

From: [REDACTED]
To: [REDACTED]
CC: [REDACTED]
Sent at: 18/01/22 18:20:27
Subject: RE: Pre-investigation - profiling - Case 2021-1120

Dear [REDACTED]

Please find attached our reply to your email regarding your pre-investigation with the case reference 2021-1120.

We remain available if you require any further clarification.

Best regards,

[REDACTED]

[REDACTED]
[REDACTED]
European Medicines Agency
Domenico Scarlattilan 6 | 1083 HS Amsterdam | The Netherlands
[REDACTED]
[REDACTED]

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From: [REDACTED]
Sent: 10 December 2021 12:50
To: [REDACTED]
Cc: [REDACTED]
[REDACTED]
Subject: RE: Pre-investigation - profiling - Case 2021-1120

Dear [REDACTED]

Received with thanks. We will reply to you in due course.
Kind regards

[REDACTED]
[REDACTED]



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.

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From: [REDACTED]
Sent: Friday, 10 December 2021 11:14
To: [REDACTED]
Cc: Data protection <Dataprotection@ema.europa.eu>; European Data Protection Supervisor <EDPS@edps.europa.eu>
Subject: Pre-investigation - profiling - Case 2021-1120

Dear [REDACTED],

I hope this email finds you well.

We are writing to you to gather further information under Article 57(1)(f) of Regulation (EU) 2018/1725 ('the Regulation') in order to clarify the EDPS' understanding of the facts in the following matter. Namely, data processing activities carried out by EMA in order to detect and prevent possible circumventions of the queuing system which it has put in place for requests for public access to documents under Regulation (EC) No 1049/2001. The information you provide will assist the EDPS in determining whether to open a formal investigation.

The file has been given case number 2021-1120. Please use this reference number in all future correspondence with the EDPS.

As indicated in [EMA's Guide on access to unpublished documents](#), circumvention of the queuing system ('circumvention') would arise if requesters whose requests should otherwise be queued in accordance with the queuing rules submit requests separately without acknowledging their relevant connection. For example, a circumvention would arise if separate individuals requested access to documents for the single use of only one requester. As further indicated in the Guide, possible circumvention may be detected based on the assessment of the links between requesters who are suspected of bypassing the queuing system. Such an assessment is based, amongst other things, on the following information: name of the requester, affiliation/employer, time of submission, content and subject matter of the request.

In accordance with Article 3(5) of the Regulation, profiling means any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements.

[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
1. Could you provide us with a systematic description of the processing activities related to the detection of a possible circumvention as well as details on any associated technical and organisational measures adopted with a view to ensuring compliance with the Regulation?
 2. What is the legal basis under Article 5 of the Regulation for the processing of personal data related to the detection of a possible circumvention?
 3. In so far as the legal basis is Article 5(1)(a) of the Regulation, could you demonstrate how EMA is complying with its obligation under Articles 15(2)(b) and 23(2) of the Regulation to explicitly inform the data subjects of the right to object to processing in accordance with Article 23(1) of the Regulation?
 4. Have you carried out, or considered carrying out, a data protection impact assessment ('DPIA') in accordance Article 39 of the Regulation, [REDACTED]
[REDACTED] If applicable, please provide us with reasons why you have not considered a DPIA to be necessary in this particular instance.

You are invited to substantiate your replies by providing any documentation you deem necessary for this purpose.

We would be grateful if you could provide the requested information by 18 January 2022. If any parts of your reply should be regarded as confidential, please indicate this clearly and provide your reasons, so that those parts can be dealt with accordingly where appropriate.

Thank you for your cooperation.

Kind regards,
[REDACTED]



[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
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

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[REDACTED]
[REDACTED]

Supervision and Enforcement Unit
European Data Protection Supervisor

By e-mail only

Amsterdam, 18 January 2022

Dear Mr. [REDACTED]

Re: Pre-investigation – profiling – Case 2021-1120

Thank you for your e-mail of 10 December 2021, informing us of your procedure 2021-1120 and your questions regarding the processing of personal data to avoid the circumvention of the queuing system in EMA’s access to documents work.

I would like to introduce myself. [REDACTED]
[REDACTED] and I look forward to a fruitful cooperation with the EDPS.

You refer to Question 14 of [EMA’s Guide on Access to Unpublished Documents](#) and the reference to prevention of possible circumvention of the queueing system. Question 14 states, amongst others, “*A possible circumvention may be detected based on the assessment of the links between requesters who are suspected of bypassing the queuing system. Such an assessment is based, amongst other things, on the following information: name of the requester, affiliation/employer, time of submission, content and subject matter of the request.*” [REDACTED]

[REDACTED]

[REDACTED]

You quote the definition of “profiling” in Article 3(5) of 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 (the ‘Regulation’). It reads:

“*‘profiling’ means any form of **automated processing of personal data** consisting of the use of personal data **to evaluate certain personal aspects** relating to a natural person, in particular to analyse or predict aspects concerning that natural person’s performance at work, economic*



situation, health, personal preferences, interests, reliability, behaviour, location or movements”
(emphasis added)

The definition requires that personal data are processed automatically “to”, i.e. with the purpose of evaluating certain personal aspects relating to a natural person.

EMA does not process the personal data of requesters for access to documents automatically to detect or prevent circumventions of the queueing system or to evaluate personal aspects of the requesters.

We will explain the queueing system for requests for access to documents (ATD) and the handling of personal data within the process the ATD Service follows upon receipt of an ATD to demonstrate that there is no profiling and in **reply to your question 1**.

This explanation will illustrate how a possible circumvention may be detected. This can only happen coincidentally by individually comparing the wording of the description of the requests (which indicates the documents that have been requested), and not by automated tools.

The handling of requests for access to documents and the queueing system

EMA treats requests for access to documents in the order in which they are received, unless the requester indicates a different order of priority. The requester is also invited to indicate the urgency (if any) into receiving their request.

The queueing system applies to a request from a requester, who has submitted an earlier request, which has not yet been finalised. His request will be handled, once his active request has been finalised.

In addition, requests that are not justified as being “urgent” are placed in the “chronological queue”, i.e. they are handled in the chronological order in which they are received, but after all urgent requests (such as requests relating to a pending administrative procedure or an ongoing patient treatment) have been handled.

The queueing mechanism is applied on the basis of the natural or legal person, for which a request for access to documents is made. In other words, when several requests are received from different individuals who indicate the same employer or affiliation or when several requesters indicate that they submit requests on behalf of each other.

Requests for access to documents are submitted through a dedicated webform on the secure web page <https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency>. The requester is required to fill the description of the request, his title, first name, surname, organisation, location and e-mail address.

When a request is placed in a queue, the ATD coordinator informs the requester. Each time a request ends, the ATD coordinator will contact the requester accordingly.

EMA’s queueing mechanism has been acknowledged by the European Ombudsman who concluded in case 1608/2017/MIG that “EMA’s queueing 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”.

Please refer to the following link for further details:
<https://www.ombudsman.europa.eu/en/decision/en/111254>.

Preventing possible circumvention of the ATD queuing system

There are no automatic measures in place to identify situations where a requester attempts to circumvent the queue by indicating a name or personal data that are not his. Hence, where the same person would use a different name or ask someone else to submit a request on his behalf, EMA cannot identify the connection through an automated tool.

EMA can only coincidentally identify an attempted circumvention of the queue in the context of joining requests in the following manner:

Daily, the team within the ATD Service performs in the system a **manual search** on the description of the request to see if any of the newly submitted requests for access to documents can be joined and processed in parallel with another ATD for efficiency purposes. Such a search uses the name of the requested document as a search term. It does not use any personal data of requesters as a search term. In this situation, the member of the ATD Service may notice requests that have very similar or identical wording of the description of the request and raise suspicion of an attempt to circumvent the queue.

In addition, all requests for access to documents are reviewed and discussed weekly at an ATD meeting where members of the ATD Service may indicate that they remember an earlier request with the same description of the request.

Such cases are discussed within the ATD Service prior to contacting the requester.

EMA admits that there can be cases of circumvention that it does not identify. Indeed, EMA only rarely identifies attempts at circumventing the queuing system. EMA also acknowledges that it is possible that an automated system might be able to identify more circumventions. Instead of investing in creating such an IT system, however, EMA invests its efforts in reducing the queue and reaching a situation, where requesters need not be queued. It is hoped that the requests currently in the queue can be handled and the queue be significantly reduced by the end of 2022.

It follows from the above that EMA does not have automated data processing in place with the purpose of detecting and preventing a possible circumvention of the queue of ATD requests. Therefore, at EMA there is no data processing activity that falls under the definition of “profiling” to avoid the circumvention of the queuing system in EMA’s access to documents work.

In reply to your **question 2**, The processing of personal data for the handling of a request for access to a document is explained in EMA’s [privacy statement concerning requests for information or access to documents](#) (hereinafter referred to as the “Privacy Statement”). The Privacy Statement is accessible, through a link that is on the abovementioned webform and on EMA’s dedicated web page for [data protection and privacy](#).

According to Section 4 of the Privacy Statement, the legal basis for the processing is the necessity for the performance of the task attributed to EMA by Article 73 of Regulation (EC) No 726/2004 and Regulation (EC) No 1049/2001. It further explains that requests for access to documents are processed in accordance with the European Medicines Agency policy on access to documents (Policy 0043) and the Guide on access to unpublished documents.

Moreover, the Privacy Statement explicitly refers to the detection of circumventions of the queueing system in the last paragraph of Section 3 on p. 4:

“Please note that - as explained in the referenced section Q14 of the ‘Guide on access to unpublished documents’ –in the context of applying the queueing mechanism your abovementioned data may be processed for the purpose of detecting possible circumvention of the system. When requesters are informed that their request have been placed in the same queue due to a detected possible circumvention, they have the opportunity to explain seemingly suspicious patterns. In case you submit such explanation, any personal data included will be processed only for the purpose of verifying your statements.”

Question 14 of the Guide on access to unpublished documents reads, amongst others:

“Preventing possible circumvention of the access to documents queueing system

The ATD Service seeks to treat all requesters fairly and equally and therefore aims to prevent requesters from circumventing the queueing system explained above.

Circumvention of the queueing system would arise if requesters whose requests should otherwise be queued in accordance with the queueing rules submit requests separately without acknowledging their relevant connection. For example, circumvention of the queueing system would arise if separate individuals requested access to documents for the single use of only one requester.

A possible circumvention may be detected based on the assessment of the links between requesters who are suspected of bypassing the queueing system. Such an assessment is based, amongst other things, on the following information: name of the requester, affiliation/employer, time of submission, content and subject matter of the request. The requesters will then be informed that their requests have been placed in the same queue due to a detected possible circumvention. At this point, should the requester(s) wish to provide further information, they are welcome to contact the ATD Service.”

In its e-mail of 17 January 2020 closing case 2018-0688, the EDPS considered the data protection notice/privacy statement and the text of Q14 at the time to address “*all the EDPS recommendations by 1) adopting rules regarding the processing of personal data to prevent the circumvention of the access to documents queueing system; as well as 2) informing data subjects about those rules in the data protection notice/privacy statement.*”

Therefore, we trust that EMA has adopted the required rules and correctly informs data subjects about them.

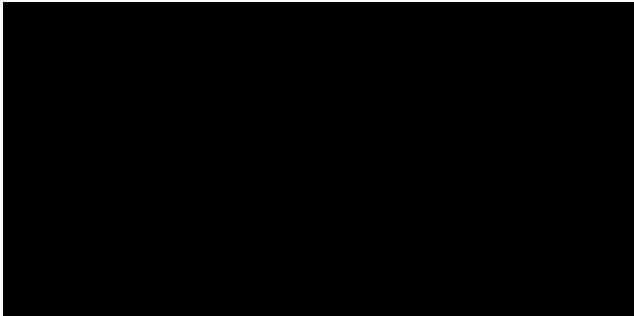
In reply to your **question 3**, we would like to draw your attention to Section 7 of the Privacy Statement. It informs the data subjects of their right to object (Articles 15(2)(b), 23(1) and (2) of Regulation (EU) 2018/1725 (the “EU Data Protection Regulation”)):

“Right to object – If the Agency processes your data for the performance of a task in the public interest (without your consent or due to the requirement of another lawful basis) you have the right to object to this processing on grounds related to your particular situation.”

In reply to your **question 4**, we considered that the handling of personal data in access to documents does not entail a high risk to the rights and freedoms of natural persons. Therefore, a data protection impact assessment was not required under Article 39(1) of the EU Data Protection Regulation. As we have explained above, there is no profiling of personal data, which would have required a data protection impact assessment pursuant to Article 39(3)(a) of the EU Data Protection Regulation.

We hope that this replies to your questions. Of course, we remain available for any clarifications.

Best regards,



From: [Redacted]

Sent: Friday, 10 December 2021 11:14:22 (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna

To: [Redacted]

Cc: Data protection; European Data Protection Supervisor

Subject: Pre-investigation - profiling - Case 2021-1120

Dear [Redacted],

I hope this email finds you well.

We are writing to you to gather further information under Article 57(1)(f) of Regulation (EU) 2018/1725 ('the Regulation') in order to clarify the EDPS' understanding of the facts in the following matter. Namely, data processing activities carried out by EMA in order to detect and prevent possible circumventions of the queuing system which it has put in place for requests for public access to documents under Regulation (EC) No 1049/2001. The information you provide will assist the EDPS in determining whether to open a formal investigation.

The file has been given case number 2021-1120. Please use this reference number in all future correspondence with the EDPS.

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natural person, in particular to analyse or predict aspects concerning that natural person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements.

[REDACTED]

[REDACTED]

[REDACTED]

1. Could you provide us with a systematic description of the processing activities related to the detection of a possible circumvention as well as details on any associated technical and organisational measures adopted with a view to ensuring compliance with the Regulation?

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3. In so far as the legal basis is Article 5(1)(a) of the Regulation, could you demonstrate how EMA is complying with its obligation under Articles 15(2)(b) and 23(2) of the Regulation to explicitly inform the data subjects of the right to object to processing in accordance with Article 23(1) of the Regulation?

4. Have you carried out, or considered carrying out, a data protection impact assessment ('DPIA') in accordance Article 39 of the Regulation, [REDACTED]
[REDACTED] If applicable, please provide us with reasons why you have not considered a DPIA to be necessary in this particular instance.

You are invited to substantiate your replies by providing any documentation you deem necessary for this purpose.

We would be grateful if you could provide the requested information by 18 January 2022. If any parts of your reply should be regarded as confidential, please indicate this clearly and provide your reasons, so that those parts can be dealt with accordingly where appropriate.

Thank you for your cooperation.
Kind regards,

[REDACTED]