EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mr Olivier Huyghe
83, Boulevard Voltaire
75558 Paris Cedex II
France

17 March 2010

EMA/131992/2010

Patient Health Protection

Dear Mr Huyghe,

Thank you for your e-mail which we received on 25 February 2010, 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 European Medicines Agency documents. As indicated in the title, these rules implement the principles and procedures established in Regulation (EC) 1049/2001 to documents held by the European Medicines Agency.

We regret to inform you that the document you requested comes under the system of exceptions set out in the implementing rules, and therefore cannot be released.

The exception that applies to the document you requested is the one set by the article 3.3 of the Rules for the implementation of Regulation (EC) No 1049/2001 on access to European Medicines Agency documents whereby "*access to a document... which relates to a matter where the decision has not been taken, shall be refused if the disclosure of the document would seriously undermine the decision-making process...*".

The Co-Rapporteur Assessment Report you refer to in your request (report which only reflects the views of the Co-Rapporteur ) is still part of an on-going procedure for which the CHMP Opinion has not been adopted yet. Preparatory acts such as Rapporteur Assessment Report and Co-Rapporteur Assessment Report that do not constitute the final position of the scientific committees are nonetheless provided to the interested parties (Marketing Authorisation Holders) of a procedure as soon as they become available further to circulation to CHMP Members. This practice is to guarantee that interested parties can fully exercise their "right to be heard" before the adoption of an administrative decision affecting their rights is taken.
The document that you are requesting can be accessible once a Commission Decision for this referral procedure has been adopted.

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 Beyond this deadline, your initial request will be considered withdrawn.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 • United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
**E-mail** info@ema.europa.eu **Website** www.ema.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 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
European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom

Fax (44-20) 74 18 84 09

Yours sincerely,

Anthony Humphreys
Head of Regulatory, Procedural and Committee Support

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mr Olivier Huyghe
Prescrire
83, Boulevard Voltaire
75558 Paris Cedex II
France

10 May 2010
EMA/280217/2010
Patient Health Protection

Dear Mr Huyghe,

Thank you for your e-mail, which we received on 19 April 2010, in which you request that the Agency reconsiders its decision of 17 March 2010. Your appeal has been handled in accordance with the Rules for the implementation of Regulation (EC) No 1049/2001 on access to European Medicines Agency documents. As indicated in the title, these rules implement the principles and procedures established in Regulation (EC) 1049/2001 to documents held by the European Medicines Agency.

We regret to inform you that the document you requested comes under the system of exceptions set out in the implementing rules, and therefore cannot be released.

The exception that applies to the document you requested is the one set by the article 3.3 of the Rules for the implementation of Regulation (EC) No 1049/2001 on access to European Medicines Agency documents whereby "*access to a document... which relates to a matter where the decision has not been taken, shall be refused if the disclosure of the document would seriously undermine the decision-making process...*".

As mentioned in the Agency's response dated 17 March 2010, the Co-Rapporteur Assessment Report you refer to in your request is still part of an on-going procedure for which the CHMP Opinion has not been adopted yet ; the document that you are requesting can be accessible once a Commission Decision for this referral procedure has been adopted.

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 228 or 263 of the Treaty on the Functioning of the European Union (TFEU), respectively.

Yours sincerely,

Thomas Lönngren
Executive Director

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