

From: DPO Euro-Ombudsman <DPO-Euro-Ombudsman@ombudsman.europa.eu>
To: [REDACTED]
CC: [REDACTED]
Sent at: 19/03/19 13:38:08
Subject: RE: Duplication of Complaints | EO-EDPS MoU

[REDACTED]

Please find attached the Ombudsman's decision in the above case, which was sent to the complainant last Friday.

If you have any additional questions about the Ombudsman's assessment of the complaint, please do not hesitate to get back to us.

Um abraço,
[REDACTED]

From: [REDACTED]
Sent: 04 March 2019 15:19
To: [REDACTED]
Cc: DPO Euro-Ombudsman <DPO-Euro-Ombudsman@ombudsman.europa.eu>
Subject: RE: Duplication of Complaints | EO-EDPS MoU

[REDACTED] [REDACTED]

Following the previous email, in case you find it useful, please do not hesitate in requesting me any additional information from a data protection point of view to address Mr Kirchner complaint against EMA.

Kind regards,
[REDACTED]



[REDACTED]
Legal Officer | Supervision and Enforcement Unit

[REDACTED]
European Data Protection Supervisor
Postal address: Rue Wiertz 60, B-1047 Brussels
Office address: Rue Montoyer 30, B-1000 Brussels
@EU_EDPS www.edps.europa.eu

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From: DPO Euro-Ombudsman <DPO-Euro-Ombudsman@ombudsman.europa.eu>
Sent: 06 September 2018 10:17
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Duplication of Complaints | EO-EDPS MoU

[REDACTED]

Thank you for your e-mail.

As discussed over the phone this morning, we are dealing indeed with a complaint from Mr Kirchner against EMA and we will be happy to inform you about the outcome of the Ombudsman's analysis of this case, once it is finalised.

Should you require any further information, please do not hesitate to contact us. (My Colleague dealing with the case, [REDACTED] is in Cc, together with [REDACTED] who you know already).

Best wishes,



European Ombudsman

[Redacted]

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From: [Redacted]
Sent: 24 August 2018 12:45
To: [Redacted]
Subject: Duplication of Complaints | EO-EDPS MoU

[Redacted]

I hope this email finds you very well! I am writing you to inform that the EDPS received a complaint from Professor Jürgen Kirchner against EMA regarding an alleged maladministration case. The complainant has said that the same complaint was also submitted by him to the European Ombudsman (EO).

Therefore, in the light of the Memorandum of Understanding signed between the EO and the EDPS^[1], the EDPS will wait for the EO's final decision before taking any action. Nonetheless, a case file at the EPDS was opened, in the view of the complainant's allegations on data protection issues.

Whereas the data protection aspects of the present case are marginal, please do not hesitate to consult us should you consider that necessary for the investigation of the case. I am this EDPS case handler and my contacts are detailed below.

Kind regards,

[Redacted]



[Redacted]
Legal Officer | Supervision and Enforcement Unit

European Data Protection Supervisor
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^[1] Memorandum of Understanding between the European Ombudsman and the European Data Protection Supervisor, OJEU C 27/21, 7.2.2007.



Decision

in case 1608/2017/MIG on the European Medicines Agency's handling of multiple requests for public access to documents made by a single applicant and its extension of deadlines

The case concerned how the European Medicines Agency (EMA) deals with multiple requests for public access to documents made by the same applicant. In particular, EMA has developed a mechanism based on which it may queue access requests and process them in turn. The complainant considers this practice to be unlawful and to constitute a delaying tactic. He is also dissatisfied with several instances where EMA extended the deadline for handling his access requests.

The Ombudsman met with EMA to gain a better understanding particularly of its 'queuing mechanism'. She found that it is reasonable for EMA to employ such a mechanism, which promotes transparency and ensures fairness amongst applicants, and that it was appropriate for EMA to extend the deadlines in question.

The Ombudsman thus closes her inquiry finding no maladministration.

Background to the complaint

1. In the period between December 2016 and early 2018, the complainant submitted 40 requests for public access to documents to the European Medicines Agency (EMA). The requests concerned 63 documents.
2. Concerning some of the requests, EMA extended the applicable 15-working-day deadline by another 15 working days¹. EMA justified this measure on the basis of "a high volume of requests resulting in an excessive workload".

¹ In accordance with Articles 7(3) of Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001R1049&from=EN> (applicable to EMA pursuant to Article 73 of Regulation 726/2004 and EMA's implementing rules).



3. Regarding other requests, EMA informed the complainant that, *“in order to avoid that [its] core business tasks and its performance being jeopardised by the administrative workload”*, it has introduced a special mechanism for processing multiple requests submitted by the same applicant. In such cases, a request may be processed only *“once the prior one has been closed”*. In other words, if the same applicant sends multiple requests for access to documents, those requests can be *“placed in a queue and processed in turn”*.

4. For example, on 20 May 2017, the complainant submitted to EMA a request for public access to several documents. EMA informed the complainant that it was currently processing four requests for review (so-called ‘confirmatory applications’) that he had submitted prior to this new request. EMA would thus apply its ‘queuing mechanism’ to the complainant’s new request and process it *“either as soon as an [access to documents] coordinator is available or at the latest once [his] confirmatory applications have been finalised”*. It would inform the complainant once it had started to process his new request.

5. In August 2017, EMA confirmed receipt of this request and informed the complainant that it had started processing the request on 9 August 2017. The complainant would receive a reply within the prescribed time limit of 15 working days or, if an extension of this deadline will be necessary, a notification thereof.

6. Dissatisfied with EMA’s practice, the complainant turned to the Ombudsman in September 2017.

The inquiry

7. The Ombudsman opened an inquiry into the complainant’s position that, in handling requests for public access to documents, EMA is wrong

- 1) to extend the 15-working-day deadline based on its high workload; and
- 2) to ‘queue’ multiple requests made by a single applicant.

8. In the course of the inquiry, the Ombudsman inquiry team met with EMA representatives to obtain clarifications, and, subsequently, received the comments of the complainant in response to the clarifications provided by EMA.

9. On several occasions, the complainant also shared with the Ombudsman further correspondence between him and EMA on old and new access requests. It is clear from this correspondence that, in order to circumvent EMA’s queuing mechanism, the complainant has asked third parties to make access requests in their own names, but on his behalf. Initially, EMA dealt with these third-party requests separately. However, the number of such requests increased and EMA



now considers them to be made by the same applicant. Accordingly, these requests were put in the same queue.

Arguments presented to the Ombudsman

10. Concerning those instances where EMA extended the applicable time limit for dealing with a request for public access or for review by 15 working days, the **complainant** argued that the extension of deadlines is allowed in exceptional circumstances only. However, EMA systematically extends deadlines based on its high workload, which does not qualify as an 'exceptional case' in the meaning of the applicable rules².

11. Regarding EMA's queuing mechanism, the complainant contended that this practice violates Regulation 1049/2001 and questioned the validity and appropriateness of EMA's reasoning, specifically that its core business may be put in jeopardy. He argued that the queuing mechanism can lead to a significant delay and thus amounts to a deliberate delaying tactic that aims to inhibit transparency. In particular, by queuing access requests, EMA limits the number of requests an applicant can make per year to seven requests³. Moreover, in the complainant's case, the mechanism undermines the freedom of the press, as he needed the information contained in the requested documents for journalistic purposes.

12. The complainant also stated that - to his knowledge - EMA applies its queuing mechanism only to access requests that are made by consumers and patients, while it handles requests that it receives from the pharmaceutical industry within the applicable time limit of 15 working days. Given that its employment depends on the applicant making a request, the mechanism is discriminatory. To prove this, the complainant has asked third parties to submit access requests to EMA on his behalf but in their own name. EMA had dealt with these requests without delay.

13. The complainant also argued that EMA is obliged to employ a sufficient workforce to ensure that it is able to deal with all access requests that it receives within the applicable time limits. EMA should be able to adapt the size of its team processing access to documents requests to the estimated number of such requests.

14. EMA explained that, over the last few years, it has experienced a sharp increase in access to documents requests, from 150 requests in 2011, to about 830 requests in 2017. To deal with these requests, EMA employs 12.5 full time equivalent staff members. On average, EMA handles between 100 and 120 access requests in parallel. Given the high volume of requests and the limited resources available, EMA has developed a queuing mechanism in order to ensure that one applicant's multiple exercise of the right to request public

² See Articles 7(3) and 8(2) of Regulation 1049/2001.

³ Elsewhere, the complainant estimated an annual maximum amount of 8 to 17 requests per applicant.



access to documents does not have a negative effect on EMA's ability to handle other applicants' access requests. In fact, with this system, EMA seeks to guarantee fairness amongst all applicants by ensuring that at least one request per applicant is being dealt with at any point in time⁴. It is based on the principle of proportionality and the power to look for a fair solution⁵.

15. The queuing mechanism may be applied to applicants who make two or more requests within a limited period of time if, during that same time period, EMA's access to documents team is already working on full capacity. Of the requests that are put in a queue⁶, EMA deals with one at a time, while putting the other requests from the same applicant on hold. In other words, EMA formally registers such requests once the processing of the 'active' request is finished, when an access to documents team member becomes available, or when another applicant requests access to the same document. It is at this point in time that EMA starts counting the processing time towards the applicable time limit. If a single request is made for a high number of documents, EMA may split the request into batches of documents, which are then also processed in turn. This means that, if a request is divided into batches, EMA applies the 15-day time limit to every individual batch. In case a request (or batch) is placed in a queue, EMA informs the applicant about this within 48 hours. EMA will then deal with such requests in the order of their receipt. However, applicants have the possibility to prioritise certain requests (or batches) and thus to ask EMA to process them in a particular order.

16. According to EMA, its queuing (and batching) system mainly affects companies and law firms, who regularly make requests for public access. So far, EMA has not received any formal complaint about it, despite the fact that usually some requests are in a queue. The queuing mechanism can therefore be said to be well-accepted amongst applicants.

17. Regarding the complainant's 40⁷ requests for access, which he made in the period from December 2016 to early 2018, EMA stated that only four were placed in a queue. At the time, EMA was already dealing with four other 'active' requests from the complainant in parallel. The four queued requests were processed in turn. The complainant was informed about this and updated every time EMA started processing the next request.

18. Moreover, of the 63 documents concerned, EMA has released 81% within the initial 15-day time limit to the complainant. In eight cases, EMA had to extend the time limit by another 15 working days to be able to consult all colleagues involved in the handling of the complainant's access requests. The reason stated in those cases was EMA's high workload. EMA does not usually

⁴ EMA checks its system twice every week to make sure that this is indeed the case.

⁵ In accordance with Article 6(3) of Regulation 1049/2001.

⁶ If an applicant makes several access requests, they are not necessarily queued. For example, EMA never places requests in a queue that will be denied or where EMA is not in possession of the requested document(s).

⁷ This figure does not include those requests that appear to have been made by other persons on the complainant's behalf.



otherwise extend the time limit for handling access requests based on its high workload. In these cases, the documents in question were released to the complainant either within the extended time limit or within one or two working days after its expiry.

19. In reply to EMA's comments, **the complainant** stated that he maintained his view that EMA's queuing mechanism violates the applicable rules. He added that - based on the figures EMA published for the year 2017 - all of his requests for access together related to fewer pages than the average request⁸. Moreover, according to the complainant's calculations, the average time to process one of his requests for access is 0.3 working days and therefore less than 10 % of the overall average time. Thus, the complainant concluded, the processing of his requests for access entailed only a comparatively low workload. There was therefore no reason to place any of his requests in the queue.

20. Regarding those requests that were made by his supporters (that is, the third parties who made access requests on the complainant's behalf), the complainant stated that EMA was not allowed to pool these requests.

21. In general, the complainant argued, the queuing mechanism is problematic because it aims to reduce the number of access requests and not to allocate resources when there is a peak of requests. In other words, EMA uses this mechanism as a means to deter applicants from making access requests.

22. Concerning the extension of deadlines, the complainant added that his access requests have been necessary and adequate. None of the requests concerned very long documents or a high number of documents. The extension of the initial 15 working-day time limit with respect to some of his requests was therefore inappropriate.

The Ombudsman's assessment

Extension of the time limit of 15 working days in individual cases

23. According to the EU rules on public access to documents, an institution may, "[i]n exceptional cases, for example in the event of an application relating to a very long document or to a very large number of documents", extend the applicable time limit by 15 working days, "provided that the applicant is notified in advance and that detailed reasons are given".⁹

24. EMA initially based the extension of deadlines on "*its current high volume of requests resulting in an excessive workload*". However, during the meeting with

⁸ In 2017, EMA received 844 requests for access to 2 807 documents and released 487 092 pages of documents, so that the average request concerned 577 pages and the average document was 173 pages long, while EMA has released 63 documents to the complainant corresponding to 2 645 pages. Counting also third party requests made on the complainant's behalf, EMA has released 130 documents corresponding to 3799 pages to him (as per June 2018).

⁹ Article 7(3) of Regulation 1049/2001.



the Ombudsman's inquiry team, EMA specified that the extensions were necessary for EMA to be able to consult all colleagues involved in the handling of the complainant's respective access requests. This explanation appears to be reasonable, though EMA should have provided the complainant with the detailed reasons for the extension when informing him of its decision to extend the deadline.

25. It is also clear now that EMA does not routinely extend deadlines. In the complainant's case, EMA released 81 % of the requested documents within 15 working days. In the remaining cases, EMA extended the time limit by 15 working days and released the requested documents within the extended period or with a delay of one or two working days. This shows that EMA assessed every request individually and extended the time limit only where the specific circumstances of the case so required.

EMA's approach to dealing with multiple requests by the same applicant

26. The EU rules on public access to documents set out that, if an access request relates *"to a very long document or to a very large number of documents, the institution concerned may confer with the applicant informally, with a view to finding a fair solution."*¹⁰

27. According to settled case law, this right to seek a fair solution *"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"*¹¹. 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."*¹² Thus, *"an institution may, in exceptional circumstances, refuse access to certain documents on the ground that the workload relating to their disclosure would be disproportionate (...)"*¹³ In other words, exceptionally, an institution may refuse access to documents on the basis that the processing of a request would entail an excessive administrative burden.

28. Given that the complainant made a number of access requests in close temporal proximity, some of which concerned several documents, it is reasonable to consider his requests as one request relating to a large number of documents. Otherwise, applicants could easily circumvent the rules that provide for exceptions in cases where access to a very long document or to a very large number of documents is requested, by splitting such requests into several smaller requests. Consequently, EMA could, in fact, have denied the

¹⁰ Article 6(3) of Regulation 1049/2001.

¹¹ See judgments of the Court of First Instance of 13 April 2005, *VKI v Commission*, T-2/03, paragraph 101, and of 10 September 2008, *Williams v Commission*, T-42/05, paragraphs 85f.

¹² *VKI*, para 102.

¹³ Judgment of the Court of 2 October 2014, *Strack v Commission*, C-127/13 P, para 28.



complainant any access to the documents that he requested in those four applications.

29. However, instead of availing itself of the option to refuse access in such cases, EMA has established a mechanism that ensures that as many applicants as possible can exercise their right of public access to documents and no request has to be denied due to the related administrative burden. In the light of the administrative workload that requests for access pose and the significant increase in such requests EMA has experienced in recent years, it is generally reasonable for EMA to look for fair solutions in order to be able to deal with all the requests for access it receives. The Ombudsman commends EMA for this approach that seeks to treat all applicants fairly and equally, and that appears to be well perceived by the vast majority of regular applicants and to be very efficient.

30. In particular, EMA does not apply automatically its queuing mechanism to every case of multiple requests made by the same applicant. Rather, EMA applies this mechanism in exceptional circumstances only when otherwise the high workload due to access requests would jeopardise its core business, that is, the protection and promotion of EU citizens' and animal health through the evaluation and supervision of medicines. This is also true for the complainant's case: EMA put only 4 out of 40 of his access requests in a queue and processed them in turn. At that time, EMA was already dealing with four other requests made by the complainant. It informed the complainant accordingly and updated him every time it started processing the next one of the four queued requests.

31. Moreover, EMA equally applies its queuing mechanism to all applicants, irrespective of who they are or why they seek access. This is illustrated (i) by the fact that those applicants affected the most are pharmaceutical companies and the law firms representing them as they also account for the highest number of access requests; and (ii) by the comparatively small number (10 %) of the complainant's requests that EMA placed in a queue. The Ombudsman also therefore considers it reasonable for EMA to pool the complainant's and his supporters' access requests. Otherwise, the complainant, by circumventing EMA's system like this, would gain an unfair advantage over all other applicants.

32. It is not clear how the complainant arrived at the conclusion that EMA's practice significantly limits the number of access requests that an applicant can make per year to seven requests¹⁴. EMA has managed to release 63 documents to the complainant within a period of about 15 months. In contrast to the complainant's assumption, these figures clearly demonstrate the efficiency of EMA's practice in handling access to documents requests.

¹⁴ Or to 17 requests (see footnote 3).



33. Regarding the complainant's claim that EMA should increase the size of its team dealing with access to document requests, EMA cannot simply increase its human resources at its will and/or at any time. Rather, EMA has to employ the resources allocated to it as efficiently and effectively as possible.

34. Finally, the Ombudsman notes that EMA clearly strives for a very high level of transparency. This is apparent, for example, from EMA's endeavours to make more and more documents proactively available on its website. Moreover, in the complainant's case, EMA proactively released a document shortly after it had received it without a need for the complainant to make a request, knowing that it would be of interest to him. The Ombudsman welcomes this attitude, which she considers to be an exceptional example of good administration in the area of public access to documents.

Conclusions

Based on the inquiry, the Ombudsman closes this case with the following findings¹⁵:

The extension of deadlines by EMA in this case was justified.

EMA's queuing mechanism constitutes a fair and appropriate solution for cases in which EMA would otherwise have to refuse public access due to an excessive administrative burden. EMA applies this mechanism in a reasonable and proportionate manner.

The complainant and EMA will be informed of this decision.

Fergal Ó Regan
Coordination of Public Interest Inquiries - Unit 2

Strasbourg, 15/03/2019

¹⁵ Information on the review procedure can be found on the Ombudsman's [website](http://www.ombudsman.europa.eu/en/resources/otherdocument.faces/en/70669/html.bookmark): <http://www.ombudsman.europa.eu/en/resources/otherdocument.faces/en/70669/html.bookmark>