



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Digital Health, European Reference Networks

Brussels
SANTE.DDG1.B.3

Lora Verheecke

By email only:
ask+request-10780-87a36cab@asktheeu.org

Dear Ms Verheecke,

Subject: Your application for access to documents – GESTDEM 2022/1270

We refer to your e-mail of 2 March 2022 in which you make a request for access to documents, registered under the above-mentioned reference number.

We refer also to our letter of 23 March 2022 extending the time limit to respond to your request according to Article 7 (3) of Regulation (EC) No 1049/2001.

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

- 1. Any documents, including briefings, reports, correspondence (email or other), between DG Sante and any external stakeholders where the European Health Data Space is concerned or mentioned.*
- 2. A list of meetings, as well as agendas and minutes or any other reports of such meetings, since 1st January 2021, between officials/representatives/experts of DG Sante and any external stakeholders related directly or indirectly to the European Health Data Space.*

The handling of your request concerns a very large number of documents, which need to be assessed individually, many of them originating from third parties or Member States. The detailed analysis of these documents, together with the need to consult the third parties concerned in accordance with Article 4(4) and 4(5) of Regulation (EC) No 1049/2001, cannot be expected to be completed within the normal time limits set out in Article 7 of Regulation (EC) No1049/2001.

However, Article 6(3) of Regulation (EC) No 1049/2001 also provides for a possibility to confer with an applicant informally with a view to finding a fair solution when an application relates to a very long document or 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 replying¹. 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.

Based on the above-mentioned provision, we would kindly ask you to specify the objective of your application and your specific interest in the documents requested², and whether you could narrow down the scope of your application (i.e. the subject matter(s) and/or timeframe covered), so as to reduce it to a more manageable amount of documents.

In order to help you to narrow down your application, please note that the following categories of documents have been provisionally identified as falling under the scope of your request:

- *Any documents, including briefings, reports, correspondence (email or other), between DG Sante and any external stakeholders where the European Health Data Space is concerned or mentioned.*

We have identified approximately 80 documents so far (as your request does not include any timeframe, this number may still increase).

- *A list of meetings, as well as agendas and minutes or any other reports of such meetings, since 1st January 2021, between officials/representatives/experts of DG Sante and any external stakeholders related directly or indirectly to the European Health Data Space.*

We have identified approximately 600 documents so far.

According to our first estimates, the handling of your request would take approximately 80 working days³, broken down as follows:

- identification of the documents falling under your request, retrieval and establishment of a complete list of the documents identified: 20 working days;
- assessment of the content of the documents in light of the exceptions of Article 4 of Regulation (EC) No 1049/2001: 20 working days;
- third-party / Member State consultations under Article 4(4) and Article 4(5) of Regulation (EC) No 1049/2001: 10 working days;
- final assessment of the documents in light of the comments received: 8 working days;
- drafting of the reply: 2 working days;
- redaction of those parts of the documents to which one or several exceptions apply: 10 working days;
- internal review and approval of the draft decision: 10 working days;

¹ 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.

² *Strack v Commission* judgment, paragraph 28; Judgment of the General Court (then 'Court of First Instance') of 22 May 2012, *EnBW Energie Baden-Württemberg v European Commission*, T-344/08, EU:T:2012:242, paragraph 105.

³ Taking into account other applications for access to documents and other tasks that the staff concerned are likely to have to deal with during the same period.

Please note that, according to our first estimates and considering the complexity of the content and the need to carry out third party consultations on a large number of documents, in this case a maximum of **60 documents** can be dealt with within the extended deadline of 30 working days, counting from the date of registration of your request.

Therefore, in order to provide a more reasonable number of documents falling within the scope of the request, we would suggest you to restrict the timeframe of your request for documents under both points 1 and 2 above to cover the period from 1 January 2022 until the date of your request, i.e. 2 March 2022.

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-consult-b3@ec.europa.eu
- cc: sante-access-to-documents@ec.europa.eu

If you have any questions concerning the invitation, you can contact us at the same address

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.

Thank you in advance for your understanding.

Yours sincerely,

Ioana-Maria GLIGOR
Head of Unit