Ombudsman concerned about change of policy at Medicines Agency as regards clinical trial data transparency

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In a letter to the European Medicines Agency (EMA), the European Ombudsman, **Emily O'Reilly** , has expressed concern about what appears to be a significant change of policy concerning clinical trial data transparency. According to documents the Ombudsman has seen, EMA is planning 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 EMA, as well as imposing wide restrictions on the use of such data."

Emily O'Reilly commented: "We were pleased when EMA announced, in 2012, a new pro-active transparency policy, giving the broadest possible public access to clinical trial data. I am now concerned about what appears to be a significant change in EMA's policy, which could undermine the fundamental right of public access to documents established by EU law. European citizens, doctors and researchers need maximum information about the medicines they take, prescribe and analyse. "

Change from pro-active transparency to a very restrictive policy?

In the last five years, the Ombudsman has conducted over a dozen inquiries into the EMA. Many concerned refusals to make public documents regarding the authorisation and regulation of medicines by the Agency, including medicines for treating multiple sclerosis, acne, bacterial infections, and obesity. In response to the Ombudsman's intervention in these cases, EMA appeared ready to adopt a pro-active approach towards transparency.

Furthermore, on 2 April 2014, the European Parliament voted in favour of legislative proposal to make clinical trial data public. As a consequence, the results of all future clinical trials in Europe should eventually be made publicly accessible online.

Against this backdrop, the Ombudsman has asked EMA's Director, Guido Rasi, to inform her by 31 May 2014 how EMA intends to deal with requests for public access to existing clinical trial data. She also asked him to list the reasons and the legal basis for what appears to be a significant change of policy.

The letter to EMA's Director is available at:
http://www.ombudsman.europa.eu/en/resources/otherdocument.faces/en/54347/html.bookmark