Decision of the European Data Protection Supervisor in complaint case ▮▮▮▮ submitted by ▮▮▮▮▮▮▮ against EMA

The EDPS,

Having regard to Article 16 TFEU, Article 8 of the Charter of Fundamental Rights of the EU (add other provisions of the Charter if relevant for the complaint), and Regulation (EU) 2018/1725[1], in particular its Article 57(1)(e),

Has issued the following decision:

PART I
Proceedings

On 26 July 2018, ▮▮▮▮▮▮▮▮(the complainant), submitted a complaint against the European Medicines Agency (EMA), to the European Data Protection Supervisor (EDPS) (case No. ▮▮▮▮).

The EDPS performed a preliminary assessment of this case. Since the complainant informed the EDPS that he had also submitted the same complaint to the European Ombudsman (EO), the EDPS suspended the case in the light of the Memorandum of Understanding signed between the EO and the EDPS[2] and on 24 August 2018 informed the complainant and the EO of this suspension.

On 19 March 2019, the EO communicated to the EDPS her decision in the case before the EO[3]. The EO closed her inquiry finding no maladministration by EMA.

By email of 1 July 2019, the EDPS invited EMA to provide its observations on the complaint's allegations regarding only the data protection issues. On 5 August 2019, EMA provided the EDPS with its comments.

On 7 August 2019, the EDPS invited the complainant to provide his comments on EMA's reply. On 7 and 12 August 2019, the complainant provided his comments to the EDPS.

PART II
The facts

   a) *Allegations of the complainant*
The complainant alleges that EMA has processed personal data relating to him and to other citizens in an unlawful manner in the context of access to documents requests. He alleges in particular an 'illegal analysis of requests and requesters', the 'pooling of requests' and 'illegal data records'.

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[1] *OJ 295, 21.11.2018.*
[2] Memorandum of Understanding between the European Ombudsman and the European Data Protection Supervisor, OJEU C 27/21, 7.2.2007.
[3] EO 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 of 15 March 2019.

The complainant states the following: 'After ASK EMA assumed to have identified "connections" between me and other requesters they categorized those as "all related with a particular requester" - although each request was submitted by a different person. Then they pooled the requests accordingly and handled those within that extremely restrictive ASK EMA Queuing System. (...) Please find the proof for this strange behaviour attached - a mail from ASK EMA to me stating that my request will be handled with requests from others one by one and not in parallel and the names of the other requesters have been disclosed (...). Later, an additional person was "integrated" into the EMA Queuing club'.

b) *Comments of the data controller*
EMA said that only the name of the requester, the name of the organisation/employer affiliated with the requester and the time of the submission of the requests are processed '...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...'.

However, EMA also stated that '... the decision to place several requests for access 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 of July 2018, altogether six requests were submitted by five requesters for a large number of different documents on the same subject.'

In addition, EMA declared that '[t]hese 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 2018. (...) evidence showing these requesters' co-ordinated behaviour in this period was the following:

- [the complainant] sent an email from the email account of another requester, signing the email with his own name.
- In another email sent by [the complainant] 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 [the complainant] have previously indicated in their submissions that they had received documents from [the complainant] (which he obtained from EMA).
- On several other occasions, these requesters submitted requests for the same documents which were previously asked for 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 [the complainant] and those other requesters pooled together in the case mentioned in the complaint.'

EMA also stated that '... in the particular case mentioned by [the complainant] 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 subject and the requesters were acting in a "colluded manner" on behalf of [the complainant] in order to circumvent the rules of the queuing system.'

Furthermore, EMA mentioned that '[t]his 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.'

The EO decision states in paragraph 29 that it is reasonable that EMA looks for fairs solutions to deal with all the requests for access it receives. Furthermore, according to the EO decision paragraph 31, it is reasonable for EMA to pool different requestors access requests so there is no circumvention of system and no unfair advantage over all other applicants.

PART III
Legal analysis

a) *Admissibility of the complaint and applicable data protection law*

The complaint concerns an alleged breach of Regulation (EC) 45/2001 governing the processing of the complainant's personal data by EMA, a European Union agency. The complaint is therefore admissible under Article 32 of Regulation (EC) 45/2001.

The data protection legal framework has changed during the handling of this complaint and Regulation (EC) 45/2001 was repealed and replaced by Regulation (EU) 2018/1725 on 11 December 2018. However, since the complaint was filed and concerns facts that happened before the entry into force of Regulation (EU) 2018/1725, the applicable law in this case is Regulation (EC) 45/2001 (hereinafter 'the Regulation').

Nonetheless, all the EDPS recommendations and concerns as regards processing by EMA of personal data of requestors asking for access to documents are also applicable under Regulation (EU) 2018/1725.

b) *Alleged violation of Article 4(1)(a) and (b) of the Regulation – fair and lawful processing for explicit purpose*

This decision does not concern the adoption of a queuing system per se, but solely regards how personal data is being processed by EMA.

Article 4 (Data quality) of the Regulation states that personal data must be:
        (a) processed fairly and lawfully;
        (b) collected for specified, explicit and legitimate purposes and not further processed in
        a way incompatible with those purposes.
        (...)
Providing individuals with the information on the processing of their personal data also contributes to ensuring data quality in the sense of Article 4 of the Regulation (e.g. fairness of the processing).

The EDPS agrees with the EO decision paragraph 29 when it is said that '... 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'.

In addition, the EDPS agrees in general with the EO finding that it is reasonable for EMA to pool different requesters' access to documents requests to prevent the circumvention of the queueing system and the consequent unfair advantage over all other applicants (EO decision par 31). However, the EUIs have to have rules how they conduct pooling and inform people about it.

The 'European Medicines Agency policy on access to documents' states that EU citizens and natural or legal persons residing or having their registered office in an EU Member State have the right to request access to documents and if a request concerns several documents it will be handled sequentially – meaning that the second request will only be processed after the first has been concluded, and so on. This is a clear and explicit set of rules regarding how the documents can be disclosed and no exceptions to this rule are stated in those documents. In particular, there are no specific rules regarding any abuse or avoidance strategy of this system. Additionally, there is no reference neither to access to documents requests by groups of people, nor to a possible grouping by EMA of different requests for similar documents.

EMA stated that the bundling of requests on the complainant's case was exceptional, in order to prevent him from circumventing '…the rules of the queuing system'. Nonetheless, the EDPS considers that there is no explicit provision in the abovementioned documents regarding the notion of abusive access to documents requests, including the assessment of links between requesters who are suspected of circumventing EMA's queuing system.

The EDPS therefore understands that, according to the current rules, when several people are requesting access to similar documents, EMA shall not apply a different purpose to the data processing regarding the submission of their access to documents requests, not even to check if a group of people is making related requests either, in a 'colluded manner' or not. There is nothing indicating that requesters should expect such an analysis of their requests.

Furthermore, EMA has treated the requests from the complainant in a different way from the standard procedure without informing the complainant and other pooled requesters of this. EMA did not inform data subjects about the data processing operations for the specific purpose of checking possible abuses of the queuing system when collecting personal data from the complainant and other pooled requesters. The EDPS considers that without this explanation of the difference in treatment, the data processing of the complainant's request is not transparent. As a consequence of EMA bundling the requests of access to documents of several requesters, that data processing is different from the original purpose of requesting access to documents and was therefore not fair and transparent, nor for an explicit[4] purpose.

Based on the above analysis, the EDPS considers that by not adopting rules regarding data processing operations with the purpose of detecting possible circumventions of the queuing system on access to documents requests, EMA is not acting in a fully lawful, fair and transparent manner in relation to the data subjects. The data subjects do not expect that their personal data related to their requests could be processed differently if it is suspected that someone or a group is trying to avoid the queuing system.

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[4] See Opinion 03/2013 on purpose limitation of the Article 29 Data Protection Working Party p. 17: 'The purposes of collection must not only be specified in the minds of the persons responsible for data collection. They must also be made explicit. In other words, they must be clearly revealed, explained or expressed in some intelligible form.' Available at: https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2013/wp203_en.pdf.

For these reasons, the EDPS finds that there has been a breach of Article 4(1)(a) and (b) of the Regulation. Information regarding how EMA detects possible circumventions and on pooling of requests from different individuals must be provided to the data subjects before the collection of their personal data. In this regard, the requester(s) should have an opportunity to explain seemingly suspicious patterns.

c) *Alleged violation of Article 5(a) of the Regulation –lawfulness of processing*

Article 5 (Lawfulness of processing) of the Regulation states that personal data may be processed only if:

(a) processing is necessary for the performance of a task carried out in the public interest on the basis of the Treaties establishing the European Communities or other legal instruments adopted on the basis thereof or in the legitimate exercise of official authority vested in the Community institution or body or in a third party to whom the data are disclosed, or

(b) processing is necessary for compliance with a legal obligation to which the controller is subject, or

(c) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract, or

(d) the data subject has unambiguously given his or her consent, or

(e) processing is necessary in order to protect the vital interests of the data subject.

In the present case, the personal data processing under analysis is the grouping of several requesters by EMA due to inferences of possible connections between those people based on the available collected personal data. As an example of such analysis, we can refer the situation mentioned by EMA of one requester receiving correspondence from EMA stating that his/her request was placed in a queue due to the high volume of documents requested by that person and another requester asking for access to that same document shortly after.

Article 5(a) of the Regulation states as a legitimacy ground the necessity of a processing for the performance of a task carried out in the public interest on the basis of the Treaties establishing the European Communities. Within this legitimate ground, EMA could implement a cross-checking mechanism to detect possible circumventions of access to document requests queuing system, that could imply a unfair treatment of the requesters of access to documents. That system needs to be transparent, lawful and fair, so that all individuals would be aware of it and could understand what EMA would consider to be abusive or circumventing the queuing system.

Article 5(b) of the Regulation refers to the cases where the processing is necessary for compliance with a legal obligation of the controller. However, there are no specific legal provisions which require EMA to check requesters of access to documents. Thus, this processing activity does not fall under Article 5(b) of the Regulation.

Articles 5(c), (d) and (e) are manifestly not applicable in this case.

For these reasons, the EDPS finds that EMA may have a legitimate ground to adopt a cross-checking mechanism with the purpose of detecting possible circumventions of the queuing

system on access to documents requests and that such a system may be lawful under Article 5 of the Regulation.

d) *Alleged violation of Articles 11 and 12 of the Regulation – right to information*

Articles 11 and 12 of the Regulation provide that data subjects must be informed of the processing of data relating to them and list a range of information to be provided. Providing information to data subjects puts them in a position to exercise their other data subject rights. It also contributes to fair processing and transparency.

EMA stated that the bundling of requests in this case was exceptional, in order to prevent the complainant from circumventing '...the rules of the queuing system'. However, EMA does not explain what is considered an infringement of the queuing system rules, how it is detected, nor inform the data subject that such rules exist.

In fact, as mentioned above, there is no specific provision regarding neither the notion of abusive access requests, nor the assessment of links between different requesters suspected of circumventing EMA's queuing system for access to documents requests.

Taking all of the above into consideration, EMA did not adopt rules regarding data processing operations with the purpose of checking if there was an attempt to circumvent the queuing system. Consequently, the complainant and all the other pooled requesters were not informed of the possibility of EMA processing their personal data for the detection of possible circumventions of EMA's access to documents queuing system.

For these reasons, the EDPS finds that there has been a breach of Articles 11(1)(b) and 12(1)(b) of the Regulation. EMA must properly inform the data subjects of all the rules that govern the processing of their personal data related to their requests.

PART IV
Conclusion

In light of the above, the EDPS considers that there was a violation of Article 4(1)(a) and (b) as well as Article 11(1)(b) of the Regulation by EMA since the complainant was treated unfairly compared to the other requesters and the grouping in this case of different requesters as one was beyond the initial purpose of this processing activity. Moreover, the data subjects were not properly informed of these rules.

Therefore, the EDPS **reprimands EMA, under Article 58(2)(b) of the Regulation, for this breach**.

Furthermore, should EMA wish to implement a system to detect and combat avoidance of the queuing system, the EDPS recommends that EMA:
- adopt rules regarding the processing of personal data to prevent the circumvention of the access to documents queuing system, as well as
- properly inform the data subjects to make sure that they are aware of such rules.

Please inform the EDPS about the implementation of abovementioned measures regarding the found breaches of the Regulation with the documentary evidence thereof within **six months** of the date of this decision.

Please note that any processing by EMA of personal data without implementing the EDPS' recommendations may constitute a breach of Regulation (EU) 2018/1725.

Done at Brussels,