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Committee on the Environment, Public Health and Food Safety

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***I
DRAFT REPORT

on the proposal for a regulation of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004
(COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Committee on the Environment, Public Health and Food Safety

PART B - Explanatory Statement

Rapporteur: Miroslav Mikolášik

Draftswoman (*): Hiltrud Breyer, Committee on Legal Affairs

(*) Enhanced cooperation between committees - Rule 47 of the Rules of Procedure

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

CONTENTS

Page

EXPLANATORY STATEMENT

Rapid development in the fields of biology, biotechnology and medicine and attempts to achieve sustainable growth of health protection within the European Union lead to the development of new treatments and highly innovative medicinal products.

In this context, products which involve intervention in gene therapy, cell therapy and tissue engineering are of great importance, having a high potential in the treatment of diseases such as cancer, cartilage or bone diseases or injuries, repair of genetic disorders, repair of post heart attack damage as well as skin replacement in burn victims.

Nowadays, the legal framework at the Community level related to these advanced therapies remains fragmented, as only gene therapy and somatic cell therapy medicinal products benefit from a legal definition. Tissue engineered products remain unregulated, which leads to the fragmentation of the market and which does not allow patients to have easy access to the necessary treatments.

The current proposal introduces a single harmonising regulatory framework for the evaluation, authorisation and supervision of advanced therapy medicinal products: marketing authorisation requirements and procedure, post-authorisation vigilance and traceability. The proposed Regulation should be seen within the wider perspective of the existing legislation in this field, such as Directive 2001/83/EC on medicinal products, Regulation (EC) No 726/2004 on the European Medicines Agency (EMEA) or Directive 2004/23/EC laying down quality and safety standards of human tissues and cells.

The proposal introduces a European centralised marketing authorisation procedure and creates a new Committee for Advanced Therapies within EMEA, composed of highly qualified and experienced experts in all fields related to these products. In addition, the proposed Regulation sets up a strengthened requirement for the post-authorisation monitoring system and for traceability of the patient and foresees specific technical requirements for tissue engineered products. Moreover, additional specific incentives for the applicants and especially for SMEs are introduced, in order to promote competitiveness within the EU.

The rapporteur welcomes this proposal for a Regulation and the introduction of a new coherent legal framework for these innovative, specific and complex medicinal products. He agrees on the necessity of a centralised authorisation procedure in order to facilitate the market access and to ensure the free movement of advanced therapy medicinal products within the Community. Priority should be given to the demonstration of quality, safety and efficacy of these products in order to ensure a high level of health protection within the EU. The highest possible level of legal certainty should be guaranteed while allowing sufficient flexibility at the technical level.

Nevertheless, the rapporteur would like to underline the importance of clear definitions in order to avoid a legal uncertainty or grey zones, particularly as regards the definition of combined advanced therapy medicinal products and their evaluation. It should also be made crystal clear that products prepared in a hospital, on a one-off basis for an individual patient, should not comply with the centralised authorisation procedure.

In addition, the rapporteur would like to stress the important role of the Committee for Advanced Therapies within EMEA. This highly qualified body should play a vital role in the process of scientific evaluation of advanced therapy medicinal products and its internal decision procedure should be clearly defined.

Moreover, advanced therapy medicinal products could raise serious ethical concerns, as they are likely to contain human cells or tissues. The Commission's proposal should not have an impact on the national legislation prohibiting or restricting the use of certain type of human or animal cells (such as embryonic stem cells) or the sale, supply or use of medicinal products derived from these cells. According to Parliament's legal service, the current drafting of this provision raises serious concerns in the light of the legal basis of the proposal. The rapporteur has asked for a written legal opinion concerning this provision, and in the meantime he has therefore reserved his position and not proposed any amendment to Article 28(2) in the draft report.

Finally, development in biotechnology and biomedicine should be carried out while fully respecting fundamental rights. Rights such as the right to human dignity or to the integrity of the person laid down in the Oviedo Convention as well as in the Charter of fundamental rights should be entirely respected. Thus the rapporteur underlines that authorisation procedure should be carried out in accordance with the principle of non commercialisation of the human body or its parts as such. Hence and for the purposes of this Regulation, the donation of tissues or cells has to be voluntary and unpaid and their procurement carried out on a non-profit basis. Moreover, the authorisation of certain products, particularly those manipulating human germ line or those derived from human-animal hybrids or chimeras, should be prohibited.