European Medicines Agency
Communications and Networking

London, 5 June 2009
Doc. Ref.: EMEA/351840/2009

Olivier HUYGHE
Prescrire
83, boulevard Voltaire
75558 Paris Cedex 11
France

Dear Mr Huyghe,

Thank you for your letter dated 23 April 2007, in which you apply for access to documents held by the Agency, namely the mock-ups for Sebivo (telbivudine) outer and immediate packaging and package leaflet.

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 document(s) you requested is Article 3.2.a) 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 Beyond this deadline, your initial request will be considered withdrawn.

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 Lönngren
Executive Director
EMEA

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

7 Westferry Circus
Canary Wharf
London
E14 4HB

Fax (44-20) 74 18 84 09

Yours sincerely,

Sabine Haubenreisser
Specialised Group Leader Anti-infective/Immunology
Post-Authorisation Safety and Efficacy of Medicines

European Medicines Agency
Directorate

London, 2 July 2009
Doc. Ref.: EMEA/404348/2009

Olivier HUYGHE
Prescrire
83, boulevard Voltaire
75558 Paris Cedex 11
France

Dear Mr Huyghe,

Thank you for your letter dated 9 June 2009, received on 12 June 2009, in which you request that the Agency reconsiders its decision of 5 June 2009 concerning access to the mock-ups for Sebivo (telbivudine) outer and immediate packaging and package leaflet.

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.

The documents you requested are part of the application dossier (Module 1.3.2). We regret to confirm that such documents 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 Article 3.2.a) 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).

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

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
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