HAI Europe calls on EMA's Management Board to stand for data transparency

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The European Medicines Agency (EMA) Management Board
is expected to vote tomorrow on a new policy on clinical trial data transparency.

Previously, the EMA appeared committed to passing a policy that would grant full public access to clinical trial data—a move that is critically important for protecting public health. Recently, however, the Agency has shown signs that it may be abandoning its commitment. Health Action International (HAI) Europe and numerous other stakeholders, including the European Ombudsman, have expressed concern about this shift in policy.

Earlier today, HAI Europe sent the following email to members of the EMA Management Board, urging them to ensure that the EMA honours its previous commitments to clinical trial data transparency.

Dear Member of the Management Board,

On Thursday, 12th of June, the European Medicines Agency (EMA) Management Board will be, in principle, voting on a new clinical trial transparency policy.

Since the implementation of its current policy on access to documents in 2010, the EMA has disclosed around 2 million pages of clinical trial data in response to safety-related requests, and therefore contributing to the unlocking of secret information that is crucial to public health. In parallel, the Agency has been working towards the proactive publication of clinical trial data with the aim to further strengthen transparency. In fact, the initial proposal for a policy on 'Publication and access to clinical trial data', published last year, deemed that clinical study reports should not be considered, in general, as commercially confidential information and should be proactively published.

In spite of these positive developments, however, the EMA is now backtracking on its long-held commitments to data transparency (1). Indeed, the policy documents that will be presented tomorrow to the Management Board for endorsement show a clear shift of policy, which raises serious concerns.

First, according to the proposed 'Terms of use', users would be obliged to contractually recognise that the data they access is protected by copyrights and proprietary rights.

Whether clinical trial data can even be protected under these rights is dubious, at best, and greatly contested; therefore, the general public should not be forced to recognise these protections. Furthermore, data users, including patients, healthcare professionals and researchers, cannot be put in a legally weak position by allowing companies to directly challenge them in court (2).

Second, as widely expressed by those in academia, the 'view on screen only' mode of clinical study reports makes the re-assessment of data a completely futile exercise—one that may even inadvertently lead to increased errors in the interpretation of data. Clearly, users should be able to save, download, print, copy and share these documents, which provide the most comprehensive information on each trial and amount to hundreds of pages.

Third, contrary to the European Ombudsman's recommendation (3) and to the spirit of the newly adopted Clinical Trials Regulation (4) , the EMA proposes in its 'Redaction principles' document to classify key sections of clinical study reports as likely to be commercially confidential information, inviting companies to redact data up front. According to the EMA's last proposal, companies would be submitting two types of clinical study reports; one for marketing authorisation and another for publication. Clearly, this process puts companies in the driver's seat regarding redaction. Even worse, the general public would never get to know the extent of data that has been redacted.

In view of tomorrow's vote, Health Action International Europe urges the members of the Management Board to reject the above-mentioned provisions and to revise the policy, in order for it to reflect the EMA's previous commitments to data transparency. Most definitely, taking into account the ongoing investigation by the European Ombudsman, this decision should be, at a minimum, postponed.

Footnotes

(1) HAI Europe. HAI Europe urges EMA not to backtrack on commitments to clinical trial data transparency. May 22, 2014. Available at http://haieurope.org/wp-content/uploads/2014/05/Statement-HAI-Europe-urges-EMA-not-to-backtrack-on-commitments-to-clinical-trial-data-transparency-22-May-2014.pdf

(2) Lemmens, T. EMA's Proposed Data Release Policy: Promoting Transparency or Expanding Pharma Control over Data? PLOS. May 30, 2014. Available at http://blogs.plos.org/speakingofmedicine/2014/05/30/emas-new-data-release-policy-promoting-transparency-expanding-pharma-control-data/

(3) European Ombudsman. Ombudsman concerned about change of policy at Medicines Agency as regards clinical trial data transparency. May 16, 2014. Available at http://www.ombudsman.europa.eu/en/press/release.faces/en/54348/html.bookmark and European Ombudsman, Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency. November 24, 2010. Available at http://www.ombudsman.europa.eu/cases/draftrecommendation.faces/en/4883/html.bookmark

(4) MEP Willmott, G. Letter to EMA's Executive Director, Prof. Guido Rasi. June 6, 2014. Available at http://www.gleniswillmott.eu/wp-content/uploads/2014/06/GWillmott-to-GRasi-060614.pdf

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