THE EUROPEAN OMBUDSMAN

P. NIKIFOROS DIAMANDOUROS

S2009-98692

Dr Peter C. Gøtzsche
Mr Anders W. Jørgensen
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2100 Copenhagen Ø
DANEMARK

Strasbourg, 22 -01- 2009

CONFIDENTIAL

Re.: Proposal of the European Ombudsman for a friendly solution in his inquiry into complaint 2560/2007/BEH against EMEA

Dear Dr Gøtzsche and Mr Jørgensen,

Please find enclosed, for your information, a copy of a proposal for a friendly solution which, in accordance with Article 3(5) of the Statute of the European Ombudsman, I have sent to the European Medicines Agency (EMEA) in the framework of your complaint. I understand that my services have discussed the possibility of such a proposal with you.

The proposal for a friendly solution is as follows:

EMEA could reconsider the complainants' request for access and grant access to the documents concerned, or provide a convincing explanation as to why no such access can be granted.

I have asked EMEA to send its reply to my proposal by 28 February 2009.

Please note that the letter is marked *confidential*. I would therefore be grateful if you would treat this proposal as being for your information only until I have assessed its outcome.

Yours sincerely,

P. Nikiforos DIAMANDOUROS

Enclosure: Copy of the proposal for a friendly solution sent to EMEA

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THE EUROPEAN OMBUDSMAN

P. NIKIFOROS DIAMANDOUROS

CONFIDENTIAL

PROPOSAL OF THE EUROPEAN OMBUDSMAN FOR A FRIENDLY SOLUTION IN HIS INQUIRY INTO COMPLAINT 2560/2007/BEH AGAINST THE EUROPEAN MEDICINES AGENCY

(Made in accordance with Article 3(5) of the Statute of the European Ombudsman[1])

THE BACKGROUND TO THE COMPLAINT

1. The complainants are researchers working for the Nordic Cochrane Centre, a research and information centre in the field of healthcare. On 29 June 2007, they applied, via the Danish Medicines Agency, to the European Medicines Agency (EMEA) for access to clinical study reports and corresponding trial protocols concerning certain anti-obesity drugs. These reports were submitted to EMEA with a view to obtaining marketing authorisation for the said anti-obesity drugs. The complainants stressed that it was essential that the clinical study reports and corresponding trial protocols be made available for additional analysis by independent researchers, given that empirical studies suggested that biased reporting on drug trials was common.

2. By letter of 20 August 2007, EMEA informed the complainants that the documents requested fell under the exceptions contained in the 'Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents'[2] ('the Rules'). EMEA decided to refuse access, invoking Article 3(2)(a) of the Rules, which refers to the protection of "*commercial interests of a natural or legal person, including intellectual property.*"

3. On 24 August 2007, the complainants submitted to EMEA's Executive Director a confirmatory application for access to the said documents. They stated that it was unlikely that clinical study reports would contain anything that could undermine the protection of a natural or legal person's commercial interests. They also asked EMEA to explain, if it were to uphold its initial decision, why it considered that commercial interests of the drug industry should override the welfare of patients.

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[1] Decision of the European Parliament of 9 March 1994 on the regulations and general conditions governing the performance of the Ombudsman's duties (94/262/ECSC, EC, Euratom), OJ 1994 L 113, p. 15.

[2] EMEA/MB/203359/2006 Rev 1 Adopted.

4. In its reply of 17 September 2007, EMEA confirmed its decision to refuse access, based on Article 3(2)(a) of the Rules. EMEA also stated that its current policy is not to disclose original data submitted as part of an application dossier for marketing authorisation. However, data submitted to EMEA were considered and assessed by the EMEA Scientific Committee for Human Medicinal Products and the outcomes of its discussions were published on EMEA's website.

5. On 8 October 2007, the complainants turned to the Ombudsman.

THE SUBJECT MATTER OF THE INQUIRY

6. The complainants took the view that they had carefully explained why concerns for patients' welfare should be given priority over concerns for the drug industry's commercial interests. They made the following allegations and claim:

Allegations:

(1) When denying access to clinical study reports and corresponding trial protocols concerning the drugs orlistat and rimonabant, EMEA gave insufficient reasons for its decision, in particular as regards the existence of a public interest in disclosure which overrides commercial interests.

(2) EMEA's decision to deny access based on the protection of commercial interests is unconvincing, given in particular that the study reports and protocols requested do not appear to indicate any commercial interest.

Claim:

The complainants should be granted access to the clinical study reports and corresponding trial protocols, as requested.

THE INQUIRY

7. The complaint was forwarded to EMEA for an opinion, which it sent on 30 January 2008. The opinion was forwarded to the complainants with an invitation to make observations, which they sent on 26 February 2008. By letter of 18 March 2008, the Ombudsman asked EMEA for further information regarding certain aspects of the complaint. EMEA's reply was forwarded to the complainants, who submitted their observations on 17 June 2008.

THE OMBUDSMAN'S ANALYSIS AND PROVISIONAL CONCLUSIONS

Preliminary remarks

8. Given that the complainants' allegations and claim relate to the reasoning underpinning EMEA's decision to refuse access, the Ombudsman considers it useful to consider both allegations and the claim together.

A. As regards the complainants' allegations and claim

Arguments presented to the Ombudsman

9. The complainants submitted that there appeared to be nothing of commercial interest in the clinical study reports and protocols to which they requested access. Even if the requested documents did in fact concern commercial interests, EMEA did not give any reasons why these should override concerns for patients' welfare. They stated that they had carefully explained why the concerns for patients' welfare should be given priority over concerns for the drug industry's commercial interests. Given that empirical studies suggested that biased reporting on drug trials was common, additional independent research was needed. In order to carry out such research, the complainants needed to have access to the requested documents. Against this background, they alleged that EMEA's decision to withhold access was unconvincing and its reasoning insufficient. They claimed that they should be granted access to the clinical study reports and to corresponding trial protocols, as requested.

10. In its opinion, EMEA submitted that it proactively disclosed a wide range of documents, such as summaries of opinions, press releases and meeting reports. However, Article 39(3) of the TRIPs agreement[3] obliged it to protect against unfair commercial use data submitted for marketing approval of pharmaceutical products. Such data had to be protected from disclosure, except where providing access was necessary to protect the public. According to EMEA, any trade secret or commercial confidence, as well as any kind of information, the disclosure of which would unreasonably undermine or prejudice the commercial interests of individuals or companies, was to be considered as commercially confidential information. In this regard, EMEA also pointed to the fact that the outcome of the assessments of the data submitted to it was published on its website.

11. As regards the public interest in disclosing the requested documents, EMEA took the view that this had to be balanced against the interests of the companies submitting data to it. According to EMEA, its task was to inform healthcare professionals and patients about medicinal products. To achieve this, it published its scientific assessments of all approved medicines. EMEA stated that it could not identify any overriding public interest that could justify disclosing the requested documents. EMEA considered that it dealt with the complainants' request for access in conformity with the Rules. It also pointed out its intention to launch a consultation with all the involved stakeholders in the near future, with an eye to further improving its approach to transparency.

12. In their observations, the complainants submitted that, as a likely consequence of EMEA's position, patients would die unnecessarily and would be treated with

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[3] The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) is an international agreement annexed to the Agreement Establishing the World Trade Organization (WTO).

inferior and potentially harmful drugs. They reiterated their view that EMEA failed to explain why granting access would undermine the protection of commercial interests and why these interests should override concerns for the welfare of patients. Referring to the ethical indefensibility of EMEA's approach, they also invited the Ombudsman to consider the view that regulatory agencies found themselves in a conflict of interest situation when they denied others access to data which was in their possession.

13. In its further comments and at the Ombudsman's request, EMEA explained why it considered clinical study reports and corresponding trial protocols to fall within the definition of commercial interests. The 'Note for Guidance on Structure and Content of Clinical Study Reports (CPMP/ICH/137/95)' ('the Guidelines'), which it enclosed, set out the required contents of clinical study reports. Reports were very detailed and extensive, and contained full details on the clinical development programme, which, both in terms of time and cost, represents the most substantial part in the development of a medicinal product. According to EMEA, the clinical development of a medicinal product continues throughout its entire lifecycle, even to a point beyond the time when marketing authorisation is granted. As was apparent from the Guidelines, reports contained considerable details on the design and methodology of the trial, the data generated and its analysis. At the same time, reports also contained substantial amounts of personal data which would require a detailed examination of the documents before disclosure. The documentation requested with regard to one drug alone covered about 500 volumes, each volume consisting of approximately 300 to 400 pages. Thus, partial disclosure was not possible, since reviewing the requested documents would require a disproportionate effort in terms of EMEA's time and resources.

14. As regards the relationship between Article 39(3) of the TRIPs agreement and the Rules, which the Ombudsman raised in his request for further information, EMEA pointed out that Article 39(3) of the TRIPs agreement was enforceable in the EU legal system and was to be considered as a *lex specialis* in relation to Article 3(2)(a) of the Rules. According to EMEA, Article 39(3) of the TRIPs agreement contained a general exception to the principle of transparency whenever the disclosure of a document would undermine the protection of commercial interests. In addition, EMEA outlined that all requests for access were handled in accordance with the Rules.

15. In their observations on EMEA's further comments, the complainants considered that, contrary to EMEA's view, the Guidelines did not indicate that clinical study reports contained commercially confidential information. Moreover, judging from their own experience in reading trial protocols, they considered it highly unlikely that clinical study reports contained commercially confidential information. In any event, there was an overriding public interest in disclosure. They also observed that, contrary to its decisions on their initial and confirmatory applications for access, EMEA now also appeared to rely on Article 3(1)(b) of the Rules, which relates to privacy and the integrity of the

individual. They pointed to Article 6 of the Rules, which provided that if only parts of a document are covered by an exception, the remaining parts shall be released. According to them, given the structured nature of clinical study reports, removing information covered by Article 3(1)(b) of the Rules would be relatively easy.

The Ombudsman's preliminary assessment leading to a friendly solution proposal

16. In the present case, the Ombudsman is called upon to decide whether EMEA was correct to refuse access. In its decisions on the complainants' initial and confirmatory applications for access, EMEA relied on Article 3(2)(a) of the Rules, which relates to the protection of commercial interests. In the course of the inquiry, however, EMEA explained that Article 39(3) of the TRIPs agreement was to be considered as a *lex specialis* in relation to the Rules. Moreover, in its further comments, EMEA made reference to a further exception contained in the Rules (privacy and the integrity of the individual). Pursuant to Article 18 of the European Code of Good Administrative Behaviour, every decision taken by an institution "*shall state* [...] *clearly* [...] *the legal basis of the decision*". Against this background of EMEA's decisions, as well as the comments it made in the course of the inquiry, the Ombudsman considers that the legal basis on the basis of which EMEA refused access is not clear. Consequently, the Ombudsman makes the preliminary finding that EMEA did not provide sufficient reasons for its refusal to grant access to the documents requested, and that failure to do so amounted to an instance of maladministration. He will therefore make a corresponding proposal for a friendly solution below, in accordance with Article 3(5) of the Statute of the European Ombudsman.

17. Having arrived at a preliminary finding of maladministration, the Ombudsman could refrain from considering further the substance of EMEA's decision to refuse access. He, nevertheless, considers it useful and indeed preferable to consider the substance of EMEA's decision, in order to give EMEA guidance on how to deal with the complainants' request for access. This having been said, the Ombudsman will therefore, as far as is possible at this stage, examine the correctness of EMEA's decision to refuse access.

18. The Ombudsman notes that EMEA referred to the TRIPs agreement as a *lex specialis* in relation to the Rules. At the same time, it explained that all requests for access were handled in accordance with the Rules. EMEA's approach therefore raises the question regarding the precise relationship between the TRIPs agreement and the Rules.

19. Article 39(3) of the TRIPs agreement reads as follows:

> "*Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data*

against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

The Ombudsman understands that this provision has apparently not yet given rise to interpretative practice by the competent bodies at the level of the WTO and the Community courts. Nevertheless, a literal interpretation suggests that, as a general rule, Article 39(3) requires an institution not to disclose data submitted in the framework of marketing approval, subject to two exceptions. Disclosure appears to be allowed where necessary to protect the public, or if steps are taken to ensure that the data are protected against unfair commercial use. In contrast, the Rules rest on the general obligation to grant access, subject to enumerated exceptions, such as the protection of commercial interests. According to Article 1(1) of the Rules, their aim is to ensure the widest possible access to the documents EMEA produces or receives and has in its possession. It follows that Article 39(3) of the TRIPs agreement and the Rules appear to pursue different aims.

20. Moreover, Article 39(3) of the TRIPs agreement refers to the protection of data submitted in the framework of marketing approval "*against unfair commercial use*". Thus, it appears that, leaving aside the issue of protecting the public, the response to whether access can be granted pursuant to this provision hinges on the future use of disclosed data or the availability of steps to prevent certain future use. On the other hand, the Rules as such are indifferent to the use of disclosed documents; instead they are predicated on a general obligation to grant access. Thus, the purpose of Regulation 1049/2001 and the Rules is to give the general public a right of access to documents.[4] At first sight, it is therefore difficult to reconcile an access regime, which takes into account the future use of disclosed data, with the Rules. It appears useful to add that the protection of commercial interests pursuant to the Rules is not necessarily the same as the protection against unfair commercial use envisaged in Article 39(3) of the TRIPs agreement.

21. On the basis of these considerations, the Ombudsman takes the view that, given the different aims and concepts underlying them, a simultaneous application of Article 39(3) of the TRIPs agreement on the one hand and the Rules on the other cannot easily be envisaged. It is not for the Ombudsman definitively to decide which set of legal rules should govern the complainants' request for access. However, in what follows, the Ombudsman will consider EMEA's decision to refuse access in light of both sets of rules, starting with the Rules before turning to Article 39(3) of the TRIPs agreement.

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[4] Case C-266/05 P *Sison v Council* [2007] ECR, I-1233, paragraph 43.

EMEA's application of the Rules

22. Article 255 of the EC Treaty provides for a right of public access to European Parliament, Council and Commission documents and foresees that the general principles and limits governing this right should be determined by the Community legislator. These rules are set out in Regulation No. 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents[5] ('Regulation 1049/2001'). Pursuant to recital 8 of Regulation 1049/2001, all agencies established by the institutions should apply the principles laid down in this Regulation. Article 73 of Regulation No 726/2004 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[6] ('Regulation 726/2004'), foresees that Regulation 1049/2001 applies to EMEA and, at the same time, empowers EMEA's Management Board to adopt arrangements for implementing Regulation 1049/2001. On this basis, EMEA's Management Board adopted the Rules on 19 December 2006.

23. In view of this legal situation, the Ombudsman considers that the case-law of the Community courts relating to Regulation 1049/2001 is relevant for the interpretation of the Rules. In its decisions on both the complainants' initial and confirmatory applications, EMEA relied on Article 3(2)(a) of the Rules, which reads as follows:

> "*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,*
>
> *[...]*
>
> *unless there is an overriding public interest in disclosure*".

24. According to Article 1(1) of the Rules, their aim is to ensure the widest possible access to the documents EMEA produces or receives and has in its possession. It emerges from the settled case-law of the Community courts regarding Regulation 1049/2001 that the exceptions to the general right of access to documents must be interpreted and applied strictly.[7] The mere fact that a

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[5] Regulation (EC) No 1049/2001/EC of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ 2001 L 145, p. 43.

[6] Regulation 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, OJ 2004 L 136, p. 1.

[7] See, for instance, Case T-403/05 *MyTravel Group v Commission*, judgment of 9 September 2008, not yet published in the ECR, paragraph 32.

document concerns an interest protected by an exception cannot itself justify the application of that exception. Therefore, before lawfully relying on an exception, the institution concerned is required to assess (i) whether access to the document would specifically and actually undermine the protected interest and (ii) whether there is no overriding public interest in disclosure. That assessment must be apparent from the reasons underpinning the decision[8].

25. According to the complainants, it is unlikely that, given their contents, the clinical study reports concern commercial interests. They also submitted that EMEA did not sufficiently address the question whether there was an overriding public interest in disclosure. Against this background, the Ombudsman will first examine whether EMEA has established that granting access would undermine commercial interests. Thereafter, he will examine the issue regarding the presence of an overriding interest in disclosure.

26. As regards the issue of commercial interests, EMEA invoked Article 3(2)(a) of the Rules, paraphrasing its content in its decisions on the complainants' initial and confirmatory applications. At the same time, it is not apparent from EMEA's reasoning why, in its view, access to the documents requested would specifically and actually undermine commercial interests.

27. In its further comments, EMEA explained that reports are, as a rule, very detailed and extensive, and contain the full details of the clinical development programme. The latter represents the most substantial part, both in terms of time and cost, in the development of a medicinal product. Reports contain considerable details on the design and methodology of the trials, the data generated and its analysis. EMEA also enclosed the Guidelines, which, in the Ombudsman's understanding, give a detailed account of the structure and content of clinical study reports. Thus, for instance, the chapter entitled "*Investigational Plan*" contains the heading "*Treatments*". Under this heading, the Guidelines list eight subheadings, such as "*Treatments administered*" and "*Method of assigning patients to treatment groups*", which are to be contained in clinical study reports. In their observations on the additional information provided by EMEA, the complainants argued that the Guidelines described general and well-known principles for drug trials. However, they did not indicate that clinical study reports contain commercially confidential information. The complainants also explained that this conclusion was confirmed by their own experience in reading industry-sponsored trial protocols.

28. On the basis of the information provided by EMEA, the Ombudsman understands that clinical study reports contain the full details of the clinical development programme, which represents the most substantial part, both in

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[8] See Case T-403/05 *MyTravel Group v Commission*, judgment of 9 September 2008, not yet published in the ECR, paragraph 33.

terms of time and cost, in the development of a medicinal product. The Ombudsman considers that commercial interests may be at stake. However, bearing in mind that exceptions to the right of access to documents are to be interpreted narrowly and taking the explanations given by EMEA into account, he fails to see how granting access would *specifically and actually undermine* commercial interests, thereby meeting the condition set by the case law of the Community courts. It appears useful to add that the risk of an interest being undermined must, in order to be capable of being relied on, be reasonably foreseeable and not purely hypothetical.[9]

29. Even if commercial interests were specifically and actually undermined by disclosure, access still has to be granted if there is an overriding public interest in disclosure. Turning therefore to the existence of an overriding public interest, the Ombudsman notes that, according to the case-law of the Community courts regarding Regulation 1049/2001, the institution concerned needs to balance the particular interest to be protected by non-disclosure against, *inter alia*, the public interest in the document being made accessible. This balancing of interests must take into account the advantages stemming from increased openness enabling citizens to participate more closely in the decision-making process and guaranteeing that the administration enjoys greater legitimacy and is more effective and accountable to the citizen in a democratic system.[10] Furthermore, the overriding public interest capable of justifying disclosure need not be distinct from the principles underlying Regulation 1049/2001.[11]

30. In its opinion, EMEA explained that it was its task to inform healthcare professionals and patients about medicinal products it approves or rejects, and pointed out that it is for this reason that it publishes its scientific assessment of all approved medicines. It went to state that there was no overriding public interest that could justify disclosure.

31. Assuming that disclosure would undermine commercial interests, EMEA had to balance these interests with the public interest in disclosure. When doing so, EMEA essentially relied on its task of informing healthcare professionals and patients, as assigned to it by Regulation 726/2004, and concluded that there was no overriding public interest in disclosure. The complainants raised a number of concerns regarding patients' health, which would establish an overriding public interest. The Ombudsman considers that, in order to establish an overriding public interest in disclosure, plausible and sufficiently concrete arguments suggesting the existence of such interest have to be submitted. At the same

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[9] See Joined Cases C-39/05 P and C-52/05 P *Sweden and Turco v Council*, judgment of 1 July 2008, not yet published in the ECR, paragraph 43.

[10] See Joined Cases C-39/05 P and C-52/05 P *Sweden and Turco v Council*, judgment of 1 July 2008, not yet published in the ECR, paragraph 45.

[11] See Joined Cases C-39/05 P and C-52/05 P *Sweden and Turco v Council*, judgment of 1 July 2008, not yet published in the ECR, paragraph 74.

time, he recalls that the question regarding the existence of an overriding public interest only has to be answered once it has been shown that commercial interests would be specifically and actually undermined by disclosure. Given that the Ombudsman finds this not to be the case, at this stage, he does not yet need to take a definitive stance on whether or not an overriding public interest exists.

32. The Ombudsman notes that, in the course of his inquiry, EMEA explained that the documents requested by the complainants contained substantial amounts of personal data which necessitated prior editing before partial disclosure could occur. However, given the large amount of information requested, editing would entail a disproportionate effort in terms of its time and resources. In its judgment in Case T-2/03, the Court of First Instance dealt with the question whether access to documents can be refused under Regulation 1049/2001, if dealing with the relevant request would constitute an overly large burden on the administration.[12] The Court held as follows:

> *"101 It should however be borne in mind that it is possible for an applicant to make a request for access, under Regulation No 1049/2001, relating to a manifestly unreasonable number of documents, perhaps for trivial reasons, thus imposing a volume of work for processing of his request which could very substantially paralyse the proper working of the institution. It should also be noted that, where a request relates to a very large number of documents, the institution's right to seek a 'fair solution' together with the applicant, pursuant to Article 6(3) of Regulation No 1049/2001, reflects the possibility of account being taken, albeit in a particularly limited way, of the need, where appropriate, to reconcile the interests of the applicant with those of good administration.*
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> *102 An institution must therefore retain the right, in particular cases where concrete, individual examination of the documents would entail an unreasonable amount of administrative work, to balance the interest in public access to the documents against the burden of work so caused, in order to safeguard, in those particular cases, the interests of good administration (see, by analogy, Hautala v Council, cited in paragraph 69 above, paragraph 86).*
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> *103 However, that possibility remains applicable only in exceptional cases.*
>
> *[...]*
>
> *112 Accordingly, it is only in exceptional cases and only where the administrative burden entailed by a concrete, individual examination of the documents proves to be particularly heavy, thereby exceeding the limits of what may reasonably be required, that a derogation from that obligation to*

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[12] Case T-2/03 *Verein für Konsumenteninformation v Commission* [2005] ECR II-1121.

examine the documents may be permissible (see, by analogy, Kuijer II, paragraph 57)."

33. In support of its view, EMEA submitted that the clinical study reports and protocols for one of the drugs comprised more than 500 volumes of documentation, each of which contained approximately 300-400 pages. EMEA further explained that these figures only referred to data submitted in support of the initial application for marketing authorisation. The Ombudsman accepts that the amount of information covered by the complainants' request for access could, in principle, entitle EMEA to rely on the derogation from a concrete and individual examination of the documents. However, he also recalls that the complainants have convincingly argued that EMEA overestimated the administrative burden involved. They pointed out that, in view of the structured nature of clinical study reports, which separate individual patient data from other sections of the reports, removing private data should be relatively easy. Against this background, and bearing in mind the exceptional nature of the derogation developed in the case-law of the Court of First Instance, the Ombudsman considers that EMEA insufficiently explained why editing the documents would entail an excessive administrative burden on it.

EMEA's application of Article 39(3) of the TRIPs agreement

34. As a general rule, Article 39(3) of the TRIPs agreement protects from disclosure test data submitted with a view to obtaining marketing authorisation. At the same time, he notes that this rule is subject to exceptions. Thus, it appears that disclosure is possible where necessary to protect the public, or if steps are taken to ensure that the data are protected against unfair commercial use. The Ombudsman thus considers that disclosure is not prohibited, if data disclosed can be protected against unfair commercial use.

35. The Ombudsman recalls that the complainants repeatedly underlined, both in their applications to EMEA, as well as in the course of his inquiry, that their request for access was motivated by purely scientific concerns. In complaint 1776/2005/GG, the European Investment Bank (EIB) granted the complainant in that case private access to certain sections of an audit report which could not be publicly disclosed. In that case, the Ombudsman emphasised that he very much appreciated the EIB's constructive and co-operative approach. He also stated that the innovative way in which the EIB complied with the complainant's request for access, whilst at the same time protecting the legitimate interests of third parties, could serve as a model for future cases.

36. The approach followed by the EIB lends itself to EMEA fulfilling its obligations under Article 39(3) of the TRIPs agreement while respecting, as far as possible, the principle of transparency in the present case. Thus, the Ombudsman considers that granting private access to the complainants, with a view to conducting the scientific study envisaged by them, could reconcile the complainants' interest in getting access with the interest in protecting data

against unfair commercial use, in line with Article 39(3) of the TRIPs agreement.

37. In its further comments, EMEA explained that the Rules do not foresee the possibility to grant access to certain categories of applicants on the basis of their motivation. Nor do they provide a basis for entering into a confidentiality agreement with an applicant. However, in the Ombudsman's view, the fact that the Rules do not foresee the possibility of granting private access cannot exclude the possibility of granting private access on the basis of Article 39(3) of the TRIPs agreement. Against this background, the Ombudsman considers that EMEA insufficiently explained why private access cannot be granted.

38. In light of the above, the Ombudsman makes the preliminary finding that EMEA did not provide sufficient reasons for its refusal to grant access to the documents requested, and that failure to do so amounted to an instance of maladministration. The Ombudsman makes the further preliminary finding that, in view of the insufficiency of its reasoning, EMEA's refusal to grant access amounted to an instance of maladministration. He will therefore make a corresponding proposal for a friendly solution below, in accordance with Article 3(5) of the Statute of the European Ombudsman.

B. The proposal for a friendly solution

Taking into account the Ombudsman's above findings:

EMEA could reconsider the complainants' request for access and grant access to the documents concerned, or provide a convincing explanation as to why no such access can be granted.

P. Nikiforos DIAMANDOUROS

Done in Strasbourg on 22 -01- 2009