THE WORLD MEDICAL ASSOCIATION, INC.
L'ASSOCIATION MEDICALE MONDIALE, INC
ASOCIACION MEDICA MUNDIAL, INC

To the
Members of the Committees on
Environment, Public Health and Food Safety (ENVI)
Internal Market and Consumer Protection (IMCO)
Industry, Research and Energy (ITRE)
European Parliament
Brussels
Belgium

7th February 2013

By e-mail

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (COM(2012) 369)

Dear Members of Parliament,

We would like to take the opportunity to raise serious concerns regarding the European Commission proposal COM(2012) 369 and the upcoming first draft committee report by Glenis Willmott, MEP:

The European Commission proposal COM(2012) 369 seeks to make fundamental revisions to the Clinical Trials Directive 2001/20/EC. The Clinical Trials Directive 2001/20/EC is based on and supplemented by a set of internationally recognized scientific quality standards in the interest of the safety, reliability and ethical acceptability of clinical research involving human subjects. Furthermore, it builds on the set of ethical principles and internationally recognized protection standards as embodied in the Declaration of Helsinki by the World Medical Association (WMA). The current proposal by the European Commission fails to uphold these basic tenets and disrespects central ethical principles as embodied in the WMA Declaration of Helsinki. WMA considers such an approach unacceptable primarily for the following reasons:

Centre International de Bureaux
Immeuble A "Keynes"
13, chemin du Levant
01210 FERNEY-VOLTAIRE
France

Website : www.wma.net
Telephone : (33) 4 50 40 75 75
Fax : (33) 4 50 40 59 37
E-mail address : wma@wma.net

Postal Address :
Boîte Postale 63
01210 FERNEY-VOLTAIRE Cedex
France

1. The WMA Declaration of Helsinki *inter alia* requires the prior approval of clinical research trials by independent ethics committees[1]. The proposal does not include an explicit referral to such a requirement. The European Commission assumes that it is sufficient to leave the determination of the responsible bodies up to the discretion of the Member States. In view of recital (50) which reads the "*Commission should be able to control whether Member States correctly supervise compliance with this Regulation. Moreover, the Commission should be able to control whether regulatory systems of third countries ensure compliance with the specific provisions of this Regulation and Directive 2001/83/EC concerning clinical trials conducted in third countries*," Without the explicit requirement of ethics committees such safeguards cannot be subject to any control, either by any Member State or by the Commission.

   Thus, the proposal undermines the protection of research subjects and researchers and the scientific quality and trust in clinical research that ethics committees have helped to guarantee, not only in the European Union but also in non-EU countries. With its explicit provisions for the establishment and operation of ethics committees, the Clinical Trials Directive 2001/20/EC has made a significant contribution to ensuring that independent ethics committees could be established in accordance with international ethical standards to protect the rights, safety and well-being of clinical trial subjects, even in countries where this previously was not the case. To waive the explicit requirement for independent ethics committees weakens this protection of research subjects in non-EU countries and in several Member States.

2. The proposed regulation stipulates the requirement of a "therapeutic benefit" (see Art. 28 para. 1 a). This requirement is a misconception about research since a therapeutic benefit can hardly ever be guaranteed. The Declaration of Helsinki covers all medical research in humans. The fact that the regulation refers only to clinical trials does not change the need for a respect for ethical principles.

3. The proposed regulation stipulates unreasonably short timelines for Member States to assess and review applications. Shortening the time for careful consideration before approval of research trials risks missing defects in protocols and puts research subjects in danger.

4. The proposed regulation provides that the decision of the reporting Member State as to whether the conduct of a clinical trial is acceptable and is generally binding for all other Member States concerned. Disagreement of the Member States concerned about the conclusion of the reporting Member State is permissible only under very narrow provisions and cannot be based on grounds of their own different assessment of the question of acceptability. Such an approach may lead to sponsors of clinical trials seeking locales for approval of their protocols in places with less rigorous requirements (ethics shopping). And worse, it may force Member States to grant or accept market authorization based on ethically or scientifically unacceptable trials.

[1] Article 15 of the WMA Declaration of Helsinki states that: "The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee."

For these reasons the WMA is deeply concerned that the current draft regulation leads to a significant paradigm shift that risks putting economic interests before ethics. In addition, in view of the scope of this regulation, applying as it does to Member States and also to third countries, its effects might be unpredictable and detrimental for research, the development of safe and ethically developed medicine, and most importantly, dangerous for research subjects and patients in Europe and elsewhere.

We urge you to revise the current proposal and stand ready to discuss this further with the appropriate personnel to achieve an optimal outcome for the people for whom we care.

Sincerely,

Cecil B. Wilson, MD, MACP
President

Dr. Mukesh C. Haikerwal AO
Chairman of Council