BEUC The European Consumer Organisation

The Consumer Voice in Europe

Clinical trials and medical devices: restore public trust

Letter sent to Permanent Representations to the EU
on 1 July 2013

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The Consumer Voice in Europe

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Brussels, 1 July 2013

Re: Clinical trials and medical devices: restore public trust

Dear Health Attaché,

On 29 May the Environment and Health Committee of the European Parliament adopted unanimously a report[1] on the proposal for a Regulation on clinical trials. BEUC, the European Consumer Organization, considers that the amendments of the European Parliament significantly improve the Commission proposal in particular with regard to ethics committee, transparency, informed consent and protection of the trials subjects. Therefore we call on the Council to support the European Parliament approach and to further reinforce the provisions regarding transparency.

Recent medical scandals like the weight-loss drug Mediator undermined consumers' confidence in regulators and ultimately in the safety of the medicines on the market. The revision of the EU clinical trials legislation is a unique opportunity to restore public trust and to bring more openness in the pharmaceutical sector.

Clinical trials results are useful not only for researchers and health professionals but also for the general public. Consumers, as patients, carers and potential users of medicines, want to be more involved in the decisions regarding their health and they have the right to access information on clinical trials. The disclosure of trials data empowers patients and contributes to better quality of health care.

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 repeated.

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[1] 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

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The volunteers taking part to a trial do so in the spirit of altruism and for the benefit of society therefore the results of the trials belong to them and to society at large: once a marketing authorization has been granted the clinical trials data should not be considered commercially confidential. We also believe that the European Medicine Agency policy on transparency and access to documents should be upheld and reinforced and for this reason BEUC decided to formally intervene in support of EMA in the cases currently pending before the European Court of Justice regarding access to clinical and non-clinical information[2].
We take this opportunity to share with you also our position on the Regulation on medical devices (attached) as we believe that clinical investigations for medical devices should comply with the same ethical, quality and transparency standards as clinical trials for medicines.

We remain at your disposal should you wish to discuss this further.

Yours sincerely,

Ilaria Passarani
Senior Health Policy Officer

[2] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/04/news_detail_001779.jsp&mid=WC0b01ac058004d5c1