WRITTEN QUESTION E-2703/09
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to the Commission

Subject: Ethical guidelines for clinical trials

In the study 'Ethical concerns in clinical trials in India: an investigation' by the Centre for Studies in Ethics and Rights (CSER), several drugs are described that were tested in India and are now available on the European market. According to the author of the report all trials violated the Indian Council of Medical Research's ethical guidelines and the World Medical Association (WMA) Declaration of Helsinki. One of the drugs described in the report is lapatinib. It was granted conditional approval by the EMEA in 2008.

According to Finding 2 of the CSER report: *'The majority of breast cancer patients in India cannot afford proper treatment. This trial required seriously ill patients who had not received treatment for their condition. Their economic vulnerability forces patients in India to take part in trials in order to get access to treatment and to disregard the potential risks that participating in clinical trials entails. By carrying out this clinical trial in India GlaxoSmithKline (GSK) took advantage of the vulnerable position of breast cancer patients.'* Finding 5 of the report states that: '*The approved drug is not available to the vast majority of Indians who could benefit from it',* which goes against Paragraph 10 of the Helsinki Declaration stating that medical research is only justified when populations involved will also benefit from the results of the research. Several experts have come out saying that the trial would not have been allowed by Western ethics committees as cancer patients are only given experimental treatments if normal protocols no longer work.

The EMEA strategy paper (February 2009) on clinical trials conducted in third countries expresses concerns and recognises the need for greater supervision of the conduct and ethical standard of clinical trials performed outside the EU.

1. Were the needs of this economically and medically disadvantaged group sufficiently recognised by the company carrying out the trial?
2. How does the Commission judge the company's actions in the light of Paragraph 10 of the Helsinki Declaration?
3. Could this trial have been carried out in Western Europe?
4. Is the Commission of the opinion that the lapatinib drugs approved by the EMEA were tested in line with the ethical guidelines for Good Clinical Practice (Directive 2001/20/EC[1]) and the Declaration of Helsinki?
5. If not, what actions will be taken?

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