WRITTEN QUESTION E-2357/07
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to the Commission

Subject: Data protection in cases where ethical guidelines are not respected

Prior to the approval and authorisation of medicines, clinical trials must be carried out. In order to protect patients, ethical guidelines have been drawn up which are laid down in European directives (2001/20/EC[1]) and in international agreements. Clinical trials are increasingly being carried out outside Europe, partly in order to reduce costs. If the clinical trials for authorisation on the European market are carried out outside Europe, the same ethical rules apply as for clinical trials within Europe (2004/27/EC[2], Article 8(3), point i b). This was confirmed in the answer to a question from Max van den Berg. A study by SOMO (Centre for Research on International Corporations, www.somo.nl) shows that these ethical rules are not always complied with. A study by Wemos shows that the registration authorities in the EU generally pay little attention to ethical guidelines, thus enabling unethically tested medicines to appear on the European market. There is a lack of effective penalties. The proposal for a regulation on such penalties is a good opportunity to introduce them. One such penalty might be not to apply data protection to data obtained on the basis of a study which fails to comply with ethical guidelines. Unlawfully obtained data do not deserve protection.

1. Is the Commission prepared to establish sufficiently deterrent penalties in its above-mentioned proposal on enforcing compliance with ethical guidelines?

2. Is the Commission prepared – if the results of the clinical trial are positive and there is no doubt about the results - to propose the suspension of data protection if it becomes clear that ethical guidelines were not fully complied with in the clinical trials?

[1] OJ L 121, 1.5.2001, p. 34.
[2] OJ L 136, 30.4.2004, p. 34.