



Decision of the European Ombudsman in case 894/2015/PMC concerning the European Medicines Agency's (EMA) handling of a request for public access to certain clinical study reports

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Case: 894/2015/PMC

Opened on 17 Jun 2015 - Decision on 09 Oct 2015

- Institution(s) concerned: **European Medicines Agency**
- Field(s) of law: **Environment, consumers and health protection**
- Types of maladministration alleged – (i) breach of, or (ii) breach of duties relating to: **Requests for public access to documents [Article 23 ECGAB]**
- Subject matter(s): **Dealing with requests for information and access to documents (Transparency)**

Lodge a complaint

Request for information

Closing summaries of cases

- Commission's public consultation did not comply with the general principles and minimum standards specified in the Commission's own rules (**Added on: 29 Sep 2015 10:00 CEST**)
- Proposals to improve the overall Civil Dialogue Groups process (**Added on: 09 Sep 2015 10:00 CEST**)

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The case concerned a request for public access to a number of clinical study reports held by the EMA concerning a vaccine against hepatitis-A and hepatitis-B. The EMA gave access

to the documents, but blanked out certain information in order to protect personal data and commercial interests. While agreeing in general with the EMA that personal data needed to be protected, the complainant argued that the EMA appeared, for reasons of practical ease, to have blanked out entire pages. The Ombudsman found that the EMA had diligently dealt with the complainant's access request. In particular, she made a finding of no maladministration as regards the EMA's decision to blank out personal data, such as the names of authors and co-authors of the reports. Moreover, the Ombudsman considered that there were insufficient grounds for conducting further inquiries into the EMA's decision not to grant access to medical articles and studies which have been published in various scientific and academic journals, given that these publications are easily accessible online.

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Upcoming events

- **21 Oct 2015** European Ombudsman meets with the Secretary General of the Council
- **22 Oct 2015** Ombudsman's keynote lecture

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Past events

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- **12 Oct 2015** Lunch meeting

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The background to the complaint △

1. In late 2014, a German citizen submitted a request to the EMA for public access to documents concerning over 20 hepatitis-A and hepatitis-B (HAB) clinical study reports (the 'HAB' reports). The EMA replied that his request related to a very large number of documents, each of which required to be individually examined before being disclosed. It stated that it would thus not be able to provide an immediate reply to the access request. Over the following months, the EMA granted access to the relevant documents in batches.

2. To give an example, in late April 2015, the EMA granted access to the report HAB 121 (pages 1-1500). However, on the basis of the exceptions to public access set out in the Access to Documents Regulation[1], it blanked out certain data for the purposes of protecting personal data and commercial interests[2]. The EMA stated that if the complainant did not agree with its redactions, he could submit a confirmatory application.

3. In mid-May 2015, the complainant informed the EMA that he disagreed with its handling of his access request from a certain report onwards. He stated that, as from the relevant report, the EMA had been blanking out entire pages. He thus asked the EMA to clarify its position.

4. In late May 2015, the EMA replied, informing the complainant in



particular that, in line with the relevant rules, it was required to blank out personal data^[3], in order to protect the privacy and the integrity of natural persons when disclosing documents to third persons. For example, any information which could lead to the identification, directly or indirectly, of patients constitutes personal data. Moreover, the EMA referred to its recommendations on transparency^[4], which provide that personal data, such as dates of birth, reporting country, and patients' identification numbers, have to be redacted to guarantee anonymity.

The inquiry △

5. The Ombudsman opened an inquiry into the complaint and identified the following allegation and claim:

- 1) The EMA acted wrongly when blanking out entire pages.
- 2) The EMA should grant public access in accordance with the applicable access to documents rules.

6. While agreeing in general that personal data needed to be protected, the complainant asked the Ombudsman to verify whether the EMA had acted in accordance with the applicable access to documents rules in its handling of his access request. The complainant in particular wished to know whether all the data blanked out - including the names of authors and co-authors of medical reports and the "test results and diseases" - is covered by the exception concerning the protection of personal data.^[5]

Inspection of the file △

7. In order to assess the validity of the complainant's allegation, the Ombudsman decided to carry out an inspection. As the complainant's concern related to a number of HAB reports consisting of a very large number of pages, the Ombudsman's inquiry team considered it reasonable first to inspect a sample HAB report in order to make appropriate use of public resources. The report that was chosen was report HAB 121 (pages 1-1500). However, all HAB reports to which the complainant was granted access relate to the same underlying matter (clinical studies concerning hepatitis-A and hepatitis-B) and they all follow a very similar general structure, as the documents submitted by the complainant show.

8. In accordance with the rules governing inspections, the EMA requested the Ombudsman to treat the report as confidential.^[6]

9. Following a careful assessment of the inspected report by the Ombudsman's inquiry team, the complainant was informed of the inquiry team's preliminary assessment that the EMA's position appeared to be reasonable and that there was no indication that the redactions went beyond the need to protect personal data and commercial interests. The complainant was given the possibility to provide comments on the inquiry team's preliminary assessment. He

was informed that the Ombudsman would take these comments into consideration in her final assessment of the case.

10. The complainant submitted comments disagreeing with the inquiry team's preliminary assessment, referring to the comments which he had put forward in his complaint and asking the Ombudsman to address them.

The Ombudsman's assessment

11. The assessment of the documents provided by the complainant, as well as the Ombudsman's inspection, confirm the complainant's statement that the EMA blanked out entire pages in the HAB reports. The text passages which were redacted relate to two categories, that is, (i) data related to the authors and co-authors of the relevant clinical study reports, as well as to patients; and (ii) medical articles and studies which have been published in various scientific and academic journals.

12. First, as regards the EMA's decision to blank out the data related to authors and co-authors of the HAB reports^[7], the Ombudsman observes that their names, CVs, signatures and contact details, as well as patients' reference numbers, are concerned. The Regulation on data protection defines personal data as "*any information relating to an identified or identifiable natural person hereinafter referred to as 'data subject'; 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.*"^[8] In view of the foregoing, it is clear that the data in question - subject to one possible exception which will be discussed below - constitutes personal data. As regards public access to documents containing personal data, the Court of Justice has concluded^[9] that the applicant has to demonstrate the necessity for transferring the personal data.^[10] The Ombudsman notes that, in the case at hand, the complainant has not done so. The EMA thus clearly acted correctly when deciding not to disclose the relevant personal data to the complainant. It thus follows that no partial access could be granted to such personal data, either.

13. The Ombudsman is not entirely convinced that this conclusion also applies to the patients' reference numbers, given that this information would not allow the complainant or any person, other than the one who assigned the reference numbers to the patients, to identify the latter. However, because these references are simply numbers which most likely would not offer any added value to the complainant if disclosed, she does not consider it appropriate to pursue this aspect further. Should the complainant however be interested in being granted access to these reference numbers, he could consider turning to the EMA with a request for it to reconsider its position, making reference to the Ombudsman's assessment in this regard.

14. Second, as regards the EMA's decision to blank out those parts of the HAB reports consisting of medical articles and studies which have been published in various scientific and academic journals, the

Ombudsman notes that the EMA also relied on the need to protect *commercial interests*. The Ombudsman notes also that the exception concerning the need to protect commercial interests also extends explicitly to *intellectual property*.^[11] It appears likely that at least some of the articles and studies that are published in scientific and academic journals are protected by copyright. However, it is not immediately obvious to the Ombudsman why disclosing a copy of these documents, in response to a request for public access to documents, would necessarily infringe this copyright. In fact, the Ombudsman notes that the EMA failed in the present case to justify properly to the complainant how disclosure of this information would have undermined the protection of commercial interests, as settled case-law demands. It should however be taken into account that the information provided by the EMA to the complainant concerning these medical articles and studies is such as to allow the latter to look for these publications in the journals concerned. In fact, the EMA provided the authors' names as well as the relevant titles to the complainant, and the relevant articles can easily be accessed on the internet, as a quick online search by the Ombudsman's services has shown. Therefore, the Ombudsman considers that there are insufficient grounds for pursuing this particular matter further.

15. Finally, the Ombudsman notes that the complainant also appeared to be unhappy with the blanking out by the EMA of "test results and diseases", as evidenced under point 6 above. It is not clear to the Ombudsman to which exact passages of the documents the complainant is referring. The only passages that may be relevant in this regard appear to be those under the 'audits' sections. While 'audits' may arguably be understood as relating to 'test results and diseases', the Ombudsman notes that these sections in fact list the names of persons authorising the introduction of tests-related information into the relevant database used for the recording of the appropriate data. This information is thus clearly covered by the exception concerning the protection of personal data invoked by the EMA (see paragraph 12 above), and the Ombudsman believes that granting partial access in relation to these deletions is not possible. In order to understand which parts of the documents the complainant was speaking of when referring to "test results and diseases", the Ombudsman asked him, in August 2015, to point out any example. However, the complainant did not reply. Consequently, the Ombudsman is not in a position to pursue this aspect of the complaint further.

Conclusion

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

There was no maladministration as regards the EMA's decision to blank out personal data.

There are no grounds for further inquiries as regards the remainder of the complaint.

The complainant and the EMA will be informed of this decision.

Emily O'Reilly

Strasbourg, 09/10/2015

Final English version of the decision on complaint **894/2015/PMC**

[1] 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.

[2] In accordance with Articles 4(1)(b) and 4(2), first indent of Regulation 1049/2001.

[3] As defined in Article 2(a) of 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.

[4]

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/12/WC500016912.pdf

[5] Article 4(1)(b) of Regulation 1049/2001.

[6] The document cannot, therefore, be disclosed to the complainant or to third parties (in line with Articles 5(2), 13(3) and 14(2) of the Implementing Provisions of the European Ombudsman).

[7] In accordance with Article 4(1)(b) of Regulation 1049/2001.

[8] See, to that effect, Article 2a of Regulation 45/2001.

[9] Case C-28/08 P *Commission v Bavarian Lager* [2010] ECR I-6055

[10] In accordance with Article 8(1)(b) of Regulation 45/2001.

[11] See Article 4(2), first indent of Regulation 1049/2001.

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