COMECE: Nieuwe behandelingen tegen elke prijs?

COMECE, 26 april 2007

Advanced Therapies at any cost?
Press declaration on the plenary vote of the European Parliament on the Regulation on Advanced Therapy Medicinal Products (Mikolášik-report)

Mgr. Noel Treanor, Secretary General of COMECE, expressed his disappointment about the result of the vote in the European Parliament regarding the Regulation on Advanced Therapies: “In fundamental ethical issues touching on the inviolability and the dignity of human life, it is indispensable that the national sovereignty of Member States be respected and not prejudiced by the application of provisions relating to the single market.”

The Secretary General of COMECE recognises the great benefit of the proposed Regulation for patients in the EU and for European competitiveness. To this end he welcomes the initiative in principle.

He highlights, however, that the Regulation is often being used to raise the hopes and expectations of patients which are not supported by scientific results. “For example, in the press statement of the European Parliament dated 25 April 2007 it is mentioned that ‘these “innovative therapies” which have a huge potential for curing diseases such as Alzheimer’s…’ Such raising of hope for sick and desperate people is irresponsible. To our knowledge there is no scientific approach envisaging therapy for Alzheimer’s.”

Moreover, the Secretary General emphasises that the proposed Regulation introducing a uniform EU authorisation procedure of Advanced Therapy Medicinal Products should not only ensure quality and safety standards. It should also safeguard fundamental ethical principles on which there is a broad European consensus. He therefore regrets very much that in yesterday’s plenary vote on the Mikolášik report all amendments were rejected which aimed at safeguarding fundamental ethical principles:
· The Principle of non-commercialisation of the human body and its parts (1)
· The prohibition of germ line interventions which may affect future generations
· The ban for EU authorisations of potential future products using hybrids or embryonic chimeras.

“When it comes to possible future products which are ethically contentious in the EU, the Regulation may not prejudice the complex ethical decisions in the Member States”, says Mgr. Treanor. For this reason he regrets in particular that the European Parliament did not adopt the proposal of the Legal Affairs Committee according to which possible future products that might be produced by the use of human embryonic or foetal cells, shall be exempt from the scope of the Regulation. At the very minimum it would at least have been necessary to improve the legal safeguard for the right of Member States to introduce new legislation restricting or prohibiting circulation of such possible future products in their countries. (2) “We regret that amendment 157 was rejected which would have clarified that this right of the Member States be existent also for the future. We nonetheless hope that this right of the Member States would – in the case of conflict – be confirmed by the European Court of Justice”.

Over and above this concrete case, the Secretary General states that the debate in the European Parliament on such ethical issues have reached a deadlock, the use of the word “ethics” already evoking objection for some deputies. “This renders a factual debate impossible. We therefore call on the European public and on politicians not to avoid these fundamental ethical issues and to debate them in a constructive, differentiated manner”, concludes Mgr. Treanor.

Notes

1. The provision in the Regulation referring to Directive 2004/23/EG for the quality and safety of cell- and tissue donation is legally not sufficient to ensure the principle of non-commercialisation of the human body since the Directive – in accordance with its legal character – does not contain an obligation of Member States, to implement free and unpaid donation.
2. This wish has also been stated by the European Commission. However, in view of the legal base of the Regulation (i.e. article 95 EC-Treaty) it is far from certain that the Member States would indeed be entitled to introduce new legislation, restricting the circulation of products on ethical grounds. It is necessary to ensure this right for the future, because – due to the current lack of any such products – there is not yet any such legislation in the Member States.