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By registered letter with acknowledgment of receipt

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Subject: Your application for public access to documents – GestDem Ref No 2019/1891; 2019/1895; 2019/1904; 2019/1905; 2019/1906; 2019/1907; 2019/1909; 2019/1910; 2019/1911; 2019/1924; 2019/1926; 2019/1927; 2019/1928; 2019/1929; 2019/1930.

Dear Ms McArdle,

We refer to your emails dated 22, 25 and 26 March 2019 in which you submitted, within the framework of Regulation (EC) 1049/2001[1], 15 applications for access to documents.

[1] 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 (OJ L 145, 31.5.2001, p. 43) , hereinafter referred to as 'Regulation (EC) 1049/2001'.

Your 15 requests were registered on 28 March 2019 under the above-mentioned reference numbers.

1. SCOPE OF YOUR REQUEST

You requests cover a period of time between 1st January 2015 and 22nd of March 2019 and concern:

- "*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;*"
- from, to, or mentioning or related to the following entities, as extracted from your different access to documents applications: the European Federation of Pharmaceutical Industries and Associations (EFPIA), EBE-Biopharma, Vaccines Europe, Innovative Medicine's Initiative and/or IMI2, MedTech Europe, ECHAlliance, GIRP - European Healthcare Distribution Association, Nanotechnology Industries Association, Bayer Pharma, Pfizer, Janssen, Thermo Fisher Scientific, Johnson & Johnson (J&J), Novo Nordisk, Imidia, Sanofi / Sanofi Pasteur, Lilly, Novartis, Abbott Vascular, Merck Seronon, DaiichiSankyo, Genzyme, Orionpharma, UCB pharma /UCB Celltech, GlaxoSmithKline (GSK), Abbvie, Biogen Idec, Lundbeck, Vifor Pharma, Miltenyi Biotec GmbH, SomaLogic Limited, Takeda, BIOASTER, Recipharm AB, bioMérieux, Taros Chemicals GmbH & Co. KG, Proteome Sciences plc, SAP Germany, Astellas Pharma Europe B.V., MIMETAS, Siemens Healthineers, The Hyve, BIOFORTIS, F.Hoffmann-La Roche AG, FASTinov SA, SCIMED Biotechnologies Ltd., Almirall, Nokia, Vodafone, Orange S.A., Hitachi Ltd, or anybody acting on its behalf or together with them.

After examination of the scope of your requests, it appeared that your applications concerned a very large number of documents, which would need to be assessed individually. In the light of the fact that such a detailed analysis cannot be carried out within the normal time limits, we informed you by email dated 09 April 2019 that you had submitted a very wide-scoped request even if formally introduced as separate requests.

Consequently, we invited you, pursuant to Article 6(3) of Regulation 1049/2001, to propose a fair solution for dealing with your wide-scoped request.

We explained that such a fair solution could consist of narrowing down the scope of your request, so as to reduce it to a more manageable amount of documents.

We also indicated that the handling of your request would require covering the following steps:

- search for documents related to the criteria as per your request;
- consultation with the operational units within the Directorate responsible for the requested documents;

- retrieval and establishment of a complete list of the documents falling under the scope of your requests;
- scanning of the documents which are not in pdf format;
- preliminary assessment of the content of the documents in light of any potential exceptions under Article 4 of Regulation 1049/2001;
- consultation of third parties, authors of documents concerned, if need be;
- final assessment of the documents in light of the results of the consultations of different services and/or third parties
- redactions of the relevant parts falling under exceptions of Regulation EC 1049/2001;
- preparation of the draft reply and finalisation of it at administrative level, formal approvals of the draft decision;
- final check of the documents to be partially released, if applicable (scanning of the redacted versions, administrative treatment…) and dispatch of the reply.

In this context, you were invited to specify the objective of your requests, your specific interest in the requested documents and to narrow down its scope. We then proposed one of the following alternative options in order to limit the excessive administrative burden relating to the handling of your request:

- either restrict the scope of your request to meetings held by the senior management (which means Commissioner Carlos Moedas, members of his cabinet and Director General of DG Research and Technological Innovation) and to documents related to the meetings published in the Transparency Register;
- or restrict the scope of your request to documents of the senior management (which means Commissioner Carlos Moedas, members of his cabinet and Director General of DG RTD) and limit the number of the requests you submitted to us to 3 requests of your choice;

while remaining open to other possible options that would have helped to narrow down significantly the request.

In your reply of 18 April 2019, you reformulated your request as follows:

"- from the Research Commissioner Moedas and/or members of his cabinet, as well as from DG RTD

- from or to:

the European Federation of Pharmaceutical Industries and Associations (EFPIA), EBE-Biopharma, Vaccines Europe, Innovative Medicine's Initiative and/or IMI2, MedTech Europe, ECHAlliance, GIRP - European Healthcare Distribution Association, Nanotechnology Industries Association, Bayer Pharma, Pfizer, Janssen, Thermo Fisher Scientific, Johnson & Johnson (J&J), Novo Nordisk, Imidia, Sanofi / Sanofi Pasteur, Lilly, Novartis, Abbott Vascular, Merck Seronon, DaiichiSankyo, Genzyme, Orionpharma, UCB pharma /UCB Celltech, GlaxoSmithKline (GSK), Abbvie, Biogen Idec, Lundbeck, Vifor Pharma, Miltenyi Biotec GmbH, SomaLogic Limited, Takeda, BIOASTER, Recipharm AB, bioMérieux, Taros Chemicals GmbH & Co. KG, Proteome Sciences plc, SAP Germany, Astellas Pharma Europe B.V., MIMETAS, Siemens

Healthineers, The Hyve, BIOFORTIS, F.Hoffmann-La Roche AG, FASTinov SA, SCIMED Biotechnologies Ltd., Almirall, Nokia, Vodafone, Orange S.A., Hitachi Ltd.;

- 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 May 1st 2016 and today.

I have considered your proposal to narrow the scope of my request to correspondence or meeting minutes between the above-mentioned groups and DG RTD's senior management; but this restriction would be excessive as it would completely exclude the technical levels of DG RTD, that are very relevant for analysing lobbying activities."

By our e-mail of 26 April 2019, we assessed the solution you proposed and we asked you to further restrict your request, as its scope was still too broad for being handled within the deadline set out in Article 7 of Regulation 1049/2001. We clarified that the purpose of this attempt to find a common agreement on the reduction of scope is to process your request and provide you with a reply, both timely and aligned to your interests. For this reason, we invited you to reconsider a restriction of the scope of your request and to identify some documents, to which, within the framework of your research project, you would like to give priority.

In your reply of 29 April 2019 you proposed that we treat a part of your request within the deadline of 16 May 2019 and the remaining parts after this deadline.

In our e-mail of 02 May 2019 we informed you that we were unable to accept such a solution. Therefore we kindly asked you to identify the documents you would like to give priority to within the deadline of the 16 May 2019. In addition, we confirmed that if after receipt of our reply you considered that in the light of your research project you would be interested in having access to further documents, you could submit a new access to documents request, the scope of which should be equally manageable within the deadline of 15+15 working days.

In your last e-mail of 6 May 2019 you raised different issues about the handling of wide-scoped requests within the Commission. In this regard, please find below some additional explanations that we hope will help you to understand our position better.

First, you pointed out that it is difficult to adapt your request and reduce its scope without knowing exactly the amount of documents that each part of your requests cover.

On this point we have to clarify (as already indicated in our e-mail of 09 April) that an electronic search in the document management systems of the European Commission for "*people acting on behalf of the entities*" or "*together with them*" (which are the terms used by you in your request) does not yield results and therefore obliges us to much more time-consuming basic search.

In this sense, and concerning your request for an approximate number of documents, please notice that in case of particularly wide-scoped requests, like this one, the mere identification in a list of the documents that would fall within the scope of the request may represent a disproportionate workload. In this case, for instance, the search in one document management system for documents relating to 4 of the entities you mentioned took several hours and resulted in the identification of a total of 102 documents. This of course even before proceeding with the detailed treatment of the request as mentioned in the steps described above.

Secondly, you highlighted that you have already made an effort to reduce the number of documents and to prioritise a set of documents, claiming that the solution proposed by us suits only the institution's interests and hampers yours. You have pointed out that we base our arguments on the impossibility to comply with the 15+15 working days deadline, which you do not consider fair 'as it is well-known that many EU institutions frequently surpass the 15+15 working days limit'.

You also point out that the fair solution suggested by you (treating the request in batches) is actually in line with the Commission's own - and other EU bodies' - good practice when it comes to handling wide-scoped requests.

As already mentioned in our email of 26 April 2019, the Commission receives numerous requests for access to documents and unfortunately the resources the European Commission can devote to handling those requests are not unlimited. For this reason, Regulation 1049/2001 itself provides for a possibility to restrict the scope of a request, by conferring with the applicant, in case of a request covering a particularly long document or a very large number of documents, in order to find a fair solution (see Article 6.3).

We are aware that unfortunately the Commission has not always been in conditions of providing a reply within the prescribed time limit, and it is still struggling to meet these deadlines with the resources available. The Commission practice of negotiating a fair solution with the applicant in cases of wide-scoped requests intends to avoid, as much as possible, late replies in cases where the request received already appears not manageable within the deadline. Indeed, and with reference to your proposal to handle your requests in different parts, as done in the past by the Commission, we would like to point out that the desire to comply with the deadlines set by the Regulation is one of the reasons why the European Commission no longer handles wide scope requests via batches (please see the rule clarified by the Court of Justice in paragraphs 26-28 of the decision of the 2 October 2014, C-127/13). Pursuant to this decision, the proposal for a fair solution may concern only the number and content of the documents applied for, not the deadline for replying. Please consider that the recent position of the Commission results from a fresh reassessment of the legal consequences of the decision.

As a consequence of the above, we proposed you to restrict your request to a volume of documents that could be handled within the current deadline while offering you the possibility to submit a new request, should you still be interested in receiving further documents.

Unfortunately, as we could not agree on a fair solution, we see ourselves obliged to balance your possible interest in access against the workload resulting from the processing of your application.

As announced in our letter of 09 April 2019 we have therefore proceeded to the unilateral restriction of the scope of your application to the documents that can be dealt with within the current deadline.

We would like to reiterate that, if after receipt of our reply you consider that in the light of your research project you would be interested in having access to further documents, you may submit a new access to documents request, the scope of which should be equally manageable within the deadline of 15+15 working days.

Taking into account the fact that you have not given us any specific criteria on how to prioritise the documents to be sent to you, and in order to provide you with as many documents as possible within the legal deadline, we have identified, examined and we are pleased to provide you with:

- documents from or to IMI and EFPIA,
- 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 May 1st 2016 and 22 March 2019 (the date of the initial request), and which can be disclosed without consultation of third parties and after redaction of the mere personal data (so that we can provide you with as many documents as possible which are not subject to the need to wait for the results of the consultation with the third party).

As mentioned above, after reception of these documents you can introduce a new request for documents. We would however kindly ask you to take into account when assessing the need for a new request the workload that they may impose on our services, to the detriment of other requests/tasks to be performed.

Having said this, we confirm that within this deadline we have identified and processed 12 documents falling under the scope of your request (hereinafter the 'requested documents'), namely:

1. Experts Reports on the Final and Interim Evaluation of IMI JU;
2. Meeting of the 07-09-2018;
3. Minutes of the 26-05-2016;
4. Minutes of the 03-10-2016;
5. Minutes of the 07-06-2017;
6. Minutes of the 22-05-2018;
7. Minutes of the 24-04-2018;
8. Minutes of the 12-11-2018;
9. Note of the 31-01-2018;
10. Note of the 20-04-2018;

11. List of briefings for meetings 1May2016 - 22Mar2019;
12. List of meetings;
13. Interim evaluation of IMI;
14. Final evaluation of IMI.

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

Having examined the requested documents under the provisions of Regulation (EC) 1049/2001 and we are pleased to inform you that full access can be granted to documents n. 13 and 14.

You can access document n. 13 at the following link:

https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/KI-04-17-527-EN-N.pdf

and document n. 14 at the following link:

https://ec.europa.eu/research/health/pdf/imi_final_evaluation.pdf

However, partial access can be granted to the documents from 1 to 12. Some information has been withheld, as it concerns personal data, as explained below.

2.1 Protection of privacy and integrity of the individual

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[2].

The requested documents contain personal data such as names, surnames, email addresses, telephone and fax number, and signatures of certain members of the Commission staff and of third parties. This information clearly constitutes personal data in the meaning of Article 3(1) of Regulation 2018/1725.

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

[2] Regulation (EU) 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 45/2001 and Decision No 1247/2002/EC ('Regulation 2018/1725').

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 request, 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.

On the basis of 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.

3. MEANS OF REDRESS

In accordance with Article 7(2) of Regulation (EC) 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 SG C.1 – Transparency, document management & access to documents
BERL 5/282
B-1049 Brussels
or by email to: sg-acc-doc@ec.europa.eu

Yours faithfully,

Reinhard Schulte

Enclosure: requested documents expunged from information protected under Regulation 1049/2001.