Regulation critical to clinical trials data transparency in Europe

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Access to full clinical trials data is crucial to evidence-based medicine and the protection of public health. Unfortunately, limited access to clinical data held by drug regulatory authorities, as well as deficiencies in the current model for reporting scientific research, prevent the full effects of medicines from being adequately known.

Although GlaxoSmithKline has made some commitments to clinical trials data transparency, we remain cautious about the amount and type of data that it—or any other pharmaceutical company—will put forward. The decision to publish clinical trial data, including the extent of data released, and the criteria that data requestors must meet, must not be left to so-called 'independent' parties appointed by pharmaceutical companies.

Based on HAI's many years of medicines advocacy experience—and the repeated, yet unfounded, concerns by the pharmaceutical industry about commercial and patient confidentiality—we know that the only way to ensure pharmaceutical industry participation in full clinical trials data disclosure is to put it into law. If data disclosure is performed by companies on a voluntary basis, key information on the safety and efficacy profile of medicines will, no doubt, be redacted by companies before release.

The on-going revision of the European Union regulatory framework on clinical trials offers a tremendous opportunity to strengthen data transparency. Health Action International welcomes the provisional agreement on the Clinical Trials Regulation adopted by the European Parliament, Commission and Council, including the statement that clinical trial data should not be considered commercially confidential.

In advance of the upcoming parliamentary vote, along with the Council's final endorsement of the regulation, we implore European Union policy makers to remain committed to clinical trial data transparency—and to the health and safety of European citizens.

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