromise package. Today's Parliament vote paves the way for an early adoption of this eagerly-awaited Regulation, which patients and industry have been waiting for too long. With this Regulation, we unleash the EU potential for innovation, often driven by SMEs, while respecting Member States decisions on ethical concerns."*

Advanced therapies open revolutionary ways of medical treatment, but the current lack of an EU-wide regulatory framework leads to divergent national approaches which hinders patients' access to products, hampers the growth of this emerging industry, and ultimately affects the EU competitiveness in a key biotechnology area.

The Commission proposed an EU Regulation on all advanced therapies in November 2005. The objectives are to ensure the free movement of advanced therapy products within Europe, facilitate access to market and foster the competitiveness of European companies in the field, while guaranteeing the highest level of health protection for patients.

Main elements of the Regulation:

- A **centralized marketing authorization procedure**, to benefit from the pooling of expertise at European level and direct access to the EU market;
- A **new and multidisciplinary expert Committee** (Committee for Advanced Therapies), within the European Medicines Agency (EMA), to assess advanced therapy products and follow scientific developments in the field;
- **Tailored technical requirements**, which are adapted to the particular characteristics of these products;
- Strengthened requirements for **risk management** and **traceability**;
- Special incentives for **small and medium-sized enterprises**.

Ethical aspects regarding advanced therapies

Advanced therapies can raise ethical issues. There is a wide range of views on these issues in Europe. The Regulation on advanced therapies only seeks to ensure that products given to EU patients are safe and work effectively, but it does not take a position on whether products are ethically acceptable, as this is addressed by Member States through national legislation.

Therefore, the Regulation guarantees that all products given to patients meet the same harmonised EU standards, but does not affect Member States' right to reject certain products on ethical grounds.

Additional information on advanced therapies can be found at:

<http://ec.europa.eu/enterprise/pharmaceuticals/advtherapies/index.htm>