# STATEMENT

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# HAI Europe urges EMA not to backtrack on commitments to clinical trial data transparency

AMSTERDAM—The European Ombudsman has publicly expressed her concerns about an apparent "significant change of policy" by the European Medicines Agency (EMA) regarding clinical trial data transparency. In a letter to the EMA on 13 May, 2014,[1] and a subsequent press release on 16 May,[2] the Ombudsman refers to draft documents produced by the EMA that indicate a turn in the Agency's long-held commitment to the proactive publication of clinical trial data.

The documents in question refer to the 'Terms of Use' and 'Redaction Principles' that will shape the EMA's future policy on proactive publication of clinical trial data if endorsed by its Management Board on 12 June, 2014. In particular, the Ombudsman is concerned about the EMA's intention to "limit access to clinical trial data by imposing strict confidentiality requirements and by allowing data only to be seen on screen using an interface provided by the EMA, as well as imposing wide restrictions on the use of such data."

Health Action International (HAI) Europe is extremely concerned that the EMA may be abandoning its commitment to grant public access to clinical trial data, which is greatly needed. This unexpected shift is particularly surprising considering that, since the adoption of its policy on access to documents in 2010, the EMA has disclosed over 2 million pages of clinical trial data in response to safety-related requests. In addition, it has worked diligently towards proactive publication of these data.

It is indisputable that public access to clinical trial data is crucial to the protection of public health. Only by disclosing the true effects of medicines can prescribers and consumers make informed choices about treatment. The independent assessment of clinical trial data can bring additional knowledge about the safety and efficacy of medicines and, therefore, help protect public health. Ethical aspects, the unnecessary repetition of trials, comparative-effectiveness analysis of treatments, and the sustainability of public health expenditure are other reasons that make clinical trial data transparency imperative.

The European Parliament is well aware of what is at stake. On 2 April, 2014, it endorsed, by an overwhelming majority, a new regulation on clinical trials.[3] The regulation supports the EMA's commitment to proactive publication by mandating the establishment of a publicly accessible European Union (EU) database, in which summaries of the results of clinical trials will be made available within one year from the end of the trial. In addition, clinical study reports submitted for marketing authorisation will also be accessible once the decision-making process has concluded.

More importantly, the regulation on clinical trials states that data included in clinical study reports should not be considered commercially confidential information (CCI) once a marketing authorisation has been granted, the procedure for granting authorisation has concluded, or the application has been withdrawn. In this regard, the Regulation is very much in line with the EMA's initial proposal for a policy on proactive publication of clinical trial data that was published for consultation on 24 June, 2013. In this proposal, the EMA stated that, "in general, however, clinical trial data cannot be considered CCI; the interests of public health outweigh considerations of CCI."[4]

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[1] European Ombudsman. EMA policy on publication of and access to clinical trial data. 13 May 2014
http://www.ombudsman.europa.eu/en/resources/otherdocument.faces/en/54347/html.bookmark

[2] European Ombudsman. Ombudsman concerned about change of policy at Medicines Agency as regards clinical trial data transparency at http://www.ombudsman.europa.eu/en/press/release.faces/en/54348/html.bookmark, 16 May 2014

[3] Position of the European Parliament adopted at first reading on 2 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

[4] European Medicines Agency. Draft policy on publication and access to clinical trial data. 24 June, 2013
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf

Taking into account these positive developments, it is of great concern to learn that the EMA is turning its back on its long-term commitment to true, proactive publication. If the provisions included in the proposed 'Terms of Use' and 'Redaction Principles' documents are adopted, public health will be severely undermined. In view of these developments, HAI Europe urges the EMA to:

- **Consider clinical trial data a public good**[5]. The EMA's policy shall be in line with the European Ombudsman's recommendation 2560/2007/BEH and with the regulation on clinical trials. By proposing a list of sections that may contain CCI, and by providing a justification for redaction, the EMA is providing incentives to companies to redact data up front.[6] [7] [8] Without doubt, the EMA must put public health ahead of commerical interests.

- **Allow users to download, save, edit, print, distribute and transfer the information provided by the database**. Reading clinical study reports, which may be hundreds of pages in length, on a 'screen-only view mode' makes proper assessment of clinical trial data impossible.[9] This may even inadvertently lead to increased errors in the interpretation of data.

- **Provide true public access to the electronic EU database**, as required by the clinical trials regulation. It is highly contradictory that a so-called 'publicly accessible' database is subject to 'restrictive terms of use'.

HAI Europe is also concerned about the impact that the proposed 'Terms of Use' and 'Redaction Principles' will have on the EMA's current policy on access to documents, through which data is disclosed on request. As indicated by the Ombudsman, a person exercising the fundamental right of public access under Regulation 1049/2001 on access to EU documents does not have to provide any reason for his or her application. Furthermore, Regulation 1049/2001, to which the EMA's policy on access to documents is tied, does not foresee any conditions an applicant would have to accept with respect to the envisaged use of the requested documents.

**Thus, it is crucial that the EMA continues providing the same level of access, and the same level of unredacted information, through its policy on access to requested documents.**

In addition, **the EMA must refrain from requiring users to acknowledge that the information is protected by copyright and proprietary rights.** By proposing this, the EMA is, in fact, obliging the general public to contractually recognise rights in clinical trial data that are legally questionable.[10] Certainly, a public institution such as the EMA cannot impose this condition on users.

Finally, in an exercise of transparency, **the EMA should publish the outcome of the out-of-court settlement with the pharmaceutical company, AbbVie, regarding the disclosure of clinical trial data of one of its medicines.** Only by doing so, will the general public be able to have an informed opinion about the potential impact of such a settlement on the EMA's policy on proactive publication.

HAI Europe reiterates the importance of public access to clinical trial data for the protection of public health. **We call upon the EMA to stay committed to true transparency for all medicines safety and efficacy data.**

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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.*

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[5] MiEF, ISDB, AIM, NCC. Backpedalling on EMA's "proactive publication of clinical-data draft policy: Was it all just a window-dressing exercise? Who or what is the EMA afraid of?. 20 May 2014
http://english.prescrire.org/Docu/DOCSEUROPE/20140520_EMATransparencyPolicy.pdf
[6] Ibid.
[7] Science Insider. Researchers slam transparency 'U-Turn' at E.U. Medicines Agency, 19 May 2014
http://news.sciencemag.org/europe/2014/05/researchers-slam-transparency-u-turn-e.u.-medicines-agency
[8] BMJ. European drug agency backtracks on plan to give researchers access to clinical trial reports. 21 May 2014
[9] Ibid
[10] Science Insider. Researchers slam transparency 'U-Turn' at E.U. Medicines Agency, 19 May 2014
http://news.sciencemag.org/europe/2014/05/researchers-slam-transparency-u-turn-e.u.-medicines-agency