

**From:** [REDACTED]  
**To:** European Data Protection Supervisor  
<EDPS@edps.europa.eu>  
**CC:** Rasi Guido <Guido.Rasi@ema.europa.eu>; [REDACTED];  
dataprotection <dataprotection@ema.europa.eu>  
**Sent at:** 05/08/19 17:40:14  
**Subject:** RE: Request for comments by the Data Controller (Case C 2018-0688)

Dear Sirs

Please find attached a letter from Prof Guido Rasi in response to your communication of 1st July 2019. This correspondence is sent by email only.

Yours faithfully

[REDACTED]  
Office of the Executive Director  
European Medicines Agency

**Temporary VISITING address** Spark building | Orlyplein 24 | 1043 DP Amsterdam | The Netherlands

**For DELIVERIES** refer to [How to find us](#)

[REDACTED]  
**We're moving again in 2020!** 🚚 For details, see [How to find us](#).

Follow us:   



This message and any attachment contain information which may be confidential or otherwise protected from disclosure. It is intended for the addressee(s) only and should not be relied upon as legal advice unless it is otherwise stated. If you are not the intended recipient(s) (or authorised by an addressee who received this message), access to this e-mail, or any disclosure or copying of its contents, or any action taken (or not taken) in reliance on it is unauthorised and may be unlawful. If you have received this e-mail in error, please inform the sender immediately.

---

**From:** European Data Protection Supervisor [mailto:EDPS@edps.europa.eu]  
**Sent:** 01 July 2019 17:46  
**To:** Rasi Guido  
**Cc:** dataprotection  
**Subject:** Request for comments by the Data Controller (Case C 2018-0688)

Dear Mr Rasi,

Please find attached letter regarding request for comments by the Data Controller (Case C 2018-0688).

Kind regards,

---

## EDPS Secretariat



| Tel. (+32) 228 31900 | Fax +32(0)22831950 | >  
Email [edps@edps.europa.eu](mailto:edps@edps.europa.eu)

### **European Data Protection Supervisor**

Postal address: Rue Wiertz 60, B-1047 Brussels

Office address: Rue Montoyer 30, B-1000 Brussels

[@EU\\_EDPS](https://twitter.com/EU_EDPS) [www.edps.europa.eu](http://www.edps.europa.eu)

This email (and any attachment) may contain information that is internal or confidential. Unauthorised access, use or other processing is not permitted. If you are not the intended recipient please inform the sender by reply and then delete all copies. Emails are not secure as they can be intercepted, amended, and infected with viruses. The EDPS therefore cannot guarantee the security of correspondence by email.

---

This e-mail has been scanned for all known viruses by European Medicines Agency.

---



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

Ms Delphine HAROU  
Head of Supervision and Enforcement Unit  
European Data Protection Supervisor  
Rue Wiertz 60  
B-1047 Brussels  
Belgium

05 August 2019  
EMA/410112/2019  
European Medicines Agency

Dear Ms Harou,

**Subject: Request for comments by the Data Controller – (Case C 2018-0688)**

Thank you for your letter dated 1 July 2019 requesting comments from the European Medicines Agency (EMA) on the processing of personal data in the context of the handling of requests for access to documents under Regulation (EC) No 1049/2001.<sup>1</sup>

In your letter you have explained that the background of your investigation is a complaint received on 26 July 2018 from Mr Jürgen Kirchner against EMA's personal data processing activities related to handling access to documents requests. For the purpose of completeness it bears noting that, the complainant also submitted a complaint on the same matter to the Data Protection Officer (DPO) of EMA on 31 July 2018. After careful consideration of the case, involving an internal investigation and consultation with the competent EMA services, the DPO provided a detailed response to the complainant. This response explained the purposes of the application of the queuing system (with reference to the then ongoing investigation of the European Ombudsman) and explained how a decision is made at the Agency to place certain requests in one queue. Mr Kirchner did not seek any clarifications on the response of the DPO, and did not submit to EMA any further comments or questions in relation to this matter.

We take note that your questions do not concern the adoption of the queuing mechanism, but focus solely on the processing of personal data in the context of the handling of requests for access to documents. Accordingly, we set out below our comments regarding your specific questions on personal data processing by the Agency in the context of the handling of access to documents requests:

**1. Is EMA making inferences of possible connections between people requesting access to documents by processing personal data?**

In accordance with the internal procedures followed when handling access to document requests, a decision to place requests for access to documents under one "queue" is only made on the basis of the following factual parameters:

- name of the requester (i.e. whether the requests belong to the same requester);

---

<sup>1</sup> Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents



- organisation/employer affiliated with the requester as indicated in the submission form (i.e. whether the requests belong to the same organisation/employer);
- time of the submission of the requests.

Accordingly, in the course of applying the queuing system to access to documents requests, no assumptions on possible connections are made and no other personal data of the requesters are processed other than the abovementioned factual parameters.

In the particular case mentioned in the complaint of Mr Kirchner the decision to place several requests for access to documents in one queue was exceptionally based on the specific circumstances of the subject matter for which the requests related. In this case, between 14 and 17 July 2018, altogether six requests were submitted by five requesters for a large number of different documents on the same subject.

These requesters had previously submitted requests in coordination with each other in order to avoid being placed in a queue. The co-ordinated action on the part of the requesters was evidenced on several occasions between July 2017 and July 2018. (Such instances of co-ordinated action between certain of those five requesters have occurred more times, in the context of requests on other subjects.) Amongst else, evidence showing these requesters' co-ordinated behaviour in this period was the following<sup>2</sup>:

- Mr Kirchner sent an email from the email account of another requester, signing the email with his own name.
- In another email sent by Mr Kirchner concerning one of his requests, he explicitly states "*please close this request as I have already got the document from one of my supporters*".
- Other requesters included in the particular queue together with Mr Kirchner have previously indicated in their submissions that they had received documents from Mr Kirchner (which he obtained from EMA).
- On several other occasions, these requesters submitted requests for the same documents which were previously asked for by another requester but were placed in a queue due to the high volume of documents requested by that person. This means that when one requester received an email about the fact that the documents would be released in queue, another requester requested the queued documents (usually within less than an hour) by sending the exact same cover message as his request for the rest of the documents. This pattern occurred repeatedly between Mr Kirchner and those other requesters pooled together in the case mentioned in the complaint.

In the case 1608/2017/MIG, the European Ombudsman (EO) confirmed that EMA's conclusion that the requesters were acting in a "colluded manner" was correct. The complainant had shared with the EO several items of his correspondence with EMA. Based on this information, the EO concluded that: "*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*".<sup>3</sup> This tactic was also explicitly admitted in Mr Kirchner's email to the DPO of the Agency: "*So, to overcome the "ASK EMA Queuing System" my supporters, who anyway help with investigations, took over to request documents from ASK EMA regarding the matter in parallel to each other*".

In addition, the European Ombudsman confirmed that it was "*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*".<sup>4</sup>

Accordingly, in the particular case mentioned by Mr Kirchner in his complaint, the decision to place requests from different requesters in one queue was made exceptionally on the basis of the very particular circumstances of the case, i.e. that the requests concerned documents on the exact same

<sup>2</sup> These documents are available for review upon request.

<sup>3</sup> Paragraph 9 of *Decision of the European Ombudsman 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*.

<sup>4</sup> *Ibid*, paragraph 32.

subject and the requesters were acting in a "colluded manner" on behalf of Mr Kirchner in order to circumvent the rules of the queuing system. However, it is not the general practice of the Agency to place requests in the same queue based on the co-ordinated behaviour of the requesters and the Agency does not assess the requesters' personal data to establish a link or relationship between them. This particular decision was necessary at the time of the receipt of the concerned requests in order to prevent the delay and obstruction when handling other requesters' access to documents requests. As the EO confirmed, the decision was reasonable and justified.

## **2. If so, what is the legal basis for this processing of personal data?**

As explained above in the answer to Question 1, in accordance with the internal procedures followed when handling access to document requests, a decision to place requests for access to documents in one queue is only made on the basis of three parameters: name of the requester, the employer/organisation to which the requester belongs, as well as the time of the submission.

The legal basis for the lawfulness of processing these details in the context of handling access to documents requests –in accordance with Article 5(1)(a) of Regulation (EU) 2018/1725<sup>5</sup> is that this processing is necessary for the performance of the task of the handling of requests for access to documents in the possession of EMA. That task, carried out in the public interest, is attributed to EMA further to the third indent of Article 73 of Regulation (EC) No 726/2004<sup>6</sup>, which foresees that "*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 shall apply to documents held by the Agency*". Article 15(1) of Regulation (EC) No 1049/2001 further states that "*the institutions shall develop good administrative practices in order to facilitate the exercise of the right of access guaranteed by this Regulation*".

Pursuant to Article 73 of Regulation (EC) No 726/2004, the Agency has adopted 'The European Medicines Agency policy on access to documents' (Policy/0043).<sup>7</sup> In addition, a 'Guide on access to unpublished documents' (EMA/304162/2014 Rev.1)<sup>8</sup> was published as well. Accordingly, the management of access to document requests is carried out in accordance with the internal procedures established in Policy/0043 and explained in the Guide. In particular, the elements of personal data processing in the context of handling requests for access to documents (including an explanation on the queuing system under questions 14-15) are addressed in the Guide and the Privacy Statement linked on the web form for submitting a request.<sup>9</sup> The Privacy Statement is currently being updated under Regulation (EU) 2018/1725 and will be published on the Agency's website.

In light of the above, EMA processes the personal data of applicants for access to documents to the extent it is required for the correct management of such requests. This processing is necessary for the performance of the task carried out by the Agency in the public interest in accordance with Regulation (EC) No 1049/2001, EMA's Policy/0043 and the 'Guide on access to unpublished documents'.

## **3. Is EMA clustering similar requests of access to documents on the basis of the data subject's personal data and treating them as one?**

No, the Agency does not cluster and treat similar access to documents requests as one on the basis of personal data.

In accordance with the internal procedures of the Agency for the handling of requests for access to documents, requests which are submitted separately are treated individually and concluded by a separate administrative decision addressed to the requester.

<sup>5</sup> Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC

<sup>6</sup> Regulation (EC) No 726/2004 laying down procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

<sup>7</sup> Publicly available here: [https://www.ema.europa.eu/en/documents/other/policy/0043-european-medicines-agency-policy-access-documents\\_en.pdf](https://www.ema.europa.eu/en/documents/other/policy/0043-european-medicines-agency-policy-access-documents_en.pdf)

<sup>8</sup> Publicly available here: [https://www.ema.europa.eu/en/documents/other/guide-access-unpublished-documents\\_en.pdf](https://www.ema.europa.eu/en/documents/other/guide-access-unpublished-documents_en.pdf)

<sup>9</sup> Publicly available here: <https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency>

**4. Why the email regarding the order of the queuing system was addressed to several recipients with all their addresses visible to each other?**

It must be clarified that in the communication sent to the requesters (mentioned in the answer to Question 1) no email or other addresses were visible to the recipients. The only personal data visible to the recipients were the surnames of four requesters.

As explained above, the particular circumstances of the case mentioned in Mr Kirchner's complaint required that the requests were handled in an exceptional manner. Accordingly, it appeared from the colluded behaviour of the requesters that they were in regular contact with each other and they were requesting the concerned documents for the same subject in order to support Mr Kirchner. Due to these special circumstances, the EMA staff member handling these requests mentioned the surnames of four requesters together in the salutation of one communication sent separately to all of them on the basis of the same subject and previous cross-references to other requests.

Accordingly, in this one communication only the requesters' surnames were present and no email addresses or other personal data were mentioned. The particular circumstances of the case showed that these requesters were in contact with each other; therefore it appears to be unlikely that the disclosure of their surnames presented a risk to their rights and freedoms. Nevertheless, this case has been followed up internally by the Agency and measures have been implemented to ensure that communications and decisions concerning access to documents requests are addressed only to respective requester.

I trust this reply satisfies your queries. My offices remain available for any further information.

Yours sincerely



Guido Kasi  
Executive Director

CC: [Redacted] Acting Data Protection Officer