THE EUROPEAN OMBUDSMAN

P. NIKIFOROS DIAMANDOUROS

Dr Peter C. Gøtzsche
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Strasbourg, 03 -09- 2010

Complaint 2560/2007/BEH

Dear Dr Gøtzsche and Mr Jørgensen,

Please find enclosed the detailed opinion that I received from the European Medicines Agency (EMA) following my draft recommendation concerning your above complaint.

If you wish to make any observations on the detailed opinion, please send them to me before 31 October 2010.

Please note that, if I do not receive any observations from you, I may close the case with a decision, based on the information you have already provided and the EMA's submissions.

Yours sincerely,

P. Nikiforos DIAMANDOUROS

Enclosure: Copy of the detailed opinion submitted by EMA

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mr. Nikiforos DIAMANDOUROS
The European Ombudsman
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F-67001 STRASBOURG Cedex
France

31 August 2010

Directorate

Dear Mr. Diamandouros,

Subject: Draft Recommendation of the European Ombudsman in his inquiry into complaint 2560/2007/BEH against EMEA

I would like to thank you for your Draft Recommendation in the inquiry 2560/2007/BEH against the European Medicines Agency of the 19/05/2010 in which you request the Agency either to grant access to the requested documents or to provide a convincing explanation as to why no such access can be given and in any case to send a detailed opinion before the 31st August 2010.

The European Medicines Agency has carefully considered the European Ombudsman's assessment of the matter. The European Medicines Agency believes that openness and transparency of European institutions and bodies are fundamental principles that have been enshrined in the Treaty on the European Union and the Treaty on the Functioning of the European Union. The Agency also believes that its institutional mandate in providing Member States and European institutions with the best possible scientific advice on the evaluation and supervision of medicinal products is only strengthened by putting into practice the above principles. The Agency's commitment to promote and protect public health has at its heart the need to build-up public trust from European citizens in the Agency's activities. For this purpose, the Agency is currently engaged in the finalization of a new policy on access to documents (related to the authorisation and supervision of medicinal products for human and veterinary use) aimed at increasing transparency while balancing the need to protect public and private interests that are legally recognized. The Agency would also like to take this opportunity to thank, once again, the European Ombudsman for the interest and the contributions presented in the public consultation concerning the proposed policy.

It is necessary to ensure with concrete steps the widest possible access to documents originated, received, or held by the Agency in line with the provisions and the exceptions of Regulation (EC) 1049/2001. In this context, and in light of recent case-law[1] related to the application of the exception set out in art. 4(2) first indent of the Regulation (EC) 1049/2001 protecting the commercial interests of natural or legal persons, the Agency shares the Ombudsman's reasoning and considers that the

[1] Joined Cases T-355/04 and T-446/04 *Co-Frutta Soc. Coop. v. Commission*, judgment of 19 january 2010, published in OJ 2010/C 51/57.

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decision to refuse access to clinical study reports and the corresponding trial protocols in this case should be revised and that the applicant should be granted access to the requested documents.

The Agency would also like to highlight that for future requests for access to clinical trial reports, it will apply the same principles.

Due to the foreseen change in the Agency's policy on providing access to pharmaceutical company data (including clinical trial reports) once the decision-making process has been finalised, there is a need for the Agency to proceed with the necessary implementing actions. This includes the adoption of an internal decision on the extent of redaction before disclosure in order to ensure protection to commercial confidential information and to comply with the protection of the privacy and integrity of individuals.

The Agency notes that as the scope of the commercial interests exception cannot be excluded *a priori* but should be examined *in concreto* on a case-by-case basis also further to consultation with the authors of the received documents, and that *in specific and concrete* circumstances in which the disclosure of the documents might undermine the commercial interests of natural or legal persons, it will consider the need to redact part of the documents in line with the limits and the principles of Regulation (EC) 1049/2001.

The Agency recalls that the application of the exception of the protection of the privacy and integrity of individuals should always be taken into consideration by the concerned institution when the documents whose disclosure is requested under Regulation (EC) 1049/2001 might contain "personal" data as defined by Art. 2(a) of Regulation (EC) 45/2001[2].

The Agency will do its utmost to implement its decision as quickly as possible, in any case within the next 3 months at the latest. The Agency will keep the European Ombudsman promptly informed of the exact implementation date.

In addition the Agency will confer with individual applicants to inform them of the exact timing for replying to their requests

I trust the above satisfies your request for a detailed opinion in relation with your Draft Recommendation of the 19/05/2010.

Yours sincerely,

Thomas Lönngren

Executive Director

[2] According to recent case-law (*Commission v. Bavarian Lager* C-28/08 judgment of the 29th June 2010 not yet reported in the ECR), institutions and bodies, in applying Regulation 1049/2001, should always protect personal data in full accordance with the provisions of Regulation (EC) 45/2001. On this point, the Agency respectfully disagrees with the Ombudsman's conclusions in para. 84 of its Draft Recommendation.