Subject: Your application for access to documents – Ref GestDem 2020/0855

Dear Mr Hoedeman,

I refer to your request of 12 February 2020 for access to documents under Regulation (EC) No 1049/20011 ("Regulation 1049/2001") and hereinafter registered as GestDem 2020/0855.

Please accept our apologies for the delay in preparing the reply to your request, which is mainly due to a high number of access to documents being processed at the same time by DG Trade.

1. **SCOPE OF YOUR REQUEST**

In your application, you request access to:

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- all reports (and other notes) from meetings between DG Trade 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,
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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).

- all correspondence (including emails) between the DG Trade and representatives of the pharmaceutical industry (companies as well as organisations such as EFPIA) from December 1st 2019 onwards.

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

I consider your request to cover documents held up to the date of your initial application, i.e. 12 February 2020. We have identified **five documents** corresponding to the scope of your request. A list of these documents providing a description and indicating their level of disclosure is attached to this letter jointly with copies of the accessible documents.

**2. ASSESSMENT AND CONCLUSIONS UNDER REGULATION 1049/2001**

In accordance with settled case law\(^2\), when an institution is asked to disclose a document, it must assess, in each individual case, whether that document falls within the exceptions to the right of public access to documents set out in Article 4 of Regulation 1049/2001. Such assessment is carried out in a multi-step approach. First, the institution must satisfy itself that the document relates to one of the exceptions, and if so, decide which parts of it are covered by that exception. Second, it must examine whether disclosure of the parts of the document in question poses a “reasonably foreseeable and not purely hypothetical” risk of undermining the protection of the interest covered by the exception. Third, if the institution takes the view that disclosure would undermine the protection of any of the interests defined under Articles 4(2) and 4(3) of Regulation 1049/2001, the institution is required "to ascertain whether there is any overriding public interest justifying disclosure"\(^3\).

In view of the objectives pursued by Regulation 1049/2001, notably to give the public the widest possible right of access to documents\(^4\), "the exceptions to that right [...] must be interpreted and applied strictly"\(^5\).

Having examined the documents requested under the provisions of Regulation 1049/2001 regarding public access to documents, I have come to the conclusion that **documents 1 to 5** may be partially disclosed, **attachment 1 to document 5** may not be disclosed and **Attachments 2 and 3 to document 5** may be fully disclosed.

Please note that these documents originating from third parties are disclosed to you based on Regulation 1049/2001. However, this disclosure is without prejudice to the rules on

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\(^2\) Judgment in Sweden and Maurizio Turco v Council, Joined cases C-39/05 P and C-52/05 P, EU:C:2008:374, paragraph 35.

\(^3\) Id., paragraphs 37-43. See also judgment in Council v Sophie in ‘t Veld, C-350/12 P, EU:C:2014:2039, paragraphs 52 and 64.


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.

In documents 1-3 and 5 only names and other personal data have been redacted pursuant
to Article 4(1)(b) of Regulation 1049/2001 and in accordance with Regulation (EC) No
2018/1725. Hence, the main content of these documents is accessible.

In document 4, in addition to personal data, additional information was redacted as it is
covered by the exception set out in Article 4(2) first indent of Regulation 1049/2001
(protection of the commercial interest of a natural or legal person). The reasons justifying
the application of the exception is set out below in Section 2.2. Section 3 contains an
assessment of whether there exists an overriding public interest in the disclosure.

Attachment 1 to document 5 may not be disclosed as it is covered by the exception set out
in Article 4(3) (protection of the institution’s decision-making process). The reasons justifying the application of the exception is set out below in Section 2.3. Section 3 contains an assessment of whether there exists an overriding public interest in the disclosure.

2.1 Protection of privacy and integrity of the individual

Pursuant to Article 4(1)(b) of Regulation 1049/2001, access to a document has to be
refused if its disclosure would undermine the protection of privacy and the integrity of
the individual, in particular in accordance with European Union legislation regarding the
protection of personal data.

The applicable legislation in this field is Regulation (EC) No 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

All the documents partially released contain personal information, such as names, e-mail
addresses, telephone numbers that allow the identification of natural persons, as well as
other personal information like signatures.

Indeed, Article 3(1) of Regulation 2018/1725 provides that personal data "means any
information relating to an identified or identifiable natural person [...]". The Court of
Justice has specified that any information, which by reason of its content, purpose or
effect, is linked to a particular person is to be considered as personal data.7 Please note in

7 Judgment of the Court of Justice of the European Union of 20 December 2017 in Case C-434/16, Peter
Novak v Data Protection Commissioner, request for a preliminary ruling, paragraphs 33-35,
this respect that the names, signatures, functions, telephone numbers and/or initials pertaining to staff members of an institution are to be considered personal data.\textsuperscript{8}

In its judgment in Case C-28/08 P (\textit{Bavarian Lager})\textsuperscript{9}, the Court of Justice ruled that when a request is made for access to documents containing personal data, the Data Protection Regulation becomes fully applicable.\textsuperscript{10}

Pursuant to Article 9(1)(b) of Regulation 2018/1725, personal data shall only be transmitted to recipients established in the Union other than Union institutions and bodies if "[t]he recipient establishes that it is necessary to have the data transmitted for a specific purpose in the public interest and the controller, where there is any reason to assume that the data subject’s legitimate interests might be prejudiced, establishes that it is proportionate to transmit the personal data for that specific purpose after having demonstrably weighed the various competing interests". Only if these conditions are fulfilled and the processing constitutes lawful processing in accordance with the requirements of Article 5 of Regulation 2018/1725, can the transmission of personal data occur.

According to Article 9(1)(b) of Regulation 2018/1725, the European Commission has to examine the further conditions for a lawful processing of personal data only if the first condition is fulfilled, namely if the recipient has established that it is necessary to have the data transmitted for a specific purpose in the public interest. It is only in this case that the European Commission has to examine whether there is a reason to assume that the data subject’s legitimate interests might be prejudiced and, in the affirmative, establish the proportionality of the transmission of the personal data for that specific purpose after having demonstrably weighed the various competing interests.

In your application, you do not put forward any arguments to establish the necessity to have the data transmitted for a specific purpose in the public interest. Therefore, the European Commission does not have to examine whether there is a reason to assume that the data subject’s legitimate interests might be prejudiced.

Notwithstanding the above, please note that there are reasons to assume that the legitimate interests of the data subjects concerned would be prejudiced by disclosure of the personal data reflected in the documents, as there is a real and non-hypothetical risk that such public disclosure would harm their privacy and subject them to unsolicited external contacts.


\textsuperscript{10} Whereas this judgment specifically related to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, the principles set out therein are also applicable under the new data protection regime established by Regulation 2018/1725.
Consequently, I conclude that, pursuant to Article 4(1)(b) of Regulation 1049/2001, access cannot be granted to the personal data, 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.

Documents 1-5 contain personal information, such as names, e-mail addresses and telephone numbers that allow the identification of natural persons, which has been redacted according to Art. 4(1)(b) of Regulation 1049/2001.

2.2 Protection of commercial interests

Article 4(2) first indent, of Regulation 1049/2001 provides that ‘‘[t]he institutions shall refuse access to a document where disclosure would undermine the protection of: […] commercial interests of a natural or legal person, including intellectual property […] unless there is an overriding public interest in disclosure’’.

In addition to containing personal information, one passage in document 4 has been withheld because it contains business sensitive information such as views and opinions expressed by members of the European Federation of Pharmaceutical Industries (EFPIA) about their commercial relations, concerns and interests in a very specific context.

I consider that public access to sensitive information provided by the European Federation of Pharmaceutical Industries would harm the competitive position of member companies of EFPIA, thus affecting their commercial interests.

This information was shared with the Commission in order to provide useful input and support for the EU’s objectives. Operators typically share information with the Commission so that the latter can determine how to best position itself in order to protect its strategic interests and those of its industry, workers and citizens. Ensuring that the Commission continues to receive access to this information and that the industry engages in open and frank discussions with the Commission, are key elements for the success of the internal and external policies of the EU. Sharing publicly business sensitive information that companies share with the Commission may prevent the Commission from receiving access to such information in the future.

2.3 Protection of the institution's decision-making process

Article 4(3) first subparagraph, of Regulation 1049/2001 provides that ‘‘[a]ccess to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution’s decision-making process, unless there is an overriding public interest in disclosure.’’

Attachment 1 to document 5 relates to a decision which has not yet been taken by the Commission and contains opinions for the Commission’s internal use as part of deliberations and consultations within the Commission.
Disclosure of this document would undermine the protection of the decision-making process of the Commission related to parameters of planned commercial policy measures further to the adjudication of a trade dispute with the United States on Measures Affecting Trade in Large Civil Aircraft under the WTO Dispute Settlement Understanding. Final commercial policy measures are currently under consideration. Therefore, the exception laid down in Article 4(3) first subparagraph of Regulation 1049/2001 applies to this document.

We have considered whether partial access could be granted to attachment 1 to document 5. However, release of parts of the document at this time would undermine the Commission’s decision-making process by revealing specific elements taken into consideration in preparation of a decision on planned commercial policy measures.

3. **OVERRIDING PUBLIC INTEREST IN DISCLOSURE**

Please note that article 4(1)(b) of Regulation 1049/2001 does not include the possibility for the exception defined therein to be set aside by an overriding public interest.

The exceptions laid down in Article 4(2) and 4(3) of Regulation 1049/2001 apply, unless there is an overriding public interest in disclosure of the documents. Such an interest must, firstly, be public and, secondly, outweigh the harm caused by disclosure.

In this context, I would like to refer to the judgment in the *Strack* case\(^{11}\), where the Court of Justice ruled that in order to establish the existence of an overriding public interest in transparency, it is not sufficient to merely rely on that principle and its importance. Instead, an applicant has to show why in the specific situation the principle of transparency is in some sense especially pressing and capable, therefore, of prevailing over the reasons justifying non-disclosure.

In your application, you do not refer to any particular overriding public interest that would warrant public disclosure of the specific type of information included in any document.

We have considered whether the risks attached to the release of the withheld passage in document 4 are outweighed by the public interest in accessing the requested documents. We have not been able to identify any elements capable of demonstrating the existence of a public interest that would override the need to protect the commercial interests of the economic operators grounded in the first indent of Article 4(2) of Regulation 1049/2001. The public interest in this specific case rather lies on the protection of the legitimate confidentiality interests of the stakeholders concerned to ensure that the Commission continues to receive useful contributions so that it can determine how to best position itself in order to protect its strategic interests and those of its industry, workers and citizens.

We have also considered whether the risks attached to the release of attachment 1 to document 5 are outweighed by the public interest in accessing the identified document. We have not been able to identify any such public interest capable of demonstrating the existence of a public interest that would override the need to protect the decision-making process of the Commission related to parameters of planned commercial policy measures.

4. **Means of Review**

In accordance with Article 7(2) of Regulation 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  
Secretariat-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

Yours faithfully,

Sabine Weyand

Enclosures:  
Annex 1: List of documents  
Documents (partially) released