WRITTEN QUESTION E-0777/07
by Margrietus van den Berg (PSE)
to the Commission

Subject: Negligence of European registration authorities in monitoring compliance with codes of ethics in trials of new drugs

The Dutch NGO Wemos has carried out a survey to ascertain the extent to which European registration authorities check whether codes of ethics have been complied with in performing clinical trials of new drugs in developing countries. It found that relatively little attention was being devoted to this aspect. Growing numbers of drugs trials are being carried out in developing countries with very vulnerable populations. The registration authorities do not examine post-trial treatment arrangements, although this is a precondition laid down in the Declaration of Helsinki. The European registration authorities mainly entrust responsibility for ethical monitoring to medical ethics committees in developing countries. It is well known that many of these medical ethics committees lack competence and independence. The European registration authorities should therefore devote more attention to this. A second conclusion from the survey was that unethical trials do not necessarily result in a refusal to register a particular drug. Finally, the survey revealed that the registration procedure was very lacking in transparency.

In answer to my Question E-1805/2006, the Commission replied, inter alia. 'They (clinical trials outside the Member States) can be taken into account for an application for marketing authorisation within the Community only if they are designed, implemented and reported on as to what good clinical practice and ethical principles are concerned, on the basis of principles which are equivalent to the provisions of Directive 2001/20/EC.[1] They shall be carried out in accordance with the ethical principles that are reflected, for example, in the Declaration of Helsinki.'

1. Can the Commission confirm the above conclusions from the survey by Wemos? How does the Commission check whether the registration authorities are complying with their obligations?

2. Does the Commission agree that a drug should not be licensed for the European market if it has undergone unethical trials?

3. Will the Commission make the work of the registration authorities more transparent?

4. How can subjects in drugs trials in developing countries hold any European drugs manufacturers liable if irregularities occur during or after the trials?

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