Revision of the ‘Clinical trials Directive’ 2001/20/EC

Centre for Research on Multinational Corporations

Concept paper submitted for public consultation

SOMO and Wemos appreciate the opportunity given by the European Commission to express our views in this public consultation.

SOMO and Wemos comments will focus on item 3.
‘**Ensuring compliance with good clinical practices in clinical trials performed in third countries**.’

Increasingly clinical trials are carried out in low income and developing countries. For SOMO and Wemos this has been a cause for concern as trial subjects in low income countries may be more vulnerable as a result of their weak economic position. Furthermore the bodies charged with overseeing and implementing ethical guidelines meant to protect the rights of trial subjects, such as regulatory agencies and ethics committees often do not function properly. This necessitates strict checks on ethics compliance on drugs that have been tested in these countries and that are granted market authorization.

The concept paper distinguishes between the provisions regarding the authorization process for a clinical trial and the provisions regarding the marketing authorization process of medicines.

Regarding the authorization process of a **clinical trial** the concept paper proposes to codify in the revised legislative framework the provision in point 2724 of the detailed guidance CT-1:

We feel that providing a statement of GCP compliance of previous clinical trials, together with a reference to the entry of this clinical trial in a public register, provides limited information to the regulatory authorities. We suggest to add to the requirements for the statement a specific reference to compliance with ethical guidelines. Furthermore, the statement should be substantiated with an explanation and verification of the implementation of ethical principles, like the relevance and the benefits of the study for the population, justification of placebo use, the post-trial treatment arrangements and whether vulnerable trials subjects were adequately compensated in case of adverse events.

Regarding the marketing authorization process of **medicines** the consultation paper refers to the annex of the directive 2001/83/EC which makes a clear reference to the Declaration of Helsinki. We appreciate the fact that the EMA is currently working on assessing various actions in relation to the implementation of this provision. When EMA will have presented its assessments we would like to urge the European Commission to support the most ambitious

interpretation of the Declaration of Helsinki to be integrated in the marketing authorization procedure.

We fully support the suggestion made in the concept paper that the legislation could provide that the results of clinical trials conducted outside the EC are only accepted in the context of the marketing authorization process in the EU if the trial had been registered in the EudraCT database. In our view, this registration should include information about ethical considerations, for example a brief public statement of the involved ethics committees on their ethical review, the justification of placebo use, the justification of the use of vulnerable trial participants in third countries and explanations of the benefits for the population in third countries and the arrangements for post- trial treatment.[1]

In addition we are of the opinion that for clinical trials conducted outside the EU, that are used to get marketing authorization of medicines in the EU, sponsors should provide verification that these trials were conducted in line with ethical principles, for instance by explaining the relevance and the benefits of the study for the population, justification of placebo use, the post-trial treatment arrangements and whether vulnerable trials subjects were adequately compensated in case of adverse events.

Finally we strongly support the suggestion to support capacity building in third countries where the regulatory framework for clinical trials is weak. We would like the Commission to explore the possibilities for the development of an international system for certification of ethics committees.

Submitted: 12.05.2011

[1] To realize this, the present revision of the Clinical Trials Directive should be closely linked to the development of the technical guidance - List of fields for result-related information to be submitted to the 'EudraCT' clinical trials database, and to be made public, in accordance with Article 57(2) of Regulation (EC) No 726/2004 and Article 41 of Regulation (EC) No 1901/2006 and their implementing guidelines 2008/C168/02 and 2009/C28/01