Subject: Request for access to documents
Ref.: Your request of 27 June 2019 registered under reference GestDem 2019/3711

Dear Ms McArdle,

We refer to your request for access to documents within the framework of Regulation (EC) No 1049/2001, addressed to the Directorate-General for Research and Innovation. Your request was registered on 27 June 2019 under the above-mentioned reference number.

1. SCOPE OF THE REQUEST

You requested the following:

“[…] documents which contain the following information:
- From DG RTD (including the cabinet of R&I Commissioner Moedas):
- from or to: Innovative Medicines Initiative (IMI), EFPIA, ECHAlliance, MedTech Europe
- including briefings, reports, correspondence (email or other), including all attachments to the said correspondence,
- a list of all meetings, as well as agendas and minutes or any other reports of such meetings.
- between March 2018 and today”.

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After a first assessment of your request, on 29 July 2019 we informed you that we had identified 70 documents falling under the scope of your request, divided in different categories, and 2 ongoing audit files, performed on projects handled by IMI2 JU. In this regard, we also informed you that on average one audit file may include approximately 300 documents which relate to the planning of the audit, the audit input file, the examination and the closure of the procedure, including exchanges with the auditee.

Considering the high number of documents involved, and the fact that many of them concern third parties which should be consulted, the analysis of these documents could not be expected to be completed within the normal time limits set out in Article 7 of Regulation 1049/2001. We therefore suggested to you to restrict the scope of your request to a manageable number. In particular we clarified that, according to our estimates, a maximum of 20 documents could be dealt with within the extended deadline of 30 working days.

In order to help you in doing so, we provided you with the below categories of documents that have been identified as falling under the scope of the request:

a) documents exchanged between the Directorate General for Research and Innovation and the identified organisations/entities (approximately 36 documents). More specifically:
   - documents concerning meetings with the JU, such as minutes of the meetings of the IMI 2 JU Governing Board, emails concerning meetings (e.g. containing their agendas), minutes/conclusions of meetings (approximately 29 documents).
   - two notes on budgetary issues, one of which concerning IMI2 JU and one concerning IMI2 JU and EFPIA.
   - miscellaneous e-mail exchanges;

b) documents exchanged between the Cabinet of Commissioner Moedas and the requested organisations/entities (approximately 33 documents):
   - approximately 25 documents referring to EFPIA,
   - 4 documents referring to IMI2 JU,
   - 4 documents referring to MedTech;

c) documents concerning the identified audit files, each of which concerns different audits performed on projects under H2020 (approximately 300 documents per audit file).

In our communication of 29 July 2019 we also clarified that no documents had been identified as falling under the scope of the request concerning ECHAlliance.

Therefore, in order to reconcile your interest in obtaining the requested documents with the efficiency of the Institution’s administration, we have proposed the following options of restricting the scope of your request:
• documents only under category **b** (e.g. 20 documents exchanged between the Cabinet of Commissioner Moedas and the requested organisations)

• documents under categories **a** and **b**, but relating only to one entity which needs to be consulted (e.g. 20 documents under categories **a** and **b** related to IMI2 ),

while remaining open to other options that could help narrowing down the request without compromising your interest in public access.

On 1 August 2019 you replied to our proposal on the restriction of the scope of your request by submitting a counterproposal covering documents falling only under category **a** (‘e.g. 20 documents exchanged between the Directorate General for Research and Innovation and the identified organisations ’).

We have therefore identified and analysed 20 documents, including attachments, falling under the scope of your request (hereinafter the ‘requested documents’), namely:

1. Minutes of the 18th extraordinary meeting of the IMI2 Governing Board held on 09.03.2018 by audio-conference, registered under reference Ares(2018)1655388.
2. Email of 19/06/2019 from DG Research and Innovation to IMI and EFPIA on the implementing rules of the Staff Regulation.
4. Email of the 19/06/2019 from DG RTD to IMI and EFPIA on the minutes of the 25th meeting of the Governing Board.
5. Minutes of the 22nd extraordinary meeting of the IMI2 Governing Board held on 13.07.2018.
6. Minutes of the meeting of 7 September 2018 between the Director-General with EFPIA.
18. Minutes of the 25th meeting of the IMI2 JU Governing Board held on 05.04.2019.
19. Decision adopting the minutes of the 25th meeting of the IMI2 JU Governing Board.
20. Email of the 09/04/2019 from DG RTD to IMI on the nomination of the reporting officers.

In addition, please note that some decisions of the Governing Board of IMI2 JU, which may be of interest to you, are publicly available on the IMI2 JU website (https://www.imi.europa.eu/about-imi/governance/governing-board).

2. EXAMINATION UNDER REGULATION (EC) NO 1049/2001

After having examined the requested documents under the provisions of Regulation (EC) 1049/2001 and having consulted the third party from which some of them originate, we have reached the following conclusion.

2.1 Partial access

A. Protection of privacy and integrity of the individual (all documents)

According to Article 4(1)(b) of Regulation (EC) 1049/2001, access to documents is refused where disclosure would undermine the protection of "privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data".

The applicable legislation in this field is Regulation (EU) 2018/1725.

All of the disclosed documents contain personal data, such as names, functions, telephone numbers, electronic and professional email addresses, office numbers, details concerning professional or academic activities, of Commission’s officials not having the function of senior management staff and of the third parties identified in the documents.

This information clearly constitutes personal data within the meaning of Article 3(1) of Regulation (EU) 2018/1725. Pursuant to Article 9(1)(b) of Regulation (EU) 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’.

According to Article 9(1)(b) of Regulation (EU) 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. In your request, you do not put

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forward any arguments to establish the necessity to have the data transmitted for a specific purpose in the public interest.

Based on the above, personal data have been withheld from the requested documents, with the exception of names of individuals forming part of senior management staff of the Commission.

Please note that the exception of Article 4(1)(b) has an absolute character and does not envisage the possibility of demonstrating the existence of an overriding public interest.

**B. Protection of decision-making (documents No 10 and 18)**

According to Article 4(3) of Regulation (EC) 1049/2001, “access 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 yet by the institution, shall be refused if disclosure of the document would seriously undermine the institution’s decision-making process”.

Documents under reference numbers 10 and 18 contain opinion for internal use as part of deliberations and preliminary consultations, the disclosure of which could seriously undermine the so-called “space to think” of the institution.

In particular, the redacted parts refer to preliminary observations on the consequences of the current negotiation linked to the “Brexit”. Disclosure of those references would lead to misinterpretations and misunderstandings that would seriously undermine the decision-making process of the Commission and/or of the Joint Undertaking, as those positions are only preliminary and not meant for the public domain. Public disclosure, at this stage, would undermine a frank and sincere discussion among the relevant services and seriously undermine the decision-making process, as it would deprive the institution and/or body of a frank internal dialogue on this and similar matters in the future.

Consequently, we consider that those parts of documents n. 10 and 18 contain information covered by the exception laid down in Article 4(3) of Regulation 1049/2001, and therefore cannot be disclosed.

3. **DISCLAIMER AND RE-USE OF THE DOCUMENTS**

The requested documents were drawn up for internal use under the responsibility of the relevant service of the Commission or sent by third parties.

You may reuse the disclosed documents, to the extent that they originate from the European Commission, 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.

With regards to the parts of the disclosed documents originating from third parties, please note that these parts are disclosed for information only and cannot be re-used without the agreement of the originator.

The disclosed documents do not reflect the position of the Commission and cannot be quoted as such.

4. **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
Unit C.1 – Transparency, document management & access to documents
BERL 7/076
B-1049 Brussels

or by email to: sg-acc-doc@ec.europa.eu

Yours faithfully,

Jean-Eric Paquet

Enclosures: The requested documents with redactions, as explained above.