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EU leaves decision on stem-cell ethics to member states [\[fr\]](#)[\[de\]](#)

Published: Wednesday 25 April 2007 | Updated: Thursday 26 April 2007

The European Parliament has backed a compromise package on a proposed EU regulation on advanced therapies. After hard battle, the decision on ethics of treatment derived, for example, from human embryonic stem cells, is finally left to member states.

Related Documents:

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Brief News:

The European Parliament adopted by a clear majority, on 25 April 2007, the amended report by Miroslav Mikolášik on the proposal for an EU regulation for advanced therapies. With this vote, the Parliament rejected all ethical amendments proposed to the report and, therefore, backed EU-wide regulation on products or cures derived from human embryonic stem cells. The decision to allow the use of these treatments in respective territories is left to member states.

The bio-industry quickly welcomed the vote, as the future regulation will create one European regulatory framework and a single European marketing authorisation for gene therapy, cell therapy and tissue engineered products. The regulation is expected to foster innovation, as it will remove industry hurdles of addressing 27 differing regulatory systems across Europe.

Patient organisations also welcome the report, as an EU regulatory framework will harmonise patient access to innovative treatments and a centralised procedure for the marketing authorisation of the new products will ensure a high level of health protection.

"Today's Parliament vote paves the way for an early adoption of this eagerly awaited regulation, for which patients and industry have been waiting too long. With this regulation, we unleash the EU potential for innovation, often driven by SMEs, while respecting member states' decisions on ethical concerns," said Commission Vice- President Günter Verheugen.

The regulation still needs an official endorsement by the Council before its publication in the official journal.

Links

EU official documents

- Commission press release: [Commission Vice-President Verheugen welcomes Parliament vote on Advanced Therapies](#) (25 April 2007)
- PreLex: [Proposal for a regulation on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation \(EC\) No 726/2004 \[FR\] \[DE\]](#)
- Parliament news: [MEPs set out safer rules for innovative therapies](#) (25 April 2007) [\[FR\]](#) [\[DE\]](#)

Political Groups

- Alliance of Liberals and Democrats for Europe press release: [Règlement sur les médicaments de thérapie innovante: les députés se rangent du côté des patients](#) (25 April 2007)
- European Parliament Socialist group press release: [The European Parliament has adopted the report on the advanced therapy medicinal products](#) (25 April 2007)
- Delegation of French Socialist in the European Parliament press release: [Oui, au développement des médicaments de thérapie innovante](#) (25 April 2007)

Business & Industry

- European Federation of Pharmaceutical Industries and Associations (EFPIA) press release: [The European Biopharmaceutical Industry welcomes today's vote by the European Parliament on the advanced therapies regulation](#) (25 April 2007)
- BioIndustry Association (BIA) press release: [BIA welcomes European Parliament support for Advanced](#)

- [Therapies Regulation](#) (25 April 2007)
- EuropaBio press release: [EuropaBio congratulates European Parliament on big step towards Advanced Therapies Regulation](#) (25 April 2007)

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