WRITTEN QUESTION E-1167/08
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to the Commission

Subject: Clinical trials in developing countries

Clinical trials are increasingly being carried out on people in low-income and developing countries, because this can reduce costs. Although international and European guidelines on good clinical practice specify the conditions and procedures under which these clinical trials must be carried out (European Directive 2001/20/EC[1]), in many developing countries these conditions and procedures cannot be met. This is because of poor health systems, inadequate supervision by the national and European drug authorities and a lack of information and transparency on clinical trials in audit reports.

As a result, there are no guarantees that clinical trials will be carried out in an ethical manner and the rights and health of trial participants respected. Indeed, there have been cases reported of violation of the ethical guidelines (see: The Wemos Foundation. December 2007. A Bitter Pill).

The European Union has a clear responsibility towards trial participants. However, the EMEA and national drug agencies authorise drugs to enter the European market without a thorough check on whether the clinical trials comply with the European ethical guidelines on good clinical practice.

1. Can the Commission guarantee that drugs authorised by the EMEA have been tested in line with the ethical guidelines on good clinical practice as laid down in European Directive 2001/20/EC and the Declaration of Helsinki?

2. If not, is the Commission willing to take action and consider the following solutions:

– imposing an obligation to publicly register in advance all clinical trials and the outcomes of these trials and create a legal framework to improve the transparency and public accessibility of all clinical trials carried out in developing countries, both in research protocols and audit reports;
– imposing obligatory supervision of each clinical trial by an independent expert;
– rejecting marketing authorisation requests or immediately withdrawing authorisation if non-compliance with ethical guidelines is discovered;
– putting in place the human and financial resources to allow European regulators to thoroughly check whether clinical trials comply with the guidelines on Good Clinical Practice?

3. What action will the Commission take to help developing countries improve their supervision of clinical trials and compliance with ethical guidelines?

4. Cases have been reported where new drugs have been tested against placebos despite the fact that appropriate treatment already exists, with fatal consequences for patients using the placebos. The EMEA rules are open to interpretation. Can the Commission clarify the conditions that allow and justify the use of placebos?

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