



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

Brussels,
SANTE.DDG1.B.5/AM/am(2022)2437741

By registered letter with AR

Ms. Astrid Viciano
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Germany

Advance copy by email:

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65256885@asktheeu.org](mailto:ask+request-8870-65256885@asktheeu.org)

Subject: Erroneously released personal data following a request for access to documents under Regulation (EC) No 1049/2001¹ - GESTDEM 2020/7877

Dear Ms Viciano,

With reference to the above request for access to documents, which concerned 65 documents in total, the Directorate-General for Sante of the European Commission regrets to inform you that the 4 documents listed below were erroneously released by email of 03/06/2021 in reply to your request:

- Ares(2020)4757463 – Doc. 32
- Ares(2020)5345071 – Doc. 34
- Ares(2020)7204029 – Doc. 36
- Ares(2020)3764341 – Doc. 48

More precisely, in reply to your request we disclosed personal information of other persons that should not have been disclosed in accordance with the applicable data protection rules, namely Regulation (EU) 2018/1725².

In order to limit any further infringement of the applicable rules and to limit any negative consequences on the data subject following this erroneous disclosure, we have to ask you to refrain from using, disseminating, sharing, duplicating, printing or processing the erroneously released version of these documents and any information contained therein in any way and from making them public. Furthermore, we have to ask you to delete the

¹ 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, Official Journal L 145 of 31.5.2001, p. 43.

² 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, Official Journal L 295 of 21.11.2018, p. 39.

4 documents, and any information contained therein, from your paper and electronic records, including your email and computer hard drive, and to confirm these actions to us in writing. Should you have shared or published the documents before receipt of this letter, we have to ask you to inform us thereof.

As the disclosure of the version of these documents you received from the Directorate-General for Sante on 03/06/2021 was erroneous and against applicable data protection rules, any further use or processing of that version of the documents, or of any information contained therein, after receipt of the present letter and information may engage your personal responsibility, which may include compensation for any damage provoked.

Please find attached the correct version of the specific documents in order to provide you with the information you are entitled to receive following your request for access to documents under Regulation 1049/2001, and to correct our erroneous disclosure.

To confirm the above mentioned necessary actions, please sign the enclosed declaration confirming the above and send it by April 8, at the latest, to the below e-mail address:

Email: SANTE-PHARMACEUTICALS-B5@ec.europa.eu

We would like to express our sincere apologies for this incident and the inconvenience it might cause for you. The European Commission attaches great importance to the protection of personal data of individuals and we thank you in advance for your cooperation in limiting the negative consequences of this incident.

Yours sincerely,

e-signed
Olga Solomon
Head of Unit

Enclosure: 1. Draft declaration to be signed

 2. Correct version of documents