European Medicines Agency
Post-Authorisation Evaluation of Medicines for Human Use

London, 20 August 2007
Doc. Ref.: EMEA/372159/2007

Mr. Anders Jørgensen
Dr. Peter C Gøtzsche
Nordic Cochrane Centre
Rigshospitalet
Copenhagen
Denmark

Dear Sirs,

Thank you for your letter of 29 June 2007, which we received on 31 July 2007 from the Danish Medicines Agency, 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 listed in Article 3.2(a) of the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents, which refers to 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 Beyond this deadline, your initial request will be considered withdrawn.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

Fax (44-20) 74 18 84 09

Yours sincerely,

Panos Tsintis
Head of Sector
Pharmacovigilance and Post-Authorisation Safety & Efficacy of Medicines Sector
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