Registered letter with acknowledgement of receipt

Subject: Your application for access to documents – GestDem 2022/1261

Dear Ms Verheecke,

We refer to your email dated 2 March 2022 wherein you make a request for access to documents pursuant to Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (hereinafter ‘Regulation 1049/2001’), registered under the abovementioned reference number. We also refer to our email, dated 23 March 2022 (under the reference number Ares(2022)2132160), whereby we informed you that the time limit for handling your application was extended by 15 working days pursuant to Article 7(3) of Regulation 1049/2001.

1. SCOPE OF YOUR APPLICATION

By your application, you request access to the following documents:

''1. Any documents, including briefings, reports, correspondence (email or other), between DG Connect 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 Connect and any external stakeholders related directly or indirectly to the European Health Data Space’’

Given the wide-scope of your request we contacted you on 23 March 2022 with a view to finding a fair solution based on Article 6(3) of Regulation 1049/2001 (our reference, Ares(2022)2132160). In order to help you narrow down the scope of the request, we
provided you with the categories of documents and estimate number of documents per category that had been identified at that stage. By your email dated 24 March 2022 (our reference, Ares(2022) 3797817), you asked as a first step that we send you the list of the concerned meetings. By our email dated 8 April 2022 (our reference Ares(2022) 2764839) we sent you the list of meetings which we have identified based on our research.

By your email dated 11 April 2022, (our reference Ares(2022)2985265), you requested access to documents related to the following meetings:

- Meeting with Bayer dated 12 October 2021;
- Meeting of the European Council - March 2021 dated 25 March 2021;
- Informal videoconference of the Ministers of Telecommunications dated 14 October 2021;
- Webinar on ‘Collaboration towards the Acceptance of the European Health Data Space’ dated 21 May 2021;
- Webinar on ‘Acceptance of the European Health Data Space’ dated 10 September 2021;
- Ministerial and High Level Conference dated 2 February 2022;
- Meeting of DIGITAL EUROPE on Virtual Twins for Health and Care dated 18 January 2022.

Please note that some of the abovementioned meetings covered several topics. Taking into account the scope of your request, we have proceeded to the identification of those documents which are relevant to the designated meetings and relate directly or indirectly to the European Health Data Space.

2. DOCUMENTS FALLING WITHIN THE SCOPE OF THE REQUEST

We have identified the following documents as falling within the scope of your application after having been restricted as set out above:

- Draft agenda from the webinar on ‘Acceptance of the European Health Data Space’ of 10 September 2021 – Document 1
- List of actions from the webinar on ‘Acceptance of the European Health Data Space’ of 10 September 2021- Scaling up cross border reuse of health data, attached to the below mentioned email of 10 November 2021 – Document 2
- Invitation to the webinar on ‘Acceptance of the European Health Data Space’ of 10 September 2021 – Document 3
- Email dated 17 May 2021 relating to the webinar on ‘Collaboration towards the Acceptance of the European Health Data Space’ of 21 May 2021 – Document 4
- Back To Office (BTO) report from the meeting on 12 October 2021 with Bayer – Document 5
- Back To Office (BTO) report from the meeting with DIGITAL EUROPE of 18 January 2022 – Document 6
- Email dated 10 November 2021- Follow-up material from the webinar on ‘Acceptance of the European Health Data Space’ of 10 September 2021 – Document 7
- Policy paper on Interoperability from the webinar on ‘Acceptance of the European Health Data Space’ of 10 September 2021, attached to the abovementioned email of 10 November 2021 – Document 8
• Working Group (WG3) document on the cross-border uptake of digital health services and products from the webinar on ‘Acceptance of the European Health Data Space’ of 10 September 2021, attached to the abovementioned email of 10 November 2021 – Document 9
• Working Group (WG4) document on the cross-border uptake of artificial intelligence for health from the webinar on ‘Acceptance of the European Health Data Space’ of 10 September 2021, attached to the abovementioned email of 10 November 2021 – Document 10
• Briefing from the meeting on 12 October 2021 with Bayer – Document 11
• Briefing from the High Level Ministerial Conference of 2 February 2022, ‘Citizenship, Ethics and Health Data’ – Document 12
• Briefing from the meeting of 25 March 2021 of the European Council (Document 13a, 13b, 13c)

3. ASSESSMENT UNDER REGULATION 1049/2001

Following an examination of the identified documents under the provisions of Regulation 1049/2001, we have arrived at the conclusion that full access can be granted to two documents. Partial access can be granted to five documents whilst access is denied for the remaining documents, as disclosure of these parts is prevented by exceptions to the right of access laid down in Article 4 of Regulation 1049/2001.

A. Full disclosure

Documents 1 and 2 are fully disclosed.

B. Partial disclosure

   (i) Protection of privacy and integrity of individuals

Full disclosure of Documents 3-6 is prevented by the exception concerning the protection of privacy and integrity of the individual outlined in Article 4(1)(b) Regulation 1049/2001, since they contain the following personal data:

- Names, functions and contact details of Commission staff members not pertaining to the senior management;

- Names, functions, and contact details of other natural persons.

Article 9(1)(b) of the Data Protection Regulation¹ 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 have concluded that, pursuant to Article 4(1)(b) Regulation 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.

(ii) Protection of commercial interests

Article 4(2) first indent of Regulation 1049/2001 provides that the 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.

This provision must be interpreted in light of Article 339 of the Treaty of the Functioning of the European Union (TFEU), which requires staff members of the EU institutions to refrain from disclosing information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components.

Part of Document 7 is covered by the aforementioned exception of Article 4(2). In particular, it contains information directly linked to Documents 8-10 for which access is refused by the application of the exception of Article 4(2) and for the reasons set out in Section C (i) below.

(iii) Protection of the decision-making process

The first subparagraph of Article 4(3) of Regulation 1049/2001 provides that ‘[a]ccess to a document, drawn up by an institution for internal use or received by the 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.’

Part of Document 7 is covered by the aforementioned exception of Article 4(3) first paragraph. In particular, it contains information directly linked to Documents 8-10 for which access is refused by the application of the exception of Article 4(3) first paragraph, as set out in Section C (ii) below.

C. Non-disclosure

We regret to inform you that access to Documents 8-13(a-c) cannot be granted as their disclosure is prevented by exceptions laid down in Article 4 of Regulation 1049/2001.

(i) Protection of commercial interests

Documents 8-10 are covered by the abovementioned exception of Article 4(2) first indent of Regulation 1049/2001, since they contain sensitive information relating to the views and positions of organisations participating in the European Health Data Space initiative. There is a real and non-hypothetical risk that disclosure of these documents could undermine and seriously affect the commercial interests of these organisations.

(ii) Protection of the decision-making process

Disclosure of Documents 8-13(a-c) is prevented by the abovementioned exception of Article 4(3) first paragraph of the Regulation 1049/2001. In particular, the documents
relate to the ongoing initiatives on the European Health Data Space. Disclosure of these parts would seriously undermine the protection of the relevant ongoing decision-making processes, if publicly released.

Moreover parts of the Documents 8, 11 and 13(a-c) contain personal data, in particular the names and contact details of Commission staff members not pertaining to the senior management and the names, contact and CV details of other natural persons, thus their disclosure is prevented by the exception of Article 4(1)(b) of Regulation 1049/2001 for the reasons set out in Section B (i).

Furthermore, parts of Documents 11 and 13(a-c) fall outside the scope of this request as they do not relate directly or indirectly to the European Health Data Space.

Consequently access to documents 8-13(a-c) is refused in full.

4. **PARTIAL ACCESS**

We have considered whether partial access could be granted to the parts of documents to which access is refused. However, partial access is not possible considering that these parts are covered in their entirety by the abovementioned exceptions of Article 4 of Regulation 1049/2001.

5. **OVERRIDING PUBLIC INTEREST IN DISCLOSURE**

The exceptions laid down in Article 4(2) and Article 4(3) of Regulation 1049/2001 apply, unless there is an overriding public interest in the disclosure of documents. Such an interest must, firstly, be a public interest and, secondly, outweigh the harm caused by disclosure. We have examined whether there could be an overriding public interest in the disclosure of the parts of the documents which are being withheld but we have not been able to identify such an interest.

6. **REUSE OF DOCUMENTS**

You may reuse documents 1-7 which have been produced by the European Commission or by public and private entities on its behalf based on the Commission Decision on the reuse of the Commission documents. 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 documents 5-6 were drawn up for internal use under the responsibility of the relevant services of DG CONNECT. 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. They do not reflect the position of the Commission and cannot be quoted as such.

7. **CONFIRMATORY APPLICATION**

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 Secretariat-General of the Commission at the following address:
Yours sincerely,

Electronically signed

Roberto Viola

Enclosures: (7)