



Health Action International welcomes adoption of new Clinical Trials Regulation by European Parliament

Health Action International (HAI) Europe commends the adoption by the European Parliament of a new Regulation on Clinical Trials. An overwhelming majority of members voted yesterday in favour of the Regulation, which will significantly increase transparency of clinical trial results.

“HAI Europe has long been calling for the public disclosure of medicines safety and efficacy data,” says Ancel-la Santos Quintano, policy advisor with HAI Europe. “This Regulation will improve the status quo, where data secrecy is the rule rather than the exception.”

Once endorsed by the Council, the Clinical Trials Regulation will legally require clinical trial sponsors to publish:

- the summary of results of *all* clinical trials conducted in the European Union (EU) within one year from the end of the trial; and
- clinical study reports that are submitted for marketing authorisation after the decision-making process by the drug regulatory authority has been completed, or the application withdrawn.

“Public disclosure of clinical trial data is necessary because it allows prescribers and consumers to make informed decisions about medicines,” explains Santos Quintano. “Adverse drug reactions are the fifth most common cause of hospital deaths—many of them could likely have been avoided if the undisclosed effects of medicines had been known.”

Room for regulatory improvement

While the Clinical Trials Regulation will improve transparency, HAI Europe regrets that the full potential of the Regulation has been somewhat diminished given that the publication requirements will not apply retrospectively. In addition, only a summary of results will be published for the clinical trial data that is not submitted for marketing authorisation.

“Summaries only offer limited information about a trial and can, therefore, still result in selective reporting of results by trial sponsors, in which the medicines’ benefits are over-rated and their harms downplayed,” says Santos Quintano. “All data from every trial is still needed to ensure people are not put at risk and to avoid the unnecessary repetition of studies. Public health, instead of commercial interests, must be the priority.”

Additional threats to clinical trials transparency

HAI Europe is also concerned about other potential threats that could jeopardise the transparency of clinical trials. The EU, for example, is currently discussing a Directive for the protection of trade secrets, and the pharmaceutical industry has openly called for clinical trials data to be categorised as such.

Furthermore, the EU is currently negotiating a new trade agreement, the Transatlantic Trade and Investment Partnership (TTIP), with the United States, in which regulatory standards are being discussed. The pharmaceutical industry is lobbying for a harmonised, restrictive approach to the disclosure of clinical trials data on the grounds of commercial confidentiality and the protection of trade secrets.

“The Regulation adopted by the European Parliament explicitly states that clinical trial data cannot be considered commercially confidential,” says Santos Quintano. “While this positive statement is in line with a previous recommendation from the European Ombudsman and the approach of the European Medicines Agency, it is, unfortunately, non-binding for EU Member States.”

This means that some clinical trials data could be redacted prior to publication on the grounds of commercial confidentiality.

HAI Europe will continue to advocate for full transparency of medicines safety and efficacy data, including both clinical trial and pharmacovigilance data. The passing of this Regulation by the European Parliament is a positive step, but continued work will be required to ensure full clinical trials transparency is achieved in the EU.

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Health Action International (HAI) is an independent, global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.

For comment and additional information:

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Further background:

HAI Europe statement on TTIP (12 March, 2014): <http://bit.ly/1cSI4eS>

Joint civil society position paper on TTIP (24 March, 2014): <http://bit.ly/1iTTPHB>