



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, 25 -10- 2007

Complaint 2560/2007/BEH

Dear Sirs,

On 8 October 2007 you made a complaint to the European Ombudsman against the European Medicines Agency (EMA), concerning EMA's refusal to grant access to certain clinical study reports and corresponding trial protocols.

To my mind, your allegations and claims can be summarised as follows, and I have asked EMA to submit an opinion on them:

- 1 The complainants allege that when denying access to clinical study reports and corresponding trial protocols with regard to the drugs orlistat and rimonabant, EMA has given insufficient reasons for its decision, in particular as regards the existence of a public interest in disclosure overriding commercial interests.*
- 2 The complainants allege further that EMA's decision to deny access based on the protection of commercial interests is unconvincing, given in particular that the study reports and protocols requested do not appear to indicate any commercial interest.*

The complainants claim that they should be granted access to clinical study reports and corresponding trial protocols, as requested.

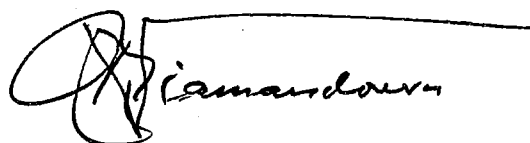
The examination of your complaint is under way and I shall let you know its preliminary outcome as soon as possible.

In accordance with Articles 2(2) and 3(1) of the Statute of the European Ombudsman, I have informed the Executive Director of EMA of your complaint and asked him to submit an opinion on it by 31 January 2008 at the latest. When the opinion is received, I will forward it to you with an invitation to submit observations, if you so wish, within one month.

Once your observations have been received, or the deadline has passed, the file will be examined by the legal officer responsible for dealing with your case: Mr Bernhard Hofstötter, Tel. ++33 388 17 81 05. You will be informed if further inquiries are necessary before the Ombudsman can make a decision on your complaint.

Every effort is made to deal with cases as quickly as possible. The Ombudsman's decision is normally made within one year of the complaint, unless there are exceptional circumstances or an exceptionally heavy workload which require a longer inquiry.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'P. Diamandouros', with a long horizontal line extending to the right from the end of the signature.

P. Nikiforos DIAMANDOUROS

Please note the reference to your complaint: 2560/2007/BEH