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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**



EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Sensitive*

RELEASABLE TO: Need to know basis

AMENDMENT NO. 4 TO PURCHASE AGREEMENT (“Amendment No. 4”) 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. 4 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

Peter Merian-Weg 10, 4052 Basel, Switzerland

CHE-344.522.989 MWST

(the ‘**Contractor**’), represented for the purposes of the signature of this Amendment No. 4 by

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**”¹,

HAVE AGREED

Article I.

Amendments to the PA

The PA is amended as follows:

¹ Capitalized terms in this Amendment No. 4 that are not otherwise defined herein will have the meanings ascribed to such terms in the PA.

The following recitals are added:

"H On 9 August 2022, the Commission, acting on behalf and in the name of the Participating Member States, and the Contractor entered into Amendment No. 4 to the PA ("**Amendment No. 4**") to (1) defer the delivery of the July/August Deferred Doses (as defined below) to later in calendar year 2022, (2) agree upon the estimated delivery schedule for the Additional Doses and Additional Option Doses, including Deferred Doses, Advanced Manufacturing Deferred Doses and July/August Deferred Doses (the "**Remaining Doses**") of Product to be delivered by the Contractor to the Participating Member States under this PA, (3) enable the Participating Member States to have the Remaining Doses of Product delivered as mRNA-1273.214 Booster Product (as defined below) or mRNA-1273.222 Booster Product (as defined below) subject to the mRNA-1273.214 Booster Product and mRNA-1273.222 Booster Product receiving Marketing Authorisation, and (4) enable the Participating Member States to purchase the Incremental Doses (as defined below) in the form of mRNA-1273.214 Booster Product or mRNA-1273.222 Booster Product for delivery in calendar year 2022 at the purchase prices set forth in Amendment No. 4."

Article 1.1 is replaced by the following:

"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. 4 take precedence over those in the PA, Amendment No. 1, Amendment No. 2 and Amendment No. 3.
- (b) The provisions of Amendment No. 3 take precedence over those in the PA, Amendment No. 1 and Amendment No. 2.
- (c) The provisions of Amendment No. 2 take precedence over those in the PA and Amendment No. 1.
- (d) The provisions of Amendment No. 1 take precedence over those in the PA.
- (e) The provisions set out in the special conditions take precedence over those in the other parts of the PA.
- (f) The provisions set out in the general conditions take precedence over those in the Vaccine Order Form (Annex II)."

Article 1.2 is replaced with the following:**"1.2. 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 1.4.2 to be allocated among the Participating Member States by the Commission in accordance with the allocation principles set out below in Article 1.4.2. 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 1.4.4. Finally, pursuant to this PA, the sum of the Participating Member States have purchased

is set out in Article 1.4.4A.

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 1.4.2, 1.4.7, 1.4.7.1A and

1.4.7.1B. In addition, the Contractor commits to supply the Additional Option Doses in accordance with the conditions set out in Articles 1.4.4, 1.4.7, 1.4.7.1A and 1.4.7.1B. Finally, the Contractor commits to supply the Incremental Doses in accordance with Articles 1.4.4A and 1.4.7.

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 1.4.4, 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. Finally, each Participating Member State which has decided to purchase Incremental Doses shall issue a Vaccine Order Form as regards its allocation of the Incremental Doses, through which the Contractor shall supply to those Participating Member States the Incremental 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 the purpose of carrying out the intent of this PA, including the amendments hereto.

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, the Additional Option Doses and the Incremental Doses in accordance with Articles 1.4.2, 1.4.4, and 1.4.4A, respectively.”

Article 1.3.2 is replaced by the following

1.3.2 Unless earlier terminated in accordance with Article 11.16 or expired in accordance with Article 1.3.3, the PA is concluded for a period of [REDACTED] with effect from the date of its entry into force. Its duration may be extended if at the end of the term of [REDACTED] not all of the Additional Doses, Additional Option Doses or Incremental Doses, as the case may be, have been supplied or in case when, as per Article 1.4.4.4A paragraph 6, [REDACTED]

In such case, the duration of the PA will be extended until (a) the delivery of, and payment in full for, all of the Additional Doses, Additional Option Doses, and Incremental Doses, or (b) [REDACTED]

The Participating Member States and the Contractor may not sign any Vaccine Order Forms after the PA expires. The obligations relating to such Vaccines Order Forms must be performed no later than [REDACTED] after the expiry of the PA.

Article 1.3.3 is replaced by the following:

"1.3.3 The PA shall automatically expire on the date on which all of the Additional Doses, Additional Option Doses and Incremental Doses have been delivered and paid in full."

A new paragraph is added to the end of Article 1.4.3 as follows:

"The Commission shall coordinate with the Participating Member States to agree to the allocation of the Incremental Doses, Deferred Doses and July/August Deferred Doses to be purchased from the Contractor. The Commission shall provide to the Contractor in writing the allocation of Product for each dose presentation for distribution among the Participating Member States on or before 23 August 2022. Each such allocation shall indicate the precise volume of each dose presentation of such Product doses to be delivered to each Participating Member State, provided that all doses of mRNA-1273.214 Booster Product purchased by all Participating Member States (including Incremental Doses, Deferred Doses, July/August Deferred Doses, Additional Doses and Additional Option Doses) are subject to a

[REDACTED]

[REDACTED]

A new Article 1.4.4A is added as follows:

"1.4.4A Incremental Doses

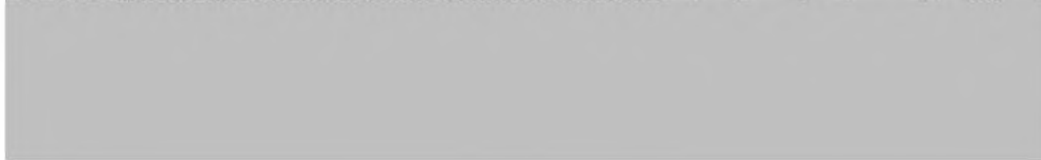
(1) Subject to the receipt of Marketing Authorisation of the Contractor's mRNA-1273.214 Booster Product and mRNA-1273.222 Booster Product, and subject to the terms of this Article 1.4.4A, the Contractor agrees to supply

[REDACTED] doses of the mRNA-1273.214 Booster Product or mRNA-



1273.222 Booster Product (the “**Incremental Doses**”) to the those Participating Member States which have decided to purchase Incremental Doses in accordance with the terms of this PA and the applicable Vaccine Order Forms.

- (2) The Commission shall coordinate with the Participating Member States to agree to the allocation of each product type and dose presentation of such Incremental Doses to be purchased from the Contractor.
- (3) Within 10 calendar days after signature of Amendment 4, the Participating Member States, each Participating Member State which decided to purchase Incremental Doses shall place an order for its full allocated portion of the Incremental Doses by sending the Contractor the duly completed and signed Vaccine Order Form in paper format or in PDF by email to the Contractor’s address specified in the Vaccine Order Form.
- (4) Within 10 calendar days of receipt of the Vaccine Order Form from a Participating Member State, 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.



- (5) The purchase price for the Incremental Doses shall be paid by the applicable Participating Member States to the Contractor as follows:



- (6) In case Marketing Authorisation is not granted, in case of (a) the mRNA-1273.214



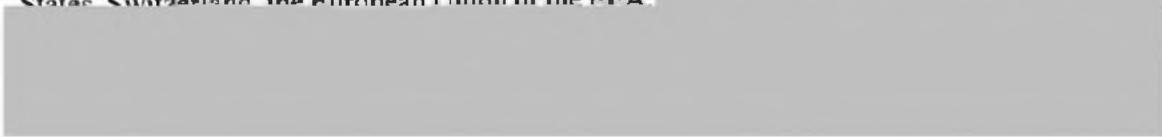
Booster Product, on or before to 1 December 2022, and in case of (b) the mRNA-1273.222 Booster Product on or before to 15 December 2022, the following applies:



- (7) The Contractor shall deliver the Incremental Doses to the Participating Member States in accordance with the allocation agreed upon in accordance with this Article 1.4.4A and subject to the other terms and conditions of this PA.
- (8) The Incremental Doses shall be delivered to the Participating Member States which have decided to purchase those Doses in a non-discriminatory manner in the quantities as set out in the Estimated Product Delivery Schedule as included in Article 1.4.7 and subject to the terms and conditions laid down therein.”

The last paragraph at the end of Article 1.4.5 is replaced by the following:

“Notwithstanding anything herein to the contrary, the Contractor may manufacture or have manufactured the Deferred Doses, the July/August Deferred Doses and the Incremental Doses at any manufacturing sites used by the Contractor as part of its supply chain for the United States, Switzerland, the European Union or the EEA.



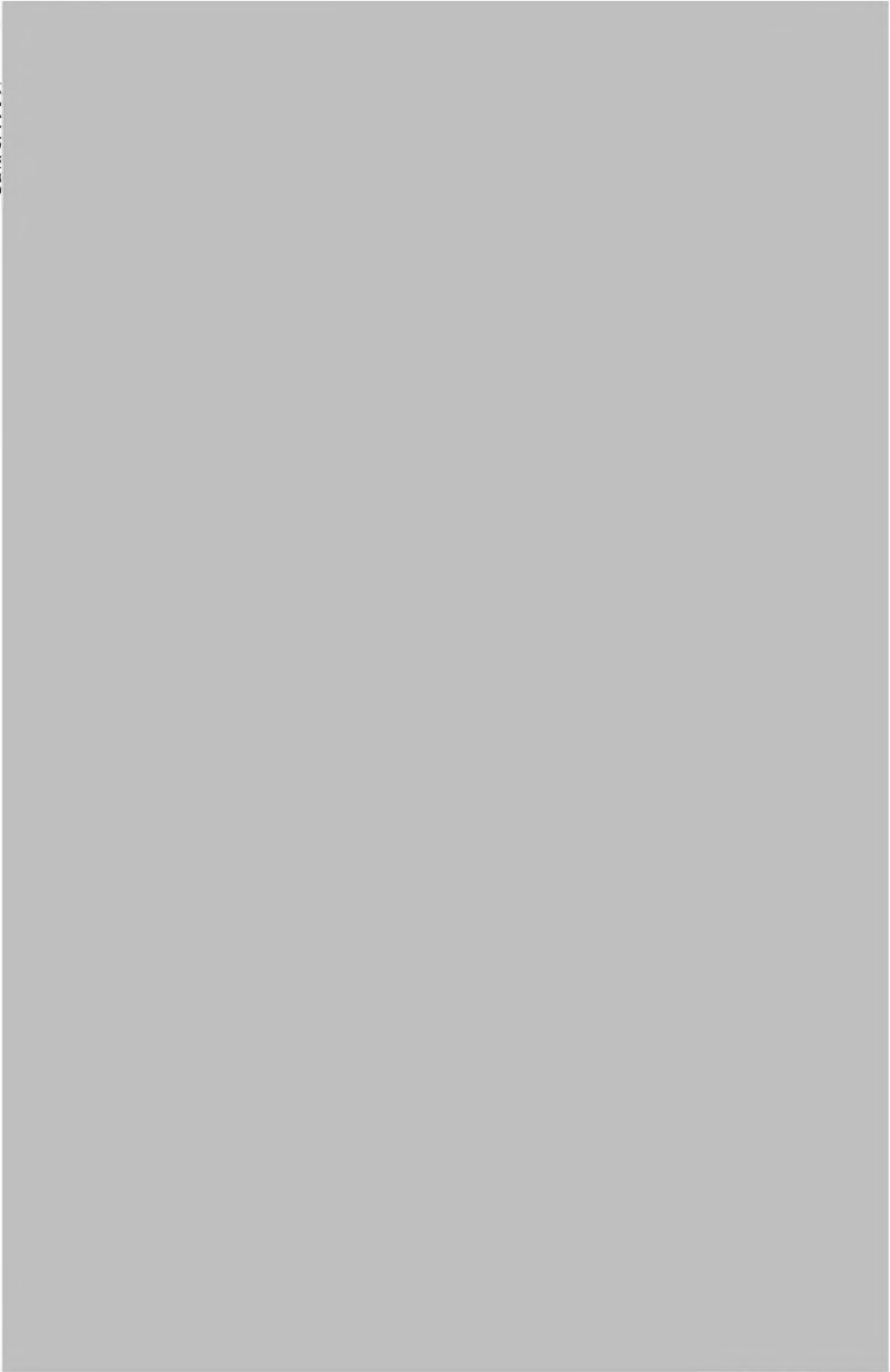
With respect to the Remaining Doses and Incremental Doses to be delivered to the Participating Member States as of the effective date of this Amendment No. 4, the second paragraph and the Product Delivery Schedule in Article 1.4.7 are amended as follows:

- (2) “Without prejudice to the remainder of this Article 1.4.7 and Articles 1.4.4.A, 1.4.7.1C and 1.4.7.1D, the Contractor shall deliver the Remaining Doses and Incremental Doses 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 estimated product delivery schedule ("**Estimated Product Delivery Schedule**")

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Final quantities are subject to the minimum shipping quantity. The Parties may negotiate in good faith to increase the number of mRNA-1273.222 Booster Product to be delivered in November 2022 or December 2022.

- (3) The Parties acknowledge that the Contractor is currently developing two Booster Product candidates adapted to SARS-CoV-2 variants: one bivalent Booster Product candidate targeting the original and omicron BA.1 variant of the SARS-CoV-2 virus, also known as mRNA-1273.214 (the "**mRNA-1273.214 Booster Product**"), and one bivalent Booster Product candidate targeting the original and omicron BA.4/5 variant of the SARS-CoV-2 virus, also known as mRNA-1273.222 (the "**mRNA-1273.222 Booster Product**"). The Parties further acknowledge that as of the effective date of Amendment No. 4, the Contractor has completed filing of a Marketing Authorization application to EMA for the mRNA-1273.214 Booster Product. The Parties assume that that Marketing Authorization will be granted and that the date of its receipt will be on or before 7 September 2022.

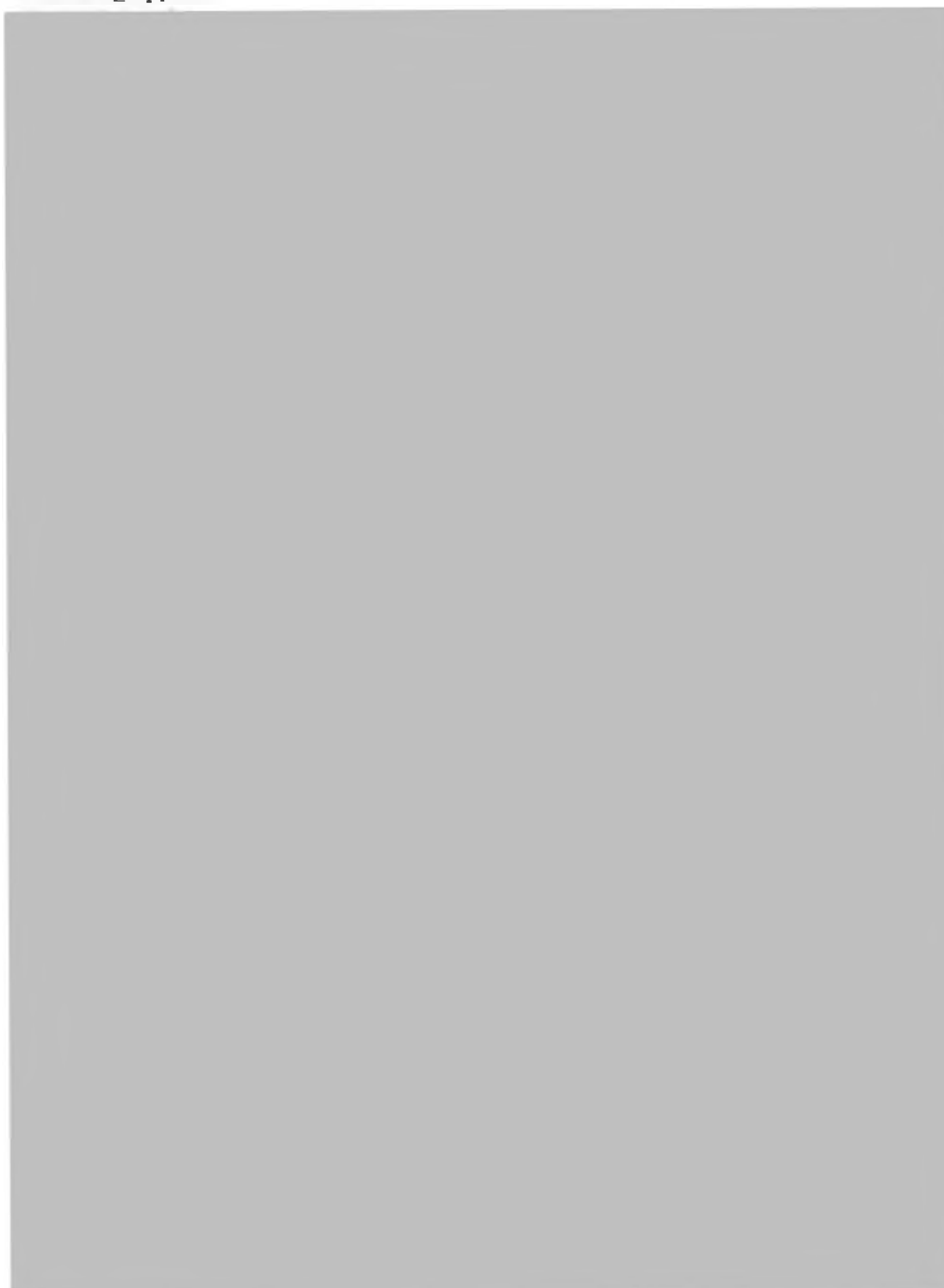


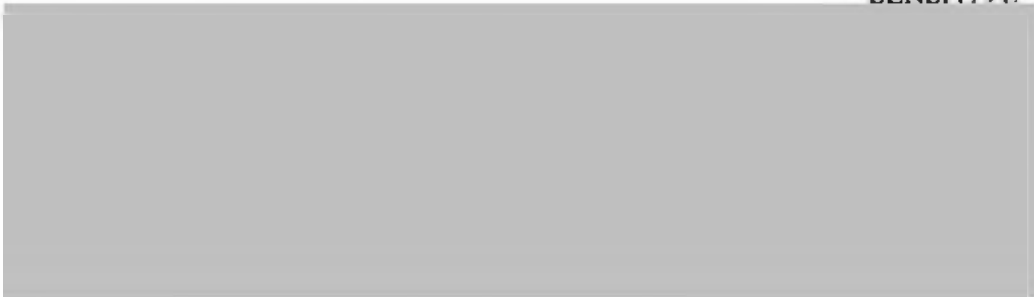
- (6) The Parties further acknowledge and agree that (a) the Estimated Product Delivery



Schedule assumes that Marketing Authorizations for the mRNA-1273.214 Booster Product in the PFS dose presentations and for the SDV presentation will be granted and that the date of receipt of the Marketing Authorization for the PFS and SDV dose presentations will be on or before 15 October 2022, and (b) the Remaining Doses of Product set forth in the Estimated Product Delivery Schedule will be delivered in 5 MDV unless ordered by a Participating Member State in PFS or SDV, subject to the maximum order volume for product dose presentations set forth in Article 1.4.3.

- (7) With respect to the Remaining Doses that are scheduled in the Estimated Product Delivery Schedule to be delivered as mRNA-1273.214 Booster Product, the following applies:





The Parties shall agree on [redacted] for the delivery of the PFS and SDV presentation of mRNA-1273.214 Booster Product in accordance with clauses (i) to (iv) above.

- (8) With respect to the Remaining Doses that are scheduled in the Estimated Product Delivery Schedule to be delivered as mRNA-1273.222 Booster Product, in the event that the date of receipt of Marketing Authorization for the mRNA-1273.222 Booster Product is after 1 November 2022 but on or before 15 December 2022, then the Contractor [redacted] to deliver the Remaining Doses as follows:



[redacted] in the event that the Marketing Authorisation for the mRNA-1273.222 Booster Product has not been granted by 15 December 2022, the Contractor shall deliver the Remaining Doses in the form of the Contractor's most recently approved Booster Product to the Participating Member States(s) by 31 March 2023.

- (9) The exchange of letters and the Product Mix Notice processes contemplated in Article I.4.7 shall not apply to the Estimated Product Delivery Schedule above without the mutual consent of the Commission and the Contractor."

Paragraph 3 of Article I.4.7.1C is deleted in its entirety.

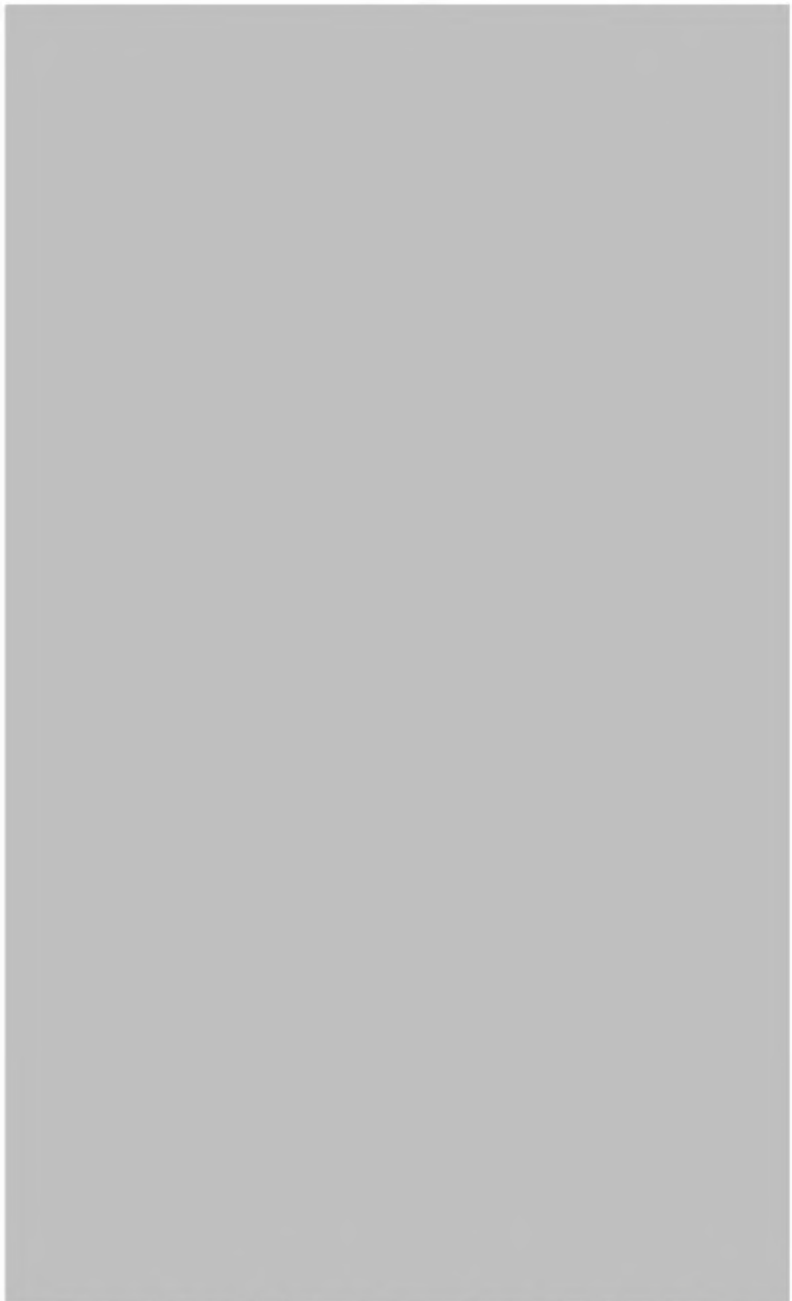
A new Article I.4.7.1D is added as follows:

"I.4.7.1D Deferral of doses of Product currently scheduled for delivery in July and August of 2022

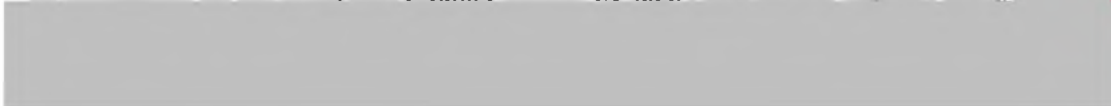
Subject to the terms and conditions of Article I.4.7.1D, the Contractor agrees to defer delivery of up to a total of [redacted] of Product currently scheduled for delivery



by the Contractor to the Participating Member States in July and August of 2022 until later in calendar year 2022. The doses of Product which are eligible for deferral by the Participating Member States are the **"July/August Deferred Doses"** and set forth:



In order to qualify for such deferral, each Participating Member State wishing to defer doses of Product must be in compliance with its payment obligations under the PA and its respective Vaccine Order Form, including payment due for all issued invoices for all doses of Product delivered by the Contractor to such Participating Member State prior to 12 August 2022 at the price per dose of Product set forth in Article 1.7.1 of the PA (as applicable) for the applicable Product ordered by such Participating Member State.



The following sentence is added at the end of the first paragraph of Article 1.4.7.2:

“For purposes of the Estimated Product Delivery Schedule and unless specified otherwise by the Contractor in writing, [REDACTED]

Article 1.7.1 is replaced by the following:

“1.7.1 Price per Dose of Product

The price per single dose of Product shall be as follows:

(a) for Product doses in [REDACTED] a price [REDACTED]

(b) for Product doses in [REDACTED] a price [REDACTED] and [REDACTED]

(c) for Product doses in [REDACTED] a price [REDACTED]

For clarity, the price for the total Product volume shall be obtained by multiplying the price of a single Product dose by the total number of Product doses covered by this PA. [REDACTED] set out under Article 1.8.2.”

A new sentence is added to the end of paragraph 2 of Article 1.7.2:

“The payment schedule for purchases of the Incremental Doses by or on behalf of the Participating Member States will be addressed in Article 1.4.4A.”

Article 1.13 is amended as follows:

The definition of New Booster Product is replaced with the followings:

‘New Booster Product’ as used in Article 1.4.4.C means the Contractor’s bivalent vaccine candidate currently under development to target the original and omicron BA.1 variant of the SARS-CoV-2 virus, also known as mRNA-1273.214;

The following definition is included as the first definition:

‘5 MDV’ means five multi-dose vial;

The following definitions are included between the definitions of ‘EPPO’ and ‘European Institutions’.

'EMA Application Package Information': has the meaning set forth in Article 1.4.7;

'Estimated Product Delivery Schedule': has the meaning set forth in Article 1.4.7;

The following definition is included between the definitions of 'Implementation of the PA' and 'Indemnified Persons':

'Incremental Doses': has the meaning set forth in Article 1.4.4A;

The following definition is included between the definitions of 'Irregularity' and 'Late Delivery':

'July/August Deferred Doses': has the meaning set forth in Article 1.4.7.1D;

The following definitions are included between the definitions of 'Marketing Authorization Notice' and 'Notification':

'mRNA-1273.214 Booster Product': has the meaning set forth in Article 1.4.7. paragraph 3;

'mRNA-1273.222 Booster Product': has the meaning set forth in Article 1.4.7. paragraph 3;

The following definition is included between the definitions of 'Preliminary Delivery Schedule' and 'Product':

'PFS': means pre-filled syringes;

The following definition is included between the definition of 'Related person' and 'Resale Country':

'Remaining Doses': has the meaning set forth in the preamble.

The following definition is included between the definitions of 'Result' and 'Shortfall':

'SDV': means single dose vial;

Article II.

Entry into Force and Duration

1. This Amendment No. 4 shall enter into force on the date on which it is signed by the Commission, and will remain in force for the duration of the PA.
2. To avoid doubt, this Amendment No. 4 shall be binding on all Participating Member States irrespective of whether they have opted in to defer or purchase Doses in accordance with this Amendment No. 4. However, any provision in the PA regarding the July/August Deferred Doses or Incremental Doses shall only apply to the Participating Member States that have opted in for such deferral of doses or purchase of Product and shall not apply to the Participating Member States that have not opted in for deferral or purchase.

3. 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. 4) as the other Party may reasonably request for purpose of carrying out the intent of this Amendment No. 4.

Article III.

Applicable Law and Settlement of Disputes

1. This Amendment No. 4 shall be governed by the laws of Belgium.
2. For the avoidance of doubt, Article 1.11 (*Applicable Law and Settlement of Disputes*) of the PA shall apply mutatis mutandis to this Amendment No. 4.

SIGNATURES

For the Contractor,

Moderna Switzerland GmbH

Done at Basel, 17 August 2022

In duplicate in English,

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, 18 August 2022