Question for written answer P-8076/2010
to the Commission
Rule 117
Riikka Manner (ALDE)

Subject: Clinical Trials Directive (and possible restrictions for European research)

Europe has invested for decades from the budget of the European Union, as well as from the national budgets, in developing biosciences and molecular medicine in particular. There is a growing need for development of new treatment methods and innovations for many widespread and lethal diseases, including different variations of cancer. Despite the massive human and economic resources invested in research, the process of developing effective pharmaceutical and medical treatments and bringing them forward to the market, for example in the field of gene therapy, has been stagnating. According to the academics, there is a huge potential for a more rapid development, but the most limiting factor to the research seems to the rigorous legislation within the EU.

The requirements for the conduct of clinical trials in the EU (Directive 2001/20/EC)[1] are claimed to be so strict that they obstruct the benefit to society. The official goals of the EU Clinical Trials Directive, implemented in 2004, were to improve the protection of patients and the reliability of reporting on research and to harmonise and increase the competitiveness of European clinical research. The outcome has restricted these goals. All clinical trials are exposed to the same procedure by this directive. This has become too expensive for scientific research groups and Europe has lost the competition to the United States, where the policy for getting permissions for clinical trials takes into account the need for research in the field of medicine. The directive has increased the administrative burden on European researchers and severely ill patients have not been able to enjoy the breakthroughs within medicine.

Research and development is one of the fields where we can create added European value. Now there is a justified fear that the innovations in areas such as gene therapy will not be European, but that our researchers will have to leave the European market.

I would like to ask the Commission if the real impact of the EU Clinical Trials Directive on research has been analysed and if it is planned to draw a reasonable conclusion and to make a needed legislative contribution to support research in the field of gene therapy within the European Union?

[1] OJ L 121, 1.5.2001, p. 34.