



European Medicines Agency
Communications and Networking

London, 08 May 2009
Doc. Ref.: EMEA/248331/2009

Mr Olivier Huyghe
Prescrire
83 Boulevard Voltaire
75558 Paris
Cedex 11
France

Dear Mr Huyghe,

Thank you for your letter, which we received on 16 April 2009, in which you apply for access to documents held by the Agency.

Your application 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.

We regret to inform you that the documents you requested come under the system of exceptions set out in the implementing rules, and therefore cannot be released.

The exception that applies to the documents you requested is *'Access to a document, produced or received and in possession of the Agency, which relates to a matter where the decision has not been taken, shall be refused if disclosure of the document would seriously undermine the decision-making process, unless there is an overriding public interest in disclosure.'* (exception listed in Article 3.3 of the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents).

Furthermore, with regard to your allegation of public interest at stake, we would like to emphasise that the public interest of access to preliminary assessments from the Rapporteur and Co-Rapporteur, when a decision has not been taken has to be balanced against the undermining of the decision-making process. On the basis of your request, the Agency cannot identify an overriding public interest that would justify the disclosure of the concerned documents.

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 Beyond this deadline, your initial request will be considered withdrawn.

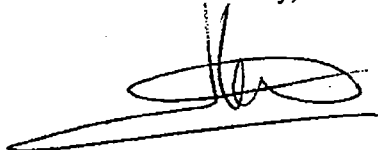
The Executive Director will inform you of the outcome of the appeal of your request within fifteen working days of receipt of your request, either by granting you access to the documents or by confirming the refusal. In the latter case, he will also inform you of any further appeal routes you may take.

All correspondence must be sent to:

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

Fax (44-20) 74 18 84 09

Yours sincerely,

A handwritten signature in black ink, appearing to be 'Noel Wathion', written over a horizontal line.

Noel Wathion
Head of Unit
Post-Authorisation Evaluation of Medicines for Human Use