Decisão no caso 2560/2007/BEH - Alegada recusa de acesso a relatórios de ensaios clínicos

Decisão
Caso 2560/2007/BEH - **Aberto em** 25/10/2007 - **Recomendação sobre** 19/05/2010 - **Decisão de** 24/11/2010

Em 2007, investigadores de um centro dinamarquês de investigação e informação no domínio dos cuidados de saúde contactaram a EMA e solicitaram acesso a relatórios de ensaios clínicos e aos correspondentes protocolos respeitantes a dois medicamentos contra a obesidade. Os investigadores explicaram que pretendiam realizar uma análise independente, pois, do seu ponto de vista, é comum a elaboração de relatórios de ensaios clínicos tendenciosos. A EMA recusou divulgar os documentos pretendidos e justificou a sua posição com os eventuais prejuízos para os interesses comerciais dos fabricantes dos medicamentos.

Na queixa que apresentaram ao Provedor de Justiça, os queixosos alegavam que as razões aduzidas pela EMA para recusar o acesso aos documentos eram insuficientes. Os queixosos exigiam acesso aos documentos e reiteravam o seu ponto de vista de que o bem¤estar dos doentes deveria sobrepor¤se aos interesses comerciais da indústria farmacêutica.

Segundo a conclusão preliminar do Provedor de Justiça, as razões apresentadas pela EMA para recusar o acesso aos documentos eram insuficientes. Por conseguinte, propôs uma solução amigável à EMA e solicitou à agência que reconsiderasse o pedido dos queixosos e concedesse acesso ou apresentasse uma explicação convincente para a recusa de acesso. Na sua resposta, a EMA reafirmou o seu ponto de vista de que não era possível conceder acesso e apresentou mais razões para fundamentar a sua decisão. Na sequência de uma inspecção dos relatórios e protocolos pertinentes realizada pela provedoria, o Provedor de Justiça concluiu que não continham informação sobre a composição dos medicamentos contra a obesidade em causa, nem informações confidenciais de carácter comercial. Assim, do seu ponto de vista, a divulgação dos documentos não acarretaria prejuízos para os interesses comerciais. Num projecto de recomendação, o Provedor de Justiça instou a EMA a divulgar os documentos ou a apresentar uma explicação convincente para a recusa de acesso.

Na sua resposta, a EMA declarou que decidira conceder aos queixosos acesso aos documentos solicitados e indicou um prazo para esse efeito. Além disso, comprometeu¤se a adoptar as medidas adequadas para aplicar o projecto de recomendação. Deste modo, a EMA aceitou o projecto de recomendação do Provedor de Justiça. Face a estes factos, o Provedor de Justiça arquivou a queixa e saudou a abordagem adoptada pela EMA em resposta ao seu projecto de recomendação.

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 (EMA) for access to clinical study reports and corresponding trial protocols concerning certain anti-obesity drugs. These reports and protocols were submitted to EMA 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 dated 20 August 2007, EMA 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 EMA documents' [1] ('the Rules'). EMA 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 EMA'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 EMA 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.

4. In its reply of 17 September 2007, EMA confirmed its decision to refuse access, based on Article 3(2)(a) of the Rules. EMA also stated that its current policy was not to disclose original data submitted as part of an application dossier for marketing authorisation. However, data submitted to EMA were considered and assessed by the EMA Scientific Committee for Human Medicinal Products and the outcomes of its discussions were published on EMA'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, EMA gave insufficient reasons for its decision, in particular, as regards the existence of a public interest in disclosure which overrides commercial interests.

(2) EMA'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 involve 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 EMA 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 dated 18 March 2008, the Ombudsman asked EMA for further information regarding certain aspects of the complaint. EMA's reply was forwarded to the complainants, who submitted their observations on 17 June 2008.

8. On 22 January 2009, the Ombudsman submitted a proposal for a friendly solution to EMA.

9. EMA replied to this proposal on 26 February 2009. The reply was forwarded to the complainants, who submitted their observations on 20 May 2009. Following a request by the Ombudsman's services, the complainants submitted, on 31 August and 1 September 2009, an example of a clinical study report as well as additional comments on this report.

10. Having examined these submissions, the Ombudsman concluded that it was necessary to inspect EMA's file. This inspection took place on 6 October 2009. A copy of the report on this inspection was sent to EMA and a further copy was sent to the complainants for observations. The complainants did not submit any observations on this report.

11. On 19 May 2010, the Ombudsman issued a draft recommendation to EMA and asked it to send a detailed opinion. EMA sent its detailed opinion on 31 August 2010, which was forwarded to the complainants for possible observations to be made by 31 October 2010. No observations were received by that date.
The Ombudsman's analysis and conclusions

Preliminary remarks

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

A. As regards the complainant's allegations and claim

Arguments presented to the Ombudsman

13. 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, EMA 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 EMA'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.

14. In its opinion, EMA 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 [2] obliged it to protect against the unfair commercial use of 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 EMA, 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, EMA also pointed to the fact that the outcome of the assessments of the data submitted to it was published on its website.

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

16. In their observations, the complainants submitted that, as a likely consequence of EMA's position, patients would die unnecessarily and would be treated with inferior and potentially harmful drugs. They reiterated their view that EMA 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 EMA'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 interested third parties access to data which was in their possession.

17. In its further comments, and at the Ombudsman's request, EMA 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 are very detailed and extensive, and contain 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 EMA, 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, these reports contained considerable details on the design and methodology of the trial, the data generated and its analysis. At the same time, the 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 EMA's time and resources.

18. 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, EMA 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 EMA, 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, EMA outlined that all requests for access were handled in accordance with the Rules.

19. In their observations on EMA's further comments, the complainants considered that, contrary to EMA'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, EMA 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

20. The Ombudsman noted that, in the present case, he was called upon to decide whether EMA was correct to refuse access. In its decisions on the complainants' initial and confirmatory applications for access, EMA relied on Article 3(2)(a) of the Rules, which relates to the protection of commercial interests. In the course of the inquiry, however, EMA 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, EMA 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 EMA's decisions, as well as the comments it made in the course of the inquiry, the Ombudsman considered that the legal provision(s), on the basis of which EMA refused access, was/were not clear. Consequently, the Ombudsman made the preliminary finding that EMA had not provided sufficient reasons for its refusal to grant access to the documents requested, and that the failure to do so amounted to an instance of maladministration. He therefore made a corresponding proposal for a friendly solution, in accordance with Article 3(5) of the Statute of the European Ombudsman.

21. Having arrived at a preliminary finding of maladministration, the Ombudsman noted that he could refrain from considering further the substance of EMA's decision to refuse access. He nevertheless deemed it useful and indeed preferable to consider the substance of EMA's decision, in order to give EMA guidance on how to deal with the complainants' request for access. Accordingly, and to the extent possible at that stage of his inquiry, the Ombudsman examined the correctness of EMA's decision to refuse access.

22. The Ombudsman noted that EMA 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. EMA's approach therefore raised the question regarding the precise relationship between the TRIPs agreement and the Rules.

23. 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 understood that this provision had 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 suggested 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 appeared 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 rested 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 EMA produces or receives and has in its possession. It followed that Article 39(3) of the TRIPs agreement and the Rules appeared to pursue different aims.

24. 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 appeared that, leaving aside the issue of protecting the public, the response to whether access can be granted pursuant to this provision hinged 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 [3] . At first sight, it was therefore difficult to reconcile an access regime, which takes into account the future use of disclosed data, with the Rules. It appeared useful to add that the protection of commercial interests pursuant to the Rules was not necessarily the same as the protection against unfair commercial use envisaged in Article 39(3) of the TRIPs agreement.

25. On the basis of these considerations, the Ombudsman took 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 could not easily be envisaged. It was not for the Ombudsman definitively to decide which set of legal rules should govern the complainants' request for access. However, in his analysis, the Ombudsman considered EMA's decision to refuse access in light of both sets of rules, starting, that is, with the Rules and subsequently turning to Article 39(3) of the TRIPs agreement.

EMA's application of the Rules

26. Article 15 of the Treaty on the Functioning of the EU 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 (EC) 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 [4] ('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 [5] ('Regulation 726/2004') foresees that Regulation 1049/2001 applies to EMA and, at the same time, empowers EMA's Management Board to adopt arrangements for implementing Regulation 1049/2001. On this basis, EMA's Management Board adopted the Rules on 19 December 2006.

27. In view of this legal situation, the Ombudsman considered 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, EMA 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 ".

28. According to Article 1(1) of the Rules, their aim is to ensure the widest possible access to the documents EMA 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 [6] . The mere fact that a 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 [7] .

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

30. As regards the issue of commercial interests, EMA 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 was not apparent from EMA's reasoning why, in its view, access to the documents requested would specifically and actually undermine commercial interests.

31. In its further comments, EMA explained that, as a rule, reports are very detailed and extensive, and contain 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. EMA also enclosed the Guidelines, which, in the Ombudsman's understanding, gave 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 EMA, the complainants argued that the Guidelines described general and well-known principles for drug trials. However, these Guidelines 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.

32. On the basis of the information provided by EMA, the Ombudsman understood that clinical study reports contain the full details of the clinical development programme, which

represents the most substantial part, both in terms of time and cost, in the development of a medicinal product. The Ombudsman considered that commercial interests might 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 EMA into account, he failed 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 appeared useful to add that, in order to be capable of being relied on, the risk of an interest being undermined must be reasonably foreseeable and not purely hypothetical [8] .

33. Even if commercial interests are 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 noted 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, among others, 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 [9] . Furthermore, the overriding public interest capable of justifying disclosure need not be distinct from the principles underlying Regulation 1049/2001 [10] .

34. In its opinion, EMA 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 on to state that there was no overriding public interest that could justify disclosure.

35. Assuming that disclosure would undermine commercial interests, EMA had to balance these interests with the public interest in disclosure. When doing so, EMA 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 considered 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 time, he recalled that the question regarding the existence of an overriding public interest has to be answered only after it has been shown that commercial interests would be specifically and actually undermined by disclosure. Given that the Ombudsman found this not to be the case, at that stage of his inquiry, he did not yet need to take a definitive stance on whether or not an overriding public interest existed.

36. The Ombudsman noted that, in the course of his inquiry, EMA 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 General Court 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 [11] . 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.*

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).

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

37. In support of its view, EMA 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. EMA further explained that these figures only referred to data submitted in support of the initial application for marketing authorisation. The Ombudsman accepted that the amount of information covered by the complainants' request for access could, in principle, entitle EMA to rely on the derogation from a concrete and individual examination of the documents. However, he also recalled that the complainants convincingly argued that EMA 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 General Court, the Ombudsman considered that EMA insufficiently explained why editing the documents would entail an excessive administrative burden on it.

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

38. 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, the Ombudsman noted that this rule is subject to exceptions. Thus, it appeared 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 considered that disclosure is not prohibited, if data disclosed can be protected against unfair commercial use.

39. The Ombudsman recalled that, both in their applications to EMA, as well as in the course of his inquiry, the complainants repeatedly underlined 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 cooperative 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.

40. The Ombudsman considered that the approach followed by the EIB would lend itself to EMA and assist it in 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 considered 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.

41. In its further comments, EMA explained that the Rules did not foresee the possibility of granting access to certain categories of applicants on the basis of their motives. Nor did 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 could not exclude the possibility of granting private access on the basis of Article 39(3) of the TRIPs agreement. Against this background, the Ombudsman considered that EMA insufficiently explained why private access cannot be granted.

42. In light of the above, the Ombudsman made the preliminary finding that EMA 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 made the further preliminary finding that, in view of the insufficiency of its reasoning, EMA's refusal to grant access amounted to an instance of maladministration. He therefore made the following proposal for a friendly solution:

" *EMA 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.* "

The arguments presented to the Ombudsman after his friendly solution proposal

43. In its reply, EMA maintained its refusal to grant access to the documents requested. It stated that its decision was based on the exception provided for in Article 4(2)(a) of the Rules (commercial interests). While it conceded that there was no precise definition of 'commercially confidential information' in the legislation or jurisprudence, it submitted that, in general, it was defined as follows: " *Information that could be of benefit for a competitor, the disclosure of which could cause a* disproportionate prejudice *to and* seriously harm *the commercial interest of the party.* " [12]

44. According to EMA, the following categories fall within the definition of " *commercially confidential information* ":

(i) Intellectual property which concerns the development and research prior to the filing of a patent or a design. EMA pointed out that development and research in the pharmaceutical industry are very costly. Disclosure of relevant information prior to obtaining a patent could prevent a patent from being registered. There was, therefore, a great interest in putting measures in place to keep relevant information secret.

(ii) Trade secrets concerning formulae, manufacturing and control processes which are or may be used in trade. These are, generally, not in the public domain and have a certain value resulting from the fact that they are not otherwise known. According to EMA, reasonable efforts are made to keep these secret.

(iii) Commercial confidences concerning every piece of information which, as such, does not have a commercial value. Nevertheless, disclosure of this information (for example, structures and development plans of companies, marketing strategies and so on) could cause damage to the holder thereof.

45. EMA reiterated its view that the data contained in the documents requested, which were to be considered as third-party documents, have commercial value.

46. It submitted that clinical study reports are the integrated full reports of an individual study concerning the use on patients of any therapeutic, prophylactic, or diagnostic agent. Clinical and statistical descriptions and analyses are integrated in a single report and, among other things, comprise the following information: the protocol; sample case report forms; investigator-related information; information relating to the drugs to be tested, including active control comparators; technical statistical documentation; related publications; patient data listings; and certain technical statistical details. In the given context, EMA also referred to the Guidelines submitted to the Ombudsman earlier.

47. As regards clinical trial protocols, EMA pointed out that they describe the objectives, design, methodology, statistical considerations, and organisation of a clinical trial. Protocols usually also give the background and reasons for conducting the trial. EMA stated that protocols contain a study plan on which the clinical trial is based. The plan is designed to

safeguard the health of participants and to answer specific research questions. The protocol also gives details on what types of person may participate in a trial; the schedule of tests, procedures, medications and dosages; and the duration of the study.

48. EMA also pointed out that the format and content of clinical trial protocols sponsored by pharmaceutical, biotechnology or medical device companies in the United States, the EU or Japan has been standardised by means of the Good Clinical Practice guidance issued by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). It further stated that clinical trial protocols allow researchers at multiple locations to perform the study in exactly the same way. Data obtained by them can therefore be aggregated as though they are working together. The protocol also serves as a common reference document for study administrators and local researchers as regards their duties and responsibilities during the trial.

49. In summary, EMA submitted that " *it would be reasonably foreseeable that the disclosure of this information would specifically undermine the interest of the third party owner of the document* ". It pointed out that the data contained in the reports and protocols could in fact be used by competitors as a basis to start developing the same or a similar medicinal product on their own, using the information and data for their own economical advantage. Moreover, competitors could gather valuable information on the long-term clinical development strategy of the sponsoring company.

50. As regards the existence of an overriding public interest in disclosure, EMA took the view that the burden of proof was with the complainants. It pointed out that, according to them, patients would die unnecessarily as a consequence of its refusal to grant access. In light of a passage from the General Court's judgment in Case T-36/04 [13] , EMA considered that the complainants did not satisfactorily prove that there was a link between disclosure and the possibility of saving patients' lives. In EMA's view, the underlying meaning of the principle of transparency is to enable citizens to scrutinise its activities. Against this background, it reiterated that it regularly publishes European Public Assessment Reports ('EPARs') and press releases. It again underlined that the evaluation of the safety and efficacy of medicinal products is its own specific task and not a shared responsibility with the general public.

51. EMA also pointed out that a public consultation on its revised access to documents policy is currently underway. This policy would allow the public to have access to many documents relating to its activities, including the Assessment Reports of its Committee for Medicinal Products for Human Use ('the CMPH') and the (Co-)Rapporteur Assessment Reports. EMA expressed the view that the disclosure of the assessment reports concerning the two medicinal products at issue could satisfy the complainants' request.

52. EMA pointed out that the Ombudsman himself stated that regulatory agencies are in a difficult position when balancing public against private interests. It submitted that it not only has to balance the interests of the holders of a marketing authorisation with the interests invoked by the complainants, but also with the institutional tasks assigned to it. EMA essentially submitted that the legislator considered it beneficial for citizens to centralise the procedure for obtaining marketing authorisations. It therefore entrusted EMA with the sole

responsibility of evaluating medicinal products. As a consequence, EMA was the reference point and body in charge of coordinating the evaluation, supervision and pharmacovigilance of medicinal products in the EU.

53. EMA took the view that its central position was supported by its actions relating to the two medicinal products at issue in the documents requested by the complainants. As regards the drug rimonabant (Acomplia), it explained that, following the findings of its CMPH, it recommended the suspension of the marketing authorisation. On 13 November 2008, marketing was suspended in all Member States where the drug was being marketed. Subsequently, the marketing authorisation holder notified the Commission of its decision to voluntarily withdraw its marketing authorisation. On 16 January 2009, the Commission issued a decision withdrawing the marketing authorisation for Acomplia, which was therefore no longer valid. In relation to orlistat (Xenical), EMA pointed out that, following its evaluation of the drug's safety and efficacy, it granted approval for its sale without prescription on 21 January 2009. This switch (apparently from a prescription to a non-prescription drug) was due to the fact that the marketing authorisation holder applied for an extension of the authorisation in relation to a lower-dose capsule with a new classification as a non-prescription drug.

54. EMA insisted on the need to redact the documents requested before partial access could be granted. This was due to the presence of a significant amount of commercially confidential information and personal data. It also expressed the view that, following redaction, documents would be deprived of all relevant information and would be worthless for the complainants. It reiterated its view that reviewing the requested documents would require a disproportionate effort in terms of EMA's time and resources. Pointing to the fact that this principle has been recognised in the case-law of the General Court, it submitted that the same principle was contained in certain national laws, including the UK Freedom of Information Act. EMA concluded that partial access should also be denied, given that the necessary redaction of the documents would entail a disproportionate effort.

55. In their observations, the complainants noted that, according to EMA, disclosure would enable competitors to use the information contained in the documents as a basis for starting to develop similar medicinal products, and to obtain valuable information about the marketing authorisation holders' long- term clinical development strategies. The complainants contradicted EMA's view and found it hard to believe that the documents could be of any use for developing a similar drug. This was because the requested documents related to the last phase of development of a drug, namely, clinical trials on patients, which were preceded by many years of preclinical development [14] . They also pointed out that papers published in scientific journals on the preclinical development stages would be of greater interest to other companies. In this regard, pharmaceutical companies have no problems publishing studies on these stages, and in fact consider it advantageous, since publication can attract investors. In light of these considerations, the complainants considered that EMA's argument had no merit at all. Given that unpublished trial data were less positive than published data, competitors would be less likely to start developing similar drugs if they had access to the unpublished data.

56. In the complainants view, EMA wrongly asserted that the information contained in the documents requested came under its definition of commercially confidential information. First, the relevant documents were based on general and well-known principles which could be applied to any drug trial and could not be patented. Second, the clinical study reports concern the clinical effects of a drug and nothing in the Guidelines suggests that any information contained in the reports could be considered as a trade secret. Third, protocols are always sent to all of the cooperating clinical investigators. If sponsoring companies feared that the protocols contained anything of commercial value, it was highly unlikely that they would leave those parts in the protocols. The complainants reiterated that, in their own previous reviews of many industry-initiated trials, they could not find anything that could be considered a trade secret.

57. As regards an overriding public interest in disclosure, the existence of which EMA disputed, the complainants admitted that they could not prove that lives would be saved if they were granted access, given that they did not have access to the relevant evidence in the present case. However, in their correspondence with EMA, they clearly documented that published reports relating to industry-conducted trials on other drugs were biased and insufficient for practising doctors and researchers alike. If doctors only relied on published information, patients would not be treated optimally and some of them would die unnecessarily. Referring to a concrete example of allegedly incomplete published reports, they took the view that EMA's argument was entirely unreasonable.

58. Commenting on EMA's view that disclosure of its assessment reports could satisfy their interests, the complainants stated that they would welcome any initiative leading to transparency. Nevertheless, they maintained that disclosure of the EPARs would not be a satisfactory substitute for clinical study reports and trial protocols, given that the former lack important details on the methodology of trials. The complainants also asserted that there were differences between the published versions of the clinical study reports and the corresponding summaries published by EMA.

59. As regards EMA's argument that redacting the documents would involve a disproportionate effort, the complainants stated that they only requested access to protocols and clinical study reports, not to entire applications including raw data for each individual patient. They pointed out that, in their experience, " *the bulk of the clinical study reports* " did not contain more than a few hundred pages per report. They further specified that they were only interested in placebo-controlled trials. The Danish Medicines Agency granted them access to these reports for another anti-obesity drug and did not consider the amount of pages to be a problem. According to information obtained by them, the studies in relation to that drug amounted to about 20 000 pages in total, many of which would be irrelevant to them, given that they were not interested in the bulk of the clinical study reports. The Danish Medicines Agency therefore indicated a much smaller amount of pages than EMA. The complainants also pointed out that, due to their fine structure, redacting the clinical study reports would be a very quick and easy task.

60. In conclusion, the complainants submitted that EMA consistently failed to provide evidence that the requested documents contained any commercially confidential

information. They also took the view that EMA's position was not in conformity with the Helsinki Declaration [15] , according to which authors have a duty to make publicly available the results of their research on human subjects. In their view, EMA was complicit in the exploitation of patients for commercial gains. Patients would consequently be treated in a suboptimal way.

61. In their further letter dated 31 August 2009, the complainants provided information in relation to a request, submitted to the Danish Medicines Agency, for access to the clinical study reports concerning another anti-obesity drug. They explained that they applied for access in June 2007 and that the Danish Medicines Agency granted access in June 2008. Following a complaint from the holder of the authorisation for that drug, the Danish Ministry of Health upheld the Agency's decision. The complainants subsequently received 36 binders totalling 14 309 pages, which included 56 clinical study reports, but did not receive the appendices including the protocols. The complainants pointed out that the documents received confirmed their view that clinical study reports are well structured. Contrary to what EMA had stated, redaction should thus be a quick and easy task.

62. The complainants specified that they would like to have access to the clinical study reports, including their appendices and protocols, of the phase III studies, as specified in the Scientific Discussion of the EPARs on orlistat and rimonabant. Their request for access therefore covered 15 studies in total; seven on orlistat and eight on rimonabant. They pointed out that, by way of comparison, they received 56 studies from the Danish Medicines Agency. On the copies received, patient numbers and descriptions of individual adverse events had been redacted. According to the complainants, this precaution was completely unnecessary, given that they had no way of knowing which concrete patient was being described. They drew attention to the fact that a whole page reporting on adverse events, which the Agency had omitted to redact, did not provide any clues which might lead to the identification of individual patients.

The results of the inspection of EMA's file

63. In his letter announcing his inspection of the file, the Ombudsman informed EMA that, in their observations on EMA's reply to the friendly solution proposal, the complainants specified that their request for access:

(i) only related to protocols and clinical study reports, more specifically, " *the bulk of the clinical study reports, with tables of the efficacy and adverse effects* ";

(ii) only related to clinical study reports and corresponding trial protocols in relation to placebo-controlled trials; and

(iii) did not relate to entire applications, including raw data for each randomised patient.

Before the inspection took place, the Ombudsman's services also informed EMA of the fact that, in their letter dated 31 August 2009, the complainants specified that they would like to

have access to the clinical study reports, including their appendices and protocols, of the phase III studies, as specified in the Scientific Discussion of the EPARs on orlistat and rimonabant.

64. During the inspection of the file carried out by the Ombudsman's services, a representative of EMA presented the structure and content of clinical trial protocols and clinical trial reports. The file presented by EMA contained the phase III controlled clinical trials concerning the drugs orlistat (Xenical) and rimonabant (Acomplia). The file relating to the phase III controlled clinical trials on orlistat consists of seven studies in total. The relevant paper-based documentation consists of 33 volumes in total. Each study consists of a core report, followed by a list of appendices, which, in turn, is followed by the clinical trial protocol. The phase III controlled clinical trials file on rimonabant was computer-based and consists of eight studies in total, which are available in pdf-format. The clinical study report of each study is followed by a list of appendices, which includes the clinical trial protocol.

65. The inspection showed that the file largely reflected the Guidelines. It also showed that, as regards orlistat, the documentation in relation to each of the seven studies consisted of approximately 1 500 - 2 000 pages in total. As regards rimonabant, the documentation consisted of an estimated 4 000 - 26 000 pages per study.

66. At their request, the Ombudsman's services were provided with copies of the tables of contents of the documents inspected. At the same time, a representative of EMA pointed out that, in EMA's view, the tables of contents also formed part of the confidential documents and should not be disclosed to the complainants.

The Ombudsman's assessment leading to a draft recommendation

Preliminary remarks

67. As regards EMA's position on Article 39 of the TRIPs agreement, the complainants essentially submitted that the wording of this provision allowed for flexibility in its interpretation. Moreover, a communication from the European Communities and their Member States to the TRIPs Council (IP/C/W/280) contained no definition of 'unfair commercial use', but only described it in the context of EMA's review of an application for marketing approval in relation to a new generic version of an already approved medicine. Therefore, EMA's concerns could not prevail in relation to their request for access, which did not involve new generic versions of already existing drugs. Given that EMA also invoked Article 39 of the TRIPs agreement as a *lex specialis* , the Ombudsman, in his friendly solution proposal, stated that the legal basis for its refusal to grant access was not clear. He invited EMA to reconsider the complainants' request for access. In its reply to the friendly solution proposal, EMA stated that it refused access on the basis of Article 4(2)(a) of the Rules in order to protect commercially confidential information of a third party. Consequently, the Ombudsman considered that EMA had clarified that its refusal was exclusively based on the

Rules and not on Article 39 of the TRIPs agreement. Given that EMA's reply did not contain any other reference to Article 39 of the TRIPs agreement, the Ombudsman saw no need further to address the potential implications which this provision could have had. He considered it appropriate to add, however, that this was without prejudice to the question whether Article 39 of the TRIPs agreement could or should have been applied in the present case.

68. In its reply to the friendly solution proposal, EMA pointed out that the Ombudsman himself stated that regulatory agencies find themselves in a difficult position whenever they need to balance private with public interests. The Ombudsman deemed it important to point out that the relevant passage of his friendly solution proposal, to which EMA referred (see paragraph 16 above), merely recorded the complainants' relevant submission, and did not put forth the Ombudsman's position on it. In view of his analysis below, the Ombudsman saw no need for him to take a position on this aspect in his draft recommendation either.

The Ombudsman's assessment

69. The Ombudsman examined whether EMA had established that the disclosure of the documents requested by the complainants would undermine the protection of commercial interests. He noted that, only if this were the case would he have to examine the issue regarding the presence of an overriding public interest in disclosure.

70. In paragraph 28 of his friendly solution proposal, the Ombudsman considered that commercial interests may be at stake, but failed to see, on the basis of EMA's submissions, how granting access would specifically and actually undermine commercial interests. In assessing whether disclosure would specifically and actually undermine commercial interests, the Ombudsman first needed to ascertain whether the documents in fact contain commercially confidential information and, accordingly, fall within the scope of the exception provided for in Article 3(2)(a) of the Rules (" *commercial interests of a natural or legal person, including intellectual property* "). While taking account of the parties' submissions during all stages of his inquiry, the Ombudsman's analysis focussed in particular on EMA's reply to his friendly solution proposal, as well as on the results of the inspection of the file by his services.

71. The Ombudsman agreed with EMA that neither the relevant legislation, such as Regulation 1049/2001, nor the case-law of the Union courts provide for a precise definition of 'commercial interests'. In spite of this, however, he noted that the case-law of the General Court sheds some light on the scope of the commercial interests exception.

72. The General Court previously held that, if one were to consider all information relating to a company and its business relations as being covered by the concept of commercial interests, one would not give effect to the general principle of providing the public with the widest possible access to documents held by the institutions [16] .

73. The General Court also found that documents containing confidential information

concerning banana importing companies and their commercial activities were covered by the commercial interests exception [17] . Moreover, it considered that precise information relating to the cost structure of an undertaking constitutes business secrets, the disclosure of which to third parties is likely to undermine that undertaking's commercial interests [18] . It followed that this kind of information falls within the scope of the commercial interests exception. As regards the temporal scope of the exception, the General Court considered that the documents to which access was requested went to the heart of a company's importing business, since they indicated the market shares, commercial strategy and the sales policy of the undertakings in question [19] .

74. On the basis of this case-law, it was clear that not all information relating to a company and its business relations is covered by the commercial interests exception. Moreover, in the context of the commercial interests exception, the General Court referred to the general interpretative maxim that exceptions to access to documents have to be interpreted and applied strictly so as not to frustrate the application of the general principle of giving the public the widest possible access to documents held by the institutions [20] . The General Court's narrow interpretation of the commercial interests exception was further underscored, for instance, by the fact that it required information relating to the cost structure to be precise in order to be covered by the commercial interests exception.

75. In its reply to the Ombudsman's friendly solution proposal, EMA submitted that "[i] *nformation that could be of benefit for a competitor, the disclosure of which could cause a* disproportionate prejudice *to and* seriously harm *the commercial interest of the party* " [21] should be considered commercially confidential information. At first sight, this definition rested on the **potential** for benefit, disproportionate prejudice and serious harm and, as such, appeared to be far-reaching. In the Ombudsman's view, it was therefore doubtful whether it was in conformity with the narrow interpretation adopted by the General Court.

76. More importantly, however, the Ombudsman noted that EMA had presented three different categories of commercially confidential information, namely, (i) intellectual property; (ii) trade secrets; and (iii) commercial confidences.

77. As regards the first category, EMA stated that it related to the development and research prior to the filing of a patent or a design. In its view, disclosure of relevant information prior to obtaining a patent could prevent a patent from being registered. The Ombudsman was unsure whether the documents at issue in the present case formed part of a file submitted with a view to patenting a medicinal product. However, it was clear that the clinical study reports and corresponding trial protocols were not submitted to EMA with a view to obtaining a patent, but instead with a view to obtaining marketing approval. It would therefore appear logical to assume that, before an application for marketing approval is submitted to EMA, drugs have already been patented. In the given context, the Ombudsman recalled that, as pointed out by EMA, its task is to coordinate the evaluation, supervision and pharmacovigliance of medicinal products. It is also responsible for granting marketing approval to medicinal products. Moreover, on the basis of the inspection of the file undertaken by his services, the Ombudsman considered that the requested documents do not contain information on the composition of medicinal products subject to the clinical

studies, or other related key information. Even if it were therefore possible to submit an application for marketing authorisation pending patenting, the Ombudsman considered it highly unlikely that the disclosure of relevant clinical study reports and trial protocols could prevent the company sponsoring relevant trials from obtaining a patent. In any event, there appeared to be no doubt that the two drugs at issue had been patented before an application for marketing authorisation was made to EMA.

78. Concerning the second category referred to by EMA, the Ombudsman noted that the requested documents do not contain information regarding the formulae, manufacturing or control processes of the relevant drugs. As pointed out by the complainants, the studies closely followed the Guidelines and thus appeared to be based on known principles. In the given context, the Ombudsman drew attention to the case-law of the General Court, which, in connection with a business contract, considered various clauses that were drafted in general and standard terms. As a consequence, the Court considered that these clauses manifestly did not touch on the contracting parties' commercial interests [22] .

79. In relation to the third category presented, EMA referred to commercial confidences as " *every piece of information which does not have a commercial value as such, but its disclosure might provoke damage to the party (e.g. structures and development plans of company, marketing strategies, etc.)* ". According to EMA, the information contained in clinical study reports and corresponding trial protocols has a commercial value. It therefore followed that these reports and protocols could not fall within the third category, as defined by EMA. Moreover, none of the requested documents contained information such as marketing or development strategies, to which EMA referred by way of example.

80. In view of these considerations, the Ombudsman provisionally concluded that EMA did not establish that the requested documents fall under any of the three categories to which it referred in support of its argument. This suggested that the documents at issue did not fall within the commercial interests exception, as provided for in the Rules.

81. In order to substantiate its view that the commercial interests exception prevented disclosure, EMA further pointed out that the data contained in the clinical study reports and corresponding trial protocols could in fact be used by competitors to start developing the same or a similar medicinal product on their own, using the information and data for their own economic advantage. The Ombudsman considered that EMA did not establish why and how disclosure of the documents could enable the development of the same or of a similar drug. Given that the parties appeared to agree that the purpose of clinical studies is to survey the clinical effects of medicinal products on human beings, the Ombudsman considered plausible the complainants' position that it was hard to believe that the documents would be of any use for the development of a similar drug. In the given context, he considered it useful to bear in mind that clinical study reports do not contain any information on the composition of medicinal products.

82. EMA also submitted that, in the event of disclosure, competitors would be able to gather valuable information on the long-term clinical development strategy of the sponsoring company. The Ombudsman recalled that the General Court has accepted, as a matter of

principle, that information which makes it possible to determine the commercial activity of a company can be covered by the commercial interests exception [23] . In the Ombudsman's understanding, however, the requested documents in the present case did not contain information on the long-term clinical development strategy of the sponsoring company. He further considered that, should EMA hold that the disclosure of the requested documents would allow indirect conclusions on a company's development strategy to be drawn, this view would still not be convincing. EMA explained that it publishes, among other things, the outcome of its assessments of the data submitted to it, as well as its scientific assessments of all approved medicines, which are therefore in the public domain. The Ombudsman therefore found it difficult to believe that disclosure of the requested documents would add any information on the long-term clinical development strategy to the information already available to the public.

83. In view of the above, the Ombudsman concluded that EMA did not establish that the requested documents fall within the scope of the commercial interests exception, as provided for in the Rules. It followed that their disclosure could not undermine commercial interests. Even if one were to assume that certain information contained in the requested documents could fall within the scope of the commercial interests exception, there appeared to be nothing to suggest that disclosure would specifically and actually undermine commercial interests. The Ombudsman further noted that EMA referred to the requested documents as third-party documents. At the same time, it did not transpire from its submissions that EMA would have already consulted the third-party authors of the documents concerning their positions on the applicability of the commercial interests exception (see Article 3(4) of the Rules).

84. The Ombudsman therefore found that EMA's refusal to grant access to the requested documents constituted an instance of maladministration. Consequently, he made a corresponding draft recommendation, in accordance with Article 3(6) of the Statute of the European Ombudsman (see paragraph 88 below).

85. EMA also submitted that, apart from commercially confidential information contained in the requested documents, the presence of personal data would require redaction. Given that EMA had raised this issue in the framework of the alleged disproportionate effort that redaction would entail, the Ombudsman understood EMA's position to be that the requested documents contain personal data of patients participating in the relevant studies. When refusing access, EMA did not invoke Article 3(1)(b) of the Rules (privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data), but instead relied on the commercial interests exception. Nevertheless, the Ombudsman considered it useful to recall that not all personal data would, by their nature, be capable of undermining the protection of the private life of the person concerned, and thus be covered by the exception in Article 3(1)(b) of the Rules [24] .

86. Article 2(a) of Regulation 45/2001 [25] defines 'personal data' as any information relating to an identified or identifiable natural person. An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his or her physical, physiological, mental, economic, cultural

or social identity. Based on the results of the inspection of the file by his services, the Ombudsman noted that the requested documents do not identify patients by name. It followed that patients are therefore not 'identified' within the meaning of Article 2(a) of Regulation 45/2001. However, they are referred to by means of identification and test centre numbers. Patients could therefore be identifiable, provided that, in case of disclosure or otherwise, information on the attribution of particular numbers to particular patients is also available. However, neither the requested documents nor other information in the public domain appeared to allow a link to be made between a given identification number and a particular patient, thus making it possible for him/her to be identified. It follows that EMA's reliance on the presence of personal patient data in the requested documents was not well-founded.

87. The Ombudsman noted, however, that the requested documents mention the study authors and principal investigators by name. It followed that the documents contained personal data within the meaning of Article 2(a) of Regulation 45/2001. At that stage, the Ombudsman did not see a need for him to take a definitive position regarding the issue as to whether, bearing in mind the relevant case-law of the General Court [26] , the presence of personal data could entitle EMA to redact the requested documents before granting access. However, he underlined that, should EMA consider it necessary to redact information on the study authors and principal investigators, this redaction would, as submitted by the complainants, appear to be a quick and easy task. This was due to the fact that, in the requested documents, information on study authors and principal investigators is clearly set apart from the other contents of the documents.

88. On the basis of his inquiries into this complaint, the Ombudsman made the following draft recommendation to EMA:

" *EMA should grant the complainants access to the requested documents or provide a convincing explanation as to why no such access can be given.* "

The arguments presented to the Ombudsman after his draft recommendation

89. In its detailed opinion, EMA submitted that it is necessary to ensure the widest possible access to documents held by it. As regards the applicability of the commercial interests exception in relation to the complainants' request for access, EMA stated that (i) in light of the recent case-law of the General Court [27] , it shares the Ombudsman's reasoning, (ii) its decision to refuse access should be revised, and (iii) the complainants should be granted access to the requested documents.

90. EMA also submitted that, in future cases, it would apply the same principles. Moreover, it underlined the need to take relevant implementing action in the course of the ongoing revision of its policy on public access to documents held by it [28] . Necessary implementing action included taking a decision on the extent of redaction required in order to ensure the protection of commercially confidential information, as well as the privacy and integrity of

individuals. EMA also submitted that a decision on the applicability of the commercial interests exception requires (i) a concrete examination on a case-by-case basis of a given document, following consultation with the third-party document authors, and (ii) taking into account the possible need to redact that document in line with Regulation (EC) 1049/2001. EMA also pointed to the importance of considering the applicability of the exception relating to privacy and the integrity of the individual if personal data are contained in a given document.

91. EMA moreover stated that it will do its utmost to implement its decision to grant access as rapidly as possible and, in any event, within the next three months. It will keep the Ombudsman informed of the exact implementation date and will inform the complainants of the exact timescale for replying to their requests for access.

92. The complainants did not submit observations on EMA's detailed opinion.

The Ombudsman's assessment after his draft recommendation

93. In its detailed opinion, EMA stated that it will grant the complainants access to the documents requested and indicated a deadline by which it will do so. EMA has therefore accepted the Ombudsman's draft recommendation. It further committed itself to taking appropriate measures in order to implement the draft recommendation.

94. The Ombudsman applauds the approach taken by EMA in its detailed opinion. It appears useful to add that, should EMA fail to take the implementation measures indicated in its detailed opinion within a reasonable time, the complainants remain free to submit a new complaint to the Ombudsman.

B. Conclusions

On the basis of his inquiry into this complaint, the Ombudsman closes it with the following conclusion:

The Ombudsman concludes that EMA has accepted his draft recommendation and committed itself to taking appropriate measures for its implementation.

The complainant and EMA will be informed of this decision.

P. Nikiforos Diamandouros

Done in Strasbourg on 24 November 2010

[1] EMA/MB/203359/2006 Rev 1 Adopted.

[2] 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).

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

[4] 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).

[5] 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).

[6] See, for instance, Case T-403/05 *MyTravel Group v Commission* [2008] ECR II-2027, paragraph 32.

[7] See Case T-403/05 *MyTravel Group v Commission* [2008] ECR II-2027, paragraph 33.

[8] See Joined Cases C-39/05 P and C-52/05 P *Sweden and Turco v Council* [2008] ECR I-4723, paragraph 43.

[9] See Joined Cases C-39/05 P and C-52/05 P *Sweden and Turco v Council* [2008] ECR I-4723, paragraph 45.

[10] See Joined Cases C-39/05 P and C-52/05 P *Sweden and Turco v Council* [2008] ECR I-4723, paragraph 74.

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

[12] Emphasis in the original.

[13] Case T-36/04 *Association de la presse internationale ASBL (API) v Commission* [2007] ECR II-3201, paragraph 94. The passage quoted by EMA reads as follows: " *It must be stated that Regulation No 1049/2001 does not define the concept of overriding public interest. It should also be pointed out that, in the case of interests protected by the exception in question ... it is for the institution concerned to strike a balance between the public interest in disclosure and the interest which is served by a refusal to disclose,* in the light, where appropriate, of the arguments put forward by the applicant *in that connection.* " (emphasis added by EMA).

[14] According to the complainants, this included in vitro and animal studies, pharmacokinetic and pharmacodynamic studies in healthy volunteers, and uncontrolled phase II studies in patients.

[15] The Declaration of Helsinki is a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data, adopted by the World Medical Association (WMA).

[16] Case T-380/04 *Terezakis v Commission* [2008] ECR II-11 (summary publication), paragraph 93.

[17] Joined Cases T-355/04 and T-446/04 *Co-Frutta Soc. coop. v Commission* , judgment of 19 January 2010, not yet reported in the ECR, paragraph 128.

[18] Case T-380/04 *Terezakis v Commission* [2008] ECR II-11 (summary publication), paragraph 95.

[19] Joined Cases T-355/04 and T-446/04 *Co-Frutta Soc. coop. v Commission* , judgment of 19 January 2010, not yet reported in the ECR, paragraph 137.

[20] Joined Cases T-355/04 and T-446/04 *Co-Frutta Soc. coop. v Commission* , judgment of 19 January 2010, not yet reported in the ECR, paragraph 122.

[21] Emphasis in the original.

[22] Case T-380/04 *Terezakis v Commission* [2008] ECR II-11 (summary publication), paragraph 98.

[23] Joined Cases T-355/04 and T-446/04 *Co-Frutta Soc. coop. v Commission* , judgment of 19 January 2010, not yet reported in the ECR, paragraph 131.

[24] Case T-194/04 *The Bavarian Lager Co. Ltd v Commission* [2007] ECR II-4523, paragraph 119.

[25] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ 2001 L 8, p. 1).

[26] See paragraph 84 above.

[27] See footnote 17 above.

[28] EMA pointed out that this new policy relates to documents concerning the authorisation for and supervision of, medicinal products for human and veterinary use and aims at increasing transparency, while taking into account the need to protect legally recognised public and private interests.