

meetings this week

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Dear Bernhard Hofstötter,

I was very grateful for getting the opportunity to meet with you and the Ombudsman last week and I am very pleased to see your press release from today and also the announcements made by EMA about greater openness and transparency.

However, I thought I should draw your attention to a very important point, which the Ombudsman has dealt with, but which EMA nevertheless does not seem to have accepted.

On page 4 in EMA's policy document (POLICY/0043), EMA writes:

"The Agency will ensure protection of commercial interest in accordance with the notion of commercial confidential information. In view of the lack of a legal definition and for the purpose of this policy 'commercial confidential information' shall mean 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."

The expression "may undermine" is very vague and opens the possibility for EMA to refuse access to important data for no good reason. It also agrees very poorly with what the Ombudsman said about this when he closed his inquiry (item 28):

"28. According to Article 1(1) of the Rules, their aim is to ensure the widest possible access to the documents EMA produces or receives and has in its possession. It emerges from the settled case-law of the Community courts regarding Regulation 1049/2001 that the exceptions to the general right of access to documents must be interpreted and applied strictly[6]. The mere fact that a document concerns an interest protected by an exception cannot itself justify the application of that exception. Therefore, before lawfully relying on an exception, the institution concerned is required to assess (i) whether access to the document **would specifically and actually undermine** the protected interest and (ii) whether there is no overriding public interest in disclosure. That assessment must be apparent from the reasons underpinning the decision[7]."

Further, it even agrees poorly with what EMA has said itself earlier (item 14 in Ombudsman's report):

"According to EMA, any trade secret or commercial confidence, as well as any kind of information, the disclosure of which **would unreasonably undermine** or prejudice the commercial interests of individuals or companies, was to be considered as commercially confidential information."

Under item 27, EMA says: ""The Agency shall refuse access to a document where disclosure **would undermine** the protection of: a) commercial interests of a natural or legal person, including intellectual property,"

It follows from these quotes, that the expression in EMA's policy document from 1 Dec 2010, "**may undermine**", is misleading, considering the Ombudsman's report.


I enclose both documents, for your convenience.

best wishes

Peter Gøtzsche

2 vedhæftede filer

 **EMA policy on access 1 Dec 2010.pdf**
219K

 **The Ombudsman decision on closing the case 24 Nov 2010_text.pdf**
280K