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Comments of DG SANTE on a request for information from the European Ombudsman - Complaint by Mr [redacted] on behalf of Corporate Europe Observatory (CEO), ref. 85/2021/MIG and 86/2021/MIG

I. BACKGROUND/SUMMARY OF THE FACTS/HISTORY

1.1) Background of the Vaccine Strategy

All Member States have endorsed the approach set out in the Vaccines Strategy[1] and signed an agreement for its implementation.

On this basis, the Commission together with Member States has engaged in intensive simultaneous negotiations to build a diversified portfolio of vaccines for EU citizens at fair prices.

Contracts have been concluded with AstraZeneca (up to 400 million doses), Sanofi-GSK (up to 300 million doses), Johnson and Johnson (up to 400 million doses), BioNTech-Pfizer up to 600 million doses, CureVac (up to 405 million doses) and Moderna (up to 160 million doses).

The Commission has concluded exploratory talks with the pharmaceutical company Novavax with a view to purchasing up to 200 million doses and with Valneva with a view to purchase up to 60 million doses.

This is an inclusive and centralised process, carried out on behalf and in the name of the Member States and in very close cooperation with them. These collective efforts involve several participants from every Member State and strive to take decisions in a coordinated and collegial manner.

All Member States take part in the Steering Board for the joint European approach to COVID-19 vaccines procurement. The Steering Board is co-chaired by a representative of the Commission and a Member State. It discusses and steers the process and reviews all aspects of the Advanced Purchase Agreement contracts before signature.

1.2) The requests for access to documents under Regulation (EC) No 1049/2001

The Directorate-General for Health and Food Safety received more than 50 access to documents requests related directly or indirectly to the procurement of COVID-19 vaccines. In the pandemic context, the Directorate-General for Health and Food Safety was not always able to reply to those requests by the deadlines set by Regulation (EC) No 1049/2001.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1597339415327&uri=CELEX:52020DC0245

More than 320 documents have been identified so far as falling under the scope of the requests. Some of those documents originate from third parties or Member States. The Commission has been consulting them on the disclosure with a view to assessing whether an exception shall apply in accordance with Article 4(4) of Regulation (EC) No 1049/2001. The consultation process is currently ongoing.

Two of these requests, for which the applicant has submitted confirmatory applications registered under reference numbers Gestdem 2020-5436 and 2020-5437, are subject to the current Ombudsman's complaint.

II. THE COMPLAINTS

The Ombudsman has received two complaints against the Commission.

More specifically, the complainant is seeking public access to the advance purchase agreements for the procurement of COVID-19 vaccines, which the Commission signed with the pharmaceutical companies[2], and to other documents related to the negotiations with the pharmaceutical companies (such as meeting reports)[3].

In the framework of request Gestdem 2020-5437, by an initial reply of 30 October 2020 the Directorate-General for Health and Food Safety refused to give public access to the advance purchase agreement signed with AstraZeneca in September 2020, based on the need to protect personal data, the commercial interests of the pharmaceutical company concerned and the need to protect the procurement procedure.

The complainant challenged the decision on 12 November 2020 by introducing a confirmatory application. The applicant argued that there was an overriding public interest in disclosure and called on the Commission to disclose at least parts of the contract with AstraZeneca, as well as the remaining advance purchase agreements that the Commission has negotiated. To date, the complainant has not received a reply to his confirmatory application.

Concerning the second access request, namely Gestdem 2020-5436, whereby the applicant requested other documents related to the vaccine negotiations, the Commission has not yet replied to the complainant's requests at initial nor at confirmatory stage.

The Ombudsman asks the Commission **to issue a confirmatory decision** on both access requests as soon as possible and at the latest by 11 February 2021 and would consider if it is necessary to inspect the documents at issue in the complainant's access requests.

Finally, the Ombudsman took note that the Commission has in the meantime published - with limited redactions - a version of the advance purchase agreement signed with CureVac.

[2] In the framework of request Gestdem 2020-5437
[3] In the framework of request Gestdem 2020-5436.

The Ombudsman asks if the Commission is considering taking a similar step in relation to the agreement at issue in this case and asks the Commission to provide any relevant information in this regard.

III. THE COMMISSION'S COMMENTS TO THE COMPLAINANT'S ARGUMENTS

The Commission acknowledges that the handling of the access to documents requests was considerably delayed.

This is due to the complexity and sensitivity of the subject matter, the number of stakeholders and interests involved, as well as the important workload due to the increasing number of requests submitted in relation to the purchase of COVID-19 vaccines. The need to provide a concrete and individual assessment of a large number of documents falling within the scope of the requests[4] and to consult third parties in light of Article 4(4) of Regulation (EC) No 1049/2001 are another factors explaining the delays in the handling.

The Commission is fully aware of the interest to ensure as much transparency as possible on the matters covered by the documents in question, and of its obligations under Regulation (EC) No 1049/2001. However, the interests protected by Article 4 of that Regulation and the need not to undermine the ultimate objective of the ongoing negotiations have to be taken into account in the final outcome of the assessment. Indeed, the ultimate objective of the negotiations is to provide Member States with a diversified portfolio of vaccines as soon as possible, which is itself an objective in the highest public interest.

The Commission acknowledges the strong need for transparency in the negotiation process and has taken significant steps in that direction.

The Commission has made the contracts with CureVac and Johnson & Johnson available to the Members of the European Parliament, in a dedicated reading room.

The Commission has engaged in consultations with all vaccine manufacturers with a view to granting the widest possible public access to the contracts. As a result, it has published the redacted versions of contracts concluded with **CureVac**, **AstraZeneca** and with **Sanofi**.

The redacted contract with CureVac can be accessed via the following link: https://ec.europa.eu/info/sites/info/files/curevac-redacted_advance_purchase_agreement_0.pdf

The redacted contract with AstraZeneca can be accessed via the following link: https://ec.europa.eu/info/files/redacted-advance-purchase-agreement-astrazeneca_

The redacted contract with Sanofi can be accessed via the following link: https://ec.europa.eu/info/files/sanofi-gsk-redacted-advance-purchase-agreement_en

[4] In particular request 2020/5436 whereby the applicant requested access to various documents related to the vaccine negotiations.

The Commission has informed the other companies on the transparency obligations to which it is subject notably in accordance with Regulation (EC) No 1049/2001 and is currently consulting them with the view to applying wide transparency and granting the widest possible public access to the advance purchase agreements. The redacted versions of the contracts will ultimately be made public.

The Commission will also provide an individual reply to every single access to documents request it has received, including to the two requests subject to the current Ombudsman's complaint, as explained in Section IV.

IV. CONCLUSIONS AND FUTURE STEPS IN RELATION TO THE SPECIFIC ACCESS TO DOCUMENTS REQUESTS

The Commission hopes to be **able to publish the remaining contracts** related to the procurement of COVID-19 vaccines very soon.

Consequently, the reply to the confirmatory application registered under number **Gestdem 2020-5437**, whereby the applicant requested access to all the advance purchase agreements has to take into account and be aligned with the ongoing publication of the contracts. The applicant will receive a final reply to his confirmatory application **following the publication of the advance purchase agreements already concluded by the Commission.**

Given the high number of documents identified as falling under the scope of the request **Gestdem 2020-5436**, and the complexity of the issues as outlined in Section III, the assessment of the documents or parts thereof that can be released, is still ongoing, and involves the consultation of third parties.

Once the assessment is concluded, the Commission will take a decision on the disclosure and provide a reply under Regulation (EC) No 1049/2001 to the applicant's request Gestdem 2020-5436. As a first step, the applicant **will be informed of this approach**, and **will receive the list of identified documents.**
Furthermore, 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 online on a Commission webpage as well.