



Ombudsman welcomes increased Humira transparency - but calls for more on global top selling drug

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The European Ombudsman, Emily O'Reilly, has welcomed increased transparency in the clinical testing of Humira, one of the world's biggest selling drugs, following her inquiry into the publication of clinical study reports.

Humira, manufactured by the AbbVie pharmaceutical company, is an anti-inflammatory medicine used to treat Crohn's disease and other common diseases including rheumatoid arthritis, psoriasis and ulcerative colitis.

But the Ombudsman also expressed concern about certain parts of four specific clinical trial reports into Humira which were withheld by the European Medicines Agency on the stated grounds of commercial interest and has asked EMA to reconsider these redactions. The Ombudsman said that the principle that public health is more important than commercial interest must be upheld.

Some information about on-going drug development may justifiably be withheld temporarily, the Ombudsman said, but she added that all information about clinical trials, other than the personal data of patients, must ultimately be disclosed. Ms. O'Reilly has asked EMA, in such cases, to require companies to detail when, and how, any withheld information will eventually be made public.



"Any clinical information of value to doctors, patients and researchers, must be disclosed in the public interest," said the Ombudsman.

Ms O'Reilly added: "The European Medicines Agency has already taken significant steps to inject greater transparency into its work, particularly with its recent policy of proactively publishing clinical reports. My calls for further transparency should be seen in light of EMA's new responsibilities. Once the Clinical Trials Regulation becomes fully operational, EMA will have an even stronger role in ensuring the transparency of clinical trials conducted in the EU."

The Ombudsman's own initiative inquiry looked at the specific issue of granting wider public access to three clinical study reports into **Humira** .

While most of the text initially withheld was disclosed during the course of the Ombudsman's inquiry, certain redactions remain, including four that the Ombudsman considers unjustified.

Ms O'Reilly said: "I very much welcome EMA's increasing transparency when it comes to three clinical trial reports on Humira. In the case of the remaining redactions of concern to me, EMA has sought to justify them on grounds of commercial interests. I am asking EMA to reconsider the need for these redactions should it receive new requests for access to these reports."

Background

Humira , an anti-inflammatory drug, has been one of the [top selling drugs of all time \[Link\]](#), with billions of euro in sales.

The Ombudsman in 2014 opened an own initiative inquiry into the decision of EMA to give only partial public access to clinical trial studies related to the approval of Humira. During her enquiry, which included 75 questions posed to EMA, most of the previously redacted text was made public. EMA's policy of proactive publication of clinical reports - welcomed by the Ombudsman - came into force in January 2015. In March 2016, EMA published detailed guidance for pharmaceutical companies on how to comply with that policy.

As the Ombudsman's inquiry had wider implications for how EMA deals with public access to documents containing information on the safety and efficacy of medicines, the Ombudsman broadened the scope of her suggestions beyond the immediate Humira context.

The European Ombudsman's decision is available [here \[Link\]](#).