

SENSITIVE



EUROPEAN COMMISSION
Directorate General for Health and Food Safety

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RELEASABLE TO: Need to know basis

AMENDMENT NO. 2 TO PURCHASE AGREEMENT ("Amendment No. 2") 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. 2 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 (c/o [REDACTED]), 4051 Basel, Switzerland

CHE-344.522.989 MWST

(the 'Contractor'), represented for the purposes of the signature of this Amendment No. 2 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 PURCHASE AGREEMENT, dated as of 1 March 2021, as amended by the Amendment No. 1 to PURCHASE AGREEMENT, dated as of 2 July 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. 2 that are not otherwise defined herein will have the meanings ascribed to such terms in the PA.

The PA is amended as follows:

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

Article 1.4.4 is amended as follows:

Under letter (c), the date [REDACTED] is replaced by [REDACTED]

Article 1.4.7 is amended as follows:

Article 1.4.7, titled **Delivery Schedule**, until the header of Article 1.4.7.1A, is replaced by the following:

1.4.7 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 1.4.7, the Contractor shall deliver the Product to the Participating Member States under this PA [REDACTED] on the schedule and in the quantities as set out in the following product delivery schedule ("Product Delivery Schedule"):



[REDACTED]

The schedule set out in the Product Delivery Schedule reflects (a) the calendar [REDACTED] delivery schedule for the Product to be delivered by the Contractor to the Participating Member States under this PA [REDACTED]

[REDACTED] and (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 [REDACTED].

The 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 as set out in the Product Delivery Schedule shall be used [REDACTED]

[REDACTED] The number of doses of Variant Product to be delivered by the Contractor to the Participating Member States under this PA [REDACTED] during the term of this PA [REDACTED] as set out in the Product Delivery Schedule shall be used for the purposes set forth in Article 1.4.7.1B.

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

[REDACTED] in accordance with the following paragraphs of this Article 1.4.7 by an exchange of letters between the Commission, represented for this purpose by the Director-General of the Directorate-General for Health and Food Safety, and the Contractor. This exchange of letters shall take place [REDACTED] in which [REDACTED]

[REDACTED] in accordance with this Article 1.4.7 in accordance with the following procedure: First, for a given calendar month, the Contractor will issue a letter [REDACTED]

[REDACTED] in which it consolidates all changes to the Product Delivery Schedule as permitted pursuant to clauses (i)-(v) below. Second, the Commission will issue a letter to the Contractor [REDACTED] after the date of the letter issued by the Contractor pursuant to the foregoing sentence and either confirm the information in the Contractor's letter or identify any proposed corrections [REDACTED]

[REDACTED] to such Contractor's letter. Third, if the Commission proposed corrections to such Contractor's letter, then the Contractor and the Commission will cooperate in good faith to issue a joint letter with a final confirmation of the [REDACTED]

[REDACTED]



The Product Delivery Schedule agreed pursuant to such exchange of letters shall replace the Product Delivery Schedule included in this Article 1.4.7 and qualify as the "Product Delivery Schedule" for all purposes under this PA. For the avoidance of doubt, this paragraph does not apply to amendments to the Product Delivery Schedule which are not expressly foreseen in this Article 1.4.7.



In addition, in the event that the Contractor provides information to the Commission or the Commission Representative pursuant to the previous paragraph or to Article 1.12.7 or 1.12.8 that the Marketing Authorisation

[REDACTED] then the Participating Member States shall have [REDACTED] as from the date of provision of such information to communicate to the Contractor.

[REDACTED] Any necessary amendments of the Product Delivery Schedule following such changes to the [REDACTED] shall be adopted following the letter exchange procedure set out in this Article 1.4.7.

Furthermore, the Contractor acknowledges and agrees that [REDACTED]

[REDACTED] Any necessary amendments of the Product Delivery Schedule following such [REDACTED] shall be adopted following the letter exchange procedure set out in this Article 1.4.7.

For clarity, with the exception of those situations expressly foreseen in this Article 1.4.7 [REDACTED]

[REDACTED] Notwithstanding anything herein to the contrary, this paragraph does not address late deliveries [REDACTED] 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 in September 2021 and continuing for the remainder of the term of this PA, on or before the last day of each calendar month during such period, the Contractor will issue a monthly update notice to the Commission and each



[REDACTED]

under this Article 1.4.7. These Notices shall lead to the adjustment of the Product Delivery Schedule in accordance with this Article 1.4.7.

[REDACTED]

If an update pursuant to this paragraph is agreed between the parties, the Product Delivery Schedule shall be amended accordingly by an exchange of letters in accordance with this Article 1.4.7.

The previous paragraph shall apply *mutatis mutandis* in case the Contractor provides information to the Commission or the Commission Representative that indicates that the Contractor reasonably

[REDACTED]

[REDACTED]

Article 1.6.3, letter (c), is replaced by the following:

[REDACTED]





Article 1.13 is amended as follows:

The following definitions are included between the definitions of "Anticipated Marketing Authorisation Date" and "Breach of Obligations":

"Booster Product": Product which is used to inoculate persons already having received primary vaccination against COVID-19, regardless of its qualification as Original Product or Variant Product.

"Booster Product Information": has the meaning set forth in Article 1.4.7.

The following definition is included between the definitions of "Marketing Authorisation for Variant Product" and "Notification":

"Marketing Authorisation Notice": has the meaning set forth in Article 1.4.7.

The definition of "Preliminary Delivery Schedule" is deleted from Article 1.13.

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. 2) as the other Party may reasonably request for purpose of carrying out the intent of this Amendment No. 2.

This Amendment No. 2 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. 2.

SIGNATURES

For the Contractor,

Moderna Switzerland GmbH



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] 10/09/2021

