

EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels SANTE.DDG1.0.3/KB

By registered letter with acknowledgment of receipt¹



Subject: Your application for access to documents – GESTDEM 2020/6122

We refer to your e-mail dated 13 October 2020 in which you make a request for access to documents, registered on 14 October 2020 under the above-mentioned reference number.

We also refer to our letter of 04 November 2020 extending the time limit to respond to your request according to Article 7(3) of Regulation (EC) No $1049/2001^2$.

1. Scope of your request

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

All draft Advance Purchase Agreements with AstraZeneca, Sanofi-GSK and Johnson & Johnson to ensure the early delivery of COVID-19 vaccines.

2. Identification and partial disclosure or non disclosure of relevant documents

So far we have identified 23 documents that fall within the scope of your request.

You will find attached a table listing the identified documents.

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

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).

partial access can be granted to the final contracts, as their full disclosure is prevented by exceptions to the right of access laid down in Article 4 of the Regulation, while no access can be granted to earlier drafts thereof, as their release is prevented by the same exceptions.

Please find a redacted version of the final contracts you request access to published on the following website:

https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/euvaccines-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 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 final and draft agreements for purchasing COVID-19 vaccines to which you request access contain information relating to the commercial interests of respectively *AstraZeneca, Sanofi-GSK and Johnson & Johnson*. If they were made fully public, their full disclosure could potentially 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, its

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

The contracts 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 they are the outcome of this specific negotiated procedure.

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 $4(5)(b)^5$.

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 contracts, 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"*⁸.

It should be concluded that the full disclosure of the final contracts would undermine not only the vaccines' manufacturers commercial interest, but also the decision-making process of the Commission, as it would reveal preliminary views and policy options, which are currently under consideration. With respect to earlier drafts of the contracts, their disclosure would also reveal important aspects of the negotiation strategy of the Commission and options which may still be relevant for other similar negotiations and therefore weaken their possible outcome. The exception laid down in Article 4(3) first and second subparagraphs of Regulation (EC) No 1049/2001 applies to the documents identified above.

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</u> reuse of <u>Commission documents</u>. You may reuse the documents disclosed free of charge and for non-commercial and commercial purposes provided that the source is acknowledged

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.
⁴Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union (OJ L

⁴Council 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.

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 make general reference to the public interest in the protection of the right to health, without however specifying why and how this right would be affected by the non-disclosure. You did therefore 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: <u>sg-acc-doc@ec.europa.eu</u>

Yours sincerely,

Enclosure: Annex with the list of documents