



DG SANTE
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**ANNEX**  
**to the**  
**COMMISSION DECISION**  
**approving an Amendment to a Purchase Agreement on vaccines against COVID-19 and**  
**Sars-Cov-2 variants**

Contract No: SANTE/2021/ C3/010



EUROPEAN COMMISSION  
Directorate-General for Health and Food Safety

Sensitive\*  
RELEASABLE TO: Need to know basis

**AMENDMENT NO. 1 TO PURCHASE AGREEMENT (“Amendment No. 1”) for the  
production, priority-purchasing options and supply of a successful COVID-19 vaccine for EU  
Member States**

**NUMBER — SANTE/2021/ C3/010**

1. The European Commission (the ‘**Commission**’), acting on behalf and in the name of the **Member States** listed in Annex I of the PA (hereinafter referred to as “**Participating Member States**”) being represented for the purposes of signature of this Amendment No. 1 by Ms Stella Kyriakides, Commissioner for Health and Food Safety;

on the one part and

2. Moderna Switzerland GmbH

a limited liability company (“Gesellschaft mit beschränkter Haftung”) organized and existing under the laws of Switzerland

Company Number CHE-344.522.989

Aeschenvorstadt 48 ( [REDACTED] ), 4051 Basel, Switzerland

(the ‘**Contractor**’), represented for the purposes of the signature of this Amendment No. 1 by [REDACTED]

on the other part.

The Commission, acting on behalf and in the name of the Participating Member States, and the Contractor are together referred to as the “**Parties**” and each individually as a “**Party**”.

have agreed to the following amendments to that certain PURCHASE AGREEMENT, dated as of 1 March 2021 (the “**PA**”) for the production, priority-purchasing options and supply of a successful COVID-19 vaccine for EU Member States. Capitalized terms in this Amendment No. 1 that are not otherwise defined herein will have the meanings ascribed to such terms in the PA.

**The PA is amended as follows:**

1. The Recitals are replaced in their entirety by the following:



## **“RECITALS**

- A. The Commission and Moderna entered into an **ADVANCE PURCHASE AGREEMENT**, dated as of December 4, 2020 (the “**Original APA**”) for the production, priority-purchasing options and supply of a successful COVID-19 vaccine for EU Member States to secure the availability of a total of 80 million doses of the Product (as defined in the Original APA), with the option to order up to a total of 80 million additional doses of the Product (as defined in the Original APA), subject to the terms and conditions of the *Original APA*.
- B. The Commission exercised the option under the *Original APA* for a total of 80 million additional doses of the Product (as defined in the Original APA).
- C. The Commission on behalf and in the name of the *Participating Member States* entered into this Purchase Agreement (the “**PA**”) with the *Contractor* to secure the availability of one hundred and fifty million (150,000,000) additional doses of the Product, to be allocated among the *Participating Member States* in accordance with the allocation principles set out in this PA.
- D. On 15 June 2021, the Commission, on behalf of and in the name of the *Participating Member States*, exercised the option to order one hundred and fifty million (150,000,000) additional doses of the Product under this PA, subject to the Parties entering into an amendment to this PA to incorporate additional terms and conditions negotiated by the Parties prior to such option exercise relating to the doses of Product to be ordered, delivered and allocated among the *Participating Member States*, including (i) terms and conditions relating to the manufacturing and supply of [REDACTED] to *Participating Member States* under this PA and (ii) a new [REDACTED] delivery schedule for the Additional Doses and the Additional Option Doses under this PA.
- E. On [ ] July 2021, the Commission and the Contractor entered into the Amendment No. 1 to the Purchase Agreement (“**Amendment No. 1**”) to incorporate such additional terms and conditions relating to the doses of Product to be ordered, delivered and allocated among the *Participating Member States* under this PA.”

## **2. Article I.1 is replaced with the following:**

### **“I.1. ORDER OF PRIORITY OF PROVISIONS**

If there is any conflict between different provisions in this PA, as amended, the following rules must be applied:

- (a) The provisions of Amendment No. 1 take precedence over those in the PA.
- (b) The provisions set out in the special conditions take precedence over those in the other parts of the PA.
- (c) The provisions set out in the general conditions take precedence over those in the Vaccine Order Form (Annex II).”

**3. Article I.2 is replaced with the following:**

**“I.2. SUBJECT MATTER**

The subject of this PA is the purchase of 150 million doses of the Product, as described below as Additional Doses in Article I.4.2 to be allocated among the *Participating Member States* by the *Commission* in accordance with the allocation principles set out below in Article I.4.2. In addition, pursuant to this PA, the *Commission* has exercised the option to order, on behalf and in the name of the *Participating Member States*, 150 million additional doses of the Product as Additional Option Doses as set out in Article I.4.4.

On the basis of this PA, the *Contractor* commits to supply the contractually agreed volumes of Additional Doses to the *Participating Member States* in accordance with the delivery schedule and subject to the terms and conditions set out below in Articles I.4.2, I.4.7, I.4.7.1A and I.4.7.1B. In addition, the *Contractor* commits to supply the Additional Option Doses in accordance with the conditions set out in Article I.4.4, I.4.7, I.4.7.1A and I.4.7.1B.

Each *Participating Member State* shall issue a *Vaccine Order Form* as regards its allocation of the *Additional Doses*, through which the *Contractor* shall supply to the *Participating Member States* the *Product* doses in accordance with the terms of this PA. In addition, pursuant to this PA, the *Commission* acting on behalf and in the name of the *Participating Member States* exercised the *Optional Increase* under Article I.4.4, and each *Exercising Member State* shall issue a *Vaccine Order Form* as regards its allocation of the *Additional Option Doses*, through which the *Contractor* shall supply to the *Exercising Member States*, the *Additional Option Doses* in accordance with the terms of this PA. The Parties agree to cooperate with each other in good faith to take such other actions (including working collaboratively to correct any clerical, typographical, or other similar errors in this PA) as the other Party may reasonably request for purpose of carrying out the intent of this PA, including Amendment No. 1.

The delivery of the *Product* to the individual *Participating Member States* shall be carried out in accordance with the terms and conditions of this PA and in particular in accordance with the allocation notified by the *Commission*, as well as the additional delivery details set out in the *Vaccine Order Forms* to be concluded between the *Contractor* and the *Participating Member States* using the model *Vaccine Order Form* provided as Annex II to this PA. The *Participating Member States* shall pay for the supply of the *Additional Doses* of the *Product* and the *Additional Option Doses* in accordance with Articles I.4.2 and I.4.4, respectively.”

**4. Article I.3.3 is replaced by the following:**

“I.3.3 [REDACTED]

**5. Article I.3.4 is replaced by the following:**

“I.3.4 Articles I.1, I.4.6, I.4.7.1A (solely with respect to amounts due and payable prior to the effective date of expiration or termination of this PA), I.4.7.1B (solely with respect to amounts due [REDACTED] I.4.7.2(b), [REDACTED]

I.4.7.2(c), I.5, I.6.5, I.7, I.8, I.10, I.11, I.12.1, I.12.2, I.12.3, I.12.4, I.12.5, I.12.6, I.13, II.1, II.3, II.4, II.5, II.7, II.8, II.12.2, II.16.5, II.17, II.18.4, II.19 and II.20 and this Article I.3 shall survive the termination or expiry of this PA.”

**6. Paragraph 3 of Article I.4.1 is replaced by the following:**

“Following entry into force of this PA, the Commission will determine the allocation of the contractually agreed doses of the Product between the Participating Member States in accordance with the procedure set out below in Articles I.4.3 and I.4.4 and will formally notify this allocation to the Contractor. The allocation notified to the Contractor by the Commission on behalf and in the name of the Participating Member States is binding upon all Participating Member States.”

**7. Article I.4.2 is replaced by the following:**

**“I.4.2 Additional Doses**

Without prejudice to the Option Increase (see Article I.4.4), subject to the terms of this Article I.4.2, the Contractor agrees to supply one hundred fifty million (150,000,000) additional doses of the Product (the “Additional Doses”) to the Participating Member States in accordance with the terms of this PA and the applicable Vaccine Order Forms.

The Commission shall coordinate with the Participating Member States to agree to the allocation of the Additional Doses to be purchased from the Contractor. The Commission shall provide to the Contractor in writing the allocation for distribution of the Additional Doses among the Participating Member States [REDACTED] after signature of this PA. Such allocation shall indicate for each Participating Member State the precise volume of Additional Doses to be delivered to each Participating Member State.

[REDACTED] the applicable Participating Member State shall place an order for its full allocated portion of the Additional Doses by sending the Contractor the duly completed and signed Vaccine Order Form (the format for which is set out in Annex II) in paper format and in PDF format by email to Contractor’s address specified in the Vaccine Order Form.

[REDACTED] the Contractor must send back to the Participating Member State the Vaccine Order Form duly signed and dated in paper format or in PDF format by email to the Participating Member State’s address specified in the Vaccine Order Form. If the Contractor refuses to sign the Vaccine Order Form under the conditions laid down in this PA and in Annex II or fails to supply the Additional Doses to the Participating Member States in accordance with the terms hereof, the Contractor may be considered in breach of its obligations under this PA as set out in Article II.16.2(b).

The purchase price for the Additional Doses shall be paid by the applicable Participating Member States to the Contractor as follows:

(a) [REDACTED]

(the "Initial Payment"); and

(b) [REDACTED]

The Contractor shall deliver the Additional Doses to the Participating Member States in accordance with the allocation and subject to the other terms and conditions of this PA.

The Additional Doses shall be delivered to the Participating Member States in [REDACTED] in the quantities as set out in the Product Delivery Schedule as included in Article 1.4.7 and subject to the terms and conditions laid down therein."

**8. Article 1.4.4 is replaced by the following:**

**"1.4.4 Option Increase**

Subject to the terms of this Article 1.4.4, on 15 June 2021, the Commission, acting on behalf of one or more of the Participating Member States, elected to increase the number of doses of Product by an additional one hundred fifty million (150,000,000) doses in the aggregate (the "Option Increase").

The Commission exercised the Option Increase by written notice from the Commission to the Contractor, which written notice specified the Participating Member States participating in such Option Increase (the "Exercising Member States") and the allocation of doses of Product to be purchased by and delivered to each such Exercising Member State (the "Additional Option Doses").

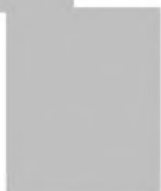
Each Exercising Member State participating in the Option Increase shall deliver to the Contractor a separate Vaccine Order Form for its allocated Product doses for the Option Increase [REDACTED]. If an Exercising Member State does not provide a Vaccine Order Form for its allocated Product doses for the Option Increase on or prior to such date, the remaining Exercising Member States participating in the Option Increase may, by written notice to the Commission, increase their respective allocation of Additional Option Doses pro rata or on the basis of any other allocation communicated to the Contractor in writing by the Commission. In such case, (i) the Commission shall provide written notification to the Contractor of any such increase in allocation of Additional Option Doses for any such Exercising Member States and (ii) such Exercising Member States shall send to the Contractor an updated Vaccine Order Form confirming such increased allocation of Additional Option Doses communicated by the Commission to the Contractor, in each case ((i)-(ii)), [REDACTED]

The purchase price for the Additional Option Doses shall be paid by the applicable Participating Member States to the Contractor as follows:



9. Article 1.4.5 is replaced by the following:

**“1.4.5 Supply Chain**



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**10. Article 1.4.6 is amended as follows:**

**(a) Clause 2(i) of Article 1.4.6 is replaced by the following:**

**“(i)** [REDACTED]

**(b) The last Paragraph of Article 1.4.6 is replaced by the following:**

[REDACTED]



[REDACTED]

**11. Article I.4.7 is replaced by the following:**

**“I.4.7 Delivery Schedule**

The Contractor shall deliver the Product doses to the Participating Member States in accordance with the allocation and the other terms and conditions of this PA.

Without prejudice to the remainder of this Article I.4.7, the Contractor shall deliver the Product to the Participating Member States under this PA in a non-discriminatory manner on the schedule and in the quantities as set out in the following preliminary delivery schedule (“**Preliminary Delivery Schedule**”):

[REDACTED]

The schedule set out in the Preliminary Delivery Schedule reflects [REDACTED] the Product is expected to be delivered by the Contractor under this PA.

[REDACTED], the Contractor and the Commission, on behalf of the Exercising Member States, will negotiate, in good faith, an agreed upon amendment to this Article I.4.7 that will reflect (a) a [REDACTED] delivery schedule for the Product (indicating the quantity of doses of Original Product and [REDACTED]

[REDACTED] b) a calculation of the aggregated number of doses of Product to be delivered by the Contractor to the Participating Member States under this PA [REDACTED] during the term of this PA for purposes of calculating the remedies relating to anticipated late deliveries, Late Deliveries and Reduced Orders as set forth in Article I.4.7.1A. For clarity, the Parties acknowledge and agree that (i) the [REDACTED] delivery schedule for Original Product under this PA will not commence earlier than [REDACTED] and (ii) the [REDACTED] delivery schedule for [REDACTED] under this PA will not commence earlier than [REDACTED]

[REDACTED] Upon the Parties' execution of such amendment, the [REDACTED] delivery schedule in such amendment will replace and supersede the Preliminary Delivery Schedule (and the [REDACTED]

Preliminary Delivery Schedule will thereafter be void and have no further force or effect) and such [REDACTED] delivery schedule will be the “Product Delivery Schedule” for all purposes under this PA.

Without prejudice to the Product Delivery Schedule (including any adjustments in accordance with the paragraphs below in this Article 1.4.7), the Contractor will use [REDACTED] to deliver the first delivery of [REDACTED] after receipt of the Marketing Authorisation for [REDACTED]

The parties acknowledge that the Product Delivery Schedule will assume that the date of receipt of the first Marketing Authorisation for [REDACTED] will be [REDACTED] (the “Anticipated Marketing Authorisation Date”).

[REDACTED]

In the event that the first Marketing Authorisation for [REDACTED] is received after the Anticipated Marketing Authorisation Date, then the Parties will negotiate and execute in good faith an amendment to this Article 1.4.7 of this PA to include an updated version of the Product Delivery Schedule that accurately reflects and incorporates the extension to the delivery schedule for the applicable number of days of such delay, and thereafter, such updated version of the Product Delivery Schedule will be the “Product Delivery Schedule” for all purposes under this PA.

In addition, the Contractor acknowledges and agrees that once the Contractor has received the first Marketing Authorisation for [REDACTED] for each [REDACTED] thereafter during the term of this PA, [REDACTED]

[REDACTED]

Notwithstanding anything herein to the contrary,

this paragraph does not address late deliveries or shortfalls, which will instead be governed by the terms and conditions of Articles 1.4.7.1A and 1.4.7.1B, respectively.

During the period commencing on the date that the Contractor has received the first Marketing Authorisation for [REDACTED] and continuing for the remainder of the term of this PA, on or before the last day of each [REDACTED] during such period, [REDACTED] update notice to the Commission and each Participating Member State (the “Product Mix Notice”) to reflect any changes to the product allocation mix in the Product Delivery Schedule (i.e., the quantity of doses of the Original Product and/or Variant Product(s) that will be delivered to each Participating Member State) as a result of any product allocation notices that are timely and properly issued by the Participating Member States under this Article 1.4.7.

#### **1.4.7.1A Late Deliveries**

During the term of this PA, the Contractor shall, without undue delay, inform the Commission of any expected delivery delays for any Product as compared to the delivery dates set forth in the Product Delivery Schedule.

In case of any expected delivery delays for any Product under this PA, the Contractor shall (after prior consultation with the Commission) as soon as reasonably possible provide written notice to the Commission (a “Delay Notice”), which Delay Notice shall include (a) the updated anticipated delivery dates for the Product that is subject to the delivery delay, (b) the basis and rationale for such delivery delay, and (c) the volume of Product expected to be delivered after the end of the applicable calendar [REDACTED]

[REDACTED] In this context, the Contractor acknowledges the strong interest of the Participating Member States in the current pandemic situation to receive the Product as early as possible in accordance with the Product Delivery Schedule. Therefore, the Contractor shall ensure that deliveries of the Product under the Delay Notice are made as close as reasonably possible to the Product Delivery Schedule [REDACTED]

If the proposed delivery date of the Product per the Delay Notice is [REDACTED]

[REDACTED] a Participating Member State (or the Commission, acting on its behalf) may cancel the number of doses of any Product, [REDACTED]

If the Commission or a Participating Member State cancels any Product during [REDACTED] period in accordance with this paragraph, [REDACTED]

Without limiting the foregoing, for sake of clarity, the Parties acknowledge and agree that in case of delays in deliveries caused by any measures taken by Participating Member States or the Commission that may affect the free movement of goods and services in the internal market of the EU, the Contractor will not be deemed in breach of this PA, and the parties will discuss in good faith a new Product Delivery Schedule for the Product.

The Contractor may agree with the Participating Member States to make multiple deliveries [REDACTED]

[REDACTED] Deliveries of Product will be made in a rolling, non-discriminatory manner between Participating Member States and pro rata to each Participating Member State based on the allocation provided by the Commission pursuant to this Article 1.4.7, subject to the Contractor's minimum delivery volume and good faith cooperation with the Participating Member States. Any schedules or delivery dates provided by Contractor pursuant to this paragraph or otherwise provided or discussed by the Parties other than the Product Delivery Schedule or a Delay Notice, as applicable, will be deemed to be provided for informational purposes only to facilitate the Participating Member States' planning of deliveries and will not create any additional obligations of any kind whatsoever other than those expressly set forth in this PA.

In the event that the Contractor has not actually delivered the full amount of doses of Product foreseen [REDACTED]

[REDACTED] ("Late Delivery"), then, [REDACTED]

[REDACTED] "Reduced Order").

The doses covered by such Reduced Order shall be deducted from the doses of Product foreseen [REDACTED] starting with the latest deliveries scheduled in accordance with the then-current [REDACTED]

The Reduced Order shall be exercised through a written notification by a Participating Member State (or the Commission acting on its behalf) to the Contractor which shall be issued [REDACTED] which shall indicate the amount of doses covered by the Reduced Order, as well as the Participating Member State(s) participating in the Reduced Order. Any such written notification with respect to Reduced Orders hereunder will be deemed effective when received by the Contractor (whether received from the Commission or a Participating Member State) and the relevant Participating Member State shall not be entitled to any deliveries with respect to any Product subject thereto. Any written notification issued after the applicable date will be deemed void and have no effect hereunder.

Regardless of whether or not the right to a Reduced Order is exercised, the Contractor shall, [REDACTED] provide written notice to communicate to the Commission the proposed timing for delivery of the doses subject to the [REDACTED]

**Late Delivery ("Late Delivery Notice").** The Contractor shall ensure that deliveries of Product subject to a Late Delivery are made as close as reasonably possible to the timing originally foreseen for such doses in the Product Delivery Schedule. If the Contractor is unable to deliver the doses subject to a Late Delivery [REDACTED]

[REDACTED] a Participating Member State (or the Commission acting on its behalf) shall have the right to cancel these doses. That right to cancellation shall be exercised through a written notification to the Contractor.

[REDACTED] In such case, the Contractor shall consequently reimburse to the relevant Participating Member State [REDACTED] the payments already made by the relevant Participating Member State to the Contractor for such cancelled Product.

If the Contractor is unable to deliver the doses subject to a Late Delivery [REDACTED]

[REDACTED], a Participating Member State (or the Commission acting on its behalf) shall have the right to cancel these doses. That right to cancellation shall be exercised through a written notification to the Contractor, which notice shall be issued [REDACTED]

[REDACTED] In such case, the Contractor shall consequently reimburse to the relevant Participating Member State [REDACTED] the payments already made by the relevant Participating Member State to the Contractor for such cancelled Additional Doses.

This Article 1.4.7.1A sets out the [REDACTED] remedy for Participating Member States for anticipated delivery delays for the Product or any Late Deliveries or Reduced Orders in accordance with this PA.

#### **1.4.7.1B Shortfalls**

In the event of the Contractor's inability to supply the scheduled quantities of the [REDACTED] in the Participating Member States [REDACTED] the Participating Member States shall be allocated quantities of such [REDACTED]

[REDACTED]

In the event that the Commission reasonably believes that a Shortfall may have occurred for a given calendar [REDACTED]

[REDACTED] upon reasonable written request by the Commission,

[REDACTED] When complying with such request, the Contractor may take reasonable measures to protect the Confidential information or documents in such documentary evidence (such as prices or the identity of purchasers) or legally privileged information whilst ensuring that redacted versions of documents still allow the Commission to effectively verify the facts relevant for ascertaining the existence or not of a Shortfall. All documentary evidence provided to the Commission under this provision will be Confidential information or documents of the Contractor.

Notwithstanding anything herein to the contrary, a Shortfall will not be deemed to have occurred and this Article 1.4.7.1B and the [REDACTED] hereunder will not apply in the event that delivery delays are caused by a force majeure event or because of the Commission's unreasonable failure to give consent to enable the Contractor to use drug substance for [REDACTED] or [REDACTED] from manufacturing sites located outside of the European Union for the deliveries to the Participating Member States during the calendar month concerned.

In the event that a Shortfall occurs [REDACTED] the Contractor agrees to pay [REDACTED] to the applicable Participating Member States for which the Shortfall occurred as set forth below. The [REDACTED] for the Shortfall shall be calculated on the percentage that the Shortfall represents of the doses due to be delivered to the applicable Participating Member States in the calendar [REDACTED] affected by the Shortfall per the Product Delivery Schedule, as follows:

[REDACTED]

For clarity, no [REDACTED] shall be due or payable by the Contractor to any Participating Member States that were not concerned by the Shortfall.

[REDACTED]

The [REDACTED] provisions in this Article 1.4.7.1B set out the [REDACTED] remedy for Participating Member States for Shortfalls for [REDACTED] in accordance with the PA.



#### **1.4.7.2. Delivery**

The actual delivery dates within the applicable Delivery Schedule for the Product doses will be agreed between the Contractor and the Participating Member State; provided that the Contractor shall have no obligation to deliver any Product to any Participating Member State under this PA until such Participating Member State has completed its payment under Article 1.4.2(a) and 1.4.2(h).

##### **(a) Form of Delivery**

The supply of Product doses will be delivered by the Contractor to the Participating Member States DAP (Delivered At Place) Incoterms 2020, to one recipient at one Delivery Address indicated by the Participating Member State concerned in the Vaccine Order Form, which recipient and Delivery Address is authorized, qualified and licensed to receive the Product in accordance with applicable law.

##### **(b) Distribution**

Following delivery of the Product doses, each Participating Member State will solely control and assume all responsibility, at such Participating Member State's own cost and expense, for conducting all distribution and related activities relating to the Product doses in the Participating Member State's territory and to countries in the EU or EEA to which the Participating Member State donates or resells Product doses in accordance with Article 1.4.6.

##### **(c) Traceability**

During the term of this PA and for a period of ten (10) years thereafter (or longer if required by applicable laws), each Participating Member State will (i) maintain an inventory control system for traceability of the Product supplied to or for the benefit of such Participating Member State, including any Product provided by such Participating Member State to a permitted Donation Country or Resale Country, and (ii) store and promptly make available to the Contractor all traceability records for the Product. The inventory control system is without prejudice to other traceability requirements in accordance with the applicable laws."

#### **12. The last sentence of Article 1.5.4 is replaced by the following:**

"Each of the Contractor and the Participating Member State will bear its own costs for any matter referred to an expert under this Article 1.5.4 and, in the absence of express agreement to the contrary, the costs and expenses of the expert will be shared equally by the Contractor and the Participating Member State."

#### **13. Clause (c) of Article 1.6.3 is replaced by the following:**

"(c) it shall not enter into any contractual agreement with any third party to intentionally or Grossly Negligently divert to such third party, or to intentionally or Grossly Negligently impede the delivery of, the Additional Doses and Additional Option Doses contemplated to be delivered to the Participating Member States under the Preliminary Delivery Schedule or Product Delivery Schedule, as applicable."

14. Article I.7.1 is replaced by the following:

**“I.7.1 Price per Dose of Product**

The price per single dose of Product within the Additional Doses purchased hereunder shall be the equivalent in euros based on

The price per single dose of Product within the Additional Option Doses purchased hereunder shall be the equivalent in euros based on

15. Paragraph 2 of Article I.7.2 is replaced by the following:

“The payment schedule for purchases of the Additional Option Doses by or on behalf of Participating Member States will be addressed in Article I.4.4.”

16. Article I.12.7 is replaced by the following:

“I.12.7 The Contractor will appoint a representative (the “Contractor Manager”) to be responsible for overseeing the conduct of the activities of the Contractor under this PA and the Original APA. The Commission will appoint a representative (the “Commission Representative”) to be responsible for overseeing the conduct of the activities of the Commission and the Participating Member States under this PA and the Original APA. The Contractor Manager and the Commission Representative will coordinate the performance of all such activities and, unless otherwise mutually agreed by the Parties, all communications between the Contractor and the Commission regarding the conduct of the activities under this PA and the Original APA will be addressed to or routed through the Contractor Manager and the Commission Representative, as applicable. The Contractor or the Commission may, at its option, appoint, designate and substitute the Contractor Manager or the Commission Representative, respectively, by providing notice to the other Party.

The Contractor shall provide to the Commission Representative the following information:



[REDACTED]

[REDACTED]

[REDACTED]

The Parties acknowledge that all information provided by the Contractor under these provisions will be the Confidential information or documents of the Contractor.

In addition, the Contractor Manager and the Commission Representative will establish, and use [REDACTED] to implement, mutually agreeable security measures for the Product after administration, including with respect to destruction, defacing and/or incineration of Product vials, packaging and related documentation.”

17. Article 1.12.8 is replaced by the following:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The Parties acknowledge that all information provided by the Contractor under these provisions will be the Confidential information or documents of the Contractor.

Commencing on the effective date of Amendment No. 1 to this PA and continuing until all Additional Doses and Additional Option Doses are delivered to the Participating Member States under this PA, [REDACTED]

[REDACTED]

[REDACTED]

At the request of the Commission, the parties will negotiate in good faith an amendment to this Article 1.12.8 to provide additional terms and conditions in the event that the Contractor proposes to supply a [REDACTED] during the term of this PA (*mutatis mutandis*)."

18. Article 1.13 is replaced by the following:

**"1.13 DEFINITIONS**

For the purpose of this PA, the following definitions (indicated in *italics* or capitalized in the text) apply:

**'Additional Doses'**: have the meaning set forth in Article I.4.2. For the avoidance doubt, all deliveries of the Product under this PA are separate and independent from the deliveries under the Original APA and may not be substituted or replaced with the deliveries foreseen under the Original APA or *vice versa*;

**'Additional Option Doses'**: have the meaning set forth in Article I.4.4;

**'Affiliate'**: with respect to the Contractor, any Person that controls, is controlled by, or is under common control with the Contractor. For purposes of this PA, such Person will be deemed to control another Person if it owns or controls, directly or indirectly, more than fifty percent (50%) of the equity securities of such Person entitled to vote in the election of directors (or, in the case that such Person is not a corporation, for the election of the corresponding managing authority), or otherwise has the power to direct the management and policies of such Person. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage will be substituted in the preceding sentence; provided, that such foreign investor has the power to direct the management and policies of such entity;

**'Amendment No. I'**: has the meaning set forth in the Recitals;

**'Anticipated Marketing Authorisation Date'**: has the meaning set forth in Article I.4.7;

**'Breach of obligations'**: failure by the Contractor to fulfil one or more of its contractual obligations under this PA;

**'Claim'**: has the meaning set forth in Article II.5.2;

**'Commission'**: has the meaning set forth in the preamble;

**'Commission Representative'**: has the meaning set forth in the Article I.12.7;

**'Confidential information or document'**: any information or document received by either party from the other or accessed by either party in the context of the *implementation of the PA*, that any of the parties has identified in writing as confidential, or, if not so identified, that would be reasonably understood in the biopharmaceutical industry to be confidential. It may not include information that is publicly available;

**'Conflict of interest'**: a situation where the impartial and objective *implementation of the PA* by the Contractor is compromised for reasons involving family, emotional life, political or national

affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the Commission, the Participating Member State or any third party related to the subject matter of the PA;

**‘Contractor’**: has the meaning set forth in the preamble;

**‘Contractor Manager’**: has the meaning set forth in the Article 1.12.7;

**‘COVE Study’**: has the meaning set forth in the Recitals;

**‘COVID-19’**: has the meaning set forth in the Recitals;

**‘COVID-19 Pandemic’**: has the meaning set forth in the Recitals;

**‘COVID 19 Virus’**: has the meaning set forth in Article 1.12.8;

**‘Deficient Product’**: has the meaning set forth in Article 1.5.1;

**‘Delay Notice’**: has the meaning set forth in Article 1.4.7.1A;

**[REDACTED]** has the meaning set forth in Article 1.4.6;

**‘EPPO’**: has the meaning set forth in Article 11.20.6;

**‘European Institutions’**: has the meaning set forth in Article 11.7.6;

**[REDACTED]** has the meaning set forth in Article 1.8.2;

**‘Exercising Member States’**: have the meaning set forth in Article 1.4.4;

**‘Force majeure’**: any unforeseeable, exceptional situation or event beyond the control of the Parties that prevents either of them from fulfilling any of their obligations under this PA. The situation or event must not be attributable to error or negligence on the part of the parties or on the part of the subcontractors and must prove to be inevitable despite their exercising due diligence. Defaults of service, defects in equipment or material or delays in making them available, labour disputes, strikes and financial difficulties, as well as the Covid-19 Pandemic, may not be invoked as *force majeure*;

**‘Formal notification’** (or ‘formally notify’): form of communication between the parties made in writing by mail or email, which provides the sender with compelling evidence that the message was delivered to the specified recipient;

**‘Fraud’**: an act or omission committed in order to make an unlawful gain for the perpetrator or another by causing a loss to the Union's financial interests, and relating to: i) the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds or assets from the Union budget, ii) the non-disclosure of information in violation of a specific obligation, with the same effect or iii) the misapplication of such funds or assets for purposes other than those for which they were originally granted, which damages the Union's financial interests, it being understood that the

Union's financial interests are impacted within the framework of this PA, as the Union is engaging resources into the coordination and preparation of the PA, resulting from the Decision which approved the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States, this agreement being based on Article 4(5)(b) of the ESI Regulation;

**'Good Manufacturing Practices' or 'GMP':** means the then-current good manufacturing practices for manufacture required by the standards, regulations and guidelines set out in Directive 2003/94/EC, Directive 2017/1572 and EudraLex - Volume 4 of the Rules Governing Medicinal Products in the EU entitled "EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, as based on the relevant provisions of Directive 2001/83/EC";

**'Governmental Authority':** any applicable government authority, court, council, tribunal, arbitrator, agency, department, bureau, branch, office, legislative body, commission or other instrumentality of (i) any government of any country, (ii) any nation, state, province, county, city, or other political subdivision thereof, or (iii) any supranational body;

**'Gross Negligence'** means [REDACTED]

**'Implementation of the PA':** the purchase of the Product envisaged in the PA through the signature and *performance of Vaccine Order Forms*;

**'Indemnified Persons':** has the meaning set forth in Article II.5.1;

**'Initial Payment':** has the meaning set forth in Article I.4.2;

**'Irregularity':** any infringement of a provision of Union law resulting from an act or omission by an economic operator, which has, or would have, the effect of prejudicing the Union's budget;

**'Late Delivery':** has the meaning set forth in Article I.4.7.1A;

**'Late Delivery Notice':** has the meaning set forth in Article I.4.7.1A;

**'Loss' or 'Losses':** has the meaning set forth in Article II.5.1;

**'Marketing Authorisation':** the approval under the relevant provisions of Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervisions of medicinal products for human and veterinary use and establishing a European Medicines Agency, by the European Commission necessary for the placing on the market of the Vaccine in the territory of the European Union, including conditional marketing authorisation in accordance with Article 14-a of Regulation 726/2004;

**'Marketing Authorisation for [REDACTED]'** a Marketing Authorisation granted separately for a [REDACTED] and/or the Marketing Authorisation for the Original Product that has been varied or extended in order to include a [REDACTED]

**‘Notification’** (or ‘notify’): form of communication between the parties made in writing including by electronic means;

**‘Option Increase’**: have the meaning set forth in Article I.4.4;

**‘Original APA’**: has the meaning set forth in the preamble;

**‘Original Product’**: the finished and packaged form of the Contractor’s proprietary mRNA-1273 vaccine against COVID-19 in the form that exists as of the effective date of this PA,

for clarity, the definition of **‘Original Product’** includes any vaccine with the same formulation and dosage as the Contractor’s proprietary mRNA-1273 vaccine against COVID-19 in the form that exists as of the effective date of this PA,

**‘Party’** and **‘Parties’**: have the meaning set forth in the preamble;

**‘Participating Member States’**: have the meaning set forth in the preamble;

**‘Performance of a Vaccine Order Form’**: the execution of tasks and delivery of the Product by the Contractor to the Participating Member State;

**‘Person’**: means an individual, partnership, corporation, limited liability company, joint stock company, unincorporated organization or association, trust or joint venture, or a Governmental Authority or political subdivision thereof;

**‘Pre-existing material’**: any material, document, technology or know-how which exists prior to the Contractor using it for the production of a result in the *implementation of the PA*;

**‘Pre-existing right’**: any industrial and intellectual property right on *pre-existing material*; it may consist in a right of ownership, a licence right and/or right of use belonging to the Contractor, the *creator*, the Commission as well as to any other third parties;

**‘Preliminary Delivery Schedule’**: has the meaning set forth in Article I.4.7;

**‘Product’**: the Original Product and the

**‘Product Claim’**: has the meaning set forth in Article I.5.1;

**‘Product Delivery Schedule’**: has the meaning set forth in Article I.4.7;

**‘Product Marks’**: MODERNA, MODERNATX, any Trademark incorporating either term, any Trademark that is used by the Contractor in association with the Product, including any Trademarks that accompany the Product when delivered by the Contractor to the Participating Member States, and any Trademark for which the Contractor has applied for registration in the

European Union. The Contractor may provide the Commission and the Participating Member States with a list of such Product Marks from time to time;

 has the meaning set forth in Article 1.4.7.1A;

**‘Professional conflicting interest’**: a situation in which the Contractor's previous or ongoing professional activities affect its capacity to implement the PA or to perform a Vaccine Order Form to an appropriate quality standard;

**‘Purchase Agreement (PA)’**: has the meaning set forth in the preamble;

  
**‘Recall’**: has the meaning set forth in Article 1.12.5;

**‘Reduced Order’**: has the meaning set forth in Article 1.4.7.1A;

**‘Related person’**: any natural or legal person who is a member of the administrative, management or supervisory body of the Contractor, or who has powers of representation, decision or control with regard to the Contractor;

**‘Resale Country’**: has the meaning set forth in Article 1.4.6;

**‘Result’**: any intended outcome of the *implementation of the PA*, whatever its form or nature. A *result* may be further defined in this PA as a deliverable. A *result* may, in addition to newly created materials produced specifically for the Participating Member States by the Contractor or at its request, also include *pre-existing materials*;

**‘Shortfall’**: has the meaning set forth in Article 1.4.7.1B;

**‘Technical Dispute’**: has the meaning set forth in Article 1.5.3;

**‘Third Party’**: any Person other than (i) the Commission or any of the Participating Member States or (ii) the Contractor or its Affiliates;

**‘Trademark’:** trademarks, service marks, certification marks, trade dress, internet domain names, trade names, identifying symbols, designs, product names, company names, slogans, logos or insignia, whether registered or unregistered, and all common law rights, applications and registrations therefor, and all goodwill associated therewith;

**‘US Supply Chain’:** has the meaning set forth in Article I.4.5;

**‘Vaccine IP Rights’:** has the meaning set forth in Article I.10;

**‘Vaccine Order Form’:** has the meaning set forth in the Recitals;

**‘Willful Misconduct’** means conduct which (i) constitutes an intentional act aimed at achieving a wrongful purpose, (ii) occurs in the absence of a legal or factual justification, and (iii) occurs in disregard of a known or obvious risk of causing harm.”

19. Paragraphs 2 and 3 of Article II.4.6 are replaced with the following:

“The remedies set forth in Article I.4.7, I.4.7.1A, I.4.7.1B, I.5, I.12.5, II.14, or II.16.1 shall be [REDACTED] remedies available to the Commission and the Participating Member States in case of breach or default of the obligations laid down in such provisions by the Contractor.

20. Article II.5.7 is replaced by the following:



**21. Paragraph 1 of Article II.7.6 is replaced by the following:**

**“Prior to any disclosure by the Commission containing Confidential information or documents contained in this PA, the draft disclosure shall be submitted by the European Commission to the Contractor by any appropriate means in order to provide the Contractor the opportunity to make any observation or request for any change to such disclosure to protect the secrecy of business in the sense of the Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets).”**

**22. Article II.14.1 is replaced by the following:**

**“II.14.1**

**23. All instances of the term “contractor” in the PA are replaced by “Contractor”.**

**24. All instances of the term “Confidential Information” in the PA are replaced by “Confidential information or documents”.**

**25. Annexes IV and V of the PA are replaced by Annexes IV and V attached to this Amendment No. 1.**

**26. Except as expressly modified herein, the terms and conditions of the PA will remain in full force and effect. The Parties agree to cooperate with each other in good faith to take such other actions (including working collaboratively to correct any clerical, typographical, or other similar errors in this Amendment No. 1) as the other Party may reasonably request for purpose of carrying out the intent of this Amendment No. 1.**

**27. This Amendment No. 1 shall be governed by the laws of Belgium. Article 1.11 (*Applicable Law and Settlement of Disputes*) of the PA shall apply *mutatis mutandis* to this Amendment No. 1.**

## **SIGNATURES**

**For the Contractor,**

[Redacted Signature]

**Signature:** \_\_\_\_\_

**Done at** *[place]* *[date]*

**In duplicate in English.**

[Redacted Signature]

**For the Commission, on behalf and in the name of the Participating Member States,**

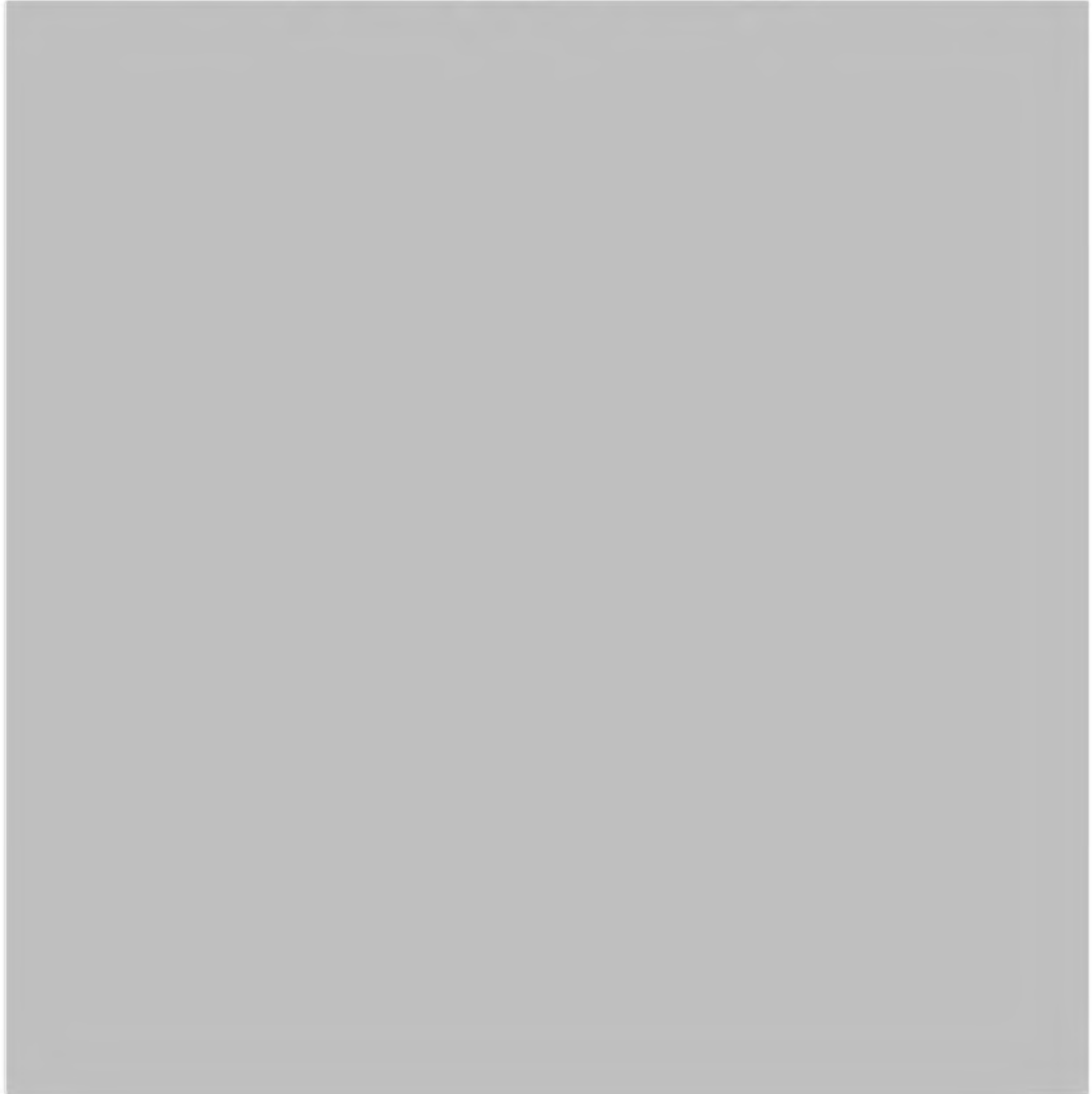
**Ms Stella Kyriakides, Commissioner for Health and Food Safety**

**Signature:** \_\_\_\_\_

**Done at Brussels,** *[date]*

[Redacted Signature]

**ANNEX IV: LIST OF CONFIRMED AND PLANNED MANUFACTURING NETWORK PARTNERS  
INCLUDING THE LOCATION(S) OF MANUFACTURING**



**ANNEX V: PRODUCT SPECIFICATIONS OF THE PRODUCT**

**HIGHLY CONFIDENTIAL MODERNA INFORMATION**

Reference is made to the product specifications approved in the Marketing Authorisation for the Original Product or the Marketing Authorisation for [REDACTED] as applicable, as the same may be updated from time to time.

