AMENDMENT 82
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

Report **A6-0031/2007**
Miroslav Mikolášik
Advanced therapy medicinal products

Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament

Amendment 82
ARTICLE 2, PARAGRAPH 1, POINT (B), SUBPARAGRAPH 2 A (new)

	Products containing or <u>consisting</u> 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, <u>shall be</u> excluded from this definition.

Or. en

AMENDMENT 83
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 83 ARTICLE 2, PARAGRAPH 1, POINT (C)
(c) ***engineered*** cells or tissues ***means cells or tissues which*** fulfil at least one of the points ***listed in Annex I***;	(c) cells or tissues ***shall be considered "engineered" if they*** fulfil at least one of the ***following*** points***:***
	1. 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;
	2. The cells or tissues are not intended to be used for the same essential function or functions in the recipient as in the donor;

Or. en

AMENDMENT 84
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 84 ARTICLE 2, PARAGRAPH 1, POINT (D), INDENT 1	
- it must incorporate, as an integral part of the product, one or more medical devices within the meaning of Article 1(2)(a) of Directive 93/42/EEC or one or more active implantable medical devices within the meaning of Article 1(2)(c) of Directive 90/385/EEC;	- it must incorporate, as an integral part of the product, one or more medical devices within the meaning of Article 1(2)(a) of Directive 93/42/EEC or one or more active implantable medical devices within the meaning of Article 1(2)(c) of Directive 90/385/EEC***, and***

Or. en

AMENDMENT 85
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 85 ARTICLE 2, PARAGRAPH 1, POINT (D), INDENT 1 A (new)
	- its cellular or tissue part <u>must contain</u> viable cells or tissues; or

Or. en

AMENDMENT 86
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 86 ARTICLE 2, PARAGRAPH 1, POINT (D), INDENT 2
- its cellular or tissue part must be liable to act upon the human body with action that ***cannot*** be considered as ***ancillary*** to that of the devices referred to.	- its cellular or tissue part ***containing non-viable cells or tissues*** must be liable to act upon the human body with action that ***can*** be considered as ***primary*** to that of the devices referred to.

Or. en

AMENDMENT 87
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 87 ARTICLE 2, PARAGRAPH 1, SUBPARAGRAPH 1 A (new)
	Where a product contains viable cells or tissues, the pharmacological, immunological or metabolic action of those cells or tissues shall be considered as the principal mode of action of the product.

Or. en

AMENDMENT 88
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 88 ARTICLE 2, PARAGRAPH 2	
2. An advanced therapy medicinal product containing both autologous (emanating from the patient himself) and allogeneic (coming from another human being) cells or tissues ***is*** considered to be for allogeneic use.	2. An advanced therapy medicinal product containing both autologous (emanating from the patient himself) and allogeneic (coming from another human being) cells or tissues ***shall be*** considered to be for allogeneic use.

Or. en

AMENDMENT 89
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 89 ARTICLE 2, PARAGRAPH 3 A (new)
	3a. A product which may fall within the definition of:
	- a "somatic cell therapy medicinal product" or a "tissue engineered product"; and
	- a "gene therapy medicinal product"
	shall be considered as a gene therapy medicinal product.

Or. en

AMENDMENT 90
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 90 ARTICLE 4, PARAGRAPH 2	
2. The Commission shall, in accordance with the procedure referred to in Article 26(2), amend Directive 2005/28/EC in order to take account of the specific characteristics of advanced therapy medicinal products.	***deleted***

Or. en

AMENDMENT 91
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 91 ARTICLE 4, PARAGRAPH 3	
3. The Commission shall draw up detailed guidelines on good clinical practice specific to advanced therapy medicinal products.	3. The Commission shall***, after consulting the Agency,*** draw up detailed guidelines on good clinical practice specific to advanced therapy medicinal products.

Or. en

AMENDMENT 92
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 92 ARTICLE 5	
Detailed guidelines in line with the principles of good manufacturing practice and specific to advanced therapy medicinal products ***shall be published by the Commission***.	***The Commission shall, after consulting the Agency, draw up*** guidelines in line with the principles of good manufacturing practice and specific to advanced therapy medicinal products.

Or. en

AMENDMENT 93
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 93 ARTICLE 7	
Specific requirements for ***tissue engineered products***	Specific requirements for ***advanced therapy medicinal products containing devices***
In addition to the requirements laid down in Article 6(1) of Regulation (EC) No 726/2004, applications for the authorisation of ***a tissue engineered product*** shall include a description of the physical characteristics and performance of the product and a description of the product design methods, in accordance with Annex I to Directive 2001/83/EC.	In addition to the requirements laid down in Article 6(1) of Regulation (EC) No 726/2004, applications for the authorisation of ***an advanced therapy medicinal product containing medical devices, bio-materials, scaffolds or matrices*** shall include a description of the physical characteristics and performance of the product and a description of the product design methods, in accordance with Annex I to Directive 2001/83/EC.

Or. en

AMENDMENT 94
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 94 ARTICLE 8	
Article 8 ***Technical requirements*** ***The Commission shall, in accordance with the procedure referred to in Article 26(2) of this Regulation, amend Annex I to Directive 2001/83/EC in order to lay down technical requirements that are specific to tissue engineered products, in particular those referred to in Article 7, with a view to taking account of scientific and technical evolution.***	***deleted***

Or. en

AMENDMENT 95
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 95 ARTICLE 9, PARAGRAPH 2	
2. The rapporteur or co-rapporteur appointed by the Committee for Medicinal Products for Human Use pursuant to Article 62 of Regulation (EC) No 726/2004 shall be a member of the Committee for Advanced Therapies. This member shall also act as rapporteur or co-rapporteur for the Committee for Advanced Therapies.	***deleted***

Or. en

AMENDMENT 96
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament

Amendment 96
ARTICLE 9, PARAGRAPH 2 A (new)

	2a. 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.

Or. en

AMENDMENT 97
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 97 ARTICLE 9, PARAGRAPH 3
3. The ***advice*** given by the Committee for Advanced Therapies under paragraph 1 shall be sent to the chairman of the Committee for Medicinal Products for Human Use in a timely manner so as to ensure that the deadline laid down in ***Article 6(3)*** of Regulation (EC) No 726/2004 can be met.	3. The ***draft opinion*** given by the Committee for Advanced Therapies under paragraph 1 shall be sent to the chairman of the Committee for Medicinal Products for Human Use in a timely manner so as to ensure that the deadline laid down in ***Article 6(3) or 9(2)*** of Regulation (EC) No 726/2004 can be met.

Or. en

AMENDMENT 98
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 98 ARTICLE 9, PARAGRAPH 4	
4. Where the scientific opinion on an advanced therapy medicinal product drawn up by the Committee for Medicinal Products for Human Use under *Article 5, paragraphs 2 and 3* of Regulation (EC) No 726/2004 is not in accordance with the ***advice*** of the Committee for Advanced Therapies, the Committee for Medicinal Products for Human Use shall annex to its opinion a detailed explanation of the scientific grounds for the differences.	4. Where the scientific opinion on an advanced therapy medicinal product drawn up by the Committee for Medicinal Products for Human Use under *Article 5(2) and (3)* of Regulation (EC) No 726/2004 is not in accordance with the ***draft opinion*** of the Committee for Advanced Therapies, the Committee for Medicinal Products for Human Use shall annex to its opinion a detailed explanation of the scientific grounds for the differences.

Or. en

AMENDMENT 99
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 99 ARTICLE 10, PARAGRAPH 1	
1. Where a combined advanced therapy medicinal product is concerned, the whole product***, including any medical device or any active implantable medical device incorporated in the medicinal product,*** shall be ***evaluated*** by the Agency.	1. Where a combined advanced therapy medicinal product is concerned, the whole product shall be ***subject to final evaluation*** by the Agency.

Or. en

AMENDMENT 100
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 100 ARTICLE 10, PARAGRAPH 1 A (new)
	1a. The application for a marketing authorisation for a combined advanced therapy medicinal product shall include evidence of conformity with the essential requirements referred to in Article 6.

Or. en

AMENDMENT 101
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 101 ARTICLE 10, PARAGRAPH 2	
2. ***Where the medical device or active implantable medical device which is part of a combined advanced therapy medicinal product has already been assessed*** by a notified body in accordance with Directive 93/42/EEC or Directive 90/385/EEC, the Agency shall ***take account of*** the results of that assessment in its evaluation of the medicinal product concerned.	2. ***The application for a marketing authorisation for a combined advanced therapy medicinal product shall include, where available, the results of the assessment*** by a notified body in accordance with Directive 93/42/EEC or Directive 90/385/EEC ***of the medical device or active implantable medical device part***. The Agency shall ***recognise*** the results of that assessment in its evaluation of the medicinal product concerned.
The Agency may request the relevant notified body to transmit any information related to the results of its assessment. The notified body shall transmit the information within a period of one month.	The Agency may request the relevant notified body to transmit any information related to the results of its assessment. The notified body shall transmit the information within a period of one month.
	If the application does not include the results of the assessment, then the Agency shall seek an opinion on the conformity of the device part with Annex I to Directive 93/42/EEC or Annex I to Directive 90/385/EEC from a notified body identified in conjunction with the applicant, unless the Committee for Advanced Therapies advised by its experts for medical devices decides that involvement of a notified body

is not required.

Or. en

AMENDMENT 102
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 102 ARTICLE 15, TITLE
Post-authorisation Risk Management	Post-authorisation ***follow-up of efficacy and adverse reactions, and*** Risk Management

Or. en

AMENDMENT 103
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 103 ARTICLE 15, PARAGRAPH 1
1. In addition to the requirements for pharmacovigilance laid down in Articles 21 to 29 of Regulation (EC) No 726/2004, the applicant shall detail, in the marketing authorisation application, the measures envisaged to ensure the follow-up of efficacy of advanced therapy medicinal products.	1. In addition to the requirements for pharmacovigilance laid down in Articles 21 to 29 of Regulation (EC) No 726/2004, the applicant shall detail, in the marketing authorisation application, the measures envisaged to ensure the follow-up of efficacy of advanced therapy medicinal products ***and of adverse reactions thereto***.

Or. en

AMENDMENT 104
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 104 ARTICLE 15, PARAGRAPH 2, SUBPARAGRAPH 1	
2. Where there is particular cause for concern, the Commission ***may***, on the advice of the Agency, require as part of the marketing authorisation that a risk management system designed to identify, prevent or minimise risks related to advanced therapy medicinal products, including an evaluation of the effectiveness of that system, be set up, or that specific post-marketing studies be carried out by the holder of the marketing authorisation and submitted for review to the Agency.	2. Where there is particular cause for concern, the Commission ***shall***, on the advice of the Agency, require as part of the marketing authorisation that a risk management system designed to identify, ***characterise,*** prevent or minimise risks related to advanced therapy medicinal products, including an evaluation of the effectiveness of that system, be set up, or that specific post-marketing studies be carried out by the holder of the marketing authorisation and submitted for review to the Agency.

Or. en

AMENDMENT 105
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 105 ARTICLE 15, PARAGRAPH 4 A (new)
	4a. 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.

Or. en

AMENDMENT 106
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 106 ARTICLE 16, PARAGRAPH 1
1. The holder of a marketing authorisation for an advanced therapy medicinal product shall establish and maintain a system ensuring that the individual product and its starting and raw materials, including all substances coming into contact with the tissues or cells it may contain, can be traced through the sourcing, manufacturing, packaging, transport and delivery to the hospital, institution or private practice where the product is used.	1. The holder of a marketing authorisation for an advanced therapy medicinal product shall establish and maintain a system ensuring that the individual product and its starting and raw materials, including all substances coming into contact with the tissues or cells it may contain, can be traced through the sourcing, manufacturing, packaging, ***storing,*** transport and delivery to the hospital, institution or private practice where the product is used.

Or. en

AMENDMENT 107
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 107 ARTICLE 16, PARAGRAPH 4
4. The marketing authorisation holder shall keep the data referred to in *the first paragraph* for a minimum of 30 years after ***placing the product on the market***, or longer if required by the Commission as a term of the marketing authorisation.	4. The marketing authorisation holder shall keep the data referred to in *paragraph 1* 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.

Or. en

AMENDMENT 108
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 108 ARTICLE 17, PARAGRAPH 2
2. By way of derogation from Article 8(1) of Regulation (EC) No 297/95, a 90% reduction shall apply to the fee payable to the Agency for any advice referred to in paragraph 1 and in Article 57(1)(n) of Regulation (EC) No 726/2004 in respect of advanced therapy medicinal products.	2. By way of derogation from Article 8(1) of 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 advice referred to in paragraph 1 and in Article 57(1)(n) of Regulation (EC) No 726/2004 in respect of advanced therapy medicinal products.

Or. en

AMENDMENT 109
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 109 ARTICLE 18, PARAGRAPH 1
1. Any applicant developing a product based on cells or tissues may request a scientific recommendation of the Agency with a view to determining whether the referred product falls, on scientific grounds, within the definition of an advanced therapy medicinal product. The Agency shall deliver this recommendation after consultation with the Commission.	1. Any applicant developing a product based on ***genes,*** cells or tissues may request a scientific recommendation of the Agency with a view to determining whether the referred product falls, on scientific grounds, within the definition of an advanced therapy medicinal product. The Agency shall deliver this recommendation, after consultation with the Commission ***and within 60 days after receipt of the request.***

Or. en

AMENDMENT 110
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 110 ARTICLE 19, PARAGRAPH 1
Small and medium-sized enterprises developing an advanced therapy medicinal product may submit to the Agency all quality and, where available, non-clinical data required in accordance with modules 3 and 4 of Annex I to Directive 2001/83/EC, for scientific evaluation and certification.	Small and medium-sized enterprises developing an advanced therapy medicinal product may submit to the Agency all ***relevant*** quality and, where available, non-clinical data required in accordance with modules 3 and 4 of Annex I to Directive 2001/83/EC, for scientific evaluation and certification.

Or. en

AMENDMENT 111
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 111 ARTICLE 19 B (new)
	Article 19b
	1. By way of derogation from Regulation (EC) No 297/95, the fee for marketing authorisation shall be reduced by 50% if the applicant is a hospital or a small and medium-sized enterprise and can prove that there is a particular public health interest in the Community in the advanced therapy medicinal product.
	2. Paragraph 1 shall also apply to fees charged by the Agency for post-authorisation activities in the first year following the granting of the marketing authorisation for the medicinal product.
	3. The provisions of paragraphs 1 and 2 shall apply during the transitional period provided for in Article 29.
	Or. en

AMENDMENT 112
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 112 ARTICLE 21, PARAGRAPH 1, POINT (A)
(a) five members ***and five alternates*** of the Committee for Medicinal Products for Human Use, appointed by the ***latter***;	(a) five members ***or co-opted members*** of the Committee for Medicinal Products for Human Use ***coming from five Member States, with alternates either proposed by their respective Member State or, in the case of co-opted members of the Committee for Medicinal Products for Human Use, identified by the latter on the advice of the corresponding co-opted member. These five members with their alternates shall be*** appointed by ***the Committee for Medicinal Products for Human Use***;

Or. en

AMENDMENT 113
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 113 ARTICLE 21, PARAGRAPH 1, POINT (C)
(c) ***four*** members appointed by the Commission, on the basis of a public call for expressions of interest, ***two of them*** to represent ***surgeons and two of them*** to represent patients associations.	(c) ***two*** members ***and two alternates*** appointed by the Commission, on the basis of a public call for expressions of interest ***after consulting the European Parliament, in order*** to represent ***clinicians***; ***(ca) 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. ***The alternates shall represent and vote for the members in their absence.***

Or. en

AMENDMENT 114
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

Report **A6-0031/2007**
Miroslav Mikolášik
Advanced therapy medicinal products

Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 114 ARTICLE 21, PARAGRAPH 2	
2. All members of the Committee for Advanced Therapies shall be chosen for their scientific qualification or experience in respect of advanced therapy medicinal products. For the purposes of point (b) of paragraph 1, the Member States shall cooperate, under the coordination of the Executive Director of the Agency, in order to ensure that the final composition of the Committee for Advanced Therapies appropriately and in a balanced way covers the scientific areas relevant to advanced therapies, including medical devices, tissue-engineering, gene therapy, cell therapy, biotechnology, pharmacovigilance, risk management and ethics.	2. All members of the Committee for Advanced Therapies shall be chosen for their scientific qualification or experience in respect of advanced therapy medicinal products. For the purposes of point (b) of paragraph 1, the Member States shall cooperate, under the coordination of the Executive Director of the Agency, in order to ensure that the final composition of the Committee for Advanced Therapies appropriately and in a balanced way covers the scientific areas relevant to advanced therapies, including medical devices, tissue-engineering, gene therapy, cell therapy, biotechnology, ***surgery,*** pharmacovigilance, risk management and ethics. ***At least two members and two alternates of the Committee for Advanced Therapies shall have scientific expertise in medical devices.***

Or. en

AMENDMENT 115
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 115 ARTICLE 21, PARAGRAPH 5
5. The names and scientific qualifications of the members shall be ***published*** by the Agency.	5. The names and scientific qualifications of the members shall be ***made public*** by the Agency***, in particular on the Agency's website***.

Or. en

AMENDMENT 116
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 116 ARTICLE 22	
1. Members of the Committee for Advanced Therapies and its experts shall undertake to act in the public interest and in an independent manner. They shall not have financial or other interests in the ***pharmaceutical sector, medical device sector or biotechnology sector*** that could affect their impartiality.	***In addition to the requirements laid down in Article 63 of Regulation (EC) No 726/2004, members and alternates of the Committee for Advanced Therapies shall have no*** financial or other interests in the ***biotechnology sector and medical device sector*** that could affect their impartiality. All indirect interests that could relate to ***these sectors*** shall be entered in the register referred to in Article 63(2) of Regulation (EC) No 726/2004.
2. All indirect interests that could relate to ***the pharmaceutical sector, medical device sector or biotechnology sector*** shall be entered in the register referred to in Article 63(2) of Regulation (EC) No 726/2004.	

Or. en

AMENDMENT 117
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 117 ARTICLE 23, POINT (A)
(a) ***to advise*** the Committee for Medicinal Products for Human Use on any data generated in the development of ***an advanced therapy medicinal*** product, ***for the formulation of an opinion on its quality, safety and efficacy***;	(a) ***to formulate a draft opinion on the quality, safety and efficacy of an advanced therapy medicinal product for final approval by*** the Committee for Medicinal Products for Human Use ***and to advise the latter*** on any data generated in the development of ***such a*** product;

Or. en

AMENDMENT 118
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament

Amendment 118
ARTICLE 23, POINT (A A) (new)

	(aa) to provide advice, pursuant to Article 18, on whether a product falls within the definition of an advanced therapy medicinal product;

Or. en

AMENDMENT 119
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 119 ARTICLE 23, POINT (E A) (new)
	(ea) to contribute to the scientific advice procedures referred to in Article 17 of this Regulation and in Article 57(1)(n) of Regulation (EC) No 726/2004;

Or. en

AMENDMENT 120
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 120 ARTICLE 24
The Commission shall, in accordance with procedure referred to in ***Article 26(2)***, amend Annexes I to IV in order to adapt them to scientific and technical evolution.	The Commission shall, ***after consulting the Agency and*** in accordance with ***the regulatory*** procedure ***with scrutiny*** referred to in ***Article 26(2a)***, amend Annexes I to IV in order to adapt them to scientific and technical evolution.
	Or. en

AMENDMENT 121
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 121 ARTICLE 25, TITLE	
Reporting	***Report and review***

Or. en

AMENDMENT 122
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament

Amendment 122
ARTICLE 25, PARAGRAPH 1 A (new)

	In this report, the Commission shall 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.

Or. en

AMENDMENT 123
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 123 ARTICLE 26, PARAGRAPH 2 A (new)
	2a. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Or. en

AMENDMENT 124
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 124 ARTICLE 27, POINT -1 (new)
	Article 13, paragraph 1 (Regulation (EC) No 726/2004)
	(-1) In Article 13, the first sentence of paragraph 1 is replaced by the following:
	"Without prejudice to Article 4(4) and (5) of Directive 2001/83/EC, a marketing authorisation which has been granted in accordance with this Regulation shall be valid throughout the Community."

Or. en

AMENDMENT 125
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 125 ARTICLE 27, POINT 2 A (new) Annex, point 3, subparagraph 2 (Regulation (EC) No 726/2004)
	(2a) In the Annex, the second subparagraph of point 3 is replaced by the following:
	"After 20 May 2008, the Commission, having consulted the Agency, may present any appropriate proposal to amend this point and the European Parliament and the Council shall take a decision thereon in accordance with the Treaty."

Or. en

AMENDMENT 126
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament

Amendment 126
ARTICLE 28, POINT -1 (new)
Article 1, point 4 a (new) (Directive 2001/83/EC)

	(-1) In Article 1, the following point 4a is added:
	"4a. <u>Advanced therapy medicinal product:</u> A product as defined in Article 2 of Regulation (EC) No .../... [on advanced therapy medicinal products]."

Or. en

AMENDMENT 127
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 127 ARTICLE 28, POINT 1 Article 3, point 7 (Directive 2001/83/EC)	
7. Any advanced therapy medicinal product, as defined in Regulation (EC) No […/of the European Parliament and of the Council (*Regulation* on Advanced Therapy Medicinal Products)*], which is ***both*** prepared ***in full*** and used in a hospital, ***in accordance with a*** medical prescription for an individual patient.	7. Any advanced therapy medicinal product, as defined in Regulation (EC) No […/of the European Parliament and of the Council (on Advanced Therapy Medicinal Products)*], which is prepared ***on a non-routine basis according to specific quality standards,*** and used ***within the same Member State*** in a hospital ***under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual*** medical prescription for ***a custom-made product*** for an individual patient. ***Manufacturing of these products shall be authorised by the competent authority of the Member State. Member States shall ensure that national traceability and pharmacovigilance requirements as well as the specific quality standards referred to in this paragraph are equivalent to those provided for at Community level in respect of advanced therapy medicinal products for which authorisation is required pursuant to Regulation (EC) No 726/2004.***

Or. en

AMENDMENT 128
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 128 ARTICLE 28, POINT 2 Article 4, paragraph 5 (Directive 2001/83/EC)	
5. This Directive and all Regulations referred to therein shall not affect the application of national legislation prohibiting or restricting the use of any specific type of human or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from these cells. The Member States shall communicate the national legislation concerned to the Commission.	5. This Directive and all Regulations referred to therein shall not affect the application <u>of national</u> legislation prohibiting or restricting the use of any specific type of human or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from these cells***, on grounds not dealt with in the aforementioned Community legislation***. The Member States shall communicate the national legislation concerned to the Commission. ***The Commission shall make this information publicly available in a register.***

Or. en

AMENDMENT 129
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 129 ARTICLE 29
1. Advanced therapy medicinal products which were legally on the Community market in accordance with national or Community legislation at the time of ***entry into force*** of this Regulation shall comply with this Regulation no later than ***2 years*** after its ***entry into force***.	1. Advanced therapy medicinal products***, other than tissue engineered products,*** which were legally on the Community market in accordance with national or Community legislation at the time of ***application*** of this Regulation shall comply with this Regulation no later than ***3 years*** after its ***application***.
	1a. Tissue engineered products which were legally on the Community market in accordance with national or Community legislation at the date of application of this Regulation shall comply with this Regulation no later than 4 years after its application.
2. By way of derogation from Article 3(1) of Regulation (EC) No 297/95, no fee shall be payable to the Agency in respect of applications submitted for the authorisation of the advanced therapy medicinal products mentioned in ***paragraph 1***.	2. By way of derogation from Article 3(1) of Regulation (EC) No 297/95, no fee shall be payable to the Agency in respect of applications submitted for the authorisation of the advanced therapy medicinal products mentioned in ***paragraphs 1 and 1a*** *of this Article*.

Or. en

AMENDMENT 130
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 130 ARTICLE 30, PARAGRAPH 2	
It shall apply from [***3 months*** after entry into force]	It shall apply from [***1 year*** after entry into force]

Or. en

AMENDMENT 131
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 131 ANNEX I	
Points referred to in Article 2(1)(c)	***Manipulations*** referred to in ***point 1 of*** Article 2(1)(c)***:***
Cells or tissues shall be considered "engineered" if they fulfil at least one of the following points:	
(1) The cells or tissues have been subject to substantial manipulation, so that their original biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement, are altered.	
The following manipulations are not considered as substantial manipulations:	
- cutting,	- cutting,
- grinding,	- grinding,
- shaping,	- shaping,
- centrifugation,	- centrifugation,
- soaking in antibiotic or antimicrobial solutions,	- soaking in antibiotic or antimicrobial solutions,
- sterilization,	- sterilization,
- irradiation,	- irradiation,
- cell separation, concentration or	- cell separation, concentration or

purification,	purification,
- filtering,	- filtering,
- lyophilization,	- lyophilization,
- freezing,	- freezing,
- cryopreservation,	- cryopreservation,
- vitrification.	- vitrification.
(2) The cells or tissues are not intended to be used for the same essential function or functions in the recipient as in the donor.	
(3) The cells or tissues form part of a combined advanced therapy medicinal product.	

Or. en

AMENDMENT 132
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 132 ANNEX II, POINT 2.2.
2.2. qualitative and quantitative composition in terms of the active substances and other constituents of the product, knowledge of which is essential for proper use, administration or implantation of the product. Where the product contains cells or tissues, a detailed description of these cells or tissues and of their specific origin shall be provided.	2.2. qualitative and quantitative composition in terms of the active substances and other constituents of the product, knowledge of which is essential for proper use, administration or implantation of the product. Where the product contains cells or tissues, a detailed description of these cells or tissues and of their specific origin***,*** ***including the species of animal in cases of non-human origin,*** shall be provided. ***For a list of excipients, see point 6.1.***

Or. en

AMENDMENT 133
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 133 ANNEX II, POINTS 4, 5 and 6
4. Clinical particulars:	4. Clinical particulars:
4.1. therapeutic indications,	4.1. therapeutic indications,
4.2. ***dosage*** and detailed instructions for use, application, implantation or administration for adults and, where necessary, for children or other special populations, if necessary with explanatory drawings and pictures,	4.2. ***posology*** and detailed instructions for use, application, implantation or administration for adults and, where necessary, for children or other special populations, if necessary with explanatory drawings and pictures,
4.3. contra-indications,	4.3. contra-indications,
4.4. special warnings and precautions for use, including any special precautions to be taken by persons handling such products and administering or implanting them to patients, together with any precautions to be taken by the patient,	4.4. special warnings and precautions for use, including any special precautions to be taken by persons handling such products and administering or implanting them to patients, together with any precautions to be taken by the patient,
4.5. interaction with other medicinal products and other forms of interactions,	4.5. interaction with other medicinal products and other forms of interactions,
4.6. use during pregnancy and lactation,	4.6. use during pregnancy and lactation,
4.7. effects on ability to drive and to use machines,	4.7. effects on ability to drive and to use machines,
4.8. undesirable effects,	4.8. undesirable effects,
4.9. overdose (symptoms, emergency procedures).	4.9. overdose (symptoms, emergency procedures).

5. Pharmacological properties:	5. Pharmacological properties:
5.1. pharmacodynamic ***and pharmacokinetic*** properties***, if applicable,***.	5.1. pharmacodynamic properties,
	5.1a. pharmacokinetic properties,
	5.2. preclinical safety data.
6. Quality particulars:	6. Quality particulars:
6.1. list of ***preservative systems and*** excipients***, if applicable***,	6.1. list of excipients, ***including preservative systems,***
6.2. ***major*** incompatibilities***, if applicable***,	6.2. incompatibilities,
6.3. shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time,	6.3. shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time,
6.4. special precautions for storage,	6.4. special precautions for storage,
6.5. nature and contents of container and special equipment for use, administration or implantation,	6.5. nature and contents of container and special equipment for use, administration or implantation, ***if necessary with explanatory drawings and pictures,***
6.6. special precautions and instructions for handling and disposal of a used advanced therapy medicinal product or waste materials derived from such product, if appropriate.	6.6. special precautions and instructions for handling and disposal of a used advanced therapy medicinal product or waste materials derived from such product, if appropriate ***and, if necessary, with explanatory drawings and pictures***.

Or. en

AMENDMENT 134
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 134 ANNEX III, POINT (B)
(b) A description of the active substance(s) expressed qualitatively and quantitatively, including, where the product contains cells or tissues, the statement "This product contains cells of human/animal [as appropriate] origin" together with a short description of these cells or tissues and of their specific origin;	(b) A description of the active substance(s) expressed qualitatively and quantitatively, including, where the product contains cells or tissues, the statement "This product contains cells of human/animal *[as appropriate]* origin" together with a short description of these cells or tissues and of their specific origin***, including the species of animal in cases of non-human origin***;

Or. en

AMENDMENT 135
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 135 ANNEX III, POINTS (C) and (D)
(c) The pharmaceutical form;	(c) The pharmaceutical form ***and if applicable the contents by weight, by volume or by number of doses of the product***;
(d) A list of ***preservative systems and*** excipients***, if applicable***;	(d) A list of excipients***, including preservative systems***;

Or. en

AMENDMENT 136
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 136 ANNEX IV, POINT (A) (I)
(i) the name of the advanced therapy medicinal product and an indication of whether it is intended for babies, children or adults. The common name shall be included ***if the product contains only one active substance and if its name is an invented name***;	(i) the name of the advanced therapy medicinal product and an indication of whether it is intended for babies, children or adults. The common name shall be included;

Or. en

AMENDMENT 137
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 137 ANNEX IV, POINT (A) (III)
(iii) where the product contains cells or tissues, a description of those cells or tissues and of their specific origin;	(iii) where the product contains cells or tissues, a description of those cells or tissues and of their specific origin***, including the species of animal in cases of non-human origin***;

Or. en

AMENDMENT 138
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament

Amendment 138
ANNEX IV, POINT (A) (III A) (new)

	(iiia) where the product contains medical devices or active implantable medical devices, a description of those devices and their specific origin.

Or. en

AMENDMENT 139
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 139 ANNEX IV, POINT (D) (I) AND (II)
(i) the ***dosage***,	(i) the ***posology***,
(ii) ***a summary of*** the method of use, application, administration or implantation and, if necessary, the route of administration;	(ii) the method of use, application, administration or implantation and, if necessary, the route of administration;

Or. en

AMENDMENT 140
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 140 RECITAL 2	
(2) Insofar as these advanced therapy products are presented as having properties for treating or preventing diseases in human beings, or that they may be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, they are biological medicinal products within the meaning of Article 1(2) and Annex I to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Thus, the essential aim of any rules governing their production, distribution and use must be to safeguard public health.	(2) Insofar as these advanced therapy products are presented as having properties for treating or preventing diseases in human beings, or that they may be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting ***principally*** a pharmacological, immunological or metabolic action, they are biological medicinal products within the meaning of Article 1(2) and Annex I to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Thus, the essential aim of any rules governing their production, distribution and use must be to safeguard public health.

Or. en

AMENDMENT 141
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 141 RECITAL 3	
(3) For reasons of clarity, complex therapeutic products need precise legal definitions. Gene therapy medicinal products and somatic cell therapy medicinal products have been defined in Annex I to Directive 2001/83/EC, but a a legal definition of tissue engineered products remains to be laid down.	(3) For reasons of clarity, complex therapeutic products need precise legal definitions. Gene therapy medicinal products and somatic cell therapy medicinal products have been defined in Annex I to Directive 2001/83/EC, but a a legal definition of tissue engineered products remains to be laid down. ***When products are based on viable cells or tissues, the pharmacological, immunological or metabolic action should be considered as the principal mode of action. It should also be clarified that products which do not meet the definition of a medicinal product, such as products made exclusively of non-viable materials which act primarily by physical means, cannot by definition be advanced therapy medicinal products.***

Or. en

AMENDMENT 142
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

Report **A6-0031/2007**
Miroslav Mikolášik
Advanced therapy medicinal products

Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 142 RECITAL 3 A (new)
	(3a) 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 should always be regulated under this Regulation.
	Or. en

AMENDMENT 143
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Miroslav Mikolášik
Advanced therapy medicinal products

Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 143 RECITAL 5	
(5) ***Advanced therapy medicinal products should be regulated in so far as they*** are intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process***, within the meaning of Article 2(1) of*** Directive 2001/83/EC**.** Advanced therapy medicinal products which are ***both*** prepared ***in full*** and used in a hospital, ***in accordance with a*** medical prescription for an individual patient, should ***thus*** be excluded from the scope of *the present* Regulation.	(5) ***This Regulation is a lex specialis, which introduces additional provisions to those laid down in Directive 2001/83/EC. The scope of this Regulation should be to regulate advanced therapy medicinal products which*** are intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process, ***in accordance with the general scope of the Community pharmaceutical legislation laid down in Title II of*** Directive 2001/83/EC. Advanced therapy medicinal products which are prepared ***on a non-routine basis according to specific quality standards,*** and used ***within the same Member State*** in a hospital ***under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual*** medical prescription ***for a custom-made product*** for an individual patient***,*** should be excluded from the scope of *this* Regulation ***whilst at the same time ensuring that relevant Community rules related to quality and safety are not undermined.***

Or. en

AMENDMENT 144
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 144 RECITAL 9	
(9) The evaluation of advanced therapy medicinal products often requires very specific expertise, which goes beyond the traditional pharmaceutical field and covers areas on the borderline to other sectors such as biotechnology and medical devices. For this reason, it is appropriate to create, within the Agency, a Committee for Advanced Therapies, which the Committee for Medicinal Products for Human Use of the Agency ***should consult on the assessment of data related to advanced therapy medicinal products, before issuing its final scientific opinion.*** In addition, the Committee for Advanced Therapies ***may*** be consulted for the evaluation of any other medicinal product which requires specific expertise falling within its area of competence.	(9) The evaluation of advanced therapy medicinal products often requires very specific expertise, which goes beyond the traditional pharmaceutical field and covers areas on the borderline to other sectors such as biotechnology and medical devices. For this reason, it is appropriate to create, within the Agency, a Committee for Advanced Therapies, which ***should be responsible for preparing a draft opinion on the quality, safety and efficacy of each advanced therapy medicinal product for final approval by*** the Committee for Medicinal Products for Human Use of the Agency. In addition, the Committee for Advanced Therapies ***should*** be consulted for the evaluation of any other medicinal product which requires specific expertise falling within its area of competence.

Or. en

AMENDMENT 145
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 145 RECITAL 10	
(10) The Committee for Advanced Therapies should gather the best available Community expertise on advanced therapy medicinal products. The composition of the Committee for Advanced Therapies 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 ***surgeons*** with scientific experience of advanced therapy medicinal products should also be represented.	(10) The Committee for Advanced Therapies should gather the best available Community expertise on advanced therapy medicinal products. The composition of the Committee for Advanced Therapies 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*** with scientific experience of advanced therapy medicinal products should also be represented.

Or. en

AMENDMENT 146
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 146 RECITAL 14	
(14) As a matter of principle, human cells or tissues contained in advanced therapy medicinal products should be procured from voluntary and unpaid donation. Voluntary and unpaid tissue and cell donations ***are a factor which*** may contribute to high safety standards for tissues and cells and therefore to the protection of human health.	(14) ***As regards the donation of human cells or tissues, principles such as the anonymity of both donor and recipient, altruism of the donor and solidarity between donor and recipient should be respected.*** As a matter of principle, human cells or tissues contained advanced therapy medicinal products should be procured from voluntary and unpaid donation. ***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, as*** voluntary and unpaid tissue and cell donations may contribute to high safety standards for tissues and cells and therefore to the protection of human health.

Or. en

AMENDMENT 147
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Advanced therapy medicinal products

Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 147 RECITAL 16	
(16) The manufacture of advanced therapy medicinal products should be in compliance with the principles of good manufacturing practice, as set out in Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use. Furthermore, guidelines specific to advanced therapy medicinal products should be drawn up, so as to properly reflect the particular nature of their manufacturing process.	(16) The manufacture of advanced therapy medicinal products should be in compliance with the principles of good manufacturing practice, as set out in Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use***, and adapted, where necessary, to reflect the specific nature of the products***. Furthermore, guidelines specific to advanced therapy medicinal products should be drawn up, so as to properly reflect the particular nature of their manufacturing process.

Or. en

AMENDMENT 148
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Advanced therapy medicinal products

Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 148 RECITAL 17	
(17) Advanced therapy medicinal products may incorporate medical devices or active implantable medical devices. Those devices should meet the essential requirements laid down in Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, respectively, in order to ensure an appropriate level of quality and safety.	(17) Advanced therapy medicinal products may incorporate medical devices or active implantable medical devices. Those devices should meet the essential requirements laid down in Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, respectively, in order to ensure an appropriate level of quality and safety. ***The results of the assessment of the medical device or the active implantable medical device by a notified body in accordance with those Directives should be recognised by the Agency in the evaluation of a combined product carried out under this Regulation.***

Or. en

AMENDMENT 149
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 149 RECITAL 18	
(18) Specific rules should be laid down, adapting the requirements in Directive 2001/83/EC as regards the summary of product characteristics, labelling and package leaflet to the technical specificities of advanced therapy medicinal products.	(18) Specific rules should be laid down, adapting the requirements in Directive 2001/83/EC as regards the summary of product characteristics, labelling and package leaflet to the technical specificities of advanced therapy medicinal products. ***These rules should comply fully with the patient's right to know the origin of any cells or tissues used in the preparation of advanced therapy medicinal products, while respecting donor anonymity.***

Or. en

AMENDMENT 150
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Advanced therapy medicinal products

Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 150 RECITAL 19	
(19) ***Long-term patient follow-up and pharmacovigilance are*** crucial ***aspects*** of advanced therapy medicinal products. Where justified on public health grounds, the holder of the marketing authorisation should ***therefore*** be required to put in place a suitable risk management system to address ***those aspects***.	(19) ***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.*** Where justified on public health grounds, the holder of the marketing authorisation should ***also*** be required to put in place a suitable risk management system to address ***risks related to advanced therapy medicinal products.***

Or. en

AMENDMENT 151
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Advanced therapy medicinal products

Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
	Amendment 151 RECITAL 19 A (new)
	(19a) The operation of this Regulation requires the establishment of guidelines, to be drawn up either by the Agency or by the Commission. Open consultation with all interested parties, in particular the Member States authorities and the industry, should be carried out in order to allow a pooling of the limited expertise in this area and ensure proportionality. Guidelines and technical requirements referred to in Articles 4 and 5 should be laid down as soon as possible, preferably during the first year after entry into force and before the time of application of this Regulation.
	Or. en

AMENDMENT 152
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Advanced therapy medicinal products

Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 152 RECITAL 21	
(21) As science evolves very rapidly in this field, undertakings developing advanced therapy medicinal products should be enabled to request scientific advice from the Agency, including advice on postauthorisation activities. As an incentive, the fee for that scientific advice should be kept at a minimal level.	(21) As science evolves very rapidly in this field, undertakings developing advanced therapy medicinal products should be enabled to request scientific advice from the Agency, including advice on postauthorisation activities. As an incentive, the fee for that scientific advice should be kept at a minimal level ***for small and medium-sized enterprises, and should also be reduced for other applicants***.

Or. en

AMENDMENT 153
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 153 RECITAL 22	
(22) The Agency should be empowered to give scientific recommendations on whether a given product based on cells or tissues meets the scientific criteria which define advanced therapy medicinal products, in order to address, as early as possible, questions of borderline with other areas such as cosmetics or medical devices, which may arise as science develops.	(22) The Agency should be empowered to give scientific recommendations on whether a given product based on ***genes,*** cells or tissues meets the scientific criteria which define advanced therapy medicinal products, in order to address, as early as possible, questions of borderline with other areas such as cosmetics or medical devices, which may arise as science develops. ***The Committee for Advanced Therapies, with its unique expertise, should have a prominent role in the provision of such advice.***

Or. en

AMENDMENT 154
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Advanced therapy medicinal products

Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 154 RECITAL 23	
(23) Studies necessary to demonstrate the quality and non-clinical safety of advanced therapy medicinal products are often carried out by small and medium-sized enterprises. As an incentive to conduct those studies, a system of evaluation and certification of the resulting data by the Agency, independently of any marketing authorisation application, should be introduced. This system should also aim at facilitating the evaluation of any future marketing authorisation application based on the same data.	(23) Studies necessary to demonstrate the quality and non-clinical safety of advanced therapy medicinal products are often carried out by small and medium-sized enterprises. As an incentive to conduct those studies, a system of evaluation and certification of the resulting data by the Agency, independently of any marketing authorisation application, should be introduced. ***Even though the certification would not be legally binding,*** this system should also aim at facilitating the evaluation of any future ***application for clinical trials and*** marketing authorisation application based on the same data.

Or. en

AMENDMENT 155
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Miroslav Mikolášik
Advanced therapy medicinal products

Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 155 RECITAL 24	
(24) In order to take into account scientific and technical developments, the Commission should be empowered to adopt any necessary changes regarding the technical requirements for applications for marketing authorisation of advanced therapy medicinal products, the summary of product characteristics, labelling, and package leaflet.	(24) In order to take into account scientific and technical developments, the Commission should be empowered to adopt any necessary changes regarding the technical requirements for applications for marketing authorisation of advanced therapy medicinal products, the summary of product characteristics, labelling, and package leaflet. ***The Commission should ensure that relevant information on envisaged measures is made available to interested parties without delay.***

Or. en

AMENDMENT 156
by Dagmar Roth-Behrendt, on behalf of the PSE Group, Frédérique Ries, on behalf of the ALDE-Group, Adamos Adamou, on behalf of the GUE-Group

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Advanced therapy medicinal products

Proposal for a regulation (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

Text proposed by the Commission	Amendment by Parliament
Amendment 156 RECITAL 27	
(27) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.	(27) The measures necessary for the implementation of this Regulation should be adopted in accordance with the Council Decision 1999/468/EC of 28 June 1999 laying down the procedures of the exercise of implementing powers conferred to the Commission. ***The regulatory procedure with scrutiny provided for in Article 5a of that Decision should 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.***

Or. en