FINNISH MEDICAL ASSOCIATION

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European Commission
Unit SANCO/C/8
BREY 10/114
BE-1049 Brussels

REVISION OF THE CLINICAL TRIALS DIRECTIVE 2001/20/EC – PUBLIC CONSULTATION

Finnish Medical Association (FMA) would like to thank the Commission on this opportunity to comment on the concept paper of the Clinical Trials Directive 2001/20/EC (9 February 2011). The FMA is a professional organization of which almost all doctors practicing in Finland are members. In the beginning of 2011 the Association had 23 130 members, 1 535 of whom were medical students. The FMA is also a member of the Standing Committee for European Doctors (CPME).

Consultation paper raises many important questions. The FMA agrees generally what is said in the CPME response, and emphasizes that ethical evaluation of a clinical trial in the ethics committees is an entirety of which it is difficult to separate certain elements, such as risk-benefit assessment, to be discussed at a different forum, and thus the mandatory or broad use of coordinated assessment procedure (CAP) is not feasible. In addition, the FMA would like to point out the following:

In Consultation item no. 14 the FMA would like to stress the utmost importance of the safety of clinical trials participants, and the unpredictable nature of clinical trials and its effects to an individual trial subject. As one of the purposes of clinical trials is to find out the safety profile of investigational medicinal product, it may not always be possible to make the risk evaluation in a way that would properly predict the individual risks. Therefore, the FMA prefers broad-based insurance/indemnisation that is not risk-adapted.

In Consultation item no. 16 the FMA considers it highly important that emergency clinical trials can be performed in all Member States. If this kind on clinical research is not done, it will affect negatively on the development of quality and safety of emergency care. We warmly support amending the Directive in a proposed way which ensures the safety and ethical soundness of clinical trials, and makes it possible to perform emergency clinical trials where necessary. In countries where ethics committees are consulted in such a situations, this procedure should be possible, but not mandatory to all countries and to all emergency clinical trials.

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