THE EUROPEAN OMBUDSMAN

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P. NIKIFOROS DIAMANDOUROS

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Strasbourg, 04 -02- 2008

Complaint 2560/2007/BEH

Dear Sirs,

Please find enclosed the opinion that I have received from the European Medicines Agency (EMEA) concerning your complaint of 8 October 2007.

If you wish to make any observations on the opinion, please send them to me before 31 March 2008.

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

Yours sincerely,

P. Nikiforos DIAMANDOUROS

Enclosure: EMEA's opinion

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2560/2007/BEH

European Medicines Agency
Directorate

London, 30 January 2008
Doc. Ref.: EMEA/14231/2008

Mr. P. Nikiforos DIAMANDOUROS
The European Ombudsman
1, Avenue du Président Robert Schuman
Cedex B.P. 403
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Re: Complaint 2560/2007/BEH

Dear Mr. Diamandouros,

Thank you for your letter dated 25 October 2007 with regard to the concerned complaint.

As per your request, I have the pleasure to send you the following opinion:

1) Case background

On 31 July 2007, the Danish Medicines Agency forwarded to the EMEA a letter signed by Anders Jørgensen and Peter C Gøtzsche, respectively PhD student and director of the Nordic Cochrane Centre in Copenhagen, in which they applied for access to documents held by the EMEA.

The applicants made a request for access to the clinical study reports of the placebo-controlled clinical trials and corresponding trials protocols concerning two medicinal products for which marketing authorisations had been previously granted, namely rimonabant and orlistat.

On 20 August 2007 the EMEA replied to the request affirming that the concerned documents came under the system of exceptions set by Regulation (EC) No 1049/2001, as implemented by the Rules for the Implementation of Regulation (EC) No 1049/2001 on access to EMEA documents, adopted by the EMEA Management Board on 19 December 2006, with particular reference to its Article 3.2(a) and therefore the requested document could not be released.

In the case at stake, in fact, the access to the requested documents could not be granted, since the disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property, as clearly stated in the mentioned Article 3.2 (a) of the Rules for implementation of Regulation (EC) No 1049/2001 on access to EMEA documents.

On 24 August 2007 a confirmatory application was lodged by the complainants against the concerned decision in accordance with Article 6.2 of Rules for the Implementation of Regulation (EC) No 1049/2001 on access to EMEA documents.

In its letter of 17 September 2007, the EMEA replied to the complainants confirming its previous position and denied access to the requested documents based on the existence of the aforementioned exception.

2) Arguments raised by the complainants

Two are the major arguments that substantiate the complaint which can be summarised as follows:

a) In their complaint, Anders Jørgensen and Peter C Gøtzsche, allege that "*the EMEA decision to deny access based on the protection of commercial interest in unconvincing*".

With regard to this allegation the Agency would like to provide some additional clarifications to counter argue the complainants' criticism.

The EMEA is committed to meet the obligations set by Article 80, Regulation (EC) No 726/2004 according to which the Agency proactively discloses a wide range of documents including European public assessment reports (EPAR) available in all EU official languages, summaries of opinions, press releases and meeting reports, Q&A documents, safety announcements, withdrawals and refusals.

On the other hand, Article 39.3 of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) imposes on the Members a specific obligation of protection of undisclosed information, with particular reference to undisclosed test or other data submitted to Members in order to obtain marketing approval for pharmaceutical products, which must be protected against unfair commercial use. In this respect, Members have also to protect such data against disclosure, except where necessary to protect the public.

In this regard, it is worth to recall that commercially confidential information has to be considered any trade secret or commercial confidence and, more in general, any kind of information which disclosure would undermine the interest or, in other words, prejudice to an unreasonable degree, the commercial interests of individuals or companies concerned.

Nonetheless, once the concerned data have been scientifically assessed by Committee for Medicinal Products for Human Use (CHMP), the outcome of the scientific discussion is made publicly available since it is reflected in the European public assessment report (EPAR) with regard to the concerned medicinal product, published on the EMEA website.

b) The complainants also allege that "*when denying access to the clinical studies report and corresponding protocols with regard to the drugs orlistat and rimonabant, EMEA has given insufficient reasons for its decision, in particular as regards the existence of a public interest in disclosure overriding commercial interest*".

Although the complainants have alleged several motivations for supporting the existence of a public interest in disclosure, the public interest of publishing these data has to be balanced against the interest of protecting a third party (the applying company) that, in case of improper disclosure of the content of the concerned documents, would be adversely affected.

Article 3(2) of the Rules for the Implementation of Regulation (EC) No 1049/2001 on access to EMEA documents specifies that, when one of the listed exceptions applies, the institution "shall refuse access to a document (...) *unless there is an overriding public interest in disclosure*". In other terms, the overriding public interest overrules the exception and restores the general rule.

The complainants motivated their request for access to these data by stating that the release of "*such additional analysis is needed before the patients and their doctors can obtain balanced view of the benefits and harms of this drugs*".

In this regard it is important to note that Article 57(1) (m) of Regulation (EC) No 726/2004 expressly gives the EMEA the task of informing healthcare professionals and patients on information relating to medicinal products that are approved or rejected by the Community. In addition to specific prescribing information for healthcare professionals ('summary of product characteristics') and specially written information for patients ('package leaflet') in all EU official languages, the EMEA systematically

publishes its scientific assessment of the benefits and risks of all centrally approved medicines. In each instance, the benefits and risks of the medicine are explained and balanced against each other.

The assessment of balance and risks is an obligation of the Agency. This balance of benefit and risk may change over time as experience is gained with a medicinal product. Working together with the national competent authorities, the EMEA constantly monitors this balance and updates the assessment report and product information as appropriate.

With this regard and on balance with the allegations of the complainants, the Agency cannot identify any overriding public interest that could justify the disclosure of the concerned documents.

3) The EMEA opinion with regard to the lodged complaint

In the light of the above, the Agency maintains that the request for access to documents filed by the complainants has been dealt in accordance with the legislation on access to documents, with particular reference to the principles stated in Article 3.2(a) of the Rules for implementation of the Regulation (EC) No 1049/2001.

Notwithstanding the above, the Agency acknowledges that transparency is considered as a key value in the public health policy throughout Europe. For this reason, it is my intention to shortly launch a public consultation with all the Agency's stakeholders with the aim to further improve the Agency's openness approach with regard to access to documents and proactive disclosure of information on quality, safety and efficacy of medicinal products.

I trust that the above supports the Agency's position with regard to the concerned complaint and confirm the full EMEA's compliance with the obligation set by the applicable rules on access to the Agency's documents, as identified before.

Yours sincerely,

Thomas Lönngren
Executive Director

Annexes:

I. Rules for the Implementation of Regulation (EC) No 1049/2001 on access to EMEA documents

European Medicines Agency

EMEA/MB/203359/2006 Rev 1 Adopted
Management Board meeting 19 December 2006

Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents

Having regard to Regulation (EC) No 726/2004[1] of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency,

Whereas Article 73 of Regulation (EC) No 726/2004 foresees that Regulation (EC) No 1049/2001[2] of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents will apply to the Agency,

Whereas it is necessary to establish rules implementing Regulation (EC) No 1049/2001,

Whereas the main purpose of the Agency is to promote the protection of human and animal health and of consumers of medicinal products throughout the Community and to promote the completion of the internal market through the adoption of uniform regulatory decisions based on scientific criteria, concerning the placing on the market and use of medicinal products,

The Management Board of the Agency has adopted the following Decision:

Article 1 - Scope

1. The scope of this Decision is to ensure the widest possible access to the documents the Agency produces or receives and has in its possession.

2. Access to certain documents shall be refused by virtue of application of one of the exceptions mentioned in Article 3.

3. In addition, the Agency's documents are subject to classification, which restricts or prevents access to them. Rules for the classification of EMEA documents are set out in the Annex to this decision.

Article 2 - Definitions

1. "Document" shall mean any content whatever its medium (written on paper or stored in electronic form or as a sound, visual or audiovisual recording) concerning a matter relating to the policies, activities and decisions falling within the Agency's sphere of responsibility;

2. "Third party" shall mean any natural or legal person, or any entity outside the Agency, including the Member States, other Community or non-Community institutions and bodies and third countries.

[1] OJ L 136, 30.4.2004, p. 1
[2] OJ L 145, 31.5.2001, p. 43

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Article 3 - Exceptions

1. The Agency shall refuse access to a document where disclosure would undermine the protection of:

   a) the public interest as regards public security, defence and military matters, international relations, the financial, monetary or economic policy of the Community or a Member State;
   b) privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data.

2. The Agency shall refuse access to a document where disclosure would undermine the protection of:

   a) commercial interests of a natural or legal person, including intellectual property,
   b) court proceedings and legal advice,
   c) the purpose of inspections, investigations and audits,

   unless there is an overriding public interest in disclosure.

3. Access to a document, produced or received and in possession of the Agency, which relates to a matter where the decision has not been taken, shall be refused if disclosure of the document would seriously undermine the decision-making process, unless there is an overriding public interest in disclosure.

   Access to a document containing opinions for internal use as part of deliberations and preliminary consultations within the Agency shall be refused even after the decision has been taken if disclosure of the document would seriously undermine the Agency's decision-making process, unless there is an overriding public interest in disclosure.

4. As regards third-party documents, the Agency shall consult the third party with a view to assessing whether an exception in paragraph 1 or 2 is applicable, unless it is clear that the document shall or shall not be disclosed.

5. A Member State may request the Agency not to disclose a document originating from that Member State without its prior agreement.

6. If only parts of the requested document are covered by any exceptions, the remaining parts of the document shall be released.

Article 4 - Classification of documents

The Agency's documents shall be classified in one of the following categories: public, restricted or confidential.

Article 5 - Requests for access

1. Applications for access to Agency documents, which are not publicly available, shall be made in writing including electronic form, and in a sufficiently precise manner to enable the Agency to identify the document(s).

2. If an application is not sufficiently precise, the Agency shall ask the applicant to clarify his request and shall assist the applicant in doing so, for example by providing information on the use of public registers of documents. The deadline for reply shall start once the Agency has sufficient information to process the request.

3. In the event of an application relating to a very long document or to a very large number of documents, the Agency may confer with the applicant informally, with a view to finding a fair solution.

Article 6 – Handling of initial applications

1. An application for access to a document shall be handled promptly. An acknowledgement of receipt shall be sent to the applicant. Within 15 working days from receipt of the application, the Agency shall either grant access to the document requested and provide access in accordance with Article 9 within that period or, in a written reply, state the reasons for the total or partial refusal and inform the applicant of his or her right to ask the Agency to reconsider its position in accordance with paragraph 2 of this Article.

2. In the event of a total or partial refusal, the applicant may, within 15 working days of receiving the Agency's reply, ask the Agency to reconsider its position by submitting a confirmatory application.

3. In exceptional cases, for example in the event of an application relating to a very long document or to a very large number of documents, the time-limit provided for in paragraph 1 may be extended by 15 working days, provided that the applicant is notified in advance and that detailed reasons are given.

4. Failure by the Agency to reply within the prescribed time limit shall entitle the applicant to a confirmatory application.

Article 7 – Handling of confirmatory applications

1. The Executive Director of the Agency shall take the decisions relating to requests to the Agency to reconsider its position. Such requests shall be handled promptly. Within 15 working days from receipt of such a request, the Agency shall either grant access to the document concerned and provide access in accordance with Article 9 within that period or, in a written reply, state the reasons for the total or partial refusal. In the event of a total or partial refusal, the Agency shall inform the applicant of the remedies open to him or her, namely to lodge a complaint to the European Ombudsman or institute Court proceedings against the Agency, under Article 195 or 230 of the EC Treaty, respectively.

2. In exceptional cases, for example in the event of an application relating to a very long document or to a very large number of documents, the time limit provided for in paragraph 1 may be extended by 15 working days, provided that the applicant is notified in advance and that detailed reasons are given.

3. Failure by the Agency to reply within the prescribed time limit shall be considered as a negative reply and entitles the applicant to lodge a complaint to the European Ombudsman or institute Court proceedings against the Agency, under Article 195 or 230 of the EC Treaty, respectively.

Article 8 – Consultations

1. Where the Agency receives an application for access to a document, which it holds, but which originates from a third party, the Agency shall check whether one of the exceptions provided for by Article 3 applies.

2. If, after that examination, the Agency considers that access to it must be refused under one of the exceptions provided for by Article 3, the negative answer shall be sent to the applicant without consultation of the third-party author.

3. The Agency shall grant the application without consulting the third-party author where the document requested has already been disclosed either by its author or under Regulation (EC) No 1049/2001 or similar provisions.

4. Unless the document originates from a Member State, the Agency shall grant the application without consulting the third-party author where it is obvious that the disclosure, or partial disclosure, of its contents would not affect one of the interests referred to in Article 3.

5. In all the other cases, and in particular if an application for access concerns a document originating from a Member State, the third-party author shall be consulted.

6. The third-party author consulted shall have a deadline for reply, which shall be no shorter than five working days but must enable the Agency to abide by its own deadlines for the reply. In the absence of an answer within the prescribed period, or if the third party is untraceable or not identifiable, the Agency shall decide in accordance with the rules on exceptions in Article 3, taking into account the legitimate interests of the third party on the basis of the information at its disposal.

7. If the Agency intends to give access to a document against the explicit opinion of the author, it shall inform the author of its intention to disclose the document after a ten-working day period and shall draw his attention to the remedies available to him to oppose disclosure.

Article 9 - Exercise of the right of access

1. Applicants shall have access to documents either by receiving a copy, in paper or electronic format, or by consulting specific documents on the Agency's premises. Copies of less than 20 pages or direct access in electronic form shall be free of charge. As regards documents of more than 20 pages, the charge shall not exceed the real cost of producing and sending the copies.

2. All documents are subject to the Agency's copyright policy available on the Agency's website (www.emea.europa.eu).

Article 10 - Register of documents

1. To make citizen's rights under this decision effective, the Agency shall provide public access to an electronic register of documents available in particular through the Agency's Internet site. References to documents shall be recorded in the register without delay.

2. The register shall contain the title of the document, an identifier, the subject matter and/or a short description of the document and the date on which it was received or drawn up and recorded in the register.

Article 11 - Report

The Management Board, acting on a proposal from the Executive Director, shall publish annually, as part of the annual report, information concerning the implementation of this decision, in particular statistics on the number of requests for access to Agency documents, the number of refusals, and the reasons for such refusals.

Article 12 – Final provision

In addition to these rules, the Agency may establish rules regarding the publication of documents in order to ensure an appropriate level of transparency, in accordance with Article 80 of Regulation (EC) No 726/2004.

Article 13 - Entry into force

1. These rules replace and annul the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents adopted by the Management Board on 8 June 2006. This decision shall enter into force on 20 December 2006. It shall be made public on the Agency's website.

2. The Management Board may review these rules whenever deemed necessary and adopt any modifications needed.

3. The European Ombudsman shall be informed of this decision and subsequent revisions.

19 December 2006

Prof Hannes Wahlroos
Chairman of the Management Board

ANNEX

Classification of documents

This Annex sets out the Agency's rules on classification of documents and provides indications on the types of documents covered by the different levels of classification.

Public

Documents not classified under one of the categories below are considered public.

Restricted

This classification shall be applied to information and material the unauthorised disclosure of which could be disadvantageous to the interests of the European Union Institutions, the Member States and the Agency. These are typically characterised by the fact that they may at some stage be made available to the public, but that their premature disclosure might be prejudicial to the interests of the Agency, including relations with Member States, EU institutions and bodies and applicants for and holders of marketing authorisations. Documents will be classified 'restricted' if they fall under any of the exceptions laid down in Article 3 of these Implementing rules.

Confidential

This classification shall be applied to information and material the unauthorised disclosure of which could harm the essential interests of the European Union Institutions, the Member States and the Agency. Documents will be classified 'confidential' if they fall under any of the exceptions laid down in Article 3 of these Implementing rules.