



P. Nikiforos Diamandouros
European Ombudsman

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Complaint 2560/2007/BEH

Dear Dr Gøtzsche,

I refer to your e-mail of 1 December 2010 addressed to Mr Hofstätter. In your e-mail, you welcomed my press release No. 22/2010 published on 1 December 2010, in which I applauded EMA's adoption of a new transparency policy. At the same time, you brought to my attention one aspect of that policy which, according to you, is not in line with what I said in the decision closing my inquiry into the above-mentioned complaint.

You highlighted that EMA identified 'commercial confidential information' by reference to any information which is not in the public domain or publicly available and where disclosure **may undermine** the economic interest or competitive position of the owner of the information. You pointed out, however, that, in my decision, I stated that an institution, before relying on an exception to public access, would have to assess whether granting access **would specifically and actually undermine** the protected interest. Moreover, you stated that, in the course of the inquiry, EMA itself did not refer to what you consider to be a vague standard ("may undermine").

As stated in the above-mentioned press release, it is my belief that EMA's new policy gives the public much broader access to documents in its possession. It is for this reason that I welcomed and applauded EMA's relevant announcement. However, as you know, EMA's new transparency policy was not in any way assessed or evaluated in the framework of my inquiry into your complaint. Welcoming EMA's adoption of a new policy is therefore not to say that I necessarily agree with each of EMA's considerations underlying that policy.

I note that the passage from my decision quoted by you summarises the relevant case law of the Court of Justice which EMA needs to respect when deciding on requests for access. Given that EMA accepted my draft recommendation and, at the same time, stated that it would apply the same principles in future cases, it appears to me that EMA intends to implement its



transparency policy in line with the case-law of the Court of Justice as well as the considerations set out in my draft recommendation in the above case.

Yours sincerely,

P. Nikiforos Diamandouros