What next for the EMA's transparency policy?

The European Medicines Agency's (EMA) much anticipated new policy on the proactive publication of clinical trial data that was originally planned for implementation in January 2014 has yet to see the light of day following a number of delays and mounting stakeholder concerns. The agency's Management Board is now expected to adopt the policy at its meeting on 2 October 2014.

In an effort to strike a balance among stakeholders, ranging from the pharmaceutical industry at one end of the spectrum, to members of Europe's academic and scientific community at the other, the agency's board had intended to adopt a revised version of the draft policy on 12 June 2014.

However, these plans began to unravel in May 2014 when European ombudsman Emily O'Reilly wrote a letter to EMA executive director Guido Rasi stating that the revised version seemingly reflected a U-turn in the agency's approach to proactively publishing full data sets for interested parties to view. In particular, the ombudsman pointed out that the modified policy would require those seeking the data to agree to 'terms of use' imposing broad legal conditions on the access to and use of such data, and would only allow them to view such data on screen.[1]

She further noted that the policy would limit access to such data because significant information deemed 'commercially confidential' would be redacted. Other groups advocating greater transparency such as AllTrials and Health Action International (HAI) Europe also urged the EMA not to water down the policy.

The result was that on 12 June, the Management Board began hammering out yet another version. The agency announced immediately thereafter that those accessing clinical trial data under the new policy would not have to view it on screen but would be able to download, save and print it for academic and non-commercial research purposes. This news was welcomed by the ombudsman and AllTrials, but it remains to be seen whether there will be changes to the redaction policy or the terms of use.

The European Federation of Pharmaceutical Industries and Associations, Efpia, declined to comment in detail but a spokesperson said: "We eagerly await the final text of the EMA's policy on the publication and access to clinical trials data. The fact [that] the wording of the policy, including practical arrangements for academic and non-commercial research users, has yet to be finalised highlights the complexities at stake. Sharing of data is complicated as it must maintain protection for individual patient privacy, intellectual property, including commercially confidential information, and contract rights. A considered and responsible solution is needed that has benefits for all, especially past, current and future patients.

It is important this is done right. In the meantime, our member companies are looking to the future and have committed to sharing study results with the public and individual patient data with researchers. Only by sharing data effectively and collaborating more will the industry be able to fully deliver on its promise."

The industry's commitment to share data such as synopses of clinical study reports is set out in its *Principles for Responsible Clinical Trial Data Sharing* document implemented on 1 January 2014. When *MedNous* asked the EMA in an interview how its policy will compare, the agency said that one of the main differences is that under the industry's policy, parties seeking data are pre-screened to determine whether they meet certain criteria regarding the legitimacy of the research. With the EMA's policy, however, "anyone can look at the data," the agency told *MedNous*.

The EMA also gave some insight into the rationale for the terms of use, saying that there were some legitimate concerns that had to be recognised and the terms "address the use of information for unfair purposes." As for the redaction policy, the EMA pointed out that if people think too much information has been redacted, they will be able to challenge this decision. "We will show in the documents what has been redacted," the agency added.

[In a related development, AbbVie Inc has withdrawn litigation brought against the EMA concerning its release of the company's trial data for Humira (adalimumab) after the agency agreed to release a new set of redacted documents for the drug. The ombudsman is reviewing the legality of this compromise deal because it says the new documents have more extensive redactions. The EMA does not expect this, or a similar ongoing case brought against it by InterMune, to impact the new policy.]

The EMA explained that the main difference between the new policy and the existing access-to-documents policy under which parties are legally permitted to request information under *Regulation (EC) No 1049/2001* is that "this is up front; we are proactively making public this information." The agency has reiterated on many occasions that the policy will not affect people's existing rights to request information under *Regulation (EC) No 1049/2001*.

The EMA has also mentioned that the policy is in line with the transparency measures set out in the recently adopted *Regulation (EC) No 536/2014* on clinical trials, which will become effective in 2016 at the earliest. "The Clinical Trials Regulation gives us a specific legal basis to publish certain information," the EMA said.

Separately, the EMA has reminded stakeholders that it is involved in a process to make summaries of the results of clinical trials publicly available through the EU Clinical Trials Database (EudraCT). To this end, on 21 July 2014 sponsors must begin posting their trial results on EudraCT.

Reference:

1. Letter from European Ombudsman to EMA, 13 May 2014, www.ombudsman.europa.eu.

This article was written by Karen Finn, contributing editor to *MedNous*.