European Ombudsman

Emily O'Reilly
European Ombudsman

Mr Peter Gøtzsche

E-mail: pcg@cochrane.dk

Strasbourg, 08/11/2016

Complaints 1475/2016/JAS and 1606/2016/JAS

Subject: Partial admissibility of your complaint

Dear Mr Gøtzsche,

On 10 October 2016, together with Karsten Juhl Jørgensen, Tom Jefferson, Margrete Auken, MEP, and Louise Brinth, you submitted a complaint to the European Ombudsman against the European Medicines Agency (EMA). Overall, your complaint is that EMA has not dealt properly with safety concerns about a particular pharmaceutical product. In your complaint, you put forward arguments about EMA's handling of the so-called referral procedure. You also raised concerns regarding an alleged lack of transparency and alleged conflicts of interest.

As a first step, and in order to address the different aspects of your complaint efficiently, I have decided to register it under two case numbers (1475/2016/JAS dealing with the referral procedure, and 1606/2016/JAS dealing with the alleged conflict of interest involving a senior EMA staff member).

My initial decision is that parts of your complaint are admissible while some other parts are not admissible. I have instructed my inquiry team to examine the substance of the allegations and, following this analysis, I will let you know which parts of your complaint I consider to be admissible and which parts inadmissible.

This decision on the admissibility of your complaint is simply an administrative step which does not imply that I have taken any position on the substance of your complaint. Further, it does not imply that I have taken any view at this stage on whether or not it will be necessary to contact EMA to obtain its view on your complaint or to obtain information or documents.

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Please note that the Ombudsman's Office is not a body with the scientific expertise to question the scientific evaluations of specialised scientific services, such as the Pharmacovigilance Risk Assessment Committee (PRAC) and the Committee for Medicinal Products for Human Use (CHMP). The Ombudsman may, however, seek to assess whether EMA has procedural safeguards in place which ensure that the scientific advice it receives is independent of outside interests and reliable.

In the normal course, I would expect to inform you of the progress of my inquiry team's substantive analysis of these cases within one month.

Please note that the contact person for this case is Mr Jan Stadler, who can be reached on +32 22843586 and jan.stadler@ombudsman.europa.eu.

Yours sincerely,

Emily O'Reilly
European Ombudsman