NEDERLANDSE VERENIGING VAN MEDISCH-ETHISCHE TOETSINGSCOMMISSIES

Ministerie van Volksgezondheid, Welzijn en Sport
Directie Publieke Gezondheid, afdeling Ethiek
T.a.v. dhr. Mr. R.J. Terwiel
Postbus 20350
2500 EJ DEN HAAG

Deventer, 27 September 2013

Comments on the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Dear Mr. Terwiel, dear Jim,

On behalf of the European Network of Research Ethics Committees in Europe (EUREC) we like to send to you our comments based on the revised draft and the amendments of the First Reading of the European Parliament (EP) of the 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.

EUREC is the representation of national associations and networks Research Ethics Committees (RECs) in Europe. In short, EUREC appreciates that the European Parliament has taken the weaknesses of the EC's draft of the proposed Regulation into account. In particular, we were troubled that the EC's draft proposed to undo positive steps established through the current Directive 2001/20/EU in substantially removing RECs from the Regulation. Since RECs are accepted world-wide as bodies which assess the ethics of all biomedical research independently, the EP amendments to the Proposal of the Regulation recorded in the Report by Glenis Willmott make significant progress to reintroduce RECs in the assessment of clinical trials applications.

However, EUREC still sees a critical need for further strengthening of independent ethical evaluation in the governance of clinical trials before the regulation comes into force. In particular EUREC considers it as absolutely essential that RECs assess both parts I and II of the trial authorization dossier. Furthermore we still estimate the modified timescales to examine a research protocol in practice to be much too short and therefore run a very real risk that Member States will not be able to include effective ethical review in their assessment process, defeating the very purpose of the Regulation.

EUREC is willing to contribute to the development of a robust an appropriate governance structure for clinical trials in Europe. As a representation of the national Networks and Associations of European RECs, we are prepared to push forward and strengthen the communication and exchange among European RECs to develop best practice models of ethical evaluation.

We would like to encourage you to contact and to convince our national representatives and delegates that they promote the EUREC position during the process of consultations of the European Council.

With kind regards,
For the Board of the NVMETC

Mr. Saskia de Weerd-Hamer
Secretary of the board

Enclosure: EUREC Statement Clinical Trials Lisboa 2013

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