



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director General

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

Olivier Hoedeman
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(CEO)
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Dear Mr Hoedeman,

Subject: Your application for access to documents – GESTDEM 2020/5437

We refer to your e-mail dated 15 September 2020 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 October 2020 extending the time limit to respond to your request according to 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:

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 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).

“- all contracts with AstraZeneca and other pharmaceutical companies about the purchase of potential vaccines against COVID-19 (Advance Purchase Agreements, APAs).

There is a clear public interest in disclosure of these contracts. The transparency rules as set out in the Lisbon Treaty oblige the EU institutions to work as openly and as closely as possible to citizens. There is clearly a lot at stake for EU citizens in the vaccine deal negotiations. Citizens have the right to know about these negotiations that are happening on their behalf, involving billions of euros of public money to be spent for the development of vaccines. Secrecy around the negotiations about the vaccines, moreover, may undermine public confidence in the EU, but also in the vaccines themselves. Blanket confidentiality cannot be the rule for the covid19 contracts. Price and other sorts of confidentiality covering commercial aspects of these contracts cannot preclude transparency around liability and other provisions with clear implications for patient safety and the protection of public health. The currently negotiated contracts for potential covid19 vaccines differ from usual medicines procurement deals. Considerable amounts of public money and public guarantees are invested into the R&D and manufacturing process through the signature of advance purchase agreements between the European Commission and individual pharma companies. APAs essentially constitute insurance policies paid for by taxpayers' money which amongst other guarantee losses sustained by pharma developers. Governments commit in advance to shouldering the cost of certain liabilities sustained by pharma companies throughout the R&D process; by doing so they de-risk it and become co-developers. This makes the need for transparency and public accountability even stronger.”

2. Identification and assessment of relevant documents

As of the date of your request (15 September 2020), we have identified the following document falling within the scope of your request:

Title	System registration date	Reference number
Advance purchase agreement signed between European Commission and Astra Zeneca	16-09-2020	Ares(2020)4849918

Having examined the document under the provisions of Regulation (EC) No 1049/2001, we have come to the conclusion, which is further explained in the next paragraph, that no access can be granted to the requested document as its disclosure is prevented by an exception to the right of access laid down in Article 4 of the Regulation.

3. Reasons for refusal

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 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) to which you request access contains information relative to the commercial interests of AstraZeneca

which could potentially damage the competitive position of the company and the procurement procedures ongoing for the purchase of COVID-19 vaccines if they were made public.

The European Court of Justice has established that, as regards bids, there is a special general presumption that access to the bids of tenderers in the context of the performance of public contracts would, in principle, undermine the protection of commercial interests.³ The rationale behind the general presumption of non-disclosure is that “operators must be able to communicate any relevant information to the contracting authorities in the procurement process, without fear that the authorities will communicate to third parties items of information whose disclosure could be damaging to them.”⁴ This rationale holds true also as regards contracts signed at the end of a negotiated procedure, given the relevance for this specific procedure of the urgency and of the very specific good to purchase, which in this case is something that does not exist on the market yet. Therefore, the contract finally concluded is not like any other public contract, but inevitably contains many elements that are commercially sensitive both for the company, such as the schedule to deploy the vaccines, and 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 several ongoing negotiated procurement procedures for the award of similar APAs as the one with Astra Zeneca to which you request access. 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,⁵ under its Article 4(5)(b).⁶ It should be recalled 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,⁷ 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.⁸ 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.

³ See judgment in case T-734/17, *Viasat Inc. v European Commission*, par. 43 as regards bids.

⁴ See judgment in case C-450/06, *Varec v Commission*, par. 36

⁵ Regulation (EU)2016/369, as modified by Regulation (EU) 2020/521.

⁶ “*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*”.

⁷ 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.

⁸ Judgment *CEE Bankwatch Network v Commission*, T-307/16, EU:T:2018:97, para. 111, last sentence.

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 public⁹, the Commission cannot disclose the specific APA with AstraZeneca. Otherwise, potential competitors of this company, including those with which the Commission is currently negotiating, could also get access either to commercial information from AstraZeneca or to any other possible information which could allow them to obtain a competitive advantage.

This would not only damage AstraZeneca's 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 Regulation¹⁰. 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*"¹¹.

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 impossible. In turn, this risk would further delay the effective and access of the EU population to the vaccines.

Therefore, we regret to inform you that no access can be granted to the above mentioned document.

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 argue that there is a public interest in the disclosure of this document. After examining your arguments, we do not find that they amount to the identification of a public interest capable of overriding the interest protected by the first paragraph of Article 4(2) of Regulation (EC) No 1049/2001, for the reasons explained in paragraph 3.

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.

⁹ Case T-439/08, *Agapiou Joséphidès v Commission and EACEA*, par. 116.

¹⁰ 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

¹¹ Case C-450/06, *Varec v Commission*, par. 35.

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 sincerely,

Sandra GALLINA
Director-General