



The Consumer Voice in Europe

Clinical trials data: stand for transparency

Letter sent to Permanent Representations to the EU
on 11 October 2013

Contact: **Ilaria Passarani** – health@beuc.eu

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Re: Clinical trials data: stand for transparency

Dear Health Attaché,

In the context of the triologue negotiations on the proposal for a Regulation on clinical trials, BEUC, The European Consumer Organisation, calls on Member States to stand for transparency and further improve the requirements for the publication of clinical trials results.

According to the Helsinki Declaration¹ all authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. Nevertheless, at present, only half of clinical trials results are published and some trials are not even registered. Information on what was done and what was found in these trials could be lost forever to doctors and researchers, leading to bad treatment decisions, missed opportunities for evidence based medicine and trials being repeated².

The volunteers who take part to clinical trials put their own life at risk of unexpected adverse drug reactions. They do so in the spirit of altruism to contribute to scientific progress for the benefit of society therefore the results of the trials belong to them and to society at large³.

Making available clinical trial data contributes to address the problem of publication bias⁴ and it is necessary to ensure that the competent authorities have complete and reliable information to make safety and cost/effectiveness analysis, avoiding exposing patients to unnecessary risks and wasting public resources on ineffective medicines.

The disclosure of trials data empowers patients, promotes better quality of health care and contributes to restore public confidence in regulators following the scandals that recently affected the medical sector.

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1 Article 30 and 33 of the WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects <http://www.wma.net/en/30publications/10policies/b3/>

2 www.Alltrials.net

3 Lemmens T and Telfer C "Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency" (September 22, 2011). American Journal of Law and Medicine 2012; 38: 63-112. <http://ssrn.com/abstract=1932436>

4 Trials with positive results are twice as likely to be published as others. <http://www.hta.ac.uk/fullmono/mon1408.pdf>

In line with the Ombudsman position⁵, on 29 May the Environment and Health Committee of the European Parliament unanimously agreed⁶ that *“in general the data included in clinical-trial study reports should not be considered commercially confidential once a marketing authorisation has been granted or the decision-making process on an application for marketing authorisation has been completed”*.

We ask the Council to endorse this principle and integrate it in the legislative text. This would also contribute to uphold and reinforce the European Medicines Agency policy on access to documents currently challenged in a procedure brought before the European Court of Justice by two pharmaceutical companies⁷.

We hope you will take these considerations into account and ensure that the revision of the EU legislation on clinical trials will bring concrete benefits to patients and to medical progress.

We would be delighted to have the opportunity to further discuss this with you at your earliest convenience.

Yours sincerely,

Ilaria Passarani
Senior Health Policy Officer

⁵ European Ombudsman. Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency (November 24, 2010).

- European Ombudsman. Decision of the European Ombudsman closing his inquiry into complaint 3106/2007/(TS)FOR against the European Medicines Agency (December 14, 2011).

⁶<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=%2f%2fEP%2f%2fTEXT%2bREPORT%2bA7-2013-0208%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN>

⁷http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/04/news_detail_001779.jsp&mid=WCOB01ac058004d5c1 BEUC has been granted leave to intervene in support of the European Medicines Agency.