

Letter to EU health ministers on International Clinical Trials' Day 2009

On 20 May, International Clinical Trials' Day 2009, we would like to draw your attention to the position of trial subjects in developing countries. We are sending this letter to health ministers in the Netherlands, Belgium, Germany, France, United Kingdom, Italy, Sweden, Spain and Denmark.

Clinical trials are increasingly being carried out in low-income and developing countries. Several studies have shown that the rights of trial subjects in these countries are not sufficiently protected due to inadequate oversight. These studies have also shown that unethically tested drugs are finding their way onto the European market unhindered.¹

A recent study (March 2009) commissioned by the European Parliament and carried out by the Centre for Research on Multinational Corporations (SOMO) shows that with the information the European registration authorities currently have at their disposal, it is almost impossible for them to ascertain whether or not clinical trials have been conducted ethically.²

In its recent strategy paper, the European Medicines Agency (EMA) states that it will give greater priority to ethics when granting marketing authorization to medicines that have been tested outside Europe.³ More specifically, the EMA states that it will consider the practical application of ethical standards for clinical trials, such as the Declaration of Helsinki, particularly in the context of developing countries.

We welcome the fact that the EMA is prioritizing ethics within the marketing authorization procedure, but regret that this process is not open to public scrutiny. **We urge you to take swift steps to guarantee that the process initiated by the EMA is implemented to ensure that the rights of trial subjects in developing countries are adequately protected. For this, it is vital that experts from developing countries and non-governmental organizations are involved in the discussions which will define the framework for implementation of ethical criteria in the marketing authorization procedure.**

Furthermore, it is essential that ethical guidelines are integrated in a harmonized way in the marketing authorization procedures of the national registration authorities in Europe. **We therefore urge you to take action to ensure that your national registration authority also prioritizes ethics in its drugs marketing authorization procedure.** As members of the European Union and consumers of drugs tested in developing countries, we all have a responsibility towards the subjects on whom these drugs are tested.

Last February, FairDrugs.org, a worldwide coalition of health and human rights organizations led by Wemos launched the *Call for Ethical Clinical Trials in Developing Countries* in Europe. This launch was the starting point for the FairDrugs.org campaign, which aims to promote the support for 'fair' drugs. Please find attached a copy of the *Call for Ethical Clinical Trials in Developing Countries*, as well as a list of organizations and individuals who have already pledged their support. Over the next few months, we will be gathering as many additional pledges of support as possible.

Yours sincerely,

Teresa Alves, European Coordinator of Health Action International Europe
Annelies den Boer, Project Coordinator Medicines of Wemos, the Netherlands
Marion Birch, Director of Medact, United Kingdom
Wim De Ceukelaire, Coordinator of INTAL, Belgium
Silvio Garattini, Director of Mario Negri Institute for Pharmacological Research, Italy
Harry de Jong, Chairman of Farmacie Mondiaal, the Netherlands
Johan van Rixtel, Policy Advisor of Cordaid, the Netherlands
Eduard Soler, Project Manager of Farmaceuticos Mundi, Spain
Robert van Voren, Chief Executive of Global Initiative on Psychiatry, the Netherlands
Christian Wagner, Managing Director of BUKO Pharma-Kampagne, Germany

Attachments:

- *Call for Ethical Clinical Trials in Developing Countries*
- Overview of supporting organizations and individuals
- Committee of Recommendation

1. These studies are available at www.wemos.nl (see: 'Unethical Testing Dossier').

2. SOMO. March 2009. *Clinical trials in developing countries: how to protect people against unethical practices?*

3. EMEA. December 2008 (published February 2009). *EMEA strategy paper: Acceptance of clinical trials conducted in third countries, for evaluation in Marketing Authorisation Applications.*