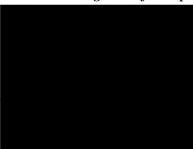


EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

SANTE.DG/DDG1/C.3/KB

By registered letter with acknowledgment of receipt¹





Subject: Your application for access to documents – GESTDEM 2021/0186

We refer to your e-mail dated 12 January 2021 in which you make a request for access to documents, registered on 13 January 2021 under the above-mentioned reference number.

We also refer to our email of 03 February 2021 extending the time limit to respond to your request in accordance with Article 7(3) of Regulation (EC) No 1049/2001.

1. Scope of your request

In your request, you ask, on the basis of Regulation (EC) No 1049/2001², access to:

"...The contract between the European Commission and pharmaceutical company Moderna to supply the company's COVID-19 vaccine..."

2. Identification and partial disclosure of the documents

We have identified two documents that fall within the scope of your request.

No.	Title	Reference
1	Moderna - Advance Purchase Agreement	Ares(2021)256592
2	Moderna - Purchase Agreement	Ares(2021)1601566

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 3 and 4, that partial access can be granted to all the documents, as their full disclosure is prevented by exceptions to the right of access laid down in Article 4 of the Regulation.

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.

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

A redacted version of the contracts you ask access to can be downloaded from the following webpage:

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

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 you request access to, 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;
- 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

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 vaccine manufacturer. If they were made fully public, their full disclosure could damage the competitive position of the company as well as the ongoing procurement procedures for the purchase of COVID-19 vaccines.

They 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 (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 Regulation³ and are the outcome of those specific negotiated procedures.

³ 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

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, 4 under its Article 4(5)(b).

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. ⁶ 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 Regulation⁷. In the words of the Court, "it is important that the contracting authorities do not release information relating to contract award procedures which could be used to distort competition, whether in an ongoing procurement procedure or in subsequent procedures".

It should be concluded that the full disclosure of the requested documents would undermine not only the commercial interest of the vaccine manufacturer, 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.

4. Overriding public interests

The exceptions to the right of access provided for in Article 4(2) and Article 4(3) of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosing the requested documents. 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.

5. 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 <u>Commission Decision on the reuse of Commission documents</u>⁹. 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

^{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.

⁴ 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.

⁵ "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".

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

⁷ 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.
⁸ Case C-450/06, *Varec v Commission*, par. 35.

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

not distort the original meaning or message of the documents. Please note that the Commission does not assume liability stemming from the reuse.

6. 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 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

Yours sincerely,

