THE EUROPEAN OMBUDSMAN

P. NIKIFOROS DIAMANDOUROS

Dr Peter C. Gøtzsche
Mr Anders W. Jørgensen
The Nordic Cochrane Centre, Dept. 3343
Rigshospitalet
Blegdamsvej 9
2100 Copenhagen Ø
DANEMARK

Strasbourg, 15 -10- 2009

Complaint 2560/2007/BEH

Dear Dr Gøtzsche and Mr Jørgensen,

Please find enclosed a copy of the report on the inspection of the file on your above complaint, which was carried out by my services on 6 October 2009.

If you wish to make any observations, please send them to me by 30 November 2009.

Please note that, if I do not receive any observations from you, I may close the case with a decision based on the information that is now in my possession.

Yours sincerely,

P. Nikiforos DIAMANDOUROS

Enclosure: 1

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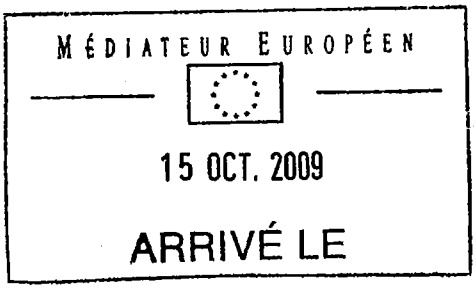
REPORT ON THE EUROPEAN OMBUDSMAN'S INSPECTION OF FILES

Case reference: 2560/2007/BEH
Name of complainants: Dr Peter C. Gøtzsche and Mr Anders W. Jørgensen
Institution involved: European Medicines Agency (EMEA)

Date: Tuesday, 6 October 2009
Location: Premises of EMEA (Rooms 2B and 549)
Written confirmation: E-mail from Mr Vincenzo SALVATORE to Mr Bernhard HOFSTÖTTER of 31 August 2009

Present: a) EMEA services:
Mr Vincenzo SALVATORE
Mr Fergus SWEENEY
Ms Beatrice FAYL
Mr Eberhard BLIND
Ms Anabela LIMA MARCAL
Mr Laurent BRASSART
Ms Gaëlle ANDRIANTAFIKA
Mr Agnis ZVAIGZNE



b) European Ombudsman services:
Mr Gerhard GRILL
Mr Bernhard HOFSTÖTTER

The inspection started at 9.12 am.

Mr SWEENEY presented the structure and content of the clinical trial protocol and the clinical trial report, notably referring to the relevant ICH standards. For their own information, Mr GRILL and Mr HOFSTÖTTER were provided with the texts of these standards. Mr GRILL briefly explained to the purpose of the inspection.

The file presented by EMEA contained the phase III controlled clinical trials concerning the drugs Orlistat (Xenical) and Rimonabant (Acomplia).

At 9.45 Mr GRILL and Mr HOFSTÖTTER started with a thorough inspection of the file relating to the phase III controlled clinical trials concerning Orlistat (Xenical). The file consists of 7 studies in total. The relevant documentation, which is paper-based, consists of 33 volumes in total. Each study consists of a core report, followed by a list of appendices which, in turn, is followed by the clinical trial protocol.

After a short lunch break, Mr GRILL and Mr HOFSTÖTTER proceeded to a thorough inspection of the phase III controlled clinical trials concerning Rimonabant (Acomplia). The computer-based file consists of 8 studies in total which are available in pdf-format. The clinical study report of each study is followed by a list of appendices, among which is the clinical trial protocol.

The inspection showed that the file largely reflects the aforesaid ICH standards.

The inspection further showed that, as regards Orlistat (Xenical), the documentation in relation to each of the seven studies consists of approximately 1 500 - 2 000 pages in total. Concerning Rimonabant (Acomplia) the documentation consists of an estimated 4 000 - 26 000 pages per study.

At their request, Ms ANDRIANTAFIKA provided Mr GRILL and Mr HOFSTÖTTER with copies of the tables of contents of the documents inspected. At the same time, Mr SALVATORE pointed out that, given that, in EMEA's view, the tables of contents formed part of confidential documents, they were also confidential and should not be disclosed to the complainants at this stage.

The inspection finished at 17.40 pm.

London, 6 October 2009

Mr Gerhard GRILL

Mr Bernhard HOFSTÖTTER