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SENSITIVE[*]

COMMISSION DECISION

of XXX

on approving a Purchase Agreement on vaccines against COVID-19 and Sars-Cov-2 variants

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COMMISSION DECISION

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EU) 2016/369 as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support[1], and in particular Article 4(5)(b) thereof,

Whereas:

(1) On 9 June 2020, the Council of Ministers for health agreed on the need for joint action to ensure the quickest development and deployment of the safest and most efficient vaccine against COVID-19 by securing rapid, sufficient and equitable supplies for Member States. To do so, it requested the Commission to run a central single procurement procedure on behalf of the Member States, with a view to signing EU-level Advance Purchase Agreements ("APA") with vaccine candidates where they would be successful, including up-front EU financing to de-risk essential investments to increase the speed and scale of manufacturing successful vaccines.

(2) On 17 June 2020, the Commission adopted a Communication[2] in which the Commission set out an EU Strategy for COVID-19 vaccines and invited companies with a promising vaccine candidate, already in or close to starting clinical trials, to contact the Commission.

(3) In line with this Commission Communication and the requirements of the ESI Regulation, the Commission and the Member States agreed that the Commission carries out procurement procedures on behalf and in the name of the Member States setting out the terms applicable to such purchase and the reciprocal commitments of the parties.

(4) So far, six APAs have been concluded with AstraZeneca AB[3], Sanofi Pasteur S.A. and Glaxosmithkline Biologicals S.A[4], Janssen Pharmaceutica NV[5], Pfizer Inc. and BioNTech Manufacturing GmbH[6], CureVac AG[7] and Moderna Switzerland GmbH[8]. The APAs with Pfizer Inc. and BioNTech Manufacturing GmbH and Moderna

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1 Council Regulation (EU) 2016/369 on the provision of emergency support within the Union as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support and amending its provisions taking into account the COVID- 19 outbreak ("ESI Regulation"; OJ L 117, 15.4.2020, p. 3).

2 COM(2020) 245 final.

3 C(2020) 5707 final.

4 C(2020) 6383 final.

5 C(2020) 7032 final.

6 C(2020) 7950 final.

7 C(2020) 8154 final.

8 C(2020) 8434 final.

Switzerland GmbH provide for optional doses. Since there was considerable demand for optional doses under those APAs, the Commission decided to exercise the options under both APAs at the same time under the same decision. These APAs are a crucial element contributing to the European response to fight the COVID-19 pandemic.

(5) So far, two purchase agreements ("PA") with Pfizer Inc. and BioNTech Manufacturing GmbH[9] and Moderna Switzerland GmbH[10] were concluded, in order to increase the number of COVID-19 vaccines available to Member States in 2021 and 2022.

(6) As of today, the EU has granted conditional Marketing Authorisations for four COVID-19 vaccines, respectively to Pfizer Inc. and BioNTech Manufacturing GmbH[11], Moderna Switzerland GmbH[12], AstraZeneca AB[13] and Janssen-Cilag International NV[14]. The COVID-19 pandemic in the EU continues to spread and mortality rate continues to remain very high, with significant economic impacts for the Member States and high burdens for hospital systems. Large-scale vaccination campaigns are ongoing. However, scientific experts indicate that the plausible waning of vaccine induced immunity over time may require booster vaccinations. Important numbers of Sars-Cov-2 variants are already increasingly spreading, increasing the likelihood of escape-variants to occur, which will require that adapted vaccines to new variants are developed as early as possible and in suffient quantities. No COVID-19 vaccine has been granted marketing authorisation in the European Union for the paediatric population under 16 years of age , with the consequence that this population is not being vaccinated.

(7) There is a high demand by Member States for availability of doses of the COVID-19 vaccines in the course of the entire year 2021, as well as in 2022 and 2023, until 2024 in order to continue vaccinating large parts of their population and in order to boost the immunity response of vaccinated population within the shortest possible timeframe, as vaccination is seen as an important factor to reach a turning point in the pandemic and limit the circulation of the virus, as well as the emergence of new variants.

(8) In the light of this demand, the Commission entered into exploratory talks with vaccine manufacturers, including Pfizer Inc. and BioNTech Manufacturing GmbH, to assess their availability and capacity to produce and deliver additional doses of COVID-19 vaccines and to develop, produce and deliver vaccines efficacious against

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9 C(2021) 919 final.

10 C(2021) 1163 final.

11 Commission Implementing Decision of 21.12.2020 granting a conditional marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Comirnaty - COVID-19 mRNA Vaccine (nucleoside modified)", a medicinal product for human use (C(2020)9598).

12 Commission Implementing Decision of 06.01.2021 granting conditional marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "COVID-19 Vaccine Moderna- COVID-19 mRNA Vaccine (nucleoside modified)", a medicinal product for human use (C(2021)094 final).

13 Commission Implementing Decision of 29.01.2021 granting a conditional marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "COVID-19 Vaccine AstraZeneca - COVID-19 Vaccine (ChAdOx1-S [recombinant])", a medicinal product for human use (C(2021)698).

14 Commission Implementing Decision of 11.03.2021 granting a conditional marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "COVID-19 Vaccine Janssen - COVID-19 vaccine (Ad26.COV2-S [recombinant])", a medicinal product for human use.

Sars-Cov-2 variants, as well as vaccines for paediatric population, to be supplied to the Member States in late 2021, and in the course of 2022 and 2023, until 2024. In order to ensure security of supply for the European Union, these exploratory talks in particular concerned the capacity of vaccine manufacturers to manufacture their vaccines in the European Union, and to obtain – as much as possible – all key inputs necessary for such vaccine production from suppliers located in the European Union.

(9) It resulted from such exploratory talks and from the analysis of the vaccine producers' manufacturing capacities and their actual deliveries that Pfizer Inc. and BioNTech Manufacturing GmbH would currently be the only companies able to address the Member States demand in terms of quantities and delivery years, security of supply from production sites within the European Union and which would also commit to develop, produce and supply to Member States vaccines efficacious against Sars-CoV-2 variants as well as vaccines for the paediatric population.

(10) Due to the absence of alternative suppliers meeting those conditions and therefore the absence for technical reasons of competitor tenderers and to the urgency of limiting the impacts of the COVID-19 pandemic, given the availability of Pfizer Inc. and BioNTech Manufacturing GmbH to, on the one hand, continue producing COVID-19 vaccines in the European Union and supply Member States, and, on the other hand, develop and produce vaccines efficacious against Sars-Cov-2 variants, and on the basis of the opinion expressed by Member States in the Steering Board about the urgency of securing vaccines doses for late 2021, 2022 and 2023, until 2024 the Commission conducted a negotiated procedure without prior publication of a contract notice, in accordance with Article 164(1)(d) and points 11(1)(b)(ii) and 11(1)(c) of Annex I to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ("Financial Regulation")[15]. Those Articles provide for such procedure to be launched in so far as strictly necessary, where alternative suppliers and therefore competitor tenderers are absent for technical reasons, Pfizer Inc. and BioNTech Manufacturing GmbH being the only companies currently on the market in a position to supply from production facilities located in the EU the Member States in a large-scale with vaccines efficacious against Sars-Cov-2 variants as well as vaccines for the paediatric population, and where for reasons of extreme urgency brought about by unforeseeable events, such as the COVID-19 outbreak, it is impossible to comply with the procedural requirements laid down in points 24, 26 and 41 of Annex I to the Financial Regulation, and where the justification of such extreme urgency is not attributable to the contracting authority. Consequently, on 9 April 2021, the Commission sent the invitation to participate in this procurement procedure to Pfizer Inc. and BioNTech Manufacturing GmbH (hereinafter jointly the "tenderer").

(11) Following negotiations with the tenderer that met the criteria set out in the tender documents, the Commission intends to sign a new Purchase Agreement ("PA") with Pfizer Inc. and BioNTech Manufacturing GmbH governing the rights and obligations for the Participating Member States to buy additional vaccine doses in the course of 2021, 2022 and 2023, until 2024 ccording to an agreed delivery schedule and at a

[15] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193, 30.7.2018, p. 1.

certain price. Member States have agreed to apply the procedures under the Agreement between the Commission and the Member States to such a PA[16].

(12) The procurement procedure falls under the scope of the ESI Regulation. However, there will be no spending of ESI budget, as the price for vaccines doses falling under the scope of the new PA would be financed entirely by Member States. Nevertheless, the Union's interests are impacted within the framework of the PA as the Union is engaging resources into the coordination and preparation thereof.

(13) As stipulated in the ESI Regulation, the procurement procedure was carried out in conformity with the requirements of the Financial Regulation, which contains rules that are equivalent to those of the European procurement Directive[17], and therefore also to national procurement rules. Vaccine doses under the PA with Pfizer Inc. and BioNTech Manufacturing GmbH will be allocated to Participating Member States according to the population distribution key, unless otherwise agreed with the Member States.

(14) While the Commission is responsible for the procurement process and the conclusion of the PA, including any liability arising out of the conduct of the negotiations, the Participating Member States acquiring the vaccine doses are responsible for the deployment and use of the vaccines under their national vaccination strategies, and shall bear any liability associated with such use and deployment. This extends to and includes the indemnification of Pfizer Inc. and BioNTech Manufacturing GmbH under the terms and conditions of the PA for liability related to the use and deployment of vaccines borne by the manufacturer in accordance with the existing legal framework.

(15) In the context of the COVID-19 pandemic the new PA with Pfizer Inc. and BioNTech Manufacturing GmbH aims to address the urgent need to secure the supply of vaccine doses efficacious against COVID-19 as well as the development, production and supply of vaccine doses against Sars-Cov-2 variants, with a priority right on the delivery according to the terms and conditions of the PA, and of vaccine doses for peadiatric population, to the benefit of all EU citizens in an equitable, safe and efficient manner. It further aims at securing manufacturing of the above vaccines doses in the European Union and it is therefore a crucial element contributing to the European response to fight the COVID-19 pandemic.

(16) Such PA has been negotiated under pandemic circumstances where safe and efficacious vaccines need to be developed and produced as soon as possible and where the global demand for such a vaccine is unprecedented. Consequently, although the Commission managed during negotiations to reduce the contractual risks allocated to the Participating Member States, the PA contains certain clauses where the risks, including on liability, are necessarily shared between Pfizer Inc. and BioNTech Manufacturing GmbH and the Participating Member States. The Commission, assisted by the Member States, has made its best efforts to limit what is required by Pfizer Inc. and BioNTech Manufacturing GmbH for the purposes of indemnification under the PA.

(17) The Commission intends to sign the PA with Pfizer Inc. and BioNTech Manufacturing GmbH as contracting parties, whilst noting that Pfizer is the group leader of the joint

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16 Commission Decision of 18 June 2020 C (2020) 4192 final and its annexed Agreement.

17 Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC, OJ L 94, 28.3.2014.

tender, and Pfizer Inc. and BioNTech Manufacturing GmbH remain fully responsible for any subcontracting carried out. The PA is for the initial purchase of 900 million doses on behalf of all EU Member States, to be ordered in the course of 2021, 2022 and 2023, until 2024 plus an option to request up to further 900 million doses. The option can be exercised by the Commission on behalf of the Member States subject to the terms and conditions of the PA.

(18) As Member States have agreed to apply the procedures under the Agreement between the Commission and the Member States also to the conclusion of the PA, the procedures thereunder apply. The PA with Pfizer Inc. and BioNTech Manufacturing GmbH provides for an obligation to purchase vaccine doses. In accordance with Article 4 of the Agreement between the Commission and the Member States, where the Commission intends to conclude an agreement containing an obligation to acquire vaccine doses, it shall inform the Member States of such intention and the detailed terms. In case a Member State does not agree with the conclusion of an agreement containing an obligation to acquire vaccine doses or its terms, that Member State has the right to opt out by explicit notification to the Commission within five working days after the Commission has communicated its intention to conclude the agreement. All Member States not having opted out within the period of five working days are deemed to have authorised the Commission to negotiate and conclude the agreement with the vaccine manufacturer in their name and on their behalf and become thus Participating Member States under the agreement. Once concluded, the terms of the agreement shall be legally binding on the Participating Member States.

(19) With the approval of the PA, the Commission formally expresses its intention to conclude a PA with Pfizer Inc. and BioNTech Manufacturing GmbH. The PA with Pfizer Inc. and BioNTech Manufacturing GmbH should be communicated to the Member States with a view to allowing them opt out, should any of them so wish.

(20) On condition that at least four Member States have not opted out, and provided that in case of any opt-out by any Member State(s) the Participating Member States provide the necessary assurances that they commit to purchasing and sharing between them the full vaccine volume of 900 million vaccine doses in accordance with the PA, the Commission should authorise the signature of the PA with Pfizer Inc. and BioNTech Manufacturing GmbH in the name and on behalf of the Participating Member States.

(21) In view of the significance of the subject matter of the PA, the authorising officers by delegation asked the Commission to decide on the approval of the PA, as provided for in Article 4(2) of Commission Decision C(2018) 5120 final ("Internal Rules")[18].

(22) Given that the PA with Pfizer Inc. and BioNTech Manufacturing GmbH is an effective and necessary mean to attain the specific aims of the Commission's and Member States' joint action to ensure the quickest development and deployment of safe and efficacious vaccines against Sars-Cov-2 and its variants, by securing rapid, sufficient and equitable supplies for Member States, and given that it effectively contributes to the achievement of the goals of the ESI Regulation, it is appropriate to approve the signature of the PA,

[18] Commission Decision of 3 August 2018 on the Internal Rules on the implementation of the general budget of the European Union (European Commission section) for the attention of the Commission departments.

HAS DECIDED AS FOLLOWS:

Article 1

(1) The Commission approves the Purchase Agreement with Pfizer Inc. and BioNTech Manufacturing GmbH set out in Annex I to this Decision.

(2) The text of the Purchase Agreement with Pfizer Inc. and BioNTech Manufacturing GmbH shall be communicated to all Member States in accordance with Article 4 of the Agreement between the Commission and the Member States.

(3) The Commission authorises the Commissioner with responsibility for Health and Food Safety to sign the Purchase Agreement with Pfizer Inc. and BioNTech Manufacturing GmbH in the name and on behalf of Member States that have not exercised their right to opt out in accordance with Article 4 of the Agreement between the Commission and the Member States, provided that at least four Member States have not exercised their right to opt out and provided that in case of any opt-out by any Member State(s) the Participating Member States provide the necessary assurances that they commit to purchasing and sharing between them the full vaccine volume of 900 million vaccine doses in accordance with the Purchase Agreement.

Article 2

(1) Provided there would be a corresponding demand expressed by the Member States, the Commission shall exercise the option under the PA with Pfizer Inc. and BioNTech Manufacturing GmbH to purchase the additional doses of up to 900 Million doses, in minimum tranches, according to the terms and conditions defined in the PA.

(2) The Commission authorises the Commissioner with responsibility for Health and Food Safety to make the necessary communications and arrangements with Pfizer Inc. and BioNTech Manufacturing GmbH to implement this decision in order to exercise the option under the PA.

Done at Brussels,

For the Commission
Stella KYRIAKIDES
Member of the Commission