



**Emily O'Reilly**  
European Ombudsman

Mr Guido Rasi  
Executive Director  
European Medicines Agency  
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ROYAUME-UNI

Strasbourg, 16/04/2014

Own Initiative Inquiry OI/3/2014/BEH

Dear Mr Rasi,

The General Court has informed the Ombudsman that the applicant in Case T-44/13, AbbVie, has withdrawn its application seeking the annulment of the decision of EMA to release clinical studies reports supplied to EMA in the context of variation procedures relating to Humira.

An EMA press release dated 3 April 2014 indicates that AbbVie has now requested EMA to consider a new set of redacted documents and related justifications for redaction. The press release goes on to indicate that EMA considers that the redactions proposed by AbbVie are consistent with EMA's "redaction practices". In that context, the press release states, a new decision on public access to the requested documents, which takes account of those suggested redactions, was communicated to AbbVie.

I understand that EMA will now provide the citizen seeking access to the clinical studies reports relating to Humira with copies of the documents redacted to reflect the recent request from AbbVie.

On 8 April 2014, EMA provided me with copies of the redacted documents. EMA also provided me with a very brief document which describes, in broad terms, the additional redactions sought by AbbVie. That document does not seek to justify why those redactions are in accordance with Regulation 1049/2001.

As I noted, in paragraph 29 of my Statement in Intervention in Case T-44/13, no general presumption exists that an exception to public access applies to the documents at issue. Therefore, EMA can only legally refuse access to the requested documents if it demonstrated that the documents contain specific information which, if released to the public, would undermine an interest protected under Article 4 of Regulation 1049/2001.

I also underlined, in my Statement in Intervention (see paragraph 84 -



88), the important public interest in ensuring that medicinal products that are placed on the market, and therefore used on our fellow human beings, are proven to be safe and effective. I noted the consequent vital public interest in ensuring that the scientific information and assessments used to obtain a marketing authorisation is subjected to constant review. In this context, I also noted that even if public disclosure of a document would affect an interest protected by an exception under Articles 4(2) or 4(3) of Regulation 1049/2001, EMA should always weigh the interest to be protected through non-disclosure of the document concerned against the public interest in the document being made accessible.

In light of the above, I take the view that EMA should only take into account a request for additional redactions from AbbVie if EMA verifies that (i) the reasons put forward supporting that request are in accordance with Regulation 1049/2001 and (ii) the material content of the redacted text reflects the reasons provided for redaction.

Furthermore, I am sure you will agree that it is important to reinforce the public's trust and confidence in the work of EMA.

With this in mind, and after examining carefully the copies of the redacted documents, and the document which describes the additional redactions sought and obtained by AbbVie, I consider it appropriate to open an own initiative inquiry into the new decision of EMA to release redacted versions of the requested documents.

In accordance with Articles 3(1) of the Statute of the European Ombudsman, I inform you hereby of the opening of this own initiative inquiry. As a first step in my inquiry, I request EMA to allow my services, at the premises of EMA, sight of:

- 1) all the correspondence between EMA and AbbVie, and minutes of any meetings between EMA and AbbVie, relating to the new redactions sought and obtained by AbbVie;
- 2) the new decision, communicated to the citizen requesting access, setting out the justifications for the redactions to the requested documents;
- 3) the non-redacted documents.

I also request you to make available, for the purposes of assisting my services in the review of the non-redacted documents, two members of the scientific staff of EMA, namely the Head of Human Medicines Evaluation, Mme Enrica Alteri, and the Head of Scientific and Regulatory Management, M. Michael Berntgen. This request is without prejudice to the possible need to consult with additional scientific staff of EMA during the inspection.

My services will immediately contact your services to arrange a suitable date for this inspection, which should take place before the end of May 2014.



Subsequent, to the inspection, I may request EMA to submit to me an opinion on the matter under inquiry.

Yours sincerely,

A handwritten signature in black ink, which appears to read 'Emily O'Reilly'. The signature is fluid and cursive, with a long horizontal stroke at the bottom.

Emily O'Reilly

Cc: Mr Kent Woods, Chairman of the EMA Management Board  
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