EUROPEAN COMMISSION
EUROPEAN HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY

The Director-General

HERA.03/KB/al(2022)3172491

By registered letter
with acknowledgment of receipt[1]

Mr Alvaro Merino
Calle Jesús Goldero 19, Planta 1
El Orden Mundial,
28045 Madrid,
Spain

Advance copy by email
ask+request-8557-a9612316@asktheeu.org

Dear Mr Merino,

Subject: Your application for access to documents – GESTDEMS: 2020/5416, 2020/5428, 2020/5426 and 2020/5600

We refer to:

- your e-mails dated 14 September 2020 in which you made requests for access to documents, both registered on 15 September 2020 under the reference numbers GESTDEM 2020/5416 and 2020/5428;
- our letters of 2 October 2020 extending the time limit to respond to your requests GESTDEM 2020/5416 and 2020/5428, according to Article 7(3) of Regulation (EC) No 1049/2001;
- your reply to our clarification request of 23 October 2020;
- your e-mails dated 14 September 2020 in which you make requests for access to documents, registered on the 22 September under GESTDEM 2020/5426 and 2020/5600;
- our letter of 12 October 2020 extending the time limit to respond to the above mentioned requests, in accordance with Article 7(3) of Regulation (EC) No 1049/2001.
- DG SANTE letter of 10 March 2021 in which we provided you the list of the identified documents falling within the scope of your requests GESTDEM 2020/5416, 2020/5428, 2020/5426 and 2020/5600.
- DG SANTE letter of 25 June 2021 with a first batch of documents. DG SANTE disclosed in that batch the emails exchanged in the context of setting up the Steering

[1] According to standard operational procedure, the reply is usually also sent to you by registered post. Please note, however, that due to the extraordinary health and security measures currently in force during to the COVID-19 epidemics, which include the requirement for all Commission non-critical staff to telework, we are unfortunately not in a position to follow this procedure until further notice. We would therefore appreciate if you could confirm receipt of the present e-mail.

Board meetings and the agendas of these meetings.

- HERA letter of 15 December 2021 with a request to consider reducing the scope of your request to 125 documents such as agenda, emails, minutes of the Steering Board meetings, and final contracts. To date, HERA has not received a disagreement to our fair solution proposal.

Scope of your requests

In your requests, on the basis of Regulation (EC) No 1049/2001[2], you ask access to:

GESTDEM 2020/5416 and 5428

"*a) Meeting records (drafts, memos, invitations, appointments, cancellations) involving AstraZeneca, Sanofi-GSK, Johnson & Johnson, CureVac and Moderna officials and/or representatives.*

b) Correspondence exchanged with AstraZeneca, Sanofi-GSK, Johnson & Johnson, CureVac and Moderna officials and/or representatives, including all emails, minutes, reports, briefing papers or any other document received or drawn up before, during or after any meeting or conversation."

In your reply to our clarification request, you specified:

"*In my request I do refer to meetings and correspondence on Covid-19 vaccines and both meetings held individually with each company and collectively with all of them*".

GESTDEM 2020/5426 and 5600

"*Documents in which the decision of reaching a first agreement with the pharmaceutical company AstraZeneca to purchase a potential vaccine against COVID-19 is based. Also, documents reflecting the output/conclusions or drawn up after the exploratory talks with Sanofi-GSK, Johnson & Johnson, CureVac and Moderna*."

2. The first batch of documents

In letter sent on 25 June, DG SANTE proposed to handle your request in batches and provided you with a first batch of documents. The first batch of the identified documents that were initially considered to fall within the scope of your requests comprised 52 documents (including the published contracts). With this reply the Commission provided you with a partial access to some of the agendas of the Steering board meetings (including their emails and some attachments).

3. Transfer of your file to HERA

Since the beginning of the Covid-19 pandemic and the subsequent adoption of the EU Vaccines strategy, the Commission has been receiving a significant number of access to documents requests, submitted under the Regulation, related directly or indirectly to the procurement of COVID-19 vaccines. These requests often included a very large amount of sensitive documents, which needed to be consulted in accordance with Article 4(4) of the Regulation.

Due to specificity of document you requested, its complexity and the lengthy ongoing consultations with numerous third parties, DG SANTE was not able to provide you with a

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

response within normal time limits set out in Article 7 of Regulation (EC) No 1049/2001. We sincerely apologies for any inconvenience caused by this delay.

The Commission has acknowledged that the high public interest in this topic requires an adequate level of transparency. However, I would like to note that the right of access to documents is not a general and absolute right, but may be subject to limitations and restrictions, as recognized by the Courts. Transparency is indeed an essential component of the decision-making process of the EU. I would like to underline in this context that the European Commission regularly publishes information on the state of play of the negotiations with vaccine manufacturers and informs the public when a contract is concluded.

Nevertheless, the Commission has to ensure that any possible disclosure would not undermine the interests as laid down in Article 4 of the Regulation. Very importantly, the Commission has to make sure that the vaccine procurement and deployment process, which is an objective of the highest public interest, is not undermined in any manner.

Your application has now been assigned to the newly established European Health Emergency Preparedness and Response authority ('HERA').

4. Identification and assessment of the second and third batch of documents

The second batch of documents identified that fall within the scope of your request is made of 106 documents. You will find attached, for your convenience, the table listing the documents we are disclosing ("A.1 List of documents_second batch"). The disclosed documents are attached to this correspondence. This batch consist of Steering Board minutes and documents exchanged in the framework of setting up Steering Board meetings. In addition, this batch consist of reassessed COVID-19 vaccine contacts. Kindly note that we are in a process of finalizing the consultation with third parties on the remaining documents and we will provide you with these documents swiftly.

4.1. Full disclosure

Having examined the documents under the provisions of Regulation (EC) No 1049/2001, we have come to the conclusion, which is further explained in paragraphs 4, that full access can be granted to the documents: No 1.2 and 1.4

4.2. Partial disclosure

Having examined the documents under the provisions of Regulation (EC) No 1049/2001, we have come to the conclusion, which is further explained in paragraphs 4, that:

- partial access can be granted to the Steering Board minutes, email and agendas, and contracts namely documents No 02, 04, 07, 07.1, 08, 09, 9.1, 10, 12, 14, 16, 17, 18, 20, 22, 23, 23.1, 24, 26, 27, 28, 29, 31, 31.1, 35, 35.1, 36, 37, 38, 39, 39.1, 40, 41, 42, 44, 45, 46, 48, 50, 52, 54, 55, 57, 60, 61, 62, 64, 65, 66, 68, 69, 72, 74, 76, 78, 80, 81, 82, 84, 85, 86, 87, 88, 90, 112, 113, 114, 174, 175, 212, 260, 366, 367, 368, 368.1, 369, 370, 371, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385 as their full disclosure is prevented by several exceptions laid down in Article 4 of the Regulation.

4.2.1. Wider partial disclosure to COVID-19 vaccine contracts.

The European Commission had already made public the redacted versions of the majority of the identified contracts, available at the following link:

https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en

In accordance with article 4(4) of Regulation (EC) No 1049/2001, the European Commission undertook new consultations with the companies concerned on the (further) disclosure of the COVID-19 vaccine contracts. Having taken the replies from the companies and the European Commission's own assessment into account, I am pleased to inform you that wider partial access can now be granted to the requested documents, compared to what was previously disclosed. Partial access is also granted to those contracts which had not yet been publicly disclosed in a redacted form.

4.2.2 Wider partial disclosure to Steering Board minutes and other documents

I am pleased to inform you that following consultation and European Commission's own assessment we decided to grant a wider access to the requested documents and to disclose the parts of Steering Board minutes that fall outside of the scope of your request. Likewise, we are disclosing additional documents, which are directly relevant to your request but fall outside of the period and hence scope of your request (No 366, 367, 368, 368.1, 369, 370, 371, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385).

4.2.3. Reasons for partial disclosure

a. Protection of the privacy and integrity of individuals- Article 4(1)(b) of Regulation (EC) No 1049/2001

With regard to the documents to which partial access may be granted, a full disclosure is prevented by the exception concerning the protection of privacy and the integrity of the individual outlined in Article 4(1)(b) of Regulation (EC) No 1049/2001, because they contain the following personal data:

- other information relating to an identified or identifiable natural person, such as professional background, role, country they represent etc.

Article 9(1)(b) of the Data Protection Regulation 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, pursuant to Article 4(1)(b) of Regulation (EC) No 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 sufficiently 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.

b. Protection of the commercial interests of a legal person - Article 4(2), first indent, of Regulation (EC) No 1049/2001

Documents containing commercially sensitive information whose full disclosure would undermine the protection of the legitimate interests of companies are covered by the exception of the protection of commercial interest (Article 4(2), first indent, of Regulation (EC) No 1049/2001).

Such documents contain references to sensitive business information of the company, its

subcontractors and affiliated companies, such as scientific information on the vaccine, its price, the schedule to deploy the vaccine, its production capacity, its know-how, the involvement of experts or partners, business strategies, and other information carrying a commercial value.

The full disclosure of the requested documents would undermine not only the commercial interest of vaccines manufacturers, but also the decision-making process of the Commission, as it would reveal preliminary views and policy options related to the COVID-19 vaccines' strategy, which are currently under consideration by the Commission and the Member States, being vaccinations' campaign still ongoing. The exception laid down in Article 4(3) first subparagraph of Regulation (EC) No 1049/2001 applies to the documents identified above.

6. Reuse of disclosed documents

You may reuse public documents, 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 Commission documents[3]. 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 some of the documents entail preliminary drafts, which do not reflect the position of the Commission and cannot be quoted as such.

Please also note that the disclosure is without prejudice to the rules on intellectual property, which may limit your right to reproduce or exploit the released documents without the agreement of the originator, who may hold an intellectual property right on them. The European Commission does not assume any responsibility from their reuse.

Finally, please note that some of the documents were drawn up for internal use under the responsibility of the relevant services of the Directorate-General for Health and Food Safety. It solely reflects the services' interpretation of the interventions made and do not set out any official position of the third parties to which the documents refer, which were not consulted on their content. They do not reflect the position of the Commission and cannot be quoted as such.

7. 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, also in relation to this specific reply.

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 Secretariat-General
Transparency, Document Management & Access to Documents (SG.C.1)
BERL 7/076
B-1049 Bruxelles
or by email to: sg-acc-doc@ec.europa.eu

[3] Commission Decision 2011/833/EU of 12 December 2011 on the reuse of Commission documents, OJ L 330, 14.12.2011, p. 39–42.

Yours sincerely,

(e-signed)

Pierre DELSAUX
Director General