



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Resource management and better regulation
Better regulation

Brussels
SANTE.A.1/CF

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Dear Sir, / Dear Madam

**1. SUBJECT: YOUR APPLICATION FOR ACCESS TO DOCUMENTS – GESTDEM
2020/7877**

We refer to your letter of 18 December 2020, in which you make a request for access to documents, registered on 07 January 2021 under the above-mentioned reference number.

In your request you ask, on the basis of Regulation (EC) No 1049/2001¹, access to:

- *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).*
- *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)*

We also refer to your reply to our clarification request dated 20 January 2021, in which you clarified the following:

I am requesting all documents which contain the following information, not only related to Covid-19: (...)

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

Your application concerns a very large number of documents, which need to be assessed individually.

The analysis of these documents cannot be expected to be completed within the normal time limits set out in Article 7 of Regulation (EC) No 1049/2001.

However, Article 6(3) of Regulation (EC) No 1049/2001 also provides for the possibility to confer with an applicant informally with a view to finding a fair solution when an application concerns a very large number of documents.

In accordance with the case law of the EU Courts, such a solution can only concern the content or the number of documents requested, not the deadline for replying². This means that the scope of the request must be reduced in a way that would enable its processing within the extended deadline of 15 + 15 working days.

Please note that potentially more than 150 documents may be identified as falling under the scope of your request.

In this respect, it would be helpful if you could be more specific about the nature or topic of the documents concerned. Thus, we invite you to choose among the following potential topics, which seem to be flagged in your request:

1. Meeting between the commissioners and association to prevent shortages of medicines, Shortages, availability, strategic autonomy;
2. Clinical Trials;
3. Falsified;
4. Health data;
5. GDPR/secondary use of data for medicines developers;
6. COVID;
7. Pharma strategy;
8. Orphan and paediatrics (revision of legislation).

According to our first estimates, the handling of your request would take 70 working days, broken down as follows:

- identification of the documents falling under your request: 10 working days;
- retrieval and establishment of a complete list of the documents identified: 10 working days;
- assessment of the content of the documents in light of the exceptions of Article 4 of Regulation (EC) No 1049/2001: 10 working days
- third-party consultations under Article 4(4): 6 working days;
- final assessment of the documents in light of the comments received: 3 working days;
- drafting of the reply: 2 working days;
- redaction of those parts of the documents to which one or several exceptions apply: 24 working days;
- internal review and approval of the draft decision: 4 working days; and
- preparation of the reply and the documents for dispatch (administrative processing etc.): 1 working day.

² Judgment of the Court of Justice of 2 October 2014, *Strack v European Commission*, C-127/13, (hereinafter referred to as the 'Strack v Commission judgment'), EU:C:2014:2250, paragraphs 26-28.

Based on the above-mentioned provision, we propose to **narrow down the scope** of your application to **four of the topics listed above**. We suggest you to restrain the scope to documents related to **topics under points 1, 2, 6 and 7** (namely, 1. Meeting between the commissioners and association to prevent shortages of medicines, Shortages, availability, strategic autonomy; 2. Clinical Trials; 6. COVID; 7. Pharma strategy).

Moreover, you requested access to the above mentioned documents from 1st March 2020. As also the temporal scope of your request would not allow the request to be completed within the normal time limits set out in Article 7 of Regulation (EC) No 1049/2001, we would ask you to reduce the time-frame, in order to reach a more manageable amount of documents.

Therefore, we would kindly ask whether you could narrow down the scope of your application to four of the topics listed above (i.e. topics under points 1, 2, 6 and 7) and to reduce the time-frame to the last four months.

Please note that this request is without prejudice to the assessment of the content of the documents that the Commission will need to make in view of their possible disclosure.

In order to enable us to respect the time-limits of Regulation (EC) No 1049/2001, we would ask you for a swift reply to our invitation to propose a fair solution, within five working days at the latest:

- by e-mail to: SANTE-ACCESS-TO-DOCUMENTS@ec.europa.eu; or

If you have any questions concerning the invitation, you can contact us:

- by e-mail at: SANTE-ACCESS-TO-DOCUMENTS@ec.europa.eu

In the absence of a reply within five working days, we will unilaterally restrict the scope of your application to those parts that can be dealt with within the extended deadline of 30 working days, counting from the registration of your application, expiring on 03 March 2021.

Thank you in advance for your understanding.

Yours faithfully,

Carmen GARAU
Head of Unit