COMECE: veronachtzaam ethische kant nieuwe behandelingen niet

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EU Legislation on Advanced Therapies: Ethical issues may not be excluded

On 30 January 2007, the Committee for Environment, Public Health and Food Safety adopted the draft report by Mr Mikolasik (EPP, Slowakia) on the proposal for a regulation on “Advanced Therapies”. Mgr. Treanor, Secretary General of the Commission of the Bishops’ Conferences of the European Community acknowledged the benefits of a uniform procedure for advanced therapies, whilst underlining that ethical issues may not be excluded.

He made the following comments:
The benefit of a uniform European procedure for the authorisation of advanced therapy medicinal products such as tissue engineering (e.g. skin or cartilage), gene therapy and somatic cell therapy is obvious. The EU regulation should ensure a single scientific evaluation of the quality, safety and efficacy of the product carried out to the highest possible standard and to facilitate access for patients to advanced therapies. It is also of considerable significance for European competitiveness.

Ethical issues to be addressed: The European Commission emphasises that the Charter of Fundamental Rights of the EU and the Convention on Human Rights and Biomedicine of the Council of Europe (Oviedo Convention) shall be taken into account. This is to be welcomed. When it comes to a single European authorisation of advanced therapy medicinal products, ethical issues may not be excluded.

Therefore, the prohibition to use the human body and its parts for financial gain must be ensured by the Regulation; this principle is enshrined both in the Oviedo-Convention and in the EU-Charter of Fundamental Rights. The current proposal which contains a reference to Directive 2004/23/EC on standards of quality and safety for the donation of human tissues and cells falls short: It does not commit Member States to this principle, but only asks member states “to endeavour to ensure” voluntary and unpaid donations.

The Regulation should also implement the prohibition of germ line interventions which introduce modifications in the genome of descendants.

It should also be clarified that no possible future products receive a European authorisation which imply the use of human-animal hybrids and chimeras. The EU stated in the Directive 98/44 on Biotechnological Inventions processes to produce chimeras from germ cells or totipotent cells of humans and animals that offend against human dignity.

It is extremely regrettable that the report adopted by the leading EP-Committee on Environment and Public Health excludes these ethical issues, in contrast to the advice of the rapporteur Mr Mikolasik. The Committee for Industry and Research and the Legal Affairs Committee, on the other hand, adopted amendments which would ensure these principles. We call on the plenary of the European Parliament as well as on the Council of Ministers to take up these issues.

Subsidiarity and ethics
The report which will be presented to the plenary of the European Parliament proposes that potential future advanced therapy medicinal products containing or being derived from human embryonic and foetal cells be

exempt from the scope of the Regulation [1]. This is greatly welcomed. It is also in line with the declared wish of the European Commission that the Regulation should not interfere with decisions made by Member States on whether to allow the use of any specific type of human cells, such as embryonic stem cells, or animal cells. [2] In fundamental ethical issues touching the inviolability and the dignity of human life, it is indispensable that the national sovereignty of member states be respected. To this end it is required that the principle of subsidiarity for ethical rules be anchored in the Regulation.

The European Parliament and the Council of Ministers now face the challenge of addressing these ethical issues with the necessary and adequate respect and in transparency. Following the national debates in the Committee of the European Parliament, one was betimes tempted to wonder if already the use of the word “ethics” for some deputies creates objection which renders a constructive discussion impossible. To make the European project credible to the citizens, an honest, respectful and constructive debate about these issues is indispensable.

Notes

1. This amendment was adopted by the Legal Affairs Committee which is competent, according to the Rules of Procedure of the European Parliament, for ethical questions arising in new technologies. For this reason the amendment was directly integrated in the report of the Environment Committee (Hughes Procedure).
2. In view of embryonic stem cells this would also avoid that the hype about expecting all kinds of therapies from embryonic stem cells would be promoted. This all the more as currently there is no Clinical Trial on humans with embryonic stem cells (as distinct from non-embryonic stem cells).