SUBJECT: YOUR APPLICATION FOR ACCESS TO DOCUMENTS – GESTAMP 2020/5436 and GESTAMP 2021/0559

Dear Mr Hoedeman,

We are contacting you concerning your application for the access to documents– GESTAMPs: 2020/5436 and 2021/0559

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

- 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

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.

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 Covid-19 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 covid-19 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.

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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/recipient 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 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.*

*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.*

Your application concerns a very large number of documents, which need to be assessed individually.

Based on an initial assessment by the Directorate-General for Health and Food Safety, 365 documents were primarily identified as falling under the scope of your request.

Due to the large number of documents, their complexity and the lengthy ongoing consultations with numerous third parties DG SANTE has not yet been able to provide you with all documents. We sincerely apologise for any inconvenience caused by this delay.

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 often originated from third parties, which needed to be consulted in accordance with Article 4(4) of the Regulation.

The Commission has acknowledged that the high public interest in this topic requires an adequate level of transparency. 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 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’).

Following a careful reassessment of the scope of your request, we are contacting you to propose a workable solution for this request. Article 6(3) of the Regulation provides for the possibility to confer with the applicant informally with a view to finding a fair solution when an application concerns a very large number of documents, which is the case here.

We would like to kindly ask you to consider reducing the scope of your request to 125 documents out of the 365 documents initially identified. Our suggestion is to grant you access to documents such as agenda, emails, minutes of the Steering Board meetings, and final contracts. The minutes of the Steering Board meetings usually include key information on negotiations and the proposed timeframe covers the core of the contacts’ negotiations between the Commission and the pharmaceutical companies.

The proposed fair solution is based on the principle of proportionality in order to provide you with a reply to your request as soon as possible while avoiding that the performance of the core tasks assigned to the DG is jeopardized (i.e. to manage the COVID-19 pandemic).

Please note that the final assessment regarding the possible disclosure of the documents remains with the Commission.

In order to enable us to reply to your request as soon as possible we would ask you to provide a swift reply to our invitation to propose a fair solution, within five working days at the latest:

- by e-mail to: HERA-CONSULT-04@ec.europa.eu

If you have any questions concerning the invitation, you can contact us:

- by e-mail to: HERA-CONSULT-04@ec.europa.eu

In the absence of a reply within five working days, we will need to unilaterally restrict the scope of your application to a more manageable amount of documents 125 documents.

We would like to thank you for your understanding and we hope that the proposed solution will be acceptable to you.

Yours sincerely,

Wolfgang Philipp
Acting Deputy Head of HERA