19 March 2013

Joint letter to Members of the European Parliament

Clinical trials Regulation: Don't be afraid to leave the dark ages, Support transparency!

Dear Member of the European Parliament,

As researchers, doctors, scientists and civil society representatives **we are asking you to support the inclusion of strong transparency provisions in the Clinical Trial Regulation** that is currently being discussed.

We ask you to support amendments that require the **disclosure of a complete clinical study report (CSR)** such as outlined by ENVI rapporteur MEP Glenis Willmott (Amendment 21) and in the ITRE MEP Rivasi opinion (Compromise Amendments 4 and 5).

Selective reporting impairs clinical practice. At present half of all clinical trials are never published. Those that get published are but a positive selection of the results where important harms have been omitted. This is a waste of research money and an abuse of clinical trial participants' altruism and trust. The lack of complete information on the efficacy and safety of the researched drugs causes significant harm to thousands of citizens, stifles scientific progress and often leaves healthcare professionals in the dark concerning the medicines they prescribe and dispense.

A summary of clinical trial results is insufficient to allow for independent analysis. The disclosure of a summary of results, as suggested by the European Commission, is of little scientific value, since it does not supply independent researchers and healthcare professionals with the information they need to judge the merit of a trial or to be able to use its results.

Clinical trials are done for the public good. The Proposal for Clinical Trial Regulation claims to be in line with the Helsinki Declaration. This declaration requires authors to make publicly available the results of their research on human subjects, and to be accountable for the completeness and accuracy of their reports, which should comply with accepted guidelines for ethical reporting. Clearly, a summary does not live up to these ethical requirements.

Clinical study report (CSR) disclosure helps the advancement of biomedical research. Establishing clinical study reports (CSR) as a disclosure format does not represent an added burden for academics or non-commercial researchers. They are already ethically obliged to write a report . **The submission and subsequent disclosure of complete reports in the EU Portal would greatly help the advancement of biomedical research and lead to better patient treatment, benefitting public health and citizens at large.**

Moreover, the disclosure of clinical trial results needs a strict timetable (within one year after completion) and the establishment of penalties for lack of compliance, as all voluntary approaches have failed thus far.

Whilst we agree that there is room for streamlining the clinical trial process, as proposed in the Willmott Report, this cannot be done at the expense of public health, by jeopardizing ethical scientific practice, economic efficiency and the protection of taxpayer investments in research.

We remain at your disposal for any questions or doubts you might have.

Thank you very much

The Cochrane Collaboration ***HAI Europe*** ***International Society of Drug Bulletins***

Medicines in Europe Forum ***Transatlantic Consumer Dialogue***