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CC: 'dataprotection@ema.europa.eu'
<dataprotection@ema.europa.eu>
Sent at: 01/07/19 17:46:07
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



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DELPHINE HAROU
HEAD OF SUPERVISION AND ENFORCEMENT UNIT

Mr Guido Rasi
Executive Director of
European Medicines Agency
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The Netherlands

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DH/GC [REDACTED]/D(2019) 1360 C 2018-0688
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correspondence

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

CONFIDENTIAL

Dear Mr Rasi,

We would like to inform you that on the 26 July 2018 the EDPS received a complaint under Article 46(a) of Regulation (EC) 45/2001 (the Regulation)¹ from Mr Jürgen Kirchner against the European Medicines Agency (EMA) – Case 2018-0688. We have started to investigate this complaint pursuant to Article 57(1)(e) of the Regulation.

a) Background

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’.

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. This means, on that way the EMA maintains the limitation of the number of documents obtainable regarding one investigation to 17 annually. Please find the proof for this

¹ OJ L 8 of 12.01.2001. At the time of writing, the new regulation has entered into force: 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) 45/2001 and Decision No 1247/2002/EC, OJ C 288 of 31.08.2017. Nevertheless, the present case is examined in the light of Regulation 45/2001, which was applicable when the facts occurred.

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'.

By email of 24 August 2018, after having analysed the matter raised in the complaint, the EDPS informed the complainant that his request appeared to be related more to maladministration than to a processing of personal data by EU institutions or bodies. Since the complainant had already addressed his complaint to the European Ombudsman (EO) – which is the competent entity to deal with this alleged maladministration case against EMA – and in the light of the Memorandum of Understanding signed between these two entities², the EDPS informed the complainant that it would wait for the EO's final decision before taking any action in his complaint.

On 19 March 2019, the EO sent her 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, to the EDPS, concluding the following: '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'.

b) Request for comments by the data controller on the complainant allegations

In the light of the allegations described above, could you please provide us with any comments you might have regarding the processing of personal data relating to the matters raised?

In particular, we would like to know the following:

1. Is EMA making inferences of possible connections between people requesting access to documents by processing their personal data?
2. If so, what is the legal basis for this processing of personal data?
3. Is EMA clustering similar requests of access to documents on the basis of the data subjects' personal data and treating them as one?
4. Why the email regarding the order of the queueing system was addressed to several recipients with the all their addresses visible to each other?

Please be informed that the questions above are not about the adoption of a queuing system per se, but solely regard how personal data is being processed.

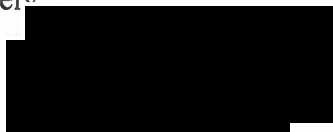
We would be grateful for receiving this information within six weeks from the receipt of this letter.

Please note that where relevant, your reply (or parts thereof) may be shared with the complainant. If any part of your comments should be regarded as confidential, please indicate

² Memorandum of Understanding between the European Ombudsman and the European Data Protection Supervisor, OJEU C 27/21, 7.2.2007, available at: https://edps.europa.eu/sites/edp/files/publication/06-11-30_eo_edps_mou_en.pdf.

this clearly and provide reasons for that, so that those parts could be dealt with accordingly where appropriate.

Yours sincerely

A large black rectangular redaction box covering the signature of Delphine Harou.

Delphine Harou

CC:  (Acting DPO)

The present transmission of personal data is carried out under Regulation (EU) 2018/1725 (see recital 21). As the controller of the personal data hereby transmitted, you are responsible for ensuring that they are lawfully processed and used only for the purpose for which they were transmitted. Processing the data in a manner incompatible with that purpose, such as transmitting them to another recipient where this is not necessary or legally required, is contrary to the conditions upon which these data have been transmitted to you.