



## EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels

SANTE.DDG1.B.5/AL/am(2022)2586021

***By registered letter  
with acknowledgment of receipt<sup>1</sup>***

Mr. Astrid Viciano  
Graefstrasse 125  
81241 Munich  
Germany

**Advance copy by e-mail:**

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

Dear Mr Viciano,

**Subject: Your applications for access to documents – Ref GestDem 2020/7877**

We refer to your emails dated 18 December 2020 in which you made a request for access to documents, registered under the above-mentioned reference number.

We refer to your reply of 20 January 2021 to our clarification letter in which you clarified the scope of your request.

We also refer to your reply of 02 February 2021 to our fair solution proposal, in which you agreed in narrowing down the scope of your request to documents related to clinical trials, COVID-19, Pharma strategy and orphan and paediatrics.

Lastly, we refer to our email of 03 March 2021 in which we further restricted the scope of your request.

### **1. Scope of your request**

In your request, you ask access to the following documents under Regulation (EC) No 1049/2001<sup>2</sup>:

*- all reports (and other notes) from meetings between DG SANTÉ and representatives of the pharmaceutical industry (companies as well as organisations such as EFPIA) from March 1st 2020 onwards. This should include the following companies: Bayer AG, Novartis International AG, Merck, GlaxoSmithKline, Amgen Inc, F. Hoffmann-La Roche Ltd, Johnson & Johnson, SANOFI, Pfizer Inc., AstraZeneca, Eli Lilly and Company, and MSD (Europe) Inc. (Merck Sharp & Dohme).*

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<sup>1</sup> According to standard operational procedure, the reply is usually also sent to you by registered post. Please note, however, that due to the extraordinary health and security measures currently in force during the COVID-19 epidemics, which include the requirement for all Commission non-critical staff to telework, we are unfortunately not in a position to follow this procedure until further notice. We would therefore appreciate if you could confirm receipt of the present e-mail.

<sup>2</sup> Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

- all correspondence (including emails) between the DG SANTÉ and representatives of the pharmaceutical industry (companies as well as organisations such as EFPIA) from March 1st 2020 onwards.

- a list of all the above-mentioned documents (including dates, names of participants/senders/recipients and their affiliation, subject of meeting/correspondence).

In your reply to our fair solution proposal, you agreed to narrow down the topics of your request to:

“...documents concerning points 2 (clinical trials), 6 (COVID), 7 (Pharma strategy), and 8 (orphan and paediatrics)...”.

Lastly, due to the still great volume of the documents resulting from the initial narrowing down, the number of documents has been unilaterally restricted to the amount of 65 documents falling within the above-mentioned four topics.

## **2. Identification and assessment of the relevant documents**

We have identified 65 documents falling within the scope of your request.

You will find attached a table listing the identified documents and summarising the outcome of the assessment on the basis of Regulation (EC) No 1049/2001.

Having examined these documents under the provisions of Regulation (EC) No 1049/2001 regarding public access to documents, we have come to the conclusion that:

1. full access can be given to document No 2;
2. partial access can be given to documents No 1, 3 to 30, 32 to 60 and 62 to 65, as their full disclosure is prevented by the exceptions to the right of access laid down in Article 4 of Regulation (EC) No 1049/2001.
3. no access can be granted to documents No 31 and 61, as their full disclosure is prevented by an exception to the right of access laid down in Article 4 of Regulation (EC) No 1049/2001.

You may reuse public documents, which have been produced by the European Commission or by public and private entities on its behalf, in accordance with the [Commission Decision on the reuse of Commission documents](#)<sup>3</sup>. You may reuse the documents disclosed free of charge and for non-commercial and commercial purposes provided that the source is acknowledged and that you do not distort the original meaning or message of the documents. Please note that the Commission does not assume liability stemming from the reuse.

Please note that preliminary drafts do not reflect the position of the Commission and cannot be quoted as such.

Please also note that documents originating from third parties are disclosed to you based on Regulation (EC) No 1049/2001. However, this disclosure is without prejudice to the rules on intellectual property, which may limit your right to reproduce or exploit the released documents without the agreement of the originator, who may hold an intellectual property right on them. The European Commission does not assume any responsibility from their reuse.

Lastly, please note that some of the documents were drawn up for internal use under the responsibility of the relevant services of the Directorate-General for Health and Food safety ('DG SANTE'). They solely reflect the services' interpretation of the interventions made and do not set out any official position of the third parties to which the documents refer, which were not consulted on the documents' content. Such documents do not reflect the position of the Commission and cannot be quoted as such.

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<sup>3</sup> 2011/833/EU: Commission Decision of 12 December 2011 on the reuse of Commission documents, (OJ L 330, 14.12.2011, p. 39).

### **3. Reasons for partial disclosure**

#### *a) Protection of personal data - Article 4(1)(b) of Regulation (EC) No 1049/2001*

With regard to the documents No 1, 3 to 30, 32 to 60 and 62 to 65, listed above, full disclosure is prevented by the exception concerning the protection of privacy and the integrity of the individual laid down in Article 4(1)(b) of the Regulation, because they contain the following personal data:

- the names/initials and contact information of Commission staff members not pertaining to the senior management;
- the names/initials and contact details of other natural persons;
- handwritten signatures/abbreviated signatures of natural persons;
- other information relating to an identified or identifiable natural person such as office/phone numbers or email addresses.

Article 9(1)(b) of the Data Protection Regulation<sup>4</sup> does not allow the transmission of these personal data, except if you prove that it is necessary to have the data transmitted to you for a specific purpose in the public interest and where there is no reason to assume that the legitimate interests of the data subject might be prejudiced. In your request, you do not express any particular interest to have access to these personal data nor do you put forward any arguments to establish the necessity to have the data transmitted for a specific purpose in the public interest.

Consequently, we conclude that, pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access cannot be granted to the personal data contained in the requested documents, as the need to obtain access thereto for a purpose in the public interest has not been substantiated and there is no reason to think that the legitimate interests of the individuals concerned would not be prejudiced by disclosure of the personal data concerned.

#### *b) Protection of the commercial interests of a legal person - Article 4(2), first indent, of Regulation (EC) No 1049/2001*

With reference to documents No 13, 22, 42, their full disclosure is prevented pursuant to the exception in Article 4(2), first indent, of Regulation (EC) No 1049/2001 because they contain information pertaining to third parties.

Pursuant to Article 4(4) of Regulation (EC) No 1049/2001, we have consulted the third parties from which the documents originated, and they have objected to the disclosure of parts of these documents on the basis of the exception in Article 4(2), first indent, of Regulation (EC) No 1049/2001.

According to the third parties involved, the retained information describes internal business strategies of these companies and therefore disclosure of this information would compromise the protection of their commercial interests.

Having examined these documents in light of the comments received from the third parties, we consider that the exception of Article 4(2) first indent of Regulation (EC) No 1049/2001 applies to the redacted parts of the documents, as they contain commercial and business strategies' information. In light of the above, a partial access to the document is granted.

### **4. Reasons for refusal**

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<sup>4</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), (OJ L 119, 4.5.2016, p. 1).

*Protection of the commercial interests of a legal person - Article 4(2), first indent, of Regulation (EC) No 1049/2001*

With reference to documents No 31 and No 61, they contain information pertaining to third parties. Having been consulted pursuant to Article 4(5) of Regulation (EC) No 1049/2001, the latter opposed to the disclosure, arguing that the requested information contains industrial and business secrets of the involved manufacturing authorization holders and therefore, their disclosure would harm their commercial interests, as protected by Article 4(2), first indent, of Regulation (EC) No 1049/2001

The Commission shares this analysis and therefore considers that the exception laid down in Article 4(2) first indent of Regulation (EC) No 1049/2001 applies to these documents.

**5. Overriding public interest**

The exception to the right of access provided for in Article 4(2) of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosing the requested document. In your application, you did not submit any grounds concerning a public interest on the basis of which the interests protected in Regulation (EC) No 1049/2001 would have to be overridden, and we could not identify any such ground either. In these circumstances, we have to conclude that there is no evidence of an overriding public interest in disclosure, in the sense of Regulation (EC) No 1049/2001.

**6. Means of redress**

In case you would disagree with our assessment, you are entitled -in accordance with Article 7(2) of Regulation (EC) No 1049/2001- to submit a confirmatory application requesting the Commission to review this position.

Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the Secretariat-General of the Commission at the following address:

European Commission  
Secretariat-General  
Unit C.1. 'Transparency, Document Management and Access to Documents'  
BERL 7/076  
B-1049 Brussels, or by email to: [sg-acc-doc@ec.europa.eu](mailto:sg-acc-doc@ec.europa.eu)

Yours faithfully,

e-signed

Sandra GALLINA  
Director General

Enclosure: List of documents; Annexes.