



EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

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PURCHASE AGREEMENT ("PA")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 (hereinafter referred to as "**Participating Member States**") being represented for the purposes of signature of this PA 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  4051 Basel, Switzerland

CHE-344.522.989 MWST

(the '**contractor**'), represented for the purposes of the signature of this PA which has the form of a framework contract 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**",

have agreed to the special conditions and the general conditions of this PA and the following Annexes and Attachments:

Annex I — List of Participating Member States

Annex II — Vaccine Order Form for Additional Doses

¹ This PA is based on the agreement between the Commission and the Member States as approved by Commission Decision C(2020) 4192 final on approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures.

Annex III – Agreement between the Commission and Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures, annexed to the Commission Decision C(2020) 4192 final of 18 June 2020

Annex IV – List of confirmed and planned manufacturing network partners including the location(s) of manufacturing

Annex V – Specifications of the Product

which form an integral part of this PA.

All documents issued by the contractor (end-user agreements, general terms and conditions, etc.) except its tender are held inapplicable, unless explicitly mentioned in the special conditions of this PA. In all circumstances, in the event of contradiction between this PA and documents issued by the contractor, this PA prevails, regardless of any provision to the contrary in the contractor's documents.

This PA sets out:

1. the procedure and conditions by which the *Commission* and the *Participating Member States* shall pay for the *Additional Doses* and the *Additional Option Doses* from the *contractor*;
2. the provisions that apply to any Vaccine Order Form which the *Participating Member States* and the *contractor* conclude under this PA; and
3. the obligations of the *Parties* during and after the duration of this PA.

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*, with the option to order up to a total of 80 million additional *doses* of the *Product*, 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*.
- C. The Commission on behalf and in the name of the *Participating Member States* and Moderna wishes to enter 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. The Commission, on behalf and in the name of the *Participating Member States*, shall furthermore have the option to order [REDACTED]

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I. SPECIAL CONDITIONS

I.1. ORDER OF PRIORITY OF PROVISIONS

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

- (a) The provisions set out in the special conditions take precedence over those in the other parts of the PA.
- (b) The provisions set out in the general conditions take precedence over those in the Vaccine Order Form (Annex II).

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, this PA gives the *Commission* the option to order, on behalf and in the name of the *Participating Member States*, [REDACTED] 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 and I.4.7. In addition, the contractor commits to supply the Additional Option Doses in accordance with the conditions set out in Article I.4.4.

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. If the *Commission* acting on behalf and in the name of the *Participating Member States* decides to exercise the *Optional Increase* under Article I.4.4, *Vaccine Order Forms* shall also be concluded with regard to such *Optional Increase*.

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.

I.3. ENTRY INTO FORCE AND DURATION OF THIS PA

I.3.1 This PA enters into force on the date on which the *contractor* and the *Commission* have signed it.

I.3.2 Unless earlier terminated in accordance with Article II.16 or expired in accordance with Article I.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 or Additional Option Doses, as the case may be, have been supplied. In such case, its duration will be extended until the delivery of, and payment in full for, all of the Additional Doses or all of the Additional Option Doses, as the case may be. The Participating Member States and the contractor may not sign any Vaccine Order Form after the PA expires. The PA continues to apply to signed Vaccine Order Forms after its expiry. The obligations relating to such Vaccine Order Forms must be performed no later than [REDACTED] after the expiry of the PA.

I.3.3 The PA shall automatically expire on (i) the date on which all the Additional Doses have been delivered and paid in full, in the event the Commission has not elected an Option Increase in accordance with Article I.4.4, or (ii) the date on which all of the Additional Doses and Additional Option Doses have been delivered and paid in full, in the event the Commission has elected an Option Increase in accordance with Article I.4.4.

I.3.4 Articles I.1, I.4.6, I.4.7.2(b), I.4.7.2(c), I.5, I.6.5, I.7, I.8, 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 shall survive the termination or expiry of this PA.

I.4. IMPLEMENTATION OF THE PA

I.4.1 Implementation of the PA

The PA shall be implemented following signature between the Commission on behalf and in the name of the Participating Member States and the contractor as follows:

Following entry into force of this PA, this PA is binding upon the contractor, the Commission and all Participating Member States on behalf and in the name of which the Commission has concluded this PA, as identified in Annex I.

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 Article I.4.3 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.

Each Participating Member State and the contractor will conclude a Vaccine Order Form, using the model Vaccine Order Form attached as Annex II to this PA, setting out the details of the delivery of the doses of the Product allocated to the respective Participating Member State. For the avoidance of doubt, and unless otherwise laid down in this PA, each Participating Member State is obligated to purchase and pay for the doses contractually allocated to it as notified by the Commission regardless of whether such Vaccine Order Form is concluded or not.

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 within 15 calendar days 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.

Within 10 calendar days after the notification by the Commission of the allocation for distribution of the Additional Doses among the Participating Member States, 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.

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. 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 as follows:

- (a) [redacted] of (i) the number of Additional Doses of Product to be delivered to such Participating Member State multiplied by (ii) [redacted] payable within thirty (30) days after the return by the contractor of the signed Vaccine Order Form followed by an invoice for the Additional Doses (the "**Initial Payment**"); and
- (b) [redacted] of (i) the number of Additional Doses of Product to be delivered to such Participating Member State multiplied by (ii) [redacted] payable within thirty (30) days after receipt of the contractor's invoice for each delivery.

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 a non-discriminatory manner in the quantities as set out in the Additional Doses Initial Delivery Schedule as included in Article 1.4.7 and subject to the terms and conditions laid down therein.

1.4.3 Allocation between Participating Member States; 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 within 15 calendar days after signature of the PA. Such allocation shall indicate for each Participating Member State the precise volume of Additional Doses to be delivered to each Participating Member State.

1.4.4 Option Increase

Subject to the terms of this Article 1.4.4, the Commission, acting on behalf of one or more of the Participating Member States, may elect to increase the number of doses of Product by [REDACTED] in the aggregate (the “**Option Increase**”). The price per single dose of Product of the Additional Option Doses shall be [REDACTED]

On or prior to 31 May 2021, the contractor shall provide to the Commission a non-binding, estimated delivery schedule for the Product comprising the Option Increase for delivery during the calendar year 2022 to enable the Commission and the Participating Member States to determine whether or not to exercise the Option Increase.

On or prior to 15 June 2021, the Commission will be entitled to exercise the Option Increase by written notice from the Commission to the contractor, which written notice shall specify the Participating Member States participating in such Option Increase (the “**Exercising Member States**”), the aggregate number of doses of Product to be purchased for the Option Increase, and the allocation of doses of Product to be purchased by and delivered to each such Exercising Member State (the “**Additional Option Doses**”). For clarity, if the Commission exercises the Option Increase for less than one hundred fifty million (150,000,000) doses in the aggregate, then all references to “Additional Option Doses” in this PA will be limited to the amount of doses of Product so exercised.

In the event that the Commission exercises the Option Increase in accordance with this Article 1.4.4, then 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 on or prior to 30 June 2021. 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)), on or before 15 July 2021.

In the event that the contractor receives the Vaccine Order Forms for the Option Increase in accordance with this Article I.4.4, then, during the period commencing on 1 August 2021 and ending upon 15 August 2021, the contractor and the Commission, on behalf of the Exercising Member States, will negotiate in good faith (a) a payment schedule for the Additional Option Doses, and (b) a delivery schedule for the Additional Option Doses, based on the estimated delivery schedule for the Option Increase and adjusted based on the number of Exercising Member States and the actual number of doses of Product in the Option Increase. If the payment schedule and delivery schedule for the Option Increase cannot be agreed between the contractor and the Commission on or prior to 15 August 2021, the corresponding Vaccine Order Forms may be cancelled by the Commission (on behalf of the Exercising Member States) or the contractor upon written notice to the other. For clarity, if the contractor and Commission reach agreement, the contractor and the Commission shall confirm in writing the agreement on the payment schedule and delivery schedule for the Additional Option Doses on or prior to 15 August 2021. Such written agreement shall be immediately communicated to the Exercising Member States and shall thereafter be deemed to apply to the Vaccine Order Forms previously submitted.

The rules laid down in Articles I.4.7 and I.4.7.1 with respect to the initial delivery schedule and any updated delivery schedule shall apply *mutatis mutandis* to the Additional Option Doses if the Commission exercises the Option Increase.

If a [REDACTED] is developed by the Contractor prior to the last delivery of Additional Option Doses, Article I.12.8 shall apply *mutatis mutandis* to the Additional Option Doses.

I.4.5 Supply Chain



Without prejudice to Article I.4.7, to produce the Additional Doses, the contractor may manufacture or have manufactured the Product at manufacturing sites used by the contractor as part of its supply chain for the United States (“**U.S. Supply Chain**”) without the prior consent of the Commission, as and to the extent permitted under the Marketing Authorisation for the Product, applicable law and the contractor’s agreements with the United States government. As between the Parties, the contractor shall bear the sole responsibility, and shall use [REDACTED] to obtain approval for the use of the U.S. Supply Chain from the European Medicines Agency under the Marketing Authorisation for the Product to manufacture or have manufactured the Product in accordance with this PA. The contractor commits to submitting an application to that end without undue delay, and on or before 31 May 2021.

[REDACTED]





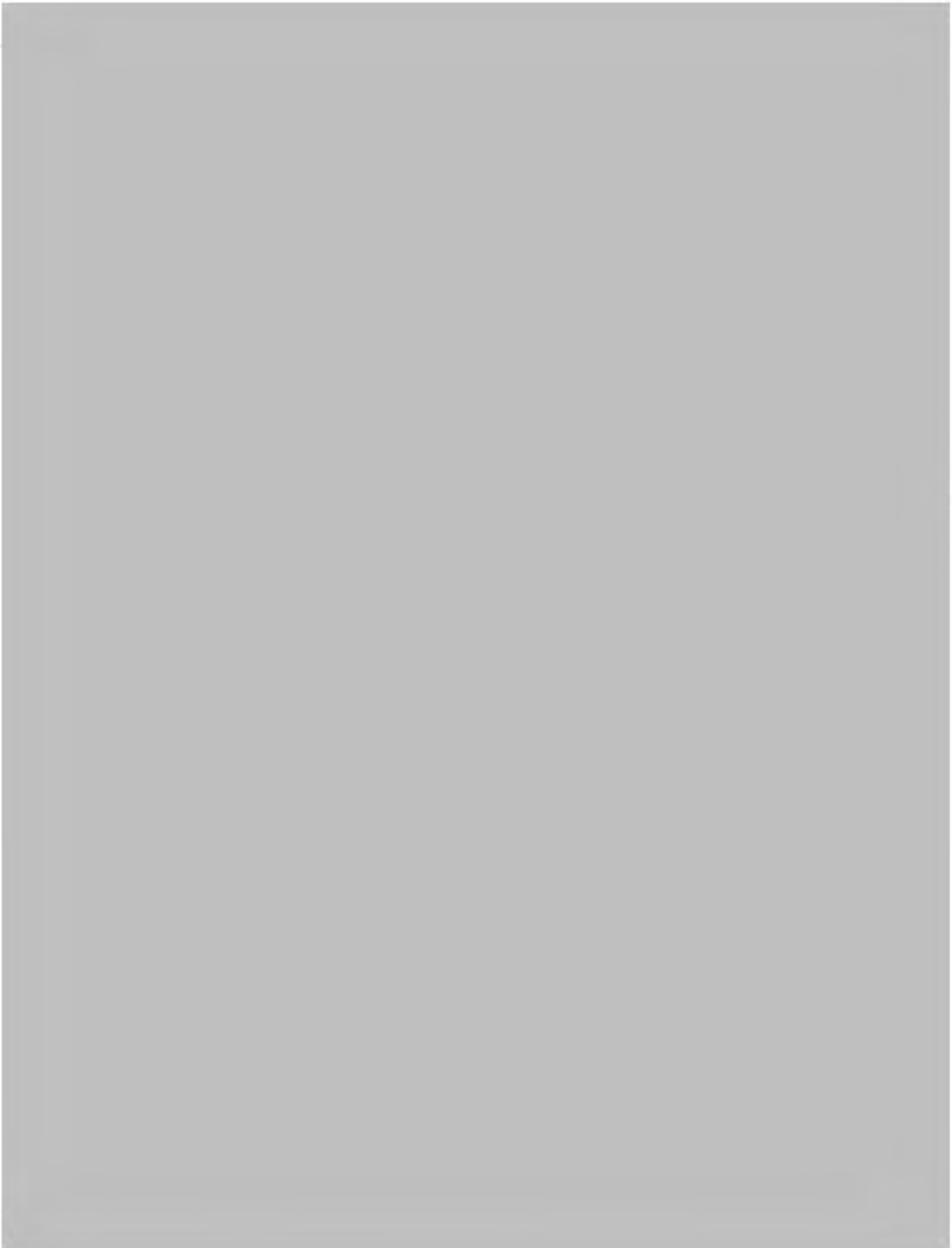
I.4.6 The possibility to re-sell, export and/or distribute

Each Participating Member State shall be entitled to re-sell, export and/or distribute the Product doses supplied to them pursuant to this PA to any other EU or EEA Member State,



Each Participating Member State must comply with each of the following obligations in order to provide any Product doses to a Donation Country, and such Participating Member State will provide the contractor with any and all information reasonably requested by the contractor to establish such compliance from time to time until the exportation, distribution or donation is completed.








I.4.7 Additional Doses Initial 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 Additional Doses to the Participating Member States in a non-discriminatory manner on the schedule and in the quantities as set out in the following initial delivery schedule for the Additional Doses (“**Additional Doses Initial Delivery Schedule**”).

Additional Doses Initial Delivery Schedule:





The schedule set out in the Additional Doses Initial Delivery Schedule reflects the  in which the Additional Doses are expected to be delivered.

On or before 31 July 2021, the contractor shall inform the Commission of any expected change in the Additional Doses Initial Delivery Schedule with respect to Q3 Additional Doses (the “**July Notice**”).

Thereafter, during the term of this PA, the contractor shall, without undue delay, inform the Commission of any other expected change in the Additional Doses Initial Delivery Schedule.

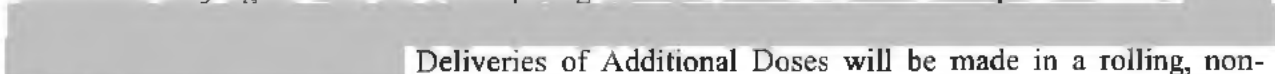
In case of any expected change in the Additional Doses Initial Delivery Schedule (including under the July Notice), the contractor shall (after prior consultation with the Commission) as soon as reasonably possible propose to the Commission an updated delivery schedule for the Additional Doses (“**Additional Doses Updated Delivery Schedule**”) which shall identify the volume of Additional Doses expected to be delivered after the end of the respective calendar quarter and the expected length of delay in number of days of the delivery after the end of that quarter. In this context, the contractor acknowledges the strong interest of the Participating Member States in the current pandemic situation to receive the Additional Doses as early as possible in accordance with the Additional Doses Initial Delivery Schedule. Therefore, the contractor shall ensure that deliveries of the Additional Doses under the Additional Doses Updated Delivery Schedule are made within a schedule that is as close as reasonably possible to the Additional Doses Initial Delivery Schedule.





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 delivery schedule for the Additional Doses.

The contractor shall provide the Participating Member States with non-binding delivery schedules with respect to Additional Doses that set forth deliveries per calendar month. The contractor may agree with the Participating Member States to make multiple deliveries






Deliveries of Additional Doses 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 I.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 Additional Doses Initial Delivery Schedule or a subsequent Additional Doses Updated Delivery Schedule, 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.



This Article I.4.7 sets out the sole and exclusive remedy for Participating Member States for anticipated delivery delays for the Additional Doses in accordance with this PA.

I.4.7.1 Late Deliveries





Any such written notification  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 Additional Doses subject thereto. Any written notification issued after the applicable date will be deemed void and have no effect hereunder.



[REDACTED]

The provisions of this Article I.4.7.1 shall apply mutatis mutandis to Late Deliveries or Reduced Orders under any applicable Additional Doses Updated Delivery Schedule.

I.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 Additional Doses to any Participating Member State until such Participating Member State has completed its payment under Article I.4.2(a) and I.4.2(b).

(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 [REDACTED]

[REDACTED] Product doses in accordance with Article I.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 [REDACTED]

[REDACTED] (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.

I.5. ACCEPTANCE/REJECTION OF PRODUCT

I.5.1 Subject to the terms of this Article I.5, a Participating Member State may claim a remedy (a "Product Claim") for any portion of Product delivered to such Participating Member

State by the contractor which at the time of delivery (a) does not comply with the final specifications for the Product as approved in the Marketing Authorisation for the Product or (b) has been affected by a failure to comply with GMP ("**Deficient Product**"). Such Participating Member State will visually inspect the Product, or review documentation provided by or on behalf of the contractor, upon delivery or receipt (as applicable) and will give the contractor written notice of all Product Claims within twenty (20) calendar days after such delivery or receipt (or, in the case of any deficiency at the time of delivery to such Participating Member State that was not reasonably susceptible to discovery upon such delivery or receipt, within twenty (20) calendar days after discovery by such Participating Member State Participating Member State, but not after the expiration date of the Product). If Participating Member State fails to provide a Product Claim within the applicable twenty (20) calendar day period, then the Product will be considered to have been accepted by Participating Member State on the twentieth (20th) day. The contractor will have no liability for any deficiency or claim for which it has not received notice from Participating Member State within the applicable twenty (20) calendar day period.

I.5.2 The contractor will have no obligation for any Product Claims to the extent the Deficient Product was caused by: (a) actions or omissions of such Participating Member State or Third Parties occurring after the time of delivery of the Product by the contractor or its designee; or (b) any breach by such Participating Member State of its obligations under this PA or the applicable Vaccine Order Form.

I.5.3 Upon receipt of a Product Claim, the contractor will have twenty (20) days to advise the Participating Member State by notice in writing whether it disagrees with the contents of the Product Claim. If, after joint testing or investigation has been performed, the Parties still cannot agree on whether such Product is Deficient Product, the contractor or the Participating Member State may refer such dispute to a technical expert for resolution in accordance with Article I.5.4 (a "**Technical Dispute**").

I.5.4 If any Technical Dispute arises, the contractor and the Participating Member State will first try to resolve it amicably. The contractor or the Participating Member State may send a notice of a Technical Dispute to the other, and each Party will appoint, within ten (10) working days from receipt of the notice, an appropriate single representative having full power and authority to resolve the dispute. The representatives will meet as necessary in order to resolve the Technical Dispute. If the representatives fail to resolve the matter within one month from their appointment, or if a Party fails to appoint a representative as required above, the expert determination procedure below may be started by either Party. Within ten (10) working days after the written request, the contractor and the Participating Member State will appoint a single agreed expert with experience and expertise in the subject matter of the dispute. As a condition of the expert's appointment, the contractor and the Participating Member State will ensure that the expert agrees to disclose any actual or potential conflicts of interest promptly as they arise. The contractor and the Participating Member State do not intend that the expert acts as an arbitrator and therefore any matters requiring legal interpretation or adjudication including disputes relating to the conduct of the Technical Dispute are solely reserved for the dispute resolution procedure under Article I.11.2. For the avoidance of doubt, any technical determination by the expert under a Technical Dispute may be used as evidence under Article I.11.2. The contractor and the Participating Member State will require the expert to provide an

opinion on each referred issue (with reasonably detailed reasoning) within fifteen (15) working days (or as agreed by the contractor and the Participating Member State with the expert). The contractor and the Participating Member State will give to the expert all the evidence and information within their respective possession or control as the expert may reasonably request, which they will disclose promptly and in any event within five (5) working days of a written request from the expert to do so. At all times the contractor and the Participating Member State will co-operate and seek to narrow and limit the issues to be determined. The technical determination of the expert will, except for fraud or manifest error or where an unapproved conflict of interest is discovered, be final and binding upon the contractor and the Participating Member State with respect to the referred Technical Dispute. Each of the contractor and the Participating Member will bear its own costs for any matter referred to an expert under this Article I.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.

I.5.5 If a Participating Member State makes a Product Claim pursuant to this Article I.5 and (a) the contractor and the Participating Member State agree the Product that is the subject of such Product Claim is Deficient Product (such agreement not to be unreasonably withheld, conditioned or delayed) or (b) any previously delivered Product is determined to be Deficient Product, the contractor will replace such Deficient Product as soon as reasonably practicable after the time of such agreement or determination (and in no event later than 90 days after the time of such agreement or determination). If such replacement products are not delivered within this time limit, the contractor shall reimburse the purchase price for the Deficient Product to the Participating Member States in question in so far as that purchase price was already paid.

I.5.6 A Participating Member State will not dispose of any Product for which it intends to assert a Product Claim against the contractor without the contractor's prior written authorization to do so. The contractor may instruct Participating Member State to return the Product to the contractor to a location identified by the contractor.

I.5.7 Except as and to the extent required by applicable law, and without prejudice to Articles II.4.6 and II.5, this Article I.5

for Deficient Products that are unsold or unused and returned, destroyed or otherwise disposed of by the Participating Member States in accordance with this PA.

I.6. WARRANTIES

I.6.1 The Commission and each of the Participating Member States warrant to the contractor that as of the date hereof, this PA has been duly executed and is a legal, valid and binding obligation on it, enforceable against it in accordance with its terms.

I.6.2 Each Participating Member State warrants to the contractor that at the time of its delivery to the contractor, each Vaccine Order Form from such Participating Member State has

been duly executed and is a legal, valid and binding obligation on it, enforceable against it in accordance with its terms.

1.6.3 The contractor warrants to the Commission and the Participating Member States that:

(a) as of the date hereof, this PA has been duly executed and is a legal, valid and binding obligation on it, enforceable against it in accordance with its terms;

(b) as of the date hereof, it is not under any obligation, contractual or otherwise, to any third party in respect of the delivery of the Additional Doses and, as appropriate, Additional Option Doses, or that conflicts with or is inconsistent in any material respect with the terms of this PA or that would impede the complete fulfillment of its obligations under this PA; and

1.6.4 The contractor warrants to the Commission and the Participating Member States that

(a) all Product doses supplied to the Participating Member States shall at the time of delivery conform with the final specifications for the Product as approved in the Marketing Authorisation for the Product;

(b) all Product doses supplied to the Participating Member States shall at the time of delivery have been manufactured in conformance with GMP and all applicable laws; and

The Parties agree that the

1.6.5 Except as expressly set forth in this PA, the contractor and its Affiliates make no other warranties of any kind, express or implied, including any implied warranties of merchantability or fitness for a particular purpose, or non-infringement, or regarding results obtained through the use of the Product.

1.7. PRICES

1.7.1 Price per Dose of Product

The price per single dose of Product purchased hereunder shall be the 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. Payments are made

1.7.2 Payment

The payment schedule for purchases of the Additional Doses by or on behalf of Participating Member States is addressed in Article I.4.2.

The payment schedule for purchases of the Additional Option Doses by or on behalf of Participating Member States will be mutually agreed by the parties in accordance with Article I.4.4.

I.8. PAYMENT ARRANGEMENTS

I.8.1 Payment for the supply of Product

1. The contractor must send an invoice in paper format or in PDF format by email to the Participating Member States for payment by the Participating Member States under Articles I.4.2 (a) or I.4.2(b), as applicable.

Invoices shall be established by the contractor for a given order of the Product and for an identified delivery scheduled within the Vaccine Order Form.

The contractor must send an invoice in paper format or in PDF format by email for payment due under the Vaccine Order Form accompanied by the following documentation (as applicable):

- Proof of delivery of the Products referred to in Article I.4.2 of this PA, to the place of delivery indicated by the Participating Member State concerned in the Vaccine Order Form

Each invoice must contain the following information (if applicable):

- Name of a concerned Member State
- PA and Vaccine Order Form number/reference
- Order reference
- Date of receipt of Marketing Authorisation for the Product
- Product
- Quantity delivered
- Delivery reference and date
- Contractor name and bank account.

2. The Participating Member States must pay within 30 days from receipt of the invoice.

I.8.2 Currency

Any payments to be made by the Commission or the Participating Member States under this PA, including under any Vaccine Order Form, shall be made, and any invoices issued pursuant to this PA shall be issued, [REDACTED]

All payments required under this PA (including under any Vaccine Order Form) are based on a unit price set in [REDACTED]. As a currency conversion in EUR will be required in connection with such invoices, the amounts payable hereunder shall be expressed [REDACTED]

The “Exchange Rate Methodology” is calculated as the average of the Euro Foreign Exchange Reference Rates as published by the European Central Bank (for the avoidance of doubt, expressed to the fourth decimal point) from the beginning of each calendar year up to the penultimate day of the month preceding the invoice, whereby all days are taken into account on which the Euro Foreign Exchange Rate is published. For the purposes of the Payment referred to in Article I.4.2(a), the conversion between the Euro and USD is calculated by applying the average exchange rate of the Euro Foreign Exchange Rate as published by the European Central Bank from 1st January to 31 January 2021, whereby all days are taken into account on which the Euro Foreign Exchange Rate is published. This rate is USD 1.2171 for 1 Euro.

I.8.3 BANK ACCOUNT

Payments must be made to the contractor’s bank account denominated [REDACTED] identified as follows:

A large rectangular area of the document is completely redacted with a solid grey block, obscuring the bank account details mentioned in the preceding text.

I.9. COMMUNICATION DETAILS

For the purpose of this PA, communications must be sent to the following addresses:

The Commission:

European Commission

Directorate-General for Health and Food Safety

E-mail: SANTE-PROCUREMENT@ec.europa.eu

EC-VACCINES@ec.europa.eu

Participating Member States will provide the communication details in the Vaccine Order Forms.

Contractor:

Moderna Switzerland GmbH

Aeschenvorstadt 48 [REDACTED] 4051 Basel, Switzerland



By derogation from this Article, different contact details for the Commission, the Participating Member States or the contractor may be provided in Vaccine Order Form.

I.10. EXPLOITATION OF THE RESULTS OF THE PA

The Commission and the Participating Member States acknowledge and agree that the contractor shall be the sole owner of all intellectual property rights generated during the development, manufacture, and supply of the Product, including all know-how (collectively, the “**Vaccine IP Rights**”). The contractor shall be entitled to exclusively exploit the results of the PA and any such Vaccine IP Rights. Except as expressly set forth in this PA, the contractor does not grant to the Commission or any of the Participating Member States by implication, estoppel or otherwise, any right, title, license or interest in or to the results of the PA, the Vaccine IP Rights or the contractor’s Pre-existing rights. All rights not expressly granted by the contractor hereunder are reserved by the contractor.

The Commission and the Participating Member States acknowledge that the Product Marks and all goodwill pertaining thereto are the exclusive property of the contractor or its Affiliates, that nothing in this PA grants the Commission or the Participating Member States or any Person any right, title or interest therein, and that all use of the Product Marks by the Commission or the Participating Member States or any Person acting under its or their authority or instructions will inure to the benefit of the contractor.

The Commission and the Participating Member States will discontinue use of any Product Marks to which the contractor objects. The Commission and the Participating Member States will not use any of the Product Marks in a manner that diminishes the value of any of the Product Marks or disparages the contractor or its Affiliates or that the contractor otherwise deems to be inappropriate.

The Commission and the Participating Member States will not modify, overprint, distort, change, remove or obscure any Product Marks associated with the Product as delivered by the contractor under this PA or the Vaccine Order Forms.

I.11. APPLICABLE LAW AND SETTLEMENT OF DISPUTES



I.11.1 This PA shall be governed by the laws of Belgium.

I.11.2 Dispute Resolution

(a) In the event of a dispute arising under this PA or a Vaccine Order Form between the contractor and the Commission or a Participating Member State, the Parties shall first refer such dispute to informal dispute resolution discussions between their respective representatives. The contractor or the Commission on behalf of itself or of the Participating Member States may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and, within twenty (20) days of such notice, the representatives shall meet and attempt to resolve the dispute by good faith negotiations.

(b) The Commission, the Participating Member States and the contractor irrevocably submit to the exclusive jurisdiction of the courts located in Brussels, Belgium to settle any dispute which may arise under or in connection with this PA or the legal relationships established by this PA including under a Vaccine Order Form.

I.12. OTHER SPECIAL CONDITIONS

I.12.1 Each Participating Member State and the contractor will each maintain records necessary to permit a Recall of any Product delivered to such Participating Member State.

I.12.2 Each Participating Member State and the contractor will notify the other party within 5 working days from notifying the European Medicines Agency of any information which might affect the marketability, safety or effectiveness of the Product or which might result in the Recall or seizure of the Product in the Participating Member State's territory.

I.12.3 Upon receiving this notice or upon this discovery, such Participating Member State and the contractor will stop making any further shipments of any Product in their possession or control in such Participating Member State's territory until a decision has been made whether a Recall or some other corrective action is necessary.

I.12.4 The decision to initiate a Recall or to take some other corrective action, if any, with respect to the Product in such Participating Member State's territory will be made by the competent authority concerned, or alternatively by the contractor, in agreement with the competent authority(ies) concerned.

I.12.5 If: (i) any regulatory authority issues a decision, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled in such Participating Member State's territory; (ii) a court of competent jurisdiction orders a recall in such Participating Member State's territory; or (iii) the contractor in agreement with the concerned competent authority(ies) determines that any Product should be recalled in such Participating Member State's territory (each a '**Recall**'), then the contractor, the Participating Member State(s) and the competent authority(ies) shall assist each other in the Recall process, as appropriate, having regard to all applicable laws, and especially (a) the EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human Use and Veterinary Use – Part 1 – Chapter 8 "Complaints, Quality Defects and Product Recalls" and (b) the compilation of Community procedures on inspections and exchange information in the meaning of article 3 (1)

of the Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use.

In the event of any Recall, the contractor will bear the costs and expenses for the Recall unless such Recall was carried out due to quality defects in the Product or other grounds justifying such recall which were caused by the Gross Negligence or Willful Misconduct of a Participating Member State, in which case such Participating Member State will bear the costs and expenses for the Recall.

Further, in the event of any Recall that was carried out due to quality defects in the Product or other grounds justifying such recall which in each case were caused by the Gross Negligence, Willful Misconduct, Fraud or failure to conform to GMP of the contractor, the contractor shall, at the election of contractor, either (i) replace such Product doses subject to the Recall within a period of 90 calendar days from the moment of the recall at no additional charge to the Participating Member State(s) or (ii) refund the Participating Member State(s) the applicable price paid by the Participating Member State(s) to the contractor for the Product doses subject to a Recall.

Except as and to the extent required by applicable law, this Article I.12.5 sets out the only liability of the contractor and the sole and exclusive remedy for Participating Member States for a Recall in accordance with this PA.

I.12.6 The contractor shall keep the Commission and the Participating Member States informed about any signal detected during the pharmacovigilance or Product monitoring programmes in relation to the Products which are the object of this PA within 5 working days from notifying the European Medicines Agency in accordance with the European Medicines Agency's guidelines on good pharmacovigilance practices.

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:

- (a) summarised key updates on progress made in the clinical development of the Product; final reports of clinical studies and safety evaluations submitted to the European Medicines Agency, promptly after submission to the European Medicines Agency;

(b) key updates on (i) challenges on establishment of the supply chain and (ii) the purchasing of materials necessary for the manufacture of the Product doses, which, in each case, materially affects the delivery schedule set forth in Article I.4.7; and

(c) scientific publications and public announcements, after such publications and announcements have been published.”

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.

I.12.8 The Parties acknowledge (a) the interest of the Participating Member States to purchase a vaccine that is effective also against variants and mutations of the SARS-CoV-2 coronavirus 2019 strain identified as the cause of the pandemic outbreak in early 2020 (the “COVID 19 Virus”), and (b) [REDACTED]

[REDACTED]

I.13. DEFINITIONS

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

‘Additional Doses’: additional doses of the Product that are delivered in addition to the doses to be delivered under this PA between the Parties. 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 Doses Initial Delivery Schedule’: has the meaning set forth in Article I.4.7;

‘Additional Doses Updated Delivery Schedule’: has the meaning set forth in Article I.4.7;

‘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;

‘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 I.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 I.12.8;

‘Deferred Option Increase’: has the meaning set forth in Article I.4.4;

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

‘Donation Country’: has the meaning set forth in Article I.4.6;

‘EPPO’: has the meaning set forth in Article II.20.6;

‘European Institutions’: has the meaning set forth in Article II.7.6;

‘Exchange Rate Methodology’: has the meaning set forth in Article I.8.2;

‘Exercising Member States’: have the meaning set forth in Article I.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 "faute lourde" under Belgian law;

'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;

'July Notice': has the meaning set forth in Article I.4.7;

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

'Late Delivery Schedule': has the meaning set forth in Article I.4.7.1

'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;

‘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;

‘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;

‘Product’: the finished and packaged form of the contractor’s **proprietary mRNA-1273 vaccine** against COVID-19 as of the date of this PA; [REDACTED]

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

‘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;

‘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;

[REDACTED] have the meaning set forth in Article I.4.7;

[REDACTED] have the meaning set forth in Article I.4.7;

‘Recall’: has the meaning set forth in Article I.12.5;

‘Reduced Order’: has the meaning set forth in Article I.4.7.1;

‘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 I.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*;

‘Technical Dispute’: has the meaning set forth in Article I.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;

[REDACTED] : has the meaning set forth in Article I.12.8;

'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.

SIGNATURES

For the contractor,

Moderna Switzerland GmbH

Signature: _____

Done at [place], [date]

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, [date]

II. GENERAL CONDITIONS FOR THE FRAMEWORK CONTRACT FOR SERVICES

II.1. SEVERABILITY

Each provision of this PA is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable to any extent, it must be severed from the remainder of the PA. This does not affect the legality, validity or enforceability of any other provisions of the PA, which continue in full force and effect. The illegal, invalid or unenforceable provision must be replaced by a legal, valid and enforceable substitute provision which corresponds as closely as possible with the actual intent of the parties under the illegal, invalid or unenforceable provision. The PA must be interpreted as if it had contained the substitute provision as from its entry into force.

II.2. PROVISION OF PRODUCT

II.2.1 The contractor must supply the Product in accordance with the state of scientific and technical knowledge in the industry for such Product at the time when the contractor put the Product into circulation, the applicable law in the Participating Member States and the provisions of this PA.

II.2.2 The contractor must comply with the requirements provided for in this PA.

II.2.3 All periods specified in the PA are calculated in calendar days, unless otherwise specified.

II.2.4 The contractor must immediately inform the Commission of any changes in the exclusion situations as declared, according to Article 137 (1) of Regulation (EU) 2018/1046.

II.3. COMMUNICATION BETWEEN THE PARTIES

II.3.1 Form and means of communication

Any communication of information, notices or documents under the PA must:

- a) be made in writing in paper or electronic format in the language of the contract;
- b) bear the PA number and, if applicable, the Vaccine Order Form number;
- c) be made using the relevant communication details set out in Article I.9; and
- d) be sent by mail or email.

If a party requests written confirmation of an e-mail within a reasonable time, the other party must provide an original signed paper version of the communication as soon as possible.

The parties agree that any communication made by email has full legal effect and is admissible as evidence in judicial proceedings.



II.3.2 Date of communications by mail and email

Any communication is deemed to have been made when the receiving party receives it, unless this PA contract refers to the date when the communication was sent.

E-mail is deemed to have been received by the receiving party on the day of dispatch of that e-mail, provided that it is sent to the e-mail address indicated in Article I.9. The sending party must be able to prove the date of dispatch. In the event that the sending party receives a non-delivery report, it must make every effort to ensure that the other party actually receives the communication by email or mail. In such a case, the sending party is not held in breach of its obligation to send such communication within a specified deadline.

Mail sent to the Commission or the Participating Member State is deemed to have been received on the date on which the department responsible referred to in Article I.9 registers it.


Formal notifications are considered to have been received by the receiving party on the date of receipt indicated in the proof received by the sending party that the message was delivered to the specified recipient.

II.4. LIABILITY

II.4.1 Without prejudice to the terms of Article II.5, the Commission and the Participating Member States are not liable for any damage or loss caused by the contractor, including any damage or loss to third parties during or as a consequence of *Implementation of the PA*.

II.4.2 If required by the relevant applicable legislation, the contractor must take out an insurance policy or self-insurance against risks and damage or loss relating to the *Implementation of the PA*. It must also take out supplementary insurance or self-insure as reasonably required by common practice in the pharmaceutical industry for a COVID-19 vaccine. Upon request, the contractor must provide evidence of insurance coverage or self-insurance to the Commission.

II.4.3



II.4.4 The Commission or the Participating Member State are not liable for any loss or damage caused to the contractor during or as a consequence of *Implementation of the PA*, unless pursuant to Article II.5, or the loss or damage was caused by its Willful Misconduct, Gross Negligence or breach of this PA or the applicable Vaccine Order Form.

II.4.5

[REDACTED]

II.4.6 No limitation of the liability of the contractor shall apply as regards damages resulting from the contractor's Gross Negligence, Willful Misconduct and Fraud.

The remedies set forth in [REDACTED] shall be the [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.

Except as otherwise expressly set forth in this Article II.4.6, the contractor's [REDACTED] will not exceed [REDACTED]

[REDACTED]

For the avoidance of doubt, no limitation of liability laid down in this Article II.4.6 shall affect the contractor's obligations vis-a-vis third parties or vis-a-vis the Participating Member States in the circumstances in which indemnification under Article II.5 is not available to the contractor.

II.4.7 For the avoidance of doubt in no event can any limitation under this PA concern Losses suffered by third parties which are subject to indemnification under the conditions set out in Article II.5.

II.5. INDEMNIFICATION

II.5.1 The Commission, on behalf the Participating Member States, declares that the use of Products produced under this PA will happen under epidemic conditions requiring such use, and that the administration of Products will therefore be conducted under the sole responsibility of the Participating Member States. Hence, each Participating Member State shall indemnify and hold harmless the contractor, its present and future Affiliates, collaborators, contractors, sub-contractors, licensees and sub-licensees, and officers, directors, employees and other agents and representatives of each (together, the "**Indemnified Persons**") from and against any and all

damages, liabilities,

and

relating to Claims for harm, damages and losses associated with death, physical, mental or emotional injury, illness, or disability, fear of physical, mental, or emotional injury, illness, or disability (including claims for medical monitoring), property loss or damage or business interruption of an injured party or related claimant (together the "Losses" and each a "Loss") relating to or arising from use or deployment of the Products supplied to or for the benefit of such Participating Member State under the applicable Vaccine Order Form with such Participating Member State.

A Participating Member State will indemnify an Indemnified Person for its reasonable, documented legal costs

incurred relating to a given Claim.

unless the Participating Member State challenges such payment based on evidence that the Losses that are the subject of the Claim in question are caused by the Willful Misconduct, Gross Negligence or failure to comply with Good Manufacturing Practices of the Indemnified Party.

II.5.2 In the event that any Indemnified Person becomes aware of any demand, claim, action, suit or proceeding, or threat of a demand, claim, action, suit or proceeding, against such Indemnified Person which may reasonably be considered likely to cause a Loss or be subject to the indemnity herein (and in the Vaccine Order Form with each Participating Member State) (a "Claim"), the contractor shall ensure that such Indemnified Persons shall give the Participating Member State prompt notice of the Claim and that such Indemnified Person shall reasonably cooperate with such Participating Member State.

In the event that a Participating Member State becomes aware of any Claim against an Indemnified Person, such Participating Member State shall promptly provide written notice to the contractor of such Claim along with all information relating to such Claim that is in such

Participating Member State's possession or control.

II.5.3

II.5.4 The Commission, on behalf of itself and the Participating Member States, acknowledges that the indemnity provisions set forth herein and in the Vaccine Order Forms with the Participating Member States are essential inducements to the contractor entering into this PA and the Vaccine Order Forms with the Participating Member States. In the event that any Indemnified Person brings any proceeding or legal action to enforce any right to indemnity under this PA or any Vaccine Order Form with a given Participating Member State and prevails in whole or in any material part,

The Indemnified Persons shall be deemed third party beneficiaries with respect to their rights of indemnity under this PA and the Vaccine Order Forms with the Participating Member States.

II.5.5

II.5.6 No Person (including any Person to whom the Product has been administered) other than the parties hereto and their respective Affiliates, and in the case of the contractor, the Indemnified Persons, and permitted assignees hereunder, will be deemed an intended beneficiary hereunder or have any right to enforce any obligation or make a claim under this PA or the Vaccine Order Forms with the Participating Member States.

II.5.7



II.6. CONFLICT OF INTEREST AND PROFESSIONAL CONFLICTING INTERESTS

II.6.1 The contractor must take all the necessary measures to prevent any situation of *conflict of interest* or *professional conflicting interest*.

II.6.2 The contractor must *notify* the Commission in writing as soon as possible of any situation that could constitute a *conflict of interest* or a *professional conflicting interest* during the *implementation of the PA*. The contractor must immediately take action to rectify the situation.

The Commission may do any of the following:

- a) verify that the contractor's action is appropriate;
- b) require the contractor to take further action within a specified deadline;
- c) decide not to award a Vaccine Order Form to the contractor.

II.6.3 The contractor must pass on all the relevant obligations in writing to:

- a) its personnel;
- b) any natural person with the power to represent it or take decisions on its behalf;
- c) third parties involved in the *Implementation of the PA*, including subcontractors.

The contractor must also ensure that the persons referred to above are not placed in a situation which could give rise to conflicts of interest.

II.7. CONFIDENTIALITY

II.7.1 The Commission, the Participating Member State and the contractor must treat with confidentiality any information or documents, in any format, disclosed in writing or orally, relating to the *Implementation of the PA* and identified in writing as confidential.

II.7.2 The Commission, the Participating Member State and the contractor shall:

- a) not use *confidential information or documents* for any purpose other than to perform its obligations under the PA or a Vaccine Order Form without the prior written agreement of the other party;

- b) ensure the protection of such *confidential information or documents* with the same level of protection as its own *confidential information or documents* and in any case with due diligence;
- c) not disclose, directly or indirectly, *confidential information or documents* to third parties unless such third parties agree to comply with this Article or are subject to substantially similar confidentiality obligations as provided in this Article.

II.7.3 The confidentiality obligations set out in this Article are binding on the Commission, the Participating Member State and the contractor during the *Implementation of the PA* and for as long as the information or documents remain confidential unless:

- a) the disclosing party agrees to release the receiving party from the confidentiality obligation earlier;
- b) the *confidential information or documents* become public through other means than a breach of the confidentiality obligation;
- c) any applicable law requires the disclosure of the *confidential information or documents* (including securities laws or as required by the stock exchange rules of the contractor or any of its Affiliates).

II.7.4 The contractor must obtain from any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the *Implementation of the PA* a commitment that they will comply with this Article or ensure that such person is subject to substantially similar confidentiality obligations. At the request of the Commission, the contractor must provide a document providing evidence of this commitment.

II.7.5 Notwithstanding the other provisions of this Article, the Commission, the Participating Member States and the contractor may issue a press release and/or other public statement. The Parties shall consult together on the timing, contents and manner of any press release relating to this *PA*. A party may subsequently publicly disclose any information previously contained in any public announcement made in accordance with this Article.

II.7.6 Prior to any disclosure by the Commission containing Confidential Information contained in the present document, 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).

The contractor acknowledges that the Commission, along with other agencies and offices of the European Union (collectively, the “**European Institutions**”), are subject to requirements under

Regulation (EC) 1049/2001², which may require the European Institutions to disclose information to third parties on request. The Commission commits itself to assess any request for access to a document that relates to this contract according to the exclusions or exceptions set forth in Regulation (EC) 1049/2001 apply.

II.8. PROCESSING OF PERSONAL DATA

II.8.1 Processing of personal data by the Commission

Any personal data included in or relating to the PA, including its implementation, shall be processed in accordance with Regulation (EU) 2018/1725. Such data shall be processed solely for the purposes of the implementation, management and monitoring of the PA by the data controller. For the purpose of this provision, the data controller for the Commission shall be the Director-General of the European Commission's Directorate-General for Health and Food Safety. The data protection notice is available at https://ec.europa.eu/info/data-protection-public-procurement-procedures_en. The contractor or any other person whose personal data is processed by the data controller in relation to this PA has specific rights as a data subject under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, rectify or erase their personal data and the right to restrict or, where applicable, the right to object to processing or the right to data portability.

Should the contractor or any other person whose personal data is processed in relation to this PA have any queries concerning the processing of its personal data, it shall address itself to the data controller. They may also address themselves to the Data Protection Officer of the data controller. They have the right to lodge a complaint at any time to the European Data Protection Supervisor.

II.8.2 Processing of personal data by the contractor

The processing of personal data by the contractor shall meet the requirements of Regulation (EU) 2018/1725 and be processed solely for the purposes set out by the controller.

II.9. SUBCONTRACTING

II.9.1 The contractor may not subcontract and have the PA implemented by third parties beyond the third parties already mentioned in this PA without prior written consent of the Commission (such consent not to be unreasonably withheld, conditioned or delayed). Without prejudice to Article I.4.5, the Commission confirms its consent for the contractor to subcontract and have the PA implemented by the subcontractors set forth on Annex IV.

II.9.2 The contractor will have the right to extend the rights, licenses, and obligations granted or imposed under this PA or any Vaccine Order Form to one or more of its Affiliates. All applicable terms and provisions of this PA and the Vaccine Order Forms will apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and

² Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

provisions apply to the contractor. The contractor will remain at all times primarily liable for any acts or omissions, including financial liabilities, of its Affiliates.

II.9.3 In the case of subcontracting, the contractor remains bound by its contractual obligations and is solely responsible for the *Implementation of the PA*.

II.9.4 The contractor must ensure that the subcontract does not affect the rights of the Commission and the Participating Member States under this PA.

II.9.5 The Commission may request the contractor to replace a subcontractor found to be in a situation provided for in one of the situations provided for in Article 136(1) and (2) of the Financial Regulation³.

II.10. AMENDMENTS

II.10.1 Any amendment to the PA or a Vaccine Order Form must be made in writing before all contractual obligations have been fulfilled. A Vaccine Order Form does not constitute an amendment to the PA.

II.10.2 No amendment can make changes to the PA or a Vaccine Order Form that might alter the initial conditions of the procurement procedure or result in unequal treatment of tenderers or contractors.

II.11. ASSIGNMENT

II.11.1 The contractor cannot assign any of the rights and obligations arising from the PA, including claims for payments or factoring, without prior written authorisation from the Commission (such authorisation not to be unreasonably withheld, conditioned or delayed). In such cases, the contractor must provide the Commission with the identity of the intended assignee.

II.11.2 Any right or obligation assigned by the contractor without authorisation is not enforceable against the Commission or the Participating Member States.

II.12. INTELLECTUAL PROPERTY RIGHTS

II.12.1 Identification of pre-existing rights

When delivering the *results*, the contractor must warrant that, [REDACTED]

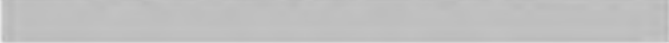
[REDACTED]

³ 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 of 30.7.2018, p.1.



II.12.2 Evidence of granting of pre-existing rights

Upon request by the Commission, the contractor must, in addition to the list mentioned under Article II.12.1, provide evidence that it has the ownership or the right to use all the listed *pre-existing rights*, except for the rights owned or licensed by the Union.



II.12.3 Disclaimer

When stating opinions about the use of the *results*, the contractor must declare that the opinions expressed are those of the contractor only and do not represent the Commission's official position. The Commission may waive this obligation in writing or provide the text of the disclaimer.

II.13. FORCE MAJEURE

II.13.1 If a party is affected by *force majeure*, it must immediately *notify* the other party, stating the nature of the circumstances, their likely duration and foreseeable effects.

II.13.2 A party is not liable for any delay or failure to perform its obligations under the PA if that delay or failure is a *result* of *force majeure*. If the contractor is unable to fulfil its contractual obligations owing to *force majeure*, it has the right to remuneration only for the services actually provided.

II.13.3 The parties must take all necessary measures to limit any damage due to *force majeure*.

II.14. CONSEQUENCES OF DELAY



II.14.1 Cancellation and Reduced Order

II.15. SUSPENSION OF THE IMPLEMENTATION OF THE PA

II.15.1 Suspension by the contractor

If the contractor is affected by *force majeure*, it may suspend the provision of the services and Product under a Vaccine Order Form.

The contractor must immediately *notify* the Commission and the Participating Member States of the suspension. The *notification* must include a description of the *force majeure* and state when the contractor expects to resume the provision of services and the Product.

The contractor must *notify* the Commission and the Participating Member States as soon as it is able to resume *performance of the Vaccine Order Form*, unless the Commission has already terminated the PA or the Vaccine Order Form.

II.15.2 Suspension by the Commission or the Participating Member State

The Commission or the Participating Member State in question may suspend the *Implementation of the PA or performance of a Vaccine Order Form* (of such Participating Member State) or any part of it:

- (a) if the procedure for awarding the PA or a Vaccine Order Form or the *Implementation of the PA* proves to have been subject to *irregularities, fraud or material breach of obligations* by the contractor;
- (b) in order to verify whether the contractor's presumed *irregularities, fraud or material breach of obligations* have actually occurred.

The Commission or the Participating Member State in question must *formally notify* the contractor of the suspension and the reasons for it. Suspension takes effect on the date of *formal notification*, or at a later date if the *formal notification* so provides.

The Commission or the Participating Member State in question must immediately *notify* the contractor as soon as the verification is completed whether:


- (a) it is lifting the suspension; or
- (b) it intends to terminate the PA or its Vaccine Order Form under Article II.16.2d) or II.16.2g).

II.16. TERMINATION OF THE PA

II.16.1 The Parties agree that the PA shall not be automatically terminated.

II.16.2 Grounds for termination by the Commission

The Commission may terminate the PA or a Participating Member State may terminate its on-going Vaccine Order Form in the following circumstances:

- a) 
- b) if the contractor is in breach of a substantial contractual obligation that is not remedied within a period of thirty (30) days following notice by the Commission or a Participating Member State to the contractor or repeatedly refuses to sign one or several Vaccine Order Forms;
- c) if the contractor or any person that assumes unlimited liability for the debts of the contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation⁴;
- d) if the contractor or any *related person* is in one of the situations provided for in points (c) to (h) of Article 136(1) or to Article 136(2) of the Financial Regulation;
- e) if the procedure for awarding the PA or the *Implementation of the PA* prove to have been subject to *irregularities, fraud or breach of obligations*;
- f) if the contractor is in a situation that could constitute a *conflict of interest* or a *professional conflicting interest*;
- g) if a change to the contractor's legal, financial, technical, organisational or ownership situation is likely to substantially affect the *implementation of the PA* or substantially modify the conditions under which the PA was initially awarded or a change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046 that calls into question the decision to award the contract;
- h) in the event of *force majeure*, where either resuming implementation is impossible or the necessary ensuing amendments to the PA or a Vaccine Order Form would mean that the tender specifications are no longer fulfilled or result in unequal treatment of tenderers or contractors.

⁴ 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 of 30.7.2018, p.1 <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1544791836334&uri=CELEX:32018R1046>

II.16.3 Grounds for termination by the contractor

The *contractor* may terminate the *PA* or the respective *Vaccine Order Form* in the following circumstances:

- (a) If the *Commission* or any of the *Participating Member States* materially fail to comply with their respective obligations.
- (b) In the event of *force majeure*, where either resuming implementation is impossible or the necessary ensuing amendments to the *PA* or a *Vaccine Order Form* would mean that the tender specifications are no longer fulfilled or result in unequal treatment of tenderers or contractors.

II.16.4 Procedure for termination

A party must *formally notify* the other party of its intention to terminate the *PA* or a *Vaccine Order Form* and the grounds for termination.

The other party has 30 days following the date of receipt to submit observations, including the measures it has taken or will take to continue fulfilling its contractual obligations. Failing that, the decision to terminate becomes enforceable the day after the time limit for submitting observations has elapsed.

If the other party submits observations, the party intending to terminate must *formally notify* it of such party's intention to terminate this *PA* or a *Vaccine Order Form* and the grounds for termination. The decision to terminate becomes enforceable the day after this second formal notification.

II.16.5 Effects of termination



In case of termination pursuant to Article II.16.3:

- a) The contractor is not entitled to compensation for any damage resulting from the termination of the *PA* or a *Vaccine Order Form*, including loss of anticipated profits, if the contractor terminated the *PA* or the relevant *Vaccine Order Form* in accordance with Article II.16.3 (b).

- b) The Commission and the Participating Member State are liable for damage incurred by the contractor as a result of the termination of the PA or a Vaccine Order Form by the contractor on the basis of Article II.16.3 (a). It is understood that all payment obligations with respect to *Products* already delivered or in delivery in compliance with the PA at the time of the termination shall remain unaffected. The contractor may claim compensation for such damage against the Commission and/or the Participating Member State(s), as allowed by Article II.4.

The Parties must take all appropriate measures to minimise costs, prevent damage and cancel or reduce their commitments.

Upon termination, at the written request of the disclosing party, each receiving party will return or destroy the Confidential Information of such disclosing party, provided that (i) one (1) copy of the Confidential Information may be retained by the receiving party for the sole purpose of monitoring its ongoing obligations hereunder; and (ii) one (1) copy of the Commission's or each Participating Member State's Confidential Information may be retained and used by or on behalf of the contractor in connection with regulatory filings for the Product. Notwithstanding the foregoing, no receiving party shall not be obliged to destroy, erase, return or provide to the disclosing party any electronic records of Confidential Information which may be stored in electronic back-ups or other digital archives in the ordinary course; but in each case the receiving party shall continue to treat those, in so far as they contain Confidential Information, as confidential pursuant to the terms of this PA.

Within sixty (60) calendar days of the date of termination, the contractor must submit any report and any invoice for Product that were already delivered or in delivery in compliance with the PA at the time of termination. The Participating Member States shall pay such invoices within 30 days from receipt of the invoice.

II.17. INVOICES, TAXES, VALUE ADDED TAX AND E-INVOICING

II.17.1 Payment Requests, Invoices and value added tax

Payment requests and invoices shall contain the following information: (i) the *contractor's* full name and address, (ii) the reference to this PA and to the *Vaccine Order Form* (to the extent already concluded), (iii) the full name and address of the recipient, (iv) the name of the *Participating Member State* concerned, (v) the invoiced amount, (vi) the currency, (vii) the quantity of *Product doses* delivered or in delivery in compliance with the PA at the time (or offered to be delivered if the *Participating Member State* illegitimately refuses acceptance of delivery), or, with respect to the *Initial Payment*, the quantity of *Product doses* allocated to the relevant *Participating Member State* pursuant to Article I.4.2, (viii) the date of delivery (if relevant), and (ix) the date of issuance of the payment request or invoice.

Invoices must indicate the place of taxation of the *contractor* for value added tax (VAT) purposes and must specify separately amounts not including VAT and amounts including VAT (where VAT is applicable).

For the avoidance of doubt, VAT may be charged on *doses* of the *Product* under the conditions of national legislation. In such cases, the taxable amount may include the amount paid by the *Participating Member State*.

For the further avoidance of doubt, the *Parties* agree that all prices set forth in the *PA* shall be exclusive of VAT and that VAT, if any, shall be paid in addition to the prices set forth in the *PA*.

The *Parties* agree that the contractor shall be indemnified by each *Participating Member State* against any import duties, charges, levies or imposts that may be required to be paid by the contractor in respect of any supplies of *Product* to such *Member State*. The contractor shall further be indemnified against any irrecoverable VAT that it may incur in any *Participating Member State* in connection with the importation of any *Product* to that *Participating Member State*.

II.18. PAYMENTS AND GUARANTEES

II.18.1 Date of payment

The date of payment is deemed to be the date on which the Commission's account or the account of the *Participating Member State* in question is debited.

II.18.2 Costs of transfer

The costs of the transfer are borne as follows:



II.18.3 Suspension of the time allowed for payment

The Commission or the *Participating Member State* in question may suspend the payment periods specified in Article II.4 at any time by *formally notifying* the contractor (or leader in the case of a joint tender) that its invoice cannot be processed. The reasons the Commission or the *Participating Member State* in question may cite for not being able to process an invoice are:

- a) because it does not comply with the *PA*;
- b) because the contractor has not produced the appropriate documents or deliverables; or
- c) because the Commission or the *Participating Member State* in question has observations on the documents or deliverables submitted with the invoice.

The Commission or the *Participating Member State* in question *must formally notify* the contractor as soon as possible of any such suspension, giving the reasons for it. In cases b) and c)

referred to above, the Commission or the Participating Member State in question shall *formally notify* the contractor the time limits to submit additional information or corrections or a new version of the documents or deliverables.

Suspension takes effect on the date the Commission or the Participating Member State in question sends the *formal notification*. The remaining payment period resumes from the date on which the requested information or revised documents are received or the necessary further verification, including on-the-spot checks, is carried out.

II.18.4 Interest on late payment

On expiry of the payment periods specified in Article II.4, the contractor (or leader in the case of a joint tender) is entitled to interest on late payment at the rate applied by the European Central Bank for its main refinancing operations in euros (the reference rate) plus five points. The reference rate is the rate in force, as published in the C series of the *Official Journal of the European Union*, on the first day of the month in which the payment period ends.

Suspension of the payment period as provided for in Article II.18.3 is not considered as giving rise to late payment.

Interest on late payment covers the period running from the day following the due date for payment up to and including the date of payment as defined in Article II.18.1.

II.19. RECOVERY

II.19.1 Recovery procedure

Before any recovery permitted under this PA, the Commission or the Participating Member State in question must *formally notify* the contractor of its intention to recover the amount it claims, specifying the amount due and the reasons for recovery and inviting the contractor to make any observations within 30 days of receipt.

If no observations have been submitted or if, despite the observations submitted, the Commission or the Participating Member State in question decides to pursue the recovery procedure, it must confirm recovery by *formally notifying* a debit note to the contractor, specifying the date of payment. The contractor must pay in accordance with the provisions specified in the debit note.

If the contractor does not pay by the due date, the Commission or the Participating Member State in question may, after informing the contractor in writing, recover the amounts due:

- (a) by offsetting them against any amounts owed to the contractor by the Commission or the Participating Member State in question; or
- (b) by taking legal action.

The contractor will be liable for any losses or damages caused by its late payment.

II.19.2 Interest on late payment

If the contractor does not honour the obligation to pay the amount due by the date set by the Commission or the Participating Member State in question, the amount due bears interest at the rate indicated in Article II.18.4. Interest on late payments will cover the period starting on the day after the due date for payment and ending on the date when the Commission or the Participating Member State in question receives the full amount owed.

Any partial payment is first entered against charges and interest on late payment and then against the principal amount.

II.20. CHECKS AND AUDITS

II.20.1 The Commission and the European Anti-Fraud Office, as well as the competent authorities of the Participating Member States, may check or require an audit on the Award or the Implementation of the PA. This may be carried out either by OLAF's own staff, or by any outside body authorised to do so on its behalf, and by the competent authorities of the Participating Member States provided that the auditor may not be a competitor of the contractor.

Such checks and audits may be initiated at any moment during the provision of the Product and up to five years starting from the payment of the balance of the last Vaccine Order Form issued under this PA.

The audit procedure is initiated on the date of receipt of the relevant letter sent by the Commission. Audits are carried out on a confidential basis.

II.20.2 The contractor must keep all original documents stored on any appropriate medium, including digitised originals if authorised under national law, for a period of five years starting from the payment of the balance of the last Vaccine Order Form issued under this PA.

II.20.3 The contractor must grant the appropriate right of access to sites and premises where the PA is implemented and to all the information, including information in electronic format, needed to conduct such checks and audits. The contractor must ensure that the information is readily available at the moment of the check or audit and, if so requested, that information is handed over in an appropriate format.

II.20.4 On the basis of the findings made during the audit, a provisional report is drawn up. The Commission or its authorised representative must send it to the contractor, who has 30 days following the date of receipt to submit observations. The contractor must receive the final report within 60 days following the expiry of the deadline to submit observations.

On the basis of the final audit findings, the Commission or the Participating Member State in question may recover all or part of the payments made in accordance with Article II.19.

II.20.5 In accordance with Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against *fraud* and other *irregularities* and Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office, the European Anti- Fraud Office may carry out investigations, including on the spot checks and inspections, to establish whether there has been *fraud*, corruption or any other illegal activity under the contract affecting the financial interests of the Union. Findings arising from an investigation may lead to criminal prosecution under national law.

The investigations may be carried out at any moment during the provision of the Product and up to five years starting from the payment of the balance of the last Vaccine Order Form issued under this PA.

II.20.6 The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939⁵ ('the EPPO') have the same rights as the Commission, particularly right of access, for the purpose of checks, audits and investigations.

⁵ Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office

ANNEX I: PARTICIPATING MEMBER STATES

Germany
France
Italy
Spain
Austria
Greece
Cyprus
Malta
Denmark
Sweden
Finland
Ireland
Portugal
Belgium
Luxembourg
Netherlands
Poland
Romania
Bulgaria
Slovenia
Croatia
Czech Republic
Hungary
Slovakia
Lithuania
Latvia
Estonia

ANNEX II: MODEL FOR VACCINE ORDER FORM

EXPLANATORY NOTE

✓ ***Who shall send a Vaccine Order Form?***

- Each Participating Member State shall send to the contractor one duly completed and signed Vaccine Order Form in paper format (by registered mail) and in electronic format (PDF by e-mail) for its relevant Allocated **Product doses** (such allocation is as communicated by the Commission to the contractor pursuant to Article 1.4.2 or 1.4.4 of the PA).
 - ***By when (deadline)?*** Please check Article 1.4.2 or 1.4.4 of the PA.
 - ***What are each Participating Member States' allocated Product doses?*** Please contact the Commission, who is responsible for allocating the Products doses among the Participating Member States.

✓ ***To Whom and how shall the Vaccine Order Form be sent?***

- To the contractor:
 - (1) by registered mail to the following address:
Moderna Switzerland GmbH
Aeschenvorstadt 48 [REDACTED] 4051 Basel, Switzerland
[REDACTED]
 - and
 - (2) by email at the following address [REDACTED] Please always send the duly completed and signed Vaccine Order Form as a PDF attachment to the email.
 - (3) Please check before sending whether the Commission will coordinate all Vaccine Order Forms on behalf of all Participating Member States.

✓ ***How to complete this Vaccine Order Form?***

- The relevant information in square brackets must be completed by each Participating Member State.
- Other than completing such information in square brackets, **no changes or amendments are permitted** to this model Vaccine Order Form unless explicitly agreed by the contractor and the Commission. If any such change or amendment is made, the Vaccine Order Form will be deemed invalid and not conform to the PA requirements.

✓ ***Whom to contact in case of questions re. how to complete this Vaccine Order Form?***

- Commission representatives:
 - c Commission will confirm the name after signature. Please copy all communications to EC-VACCINES@ec.europa.eu
- Contractor's representatives:
Moderna Switzerland GmbH
Aeschenvorstadt 48 [REDACTED] 4051 Basel, Switzerland
[REDACTED]

C

[Letterhead of Government if available]

This Vaccine Order Form is submitted by:

[The Government of [•]] (the “**Member State**”), represented for the purposes of signing this specific order form by *[forename, surname, function, department of authorising officer]*,

to:

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  4051 Basel, Switzerland

CHE-344.522.989 MWST

(hereinafter referred to as “the contractor”)

The Member State and the contractor are together referred to as the “**Parties**” and each individually as a “**Party**”.

WHEREAS

- The contractor and the European Commission, acting on behalf of and in the name of the Participating Member States, entered into a Purchase Agreement for the production, purchase and supply of the contractor’s COVID-19 vaccine for EU Member States [SANTE/2021/C3/010], as amended or restated by the Parties from time to time (the “PA”), the terms of which are binding on the Participating Member States.
- The PA provides that the relevant Participating Member States will submit to the contractor a Vaccine Order Form through which the contractor shall (subject to the terms and conditions of the PA) deliver to the relevant Participating Member State a proportion of the Additional Doses at the price and conditions as set out in the PA.
- In the event the Commission, acting on behalf of the Participating Member State(s), has exercised the Option Increase, the relevant Participating Member State(s) will submit to the contractor a separate Vaccine Order Form through which the contractor shall (subject to the terms and conditions of the PA) deliver to the relevant Participating Member States a portion of the Additional Option Doses,

- In accordance with Article I.4.2, the Member State hereby places its order for its full allocation of Additional Doses or the relevant Additional Option Doses (as applicable).

Article I

Definitions

Capitalized terms used but not defined in this Vaccine Order Form shall have the meaning given in the PA.

Article II

Subject matter

1. This Vaccine Order Form is submitted by the Member State to the contractor in accordance with the terms of the PA, and forms an integral part of the PA. The terms and conditions of the PA are incorporated into this Vaccine Order Form by reference. In the event of contradiction between this Vaccine Order Form and the PA, the terms of the PA prevail regardless of any provision to the contrary.
2. This Vaccine Order Form relates to the order for the Member State's full allocated Additional Doses or the relevant Additional Option Doses (as applicable) as set out in the Allocation provided by the Commission to the contractor pursuant to Article I.4.2 or I.4.4 of the PA. The provision of this Vaccine Order Form by the Member State to the contractor constitutes a binding order by the Member State for the purchase of its full allocated Additional Doses at the Price or the relevant Additional Option Doses (as applicable).

Article III

Delivery; Quality

1. Delivery Address. The Delivery Address for the Member State is as follows:

[• - Member State to enter location]

2. Quality. The roles and responsibilities between the contractor and the Member States in relation to acceptance/rejection matters related to the Product doses are set out in Article I.5 of the PA.

Article IV

Invoices; Notices

1. **Invoice and Payments.** The contractor shall invoice the Member State in accordance with the terms of the PA. All payments to the contractor shall be made in accordance with the terms of the PA.
2. **Notice.** Any notice given under this Vaccine Order Form must be made in writing in English in paper or electronic format; bear the PA number and the number of this Vaccine Order Form; be made using the relevant communication details set out below with respect to the Member State and the contractor (as applicable); and be sent by mail and email:

Member State:

[Name of Member State]

[Full official address of Member State]

[VAT number]

[Full name of addressee physical person (contact person)]

[Function of addressee physical person (contact person)]

E-mail: *[complete email of addressee physical person (contact person)]*

Contractor:

Modema Switzerland GmbH

Aeschenvorstadt 48 [REDACTED] 4051 Basel, Switzerland

Article V.

Entry into Force and Duration

1. This Vaccine Order Form shall become effective upon execution and delivery by the Member State to the contractor in accordance with I.4.2 or I.4.4 of the PA as applicable.
2. This Vaccine Order Form shall automatically expire upon Delivery of the Member State's full allocated Additional Doses or the relevant Additional Option Doses (as applicable) as set out in the Allocation provided by the Commission to the contractor pursuant to Article I.4.2 or I.4.4 of the PA as applicable.
3. Expiry of the Vaccine Order Form shall be without prejudice to Article I.3.4 of the PA (*Surviving Provisions*).

Article VI.
Applicable Law and Settlement of Disputes

Article I.11 (*Applicable Law and Settlement of Disputes*) of the PA shall apply *mutatis mutandis* to this Vaccine Order Form.

(Signature page follows)



SIGNATURES

For the Member State,

[forename/surname/position]

Signature: _____

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

For acceptance of the Vaccine Order Form,

[forename/surname/position]

Signature: _____

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



**ANNEX III: AGREEMENT BETWEEN THE COMMISSION AND MEMBER STATES ON PROCURING
COVID-19 VACCINES ON BEHALF OF THE MEMBER STATES AND RELATED PROCEDURES, ANNEXED TO
THE COMMISSION DECISION C(2020) 4192 FINAL OF 18 JUNE 2020**

Agreement

Preamble

Having regard to Article 4(5)(b) of 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 under regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak (hereinafter “ESI” or “ESI regulation”);

The European Commission (“the Commission”)

and

The following Member States: (XXX), hereinafter referred to as “the Participating Member States”

Together referred to as “the Parties”

Agree on the Following:

Article 1: Objective and mandate of the Commission

On the basis of the present agreement, the Commission is mandated to conclude, on behalf of the Participating Member States, Advance Purchase Agreements (“APA”) with vaccine manufacturers with the objective to procure vaccines for the purposes of combatting the COVID 19 pandemic at Union level.

The Annex to this agreement sets out the negotiating directives for this purpose.

Article 2: Acquisition of vaccine doses

It is the Participating Member States, and not the Commission, that shall acquire vaccine doses from the manufacturers on the basis of the APAs unless otherwise agreed. All relevant vaccination policies shall therefore remain matters for the Participating Member States.

Article 3: APAs containing a right to acquire vaccine doses

Where the Commission concludes an APA in conformity with the present agreement that provides the right for the Participating Member States to acquire vaccine doses, the use

of such a right shall take place by means of the conclusion of contracts between the Participating Member States and the vaccine manufacturers. There shall be no obligation for any Participating Member State to conclude such a contract on the basis of the APA. The APA shall contain a clause to this end.

Article 4: APAs containing an obligation to acquire vaccine doses

Where the Commission intends to conclude, in conformity with the present agreement, an APA containing an obligation to acquire vaccine doses, it shall inform the Participating Member States of such intention and the detailed terms. In case a Participating Member State does not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the Commission within 5 working days after the Commission has communicated its intention to conclude the APA. All Participating Member States not having opted out within the period of 5 working days are deemed to have authorised the Commission to negotiate and conclude the APA with the vaccine manufacturer in their name and on their behalf.

Article 5: The legally binding nature of APAs

Once concluded, the terms of the APA shall be legally binding on the Participating Member States, except for those who have exercised their right to opt out.

Article 6: Responsibility and liability

The present Agreement regulates only the division of potential liability and indemnification between the Commission and the Participating Member States. It does not regulate the extent to or the conditions under which potential liability of the vaccine manufacturer may be taken over or indemnified under the APAs.

The Commission shall be exclusively responsible for the procurement process and the conclusion of APAs including any liability arising out of the conduct of the negotiations.

Participating Member States acquiring a vaccine shall be 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 shall extend to and include any indemnification of vaccine manufacturers under the terms and conditions of the relevant APA for liability related to the use and deployment of vaccines normally borne by such manufacturer.

Article 7: Obligation not to negotiate separately

By signing the present Agreement, the Participating Member States confirm their participation in the procedure and agree not to launch their own procedures for advance purchase of that vaccine with the same manufacturers.

In case an APA containing an obligation to acquire vaccine doses has been concluded with a specific manufacturer, the Member States having made use of the opt-out provided under the present Agreement can enter into separate negotiations with the same manufacturer after the APA under the present Agreement has been signed.

Annex

Initial considerations

A permanent solution to the COVID-19 crisis is most likely to be brought about by the development and deployment of a safe and effective vaccine against the virus. Every month gained in the deployment of a vaccine will save many lives, many jobs and billions of euros.

Therefore, it is the objective of the present Agreement that the EU takes steps to secure sufficient supplies of a safe and effective vaccine for Member States.

Structure and purpose of the procurement

Work on a COVID-19 vaccine is challenging for many reasons: the shortened development timeframe, the large upfront costs for manufacturers, the high failure rate during clinical trials. If vaccine producers follow their usual practice of making investments in production capacity only when they are sure of a viable product, this will result in considerably longer waiting times for a vaccine. Investments need to be made now in order to ensure that vaccines are being produced at the scale required as early as possible.

Under the present agreement, this challenge will be addressed through concluding EU-level Advance Purchase Agreements ("APA") with vaccine manufacturers when necessary, to secure access to vaccine candidates where they are successful, including up-front EU financing to de-risk essential investments to increase the speed and scale of manufacturing successful vaccines. Funding for the up-front payments will come from the Emergency Support Instrument (ESI).

The Parties understand that developing a safe and effective vaccine is a highly complex process and the risk of failure in any such venture is very high. Therefore, the aim is to put in place APAs with a number of manufacturers of leading vaccine candidates, to maximise the chances of having access to at least one successful vaccine.

The Commission will invite all vaccine manufacturers to manifest interest. In general, the Commission will give priority to negotiating specific APAs with those manufacturers that (a) have entered or have firm plans to enter clinical trials still in 2020, (b) have the capacity to develop a successful vaccine and (c) have a proven capacity to produce at scale already in 2021.

Process and governance

In order to run the procurement centrally and efficiently, the European Commission will set up a steering board for the process subject to Article 6 of the present Agreement. It will be co-chaired by the European Commission and a Participating Member State with experience in the negotiations and production capacities for vaccines. The steering board will include senior officials from all Participating Member States to assist and provide guidance throughout the evaluation process.

The co-chairs of the steering board will propose a team of a limited number of experts with relevant experience for the ongoing negotiations from six Participating Member States with production capacities for vaccines. These experts will join with the European Commission in a negotiation team ("joint negotiation team"), which will work on a continuous basis as one unit. That joint negotiation team will start work immediately building on previous contacts with individual companies by the European Commission and Participating Member States. In order to launch negotiations with a specific manufacturer, there needs to be support from at least four Participating Member States. The joint negotiation team will make its best effort to take the advice of the steering board into account in the negotiations and will report back to the steering board on a regular basis on the progress made in negotiating with individual companies.

For compliance with the applicable rules, all members of the steering board and the joint negotiation team will obtain the status of experts associated to the procurement process as provided in the Financial Regulation. Given their access to highly sensitive business information, all those members will be required to sign strict confidentiality and no-conflict-of-interest agreements.

Assisted by the steering board, the European Commission will then decide which of the resulting APAs should be concluded, in particular if financing under ESI is insufficient to finance all relevant packages. The Commission will only consider those APAs for financing where at least four Participating Member States have expressed agreement. Before making any final decisions, the Commission will seek independent scientific advice on the state of progress and the available data on quality, safety and efficacy for the vaccine candidate in question.

Should financing under ESI be insufficient, Participating Member States can decide to top up ESI funding to make up the gap to finance all packages. In such a case where there are opportunities to conclude further APAs but money from ESI is no longer sufficient, Participating Member States will have the opportunity to express their interest in such opportunities. If at least four Participating Member States express interest, those Participating Member States will make use of the possibility of a voluntary contribution to ESI to the required amount allowing the Commission to proceed with signing the APA only on behalf of those Member States that have expressed interest and contributed the funds to ESI.

For full transparency, the European Commission will report to the IPCR at least once every two weeks on overall progress more generally.

Advanced Purchase Agreements and conditions

To conclude APAs, the joint negotiating team will negotiate funding packages with individual vaccine producers in return for the right to buy a specific number of vaccine doses in a given timeframe and at a certain price.

As outlined in the present Agreement, the European Commission also has the possibility to conclude APAs including an obligation to procure the vaccine if it becomes available, where the conditions (notably the pricing) of those APAs make this worthwhile and in line with the conditions in the present Agreement. If in such a case the distinction between upfront payments and purchase price is difficult to draw, the Commission will share the total cost related to the vaccine purchase but will in any case contribute no more than 50% of the total cost.

Funding provided up front will be considered as an advance payment for any eventual purchase by Member States, thus reducing the amount that Member States will have to pay when eventually purchasing that vaccine.

The up-front payments under the APAs shall be used by manufacturers to de-risk the necessary investments related to both vaccine development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production value chain in the EU required for a rapid deployment of millions of doses of an eventual vaccine. The relevant payments should be structured according to the need of the manufacturer, but subject to the state of the vaccine development, in particular relying on transparency of the associated clinical data and its assessment, at the time of payment. This is in order to avoid obligations to pay in situations where the development work has shown a vaccine candidate likely to be unsuccessful.

The purchase price of the vaccine, as well as the amount of funding provided up front will take into account a transparent estimation of production costs (supported by independent audits where available), as well as the resources already granted from other public sources. Under the APA, the manufacturer can be asked to provide ex post proof supported by independent audits concerning the activities financed by these payments.

The aim of the negotiation is to conclude APAs with individual companies under the best possible conditions. These APAs should specify details with respect to:

- a) Payments to be made, such as payment amounts, payment schedules, type of payments requested and the use of those payments related to de-risk investment, financing clinical trials, providing working capital and scaling-up production capacity;
- b) Delivery details of the vaccine if successful, such as price per person immunised (or alternatively, number of doses required per person immunised and price per dose), quantity of doses to be delivered and delivery timeline following approval;

and

- c) Any other relevant conditions, such as production capacity built or used in the EU or liability arrangements.

For liability arrangements, the joint negotiation team will make its best effort to limit what is required by individual companies for the purpose of indemnification to be included in the terms and conditions of the APA.

The APAs will contain provisions to clarify the law applicable to both the APA and resulting purchase orders as well as the competent courts. The Participating Member States agree that each APA negotiated by the Commission on their behalf with a vaccine manufacturer will have the same applicable law for all Participating Member States, and that the courts corresponding to that applicable law will be competent to hear disputes arising from that APA.

When taking a decision to finance individual APAs, the European Commission, in consultation with the steering board, will take into account the following elements: any available data on quality, safety and efficacy of the vaccine at time of negotiation of the contract, speed of delivery at scale, cost, risk-sharing, diversification of technologies, capacity to supply through development of production capacity within the EU, possible flexible future use of any capacity funded, engagement at an early stage with EU regulators with the intention to apply for an EU marketing authorisation for the candidate vaccine(s), commitment to supply vulnerable countries.

The procedure outlined above complies with the ESI Regulation and the Financial Regulation. The latter is aligned to the European procurement Directives, which also provide the basis for national procurement rules. Participating Member States may rely on the procedure run by the European Commission to directly purchase vaccines from the manufacturers as and when any of the vaccines becomes available based on the conditions laid down in the APA. Access to vaccine doses will be allocated to Participating Member States according to the population distribution key.

In the negotiations with the pharmaceutical industry under the present Agreement, the Commission will promote a Covid-19 vaccine as a global public good. This promotion will include access for low and middle income countries to these vaccines in sufficient quantity and at low prices. The Commission will seek to promote related questions with the pharmaceutical industry regarding intellectual property sharing, especially when such IP has been developed with public support, in order to these objectives. Any vaccines available for purchase under the APAs concluded but not needed and purchased by Participating Member States can be made available to the global solidarity effort.

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



ANNEX V: PRODUCT SPECIFICATIONS OF THE PRODUCT

