



European Medicines Agency  
*Communications and Networking*

London, 30 June 2009  
Doc. Ref.: EMEA/410690/2009

Mr Olivier Huyghe  
Prescrire  
83, boulevard Voltaire  
75558 Paris Cedex 11  
France

Dear Mr Huyghe,

Thank you for your letter of 9 June 2009, which we received on 9 June 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 document, which I hope you will find useful.

Please be informed that for the variation II-11, the EPAR was updated together with the PI on 18 May 2009 (adopted on 5 May 2009). The supporting CHMP document together with the annexes is sent to you as per your request. The PSUR is not provided as it is considered a confidential document as per Article 3.2.c).

The document may be reproduced provided the EMEA is acknowledged as the source.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'C. Draï', with a stylized flourish at the end.

Catherine Draï  
Scientific Administrator