Advanced therapy medicinal products

2005/0227(COD) - 25/04/2007 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution based on the draft by Miroslav MIKOLÁ?IK (EPP-ED, SK) and made some amendments to the proposed regulation on advanced therapy medicinal products. Parliament voted by 403 votes for, 246 against and 11 abstentions in favour of the compromise package submitted by the PSE, ALDE and GUE/NGL Groups, reflecting an agreement found between the three Shadow Rapporteurs from these Groups, against the wish of the Rapporteur. The main amendments were as follows:

- the "ethical" amendments (submitted originally by the Legal affairs Committee and taken over by the Environment in the framework of enhanced cooperation) were rejected. These amendments stipulated that the regulation should not apply to advanced therapy medicinal products that contain or are derived from human embryonic or foetal cells, primordial germ cells or cells derived from those cells;

- a number of definitions were clarified. On ?tissue engineered product?, Parliament stated that products containing or consisting exclusively of non-viable human or animal cells and/or tissues, which do not contain any viable cells or tissues and which do not act principally by pharmacological, immunological or metabolic action, shall be excluded from this definition. It felt that the Medical Devices Directives (MDD) provide a regulatory framework which is readily adapted to the control of devices containing or made of tissue engineered products. If a tissue engineered product falls within the definition of ?medical device? in Article 1 of the MDD (and therefore does not have a mode of action which is primarily pharmacological, immunological or metabolic), it should be regulated under the MDD;

- cells or tissues shall be considered "engineered" if they fulfil at least one of the following points: the cells or tissues have been subject to substantial manipulation, so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved. The manipulations listed in Annex I, in particular, shall not be considered as substantial manipulations; or the cells or tissues are not intended to be used for the same essential function or functions in the recipient as in the donor;

- according to Directive 2001/83/EC and the Medical Device Directives the basis for deciding which regulatory regime is applicable to combinations of medicinal products and medical devices is the principal mode of action of the combination product. However, the complexity of combined advanced therapy medicinal products containing viable cells or tissues requires a specific approach. For these products, whatever the role of the medical device, the pharmacological, immunological or metabolic action of these cells or tissues should be considered to be the principal mode of action of the combination product. Such combination products must always be regulated under this Regulation;

- Member States should be urged to take all necessary steps to encourage a strong public and non-profit sector involvement in the procurement of human cells or tissues;

- the fee for scientific advice from the Agency should be kept at a minimal level for small and medium-sized enterprises, and should also be reduced for other applicants. The 90% reduction in the fee payable to the EMEA for scientific advice, which the Commission was proposing in order to boost innovation in the field of advanced therapy medicinal products, should be granted only to SMEs; other firms should get a maximum reduction of 65%. Parliament also introduced new articles providing for financial incentives for biotech SMEs, a reduction of 50% in the marketing authorisation fee they pay;

- Parliament emphasised that the Commission should consult the European Medicines Agency (EMEA) on drawing up guidelines;

- the European Parliament should be consulted on the appointment of members of the CAT representing clinicians. There will also be two members and two alternates appointed by the Commission, on the basis of a public call for expressions of interest and after consultation of the European Parliament, in order to represent patients associations. At least two members and two alternates of the Committee for Advanced Therapies shall have scientific expertise in medical. One amendment spelled out more clearly that members and alternate members of the committee must "have no financial or other interests in the biotechnology sector and medical device sector";

- when preparing a draft opinion for final approval by the Committee for Medicinal Products for Human Use, the Committee for Advanced Therapies shall endeavour to reach a scientific consensus. If such consensus cannot be reached, the Committee for Advanced Therapies shall adopt the position of the majority of its members. The draft opinion shall mention the divergent positions and the grounds on which they are based.

- Parliament was concerned about the notification of adverse reactions, and stipulated that the follow-up of efficacy and adverse reactions is a crucial aspect of the regulation of advanced therapy medicinal products. The applicant should therefore detail in its marketing authorisation application whether and, if so, which measures are envisaged to ensure such follow-up. If serious adverse events or reactions occur in relation to a combined advanced therapy medicinal product, the Agency shall inform the relevant national competent authorities responsible for implementing the requirements of Directive 2004/23/EC, Directive 93/42/EEC and Directive 90/385/EEC;

- on comitology, a new clause states that the regulatory procedure with scrutiny provided for in Article 5a of that Decision will apply to the adoption of amendments to Annexes I to IV to this Regulation and to Annex I to Directive 2001/83/EC. Since these measures are essential for the proper operation of the whole regulatory framework, they should be adopted as soon as possible;

- in its report, the Commission must assess the impact of technical progress on the application of this Regulation. It shall also review the scope of the Regulation, including in particular the regulatory framework of combined advanced therapy medicinal products;

- advanced therapy medicinal products, other than tissue engineered products, which were legally on the Community at the time of application of this Regulation will comply with this Regulation no later than 3 years after its application. Tissue engineered products which were legally on the Community market at the date of application of the Regulation shall comply with it no later than 4 years after its application. The Regulation must apply from 1 year after entry into force.