Despite concrete steps forward, the ENVI vote on clinical trials regulation falls short on transparency

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On 29 May 2013 the European Parliament's Environment, Public Health and Food Safety (ENVI) Committee voted unanimously in favour of a draft body of rules governing the authorisation and conduct of clinical trials in the EU. HAI Europe welcomes advancements in this legislative process towards increased access to clinical trial data but notes that more needs to be done.

A significant improvement is that the adopted report provides that alongside the summaries of the results, clinical study reports from trials supporting market authorisation have to be publicly accessible in the EU database. However, it still allows for clinical data to be withheld on the grounds of commercial confidentiality. In this respect, it is important that in the recital the ENVI Committee has explicitly acknowledged the European Medicines Agency's policy on access to documents and has clarified that clinical trial data shall not be considered commercially confidential. In spite of this being a welcomed clarification, as the recital has a limited binding effect it would have been a major improvement if this was mentioned in an article.

Public access to clinical trial results, and its corresponding raw data, is crucial to help advance biomedical research and rational decision-making. Depriving access of data on the effect of medicines on human health to prescribers and consumers leads them to make decisions based on inaccurate information, thereby increasing the risk of otherwise avoidable harm.

In view of the upcoming trilogue negotiations, HAI Europe urges the European Parliament, the EU Council and European Commission to reach an agreement that is, at minimum, in line with the prevailing policy of the EMA. The EMA, following the opinion of the European Ombudsman and in accordance with the EU Regulation on Access to Documents, submits clinical study reports on request and is working towards the proactive publication of these reports.

Optimal public access to clinical trial data, however, can only be achieved if disclosure requirements apply to all trials – regardless of their purpose. Stakeholders at large are advocating for all clinical trials to be registered and their full methods and results disclosed. For example, the AllTrials campaign, a Sense About Science, BMJ, and Bad Science initiative, supported by the Cochrane Collaboration, has been endorsed by over 40,000 individuals and hundreds of organisations that represent patients and consumers, researchers, healthcare professionals, regulators and the private sector.

The call from AllTrials, as well as that of numerous health NGOs and thousands of people advocating for full transparency of clinical trial data, must be taken into account. In view of the negotiations on the Clinical Trials Regulation, HAI Europe calls upon EU institutions to provide Europe with a regulatory framework that upholds, once and for all, the principle that health is an overriding public interest.