



EUROPEAN COMMISSION
EUROPEAN HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY

The Director-General

HERA.3/KB/al (2022)1387040

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

Olivier Hoedeman
Corporate Europe Observatory
(CEO)
Rue d'Edimbourg 26,
1050 Brussels, Belgium

Advance copy by email
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0318d986@asktheeu.org
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3951dcbe@asktheeu.org

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.
- DG SANTE's 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.
- DG SANTE's 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.
- DG SANTE's letter of 15 March 2021 in which we provided you the list of the

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.

identified documents falling within the scope of your requests GESTDEM 2020/5436 and GESTDEM 2021/0559.

- DG SANTE's letter of xxx in which you received a first batch of the documents falling within the scope of your requests GESTDEM 2020/5436 and GESTDEM 2021/0559.
- Follow up communication between you and DG SANTE between 6 June and 28 October on the status of the file.
- HERA letter sent on 7 January 2022 proposing a fair solution to reduce the scope of your request to 125 documents out of the 365 documents initially identified.
- Your response sent on 20 January.
- HERA letter sent on 4 February with further explanations concerning the fair solution we offered, clarifying the scope and addressing the points you made.

1. Scope of your request

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

GESTDEM 2020/5436

- *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).

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

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.

GESTDEM 2021/0559

- 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. The first batch of documents

In letter sent on 8 June, DG SANTE proposed to handle your request in batches and provided you with a first batch of documents. The first batch of the identified documents that were initially considered to fall within the scope of your requests comprised 80 documents (including the published contracts). With this reply the Commission provided you with a partial access to some of the agendas of the Steering board meetings (including their emails and some attachments) and communications, in particular emails, exchanged between the Commission and Members of the JNT and BioNTech SE.

3. Transfer of your file to HERA

Since the beginning of the Covid-19 pandemic and the subsequent adoption of the EU Vaccines strategy, the Commission has been receiving a significant number of access to documents requests, submitted under the Regulation, related directly or indirectly to the procurement of COVID-19 vaccines. These requests often included a very large amount of sensitive documents, which needed to be consulted in accordance with Article 4(4) of the Regulation.

Due to specificity of document you requested, its complexity and the lengthy ongoing consultations with numerous third parties, DG SANTE was not able to provide you with a response within normal time limits set out in Article 7 of Regulation (EC) No 1049/2001. We sincerely apologies for any inconvenience caused by this delay.

The Commission has acknowledged that the high public interest in this topic requires an adequate level of transparency. However, I would like to note that the right of access to documents is not a general and absolute right, but may be subject to limitations and restrictions, as recognized by the Courts. Transparency is indeed an essential component of the decision-making process of the EU. I would like to underline in this context that the European Commission regularly publishes information on the state of play of the negotiations with vaccine manufacturers and informs the public when a contract is concluded.

Nevertheless, the Commission has to ensure that any possible disclosure would not undermine the interests as laid down in Article 4 of the Regulation. Very importantly, the Commission has to make sure that the vaccine procurement and deployment process, which is an objective of the highest public interest, is not undermined in any manner.

Your application has now been assigned to the newly established European Health Emergency Preparedness and Response authority ('HERA').

4. Identification and assessment of the second and third batch of documents

The second and third batches of the 365 documents identified that fall within the scope of your request are made of 106 documents. You will find attached, for your convenience, the table listing the documents we are disclosing ("A.1 List of documents _second and third batch"). The disclosed documents are attached to this correspondence. These two batches consist of Steering Board minutes and documents exchanged in the framework of setting up Steering Board meetings. In addition, this batch consist of reassessed COVID-19 vaccine contacts. Kindly note that we are in a process of finalizing the consultation with third parties on the remaining documents and we will provide you with these documents swiftly.

4.1. Full disclosure

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 4, that full access can be granted to the documents: No 1.2 and 1.4

4.2. Partial disclosure

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 4, that:

- partial access can be granted to the Steering Board minutes, email and agendas, and contracts namely documents No 02, 04, 07, 07.1, 08, 09, 9.1, 10, 12, 14, 16, 17, 18, 20, 22, 23, 23.1, 24, 26, 27, 28, 29, 31, 31.1, 35, 35.1, 36, 37, 38, 39, 39.1, 40, 41, 42, 44, 45, 46, 48, 50, 52, 54, 55, 57, 60, 61, 62, 64, 65, 66, 68, 69, 72, 74, 76, 78, 80, 81, 82, 84, 85, 86, 87, 88, 90, 112, 113, 114, 174, 175, 212, 260, 366, 367, 368, 368.1, 369, 370, 371, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385 as their full disclosure is prevented by several exceptions laid down in Article 4 of the Regulation.

4.2.1. Wider partial disclosure to COVID-19 vaccine contracts.

The European Commission had already made public the redacted versions of the majority of the identified contracts, available at the following link:

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

In accordance with article 4(4) of Regulation (EC) No 1049/2001, the European Commission undertook new consultations with the companies concerned on the (further) disclosure of the COVID-19 vaccine contracts. Having taken the replies from the companies and the European Commission's own assessment into account, I am pleased to inform you that wider partial access can now be granted to the requested documents, compared to what was previously disclosed. Partial access is also granted to those contracts which had not yet been publicly disclosed in a redacted form.

4.2.2 Wider partial disclosure to Steering Board minutes and other documents

I am pleased to inform you that following consultation and European Commission's own assessment we decided to grant a wider access to the requested documents and to disclose the parts of Steering Board minutes that fall outside of the scope of your request. Likewise, we are disclosing additional documents, which are directly relevant to your request but fall outside of the period and hence scope of your request (No 366, 367, 368, 368.1, 369, 370, 371, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385).

4.2.3. 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 to which partial access may be granted, 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:

- other information relating to an identified or identifiable natural person, such as

professional background, role, country they represent 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 sufficiently 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

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).

Such documents 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 full disclosure of the requested documents would undermine not only the commercial interest of vaccines manufacturers, but also the decision-making process of the Commission, as it would reveal preliminary views and policy options related to the COVID-19 vaccines' strategy, which are currently under consideration by the Commission and the Member States, being vaccinations' campaign still ongoing. The exception laid down in Article 4(3) first subparagraph of Regulation (EC) No 1049/2001 applies to the documents identified above.

5. 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. You refer in your letter to grounds of public interest, on the basis of which the interests protected in Regulation (EC) No 1049/2001 would have to be overridden.

We have thoroughly assessed them and their relevance against the interest of the general public in good faith negotiations, as well as in the respect by all actors of the commitments taken with the signature of the contracts, including in the good faith implementation of the same.

In these circumstances, we have to conclude that, in accordance with the settled case-law, a general consideration of public interest in disclosure of documents cannot provide an appropriate basis for establishing that, in the present case, the principle of transparency

could thus prevail over the reasons justifying the partial refusal³.

6. 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 [Commission Decision on the reuse of Commission documents](#)⁴. 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.

Please note that some of the documents entail preliminary drafts, which do not reflect the position of the Commission and cannot be quoted as such.

Please also note that the disclosure is without prejudice to the rules on intellectual property, which may limit your right to reproduce or exploit the released documents without the agreement of the originator, who may hold an intellectual property right on them. The European Commission does not assume any responsibility from their reuse.

Finally, please note that some of the documents were drawn up for internal use under the responsibility of the relevant services of the Directorate-General for Health and Food Safety. It solely reflects the services' interpretation of the interventions made and do not set out any official position of the third parties to which the documents refer, which were not consulted on their content. They do not reflect the position of the Commission and cannot be quoted as such.

7. 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, also in relation to this specific reply.

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

8. Request for information of the names of the Members of the JNT

In your request you ask the Commission to release the names of the members of the Joint Negotiation Team. The Joint Negotiation Team is made of representatives of seven member States with production capacity, namely, in alphabetical order, France, Germany, Italy, Poland, Spain, Sweden, The Netherlands.

Article 9(1)(b) of the Data Protection Regulation does not allow the transmission of the names (which are personal data) of those members, 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

³ See, to that effect and by analogy, judgment of 21 September 2010, *Sweden and Others v API and Commission*, C-514/07 P, C-528/07 P and C-532/07 P, EU:C:2010:541, paragraphs 157 and 158.

⁴ Commission Decision 2011/833/EU of 12 December 2011 on the reuse of Commission documents, OJ L 330, 14.12.2011, p. 39–42.

to assume that the legitimate interests of the data subject might be prejudiced. In your request, you express only a generic reference to a purpose in the public interest to have access to these personal data and you do not put forward any arguments to establish the necessity to have the data transmitted for a specific purpose in the public interest.

Consequently, 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, we are therefore maintaining our position that the Commission will not disclose this personal data.

Yours sincerely,

Pierre DELSAUX
Director General
(e-signed)