

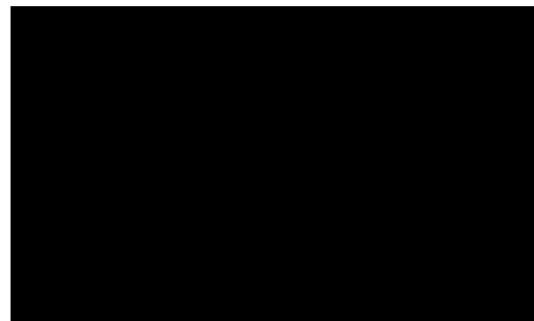


EUROPEAN COMMISSION
 DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels
 SANTE.DDG1.C.3/KB

***By registered letter
 with acknowledgment of receipt¹***



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Subject: Your application for access to documents – Gestdem 2021/0156

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

We also refer to our letter of 02 February 2021 extending the time limit to respond to your request according to Article 7(3) of Regulation (EC) No 1049/2001

1. Scope of your requests

In your requests, you ask, on the basis of Regulation (EC) No 1049/2001², access to: *“the contract with CureVac regarding the Covid-19 vaccine, which is currently being made available to the members of the European Parliament”*.

2. Identification and assessment of relevant documents

We have identified 1 document that falls within the scope of your requests, namely:

No.	Title	Reference
1	Contract signed - Sante/2020/C3/049 - SI2.838442 - APA for the development, production, priority-purchasing options and supply of covid-19 vaccine	Ares(2021)256728

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.

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

Having examined the document 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 the requested document, as its full disclosure is prevented by exceptions to the right of access laid down in Article 4 of the Regulation as further explained in the next paragraph.

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 document your request for 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 the document contains 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 document, 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 subparagraph 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 agreement (APA) for purchasing COVID-19 vaccines to which you request access contain information relating to the commercial interests of the relevant companies, which could potentially damage their competitive position and the ongoing procurement procedures for the purchase of COVID-19 vaccines, if they were made public.

Contracts with the above mentioned companies have been negotiated in the framework of procurement procedures without publication of a contract notice on the basis of Article 164(1)(d) of the Financial Regulation³.

Such contracts have been and still are being negotiated with the tenderers and are a unique outcome of the specific negotiated procedure.

They contain references to sensitive business information of the companies and tenderers such as (alternatively or cumulatively) methodologies, know-how, specific pricing, breakdown of budgets, involvement of experts or partners, information on detailed operational aspects, business strategies, detailed description of the proposed actions and other information carrying a commercial value.

Giving full access to the requested information could distort competition in current and future procedures, because of its commercial value or because its disclosure can prejudice the legitimate interests of economic operators who participate in the relevant procedures.

As such they must be protected in the same way as some of the elements in the evaluation report and the offer submitted by tenderers in the framework of the still pending procurement process in order to avoid economic operators with which the Commission is still negotiating to benefit from information becoming available on:

- contracts that have been already signed,
- tenders still under negotiations and
- commercial information belonging to competitors.

Therefore, documents outlining the position of the tenderer about single elements of the agreement deserve protection inasmuch as the offer of the tenderer includes each individual clause of each contract. In a procedure as the current one, where the submission of bids by different tenderers is not synchronised, releasing to the public any information on elements of an individually negotiated contract or commercial information on a product produced and sold by a company is susceptible of harming the competitive position of the tenderer vis à vis other tenderers or economic operators whose contracts are not yet signed, and vis à vis other possible procurement procedures they might wish to take part in.

The document you request access to contains many elements that are commercially sensitive not only for the company, such as scientific information on the relevant vaccine, its price, the schedule to deploy the vaccine, its production capacity etc. but also to the Commission, like for instance the time of payments and of scale up funding for investments in research.

Furthermore, in the concrete case of COVID-19 vaccines, as you may be aware, there are not only several closed negotiated procurement procedures for the award of similar APAs, but also procedures, which are still ongoing. 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).⁵ It should be recalled

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 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

that, as indicated by this provision and as further confirmed in the Commission Decision on the advance purchase of Covid 19 vaccines and in the agreement with the Member States appended thereto,⁶ this role has been granted to the Commission by the Member States not individually for the management of each single procurement procedure, but to run the whole procurement process.

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. Indeed, 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 contracts, in which the Commission has the same position.⁷ This is all the more true in the case at hand, given that these further contracts are actually on the point of being negotiated by the Commission on behalf and in the name of the Member States.

As regards the concrete effects that a public access to documents could have, given that disclosure of documents under Regulation (EC) No 1049/2001 is reputed to have *erga omnes* effect and therefore considered as a disclosure to the general public⁸, the Commission cannot disclose in full all the specific documents you are requesting access to. Otherwise, potential competitors of the companies you mention in your access request, including those with which the Commission is currently negotiating, could also get access either to commercial information from them or to any other possible information which could allow them to obtain a competitive advantage.

This would not only damage the companies' commercial interests, but also undermine the objective of genuine competition in the current procurement procedures, currently on the point of being negotiated by the Commission, as protected by Article 170(3) last subparagraph of the Financial Regulation⁹. 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*"¹⁰.

Moreover, this would be harmful for the whole procurement procedure run by the Commission, with a high risk of making the advance purchase of Covid 19 vaccines for all the Member States difficult if not impossible. In turn, this risk would further delay the effective access of the EU population to the vaccines.

It should be concluded that the full disclosure of the requested document would undermine the decision-making process of the Commission, as it would reveal preliminary views and policy options, which are currently under consideration; the Commission's services must be free to explore all possible options in preparation of a decision free from external pressure. The exception laid down in Article 4(3) first subparagraph of Regulation (EC) No 1049/2001 applies to the document identified above.

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 Commission Decision of 18.06.2020 approving the agreement with Member States on procuring Covid- 19 vaccines on behalf of the Member States and related procedures (C(2020) 4192 final).

⁷ Judgment CEE *Bankwatch Network v Commission*, T-307/16, EU:T:2018:97, para. 111, last sentence.

⁸ Case T-439/08, *Agapiou Joséphidès v Commission and EACEA*, par. 116.

⁹ 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.

¹⁰ Case C-450/06, *Varec v Commission*, par. 35.

In an effort to ensure as complete as possible transparency of the procurement process, we started discussions with the companies involved in that process about the possibility to disclose APAs concerning the purchase of COVID-19 vaccines.

You will be aware that those efforts have already born some fruit. Following consultations with CureVac AG on the public disclosure of a redacted version of their agreement with the European Commission for the purchase of COVID-19 vaccines, the decision was taken to make a redacted version thereof available on a webpage of the European Commission:

https://ec.europa.eu/info/files/curevac-redacted-advance-purchase-agreement_en

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](#). 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.

4. Overriding public interests

The exceptions to the right of access provided for in Article 4(2) 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.

5. 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 faithfully,

Sandra GALLINA

Director General