Advanced therapy medicinal products

2005/0227(COD) - 13/11/2007 - Final act

PURPOSE: to establish specific rules concerning the authorisation, supervision and pharmacovigilance of advanced therapy medicinal products.

LEGISLATIVE ACT: Regulation (EC) No 1394/2007 of the European Parliament and of the Council concerning advanced therapy medicinal products and amending Directive 2001/83/EC as well as Regulation (EC) No 726/2004.

CONTENT: the Council adopted the Regulation, unanimously accepting all the amendments suggested by the Parliament on first reading.

The main objective of this Regulation is to create a single legal framework for three types of advanced therapies (gene therapy, somatic cell therapy and tissue engineering), for which scientific and technical evolution has been very rapid due to scientific progress in cellular and molecular biotechnology.

The main elements of the Regulation are as follows:

- setting up a centralised authorisation procedure in the market, enabling a gathering of expertise at European level and direct access to the EU market;
- definition of customised technical requirements, adapted to the specificities of these products;
- definition of stricter requirements concerning risk management and traceability: in order to ensure the efficacy of the risk management system, efficacy and adverse reactions of medicinal products must be followed up. The Commission will have to demand necessary action when there is a particular cause for concern. Moreover, in order to ensure better traceability, the marketing authorisation holder shall keep the data referred to by the Directive for a minimum of 30 years after the expiry date of the product, or longer if required by the Commission as a term of the marketing authorisation;
- special incentives for small and medium-sized enterprises (SMEs): by way of derogation from Regulation (EC) No 297/95, a 90% reduction for small and medium-sized enterprises (and 65% for other applicants) shall apply to the fee payable to the Agency for any scientific advice given in respect of advanced therapy medicinal products. The fees for marketing authorisation shall be reduced by 50% for SMEs and hospitals;
- creation of a committee of experts from many disciplines (Committee for Advanced Therapies) within the European Medicines Agency (EMEA), responsible for evaluating advanced therapy medicinal products and following up scientific progress in this field. When formulating a draft opinion for final approval by the Committee for Medicinal Products for Human Use, the Committee for Advanced Therapies shall strive to reach a scientific consensus.

  This new Committee will be composed of representatives of Member States? competent authorities, and those representing patients and clinicians. The European Parliament shall be consulted regarding the nomination of members, representing clinicians and patient associations, to the Committee for Advanced Therapies. At least two members and two alternates of the Committee for Advanced Therapies shall have scientific expertise in medical devices. Finally, members and alternates of the Committee shall have no financial or other interests in the biotechnology sector and medical device sector.
- comitology: future amendments with be made in respect of the new rules of comitology, that is, controlled by Parliament (regulatory procedure with scrutiny).
- report and review: by 30 December 2012, the Commission shall publish a general report on the application of this Regulation, which shall include comprehensive information on the different types of advanced therapy medicinal products authorised pursuant to this Regulation. In this report, the Commission will examine the impact of technical progress and review the scope of this Regulation, including in particular the regulatory framework of combined advanced therapy medicinal products.
- transitional period: advanced therapy medicinal products, other than tissue engineered products, legally on the Community market in accordance with national or Community legislation on 30 December 2008, shall comply with this Regulation no later than 30 December 2011.

ENTRY INTO FORCE: 30/12/2007

APPLICATION: from 30/12/2008.