



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels  
SANTE.A.1/RM/CG(2020)

Dear Mr Hoedeman,

**Subject: Your application for access to documents – Ref GestDem 2020/0261**

We refer to your email dated 14 January 2020 in which you make a request for access to documents, registered on the same date with the above-mentioned reference number.

We also refer to our letter dated 2 February 2020 extending the time limit for responding to your request pursuant to Article 7(3) of Regulation (EC) No 1049/2001<sup>1</sup> (or “the Regulation”).

**1. Scope of your request**

On the basis of Regulation (EC) No 1049/2001, you requested access to:

- [Part 1] ‘all reports (and other notes) from meetings between DG SANTE and representatives of the pharmaceutical industry (companies as well as organisations such as EFPIA) from December 1st 2019 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).
- [Part 2] all correspondence (including emails) between the DG SANTE and representatives of the pharmaceutical industry (companies as well as organisations such as EFPIA) from December 1st 2019 onwards.
- [Part 3] a list of all the above-mentioned documents (including dates, names of participants/senders/recipients and their affiliation, subject of meeting/correspondence).’

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<sup>1</sup> Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

***By registered mail with acknowledgment of receipt***

Mr Olivier Hoedemann  
Corporate Europe Observatory  
Rue d'Edimbourg 26,  
1050 Brussels  
Belgium

***Advance copy by email:***

ask request-7572-d073a613@asktheeu.org

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

We have identified 12 documents with their respective attachments falling under the scope of your request.

Having examined these documents under the provisions of Regulation (EC) No 1049/2001 and after having consulted the concerned third parties, we have come to the following conclusion:

- Partial access can be given to documents No 1 to 5.03, 5.05, 5.06 and from 5.09 to 11.2 and 12 as their full disclosure is prevented by the exceptions to the right of access laid down in Article 4 of the Regulation and/or they contain parts that are out-of-the-scope of your request.
- Full access can be given to documents No 5.04, 5.07, 5.08 and 11.3.

You will find attached a table listing the identified documents and summarising the outcome of the assessment carried out on the basis of the Regulation. We understand this table to correspond to the list you requested in part three of your application.

We enclose a copy of the above-listed documents redacted of the parts which cannot be disclosed as covered by the exceptions to the right of access laid down in Article 4 of the Regulation. In addition, parts falling out-of-scope of your request have been removed.

You may reuse the documents requested free of charge for non-commercial and commercial purposes provided that the source is acknowledged, 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.

Some of these documents were drawn up for internal use under the responsibility of the relevant service of the Directorate-General for Health and Food Safety. They solely reflect the service's interpretation of the interventions made and do not set out any official position of the third parties to which the documents refer. They do not reflect the position of the Commission and cannot be quoted as such.

Documents originating from third parties cannot be re-used without the agreement of the originators. They do not reflect the position of the Commission and cannot be quoted as such.

## **3. Reasons for partial refusal**

*Protection of the privacy and integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data - Article 4(1)(b) of Regulation (EC) No 1049/2001*

With regard to the documents No 1 to 5.03, 5.05, 5.06, from 5.09 to 11.2 and 12, a complete disclosure is prevented by the exception concerning the protection of privacy and the integrity of the individual outlined in Article 4(1)(b) of Regulation (EC) No 1049/2001, 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 the names, office and phone numbers of the companies' representatives.

Article 9(1) of the Data Protection Regulation<sup>2</sup> allows the transmission of personal data only while respecting specific conditions specified therein. In your request, you do not provide any elements that would fulfil these conditions (e.g. you do not establish that it is necessary to have the data transmitted for a specific purpose in the public interest) and therefore 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.

In accordance with the above mentioned, partial access is granted to the requested documents, expunged of personal data.

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

Documents No 1 and 3 are partially covered by this exception.

Document No 3 contains information extracted from the requests of right holders for custom authorities to act. This information is confidential and not shared with other actors than the customs authorities which have been asked to act. Disclosing this information would undermine the commercial interests of the right holders.

Documents No 1, 2 and 5 contain information or originate from EFPIA. The third party has been consulted on the documents originating from them in accordance with Article 4(4) of Regulation (EC) No 1049/2001, in order to assess whether an exception under Article 4 of the Regulation is applicable.

For what concerns document No 1, EFPIA objected to the disclosure of a power point presentation invoking the argument that their commercial interests would be damaged by the disclosure of the slides included in said presentation, which represent the background in draft format to a project that is still ongoing. These slides were not intended for wider sharing before publication of results of the project on the EFPIA website in the near future.

We consider that releasing these slides prior to the publication of the EFPIA report would undermine the ability for EFPIA to give publicity to its project with a timing and form of their choosing and could therefore affect their competitive position in the market.

Documents No 2 and 5 have not been found to contain any commercially sensitive information.

Therefore, having considered the opinion of the third party, we concluded that the disclosure of parts of documents No 1 and 3 is prevented by the exception protecting the commercial interests of a legal person, laid down in Article 4(2), first indent, of the Regulation.

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<sup>2</sup> 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 (OJ L 295, 21.11.2018, p. 39–98)

The documents in question are therefore disclosed, expunged of the parts to which the above-mentioned exception applies.

*Protection of the purpose of inspections, investigations and audits, Article 4(2), third indent, of Regulation (EC) No 1049/2001*

Some parts of document No 3 detail information on the basis on which customs authorities within Member States perform their risk analysis in view of targeting controls on certain shipments. This information is restricted and not shared with other actors than the customs authorities. Its disclosure would undermine the purpose of inspections carried out by customs authorities by providing access to information regarding the targeting of controls.

Therefore, we concluded that the disclosure of parts of document No 3 is prevented by the exception laid down in Article 4(2), third indent, of Regulation (EC) No 1049/2001, protecting the purpose of inspections, investigations and audits. The parts in question have therefore been redacted from the disclosed document.

#### **4. Overriding public interests**

The exceptions 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 the regulation 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 the Regulation.

#### **5. Means of redress**

In accordance with Article 7(2) of Regulation (EC) No 1049/2001, you are entitled to make 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 Secretary-General of the Commission at the following address:

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

Yours sincerely,

Anne BUCHER

Enclosures (sent only by email): List of documents identified as under Section 2.  
Documents to which partial access can be given, as  
identified under Section 2 of this letter.