European Medicines Agency
Communications and Networking

London, 07 October 2008
Doc. Ref.: EMEA/502172/2008

Mr Olivier Huyghe
Prescrire
83 Boulevard Voltaire
75558 Paris
Cédex 01
France

Dear Mr Huyghe

Thank you for your letter which we received on 18 September 2008 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.

Access has been granted to the assessment reports on variations II/0008 and II/0011, where confidential information has been redacted.

With regards to your request made in bullet point 3 of your letter of 18th September 2008, please be aware that the response will be sent to you by 16th October 2008, as discussed in our e-mail of 26th September 2008.

Finally, we regret to inform you that the 3 PSURs 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 2a ('*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*'), listed in Article 3 of the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA 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 Beyond this deadline, your initial request will be considered withdrawn.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.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu www.emea.europa.eu

All correspondence must be sent to:

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

Fax (44-20) 74 18 84 09

Yours sincerely,

p.p.

Anabela Luis de Lima Marçal
Specialised Group Leader CNS/Endocrinology
Pharmacovigilance and Post-Authorisation Safety and Efficacy of Medicines

European Medicines Agency
Communications and Networking

London, 16 October 2008
Doc. Ref.: EMEA/541210/2008

Mr Olivier Huyghe
Prescrire
83 Boulevard Voltaire
75558 Paris
Cédex 01
France

Dear Mr Huyghe,

Thank you for your letter which we received on 18 September 2008 requesting access to documents held by the Agency, and for your e-mail of 25 September 2008 providing further clarifications on your request.

As discussed in our e-mail of 26 September 2008, we hereby send you the response to your request made in bullet point 3 (all documents related to the Risk Management Plan for rimonabant).

Your application has been handled in accordance with the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents. These rules implement the principles and procedures established in Regulation (EC) 1049/2001 to documents held by the EMEA.

Access has been granted to the Assessment Reports on Acomplia's Risk Management Plan (RMP), where confidential information has been redacted.

However, we regret to inform you that the actual RMP submitted by the MAH comes under the list of exceptions set out in the implementing rules, and therefore cannot be released.

The exception that applies to the documents you requested is 2a ('*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*'), listed in Article 3 of the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA 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.

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All correspondence must be sent to:

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

Fax (44-20) 74 18 84 09

Yours sincerely,

pp.

Anabela Luis de Lima Marçal
Specialised Group Leader CNS/Endocrinology
Pharmacovigilance and Post-Authorisation Safety and Efficacy of Medicines

European Medicines Agency
Directorate

London, 30 October 2008
Doc. Ref.: EMEA/572965/2008

Mr Olivier Huyghe
Prescrire
83 Boulevard Voltaire
75558 Paris
Cédex 01
France

Dear Mr Huyghe,

Thank you for your letters dated 13 and 21 October 2008, in which you request that the Agency reconsiders its decision of not disclosing all PSURs and the Risk Management Plan (RMP) for Acomplia, and of redacting parts of the assessment reports on the RMP. 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.

After considering your appeal I confirm our decision not to release the requested documents since they 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 2a ('*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*'), listed in Article 3 of the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents.

As per your request dated 18 September and clarified in your email dated 25 September 2008, access was granted to the assessment reports of the Acomplia's RMP on 16 October 2008, where confidential information was redacted. These assessments were part of wider documents, the PSUR assessment reports. Could you please clarify whether you would be interested to receive these documents, as this was not part of your original request?

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.

Yours sincerely,

Thomas Lönngren
Executive Director

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