



EUROPEAN COMMISSION

Brussels, 28.5.2024  
C(2024) 3713 final

Mr AZALBERT Xavier

**DECISION OF THE EUROPEAN COMMISSION PURSUANT TO ARTICLE 4 OF THE  
IMPLEMENTING RULES TO REGULATION (EC) No 1049/2001<sup>1</sup>**

**Subject: Your confirmatory application for access to documents under  
Regulation (EC) No 1049/2001 - EASE 2023/5267**

Dear Mr Azalbert,

I refer to your letter of 16 October 2023, registered on the next day, in which you submitted a confirmatory application in accordance with Article 7(2) of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents<sup>2</sup> (hereafter ‘Regulation (EC) No 1049/2001’).

Please accept our sincere apologies for this delay.

This decision is issued in English so as to provide a reply to your request EASE 2023/5267 as promptly as possible. A translation of the present decision into French will be sent to you shortly.

**1. SCOPE OF YOUR REQUEST**

In your initial application of 12 September 2023 addressed to the Directorate-General Health Emergency Preparedness and Response Authority you requested access to ‘l’ensemble des contrats d’acquisition de vaccins contre la COVID-19 conclus par la Commission Européenne avec les sociétés pharmaceutiques PFIZER Inc/BION’TECH – MODERNA – JANSEEN non caviardées’.

In its letter of 2 October 2023, the Directorate-General Health Emergency Preparedness and Response Authority referred you to the redacted versions of the contract in question, available at the following link:

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<sup>1</sup> OJ L 345, 29.12.2001, p. 94.

<sup>2</sup> OJ L 145, 31.5.2001, p. 43.

- [https://commission.europa.eu/strategy-and-policy/coronavirus-response/public-health/eu-vaccines-strategy\\_fr](https://commission.europa.eu/strategy-and-policy/coronavirus-response/public-health/eu-vaccines-strategy_fr)

On 16 October 2023, you submitted a confirmatory application, asking the Commission to reconsider its position and release the documents concerned without any redactions.

## **2. ASSESSMENT AND CONCLUSIONS UNDER REGULATION (EC) No 1049/2001**

When assessing a confirmatory application for access to documents submitted pursuant to Regulation (EC) No 1049/2001, the Secretariat-General conducts a review of the reply given by the Directorate-General concerned at the initial stage.

Your request concerns the following documents:

- Advance purchase agreement signed between the European Commission and Janssen Pharmaceutical, reference Ares(2020)5806059, (hereafter ‘the document 1’)
- Advance purchase agreement signed between the European Commission and BioNTech-Pfizer , reference Ares(2021)256798, (hereafter ‘the document 2’);
- Purchase agreement signed between the European Commission and BioNTech-Pfizer, reference Ares(2021)1601544, (hereafter ‘the document 3’);
- Second purchase agreement signed between the European Commission and BioNTech-Pfizer , reference Ares(2021)3404228 (hereafter ‘the document 4’);
- Consolidated version of the Second Purchase Agreement between the European Commission and BioNTech-Pfizer, Amendments 1-5, reference Ares(2023)4017130 (hereafter ‘the document 5’);
- Advance purchase agreement signed between the European Commission and Moderna, reference Ares(2021)256592, (hereafter ‘the document 6’);
- Purchase agreement signed between the European Commission and Moderna, reference Ares(2021)1601566 (hereafter ‘the document 7’);
- Amendment 1 to purchase agreement signed between the European Commission and Moderna, reference Ares(2021)7098313 (hereafter ‘the document 8’);
- Amendment 2 to purchase agreement signed between the European Commission and Moderna, reference Ares(2021)5602046 (hereafter ‘the document 9’);
- Amendment 3 to purchase agreement signed between the European Commission and Moderna, reference Ares(2023)7762408 (hereafter ‘the document 10’);

- Amendment 4 to purchase agreement signed between the European Commission and Moderna, reference Ares(2022)5981663 (hereafter ‘the document 11’);
- Amendment 5 to purchase agreement signed between the European Commission and Moderna, reference Ares(2023)7762495 (hereafter ‘the document 12’).

As a preliminary remark, please note that the European Commission had already made public redacted versions of the majority of the identified contracts and amendments, available at the following link:

[https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy\\_en](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 has since then undertaken renewed consultations with the companies concerned on the (further) disclosure of the documents in question, and most recently in the period December 2023 to April 2024.

Having taken the replies from the companies and the European Commission’s own assessment into account, please be informed that:

- wide partial access subject to the redaction of personal data under Article 4(1)(b) of Regulation (EC) No 1049/2001 can be granted to the advance purchase agreement with Moderna (document 6);
- partial access is granted to the documents 1-4 and documents 7-12;
- access must be refused to the consolidated Second Purchase Agreement with BioNTech-Pfizer (document 5).

Disclosure of the redacted parts of the requested documents must be refused on the basis of the exceptions in Article 4(1)(b) (protection of personal data) and Article 4(2) first indent (protection of the commercial interests) of Regulation (EC) No 1049/2001.

For ease of reference, for Advance Purchase Agreements, i.e. agreements concluded on the basis of the Agreement annexed to the Commission Decision C(2020)4192 of 18 June 2020 by having recourse to a financial contribution from the Emergency Support Instrument (ESI) of the European Union set up under Regulation (EU) 2016/369<sup>3</sup>, the term ‘APA’ will be employed. In addition, the term ‘PA’ will be employed for Purchase Agreements, which are the contracts whereby the Commission acted as a central purchasing body in the name and on behalf of the Member States in order to procure the COVID-19 vaccines on the basis of that agreement with Member States, but without using the ESI contribution recalled above.

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<sup>3</sup> OJ L 70, 16.3.2016, p.1, as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID- 19 outbreak, OJ L 117, 15.4.2020, p. 3.

Finally, in your confirmatory application you argue that since the initial decision was signed by the Director of the Directorate-General Health Emergency Preparedness and Response Authority, and not by the Secretary-General of the European Commission, the decision should be considered as unlawful.

In this context, it should be noted that Regulation (EC) No 1049/2001 provides for a two-step review process. In accordance with Article 7, paragraph 2 of the Regulation, in the event of a total or partial refusal, the applicant may, within 15 working days of receiving the institution's reply, make a confirmatory application asking the institution to reconsider its position.

In accordance with Article 3, paragraph 3 of Commission Decision of 5 December 2001 amending its rules of procedure which concerns the treatment of initial replies<sup>4</sup>, 'the applicant shall be informed of the response to his application either by the Director-General or the head of department concerned [...].' Only confirmatory decisions should be signed by the Secretary-General, with the exception of confirmatory decisions issued by the European Anti-Fraud Office<sup>5</sup>.

It should be noted that you have received an initial reply signed by the Director of the Directorate-General Health Emergency Preparedness and Response Authority in full compliance with the procedures set in the above-mentioned acts. Consequently, your argument regarding the unlawfulness of the initial reply is unfounded.

## **2.1. Protection of privacy and the integrity of the individual**

Article 4(1)(b) of Regulation (EC) No 1049/2001 provides that '[t]he institutions shall refuse access to a document where disclosure would undermine the protection of [...] privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data'.

In its judgment in Case C-28/08 P (*Bavarian Lager*)<sup>6</sup>, the Court of Justice ruled that when a request is made for access to documents containing personal data, Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data<sup>7</sup> (hereafter 'Regulation (EC) No 45/2001') becomes fully applicable.

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<sup>4</sup> OJ L 345, 29.12.2001, p. 94–98.

<sup>5</sup> See Article 4 of Commission Decision of 5 December 2001 amending its rules of procedure.

<sup>6</sup> Judgment of the Court of Justice of 29 June 2010, *European Commission v The Bavarian Lager Co. Ltd* (hereafter referred to as '*European Commission v The Bavarian Lager* judgment') C-28/08 P, EU:C:2010:378, paragraph 59.

<sup>7</sup> OJ L 8, 12.1.2001, p. 1.

Please note that, as from 11 December 2018, Regulation (EC) No 45/2001 has been repealed by Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC<sup>8</sup> (hereafter ‘Regulation (EU) 2018/1725’).

However, the case law issued with regard to Regulation (EC) No 45/2001 remains relevant for the interpretation of Regulation (EU) 2018/1725.

In the above-mentioned judgment, the Court stated that Article 4(1)(b) of Regulation (EC) No 1049/2001 ‘requires that any undermining of privacy and the integrity of the individual must always be examined and assessed in conformity with the legislation of the Union concerning the protection of personal data, and in particular with [...] [the Data Protection] Regulation’<sup>9</sup>.

Article 3(1) of Regulation (EU) 2018/1725 provides that personal data ‘means any information relating to an identified or identifiable natural person [...]’.

As the Court of Justice confirmed in Case C-465/00 (*Rechnungshof*), ‘there is no reason of principle to justify excluding activities of a professional [...] nature from the notion of private life’<sup>10</sup>.

The documents contain personal data, such as the names and surnames of representatives of the companies concerned as well as handwritten signatures of representatives of the European Commission.

Please note that in accordance with the Commission’s internal administrative practice, the names and surnames of staff members forming part of the senior management of the Commission are disclosed and only the handwritten signatures are redacted.

As far as the representatives of the companies are concerned, the names<sup>11</sup> of the persons concerned as well as other data from which their identity can be deduced undoubtedly constitute personal data in the meaning of Article 3(1) of Regulation (EU) 2018/1725.

Pursuant to Article 9(1)(b) of Regulation (EU) 2018/1725, ‘personal data shall only be transmitted to recipients established in the Union other than Union institutions and bodies if ‘[t]he recipient establishes that it is necessary to have the data transmitted for a specific purpose in the public interest and the controller, where there is any reason to assume that the data subject’s legitimate interests might be prejudiced, establishes that it is proportionate to transmit the personal data for that specific purpose after having demonstrably weighed the various competing interests’.

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<sup>8</sup> OJ L 205, 21.11.2018, p. 39.

<sup>9</sup> *European Commission v The Bavarian Lager* judgment, cited above, paragraph 59.

<sup>10</sup> Judgment of the Court of Justice of 20 May 2003, *Rechnungshof and Others v Österreichischer Rundfunk*, Joined Cases C-465/00, C-138/01 and C-139/01, EU:C:2003:294, paragraph 73.

<sup>11</sup> *European Commission v The Bavarian Lager* judgment, cited above, paragraph 68.

As regards your arguments invoking Article 9 of Regulation (EU) 2016/679<sup>12</sup> (the ‘General Data Protection Regulation’), please note that the Commission is not referring to that Regulation, which is in any event not applicable to the case at hand.

Only if the conditions of Article 9(1)(b) of Regulation (EU) 2018/1725 are fulfilled and the processing constitutes lawful processing in accordance with the requirements of Article 5 of Regulation (EU) 2018/1725, can the transmission of personal data by the European Commission occur.

The first condition of Article 9(1)(b) of Regulation (EU) 2018/1725, namely the need for the recipient to establish that it is necessary to have the data transmitted for a specific purpose in the public interest, has not been fulfilled in the case in hand.

In Case C-615/13 P (*ClientEarth*), the Court of Justice ruled that the institution does not have to examine by itself the existence of a need for transferring personal data<sup>13</sup>. This is also clear from Article 9(1)(b) of Regulation (EU) 2018/1725, which requires that the necessity to have the personal data transmitted must be established by the recipient.

Consequently, your argument by which you claim that the Directorate-General Health Emergency Preparedness and Response should have demonstrated that the exception under Article 4(1)(b) of the Regulation is applicable, is unfounded. As explicitly confirmed by Article 9(1)(b) of Regulation (EU) 2018/1725, the burden of proof for demonstrating necessity of transferring personal data falls on the *recipient* of that personal data.

In addition, according to Article 9(1)(b) of Regulation (EU) 2018/1725, the European Commission has to examine the further conditions for the lawful processing of personal data only if the first condition is fulfilled, namely if the recipient establishes that it is necessary to have the data transmitted for a specific purpose in the public interest. It is only in this case that the European Commission has to examine whether there is a reason to assume that the data subject’s legitimate interests might be prejudiced and, in the affirmative, establish the proportionality of the transmission of the personal data for that specific purpose after having demonstrably weighed the various competing interests.

In your confirmatory application, you do not put forward any arguments to establish the necessity to have the personal data transmitted for a specific purpose in the public interest. The European Commission therefore does not have to examine whether there is a reason to assume that the data subjects’ legitimate interests might be prejudiced.

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<sup>12</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

<sup>13</sup> Judgment of the Court of Justice of 16 July 2015, *ClientEarth v European Food Safety Agency*, C-615/13 P, EU:C:2015:489, paragraph 47.

Notwithstanding the above, there are reasons to assume that the legitimate interests of the data subjects concerned would be prejudiced by the disclosure of the personal data reflected in the documents, as there is a real and non-hypothetical risk that such public disclosure would harm their privacy and subject them to unsolicited external contacts.<sup>14</sup> To that end, please note that the General Court in T-39/17 *Port de Brest*, rejected the necessity of a transfer of data relying on a right of interpellation of a public official.<sup>15</sup>

Consequently, pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access cannot be granted to the personal data, 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 the disclosure of the personal data concerned.

## **2.2. Protection of the commercial interests**

### *2.2.1. Preliminary remarks*

The European Commission has engaged in extensive consultations with the companies with which it had previously signed agreements for the purchase of vaccines against COVID-19. Following these consultations, the Commission concludes that parts concerning the contractual obligations still require protection, as the disclosure of those parts would undermine the legitimate commercial interests of the companies.

Regulation (EC) No 1049/2001 provides that ‘[i]n principle, all documents of the institutions should be accessible to the public. However, certain public and private interests should be protected by way of exceptions’<sup>16</sup>.

Furthermore, in accordance with Article 4(4) of the Regulation, ‘[a]s regards third-party documents, the institution shall consult the third party with a view to assessing whether an exception in paragraph 1 or 2 is applicable, unless it is clear that the document shall or shall not be disclosed’.

Article 4(2) first indent of Regulation (EC) No 1049/2001 provides that ‘[t]he institutions shall refuse access to a document where disclosure would undermine the protection of the commercial interests of a natural or legal person, including intellectual property’.

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<sup>14</sup> See, to that end, the findings of the General Court in judgment of 6 April 2022, *Hans-Wilhelm Saure v European Commission*, T-506/21, EU:T:2022:225;

<sup>15</sup> Judgment of 19 September 2018, *Chambre de commerce et d'industrie métropolitaine Bretagne-Ouest (port de Brest) v European Commission*, T-39/17, EU:T:2018:560.

<sup>16</sup> Recital 11 of the Regulation.

The Courts have concluded that commercially sensitive information relating in particular to the business strategies of the undertakings concerned, to their commercial relations, or where those documents contain information particular to that undertaking which reveal its expertise, are covered by the protection provided for in Article 4(2) first indent of Regulation (EC) No 1049/2001<sup>17</sup>.

Article 4(2), first indent, of Regulation (EC) No 1049/2001 must be interpreted consistently with Article 339 of the Treaty on the Functioning of the European Union (hereafter ‘TFEU’), which requires staff members of the EU institutions to refrain from disclosing information of the kind covered by the obligation of professional secrecy, in particular information about undertakings and their business relations. Applying Regulation (EC) No 1049/2001 cannot have the effect of rendering ineffective Article 339 TFEU, over which it does not have precedence.

The redacted parts of the contracts you request contain information that, if disclosed, would damage the competitive positions of the companies concerned as business actors on the global market for the production and commercialisation of these pharmaceutical products. This is the reason why the contracts themselves contain confidentiality requirements. As stated for instance in the PA with BioNTech-Pfizer, not respecting the confidentiality obligations would amount to a breach of the contracts and could be subject to sanctions under applicable securities laws and regulations.

At the outset, it is important to underline that all the contracts for the purchase of a vaccine against COVID-19 were individually negotiated with each of the companies (hereinafter also the “contractor[s]”) and contain terms which often diverge from one contract to another.

The breadth of the redactions differs according to whether the contractual provisions concerned are contained in contracts concluded at the beginning of the pandemic in 2020 or at a later stage and whether the contracts are still being implemented.

In addition, the General Court has already confirmed<sup>18</sup> that the “commercial interests” exception covers commercially sensitive information relating, in particular to:

- the business strategies of the undertaking(s) concerned;
- their commercial relations;
- expertise;
- prices;
- offers comparative attractiveness;
- financing arrangements;
- amounts of their sales, their market shares; etc.

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<sup>17</sup> Judgment of 9 September 2014, *MasterCard and Others v Commission*, T-516/11, EU:T:2014:759, paragraphs 82 to 84 (hereafter *MasterCard and Others v Commission*).

<sup>18</sup> Judgment of the General Court of 7 February 2018 in case T-718/15, *PTC Therapeutics International v European Medicines Agency (EMA)*, EU:T:2018:66, paragraph 85.  
Judgment of the General Court of 7 September 2022 in case T-448/21, *Saure v European Commission*, EU:T:2022:525, paragraph 88.



It should be noted that the individual negotiation process with each vaccine manufacturer entails that some technical parts of the bid of the tenderer are often taken, normally without significant modifications, in the individual clauses of each APA and PA.

Please note that the bids of tenderers are normally protected by default according to the case-law, which has recognised the existence of a general-presumption of non-disclosure, since their disclosure could be used to distort competition, whether in an ongoing procurement procedure or in subsequent procedures<sup>19</sup>.

The redacted parts in all APAs and PAs which are subject to the present decision contain commercially confidential information such as information about how the companies handle requests to supply vaccine doses, product specifications and component parts, performance and liability apportionment, indemnity regime, timelines, delivery schedules and deadlines, detailed pricing information, as well as other contract specific terms such as applicable modalities and notices in case of late payment and suspension of obligations, intellectual property, information on subcontractors, etc.

The amendments to the APAs/PAs equally contain commercially confidential information, as accepted by the case-law cited above. For instance, in the amendments to the PA with Moderna, specific and detailed information on the delivery schedules and deadlines (amendments no. 1, 2, 4, 5), on the duration of the agreement and the parties' obligations under the agreement (amendments no. 1, 4), on the detailed payment terms and pricing (amendments no. 1-5), on the allocation of additional doses (amendments no. 1,4), on the standard of performance of Contractor's contractual obligations (amendments no. 1, 2, 5), on the supply chain (amendments no. 1-5), on Contractor's contractual obligations regarding delivery of Product doses to applicable Donation Countries and to Resale Countries (amendment no. 1,5), Contractor's contractual obligations in case of late deliveries and the in the event that a shortfall occurs (amendment no. 1, 2), on further contractual obligations to be performed by Contractor under the PA (amendment no. 1), on Contractor's obligations with respect to the development of Variant Products (amendment no. 1), on the possibility that Contractor might supply a Combination Vaccine Product (amendment no. 1), on the parties' liabilities, remedies and indemnification (amendment no. 1,5), on the manufacturing process and network partners involved in the manufacturing process (amendment no. 1), on the deferral conditions (amendment no. 3,4,5), on the amount of incremental doses under the agreement (amendment no.4, 5).

As regards the amendments to the BioNTech-Pfizer Second PA, in particular the fifth amendment includes commercially confidential information on delivery schedules, volumes, and detailed pricing information.

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<sup>19</sup> Judgment of the General Court of 26 March 2020, *Viasat Inc. v European Commission*, T-734/1, EU:T:2020:123, paragraph 43, 50 and 65.  
Judgment of the General Court of 7 September 2022 in case T-651/21, *Saure v European Commission*, EU:T:2022:526, paragraph 104, which concerned the procurement of COVID-19 vaccines.

The disclosure of these details would prejudice companies' negotiations with their other customers or suppliers and would therefore harm the companies economic and commercial interests. It would disclose to competitors detailed information how the companies are performing the vaccine contracts and provide indications to competitors how they might present offers for future public and private contracts for vaccines and other medicinal products. This is the case for instance as far as the contracts concluded with BioNTech-Pfizer are concerned.

In the following paragraphs, the extent to which the exception of the protection of commercial interests of the different companies is established in the present case according to the different contractual provisions that are at stake will be clarified. The risk to harm those interests exists in three respects.

First, as regards the production process followed by the contractor (section '2.2.2.' below), this concerns commercially sensitive information on the industrial organisation and capacity of the contractor to manufacture the vaccine.

Second, this risk exists as to certain financial aspects of the contracts (section '2.2.3. below) and is linked with the economic capacity to continue to produce and deliver the vaccine over time.

Third, the risk at hand exists as to the possible implementation of specific contractual provisions, such as those on liability and indemnification (section '2.2.4.' below), since their full disclosure would reveal to the competitors the precise advantage for the contractor resulting from the negotiations.

#### *2.2.2. Information on contractors' industrial organisation and capacity*

Some of the redacted parts of the documents clearly contain elements that are directly linked with the know-how concerning the development and production of the vaccine.

This for instance occurs in Article I.2 concerning the definition of 'Vaccine' in the first PA with BioNTech-Pfizer and in Article I.6.2 thereof as regards the definition of what is an 'adapted vaccine'.

This also occurs as to the information contained in the annexes to the contracts that contain the production specifications of the vaccines.

If publicly disclosed, details on the product and technology developed by the companies could be used by competitors for their own products, in particular by those pharmaceutical companies that could have recourse to the same technology, thereby creating a subsequent prejudice to their position on the market.

A similar concern exists as regards the delivery process, when this information can be used to glean technical information on the production process, given the very particular features of the product. This is the case as regards for instance ‘Delivery Specification’ in the attachment 3 to the APA concerning the cold chain in the -BioNTech-Pfizer APA and its Article I.6.9, given that the vaccine produced by this company is known as having to be stocked and kept at very cold temperatures<sup>20</sup>.

Moreover, the disclosure of the definition of the mutual obligations of the parties in the field of intellectual property rights can bring prejudice to the contractor.

Disclosure of these provisions would in particular weaken companies’ negotiating positions in future contracts negotiations.

A similar concern exists, finally, as regards, on the one hand, the indication of the production sites, such as in Article I.6.3 of the APA with -BioNTech-Pfizer -, and, on the other, the indication of subcontractors (it is for instance in the Annexes to the contracts with BioNTech-Pfizer). In both cases, the identity of these sites and, more importantly, of their economic or industrial connection with the contractor is not in the public domain. It is often part of the commercial strategy of the operator to have a site in a particular geographic location or to have recourse to a specific manufacturer. Indeed, that specific location (for instance in the EU or outside the territory of the Union) or the recourse to that specific subcontractor (for example only for fill and finish, or also for the distribution) follows from a precise economic choice of the contractor, which reflects its internal business strategy.

In your confirmatory application you argue that ‘[...] Les entreprises sont soumises à l’obligation légale de divulguer des informations d’intérêt public, par exemple dans les secteurs chimique et pharmaceutique. Ces réglementations, qui garantissent un niveau élevé de transparence, ne sont pas affectées. La directive ne permet pas aux entreprises de dissimuler les informations qu’elles sont tenues de soumettre aux autorités de régulation ou au grand public.’

It must be noted that the redactions contain information which is not in the public domain and exceeds the information available following publication of the Marketing Authorisation (MA) and of its annexes on the website of the European Medicines Agency (EMA).

Accordingly, in each of the situations described above, disclosure of the information contained in the redacted contractual provisions would inevitably reveal to the contractors’ competitors a significant element of the contractor’s industrial capacity.

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<sup>20</sup> [https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf), at page 53.

### 2.2.3. *Information on contractors' financial risks*

APAs and subsequent PAs are necessarily similar in nature, since they aim at meeting the same demand, and follow the same procurement procedure under the same legal basis. Those agreements set out the procedures and conditions according to which the Participating Member States shall pay for the COVID-19 doses ordered by them under the contract. They also specify the obligations of the parties during and after the duration of the contracts. However, and in general, while the contractual terms are not necessarily the same for PAs and APAs, namely due to the absence of down payment in the PAs, the negotiations of the APA (including on prices) are always relevant for any following PA.

As regards more specifically the price per dose, total price and currency details (such as exchange rate methodology used for currency conversion) in the contracts, disclosure of such sensitive commercial information would allow the public to draw conclusions on the companies' commercial and pricing strategies which in turn could be used by competitors to plan their own strategies for their own products. In turn, it could seriously undermine the current and future negotiations these companies have worldwide with other entities purchasing their product, with whom they have not yet negotiated the pricing and currency terms.

As regards some specific provisions concerning the EU budget support to the contractors (also known as 'down payment'), the Commission has disclosed the amount of the so-called 'down payment', i.e. the contribution given to the industrial efforts of the contractor by the ESI resources as stipulated in the APAs in almost all contracts.

The Commission allocated €2.15 billion to the ESI budget to fund vaccine APAs, which the Member States topped up with a further €750 million to create a total budget of €2.9 billion. "

The companies concerned by the contracts in which the EU budget support has to be redacted (i.e. Johnson and Johnson and BioNTech-Pfizer) have put forward specific reasons to justify why the amount provided to them by the European Commission is commercially confidential.

Notably, by providing the amount of the down payment, it is possible to make an assessment (e.g. based on market practice) and determine the value of the full contract amount and ultimately of the price per dose, which constitute sensitive commercial information for the companies. The amounts are commercially sensitive information relating to the structure of payments under the APA.

As explained above, this could negatively impact the negotiations of these companies with other entities purchasing the product in question to whom they might offer different pricing terms and be detrimental to the overall operations of these companies as it would provide an insight into the companies' pricing strategy and structure.

The case law of the EU Courts has already clarified that commercially sensitive information relating, in particular, to the business strategies of the undertakings concerned or to their commercial relations, as well as information particular to that undertaking and that can reveal its expertise, are covered by the protection provided for in Article 4(2) first indent of Regulation (EC) No 1049/2001<sup>21</sup>.

Potential business risks and related advice on the reduction of those risks, prices charged as part of a sensitive contract, and thresholds of financial covenants concluded in that framework can also be commercially sensitive, especially for contracts which are still under implementation<sup>22</sup>.

The disclosure of those parts of the contracts would clearly put the contractor in a disadvantageous position vis-à-vis its competitors, because it would let them know the level of financial risk the contractor has accepted with the conclusion of the contracts and would provide an insight to competitors into the companies' pricing strategies.

For these reasons, it must be considered that certain financial aspects in the contracts should remain protected on the basis of the exception provided for in Article 4(2) first indent of Regulation (EC) No 1049/2001.

#### 2.2.4. *Information on contractors' risks of incurring liability*

Contractual provisions on liability and indemnification have been partially redacted in each contract, as disclosure of those parts would cause serious and non-hypothetical prejudice to the commercial interests of the contractor, on the basis of three reasons.

First, a precise knowledge of the boundaries of the contractor's liability would allow for strategic behaviour against the latter, which could face the economic consequences of multiple legal actions initiated only for the purpose of receiving compensation from the use of those products.

Second, a full disclosure of the contractual provisions on indemnification, in particular of those concerning the exact conditions which do not allow the contractor to have recourse to indemnification, would inevitably reveal to the contractor's competitors – namely to all pharmaceuticals companies, even those that do not produce vaccines – the 'weak points' of the contractor's coverage of its possible liability, and provide them with a competitive advantage that they could further exploit.

Third, the precise knowledge of the boundaries of the contractor's liability would also have an impact on the general reputation of the contractors towards both the consumers and possible business partners.

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<sup>21</sup> *MasterCard and Others v Commission*, cited above, paragraphs 82 to 84.

<sup>22</sup> Judgment of the General Court of 27 February 2018 in case T-307/16, *CEE Bankwatch Network v Commission*, paragraph 110.

This is liable to undermine the interests of the contractors in a non-hypothetical manner, exposing them to external pressure which does not form part of the ordinary business environment in which the APAs and PAs were negotiated.

This explains why some parts of the contractual clauses on indemnification (i.e. of the conditions according to which the contractor is indemnified) cannot be disclosed, as, for instance, is the case for the redactions in Article I.12 of the APA with BioNTech-Pfizer.

In addition, some specific contractual provisions have a commercial dimension which has been measured and agreed upon by the contractor and whose disclosure would reveal to possible competitors information about the internal business capacity and strategy of the individual economic operator.

This is the case for Article I.6.3 (iv) of the APA with BioNTech-Pfizer concerning possible issues the contractor might incur in the supply mechanism and for Article I.6.7 thereof, concerning a waiver.

The same holds true as to the contractual provisions on the delivery schedule and the contractual obligations relating thereto.

Finally, this also occurs as regards, for example, Article II.6.4(iii) of the PA with BioNTech-Pfizer, concerning the financial cap on contractual liability and Article II.8.4, of the same contract, concerning contractor's warranties.

In all these cases, the redacted information is commercially sensitive because it gives the precise understanding of the costs that a breach of contract could generate for the contractor. Such a possible consequence on the contractor is self-explanatory if one considers the case of the provisions regulating the delivery schedule that often contain rules on liquidated damages in case of late deliveries or shortfall.

As explained, the disclosure of this information would be detrimental to the contractor if known by a competitor, because it would provide the latter with a very realistic view of the actual profits the former generated when concluding the contract with the Commission. This is particularly true if one considers, on the one hand, the fact that the same contractors are also engaged with negotiating contracts for the delivery of COVID-19 vaccines with other constituencies throughout the world and, on the other, that it is on this global market that the competition takes place. This risk is foreseeable and may very well materialise. The possible conflict with the contractor's commercial interests is all the more harmful for the latter if the contract is on the point of being implemented, as it is the case for the Second PA concluded with BioNTech-Pfizer.

Furthermore, there continues to be a global market for COVID-19 vaccines on which constituencies conclude also new contracts after the expiry of the contracts concluded at the onset of and during the pandemic.

In this context, the global market in which the companies operate has to be taken into account when assessing the effects of public disclosure under Regulation (EC) No 1049/2001. Indeed, when assessing the applicability of the exception “commercial interests” to some redactions, different factors were considered such as the specific situation on the market of each vaccine manufacturer, its characteristics, its relations with other commercial actors, its market and business strategies and the use that competitors could make of information disclosed.

Therefore, it must be concluded that the full disclosure of the agreements with the companies would undermine the commercial interests of the latter, mainly by undermining their competitive positions on the global market. In particular, disclosure of document 5 and the redacted parts of documents 1-4, 6-12 would undermine the commercial interests of Moderna, Jansen Pharmaceuticals and BioNTech-Pfizer in a reasonably foreseeable and non-hypothetical manner.

Consequently, it should be concluded that access to the entirety of the documents cannot be granted, on the basis of the exception provided for in Article 4(2) first indent (protection of the commercial interests) of Regulation (EC) No 1049/2001.

### **3. OVERRIDING PUBLIC INTEREST IN DISCLOSURE**

Firstly, please note that Article 4(1)(b) of Regulation (EC) No 1049/2001 does not include the possibility for the exception defined therein to be set aside by an overriding public interest.

The exception laid down in Article 4(2) first indent (protection of the commercial interests) of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosure. Such an interest must, firstly, be public and, secondly, outweigh the harm caused by disclosure.

In your confirmatory application, you refer to a judgment of the High Court of South Africa – Pretoria Division » of 17 August 2023, in which the Court ruled that there is a public interest in the disclosure of the contracts.

With respect to this statement, as already explained by the Directorate-General for Health Emergency Preparedness and Response Authority, the European Union is not legally obliged to adhere to a judgment issued in a third country, especially when it pertains to the disclosure of documents in which the European Union has no implication. Furthermore, as already explained in the preceding sections, the contracts concluded between the European Commission and the pharmaceutical companies result from a long negotiation process; they contain terms and conditions which have been agreed upon with regard to the interests of the EU.

The conclusions from a third country Court judgment do not by themselves constitute substantial grounds for demonstrating that a prevailing overriding public interest in the European Union would outweigh the grounds justifying the refusal of a full disclosure of the documents you request access to.

This does not in any way mean that the public order of the European Union is less protective for the European citizens than the one of South Africa, contrary to what you argue in your application.

You further explain that ‘[...] il convient de souligner que lorsque la Commission commet une erreur de droit lorsqu’elle indique « il appartient à la personne qui fait valoir l’existence d’un intérêt public supérieur de démontrer l’existence de circonstances spécifiques justifiant la divulgation » puisque dans un tel cas c’est justement à la Commission d’effectuer un contrôle de proportionnalité afin de déterminer si la production du contrat sans occultation n’est pas néanmoins justifiée par un intérêt supérieur. Or, la Commission ne le fait pas, elle n’a même pas un mot sur ce point, ignorant totalement l’intérêt public supérieur de l’Union Européenne et des citoyens. Pire encore, alors que l’Afrique du Sud comme l’ensemble des Etats Membres de l’UE ont adhéré à la Déclaration Universelle des Droits de l’Homme et donc partagent les mêmes Valeurs Fondamentales, la Commission prétend que l’intérêt public supérieur des habitants de l’Afrique du Sud serait différent de celui des citoyens de l’UE qui eux auraient moins de droit à la Transparence. Là encore, la Commission procède par affirmations péremptoires au lieu de raisonner en droit et d’effectuer un contrôle de proportionnalité des intérêts en présence.’

As a preliminary remark, please note that according to settled case-law of the Court of Justice, the burden of proof to demonstrate the existence of an overriding public interest falls on the applicant who must, on the one hand, demonstrate the existence of a public interest likely to prevail over the reasons justifying the refusal of access to the documents concerned and, on the other hand, demonstrate precisely in what way disclosure of the documents would contribute to assuring protection of that public interest to the extent that the principle of transparency takes precedence over the protection of the interests which motivated the refusal<sup>23</sup>. It is therefore for the person making the application for access who wishes, by arguing that there is an overriding public interest, to convince the institution in question to reconsider its position, to submit arguments to that effect.<sup>24</sup>

It must be underlined that the Court of Justice acknowledged that a general reference to transparency is not sufficient to substantiate an overriding public interest<sup>25</sup>, including convincing arguments, explaining that the requested documents would be necessary for the effective participation in the legislative process, with the aim of increasing the protection of human health and the environment<sup>26</sup>.

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<sup>23</sup> Judgment of the General Court of 9 October 2018, *Anikó Pint v European Commission*, T-634/17, EU:T:2018:662, paragraph 48; Judgment of the General Court of 23 January 2017, *Association Justice & Environment, z.s v European Commission*, EU:T:2017:18, paragraph 53; Judgment of the General Court of 5 December 2018, *Falcon Technologies International LLC v European Commission*, T-875/16, EU:T:2018:877, paragraph 84.

<sup>24</sup> Judgment of the General Court of 5 October 2022, *Múka v European Commission*, T-214/21, EU:T:2022:607, paragraph 66.

<sup>25</sup> Judgment of the Court of Justice of 16 July 2015, *ClientEarth v Commission*, C-612/13 P, EU:C:2015:486, paragraph 93.

<sup>26</sup> Judgment of the General Court of 1 February 2023, *ClientEarth v Commission*, EU:T:2023:34T-354/21, paragraph 94.



General assertions that the disclosure of the documents is necessary for the protection of human health without providing specific grounds showing to what extent such disclosure would serve that general interest<sup>27</sup>.

It results from the above that the threshold for demonstrating the existence of an overriding public interest, thereby waiving the application of the exceptions under Article 4 of Regulation (EC) No 1049/2001, is very high.

You have not provided such reasons to demonstrate the existence of an overriding public interest.

Contrary to what you argue, the Commission has conducted its own assessment in order to determine whether any public interest is capable of overriding the public and private interest protected by Article 4(2) first indent (protection of the commercial interests). The result of this assessment is that the circumstances of the case do not substantiate a finding that the principle of transparency is especially pressing to constitute an overriding public interest in disclosure.

The Commission has consulted the companies concerned and has performed a careful examination of the interests at stake which has resulted in granting partial access to the contracts in question.

The Commission fully adheres to the principle that transparency is an essential component of the decision-making process of the EU. Sharing information regarding vaccine development and funding with the public is particularly important and the Commission is aware of the high level of transparency required for this type of negotiations, which are not conducted in secrecy.

The importance of transparency in the process of vaccine procurement was repeatedly stated by the Commission on various occasions.

This is also the reason why the Commission has engaged in several consultations with the companies, the result of which was to grant further partial access to the documents compared to what was released initially.

The Commission re-examines its position regarding disclosure of the contracts progressively with the passage of time since the end of the contracts' negotiations. The Commission has replied and is still replying on a regular basis to a very large number of access to documents requests submitted under Regulation (EC) No 1049/2001 on the subject matter of the vaccine negotiations.

While the Commission agrees on ensuring a high level of transparency of contracts, it has to protect commercially sensitive information which, if disclosed, would damage the competitive positions of the companies concerned, as explained above.

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<sup>27</sup> Judgment of the Court of Justice of 11 May 2017, *Sweden and Spirlea v Commission*, C-562/14 P, EU:C:2017:356, paragraphs 55-57.

This is why the contracts themselves contain confidentiality clauses, which need to be respected by the Commission, as addressed in the speech by Commissioner Kyriakides. Indeed, the right of access to documents is not a general and absolute right, but may be subject to limitations and restrictions, as recognised by the Courts<sup>28</sup>.

It should be noted that the confidentiality requirements persist even after the expiry of the contracts.

The Commission has taken various steps to provide the widest possible transparency of the negotiations, without nonetheless undermining the commercial interests of the actors involved. The Commission is working to ensure the utmost transparency and inclusion in stepping up preparedness and availability of medical countermeasures in the EU.

In this context, the European Commission has regularly published information on the state of play of the negotiations with vaccine manufacturers and has informed the public when a contract was concluded. Furthermore, it is public knowledge that part of the related funding for concluding the advance purchase agreements with the companies has come from the Emergency Support Instrument (ESI).

The Commission has endeavoured to provide first-hand information to the European Parliament at the plenary debates, Committees, in 21 meetings of the Vaccines Contact Group, and in writing (parliamentary questions, follow-up questions, letters).

Concerning your argument that ‘L’on constate donc qu’il existe en la matière un monopole des État Membres et donc une interdiction – et par là même une contrainte – faite à toute autre personne, qu’elle soit une entité économique ou un particulier, de se procurer les vaccins. Ce monopole, accompagné de l’interdiction faite à toute autre personne de se procurer les vaccins, ne peut que conduire à considérer que les actes (en l’occurrence les contrats) par lesquels les État Membres s’octroient seuls le droit de se procurer les vaccins, constituent une manifestation évidente d’un intérêt public supérieur’, In the context of the COVID-19 crisis, the European Commission has issued a European Strategy to accelerate the development, manufacturing and deployment of vaccines<sup>29</sup>. With the Vaccines Strategy – which did not entail the granting of a monopoly to Member States – the Commission supported efforts to make the process more efficient, resulting in the timeframe being reduced to less than one year for most vaccines.

Notwithstanding the above, it should be noted that these considerations exceed the scope of application of Regulation (EC) No 1049/2001.

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<sup>28</sup> See judgment of the General Court of 3 May 2018, *Malta v Commission*, T-653/16, EU:T:2018:241 paragraph 160.

<sup>29</sup> [https://commission.europa.eu/strategy-and-policy/coronavirus-response/public-health/eu-vaccines-strategy\\_en](https://commission.europa.eu/strategy-and-policy/coronavirus-response/public-health/eu-vaccines-strategy_en).

Moreover, it should be noted that according to the Court of Justice's case-law, administrative activities, such as the ones in hand, do not require the same breadth of access to documents as that required by the legislative activities of an EU institution<sup>30</sup>.

For the reasons explained above and taking into account the careful balance of the interests at stake, the Commission has not been able to identify any public interest capable of overriding the interests protected by Article 4(2) first indent (protection of the commercial interests).

Consequently, no overriding public interest in disclosure of the redacted parts of the contracts and the disclosure of document 5 could be established.

#### **4. PARTIAL ACCESS**

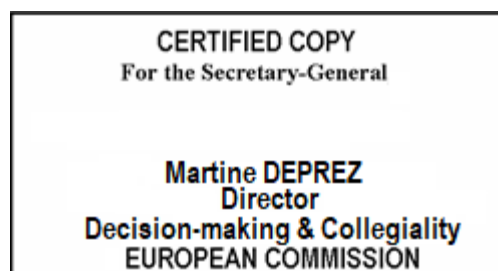
In accordance with Article 4(6) of Regulation (EC) No 1049/2001, with the exception of document 5, partial access is granted to the documents requested to the widest possible extent. No further partial access is possible without undermining the interests protected by the exceptions described above.

#### **5. MEANS OF REDRESS**

Finally, I draw your attention to the means of redress available against this decision. You may either bring proceedings before the General Court or file a complaint with the European Ombudsman under the conditions specified respectively in Articles 263 and 228 of the Treaty on the Functioning of the European Union.

Yours sincerely,

*For the Commission*  
*Ilze JUHANSONE*  
*Secretary-General*



Enclosures: 11

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<sup>30</sup> See judgments of the Court of Justice of 29 June 2010, *Commission v Technische Glaswerke Ilmenau*, C-139/07 P, EU:C:2010:376, paragraph 60, and Judgment of the Court of Justice 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, paragraph 77.