



## EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

SANTE.DG/DDG1/C.3/KB

***By registered letter  
with acknowledgment of receipt<sup>1</sup>***

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](mailto:ask+request-8557-a9612316@asktheeu.org)

Dear Mr Merino,

**Subject: Your application for access to documents – GESTDEM 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.

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<sup>1</sup> 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 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.

- our 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.

## 1. Scope of your requests

In your requests, on the basis of Regulation (EC) No 1049/2001<sup>2</sup>, 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 COVID-19 pandemic

Aware of the considerable delay in handling your request, we would like to offer you our apologies.

The sensitivity of the documents you are seeking access to required (and still requires) a thorough assessment, as their disclosure could potentially weaken the Commission position in ongoing negotiations, nullifying the beneficial effects of fair competition and seriously undermining the commercial interest of vaccines manufacturers.

In spite of the above and in the interest of providing as much transparency as we can within the constraints set by the ongoing challenges, we are doing our utmost to provide you with the documents listed in the table sent to you with our letter of 10 March 2021 and re-attached for your convenience.

As your applications relate to a significant number of documents, for some of which the assessment is still ongoing, we propose to handle your requests in batches.

Please find attached to this reply the first batch of documents.

With this reply, the Commission is providing partial access to some of the agendas of the Steering board meetings (including their emails and some attachments). The Commission has not yet concluded the assessment on whether access can be provided to the other documents listed in table sent to you with our letter of 10 March 2021.

For these documents, we will provide you with the outcome of that assessment in the coming

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

weeks.

### **3. Identification and assessment of the first batch of documents**

The first batch of the identified 280 documents that fall within the scope of your requests is made of 52 documents (including the published contracts).

You will find attached, for your convenience, the table sent to you with our letter of 10 March 2021 ("A. List of documents") and also a table listing the first batch of documents we are disclosing ("A.1 List of documents\_first batch").

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

- full access can be granted to documents No 1, 3, 5, 11, 13, 15, 25, 43, 47, 49, 49.2, 51, 51.2, 51.3, 53, 59, 63, 67, 69, 71, 75, 77, 79, 81 and 87
- partial access can be granted to documents No 1.1, 3.1, 5.1, 11.1, 13.1, 15.1, 21, 25.1, 43.1, 47.1, 49.1, 51.1, 53.1, 59.1, 63.1, 67.1, 71.1, 75.1, 77.1, 79.1, 81.1, 87.1, 107, 131, 168, 202 and 245 as their full disclosure is prevented by one of the exceptions to the right of access laid down in Article 4 of the Regulation.

Please note that redacted versions of the contracts signed with the pharmaceutical companies (documents No 107, 131, 168, 202 and 245) are publicly available and can be accessed from the following webpage:

[https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy\\_en#documents](https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en#documents)

Also more recent purchase agreements are published on the same webpage.

### **4. 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 documents No 1.1, 3.1, 5.1, 11.1, 13.1, 15.1, 21, 25.1, 43.1, 47.1, 49.1, 51.1, 53.1, 59.1, 63.1, 67.1, 71.1, 75.1, 77.1, 79.1, 81.1, 87.1, 107, 131, 168, 202 and 245, 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:

- the names/initials and contact details of natural persons;
- handwritten signatures/abbreviated signatures of natural persons;
- other information relating to an identified or identifiable natural person, such as professional background, role 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 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*
- c. *Protection of the decision making process- Article 4(3) first and second subparagraphs of Regulation (EC) No 1049/2001*

With regard to documents 107, 131, 168, 202 and 245 a full disclosure is prevented by the exceptions laid down in paragraphs (2) and (3) of Article 4 of Regulation (EC) No 1049/2001, concerning the protection of commercial interest of a legal person and the protection of the decision making process.

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). The (advanced) purchase agreements for purchasing COVID-19 vaccines to which you request access contain information relating to the commercial interest of vaccines manufacturers. If they were made fully public, their full disclosure could damage the competitive position of the companies as well as the ongoing procurement procedures for the purchase of COVID-19 vaccines.

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

The (advance) purchase agreements have been negotiated in the framework of a procurement procedure without publication of a contract notice on the basis of Article 164(1)(d) of the Financial Regulation<sup>3</sup> and are the outcome of those specific negotiated procedures.

In this regard, the Commission is acting as a central purchasing body in the name and on behalf of all Member States in order to ensure the (advance) purchase of vaccines against COVID-19, as provided for by the legislator in the ESI Regulation,<sup>4</sup> under its Article 4(5)(b).<sup>5</sup>

The Commission considers therefore all individual negotiated procurement procedures as a unique process for the (advance) purchase of COVID-19 vaccines from different companies, as the final objective is to build a sound and diverse portfolio of vaccine candidates at disposal of Member States.

As the case-law has confirmed, the protection of commercial interests within the meaning of Article 4(2) of Regulation 1049/2001 can be validly argued also as regards further similar (advance) purchase agreements, in which the Commission has the same position.<sup>6</sup> Full disclosure would also undermine the objective of genuine competition in the procurement procedures, currently on the point of being negotiated by the Commission, as protected by Article 170(3) last subparagraph of the Financial Regulation<sup>7</sup>. In the words of the Court, “*it is important that the contracting authorities do not release information relating to contract*

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<sup>3</sup> Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193, 30.7.2018, p. 1–222.

<sup>4</sup> Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union (OJ L 70, 16.3.2016, p. 1), as modified by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID- 19 outbreak.

<sup>5</sup> “*Emergency support under this Regulation may be granted in any of the following forms: [...] b) procurement by the Commission on behalf of Member States based on an agreement between the Commission and Member States*”.

<sup>6</sup> Judgment *CEE Bankwatch Network v Commission*, T-307/16, EU:T:2018:97, para. 111, last sentence.

<sup>7</sup> Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, published in the OJ L 193, 30.7.2018, p. 1–222.

*award procedures which could be used to distort competition, whether in an ongoing procurement procedure or in subsequent procedures”<sup>8</sup>.*

It should be concluded that 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, which are currently under consideration. Their disclosure would also reveal important aspects of the negotiation strategy of the Commission and options that may still be relevant for other similar negotiations, and thus weaken their possible outcome. Therefore, the exceptions laid down in Article 4(3) first and second subparagraphs of Regulation (EC) No 1049/2001 apply to the documents identified above.

## **5. Overriding public interests**

The exceptions to the right of access provided for in Article 4(2) and (3) of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosing the requested document. In your application, you did not submit any grounds concerning a public interest on the basis of which the interests protected in Regulation (EC) No 1049/2001 would have to be overridden, and we could not identify any such ground either. In these circumstances, we have to conclude that there is no evidence of an overriding public interest in disclosure, in the sense of Regulation (EC) No 1049/2001.

## **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](#)<sup>9</sup>. 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:

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<sup>8</sup> Case C-450/06, *Varec v Commission*, par. 35.

<sup>9</sup> Commission Decision 2011/833/EU of 12 December 2011 on the reuse of Commission documents, OJ L 330, 14.12.2011, p. 39–42.

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](mailto:sg-acc-doc@ec.europa.eu)

Yours sincerely,

(e-signed)

Sandra GALLINA  
Director General

Enclosure: Annexes with the lists of documents and documents disclosed