



EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

SANTE.DG/DDG1/C.3/KB

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

Olivier Hoedeman
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Dear Mr Hoedeman,

**Subject: Your application for access to documents – GESTDEM2020/5436 and
GESTDEM 2021/0559**

We refer to

- your e-mail dated 15 September 2020 in which you made a request for access to documents, registered on the same date under the reference number GESTDEM 2020/5436.
- our email of 2 October 2020 extending the time limit to respond to your request GESTDEM 2020/5436, according to Article 7(3) of Regulation (EC) No 1049/2001.
- your e-mail dated 01 February 2021 in which you made a follow-up request for access to documents, registered on the same date under the reference number GESTDEM 2021/0559.
- our email of 22 February 2021 extending the time limit to respond to your request GESTDEM 2021/0559, 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:

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.

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- all reports (and other notes) from meetings of the Vaccines Procurement Steering Committee and the Joint Negotiation Team (JNT) with representatives of pharmaceutical companies about Advance Purchase Agreements (APAs) and the purchase of potential vaccines against COVID-19.
- all correspondence (including emails and their attachments) between the Vaccines Procurement Steering Committee and the Joint Negotiation Team (JNT) and representatives of pharmaceutical companies (including Sanofi-GSK, Johnson & Johnson, CureVac, AstraZeneca, Moderna and others) about Advance Purchase Agreements (APAs) and the purchase of potential vaccines against COVID-19.
- a list of all the above-mentioned documents (including dates, names of participants/senders/recipients and their affiliation, subject of meeting/correspondence).

To your request you add the following:

There is a clear public interest in disclosure of these documents. 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 and its handling of the pandemic, but also in the vaccines themselves (with negative consequences for public health beyond the current pandemic).

Blanket confidentiality cannot be the rule for the negotiations about the Covid19 vaccine contracts. Price and other sorts of confidentiality covering commercial aspects of these contracts cannot preclude transparency, for instance around negotiations about 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 around the negotiations even stronger.

Please note that there is also a clear public interest in the release of the names of the members of the Joint Negotiation Team (JNT). The public has the right to know who is negotiating on the EU's behalf. Knowing the names of the negotiators is a pre-condition for assessing potential conflicts of interest.

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

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- all reports (and other notes) from meetings of representatives of the European Commission, members of the Vaccines Procurement Steering Committee and members of the Joint Negotiation Team (JNT) with representatives of pharmaceutical companies (AstraZeneca and others) about Advance Purchase Agreements (APAs) and the purchase of vaccines against COVID-19.

- all correspondence (including emails and their attachments) between representatives of the European Commission, members of the Vaccines Procurement Steering Committee and members of the Joint Negotiation Team (JNT) and representatives of pharmaceutical companies (AstraZeneca and others) about Advance Purchase Agreements (APAs) and the purchase of vaccines against COVID-19.

- a list of all the above-mentioned documents (including dates, names of participants/senders/recipients and their affiliation, subject of meeting/correspondence).

To your request you add the following:

There is a clear public interest in disclosure of these documents. The Lisbon Treaty obliges 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.

Please note that there is also a clear public interest in the release of the names of the members of the Joint Negotiation Team (JNT). The public has the right to know who was negotiating on the EU's behalf. Knowing the names of the negotiators is a pre-condition for assessing potential conflicts of interest.

This request covers the period September 2020 until today (including meeting notes and correspondence from January 2021). It is a follow-up request to our previous request with reference number GESTDEM 2020/5436 (registered on 15/09/2020), currently the subject of an inquiry by the European Ombudsman.

2. Identification and assessment of relevant documents

We have so far identified 365 documents that fall within the scope of your requests and, more in particular, under the first and second bullets thereof.

You will find attached a table listing the identified documents.

In an effort to ensure as complete as possible transparency of the process for the purchase of COVID-19 vaccines, the Commission has engaged in consultations with vaccines manufacturers involved in that process about the possibility to disclose APAs concerning such purchase.

You will be aware that those efforts have already born some fruits. 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

It was further decided to make a redacted version of the agreement with AstraZeneca AB and with Sanofi Pasteur SA and GlaxoSmithKline Biologicals SA available other webpages.

https://ec.europa.eu/info/sites/info/files/apa_astrazeneca.pdf

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

We are progressing with the assessment of the other documents included in the attached list in view of their disclosure; such assessment includes, in relation to some documents, the consultation of third parties concerned and has not been concluded yet. Therefore, we are not in the position to attach a copy of those documents to our reply.

As soon as the assessment is concluded for each document or group of documents, should it result in a decision to fully or partially disclose and publish the documents, the latter will be made progressively available on a Commission webpage.

You will be informed in due course of the outcome of the ongoing assessment of the documents falling under the scope of your requests and of the decision that will be taken regarding disclosure and publication of each of the documents.

In all cases where documents are only partially released or published because full disclosure would undermine the protection of one of the interests referred to in Art 4 of Regulation 1049/2001, should the interest in question cease to warrant the protection afforded by that provision, the Commission will review and adjust the corresponding redactions as needed. As a consequence, the released version of the relevant documents will be replaced with a more recent one with fewer redactions.

I trust that you will appreciate the complexity of the task undertaken by the Commission and the sensitivity of the assessment, which prevents the Commission to respond within the deadlines set out by Regulation (EC) No 1049/2001.

Yours sincerely,

Sandra GALLINA
Director-General

Enclosure: Annex with the list of documents