EMA policy on clinical data publication a step ahead, but falls short of true potential

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Although it's a step in the right direction, the European Medicines Agency's (EMA) long-awaited clinical data publication policy—adopted on 2 October and coming into effect on 1 January, 2015—falls short of its maximum potential and could be setting the wrong precedent for the implementation of the Clinical Trials Regulation.

Independent reviews of complete and uncensored clinical trial data are crucial to bringing further insight into pharmaceutical therapies. Evidence shows that independent reviews of detailed clinical study reports have identified dangerous (and previously unreported) side-effects of medicines, helping to strengthen patient safety. In addition, independent reviews of data have found that some medicines (e.g.,oseltamivir, known as Tamiflu®) are not as effective as claimed, despite immense public health spending on them. Although full data transparency offers many benefits to public health, it appears that commercial interests have steered the EMA into embracing a weakened policy that will allow clinical data to be withheld from public scrutiny.

HAI Europe is disappointed that the EMA's new policy gives pharmaceutical companies the opportunity to redact vital clinical data within the reports that they submit to the EMA. Information about trial methods, as well as safety and efficacy profiles of medicines (including their associated adverse reactions), is vital to safeguarding public health. Literature on publication and reporting bias shows that the biggest misuse of clinical data is keeping it secret—not making it publicly available.

Redactions of trial data hinder independent review and, ultimately, prevent prescribers, dispensers and consumers from being aware of the true effects of medicines. HAI Europe

believes that the EMA's policy gives incentives to companies to redact data up front by stating that a number of sections *may* be commercially confidential information, and by providing justifications for redaction. It is also of great concern to know that redactions beyond those sections can be allowed, and that companies will be given a defined period to seek interim injunctions in case of disagreement on the level of data to be published. Taking into account the pharmaceutical industry's opposition to full transparency of clinical trial data, the EMA should not be encouraging companies to challenge, in court, its decision to make data publicly available.

HAI Europe commends the EMA for allowing users to download, save and print clinical reports for academic and non-commercial research purposes, rather than only allowing them to view the data on screen. We are disappointed, however, that users will be inappropriately forced to regard the data as protected under copyright and other intellectual proprietary rights and be at risk of litigation from pharmaceutical companies. Legal threats will most definitely stifle open scientific debate.

HAI Europe looks forward to the implementation of the policy's second phase, which is expected to provide access to individual patient data. This information is crucial for proper re-evaluation of clinical trial results. It is disappointing that re-identification risks are being greatly exaggerated by those with vested interests. We look forward to contributing to the public consultation on how to best provide access to individual patient data and call upon concerned stakeholders to develop solutions that could strengthen the much-needed transparency of clinical trial data.

Finally, HAI Europe calls upon the EMA to take into account the question of the 'overriding public interest in disclosure' provided in Regulation (EC) 1049/2001 to provide the widest possible access to requested clinical trial data. We see, in the upcoming revision of the clinical data publication policy (18 months from the date of implementation), an opportunity to continue advancing transparency in the EU.