Decision of the European Ombudsman closing his inquiry into complaint 693/2011/(ELB)RA against the European Medicines Agency

Decision
Case 693/2011/RA - **Opened on** 06/04/2011 - **Decision on** 28/08/2013 - **Institution concerned** European Medicines Agency (Friendly solution) |

This complaint concerns a request for public access to documents held by the European Medicines Agency (EMA) and relating to clinical studies carried out on Avonex, a pharmaceutical product used to treat multiple sclerosis. The complainant argued that EMA did not provide him with any of the documents he requested, in particular, the marketing authorisation.

The Agency provided a number of reasons for its refusal to provide public access to the requested documents, including that, in some instances, it was not able to find them in its off-site archives.

The Ombudsman made a friendly solution proposal, according to which EMA should (i) diligently search its archives for the documents requested by the complainant; (ii) if the documents are found, provide the complainant with full access to them, or explain why one of the exceptions laid down in Article 4 of Regulation 1049/2001 applies; (iii) provide the Ombudsman with detailed information on its e-archive plan.

EMA fully accepted the Ombudsman's friendly solution proposal. It clarified, however, that certain of the requested documents were not in its possession. While the complainant expressed concerns regarding EMA's argument that it did not have all the documents he requested, the Ombudsman noted that the present inquiry only concerned a refusal to give access to documents, and not a failure to gather documents.

The background to the complaint

1. This complaint concerns a refusal by the European Medicines Agency (hereinafter 'EMA') to grant a request for public access to documents relating to clinical studies carried out on Avonex, a pharmaceutical product used to treat multiple sclerosis.

2. In 1995, the pharmaceutical company Biogen Idec applied to EMA for a marketing authorisation for Avonex, a drug used to treat multiple sclerosis. A Common Technical Dossier, containing a clinical study and individual data, was submitted to EMA. The Common Technical Dossier was examined by the rapporteur and co-rapporteur of the Committee for Medicinal Products for Human Use ('CHMP'). They then submitted a report to the CHMP in July 1995. The CHMP, in turn, drafted a report (hereinafter the 'CHMP assessment report'). A marketing authorisation for Avonex was granted in May 1997. In 2002, on the basis of another clinical study, Biogen Idec obtained an authorisation for another indication of Avonex, namely, early onset multiple sclerosis.

3. On 30 November 2010, the complainant requested EMA to grant him access to documents related to Avonex, notably to two clinical studies: (i) MSCRG trial: pivotal study for the initial approval, and (ii) clinical trial C95-812: pivotal study for the extension of the indication of Avonex in those patients characterised by one demyelinating event accompanied by MRI abnormalities (early onset multiple sclerosis). He also asked EMA to provide him with all documents related to these two studies, such as " *clinical study reports, CHMP Assessments, CHMP reports, Advice/assessments/reports from experts, meeting minutes, Marketing Authorisation dossier, if ever possible anonymised raw data* ".

4. On 20 December 2010, EMA asked the complainant to clarify his request, namely, as regards the documents referred to in italics above. With regard to " *CHMP assessments, CHMP reports* ", it specified that EMA uses the term " *CHMP assessment reports* " and asked the complainant to clarify which CHMP assessment reports he requested. With regard to " *advice/assessments/reports from experts* ", EMA asked the complainant to clarify whether he intended to refer to specific expert meetings. Similarly, with regard to " *meeting minutes* ", EMA asked the complainant to specify to which meetings he was referring. Finally, with regard to the marketing authorisation dossier, EMA noted that the complainant had requested clinical study reports and asked him to clarify whether he intended to refer to another document.

5. The complainant replied the following day, specifying that he wanted to obtain the documents that led EMA to issue a positive opinion on the two clinical studies. He indicated that it was difficult for him to specify which documents he was requesting access to since he did not know what procedure EMA followed to evaluate the two clinical studies. With regard to the " *CHMP assessment reports* ", the complainant asked for the CHMP assessment reports relating to the two clinical studies [1] . With regard to " *advice/assessments/reports from experts* ", he clarified that he requested the evaluation carried out by experts and provided to EMA. As far as " *meeting minutes* " were concerned, the complainant asked for the minutes of the meetings during which the two clinical studies were discussed. Regarding the marketing authorisation dossier, he requested sections 2.5 and 2.7 of the Common Technical Dossier (Clinical Overview and Clinical Summaries), as well as Module 5. He indicated that he was not interested in pharmacokinetic and pharmacodynamic data. Finally, concerning " *anonymised raw data* ", the complainant stated that he was interested in an electronic database of the raw data for the two clinical studies with a clear correspondence with the Case Report Form items. If there was no such database, he requested the Case Report Form (part 5.3.7 of Module 5).

6. On 4 February 2011, EMA replied to the complainant's request for access. It identified the following documents as being relevant to his request and provided him with a copy of them: (i) CHMP assessment report dated 20 November 1996 (the initial marketing authorisation application and the pivotal study); and (ii) CHMP assessment report dated 16 January 2002 (the appeal procedure for variation II-22 and the pivotal study for the extension of the indication). Parts of these documents were redacted because, according to EMA, they did not relate to the complainant's request. With respect to any " *source documents* " in the dossier including the Clinical Overviews, Clinical Summaries, Clinical Study Reports, and Case Report Forms, EMA said that it was unable to find any relevant documents.

7. On 25 February 2011, the complainant made a confirmatory application for access to documents concerning Avonex and its two indications (relapsing remitting multiple sclerosis and first demyelinating event), as specified in paragraph 5 above, namely, CHMP assessment reports, advice/assessments/reports from experts, meeting minutes, market authorisation dossier (sections 2.5 and 2.7 of the Common Technical Dossier - Clinical Overview and Clinical Summaries, and Module 5 for both indications), and anonymised raw data.

8. On 18 March 2011, EMA sent the complainant its reply to his confirmatory application. In its view, the complainant had already received the relevant parts of the two Assessment Reports for Avonex, as they were released to him on 4 February 2011. EMA also attached extracts of minutes of meetings of the Committee for Proprietary Medicinal Products ('CPMP') held in January, June, and July 2001, and January 2002, referring to discussions on Avonex with regard to the pivotal study for the extension of the indication. EMA indicated that no other meeting minutes were available. It further stated that, although the extract from the June 2001 CPMP meeting minutes refers to an Efficacy Working Party (EWP) meeting and to an ad hoc expert group meeting, the minutes of the former do not include any specific Avonex related discussion and no meeting minutes are available for the latter. Furthermore, according to EMA, the CPMP meeting minutes regarding the initial marketing authorisation application procedure only cover administrative and procedural notes and do not address the discussion of the scientific aspects related to the pivotal clinical trial, which is, in any case, fully reflected in the CPMP Assessment Report. Finally, EMA stated that it had performed a reasonable search in the archives for the other documents and indicated that they had not been retrieved.

9. In his complaint to the European Ombudsman, the complainant argued that EMA did not provide him with any of the documents he requested, in particular, the marketing authorisation. According to him, 15 years after Avonex was placed on the market, these documents are unlikely to contain information that, if released, could damage public or private interests.

The subject matter of the inquiry

Allegations

10. The complainant alleges that

(i) EMA refused to give him access to the following documents relating to Avonex:

the reports of the rapporteurs and co-rapporteurs for both indications;

the minutes of the Efficacy Working Party (EWP) and Committee for Proprietary Medicinal Products (CPMP) referred to by EMA in its reply of 18 March 2011;

the files (including the individual data) sent by a company called Biogen to EMA to request the marketing authorisation for both the drug's indications (relapsing remitting multiple sclerosis and first demyelinating event).

(ii) EMA wrongly gave him only partial access to some of the documents he requested, namely, CPMP assessment reports of 20 November 1996 and of 16 January 2002, and the minutes of CPMP meetings held in January, June, and July 2001, and January 2002.

Claims

11. The complainant claims that

(i) EMA should give him access to all requested documents.

(ii) EMA should give him full access to the CPMP assessment reports of 20 November 1996 and of 16 January 2002, and the minutes of CPMP meetings held in January, June, and July 2001, and January 2002.

12. In his letter to EMA requesting an opinion on these allegations and claims, the Ombudsman asked EMA, in relation to the first allegation and claim, to clarify (a) its statement that the documents could not be retrieved; and (b) whether the relevant documents were in its possession at a previous stage and, if so, what became of them. As regards the second allegation and claim, the Ombudsman asked EMA to explain why an exception in Article 4 of Regulation 1049/2001 [2] applied to the redacted parts of the documents.

13. In light of EMA's opinion and the complainant's observations, the Ombudsman will deal with the two allegations and the two related claims together.

The inquiry

14. The complaint was submitted to the Ombudsman on 19 March 2011. On 6 April, the Ombudsman opened an inquiry by asking the complainant for clarifications relating to the documents he had requested. In light of the clarifications provided, the Ombudsman asked EMA for an opinion on 23 May 2011. On 22 August 2011, EMA sent its opinion, which was forwarded to the complainant with an invitation to submit observations. The complainant submitted

observations on 12 September 2011.

15. After having analysed the information submitted to him, the Ombudsman made a proposal for a friendly solution, which was sent to EMA on 21 January 2013. EMA replied on 28 February. This reply was forwarded to the complainant, who submitted observations on 7 March 2013. The complainant subsequently forwarded further information to the Ombudsman in relation to his complaint, notably, emails he sent to EMA on 27 March 2013, 11 April, and 18 April 2013, and the replies he received.

The Ombudsman's analysis and conclusions

A. Allegation of failure to provide full access to documents relating to Avonex and related claims

Arguments presented to the Ombudsman

16. According to the complainant, the reports which were sent to him on 4 February 2011, in reply to his initial application for access to documents, are the CHMP assessment reports. He stated that he never received the reports from the rapporteurs and co-rapporteurs, drafted in 1995 and 2000. On 18 March 2011, in response to his confirmatory application, EMA sent him four pages corresponding to meetings relating to the second marketing authorisation for Avonex.

17. The complainant does not accept that EMA cannot retrieve the documents in question. He provided the following information in this regard: until 2006, the marketing authorisation for Avonex was given on an exceptional basis, which justifies the need to retain the related file. According to the complainant, many drugs are developed for multiple sclerosis and Avonex serves as a benchmark. He stated that some studies have questioned the effectiveness of Avonex. This could have led to a new analysis of the file. Moreover, EMA is drafting guidelines on similar biological products containing recombinant interferon beta (Avonex is the lead drug, he says). Finally, the marketing authorisation file of Avonex is regularly modified, as can be seen in EMA's document entitled ' *Avonex - procedural steps taken and scientific information after the authorisation* ', which he attached to his complaint. The complainant added that marketing authorisation files contain thousands of pages and several paper or electronic copies are sent to EMA.

18. In its opinion on the complaint, EMA began by underlining that transparency is a fundamental principle of EU law which EMA is fully committed to uphold and to put into practice. EMA recognizes the role of information on medicinal products and the relevance it has for EU citizens. In December 2010, it adopted a framework policy to streamline the numerous requests for access to documents pertaining to medicinal products for human and veterinary use [3] .

19. EMA underlined that this case constitutes a clear example of the attention it gives to all requests for access to documents, the diligence with which it treats them, and the substantive efforts in terms of resources it makes in releasing documents. The disclosure of documents is aimed at strengthening the trust of citizens in the activities of the EU institutions. Specifically, EMA stated that, on the basis of its extensive correspondence prior to the release of the first set of documents on 4 February 2011, it is possible to appreciate the efforts the Agency has made, in accordance with Article 6(2) of Regulation 1049/2001, to assist the applicant in identifying with more precision the scope of his request for access to documents.

20. EMA further pointed out, in this regard, that the number of pages related to documents drawn up, received, prepared, and circulated in a procedure aimed at granting a marketing authorization can be in the range of hundreds of thousands/millions. In the present case, with a view to ensuring respect for the principles of good administration, EMA engaged in a dialogue with the applicant in order to identify the relevant parts of the documents he requested and to avoid an unreasonable amount of administrative work to be performed with no clear benefit for the applicant. EMA referred in this regard to Case T-42/05 *Williams v Commission* [4] and, in particular, paragraphs 72 to 85 thereof.

21. According to EMA, in his e-mail of 21 December 2010, the applicant clarified that, within the set of documents that he had identified in his initial request of 30 November, his interest lay exclusively in the parts of these documents dealing with the two clinical studies (MSCRG Trial and clinical trial C95-812). EMA stated that these are just a small part of the file submitted by the marketing authorisation applicant. According to EMA, this is confirmed in the complainant's request, since in the last paragraph of his e-mail, he stated: " *Considering the potential workload for the management of these documents if you have to check which documents* **are dealing with the two clinical studies** *I can propose you send me* [...]" (emphasis added).

22. With regard, specifically, to the first allegation made by the complainant, EMA stated that it did not provide the applicant with the minutes of the Efficacy Working Party since they do not contain any information or discussion on Avonex. They are therefore outside the scope of the request made by the applicant. EMA added that this was expressly confirmed to the applicant in its 18 March reply to his confirmatory application [5] .

23. With regard to the documents which it was not able to retrieve from its off-site archives, EMA explained that, since 1995, an external service provider has been operating an archiving system for all the documents received by EMA in the framework of marketing authorisation applications. The purpose of the off-site archive is the long-term preservation of documents in accordance with good administrative practice. However, the archive system has not been designed to retrieve documents on a regular basis in response to requests for access to documents. In light, however, of the provision governing access to documents held by EMA [6] , and of the increasing number of requests related to documents stored in its archives, EMA is taking action to update its record management policy and practice, in particular, by digitising its archive. According to EMA, the " *e-archive* " would make all documents received by marketing authorisation applicants easier to retrieve. EMA further confirmed that it aims to preserve all the documents that are held in its archives. There is no procedure for the destruction of documents.

24. EMA further explained that its off-site archives consist of approximately 36 000 large boxes of documents (each having at least 4000/5000 pages) containing almost 150 million pages in total. The system is organized by way of a directory, that is, an Archive database [7] with an index and limited defined meta-data on the content of the boxes, which makes attempts to retrieve the documents particularly burdensome and time-consuming.

25. EMA stated that, in the present case, it has made every reasonable effort in order to retrieve the documents in question. It has searched through a large number of boxes of documents in an attempt to find the documents requested. However, due to the fact that the documents in question were stored a long time ago, EMA was not able to retrieve the documents.

26. With regard to the second allegation made by the complainant, that is, that EMA wrongly gave him only partial access to some of the documents he requested, EMA rebuts it as entirely unfounded. In its reply of 4 February 2011 accompanying the release of the documents, EMA expressly stated that "[t] *he first page of each of the documents above together with other pages relevant to your request is being sent to you. Please note that parts of the documents have been redacted as they did not specifically pertain to your request.* " This message was further confirmed in its decision of 18 March 2011 in which EMA, in reply to what it called the " *generic confirmatory application* " submitted by the complainant, stated that "[t] *he CPMP Assessment Reports for the product Avonex have been released. In accordance with the indication of the scope of your initial request of 30 November 2010, you have already received the relevant parts of these two documents; therefore the request to reconsider our previous decision on the release of the CPMP Assessment Reports is immaterial. If you wish to receive a copy of the two CPMP Assessment reports which include also parts that are out of the scope of your initial request, the Agency will be able to consider any new application for documents in line with the principles and limits of Regulation (EC) 1049/2001.* "

27. EMA insisted that the redaction of the parts of the documents which do not pertain to the original scope of the complainant's request cannot be considered to constitute an instance of maladministration. Moreover, as EMA informed the complainant, had he filed a request for access to documents for the other parts of the documents that were not within the scope of his original request, EMA would have provided him with a copy of the documents in their entirety, in accordance with the principles and within the limits of Regulation 1049/2001. The same considerations apply by analogy to the other documents which were released to the applicant further to his request (that is, the minutes of the CPMP meetings held in January, June and July 2001 and January 2002).

28. In his observations on EMA's opinion, the complainant stated that his initial request concerned all the information available on the two clinical studies, which served as a basis for the marketing authorisation files for Avonex. He claimed to have received around two pages in total. He therefore concluded that all the documents, analyses, and reports drawn up by EMA concerning the two clinical studies for Avonex are summarised in the unredacted parts of the documents he received, in other words, two pages in total [8] and that no other question was

raised during the evaluations of these studies. He stated that he is amazed that the matters discussed during the CPMP meetings or the questions asked to Biogen are not based on internal evaluation reports. The complainant further mentioned that all the information that he has received corresponds to clinical trial C95-812 and that the MSCRG study seems not to have been the object of any question, report, or discussion.

29. The complainant took issue with the fact that the experts' studies and the individual data on the clinical trials have not been given to him. The reason given by EMA is the difficulty of retrieving the boxes containing the requested documents in its archives. Conscious of the work that this might entail, the complainant proposed that EMA look in the archives only for the data concerning the MSCRG study. The marketing authorisation based on this study dates from 1997. According to the complainant, the archive list provided by EMA in its opinion makes clear that only two boxes (or three if the figure in the volume column corresponds to the number of boxes) date from 1997. He argued that the initial marketing authorisation file containing the expert report and the individual data relating to the MSCRG study must be located there. As indicated on the archive list, it is easy to verify in which box the marketing authorisation file can be found as one can have access to the contents of the box by clicking on ' *description* '.

30. The complainant therefore asked whether it would be possible to obtain the requested data (expert report on the MSCRG study and individual data) concerning only the MSCRG study, thereby allowing EMA to target only three boxes in its search. The complainant further expressed the hope that the reduction in his demands will enable him to obtain the requested documents.

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

Preliminary remark

31. The Ombudsman notes the complainant's argument that the file on the MSCRG study is incomplete (see paragraph 28 above). The Ombudsman recognises that it is vital that EMA obtain and retain all information necessary to allow it to carry out its regulatory role. However, the Ombudsman underlines that the present inquiry concerns only the issue of access to documents that are **already** in the possession of EMA. It does not concern the issue of whether EMA has erred by not ensuring that a file is complete.

32. The Ombudsman could examine a future complaint on the issue of whether EMA has exercised its powers correctly to ensure that a file is complete. There are, however, procedural steps which the complainant would need to undertake before the Ombudsman could investigate such a complaint. In accordance with Article 2(4) of the Ombudsman's Statute, a complainant would need to bring any alleged omissions to the attention of EMA. If EMA's response were to be unsatisfactory, the complainant could then turn to the Ombudsman. The Ombudsman also draws attention to a further requirement laid down in Article 2(4) of his Statute, that is, that a

complaint must be made within two years of the date on which the facts on which it is based came to the attention of the person lodging the complaint.

'Scope' of the complainant's request

33. Article 6(2) of Regulation 1049/2001 provides that, in the event that a request for public access to documents is not sufficiently precise, the institution shall ask the applicant to clarify the application and must assist the applicant in doing so, for example, by providing information on the use of the public registers of documents. The aim of this provision is, first, to allow the applicant clearly to identify the document(s) to which access is sought, and, second, to allow the institution to identify precisely which document(s) is, or are, being requested, which, in turn, limits the latter's administrative and legal work when deciding whether to give access to the document(s) requested. It is therefore clear that, if an institution cannot precisely identify the document(s) requested, it should, on the basis of Article 6(2) of Regulation 1049/2001, seek to obtain clarification regarding the scope of the request, instead of making assumptions about what exactly the applicant is applying for [9] .

34. The Ombudsman notes that EMA did make some attempts to obtain clarification in its communications with the complainant following his initial application and notes that such conduct is in accordance with good administrative practice. He points out, however, that it would have been better had EMA explained to the complainant exactly what documents were contained in the relevant marketing authorisation files and, on that basis, asked him which documents he wished to have access to. The Ombudsman notes, in this regard, that the complainant specifically informed EMA that it was difficult for him to specify which documents he was requesting access to since he did not know what procedure EMA followed to evaluate the two clinical studies (see paragraph 5 above).

35. The Ombudsman also notes that parts of the two documents (that is, the two CPMP assessment reports) the complainant received on 4 February 2011 were redacted. EMA explained that they were redacted because parts of those documents did not specifically pertain to the complainant's request. It added that if the complainant wished to have access to the remaining parts of the two CPMP assessment reports, he should make a request for access thereto. Parts of the documents the complainant received on 18 March 2011 (that is, CPMP meeting minutes of January, July, and June 2001, and January 2002) were also blanked out. EMA explained that other parts of these documents were redacted because they do not pertain to the discussion on the study in which the complainant is interested.

36. In order to justify redacting parts of the documents it provided to the complainant, EMA referred, in its opinion to the Ombudsman, to Article 6(3) of Regulation 1049/2001. Article 6(3) refers to an application relating to a very long document or to a very large number of documents and provides that the institution concerned may confer with the applicant informally, with a view to finding a fair solution [10] . The Ombudsman notes that the very reference in Article 6(3) to a " *very long document* " necessarily implies that the possibility exists for an institution to confer with an applicant with a view to providing access to only a part of that document which the

applicant agrees is relevant to his or her request. In principle, therefore, EMA is entitled to redact parts of the document(s) which are not relevant to the applicant's request without having to carry out an in-depth (and possibly time-consuming) analysis of whether the exceptions to public access apply to those parts of the documents. The Ombudsman finds, however, that, in order to apply this article correctly, a number of important procedural requirements must be respected.

37. The Ombudsman notes that, in order for Article 6(3) to apply, the institution should explain clearly to the applicant that, in its view, parts of the document(s) in question are not relevant to the applicant. Furthermore, the institution should explain, in general, what those parts of the documents concern, in order to allow the applicant to make an informed choice as to whether or not he or she wishes to request access to them.

38. In his observations on EMA's opinion, the complainant did not question the limitations set by EMA on the scope of his request. The Ombudsman will therefore not examine, in the present inquiry, whether EMA applied properly the guidelines set out above as regards the application of Article 6(3) of Regulation 1049/2001.

EMA's archives

39. The complainant contests EMA's statement that it cannot retrieve the documents in question. The Ombudsman has serious concerns about EMA's argument that it has encountered difficulties in retrieving the documents in its archive. The Ombudsman notes that the keeping of adequate records constitutes a principle of good administration which helps to ensure both effectiveness and accountability. In this regard, while the Ombudsman welcomes the fact that EMA conserves the documents that are submitted to it in the course of its regulatory work, the Agency's apparent failure to retrieve the relevant documents after a request for public access gives rise to serious questions. The Ombudsman's considered view is that conserving documents is part of EMA's regulatory work of ensuring that only safe and effective medicines are placed on the EU market. He notes, for instance, that, as part of EMA's regulatory duties, it may be necessary for it to retrieve urgently archived documents in order to carry out reassessments. One would therefore expect the archive maintained by EMA to be complete and fit for purpose, and to be organised in a way that makes it possible to identify and retrieve documents quickly. In sum, the Ombudsman finds it difficult to understand, and impossible to accept, that EMA has had difficulty retrieving the documents in question. In light of the information provided by EMA, according to which it has e-archive plans, the Ombudsman calls on EMA to provide him with information in this regard.

40. The Ombudsman further notes that EMA's apparent failure to retrieve the documents has implications for its application of the rules on public access to documents. The rules on public access to documents apply to all documents **in the possession of EMA** . EMA has not argued that the documents are not in its possession, but only that it cannot find them. Its failure to find documents which are in its possession is therefore contrary to EMA's obligations as regards public access to documents.

41. In an effort to help EMA find the documents, the complainant himself attempted to identify exactly where in EMA's archives the documents might be located. The Ombudsman finds the complainant's suggestions to be helpful and will ask EMA to follow up on these suggestions in his proposal for a friendly solution made below.

42. In light of the foregoing, the Ombudsman makes the preliminary finding that EMA's failure to provide the complainant with access to the documents in question in this case amounted to an instance of maladministration. He therefore makes a corresponding proposal for a friendly solution below, in accordance with Article 3(5) of the Statute of the European Ombudsman.

Current situation regarding access to EMA's documents

43. As regards the application of the rules on transparency to the requested documents, if they are found after a further search of the EMA archives, the Ombudsman notes that EMA adopted a new Transparency Policy concerning medicines for human and veterinary use on 30 November 2010 [11] . The new policy took effect on 1 December 2010. The Ombudsman notes that EMA's Transparency Policy clarifies that, in line with Article 15 of the Treaty on the Functioning of the EU, EMA is committed to granting the widest possible access to documents according to the principles and further conditions defined in Regulation 1049/2001 [12] . According to the document entitled ' *Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use* ', the following documents can be made public once the Commission decision granting the marketing authorisation is available [13] : CHMP assessment reports and minutes of CHMP meetings, as well as the reports of rapporteurs and co-rapporteurs. With regard to the minutes of the meetings of the Efficacy Working Party (EWP) and the Committee for Proprietary Medicinal Products (CPMP), the Ombudsman notes that these documents are currently not listed in EMA's output document. However, given the fact that the minutes of meetings of other similar bodies, such as CHMP and CVMP (the Committee for Medicinal Products for Veterinary Use) are deemed to be public once the Commission decision granting the marketing authorisation is available, the Ombudsman does not see why the same approach could not be applied by analogy to these documents. The same argument applies to CPMP assessment reports.

44. The Ombudsman further notes that the issue of public access to clinical study reports has already been brought before him with the result that EMA agreed to provide access to them [14] .

45. In sum, the Ombudsman notes that, in principle, providing public access to most of the documents requested in this case should not prove controversial. It is his understanding that the documents in question are already anonymised, with the result that Article 4(1)(b) of Regulation 1049/2001, pertaining to the protection of personal data, is not relevant. Moreover, given the time that has elapsed since the documents were drawn up, the Ombudsman's considered opinion is that it is extremely unlikely that any convincing argument could be made in relation to Articles 4(2) and 4(3) of Regulation 1049/2001, specifically concerning the exceptions pertaining

to the protection of commercial interests and the protection of the institution's decision-making process.

46. The Ombudsman therefore made a proposal for a friendly solution, as follows:

"Taking into account the Ombudsman's findings, EMA should (i) diligently search its archives for the documents requested by the complainant; (ii) if the documents are found, provide the complainant with full access to them, or explain why one of the exceptions laid down in Article 4 of Regulation 1049/2001 applies; (iii) provide the Ombudsman with detailed information on its e-archive plan."

The arguments presented to the Ombudsman after his friendly solution proposal

47. EMA replied to the Ombudsman's proposal for a friendly solution by outlining the measures it had adopted in response to each of the three action points identified above.

48. With regard to (i), namely, that EMA should diligently search its archives for the requested documents, EMA explained that it had conducted a more comprehensive search than previously and had succeeded in identifying the precise location of the documents. It is now taking concrete action to release a copy of the documents to the complainant, it said.

49. With regard to (ii), namely, that EMA should provide the complainant with full access to the documents, EMA agreed with the Ombudsman's assessment that, in accordance with its Transparency Policy of 30 November 2010 concerning medicines for human and veterinary use, the documents can be made public, with redactions where applicable [15] .

50. With regard to (iii), namely, that EMA should provide the Ombudsman with detailed information on its e-archive plan, EMA explained as follows: in 2005, the Agency addressed the issue of receiving marketing authorisation applications electronically. During a transitional period, which ended in 2010, it accepted both electronic and paper-based submissions. Since 1 January 2010, it has been mandatory to use only the electronic version (e-CTD format) [16] for all applications to EMA in the context of the centralised marketing authorisation procedure provided for in Regulation 726/2004 [17] .

51. As a result of the adoption of e-CTD, the retrieval of information has become automatic and easier than with the previous paper-based submission system. Nevertheless, electronic submission is an ongoing project which will continue to evolve with a view to enhancing both standardisation and transparency.

52. EMA further explained that, in 2007, it developed a records management policy, which was updated in 2012. This policy is supplemented by a filing plan which is applied to the internal Document Records Electronic Archive Management system (DREAM). Another project under development is the electronic signature project, which seeks to improve electronic information

management.

53. With regard to files submitted before the entry into force of e-CTD, EMA explained that it normally needs to access them via off-site archives. For instance, with regard to the product in which the complainant is interested, namely, Avonex, studies from 2007 onwards are accessible from EURS [18] , whereas older studies are located in the off-site archives and only in paper format.

54. By way of conclusion, EMA stated that it is now better equipped to deal with requests for access to documents under Regulation 1049/2001. The electronic submission system is a major development that has allowed EMA better to manage documents submitted in the context of centralised marketing authorisation applications and to access them more quickly.

55. In his observations on EMA's reply, the complainant pointed out that more than two years after he submitted his request for access to documents, he has only now been informed that EMA knows where the documents are. As his objective is to get the data he has asked for, he asked the Ombudsman to give a short deadline to EMA to finalise its response to his request for public access.

56. Second, the complainant agreed with EMA that e¤submission will enable it to respond more quickly to future requests for public access to documents. He noted, however, that this will only be of help for products approved after the end of 2009. Many products used by European citizens were approved before 2009 or are based on data submitted on paper. It is not clear how old files will be retrieved from the archive, he said.

57. According to information which the complainant forwarded to the Ombudsman, EMA provided the complainant with the clinical study reports for the two studies on 27 March 2013. The complainant informed EMA, by return email, that these study reports did not include the appendix and the raw data, namely, data for each patient. As anonymising the raw data could be very time consuming, the complainant proposed that EMA send him the appendix and raw data for the first Avonex study only (Study Number NS 26321, referred to above as the MSCRG trial).

58. EMA replied to the complainant on 11 April 2013, explaining that it was unable to disclose raw data for the first Avonex study because these are not in its possession. It further explained that the appendices physically available in the dossier comprise only the protocol and protocol amendments, specimen case report forms, and CVs.

59. The complainant replied to EMA that same day, stating that he had still not received all the information he had requested. He drew attention, in particular, to appendix XIV of the MSCRG study on exacerbation rates. He asked whether EMA's reply meant that it had not received all the appendices from the sponsor or that they cannot be found now.

60. EMA replied to the complainant on 18 April 2013, confirming that it is not in possession of the relevant documents, as Appendices IV-XV are not in the file. It explained that raw data and

individual patient listings did not constitute a mandatory part of the clinical module at the time the applicant submitted the marketing authorisation application.

61. The complainant replied that same day. He pointed out that the marketing authorization file for Avonex did not include data that were listed in the clinical study report. Moreover, those responsible for analysing the file do not appear to have asked for this information, which may have been relevant in analysing the trial. In his view, many multiple sclerosis patients in Europe have been treated, at a cost of approximately 1000 EUR per month, with a poorly evaluated product, whose efficacy is probably not that which has been promoted.

The Ombudsman's assessment after his friendly solution proposal

Preliminary remark

62. As outlined in paragraphs 31 and 32 above, the Ombudsman recognises that it is vital that EMA obtain and retain all information necessary to allow it to carry out its regulatory role. However, the Ombudsman underlines that the present inquiry concerns **only** the issue of access to documents that are **already** in EMA's possession. It does not concern the issue of whether EMA erred by not ensuring that a file is complete, that is, that it contains all of the information necessary for EMA to take an informed decision on the authorisation of a product.

Response to the Ombudsman's friendly solution proposal

63. The Ombudsman notes that, in response to his friendly solution proposal, EMA has now (i) diligently searched its archives for the documents requested by the complainant; (ii) agreed, in principle, to provide the complainant with full access to them, and (iii) provided the Ombudsman with detailed information on its e-archive plan. As such, EMA has fully accepted the Ombudsman's friendly solution proposal.

64. With regard to EMA's implementation of (ii) above, namely, the actual disclosure of the requested documents, the Ombudsman notes the further exchanges between EMA and the complainant, detailed in paragraphs 57 to 61 above. As the Ombudsman explained in paragraph 40 above, the rules on public access to documents apply to all documents **in the possession of EMA** . To the extent, therefore, that EMA has now clarified that certain documents are not in its possession, the Ombudsman finds that there are no grounds to pursue further the issue of a refusal to give public access to documents. In the event the complainant wishes to pursue the separate issue of whether EMA erred by not ensuring that a file is complete, the Ombudsman draws his attention to paragraph 32 above, which describes the circumstances in which the Ombudsman could examine a future complaint on the issue of whether EMA has exercised its powers correctly to ensure that a file is complete.

B. Conclusions

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

A friendly solution has been achieved in this case.

The complainant and EMA will be informed of this decision.

P. Nikiforos Diamandouros

Done in Strasbourg on 28 August 2013

[1] On 6 January 2011, EMA asked the complainant to clarify whether the CHMP assessment report relating to the appeal procedure is sufficient or if he also requested the CHMP assessment report regarding the initial negative opinion. The complainant replied, on the same day, that the CHMP assessment report relating to the appeal procedure was enough.

[2] 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, OJ 2001 L 145, p. 43.

[3] European Medicines Agency policy on access to documents concerning medicines for human and veterinary use (ref EMA/110196/2006), adopted on 30 November 2010, effective as from 1 December 2010.

[4] Case T-42/05 *Williams v Commission* [2008] ECR II-156.

[5] " *Please note that no other (more specific) meeting minutes are available. Although the extract from June 2001 CPMP meeting minutes refers to (1) EWP meeting and (2) to an Ad Hoc expert group meeting, the minutes of the former do not include any specific Avonex related discussion and no meeting minutes are available for the latter* ".

[6] Article 73 of Regulation (EC) 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, OJ 2004 L 136, p. 1.

[7] EMA included the outline of this directory with its opinion. It also enclosed a brief description of the current procedure for archiving. It stated that a detailed document will be made available as soon as the procedure is updated and agreed with the new off-site document storage provider.

[8] It is necessary to add to these two pages the scientific discussion document which can be downloaded from EMA's website, although, according to the complainant, this only constitutes a repetition of what is published in the medical literature.

[9] See the Ombudsman's decision in case 1633/2008/DK, paragraph 48.

[10] The Ombudsman notes that EMA's Transparency Policy refers to the following general principles in this regard: " *In dealing with requests for access to documents, the Agency will also apply the principle of proportionality in order to avoid that performance of core tasks assigned to the Agency is jeopardised. Accordingly, the Agency will liaise with the applicant in order to seek an agreement on a fair and reasonable solution whenever the request addresses a long list of documents or* **the document(s) the applicant is interested in require extensive redaction before being disclosed** " (emphasis added).

[11] See footnote 4 above.

[12] See the Ombudsman's decision in case 2493/2008/(BB)(TS)FOR concerning EMA's application of Regulation 1049/2001 on public access to documents, paragraphs 39 to 48.

[13] See the 'Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use', available at: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/11/WC50009 [Link]

[14] See the Ombudsman's decision in case 2560/2007/BEH.

[15] EMA further pointed out that, in the two years since this policy was adopted, it has released more than 1.5 million pages of documents concerning clinical and non-clinical information related to medicinal products, following requests made pursuant to Regulation 1049/2001. EMA further informed the Ombudsman that it has been made aware of three applications lodged before the General Court for the annulment of decisions to release clinical study reports contained in marketing authorisation dossiers of different medicinal products (cases T-29/13 and T-44/13 *Abbvie and others v EMA* , and case T-73/13 *InterMune and others v EMA*). According to EMA, the Court's rulings in these cases should provide an authoritative interpretation as to whether the documents requested can be covered by the exception laid down in the first indent of Article 4(2) of Regulation 1049/2001 pertaining to the protection of commercial interests.

[16] EMA hosts a dedicated website for e-CTD: http://esubmission.ema.europa.eu/ectd/index.html [Link]

[17] Regulation (EC) 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, OJ

2004 L 136, p. 1.

[18] EURS is the central repository to which e-CTD submissions are uploaded.