

European Commission
Att. Sandra Gallina
Rue de la Loi / Wetstraat 200
1049 Bruxelles
Belgium

Brussels, 30 June 2021

**Subject: Confirmatory application for access to documents GESTDEM 2021/0389
Commission decision of 9 June 2021 – Ares(2021)3768741**

Dear Director-General,

We acknowledge receipt of your decision of 9 June 2021 (your reference GESTDEM2021/0389) to our request for access to documents of 20 January 2021, complementing your reply of 11 March 2021. We requested access to the agreements signed between the Commission and pharmaceutical companies with regard to the advance purchase of COVID-19 vaccines, as well as to those that might be concluded after our request.

In your response, you have identified nine documents, which fall within the scope of our request. Redacted versions of these contracts were disclosed.

While you share our views with regard to the need for a transparent process, following consultations with the vaccine manufacturers concerned, you have decided to redact the agreements that you have released. You refer to Article 4(1)b, Article 4(2) first indent and Article 4(3) first subparagraph of Regulation (EC) No 1049/2001 to justify partial disclosure.

We herewith submit a confirmatory application asking you to reconsider your position and to release all the documents concerned without redactions, except parts that fall under the protection of the privacy and integrity of individuals under Article 4(1)(b) of Regulation (EC) No 1049/2001.

1. Undue application of exceptions under Article 4 of Regulation (EC) No 1049/2001

Thanks to the investigative work of the Italian broadcaster RAI, the agreement with AstraZeneca has been [released](#) in its entirety on 19 February 2021, and those with [PfizerBioNTech](#) and [Moderna](#) on 17 April 2021. This allows identifying the parts that have been blacked in the redacted versions. In the redacted versions published, all information related to prices, payment and delivery schedules, production sites, as well as key information with regard to liability and indemnification, IP rights and termination clauses have been blacked.

Furthermore, the definitions of “willful misconduct”, “force majeure”, “vaccine” and in part of “irregularity” and of “key supply/ies”, provisions with regard to timelines for audits and data storage, expenses with regard to post-launch safety and risk management studies as well as liability clauses in case of breach of personal data protection have been hidden.

It is difficult to understand why e.g. provisions with regard to definitions as well as timelines for audits and data storage should be considered to be of commercial interest.

2. Failure to justify the application of exceptions under Article 4 of Regulation (EC) No 1049/2001

Under the first indent of Article 4(2) of Regulation (EC) No 1049/2001, the institutions shall refuse access to a document where its disclosure would undermine the protection of ‘commercial interests of a natural or legal person, including intellectual property’, unless there is an overriding public interest in disclosure.

Under Article 4(3) of that Regulation, the institutions shall refuse access to a document, which relates to a matter where the decision has not been taken by the institution, if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure.

Since exceptions derogate from the principle of the widest possible public access to documents of the EU institutions, the exceptions must be interpreted and applied strictly.¹ You argue that the (advance) purchase agreements contain commercially sensitive information and indicate as reasons for refusing full access that: “[a]s 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 (advance) purchase agreements, in which the Commission has the same position. Full disclosure would also undermine the objective of genuine competition in the procurement procedures, currently on the point of being negotiated by the Commission, as protected by Article 170(3) last subparagraph of the Financial Regulation. 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.”

However, the case-law cited, C-450/06, *Varec v Commission*, is not about access to documents under Regulation (EC) No 1049/2001, the proceedings was about a competitor’s access to information under Directive 89/665/EEC, so it is not relevant here.

You also argue that it “*should be concluded that the full disclosure of the final contracts would undermine not only the vaccine manufacturers’ commercial interest, but also the decision-making process of the Commission, as it would reveal preliminary views and policy options, which are currently under consideration*”, invoking Article 4(3) of Regulation (EC) No 1049/2001.

In order to justify a refusal to grant full access to a document whose disclosure has been requested, it is not sufficient, in principle, according to the case-law, for the requested document to be covered by an activity mentioned in Article 4(2) or (3) of Regulation (EC) No 1049/2001. As a rule, the institution to which the request has been addressed must also provide explanations as to how access to that document could specifically and actually undermine the interest protected by the exception or exceptions relied on. Moreover, the risk

¹ *Cosepuri v EFSA*, T-339/10 and T-532/10, EU:T:2013:38, paragraph 89 and *Sweden v MyTravel and Commission*, C-506/08 P, ECLI:EU:C:2011:496, paragraph 72 and 74

of that interest being compromised must be reasonably foreseeable and not purely hypothetical.²

With regard to the requested information, there is no general presumption of confidentiality comparable with the presumption related to access to bids submitted by tenderers in the context of the performance of public contracts.³ The Commission may arguably indicate that the agreement finally concluded contains elements that are commercially sensitive both for the company as for the Commission. Furthermore, in the concrete case of COVID-19 vaccines, negotiations take place for further agreements with other companies, and more might follow.

However, this argument does not stand. As indicated above, the agreement with AstraZeneca has been publicly released entirely by a third party on 19 February 2021, those with Pfizer/BioNTech and Moderna on 17 April 2021, respectively, and the prices indicated in all advance purchase agreements have already been [publicly released](#) by another third party on 18 December 2020. So far, to the best of our knowledge, the Commission has not reported any issues in the ongoing procurement process due to such disclosures. The contested decision does not contain any example or explanation as to how this full disclosure and publishing of prices has affected the Commission's or the companies' commercial interests, nor why it would seriously undermine the institution's decision-making.

However, as follows from the case-law, it is on the Commission to establish why Article 4(2) first indent or Article 4(3) nevertheless would apply. The decision of 9 June 2021 however does not contain any substantiation with regard to any supposed harm to commercial interests, let alone any serious undermining of the decision-making process. You omitted to state any facts that could lead to the conclusion that the full disclosure of the information concerned would specifically and actually undermine commercial interests and seriously undermine the institution's decision-making. Therefore, the risks invoked of harm to the commercial interests of the companies or market position of the Commission or decision-making by the Commission are purely hypothetical.

We would further like to highlight that there is a fundamental difference between advance purchase agreements and purchase agreements. According to the Commission, “[advance purchase] agreements will be negotiated with individual companies according to their specific needs and with the aim of supporting and securing an adequate supply of vaccines. They will de-risk the necessary investments related to both vaccine development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production chain which is required for a rapid deployment of sufficient doses of an eventual vaccine in the EU and globally. The conditions of the contract will reflect the balance between the prospect of the producer providing a safe and effective vaccine quickly and the investment needed to deploy the vaccine on the European market.”⁴ In a nutshell, an advance purchase agreement seeks to secure supplies of a product, which is not on the market yet. In contrast to that, a purchase agreement is a standard contract to buy an existing product. As such, while lessons may be drawn from advance purchase agreements for the adoption of subsequent purchase agreements, advance purchase agreements cannot be claimed to be predictive of purchase agreements.

² *Deutsche Telekom v Commission*, T-210/15, EU:T:2017:224, paragraph 27, *Sweden v MyTravel and Commission*, C-506/08 P, EU:C:2011:496, paragraph 76

³ *Cosepuri v EFSA*, T-339/10 and T-532/10, EU:T:2013:38, paragraph 101

⁴ Commission Communication on the EU strategy for COVID-19 vaccines, COM(2020) 245

As a matter of fact, the advance purchase agreements apply to limited volumes, and the situation has changed significantly after the adoption of the advance purchase agreements. Sanofi did not yet succeed in developing a vaccine, CureVac did not yet succeed in getting market approval, and AstraZeneca and Johnson&Johnson had and are still having serious delivery problems. Moreover, the efficacy of the vaccines in general and with regard to variants is different, and some showed extremely rare but also extremely serious side effects. For that reason, purchase agreements have so far only been adopted with Pfizer/BioNTech and Moderna, as their mRNA platform was considered the most successful, also with regard to the adaptation of the vaccines to variants.

As such, information on e.g. prices and purchase conditions in the advance purchase agreements are not automatically relevant for purchase agreements. All the changes seen lead to the conclusion that advance purchase agreements are not predictive of purchase agreements future contracts as the situation changes and is likely to continue to change due to new insights. You failed to explain why the disclosure of these contracts would undermine the commercial interests of vaccine producers or of the Commission and why it would seriously undermine the the institution's decision-making.

3. Incoherent application of Regulation (EC) No 1049/2001

A superficial comparison between redacted versions of different advance purchase agreements released shows that the agreements with Pfizer-BioNTech and the agreement with Moderna are far more redacted than the other ones.

Moreover, similar parts are blacked in one agreement but not in another e.g.:

- the definition of “best reasonable efforts” - available in the redacted version of the agreement with [AstraZeneca](#), is blacked in the redacted version of the agreement with [Pfizer-BioNTech](#)
- timelines for audits - available in the redacted version of the agreement with [CureVac](#), are blacked in the redacted version of the agreement with AstraZeneca.

This discrepancy illustrates that the Commission did not follow a coherent approach with regard to the application of Regulation (EC) No 1049/2001, which in turn raises questions to which extent the Commission actually applied the provisions thereof, or rather left it to the companies concerned.

4. Overriding public interest

a) General considerations

Even if the protection of the contractors' commercial interests had been specifically shown to exist - which is not the case - we consider that there would clearly be an overriding public interest in the disclosure of the documents concerned pursuant to Article 4(2) of Regulation (EC) No 1049/2001.

You state that “We have thoroughly assessed them [grounds of public interest] 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 the exceptions to the right to access prevail.”

As you rightly observed in your initial response of 11 March 2021, we are currently in the middle of the most severe public health crisis in modern times. Public health measures taken to contain the spread of the virus are affecting fundamental rights of all people living in the EU. The Commission is taking a leading role in addressing this crisis. We agree with your statement in your response of 11 March 2021 that access to, and smooth deployment of safe and effective COVID-19 vaccines is “*key in containing the pandemic, saving lives, protecting health care systems and helping to restore our economy*”.

As such, public confidence in the actions by the Commission with regard to the purchase of vaccines is of key importance - all the more so as this is the first time that the Commission adopts advance purchase agreements on vaccines.

Moreover, according to a global survey undertaken by the Vaccine Confidence Project, the European region has the highest negative responses in terms of perception of the importance of vaccines and their safety and effectiveness, leading to the highest degree of vaccine hesitancy in the population (see Recital F of the European Parliament [resolution](#) of 19 April 2018 on vaccine hesitancy and the drop in vaccination rates in Europe). In the resolution, the European Parliament therefore “*recalls the importance of transparency in building and maintaining public trust in medicines*” (see Paragraph 14).

In addition, based on a survey [published](#) by the Commission in December 2020, in 24 Member States, respondents agree that public authorities are not sufficiently transparent about COVID-19 vaccines (see page 10).

It is obvious that confidence can only be established when there is full transparency. The obligations of both sides of the contractors and the way public money is spent need to be open to public scrutiny in the interest of public confidence in the vaccines concerned, as will be set out further below.

However, the redaction of the agreements makes it completely impossible to understand the agreements. The release of the redacted agreements therefore does not help to build confidence in the Commission’s key role in addressing the crisis and its capability to obtain the best result in the interest of public health when negotiating and making agreements with companies.

To the contrary, lack of public information about the agreements, in particular with regard to key information such as delivery schedules and liability provisions, led to serious attacks on the Commission since the beginning of 2021 with regard to the joint procurement of vaccines for the European Union. In many Member States, the Commission was attacked for acting too slowly, or for being too conservative.

While the approval of the first vaccines in December 2020 had created major expectations, lack of public information about the actual delivery schedules led to strong criticism of the joint procurement. The Commission defended the benefits of a joint procurement system, and explained in public that the deliberate decision to go for conditional market authorisations instead of emergency authorisations led to certain delays, as some companies did not want to be liable whatsoever. However, to reassure the public and to avoid false expectations, it is of

paramount importance not only to explain what happened, but also to disclose the provisions with regard to liability and delivery schedules.

In the first months of 2021, we saw high-level discussions about alleged parallel negotiations between Member States and companies with whom the Commission had adopted agreements. There were major discussions about the failure of AstraZeneca to honour its contractual obligations, which in turn triggered a debate on export bans. Such discussions were fuelled by the failure of the Commission to disclose the agreements.

b) Specific considerations and calls by the European Parliament

In the European Parliament resolution of 10 July 2020 on the EU's public health strategy post-COVID-19 July 2020, the European Parliament called on the Commission and the Member States *"to incorporate collective safeguards in favour of the public regarding public funding, such as transparency, accessibility and affordability clauses and non-exclusive licences for the exploitation of the final products, in all current and future calls for funding and investment"*

A total of at least € 2,85 billion of public money has been spent by the Commission on behalf of European citizens in the context of the adoption of the advance purchase agreements. This alone should be sufficient to invoke an overriding public interest in the disclosure of these agreements.

i) Requests by the Committee on Budgets and the Committee on Budgetary Control

In fact, in a resolution of 12 November 2020 on the EU budget 2021⁵, the European Parliament adopted the following: *"Deeply regrets that the Commission still has not responded to Parliament's call for full access to contracts and information regarding the COVID-19 vaccines-related contract covered by Draft amending budget No 8/2020; demands that the Commission grant the budgetary authority access to the COVID-19 vaccines-related contract before the end of 2020;"*

On 1 February 2021, during the public exchange of views in the Committee on Budgets on the Financing from the EU budget in the context of the EU vaccines strategy, you committed to send to the chairs of the Committee on Budgets and the Committee on Budgetary Control a detailed breakdown of the amounts paid under the Emergency Support Instrument (ESI) to each of the six pharmaceutical companies in the context of the advance purchase agreements (recording available [here](#)). On 8 February 2021, the chairs of both committees followed up with a letter to Commissioners Hahn and Kyriakides, writing the following:

"Ms Gallina agreed to share with us a detailed breakdown of EU budget expenditure in support of the EU's vaccines strategy and of other actions related to the health response to Covid-19. We are looking forward to receiving such comprehensive information, and our services have been in contact. We refer to funding provided under the Emergency Support Instrument but also to research, EIB and external funding as well as any other relevant source. We would also welcome any tentative overview of national spending on the development of Covid-19 vaccines, in order to be able to counter the perception that other countries have invested much more than the EU and its Member States combined. We would in particular require further

⁵ European Parliament resolution of 12 November 2020 on the Council position on the draft general budget of the European Union for the financial year 2021, https://www.europarl.europa.eu/doceo/document/TA-9-2020-0302_EN.html

explanation of the Commission's initiative to collect EUR 750 million of additional contributions from the Member States".

However, the Commissioners replied without providing the requested information on ESI vaccines' spending nor about the Commission's initiative to collect EUR 750 million of additional contributions from the Member.

On 23 March 2021, during an exchange of views in the Committee on Budgetary Control, you committed that the EP would receive the requested information in one week (recording available [here](#)).

However, as the Committee on Budgetary Control did not receive the information in time, its chair sent a letter on 21 April 2021, asking for a detailed breakdown of the EU budget paid under ESI, including on the cost structure of vaccine R&D and production and exact prices per dose and per producer.

On 11 May 2021, the Committee on Budgetary Control finally received the Commission's written reply, which did however not answer our key questions about ESI spending. This means that Members of the European Parliament are kept in the dark and cannot verify the spending of EU money under ESI for advance purchase agreements.

ii) Requests by the Committee on the Environment, Public Health and Food Safety

On 22 October 2020, Pascal Canfin, the Chairman of the Committee on the Environment, Public Health and Food Safety, wrote to Commissioner Stella Kyriakides on the need for transparency on the Advance Purchase Agreements concluded with vaccine producers:

“Against the backdrop of the significant EU funding already committed to the creation of a portfolio of potential vaccines, and the high number of transparency demands, not only from Members of Parliament, but also from EU citizens, I would like to convey the message, on behalf of a majority of coordinators, that the ENVI committee expects the Commission, the Member States and the pharmaceutical companies involved to increase the level of transparency with regard to the contracts concluded. The minimum would be that following provisions in the contracts are made public:

- *the cost structure for the production of the various vaccines, and the prices to be paid,*
- *the production locations,*
- *the intellectual properties arrangements, including any arrangements linked to non-exclusive licensing,*
- *the liability and indemnification linked to any damage caused by a vaccine, and*
- *access to the vaccine.”*

Pascal Canfin followed up with another letter to Commissioner Kyriakides on 21 December 2020:

“Furthermore, ENVI coordinators continue to underline the need for more transparency on the specific demands included in our previous letter, and especially for more clarity with regard to the legal rules regulating the liability and indemnification linked to any damage or side effects caused by a vaccine and the conditions laid down in the APAs with regard to this. We point out that this transparency should allow us to explain to the EU citizens the aspects of the contracts for which information will be made available.”

On 12 January 2021, MEPs of the Committee on the Environment, Public Health and Food Safety called for more clarity and transparency, finding that the “Lack of transparency has recently fuelled uncertainty and disinformation regarding COVID-19 vaccination in Europe” (see EP press release [here](#)).

iii) Plenary debates

A plenary debate was held with Commissioner Kyriakides on 19 January 2021, during which MEPs from all groups stressed the need for transparency (see verbatim report [here](#)).

A plenary debate was held with Commission President Von der Leyen on 10 February, during which many MEPs recalled the need for transparency with regard to contracts, and called for EU and global solidarity (see EP press release [here](#), verbatim report first part [here](#) and second part [here](#)).

The Commission reacted to this over time by first making one of the redacted agreements available in a reading room, then gradually making more and more redacted agreements available on line, and then accepting to set up a Contact Group with selected MEPs to provide further information in a confidential setting. In other words, while the Commission gradually reacted to the pressure for public information, it still keeps the most important information in the agreements confidential despite the long-standing and repeated calls by the European Parliament for transparency.

As follows from the survey from the Vaccine Confidence Project cited above, European countries have the highest negative responses in terms of perception of the importance of vaccines and their safety and effectiveness, leading to the highest degree of vaccine hesitancy in the population. Full transparency is necessary to build public trust in the COVID-19 vaccines, and public trust is likely to have a positive effect on the vaccination degree within in the European Union. Therefore, transparency with regard to the vaccine contracts is of the utmost importance for a high level of protection of public health.

We therefore request you to take into account the overriding public interests set out in our initial request for information as specified above.

5. The overriding public interest due to the global dimension

On 22 June 2020, the Commission adopted the EU-strategy for COVID-19 vaccines. It says the following:

“This is not only a European challenge, it is also a global one. All regions of the world are affected. The spread of the virus has shown that no region is safe until the virus is under control everywhere. In addition to it being in their clear self-interest to do so, high-income countries have a responsibility to accelerate the development and production of a safe and effective vaccine and make it accessible for all the regions of the world.”

As stated above, the European Parliament had called on the Commission and the Member States “to incorporate collective safeguards in favour of the public regarding public funding, such as transparency, accessibility and affordability clauses and non-exclusive licences for the exploitation of the final products, in all current and future calls for funding and investment” (European Parliament resolution of 10 July 2020 on the EU’s public health strategy post-COVID-19 July 2020).

To see whether the Commission has effectively delivered on its commitment to “*accelerate the development and production of a safe and effective vaccine and make it accessible for all the regions of the world*”, it is of paramount importance to be able to see the provisions in the agreements with regard to intellectual properties arrangements, including any arrangements linked to non-exclusive licensing (see also the latter by Chairman Canfin referred to above) as well as technology transfer.

6. Overriding public interest based on the Charter of Fundamental Rights

In accordance with Article 51(1) of the Charter of Fundamental Rights, the Charter is binding on the Commission. The right to freedom of expression in accordance with Article 11(1) of the Charter includes freedom to receive information, and the Charter guarantees a right to access to documents in Article 42.

Article 52(3) of the Charter stipulates that, insofar as the Charter contains rights, which correspond to rights guaranteed by the Convention for the Protection of Human Rights and Fundamental Freedoms, the meaning and scope of those rights shall be the same as those laid down by the said Convention. Article 10(1) of the Convention indicates that everyone has the right to freedom of expression; this right shall include freedom to receive information.

Whether and to what extent the denial of access to information constitutes an interference with the freedom-of-expression rights must be assessed in each individual case and in the light of its particular circumstances.⁶

The following criteria are relevant:

- The purpose of the information request
- The nature of the information sought
- The role of the applicant
- The availability of the information

As regards the purpose, the disclosure of documents under Regulation (EC) No 1049/2001 is reputed to have *erga omnes* effect and therefore considered as disclosure to the general public.⁷ The applicants, apart from using the information for the purposes of the activities as Members of European Parliament, also seek to constitute an essential element of public debate.

As regards the nature, there is a clear public interest in disclosure of the agreements. The transparency rules as set out in the Treaties oblige the EU institutions to work as openly and as closely as possible to citizens (Article 15 TFEU). There is clearly a lot at stake for EU citizens in the vaccine deal negotiations. Citizens have the right to know about the 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. Considerable amounts of public money and public guarantees are invested into the R&D and manufacturing process. This makes the need for transparency and public accountability even stronger.

⁶ *Magyar Helsinki Bizottság v. Hungary* [GC], no. 18030/11, §157, 8 November 2016

⁷ *Agapiou Joséphidès v Commission and EACEA*, T-439/08, EU:T:2010:442, paragraph 116.

As regards the applicants, they are Members of European Parliament. In accordance with Article 10(2) TEU, they directly represent citizens. On the citizens' behalf, they ensure oversight of the Commission, which is responsible to the Parliament (Article 17(8) TEU). In such a way, they have a special role in enhancing the public's access to information and facilitating the dissemination of information assimilated to that of "public watchdogs".

As regards the availability of the information, the partial publication of several agreements, demonstrates that the requested information is fully available to the Commission.

Conclusion

To conclude, we ask you to reconsider your position and make fully available all (advance) purchase agreements between you and pharmaceutical companies with regard to COVID-19 vaccines, redacting only elements that concern the protection of the privacy and integrity of individuals.

Yours sincerely,

Tilly Metz
Margrete Auken
Ville Niinistö
Jutta Paulus
Michèle Rivasi
Kim van Sparrentak