Setting precedents: EMA must get clinical trial data policy right to truly act in public interest

by Ancel.la Santo Quintano

Following its management board meeting on 12 June, the European Medicines Agency (EMA) announced that it had agreed on a “more user-friendly” policy on the publication of clinical trial data. The policy, according to the EMA, will enable the Agency to “proactively publish clinical trial data that are submitted as part of marketing authorisation applications” and provide “the possibility [for users] to download, save and print the trial data for academic and non-commercial research.”

Maybe a bit of good news, but probably not a lot.

Health Action International (HAI) is pleased to hear that the EMA will likely allow users to download, save and print trial data. Really, it’s the very least it could do. (Imagine trying to accurately evaluate hundreds of pages of clinical trial data on a computer screen.)

But HAI, along with a myriad of other health and transparency advocates, as well as the European Ombudsman, still has serious concerns about other aspects of the EMA’s soon-to-be-released policy, which will come into effect on 1 October. This policy, after all, will indeed set the precedent for the amount of information and level of access allowed on the European Union’s clinical trial database—which the EMA is responsible for developing and managing—when it comes into force in 2016.

In order for a true policy on proactive publication to be in place, HAI continues urging the EMA to:

1: Refrain from imposing restrictive ‘terms of use’ conditions on clinical trial data. A public body such as the EMA cannot oblige data users to acknowledge—and, of course, obey—copyrights and proprietary rights that are not firmly established in law. In addition, by referring to proprietary rights, the EMA implies that clinical trial data belongs to the companies when, in fact, it is a public good.

2: Provide full access to clinical study reports. Proposing a list of sections that may contain commercially confidential information and providing a justification for redaction provides pharmaceutical companies with the incentive to redact data up front. This would severely limit the transparency of information that is crucial to public health. Under no circumstance can companies be left in the driver’s seat regarding redaction. Instead, the EMA’s policy must reflect the open access approach that was proposed in an earlier version of the policy, according to which, these sections were to be fully disclosed to the general

public.

3: Publicly release the outcome of the out-of-court settlement with AbbVie. Almost three months have passed since the EMA reached an out-of-court settlement with AbbVie over the disclosure of clinical trial data for its drug, Humira. Still, the EMA has not publicly explained its rationale for settling with, and conceding to, the company, nor released an outcome of the agreement. Documents obtained through a freedom of information request by BMJ show, however, a significant overlap between the redactions that AbbVie won in the settlement and the EMA's new policy on clinical trial data (e.g., exploratory endpoints and determination of sample size). As a public institution, the EMA has an obligation to make details of the case publicly available so citizens can develop an informed opinion about the impact of the settlement on the policy.

Is any of this too much to ask? We don't think so.

HAI hopes that the EMA takes the responsible step of endorsing a bold clinical trial data policy that will place public health above claims on, or of, commercial confidentiality by the pharmaceutical industry. Only by agreeing to the above-mentioned points—by adopting a policy in which full clinical trial transparency is truly achieved—will the EMA be in a position to claim that it acts in the public interest.

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