



The Consumer Voice in Europe

Public Disclosure of Clinical Trial Results

BEUC comment on the World Health Organisation (WHO) statement

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

Ref.: BEUC-X-2014-085 - 14/11/2014

Summary

Presently, only half of clinical trial results are published. Consequently, useful information on what was found in these trials can be kept forever from doctors and researchers, which in turn can lead to bad treatment decisions, missed opportunities for evidence-based medicine and trials being repeated.

Making clinical trial data available is necessary to ensure competent authorities have complete and reliable information to carry out safety and cost/effectiveness analyses, avoid exposing patients to unnecessary risks and waste of public resources on ineffective medicines.

Disclosure of trial data empowers patients, promotes a better quality of healthcare and contributes to a restoration of public confidence in regulators following recent scandals which have affected the medical sector.

Results of all trials – both past trials on medicines currently in use and future trials - should be disclosed by way of a publicly available register, within 12 months of the clinical trial's completion.

The European Consumer Organisation (BEUC) welcomes the World Health Organisation (WHO) statement¹ on 'Public Disclosure of Clinical Trial Results'.

The volunteers who take part in clinical trials put their bodies and lives at risk of unexpected, adverse drug reactions. They do so in a spirit of altruism to contribute to scientific progress and for the benefit of society. Therefore the results of the trials should belong to them and to society at large². Clinical trial data cannot be considered trade secrets, nor can they be compared to vehicular prototypes³, as they are generated by the input and involvement of human beings.

According to the Helsinki Declaration⁴, all authors have a duty to make the results of their research on human subjects publicly available and are accountable for the completeness and accuracy of their reports. Nevertheless, at present, **only half of clinical trial results are published** and some trials are not even registered.

Information on what was done and what was found in these trials could be kept forever from doctors and researchers, leading to bad treatment decisions, missed opportunities for evidence based medicine and trials being repeated⁵.

Consumers have the right to be informed about the medicines they use. Information about medicines is essential to **empower consumers** and to help them make an informed choice about their treatments. Regulators have an obligation to be accountable towards those who are most affected by its decisions. Therefore, in the case of medicines regulators, patients have the right to know the basis or bases on which a medicine has been either granted or refused market access.

Moreover, transparency helps strengthen the principles of democracy and respect for fundamental rights as laid down in Article 6 of the EU Treaty and in the Charter of Fundamental Rights of the European Union.

Publication of clinical trial data is essential to allow **secondary analysis** and avoid regulators relying only on the manufacturer's risk/benefit assessment of their own products. If independent researchers can re-assess the data, conduct systematic reviews and make comparative analyses, they can generate valuable additional information on the safety and the efficacy of medicines. This will contribute to

¹ http://www.who.int/ictrp/results/Draft_WHO_Statement_results_reporting_clinical_trials.pdf?ua=1

² T. Lemmens and C.Telfer '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.

³ Science, Vol 339, 2013.

⁴ 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/>

⁵ www.Alltrials.net

evidence-based medicines and **cost-effective treatments**, while helping **reducing unnecessary risks** for patients.

Making clinical trial data available can help avoid waste of public expenditure on ineffective medicines (e.g. the 'Tamiflu' case⁶), can **reduce harm to patients** and can **promote competition among pharmaceutical companies** for the discovery of new and more effective medicines.

Moreover, health technology assessment bodies require complete information on clinical trial results in order to make sound cost/effectiveness analyses on which pricing and reimbursement decisions will be made.

Public money is used to cover both pharmaceutical spending⁷ as well as mortality and morbidity costs⁸ associated with adverse drugs reactions (which could be better detected if clinical trial data were shared).

Many serious adverse drug reactions caused by rosiglitazone (Avandia) and rofecoxib (Vioxx) could have been avoided, had the real effects of these medicines been known by the general public. In particular, it is estimated that the use of the non-steroidal, anti-inflammatory drug used as an anti-arthritic and an acute pain reliever Vioxx, led to 10,000 avoidable deaths and 100,000 additional heart attacks in the United States⁹. Similarly, Avandia has been associated with a significant increase in risk of heart attack and cardiovascular death¹⁰.

Moreover, data collected in clinical trials are useful and relevant not only for the purpose of marketing authorisation and they can provide insights on diseases and other clinical elements etc. Therefore, others than those who sell the medicine tested in the trial can benefit of the information.

The pharmaceutical industry claims that the publication of clinical trials data would undermine trust in the regulatory approval system governing pharmaceuticals and heighten risk of misinterpretation and misuse of clinical data. On the contrary, we believe that many recent drug related scandals like that with Mediator undermined public trust in regulators and that granting access to the data on which decisions are made is a necessary tool for **restoring trust** in the work of medicine

⁶ P Doshi, T Jefferson et al. 'The imperative to share clinical study reports: Recommendations from the Tamiflu experience'. PLoS Medicine, 9:4 (2012).

⁷ Eurostat, OECD Health Data 2012, Commission services (DG ECFIN) http://ec.europa.eu/economy_finance/publications/economic_paper/2012/pdf/ecp_461_en

⁸ Directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

⁹ P.Gøtzsche (2011). 'Why we need easy access to all data from all clinical trials and how to accomplish it'. Trials 2011, 12:249

<http://www.trialsjournal.com/content/12/1/249>

¹⁰ D. Graham et al., 'Risk of acute myocardial infarction, stroke, heart failure, and death in elderly Medicare patients treated with rosiglitazone or pioglitazone'. JAMA, 304:4 (2010).

regulation agencies and ultimately the safety of the medicines on the market. So far, there is no evidence on potential misuse of data that generated unsubstantiated health scares while there is evidence on the risks of the lack of public disclosure of important information.

Trials with positive results are twice as likely to be published as others¹¹: the publication of all clinical trial results can effectively address the problem of **publication bias** and ensure the available information is reliable and complete.

The new EU regulation on clinical trials¹², as well as the new European Medicines Agency policy on publication of clinical data, represent major steps towards transparency, however we are concerned that their implementation might be undermined by too extensive an interpretation of what constitutes commercially confidential information (also taking into account the ongoing discussions on commercial confidentiality within the Transatlantic Trade and Investment Partnership¹³ (TTIP) negotiations and the EMA policy terms of use and redaction principles¹⁴).

We are also concerned that the regulation and the **EMA policy** only apply to new medicines - which effectively leave out most of the medicines prescribed to or purchased over the counter by consumers - while we consider it also necessary that the results of all past clinical trials are reported. The WHO statement should call for the disclosure of the results of **past trials** on the treatments in use today.

As foreseen in the EU regulation on clinical trials results should be reported within in **12 months**, rather than permitting delays of 18-30 months as mentioned in the WHO Statement. Researchers should put results on publicly accessible registers, in useful, standardised formats.

END

¹¹ <http://www.hta.ac.uk/fullmono/mon1408.pdf>

¹² Regulation 536/2014 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.158.01.0001.01.ENG

¹³ <http://www.beuc.eu/blog/how-will-ttip-affect-the-health-of-europeans/>

¹⁴ <http://www.beuc.org/publications/clinical-trials-transparency-partially-boosted-european-medicines-agency/html>