European Medicines Agency
Communications and Networking

London, 14 January 2009
Doc. Ref.: EMEA/13293/2009

Mr Olivier Huyghe
Prescrire editorial team
www.prescrire.org

Dear Mr Huyghe,

Thank you for your e-mail concerning Ketek, which we received on 22 December 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.

Please find enclosed a copy of the CHMP Variation Assessment Report for Variation EMEA/H/C/354/II/0047 for Ketek with confidential information deleted. This document may be reproduced provided the EMEA is acknowledged as the source.

We regret to inform you that the document requested PSUR 12 for Ketek comes under the system of exceptions set out in the implementing rules, and therefore cannot be released. The exception that applies to this document is Article 3.2a of the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents (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 Beyond this deadline, your initial request will be considered withdrawn.

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

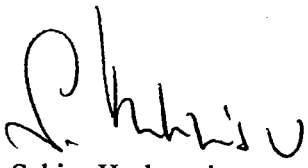
The Executive Director will inform you of the outcome of the appeal of your request within fifteen working days of receipt of your request, either by granting you access to the document or by confirming the refusal. In the latter case, he will also inform you of any further appeal routes you may take.

All correspondence must be sent to:

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

Fax (44-20) 74 18 84 09

Yours sincerely,



Sabine Haubenreisser
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