WRITTEN QUESTION E-4022/07
by Margrietus van den Berg (PSE)
to the Commission

Subject: Supervision by the Commission of European registration authorities with regard to reviewing ethical aspects of medicines

Further to my Question E-0777/07 and the answer to it, in which the Commission states that it is not aware of the research by the Dutch NGO Wemos, I am forwarding a reference to this research[1]. The research shows that, when assessing new medicines on the European market, European registration authorities give little consideration to ethical aspects of clinical trials conducted in developing countries, although this is a requirement under European directives[2].

The inspectorates to which the Commission refers in its reply can only perform limited checks. This is so on the one hand because the checks are generally only performed retrospectively and on the other hand because inspections are often only initiated after the registration authority has indicated their desirability. As the research by Wemos indicates that registration authorities are not very interested in ethical aspects, it may be concluded that they will propose checks on ethical aspects in only a limited number of cases.

1. Does not the Commission agree that it is its task to monitor how the central European registration authority EMEA checks ethical aspects when it receives applications for authorisation to market new medicines? If so, how does the Commission check whether EMEA is complying with its obligation?

2. Will the Commission refuse to issue a trading licence if it finds that a medicine has been tested unethically?

3. There are indications that, when assessing medicines, registration authorities rely on the summaries of the registration file. These summaries are generally compiled not by independent experts but by the applicant in person. Can the Commission confirm that this is the practice and if so, does the Commission consider this to be an adequate way of assessing a new medicine?

---

1 http://www.wemos.nl/Documents/summary_english.pdf.

2 With regard to clinical trials in connection with an application for a licence to place a product on the market, Directive 2001/83/EC, as amended by Directive 2003/63/EC, lays down that they must comply with the requirements of Directive 2001/20/EC. These provisions also apply to clinical trials performed outside the Community.