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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. 3 TO PURCHASE AGREEMENT ("**Amendment No. 3**") 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. 3 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. 3 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**"[1],

HAVE AGREED

**Article 1.**

**Amendments to the PA**

**The PA is amended as follows:**

[1] Capitalized terms in this Amendment No. 3 that are not otherwise defined herein will have the meanings ascribed to such terms in the PA.



[redacted]

**The following recitals are added:**

F. On 10 September 2021, the Commission, acting on behalf and in the name of the Participating Members States, and the Contractor entered into No. 2 to the PA ("Amendment No. 2") to update the Delivery Schedule and to [redacted] It also defines more precisely the steps for introduction of a Booster Product or Variant Product;

G. On 10 June 2022, the Commission, acting on behalf and in the name of the Participating Members States, and the Contractor entered into Amendment No. 3 to the PA ("Amendment No. 3") to give the Participating Member States the possibility to defer the delivery of [redacted] of Booster Product due to be delivered in the second quarter (Q2) of 2022 to later in calendar year 2022 or early calendar year 2023 depending on the options chosen by each Participating Member State under the provisions of this Amendment No. 3. Subject to the provisions of this Amendment No. 3, the Participating Member States shall have the right – but shall not be obliged – to opt for the such deferral of doses of Booster Product as provided for in this Amendment No. 3. For the Participating Member States that do not opt for such deferral, any provision in this PA which refers to "Amendment No. 3" or "Deferred Doses" shall not apply to that Participating Member State. In such a case, there will be no changes to the obligations and commitments of that Participating Member State under the PA;

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

**Article I.4.5 is amended to add a new paragraph at the end of Article I.4.5 as follows:**

"Notwithstanding anything herein to the contrary, the Contractor may manufacture or have manufactured the Deferred 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. [redacted]

**A new Article I.4.7.1C is added as follows:**



[redacted]

"**I.4.7.1C Deferral of doses of Booster Product**

Subject to the terms and conditions of this Article I.4.7.1C, the Contractor agrees to defer delivery of [redacted] of Booster Product currently scheduled for delivery by the Contractor to the Participating Member States in Q2 2022 until later in calendar year 2022 or early calendar year 2023, as applicable pursuant to the subsequent provisions. The doses of Booster Product which are eligible for deferral by the Participating Member States are the "**Deferred Doses**" and set forth as follows:

[redacted]

In order to qualify for such deferral, each Participating Member State wishing to defer doses of Booster 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 10 June 2022 at the price per dose of Product set forth in Article I.7.1 of the PA [redacted] for the applicable Product ordered by such Participating Member State (Original Product, Booster Product, or Variant Product, as applicable).

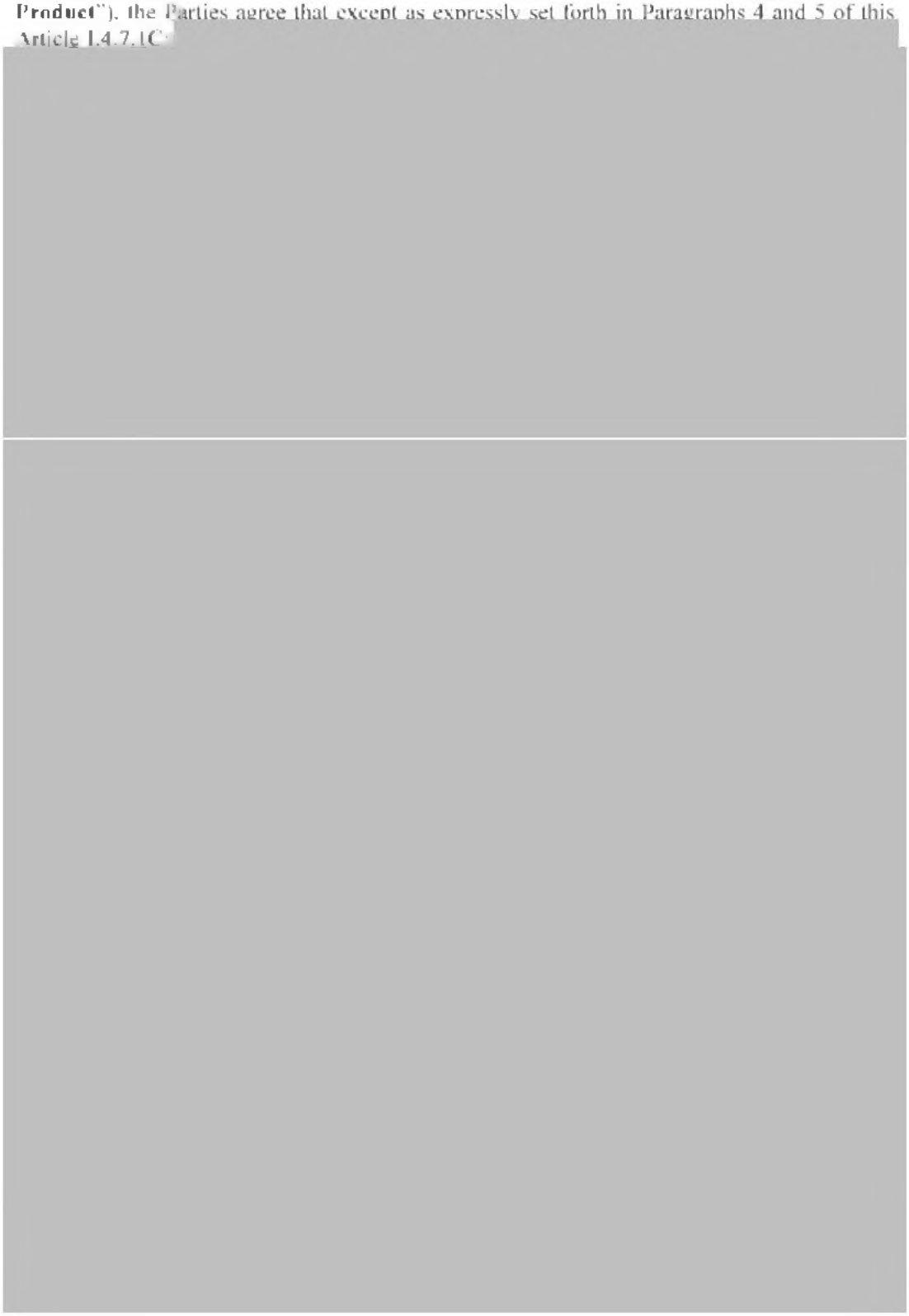
[redacted]

Recognising that the Contractor currently holds a Marketing Authorisation for one Booster Product (50 mcg of mRNA-1273) (the "**Current Booster Product**") and that the Contractor is currently developing alternative Booster Product candidates adapted to SARS-CoV-2 variants



[redacted]

and that Contractor will file an application for Marketing Authorization for one of the alternative Booster Product candidates currently under development (the "**New Booster Product**"), the Parties agree that except as expressly set forth in Paragraphs 4 and 5 of this Article I.4.7.1C



**Article I.13 is amended as follows:**

The following definitions are included between the definition of 'Additional Option Doses' and 'Affiliate':

> '**Advanced Manufacturing Deferred Doses**': has the meeting set forth in Article I.4.7.1.C

The following definitions are included between the definition of 'COVID-19 Virus' and 'Deficient Product':

> '**Current Booster Product**': has the meaning set forth in Article I.4.7.1C.
>
> '**Deferred Doses**': has the meaning set forth in Article I.4.7.1C.

The following definition is included between the definition of 'Marketing Authorisation Notice' and 'Notification':

'**New Booster Product**': has the meaning set forth in Article I.4.7.1C.

**Article II.**

**Entry into Force and Duration**

1. This Amendment No. 3 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. 3 shall be binding on all Participating Member States irrespective of whether they have opted in to defer Doses in accordance with Article I.4.7.1C. However, any provision in the PA regarding the "Deferred Doses" shall only apply to the Participating Member States that have opted in for such deferral of doses of Booster Product and shall not apply to the Participating Member States that have not opted in for deferral.

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

**Article III.**

**Applicable Law and Settlement of Disputes**

1. This Amendment No. 3 shall be governed by the laws of Belgium.

2. For the avoidance of doubt, Article I.11 (*Applicable Law and Settlement of Disputes*) of the PA shall apply mutatis mutandis to this Amendment No. 3.

**SIGNATURES**

For the Contractor,

Moderna Switzerland GmbH/

Done at Basel, 10 June 2022

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 Dublin, 10 June 2022

In duplicate in English.