



European Medicines Agency
Communications and Networking

London, 12 February 2009
Doc. Ref.: EMEA/55797/2009

Olivier Huyghe
Prescrire editorial team
Prescrire
83, boulevard Voltaire
75558 PARIS CEDEX 11
FRANCE

Dear Mr. Huyghe

Thank you for your letter of 22 January 2009 in which you apply for access to documents in accordance with the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents. As indicated in the title, these rules implement the principles and procedures established in Regulation (EC) 1049/2001 to documents held by the EMEA.

Please find enclosed a copy of the CHMP variation assessment report for variation II/0055, which I hope you will find useful. The document may be reproduced provided the EMEA is acknowledged as the source.

We regret to inform you that the document (PSUR9) you requested comes under the system of exceptions set out in the implementing rules, and therefore cannot be released.

The exception that applies to the document you requested is the following:

- Article 3.2.a (The Agency shall refuse access to a document where disclosure would undermine the protection of: commercial interests of a natural or legal person, including intellectual property).

If you wish to appeal against this decision, you should write to the Executive Director of the Agency, Mr Thomas Lönngren at the address below, repeating your initial request. You have fifteen working days from receipt of this letter in which to appeal. Beyond this deadline, your initial request will be considered withdrawn.

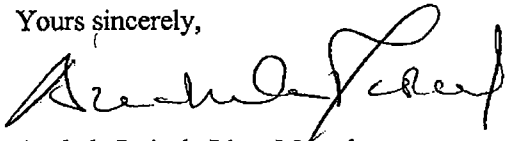
The Executive Director will inform you of the outcome of the appeal of your request within fifteen working days of receipt of your request, either by granting you access to the documents or by confirming the refusal. In the latter case, he will also inform you of any further appeal routes you may take.

All correspondence must be sent to:

Mr Thomas Lönngrén
Executive Director
EMA
7 Westferry Circus
Canary Wharf
London
E14 4HB

Fax (44-20) 74 18 84 09

Yours sincerely,



Anabela Luis de Lima Márçal
Specialised Group Leader CNS/Endocrinology
Post-Authorisation Safety & Efficacy of Medicines



European Medicines Agency
Communications and Networking

London, 6 March 2009
Doc. Ref.: EMEA/112985/2009

Mr. Olivier Huyghe
Prescrire editorial team
Prescrire
83, boulevard Voltaire
75558 PARIS CEDEX 11
FRANCE

Dear Mr. Huyghe

Thank you for your letter of 13 February 2009 which we received on 13 February 2009, in which you request that the Agency reconsiders its decision of 12 February 2009 to not release the PSUR 9 for Ebixa (*memantine*). In addition, you also applied for access to the Rapporteur's Assessment Report for Ebixa variation II/55. Your appeal has been handled in accordance with the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents. As indicated in the title, these rules implement the principles and procedures established in Regulation (EC) 1049/2001 to documents held by the EMEA.

Please find enclosed a copy of the Rapporteur's variation assessment report for Ebixa variation II/0055, which I hope you will find useful. The document may be reproduced provided the EMEA is acknowledged as the source.

We regret to inform you that the other document you requested (Ebixa PSUR No. 9) comes under the system of exceptions set out in the implementing rules, and therefore cannot be released.

The exception that applies to the document you requested (Ebixa PSUR No. 9) is the following:

- Article 3.2.a (The Agency shall refuse access to a document where disclosure would undermine the protection of: commercial interests of a natural or legal person, including intellectual property unless there is an overriding public interest in disclosure).

However, if you wish to appeal against this decision, the legal remedies open to you are either to lodge a complaint to the European Ombudsman or to institute Court proceedings against the Agency, under Article 195 or 230 of the EC Treaty, respectively.

Furthermore, in relation to the views expressed in your letter we would like to point out the following:

1) The European Medicines Agency works in collaboration with the network of National Competent Authorities and its role is to monitor the safety and efficacy of all medicines within the scope of the Agency's mandate. On this regards systems are in place to ensure that the balance of the benefits and the risks of all authorised medicinal products is under constant review and that actions are taken where appropriate to protect public health. As a result of this constant monitoring, which includes the assessment of Periodic Safety Update Reports, the EMEA regularly updates the Product Information

for Centrally Authorised Products. Healthcare professionals and patients are informed on these changes through the European Public Assessment Report and other communication tools as relevant. With this regard and considering the Agency's obligation on the assessment of balance and risks of medicinal products, we cannot identify any overriding public interest that could justify the disclosure of the concerned document.

2) The reference in your letter to the "Principles to be applied for the deletion of commercial confidential information for the disclosure of EMEA documents" should be put in context. Annex I of this document, where is mentioned that as a general rule clinical data is not commercially confidential, applies to "the publication of assessment reports as foreseen by the pharmaceutical legislation, and disclosure of any other assessment report related to the outcome of an EMEA Committee's assessment of a marketing authorisation application" (our emphasis).

Yours sincerely,

A handwritten signature in black ink, appearing to be 'T. Lönngren', written in a cursive style.

Thomas Lönngren
Executive Director