European Ombudsman reaction to EMA's 2 October 2014 adoption of its transparency policy concerning clinical trial data

Letter - 03/10/2014

The European Ombudsman, Emily O'Reilly, welcomes EMA's decision to publish the clinical reports that underpin the decision-making on medicines from January 2015.

She particularly welcomes the decision of EMA to abandon its insistence that clinical data would only be made public through a read-only format. EMA's decision will allow the public, including researchers and doctors, to download and analyse clinical data relating to medicines placed on the market in the EU. This is an important step towards ensuring the transparency that is vital in order to build and maintain citizens' trust in the reliability of the EU's system of making sure that the medicines placed on the market in the EU are safe and effective. The Ombudsman will continue to examine closely the manner in which EMA makes available clinical data to ensure that EMA meets the highest standards, in particular as regards the extent of the information that is disclosed and the way in which it is made available.

The Ombudsman is currently examining how EMA has dealt with various requests for access to documents, including clinical trial data and EMA's databases. She will verify, in this context, whether EMA is justified in redacting certain information from the documents it releases. The results of these inquiries will also be relevant as regards how EMA implements its proactive transparency policy.

The Ombudsman will also examine in detail whether the terms of use which users are required to sign up to before getting access to documents published by EMA are justified.