European Ombudsman

P. Nikiforos Diamandouros
European Ombudsman

1877/2010/FOR
S2011-132627

Mr. Olivier Huyghe
83 boulevard Voltaire
75011 Paris

ohuyghe@prescrire.org

Strasbourg, 14 -02- 2011

Complaint 1877/2010/FOR

Dear Mr Huyghe,

Please find enclosed the opinion that I received from the European Medicines Agency concerning your above complaint.

If you wish to make any observations on the opinion, please send them to me before 31 March 2011.

Please note that, if I do not receive any observations from you, I may close the case with a decision, based on the information you have already provided and the European Medicines Agency's opinion.

Yours sincerely,

P. Nikiforos Diamandouros

Enclosure:
- Copy of the opinion submitted by the European Medicines Agency

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EUROPEAN MEDICINES AGENCY
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European Ombudsman
1 Avenue du President Robert Schuman
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31 January 2011
EMA/82777/2011
Directorate

Dear Mr. Diamandouros

Subject: **Complaint 1877/2010/FOR**

The European Medicines Agency has received your letter of the 21st October 2010 and has taken note of the complaint from Prescrire about a series of alleged acts of maladministration concerning the right to have access to documents held by the Agency.

You have invited the Agency to submit an opinion on the allegations and claims presented by the complainant, which I am pleased to include in this letter.

The details of the allegations and claims made by the complainant are contained in a letter of the 30th August 2010 addressed to the European Ombudsman. The letter provides partial factual elements related to the procedures for access to documents concerned. The letter is also accompanied by an article and other material published by the complainant on the complainant's journal (*Rev Prescrire* International October 2009/Volume 118 n.103) titled "*Legal obligations for transparency at the European Medicines Agency: Prescrire's assessment over four years*".

The Agency will limit its considerations to the allegations of specific acts of maladministration in the application of Regulation (EC) 1049/2001. In particular, it will provide the European Ombudsman with additional elements to understand the reasons for refusing access to the documents or parts of the documents requested, and the steps taken in order to ensure transparency and openness of Agency's activities.

The Agency does not consider neither appropriate, nor necessary, to respond to criticisms and assumptions of a general nature that the complainant is making with regard to the transparency of the Agency. The Agency takes the opportunity to recall the importance of a sound system of communication of information related to the safety of authorized medicinal products and welcomes the efforts of the complainant as well as of similar organizations to contribute to "*reinforcing transparency rules applicable to drug regulatory agencies*". The Agency also notes that there are a number of provisions in EU pharmaceutical law that require the Agency to undertake actions for the prompt communication to the public of information and documents related to authorized medicinal products. This observation is without prejudice to the application of the obligations stemming from Regulation (EC) 1049/2001 applicable to the Agency in force of art. 73 of Regulation (EC) 726/2004.

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It is of note to recall that a new *Policy on Access to Documents (related to medicinal products for Human and Veterinary Use)* has been adopted by the Management Board of the Agency the last 30th November 2010 (Doc. Ref. EMA/110196/2006) whereby the Agency has committed to apply in a stricter way the exceptions under Art. 4 of Regulation (EC) 1049/2001.

First complaint: A Reference Member State assessment report

On the first complaint, the Agency would like to give additional information on the processing of this request for access to documents to explain the Agency's conduct. The original request for access to documents was received in an e-mail sent by the complainant on the 18th September 2008 (Annex I). The documents requested were: a) copies of the assessment reports on variations II/0008 and II/0011 for Acomplia (rimonabant); b) the three PSURs referred to in these variations c) all other documents related to the risk management plan (RMP) for rimonabant. The request of documents under point a) and b) was acknowledged on the 23rd of September, and simultaneously a request for clarification as regards the scope of the request under c) was put forward to the applicant. On the 24th September, the Agency, with a communication by e-mail, presented the applicant with a list of eligible documents (Annex II). On the 25th September the applicant clarified that he wanted to have access to "*-assessment reports on variations II/0008 and II/0011 for Acomplia; -all the PSURs for Acomplia; -risk management plan; **- assessments reports on risk management plan**" (emphasis added).* On the 09th October 2008, the Agency decided to grant access to the documents under point a) (Annex III) providing the complainant with a redacted copy and refused access to the documents under point b) as they were deemed to be covered by the exception of art. 4(2) first indent. As for the outstanding request under point c) which the applicant had expressly limited to "*the risk management plan and the assessments reports on risk management plan*", the Agency, contrary to the statement made by the complainant, granted access on the 16th October 2008. The document containing the Risk Management Plan (RMP) that had been submitted by the marketing authorization holder was considered to be covered by the exception under art. 4(2) first indent of Regulation 1049/2001.

The complainant has annexed to the complaint a copy of the released document containing the Assessment Report of the RMP. The Agency would like to clarify that the relevant assessment reports of the RMP as requested by the applicant was contained only in few paragraphs of the 68-pages that were released. The reason for such an extensive redaction process concerning other parts (including date) of the document was that the parts redacted contained the assessment reports of the PSURs which were not requested from the applicant. The document in fact contained the assessment report on the RMP and on the PSURs submitted by the marketing authorization holder. The Agency accepts that such course of action (redaction of all other **not** relevant parts of a document) could be criticized, in particular as the applicant was not made in that occasion fully aware of the justifications for the redacted parts of the released document. The Agency could have extracted from the Assessment Report received by the Swedish Medicines Agency the parts concerning the assessment reports of the RMP and selectively release them to the applicant to fulfil the request, however this was not at that time to be considered an acceptable practice under Regulation (EC) 1049/2001. Moreover, the Agency would like to point out that, further to receiving a confirmatory application from the applicant questioning the decision of the Agency, on the 30th October 2008, the applicant received a letter from the Agency (annexed to the complaint submitted by Prescrire) in which the reasons for the extensive redactions were manifested ("*These assessments were part of wider documents, the PSUR assessment reports*"). In that occasion, the Agency asked explicitly whether the applicant would be interested to receive also a copy of the PSURs assessment reports as this was not part of the original request, but the Agency's request was not followed-up by the applicant.

The Agency therefore would like the European Ombudsman to assess whether, taking into account the inertia of the applicant with regard to the possible access of other parts of the document concerning PSURs assessment reports, the complainant could legitimately claim that there has been an instance of maladministration in the alleged refusal to release other parts of the document (i.e. the 65 redacted pages).

Second complaint: refusal to provide PSURs

At the time of filing of the respective applications for access to documents, the European Medicines Agency considered the Periodic Safety Update Reports (PSURs) confidential documents originated by marketing authorization holders and received by the Agency in accordance with art. 24(3) of Regulation (EC) 726/2004, hereby requests for access to these documents have been refused on the basis of the exception set up in art. 4(2) first indent of the Regulation (EC) 1049/2001.

As already highlighted, the Agency has revised the interpretation of the scope of the exceptions set up in art. 4 of Regulation (EC) 1049/2001 in particular with regard to the documents originated by pharmaceutical companies in the framework of marketing authorization procedures. The European Medicines Agency has reconsidered the application of the exception under art. 4(2) first indent to a series of "third party" documents received by the European Medicines Agency within the framework of marketing authorization procedures, and this includes also PSUR. The European Medicines Agency would like to inform the European Ombudsman that the same complainant is fully aware that currently requests for access to PSURs are being accepted and access is being granted.

Third complaint: mock-up packaging

On the third complaint, I would like to clarify that in processing the application, the Agency considered the document requested by the complainant ("coloured mock-ups") falling under the exception of art. 4 (2) first indent. The documents requested are presented at time of submission of marketing authorization application as part of their technical dossier.

In accordance with published Guidelines on *The Revised Checking Process of Mock-ups and specimens of outer immediate labelling and package leaflets of human medicinal products in the Centralized procedure* (Doc. Ref. EMEA/305821/2006) available from the Agency's website (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004891.pdf) , *"mock-ups...must be submitted by the applicant/MAH to the Agency for review, before commercialisation of the medicinal product"* (p.2). the Agency would then provide the applicant with an Opinion on the mock-ups received. Paragraph 2.3 of the document explains that after the Opinion of the Agency on the "mock-ups" that have been submitted, *"MAHs are responsible for the correct implementation of the agreed product information texts in their printed packaging materials, in line with the Commission Decision and relevant EU legislation"* (p.3).

Therefore, the Agency would like to highlight that the documents in possession of the Agency - the "mock-ups" presented by the applicant at time of filing the marketing authorization application- might not correspond to the commercialized packaging materials, therefore they might not be publicly available and might contain information on colouring options and other artwork designs elements that could be considered proprietary material.

The Agency would then like to submit that it correctly applied the exception set out in art. 4(2) first indent of Regulation (EC) 1049/2001 in denying access to the concerned documents.

Fourth complaint: refusal to give access to documents related to the referral of the *dextropropoxyphene + paracetamol* combination

On the fourth complaint, we would like to inform the European Ombudsman that the request submitted by the complainant to the European Medicines Agency for having access to the Rapporteur and Co-Rapporteur assessment reports was duly satisfied on the 19th October 2010 as soon as the European Commission issued a final decision on the referral procedure. The Agency has released all assessment reports and other documents related to the concerned procedure (Annex IV).

The request of having access to the documents concerned was "withheld" until the point in time in which a final decision was taken by the European Commission. This is in line with the exception set out in art. 4 (3) first paragraph of regulation (EC) 1049/2001 as at the time of filing the original application they were merely preparatory acts whose disclosure could undermine the decision-making process.

Fifth complaint: Co-Rapporteur report related to topical ketoprofen

A similar rationale has been upheld in the decision to refuse access to the Co-Rapporteur Assessment Report requested by the complainant at the specific point in time when the application for access to documents was filed with the European Medicines Agency.

The fifth complaint brought forward by Prescrire in fact concerns the refusal from the Agency to grant access to a Co-Rapporteur assessment report related to "topical ketoprofen". In this regard, the Agency would like to present its position that the decision to deny access to this document was indeed justified at the time of the filing of the application.

It is useful to provide additional factual circumstances to describe the broader context in which the decision has been taken. On the 25th February 2010, the complainant requested access to the Co-Rapporteur Assessment Report on topical ketoprofen produced in the framework of a procedure under art. 107 of Directive 2001/83/EC. This procedure had started on 17th December 2010 subsequent to a decision of the French competent authority (Afssaps) to suspend at national level the marketing authorisation of all topical medicines containing ketoprofen in France. Article 107 (2) of Directive 2001/83/EC provides that *"when the Agency is informed of suspensions or revocations adopted at national level"*, a collegial scientific body of the Agency, the Committee for Human Medicinal Products (CHMP) shall prepare an opinion. Therefore, it should be made clear that the administrative decision taken at national level to suspend the marketing authorization of medicinal products and the procedure at European level under art. 107 of Directive 2001/83/EC are linked but independent. It appears that pending the referral procedure, the decision of Afssaps to suspend the marketing authorization of the concerned medicinal products has been challenged before the *Conseil d'Etat* by one of the marketing authorization holders. Marketing authorization holders whose products are subject to a procedure under art. 107 of Directive 2001/83/EC are provided with copies of the reports drafted by the Rapporteur and the Co-Rapporteur as soon as they become available in order to enable parties to duly exercise their right to be heard. One of the applicant in the judicial proceeding before the *Conseil d'Etat* has made use of a document received in the framework of the on-going referral procedure to challenge the decision of the national competent authority to suspend the product. Following the judgement of the 25th February 2010 Prescrire requested access to the Co-Rapporteur Assessment Report. At this point in time while the art. 107 referral procedure was still pending, the document was still considered a preparatory act of the final opinion of the CHMP, therefore, the Agency refused the access to this document in its letter of the 17th March 2010, subsequently confirmed by a decision of the 10th May 2010 in accordance with art. 4(3) first paragraph of Regulation (EC) 1049/2001. As it can be seen from this feedback, access to this concerned document has been refused due to its preparatory nature combined with the fact that it formed part of an ongoing procedure.

The Agency would like to stress the fact that the refusal to release these documents as long as the procedure is ongoing does not have a negative impact on the transparency of the process as such, since they will become accessible as soon as the decision is taken.

The Agency hopes that this could clarify the decision taken and wants to emphasize its availability for further questions in this regards. Concluding, it remains to be said that the requested document will of course become available for public access as soon as the European Commission has adopted its decision on the matter as the exception under art. 4(3) first indent of Regulation (EC) 1049/2001 would not any longer be applicable.

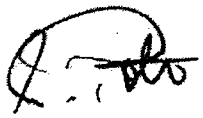
Conclusion

On the basis of the above submissions, the European Medicines Agency believes that the five complaints brought forward by Prescrire should be dismissed as they are either unfounded as in the case of the first, third, and fifth complaint or are not any longer material as the Agency has taken actions to remediate the alleged maladministrations and the documents requested would be or have already been made available to the applicant.

The European Medicines Agency thanks the complainant for acknowledging the high volume of request for access to documents and information filed on a regular basis. In the year 2010, the European Medicines Agency has responded to 21 requests for access to documents made by Prescrire, releasing approximately 2420 pages of documents which need careful examination in order to guarantee the protection of personal data or commercially confidential information. The Agency strives to meet the demand of access to documents made by interested parties and has taken substantial concrete steps to ensure transparency and openness of its activities in accordance with its public interest mission.

The Agency would like to thank you for your attention and interest in this matter.

Yours sincerely,



Andreas Pott

Acting Executive Director

List of Annexes

Annex I: Request of access to documents from Prescrire to the EMA of the 18th September 2008.

Annex II: Communication by e-mail from the EMA to Prescrire of the 24th September 2008.

Annex III: Copies of the assessment reports on variation II/0008 and II/0011 sent to Prescrire by the EMA on the 9th October 2008.

Annex IV: Assessment reports and other documents released from the EMA to Prescrire in relation to the referral procedure *dextropropoxyphene + paracetamol* combination products of the 19th October 2010.