

**SENSITIVE**

EN

**ANNEX  
to the**

**COMMISSION DECISION**

**approving an Advance Purchase Agreement on COVID-19 vaccines**



EUROPEAN COMMISSION  
Directorate-General for Health and Food Safety

Sensitive\*

RELEASABLE TO: Need to know basis

ADVANCE PURCHASE AGREEMENT (“APA”)<sup>1</sup> for the development, production,  
purchasing and supply of a successful COVID-19 vaccine for EU Member States

NUMBER — [complete]

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 APA by Ms Stella Kyriakides, Commissioner for Health and Food Safety:

on the one part and

2. **Valneva Austria GmbH**, a limited liability company (“Gesellschaft mit beschränkter Haftung”) incorporated under company number [REDACTED], whose registered office is at Campus Vienna Biocenter 3, 1030 Vienna, Austria

VAT registration number: [REDACTED]

(the ‘**contractor**’), represented for the purposes of the signature of this APA which has the form of a framework contract by [REDACTED]

on the other part,

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

HAVE AGREED

to the **special conditions** and the **general conditions of this APA** and the following annexes:

**Annex I** – List of Participating Member States and allocated volumes

<sup>1</sup> This APA 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 II –** Model for Vaccine Order Form

**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 –** Target Product profile

**Annex VI –** Contractor's insurance

**Annex VII –** Details of the utilisation of the Down Payment

which form an integral part of this APA.

#### **RECITALS**

- A. The world is experiencing an emergency healthcare crisis due to the SARS-CoV-2 ("COVID-19") pandemic (the "**COVID-19 pandemic**") and the global demand for vaccines to prevent COVID-19 virus infection is expected to be in order of magnitude of billions of doses.
- B. The contractor is currently working to develop and manufacture a highly purified, inactivated and adjuvanted vaccine candidate against the SARS-CoV-2 virus, consisting in an inactivated whole virus of SARS-CoV-2 [REDACTED] to help protect against COVID-19 virus infection in humans.
- C. The Commission intends to create the environment required to support a secure manufacturing network and optimisation for the production of vaccines against COVID-19. To this effect the Commission has concluded an Agreement with all Member States of the European Union to conclude, on behalf and in the name of the Member States, Advance Purchase Agreements with vaccine manufacturers with the objective to procure vaccines for the purposes of combatting the COVID-19 pandemic at Union level.
- D. The Commission wishes to secure the supply of the Product for human use for the Participating Member States during the COVID-19 pandemic as promptly as possible.
- E. The intention of the Commission, on behalf of the Member States, is to ensure that the population in the European Union will be able to access a vaccine in sufficient quantities and at a fair price, but also in safe conditions. The vaccine should only be available to the population once its safety and efficacy will have been cleared by the competent regulatory bodies.

- F. According to the Agreement between the Commission and the Member States<sup>2</sup> and in particular Article 4 thereof, the Commission can conclude an Advance Purchase Agreement that contains a right and an obligation for Participating Member States to acquire vaccine doses. Where the Commission intends to enter into such an agreement, it shall inform the Member States of such intention and the detailed terms. In case a 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. All Participating Member States not having opted out in accordance with the Agreement between the Commission and the Member States are deemed to have authorised the Commission to negotiate and conclude an Advance Purchase Agreement with the vaccine manufacturer in their name and on their behalf.
- G. This APA is such an agreement which the Commission enters into on behalf and in the name of the Participating Member States which have not opted out of the agreement. These Participating Member States will then have an obligation to acquire the Product and a right to be supplied with the respective Product doses. While the APA is legally binding upon those Participating Member States, it will be further implemented by means of the conclusion of contracts between the Participating Member States and the contractor. The present APA is complemented by a Vaccine Order Form ("**Vaccine Order Form**") between each of the Participating Member States and the contractor. A model Vaccine Order Form is attached in Annex II.
- H. The development, production, advance sale and supply of the Product as per this APA require significant investments by the contractor to increase the speed of clinical development, and the preparation of the at-scale production capacity along the entire production value chain in the EU required for a rapid deployment of the millions of doses of the Product. The Participating Member States are willing to contribute to financing of those investments in the form of up-front payments.
- I. Pursuant to these terms and conditions, access to Product doses will be allocated to Participating Member States as provided in Annex I. The up-front payments, paid by the Participating Member States, should be taken into account in equal terms *per dose* ordered by the Participating Member States.
- J. The Parties recognise that the timelines to develop, produce, sell and supply the Product are accelerated and that the Participating Member States are willing to share risks arising from this accelerated timetable, which includes an obligation of the Participating Member States to indemnify the contractor and its Contract Manufacturing Organisations ("**CMOs**") at the conditions set out in Article II.5 of this Advance Purchase Agreement in case of certain costs relating to third party claims with respect to those risks under the conditions set out in this APA.

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<sup>2</sup> Such agreement is based on Article 4(5)(b) of Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union, OJ L 70, 16.3.2016, p.1, 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, OJ L 117, 15.4.2020, p. 3. The agreement was approved Decision C(2020) 4192 final of 18 June 2020 (see Annex III to this APA).



- K. Against this background, the Commission wishes to enter into, on behalf and in the name of the Participating Member States, an Advance Purchase Agreement with the contractor to secure the availability of a total of 24.341.449 doses of the Product and 35.658.551 optional doses of the Product, to be allocated among the Participating Member States in accordance with the allocation principles set out in this APA.

This APA sets out:

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

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

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## **I. SPECIAL CONDITIONS**

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

If there is any conflict between different provisions in this APA, 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 APA, including its annexes.
- (b) The provisions set out in the general conditions take precedence over those in the Vaccine Order Forms signed by the Participating Member States.
- (c) All terms and conditions issued by the contractor (such as end-user agreements, general terms and conditions, etc.) are held inapplicable, unless they are issued under or in accordance with this APA (such as the final specifications, (Formal) Notifications, etc.). In all circumstances, in the event of contradiction between this APA and documents issued by the contractor, this APA prevails, regardless of any provision to the contrary in the contractor's documents.

### **I.2 SUBJECT MATTER**

The subject of this APA is the advance purchase of (i) 24.341.449 doses of the Product, as described below 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.4.3, and (ii) the optional and additional purchase of up to 35.658.551 Option Doses, according to the conditions laid down in Article I.4.4.

On the basis of this APA, the contractor (i) commits to [REDACTED] obtain a Marketing Authorisation for the Product; and, (ii) if a Marketing Authorisation for the Product is obtained, [REDACTED] supply the contractually agreed volumes of the Product to the Participating Member States in accordance with said Marketing Authorisation and the Delivery Schedule set out below in Article I.4.7.

Each Participating Member State shall issue a Vaccine Order Form as regards its allocation of the Doses, through which the contractor shall supply to the Participating Member States the Product doses in accordance with the terms of this APA.

The delivery of the Product to the individual Participating Member States shall be carried out in accordance with the terms and conditions of this APA and in particular in accordance with the allocation set out in Annex I, as well as the additional delivery details set out in the Vaccine Order Forms concluded between the contractor and each Participating Member State using the model Vaccine Order Form provided as Annex II to this APA.

### **I.3 ENTRY INTO FORCE AND DURATION OF THE APA**

**I.3.1** The APA 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.3.5, the APA is concluded for a period of [REDACTED] with effect from the date of its entry into force.

**I.3.3** Its duration may be extended upon mutual agreement if at the end of the term of [REDACTED] not all of the Doses, and, as the case may be, doses of Product purchased under the 2023 Option (as defined below) have been supplied. [REDACTED]

[REDACTED]. The Participating Member States and the contractor may not sign any Vaccine Order Form after the APA expires.

**I.3.4** The APA continues to apply to signed Vaccine Order Forms after its expiry.

**I.3.5** The APA shall automatically expire on the date on which all the Doses and, as the case may be, all doses of Product purchased under the 2023 Option, have been delivered and paid in full.

**I.3.6** Articles I.4.6, I.4.7.3(d), I.4.7.4(5), I.4.7.6, I.8, I.10, I.11.1, I.11.2, I.11.3, I.11.4, I.11.5, II.4, II.5, II.7, II.16.5, II.18, II.19, II.20 and any other clause which produces legal effects after the termination or expiry of this APA according to its wording, shall survive the termination or expiry of this APA.

## **I.4 IMPLEMENTATION OF THE APA**

### **I.4.1 General principles and Variant Switch**

#### **I.4.1.1 General principles**

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

(1) Following entry into force of this APA, this APA 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 APA, as identified in Annex I.

(2) Within 10 days after the signature of the APA by the Commission, each Participating Member State shall place an order for its allocated portion of the Doses by sending the contractor the duly completed and signed Vaccine Order Form (the format for which is set out in Annex II) in PDF format and by email, to the contractor's address specified in the Vaccine Order Form.

(3) Within 10 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 PDF format and by email, to the Participating Member State's address specified in the Vaccine Order Form.

(4) The Parties acknowledge that any delivery is dependent on the date on which the Marketing Authorisation for the Product is obtained.

(5) Wherever this APA provides that:

- a) certain rights enjoyed by the Participating Member States under the APA shall be exercised by the Commission, the Commission alone shall be entitled to (Formally) Notify the contractor of the exercise of such rights. Such (Formal) Notification shall be binding upon all Participating Member States, or, in situations where this APA provides that the Commission can exercise certain rights on behalf of some but not necessarily all Participating Member States, upon the Participating Member States concerned by such notification;
- b) certain Notifications of the contractor shall be issued to the Commission, such Notification to the Commission shall bind all Participating Member States. The Commission is acting on behalf and in the name of the Participating Member States in such cases.

The foregoing sub-sections a) and b) shall not apply to the Vaccine Order Forms, unless provided otherwise in the APA or the relevant Vaccine Order Form. The Vaccine Order Forms shall only be implemented, performed and consummated by the contractor and the relevant Participating Member State (but not the Commission).

#### **1.4.1.2 Variant Switch**

The contractor will keep the Commission informed of the availability of any new strains which contractor may use as basis to manufacture COVID-19 vaccines and the impact on production of contractor's arrangements to address any new strains. The Participating Member States can then elect to request contractor to switch the strain used as basis for the Doses to such a new strain ("Variant Switch"). The following conditions shall apply to any such Variant Switch:

- [REDACTED];
- [REDACTED];
- o [REDACTED];
- [REDACTED];
- [REDACTED];





- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

#### **1.4.2 Doses**

The contractor commits to supply 24.341.449 doses in the aggregate of the Product (the “Doses”) to all Participating Member States in accordance with the terms of this APA and the applicable Vaccine Order Forms. Annex V provides the target Product profile, as at the date of signature of the APA, which contractor may vary as the Product is being developed.

Each Participating Member State shall, in proportion to the Doses allocated to such Participating Member State in accordance with Article 1.4.3, contribute to the relevant costs for the Doses in the form of an up-front payment of [REDACTED] of the total price of the Doses as laid down in Article 1.7.1 (the “Down Payment”). This amount shall be invoiced upon signature of the APA and paid as provided in Article 1.8.1.

[REDACTED] of the price of the Doses actually delivered to such Participating Member State is invoiced upon delivery and paid as provided in Article 1.8.3.

#### **1.4.3 Allocation between Participating Member States; Vaccine Order Forms**

a) The volumes of Doses shall be allocated between Participating Member States in accordance with Annex I.

b) 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 APA, 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, each Participating Member State is obligated to conclude a Vaccine Order Form for the Doses contractually allocated to it in Annex I, unless such Member State has opted out of this APA pursuant to the Agreement between the Commission and the Member States.

#### **1.4.4 Increase of Doses**

##### **1.4.4.1 General principle**

If the Commission, acting on behalf of one or more of the Participating Member States, wishes to purchase doses of Product in addition to the Doses, it may elect to purchase such doses in accordance with the provisions of this APA.

#### 1.4.4.2 Option for deliveries in 2023

The contractor will keep the Commission informed of its manufacturing capacity for 2023. The Participating Member States may then, to the extent permitted by such capacity and [REDACTED] from the contractor's informing the Commission of such capacity, elect to purchase doses of Product in addition to the Doses for delivery in 2023 up to 35.658.551 doses in the aggregate (the "2023 Option"). The following conditions shall apply to any 2023 Option:

- [REDACTED];
- [REDACTED];
- the request for the 2023 Option shall be notified to the contractor by the Commission, acting in the name and on behalf of the relevant Participating Member States and shall specify the Participating Member States participating in such 2023 Option (the "Exercising Member States") and the allocation of doses of Product to be purchased by and delivered to each such Exercising Member State (the "Option Doses");
- the contractor shall confirm the available supplies of the Product for the order for Option Doses to the Commission [REDACTED];
- the order for the Option Doses shall be formalized through the conclusion of Vaccine Order Forms by the Exercising Member States;
- each Exercising Member State shall, in proportion to the Option Doses allocated to such Exercising Member State, contribute to the relevant costs for the Option Doses in the form of an up-front payment of [REDACTED] of the total price of the Option Doses (the "Down Payment for Option Doses"), payable [REDACTED] after the receipt of an invoice issued by contractor following the receipt of a Vaccine Order Form signed by the Exercising Member State. The balance of payments for the supply of Option Doses will be paid by each Participating Member State upon delivery as provided under the APA.
- subject to the above provisions, the other terms of this APA applicable to the Doses shall apply *mutatis mutandis* to the Option Doses.

#### 1.4.5 Development timeline; Special Commitments

The contractor's current assumptions on development timelines in support of an EU Marketing Authorisation for a Vaccine based on the Wuhan Strain are:

[REDACTED]

To produce the Doses, the contractor shall not manufacture or have manufactured the Product at manufacturing sites located outside the territory of the European Union or the European Economic Area without the prior consent of the Commission, which consent may not be unreasonably withheld, conditioned or delayed if the manufacturing at such sites is required to accelerate the production of the Doses for delivery to Participating Member States. However, consent may be refused if the sites located outside the territory of the European Union or the European Economic Area (EEA)

[REDACTED]

#### **1.4.6 Right of the Participating Member State to re-sell, export, donate and/or distribute**

The Participating Member States shall be entitled to re-sell, export, distribute and/or donate for free any of the Products supplied to them pursuant to this APA to any other EU Member State, EEA Member State and/or Switzerland,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] For the avoidance of doubt, any re-sale, export, distribution or donation activities shall be carried out under the sole cost and responsibility of the relevant Participating Member State, unless the Parties agree otherwise in writing.

#### **I.4.7 Delivery**

The contractor shall deliver the Product doses to the Participating Member States in accordance with the allocation provided in Annex I and the other terms and conditions of this APA. The Parties acknowledge and agree that the allocation provided in Annex I, as well as the numbers in the Delivery Schedule in accordance with Article I.4.7.2, can be amended by an exchange of letters between the Commission, represented for this purpose by the Deputy Director-General for Health of the European Commission's Directorate-General for Health and Food Safety, and the contractor.

##### **I.4.7.1 Delivery Schedule**

The contractor commits to deliver Product doses to the Participating Member States [REDACTED] (as between them) and [REDACTED] supply such doses on the schedule and in the quantities as set out in the initial delivery schedule provided below ("**Delivery Schedule**").

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The schedule and quantities set out in the Delivery Schedule are based on the contractor's current expectation that the Marketing Authorisation for the Product based on the Wuhan Strain will be granted [REDACTED] (the "Expected Approval Date"). [REDACTED]

The contractor shall use Best Reasonable Efforts to obtain Marketing Authorisation for the Product as soon as reasonably possible in order to meet the Expected Approval Date. [REDACTED]

[REDACTED] Under no circumstances will any delivery of Product doses be required under this APA prior to receipt of a Marketing Authorisation for the Product.

#### **L.4.7.2 Performance under the Delivery Schedule**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The contractor shall henceforth comply with such updated Delivery Schedule.

In case any updated Delivery Schedule [REDACTED] of the Doses with a delay of more than [REDACTED] compared to the initial Delivery Schedule (the "Delayed Doses"), then any concerned Participating Member State may [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

b) The schedule set out in the Delivery Schedule reflects the [REDACTED] delivery rate in which Product doses are expected to be delivered. The actual delivery dates within the applicable Delivery Schedule for the Product doses will be agreed between the contractor and the Participating Member States in line with the Delivery Schedule which may not be derogated from, [REDACTED]. Once the Marketing Authorisation for the Product is obtained, the contractor shall make the first delivery of Doses within the later of [REDACTED] after receipt of the Marketing Authorisation for the Product if the Marketing Authorisation is granted on or after the Expected Approval Date and subject to the labelling and packaging material being approved by the EMA [REDACTED] before the Expected Approval Date, or [REDACTED].

Save in exceptional circumstances and as mutually agreed between the contractor and the relevant Participating Member State(s), deliveries of Product doses shall be made [REDACTED]

[REDACTED]

#### **I.4.7.3 Late Deliveries**

[REDACTED]

[REDACTED]

[REDACTED]



[REDACTED]

[REDACTED]

- [REDACTED]

- [REDACTED]

d) [REDACTED]

[REDACTED]

[REDACTED]

#### **I.4.7.4 Marketing Authorisation** [REDACTED]

[REDACTED]

1) [REDACTED]

2) [REDACTED]

3) [REDACTED]



[REDACTED]

[REDACTED]

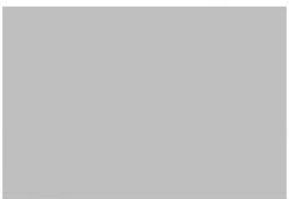
4) [REDACTED]

5) [REDACTED]

6) [REDACTED]


[REDACTED]


[REDACTED]





#### **I.4.7.5 Form of Delivery and transfer of title**

The Product doses will be delivered by the contractor to the Participating Member States 



Title on the Product will transfer upon full payment of the corresponding invoice by the relevant Participating Member State, such retention of title not preventing, however, the administration of the Product to the patients as and when deemed necessary by the relevant treating healthcare professionals.

#### **I.4.7.6 Distribution**

Following delivery of the Product doses, each Participating Member State will solely control and assume all responsibility, at such Participating Member State's own cost and expense, for conducting all distribution and related activities relating to the Product doses in the Participating Member State's territory and to countries in the EU, EEA or Switzerland, or other countries/entities, to which the Participating Member State re-sells, exports, distributes and/or donates Product doses in accordance with Article I.4.6. If a Participating Member State re-sells, exports, distributes and/or donates Product doses in accordance with Article I.4.6, contractor may agree to deliver directly such doses to the recipient country provided the relevant parties agree reasonable terms for such delivery and contractor does not incur additional costs.

#### **I.4.7.7 Traceability**

During the term of this APA and for a period of ten (10) years thereafter (or longer if required by applicable laws), each Participating Member State will maintain an inventory control system for traceability of the Product supplied to or for the benefit of such Participating Member State, including any Product provided by such Participating Member State to a Donation Country or Resale Country. 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** Contractor warrants that the Product (1) shall comply with the final specifications for the Product as approved in the Marketing Authorisation for the Product and (2) shall be manufactured in all material respects in accordance with the Good Manufacturing Practices in effect at the time of manufacture in the place of manufacture. Subject to the terms of this Article I.5 and Article I.6.2, 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 not been manufactured in accordance with the said Good Manufacturing Practices ("**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 the Product Claims:

- immediately in case of visible damages resulting from transportation; or
- [REDACTED] for other apparent damage 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, [REDACTED]

In the absence of notice, the Product is deemed to be accepted by the Participating Member State.

**1.5.2** The contractor will have no obligation for any Product Claims to the extent the Deficient Product was caused exclusively by 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.

**1.5.3** Upon receipt of a Product Claim, the contractor will have [REDACTED] to advise the Participating Member State by notice in writing whether it disagrees with the content of the Product Claim. If, after joint testing or investigation has been performed, the Parties still cannot agree on whether such Product is a Deficient Product, the contractor or the Participating Member State may refer such dispute to a technical expert for resolution in accordance with Article 1.5.4 (a "Technical Dispute").

**1.5.4** 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, [REDACTED], 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 [REDACTED], or if a Party fails to appoint a representative as required above, the expert determination procedure below may be started by either Party. [REDACTED], 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 1.10.2. For the avoidance of doubt, any technical determination by the expert under a Technical Dispute may be used as evidence under Article 1.10.2. The contractor and the Participating Member State will require the expert to provide an opinion on each referred issue (with reasonably detailed reasoning) [REDACTED].

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 [REDACTED].

[REDACTED] 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 State 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 State.

**I.5.5** If a Participating Member State makes a Product Claim pursuant to this Article I.5 and (a) the contractor and this Participating Member State agrees the Product that is the subject of such Product Claim is a Deficient Product (such agreement not to be unreasonably withheld, conditioned or delayed) or (b) any previously delivered Product is determined to be a Deficient Product, the contractor will replace such Deficient Product [REDACTED] after the time of such agreement or determination, any other remedy under this APA being excluded in case of Deficient Product unless the concerned Participating Member State and contractor agree otherwise.

**I.5.6** In the cases referred to in Article I.5.5, the contractor may instruct the concerned Participating Member State to place the Product at the contractor's disposal. The contractor will bear the cost of [REDACTED] disposal of any Deficient Product.

## **I.6 WARRANTIES AND RELEASE**

**I.6.1.** The contractor warrants to the Commission and the Participating Member States that:

(a) as of the date hereof, this APA 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 Doses that conflicts with or is inconsistent with the terms of this APA or that would impede the complete fulfilment of its obligations under this APA;

(c) it will not undertake any contractual obligations, including any settlements, that would conflict with, hinder or impede the fulfilment of its obligations under this APA; and

(d) [REDACTED]

**I.6.2.** The Commission and each of the Participating Member States each within their respective competencies, on behalf of itself, waive and release any claim against the contractor arising out of or relating to:

(a) lack of safety or efficacy of the Vaccine, [REDACTED]

(b) use or administration of the Vaccine under pandemic conditions, except to the extent such claim arises from contractor's breach of this APA which classifies as Willful Misconduct or Gross Negligence; or

(c) delays in delivery of the Vaccine doses under this APA, the only remedies available in case of delays being, if applicable, [REDACTED]

## **I.7 PRICES**

### **I.7.1 Price per Dose of Product**

The price per single dose of Product purchased hereunder, [REDACTED], shall be [REDACTED]

For clarity, the price for the total Product volume shall be obtained by multiplying the price of a single Product dose by the total number of Product doses covered by this APA.

The total price of the Doses shall be [REDACTED] doses, equalling [REDACTED]

### **I.7.2 Down payment and payment schedule under the APA**

The Down Payment for the Doses is [REDACTED] of the total price of the Doses as laid down in Article I.7.1, equalling [REDACTED]

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

## **I.8 PAYMENT ARRANGEMENTS**

### **I.8.1 Payment of the Down Payment**

The invoices for the Down Payment shall be issued by contractor upon signature of the APA.

The contractor must send the invoice for the Down Payment to each Participating Member State in PDF format by email.

Each invoice for the Down Payment shall be paid in a single instalment.

The invoice for the Down Payment must contain the following information:

- Name of the addressee
- APA number
- Contractor name and bank account.



The invoice 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).

Provided that the invoice includes the above information, each Participating Member State shall pay the invoice [REDACTED] after receipt of the invoice.

### **1.8.2 Utilisation of the Down Payment**

The Parties acknowledge and agree that the Down Payment is intended to cover costs incurred by the contractor for [REDACTED]

The contractor intends to use the Down Payment as further specified in Annex VII.

### **1.8.3 Payment for the supply of Product**

The contractor must send an invoice in PDF format by email to the Participating Member States for payment by the Participating Member States under Article I.4.2.

Invoices shall be established by the contractor for a given order of Product doses and for an identified delivery scheduled in accordance with the APA.

Each invoice shall be accompanied by the following documentation (as applicable):

- Proof of delivery of the Products referred to in Article I.4.2 of this APA, to the place of delivery indicated by the Participating Member State concerned in the Vaccine Order Form (or offer of such delivery if the Participating Member State illegitimately refuses acceptance of delivery).

Each invoice must contain the following information:

- Name of the concerned Participating Member State
- APA and Vaccine Order Form number/reference
- Order reference
- Date of receipt of the Marketing Authorisation for the Product
- Product name
- Quantity delivered (or offered to be delivered if the Participating Member State illegitimately refuses acceptance of delivery),
- Delivery reference and date
- Contractor name and bank account.

The Participating Member States must pay these invoices [REDACTED] from their respective date of issuance.

### **1.8.4 Currency**

Any payments to be made by the Participating Member States under this APA, including under any Vaccine Order Form, shall be made, and any invoices issued pursuant to this APA shall be issued, in euros (EUR).

#### **1.8.5 Refundability of Unspent Amounts**

If this APA is terminated pursuant to Article II.16.1, then the Participating Member States will be entitled to a refund of Unspent Amounts in accordance with Article II.16.5.

#### **1.8.6 Bank account**

Payments must be made to the contractor's bank account denominated in euro, identified as follows:



#### **1.8.7 Communication Details**

For the purpose of this APA, 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](mailto:SANTE-PROCUREMENT@ec.europa.eu)

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

Contractor:



E-mail [REDACTED] valneva.com

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

#### **1.8.8 Suspension if no payment**

Timely payment by all the Participating Member States of amounts under this APA is of essence. If any Participating Member State fails to pay any amounts when due, contractor shall have the right to suspend performance of the APA in relation to that Participating Member State until full payment. In particular, the Parties acknowledge and agree that (i) compliance by contractor with delivery schedules is conditional on timely payments, (ii) any such suspension of manufacturing and deliveries may cause subsequent delay in supply, and that (iii) related quantities of Products may be redirected by contractor to other entities.

#### **1.9 EXPLOITATION OF THE RESULTS OF THE APA**

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 any such Vaccine IP Rights. Except as expressly set forth in this APA, 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 the Vaccine IP Rights. All rights not expressly granted by the contractor hereunder are reserved by the contractor.

#### **1.10 APPLICABLE LAW AND SETTLEMENT OF DISPUTES**

**1.10.1** This APA is based on Article 4(5)(b) of Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union (ESI Regulation, as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369.

This APA shall be governed by the laws of Belgium, in particular general Belgian contract law.

##### **1.10.2 Dispute Resolution**

(a) In the event of a dispute arising under this APA 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, [REDACTED], 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 APA or the legal relationships established by this APA including under a Vaccine Order Form.

#### **I.11 OTHER SPECIAL CONDITIONS**

**I.11.1** 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.11.2** Each Participating Member State and the contractor will Notify the other Party [REDACTED] 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.11.3** Upon receiving this notice or upon this discovery, and save where contractor challenges any decision regarding a Recall, 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.11.4** 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 by the contractor (after having consulted with the competent authority(ies) concerned).

**I.11.5** 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 (after having consulted 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, [REDACTED]

[REDACTED]

**I.11.6** The contractor shall use Best Reasonable Efforts to obtain Marketing Authorisation for the Product. [REDACTED]

**I.11.7** The contractor shall provide to the Commission and the Participating Member States, via the Commission, the following information as part of and until its submission for Marketing Authorisation and full production:

- (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 [REDACTED]
- (c) the use of the Down Payment, linked to points (a) to (b), in general terms [REDACTED] and [REDACTED];
- (d) scientific publications and public announcements, after such publications and announcements have been published.

## **I.12 DEFINITIONS**

For the purpose of this APA, the following definitions apply:

**‘2023 Option’:** has the meaning set forth in Article I.4.4.2; **‘Affiliate’:** with respect to a Party, any other individual, partnership, corporation, limited liability company, association, a joint stock company, trust, joint venture, unincorporated organization, or a governmental entity (or any department, agency, or political subdivision thereof) (“Person”) that controls, is controlled by, or is under common control with such Person. For the purpose of this definition only, “control” (including, with correlative meaning, the terms “controlled by” and “under the common control”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of any Person, whether by the ownership of more than 50% of the voting security of such Person, by contract or otherwise;

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

**‘Best Reasonable Efforts’** shall mean with respect to the diligence to be expected by the contractor

**‘Breach of obligations’**: failure by a Party to fulfil one or more of its contractual obligations under this APA;

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

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

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

**‘Confidential information or document’**: any information or document, in any format, disclosed in writing or orally, received by either Party from the other or accessed by either Party in the context of the Implementation of the APA, that any of the Parties has identified in writing as confidential or which, due to the context in which it is disclosed, should be considered as confidential. It may not include information that is publicly available;

**‘Conflict of interest’**: a situation where the impartial and objective Implementation of the APA 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 APA;

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

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

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

**‘Delayed Doses’**: has the meaning set forth in Article I.4.7.2;

**‘[REDACTED]’**;

**‘Delivery Schedule’**: has the meaning set forth in Article I.4.7.1;

**‘Donation Country’**: means a country to which Product is donated in accordance with Article I.4.6;

**‘Doses’**: has the meaning set forth in Article I.4.2;



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

**'Down Payment for Option Doses'**: has the meaning set forth in Article I.4.4.2;

**'EMA'**: means the European Medicines Agency;

[REDACTED];

**'European Institutions'**: has the meaning set forth in Article II.7.6;

**'Exercising Member State'**: has the meaning set forth in Article I.4.4.2;

**'Expected Approval Date'**: has the meaning set forth in Article I.4.7.1;

**'Financial Statement'**: has the meaning set forth in Article II.16.5;

**'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 the APA; 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 reasonable due diligence. The situation or event must not be attributable to a Breach of obligations of the APA on the part of the Parties or on the part of the subcontractors.

[REDACTED];

**'Formal notification'** (or **'Formally notify'**): form of communication between the Parties made in writing by mail, 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 European 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 European Union's financial interests;

**'Good Manufacturing Practices' or 'GMP'**: means the current practices for manufacture required by the standards, rules, principles and guidelines set out in Directive 2001/83/EC (as last amended), 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";

[REDACTED];



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

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

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

[REDACTED];

**'Losses'**: has the meaning set forth in Article II.5.4;

[REDACTED];

**'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 European 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;

[REDACTED];

**'Notification'** (or **'Notify'**): form of communication between the Parties made in writing including by electronic means (except for Formal notifications which must be sent by mail);

**'Option Doses'**: has the meaning set forth in Article I.4.4.2;

**'Participating Member State(s)'**: has the meaning set forth in the preamble;

**'Party'** and **'Parties'**: 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 States;

**'Potential Termination Event'**: has the meaning set forth in Article II.16.1;

**'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 APA;

**'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'** or **'Vaccine'**: the finished and packaged form of the contractor's vaccine against COVID-19 based on the Wuhan Strain or any other strain agreed by the Parties. The Product will be delivered in a 10-dose vial;

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

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

**'Recall'**: has the meaning set forth in Article I.11.5;

**'Refundable Items'**: has the meaning set forth in Article II.16.5;

**'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'**: means a country to which Product is re-sold, exported or distributed in accordance with Article I.4.6;

**'Result'**: any intended outcome of the Implementation of the APA, whatever its form or nature. A Result may be further defined in this APA 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;

[REDACTED]

**'Technical Dispute'**: has the meaning set forth in Article I.5.3;

**'Termination Intent Notice'**: has the meaning set forth in Article II.16.1;

**'Third Party'**: any Person other than (a) the Commission or any of the Participating Member States or (b) the contractor or its Affiliates;

**'Third Party Claim'**: has the meaning set forth in Article II.5.9;

**'Unspent Amounts'**: has the meaning set forth in Article II.16.5;

**'Vaccine IP Rights'**: has the meaning set forth in Article I.9;

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

**'Variant Product'**: has the meaning set forth in Article I.4.1.2;

**'Variant Switch'**: has the meaning set forth in Article I.4.1.2;

[REDACTED];

**'Wuhan Strain'** means the strain BetaCoV/Italy/SPL1/2020/EPI ISL 412974/2020-01-29 originating from Wuhan/NC 045512.2.

## SIGNATURES

For the contractor,

[Redacted signature area]

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

Done at [place], [date]

[Redacted text]

AND

[Redacted signature area]

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

Done at [place], [date] in duplicate in English.

[Redacted text]

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

Ms Stella Kyriakides, Commissioner for Health and Food Safety

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

Done at Brussels, [date]

[Redacted text]

[Redacted text]

## **II. GENERAL CONDITIONS FOR THE FRAMEWORK CONTRACT**

### **II.1 SEVERABILITY**

Each provision of this APA 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 APA. This does not affect the legality, validity or enforceability of any other provisions of the APA, 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 replacement of such a provision must be made in accordance with Article II.10. The APA 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 provisions of this APA.

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

**II.2.3** All periods specified in the APA 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 APA must:

- (a) be made in writing in paper or electronic format in the language of the contract;
- (b) bear the APA number and, if applicable, the Vaccine Order Form number;
- (c) be made using the relevant communication details set out in Article I.8.7; and
- (d) be sent by mail or email (except for Formal notifications which must be sent by mail).

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, except for Formal notifications which must be sent by mail.

#### **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 APA 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.8.7. 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 obligation to send such communication within a specified deadline.

Mail sent to the Commission or a Participating Member State is deemed to have been received on the date on which the department responsible referred to in Article I.8.7 or in the relevant Vaccine Order form 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 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 the Implementation of the APA.

**II.4.2** Annex VI sets out a summary of contractor's insurance coverage. Contractor shall maintain such policy during the term of this APA. Upon request, the contractor must provide evidence of such insurance coverage to the Commission.

#### **II.4.3**


The Commission and the Participating Member State shall, upon request, cooperate with the contractor and its legal representatives in connection with the investigation and defense against such action, including by providing or otherwise making available information in their possession with respect thereto. The Commission and the Participating Member State shall only be allowed to settle a Third Party Claim with the prior consent of the contractor, such consent not to be unreasonably withheld, conditioned or delayed.

#### **II.4.4**

This liability cap shall not apply in case



of liability for loss or damages caused by the contractor's Breach of obligations classified as Willful Misconduct or Gross Negligence, in which case the contractor's liability shall be uncapped.



**II.4.5** The Parties acknowledge that they are not relying on any understanding, arrangement, statement, representation (including, any negligent misrepresentation but excluding any fraudulent misrepresentation), warranty, condition, term, customary practice, course of dealing or provision except for the warranties set out in this APA. All statements, representations, warranties, terms, conditions and provisions (including, any implied by statute or equivalent, case law or otherwise and any implied warranties and/or conditions as to merchantability, satisfactory quality, fitness for purpose and skill and care), other than fraudulent misrepresentations and the provisions set out in this APA, are hereby excluded to the maximum extent permissible by law.

## **II.5 INDEMNIFICATION**

**II.5.1** Due to the exceptional circumstances of the COVID-19 pandemic and the request to develop new vaccines at an unprecedented speed, the Commission, on behalf of the Participating Member States, declares that the use of the Vaccine supplied under this APA will happen under pandemic conditions requiring such use, in a context where it is impossible for the contractor to detect all possible defects of the Vaccine despite its observance of all Good Manufacturing Practices and obligations under the EMA pharmacovigilance regulations, and that the administration of doses of the Vaccine will therefore be conducted under the sole risk and responsibility of the Participating Member States.

Hence, each Participating Member State shall indemnify for and hold harmless the contractor and/or its Affiliates, as well as their respective sub-contractors and sub-licensees, officers, directors, employees, other agents and representatives (together, the "**Indemnified Persons**") against:

(a) liability incurred by an Indemnified Person in relation to Losses (defined in Article II.5.4) caused by doses of Vaccine administered in the jurisdiction of the Participating Member State in question;

(b) the consequences of any settlements to which the concerned Participating Member State(s) has/have consented to as per Article II.5.11; and

(c) reasonable and necessary direct external legal fees (including attorneys' and courts fees) and experts' fees, which an Indemnified Person incurs in relation to (i) claims connected to liability under sub-paragraph (a) above, and/or (ii) the circumstances referred to in sub-paragraph (b) above. Each Participating Member State agrees that any Indemnified Person has the right to select an attorney who is experienced and reputable in relation to the subject matter and in the Participating Member State concerned to defend itself in case of a Third Party Claim. For the avoidance of doubt, (1) the indemnification of legal and experts' fees subject to the conditions of this clause shall not be dependent on the success of a Third Party Claim; and (2) legal and experts'

fees recovered from the claimant by an Indemnified Person following a court order, and legal and experts' fees covered by insurance, shall not be subject to indemnification under this clause.

Such indemnification shall be available regardless of whether the properties of the Vaccine causing the Losses originate from the testing, development, manufacture, delivery, export, import, distribution, sale, offer for sale, administration, use or deployment of the Vaccine.

[REDACTED]

[REDACTED]

**II.5.4**

[REDACTED]

**II.5.5** Specifically and only for the purposes of this Article II.5:

**"Best Reasonable Efforts"**

[REDACTED]

**II.5.6**

[REDACTED]

**II.5.7.** In case an Indemnified Person requests indemnification pursuant to Article II.5.1, the contractor shall give the Participating Member State(s) in question, or an independent expert as referred to in Article II.5.8, access to reasonable information necessary for the Participating Member State(s) to indemnify the Indemnified Persons and to verify whether the conditions



pursuant to Articles II.5.1 to II.5.4 are fulfilled. [REDACTED]

**II.5.8** A Participating Member State shall be allowed to access the information as referred to in Article II.5.7 through an independent expert in the field of the Losses, in particular in the field of public health. In that case, this Participating Member State shall Notify the contractor in advance of its intention to use an expert to conduct the verification pursuant to Article II.5.7 above, and shall specify the identity of such expert. The contractor shall be allowed to object to the use of and/or access to the information referred to in Article II.5.7 by such expert [REDACTED] counted from the date of receipt of such Notification. T [REDACTED]

[REDACTED]. In such case, the Participating Member State shall designate another independent expert and observe the same Notification process as the one described herein until the designated expert is approved by the contractor. The expert shall complete its assessment [REDACTED] of its appointment, and shall share its assessment report with the Parties. The expert's assessment shall not be binding on any Indemnified Person.

**II.5.9** The contractor shall promptly inform the relevant Participating Member State(s) of any claim for a Loss which is brought against any of the Indemnified Persons and which an Indemnified Person considers asking for indemnification under this Article II.5 ("**Third Party Claim**"), stating the nature and basis of such claim and the maximum amount of damages, external legal fees, experts' fees and related disbursements estimated by the contractor, which could be payable by all Indemnified Persons as a result of such claim. The contractor shall keep the Participating Member State informed of any developments relating to such Third Party Claim, including updates in this estimated maximum amount of damages, fees and disbursements. The contractor's assessment of said maximum amount shall have no consequences on any indemnification unless the contractor has estimated such amount in bad faith.

**II.5.10** [REDACTED]

**II.5.11** [REDACTED]

[REDACTED]

The Indemnified Persons shall only be allowed to settle a Third Party Claim with the prior consent of the relevant Participating Member State(s) in question, such consent not to be unreasonably withheld, conditioned or delayed. The relevant Participating Member States shall have the right to assume and control the defense of the Indemnified Persons against Third Party Claims, in which case the Indemnified Persons shall nevertheless have the right to retain and be advised by independent counsel and experts. [REDACTED]

[REDACTED]

## **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 as soon as possible of any situation that could constitute a Conflict of interest or a Professional conflicting interest during the Implementation of the APA. 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 which shall be reasonable taking into account the context of the situation;
- (c) decide, in the name and on behalf of a Participating Member State, not to award a Vaccine Order Form to the contractor.

The Commission cannot implement the action referred to in (c) above before having given to contractor the possibility to complete the rectification of the situation [REDACTED] or a shorter period if the urgency of the situation requires such shorter period.

**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 APA, 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 Confidential Information. Contractor's Confidential Information includes, in particular, any and all know-how, software, algorithms, designs, plans, forecasts, analyses, evaluations, research, business information, financial information, business plans, strategies, customer lists, marketing plans, or other information whether oral, in writing, in electronic form, or in any other form; and any physical items, compounds, components, samples or other materials; disclosed by or on behalf of contractor to the Commission or to the Participating Member States or any of their Affiliates before, on or after the effective date of this APA.

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

- (a) not use Confidential information or documents of another Party for any purpose other than to perform its obligations under the APA or a Vaccine Order Form without the prior written agreement of such 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 States and the contractor during the Implementation of the APA 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) the applicable law requires the disclosure of the Confidential information or documents

**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 APA 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 APA. A Party may subsequently publicly disclose any information previously contained in any public announcement made in accordance with this Article.



**II.7.6** 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) 1049/2001<sup>3</sup>, which may require the European Institutions to disclose information to Third Parties on request.

## **II.8 PROCESSING OF PERSONAL DATA**

Both Parties agree each act as data controllers with regards to the processing of personal data they each undertake.

### **II.8.1 Processing of personal data by the Commission**

Any personal data included in or relating to the APA, 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 APA by the data controller. For the purpose of this provision, the data controller for the Commission shall be the Deputy Director-General for Health 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](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 APA 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 APA 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**

<sup>3</sup> 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.



## **II.10 AMENDMENTS**

**II.10.1** Any amendment to the APA (including a Vaccine Order Form) must be made in writing before all contractual obligations have been fulfilled.

**II.10.2** No amendment can make changes to the APA (including 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 APA without prior written authorisation from the Commission, which shall not 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.11.3** As an exception to Articles II.11.1 and II.11.2, contractor can assign, without the Commission's or the Participating Member States' authorization:

- any receivables under this APA to Third Parties, such as financial institutions, for the purposes of obtaining and maintaining funding, and/or providing such receivables as security to its creditors;
- this APA to:
  - o a person that succeeds to all or substantially all of contractor's business or assets or all or substantially all of contractors' business or assets relating to this APA, whether by sale, merger, operation of law or otherwise;
  - o a person that acquires all rights to the Product; or
  - o an Affiliate of contractor;

<sup>4</sup> 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.

and contractor shall provide notice of such assignment to the Commission and the Participating Member State.

## **II.12 INTELLECTUAL PROPERTY RIGHTS**

### **II.12.1 Identification of Pre-existing rights**

When delivering the Results, the contractor must warrant that, for any use that the Commission or the Participating Member States may envisage within the limits set in this APA, the newly created parts and the Pre-existing material incorporated in the Results are free of claims from creators or from any Third Parties and all the necessary Pre-existing rights have been obtained or licensed.

[REDACTED]

### **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 European Union. [REDACTED]

[REDACTED]

This evidence must include, as appropriate:

[REDACTED]

[REDACTED]

[REDACTED]

### **II.12.3 Copyright notice for Pre-existing rights**

When the contractor retains Pre-existing rights on parts of the Results, reference must be inserted to that effect when the Result is used as set out in Article I.12.1, with the following disclaimer: '©

— year — European Union. All rights reserved. Certain parts are licensed under conditions to the EU', or with any other equivalent disclaimer as the Commission may consider best appropriate, or as the Parties may agree on a case-by-case basis. This does not apply where inserting such reference would be impossible, notably for practical reasons.

#### **II.12.4 Visibility of Union funding and disclaimer**

When making use of the Results, the contractor must declare that they have been produced under a contract with the European Union and 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 Notify the other Party without undue delay, 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 APA if that delay or failure is a result of Force majeure. The obligations affected by a Force majeure event shall be suspended and the time for performance shall be extended for a period equal to the time lost by reason of such event. If the contractor is unable to fulfil its contractual obligations owing to Force majeure, it has the right to remuneration only for the services and doses of Product actually provided.

**II.13.3** The Parties must take all necessary measures to limit any damage due to Force majeure, it being specified that nothing herein shall require a Party to settle on terms unsatisfactory to such Party any strike or dispute.

**II.13.4.** To the extent that an event of Force majeure continues for a period [REDACTED], the Parties agree (i) to negotiate in good faith [REDACTED] of the end of that period either to (ia) resolve the event of Force majeure, if possible, or (ib) to extend the time period to resolve, eliminate or overcome such event, or (ii) to terminate the APA if such negotiations are unsuccessful. If the Force majeure event affects only one or more Vaccine Order Forms, but not the APA in its whole, then such termination shall apply only to those affected Vaccine Order Form(s). [REDACTED]

#### **II.14** [REDACTED]

- [REDACTED]

[REDACTED]

- [REDACTED]

- [REDACTED]

- [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

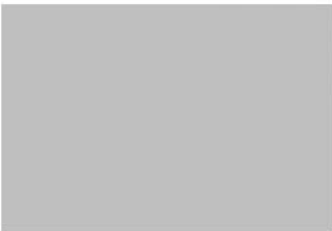
**II.15 SUSPENSION OF THE IMPLEMENTATION OF THE APA**

**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, as provided under Article II.13.

In accordance with Article II.13, the contractor must 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 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 APA or the Vaccine Order Form in accordance with Article II.13.





#### **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 APA or Performance of a Vaccine Order Form (of such Participating Member State) or any part of it if the procedure for awarding the APA or a Vaccine Order Form or the Implementation of the APA proves to have been subject to Irregularities or Fraud by the contractor.

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 Notify the contractor as soon as the verification is completed whether:

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

[REDACTED]

#### **II.16 TERMINATION OF THE APA**

##### **II.16.1 Termination due to failure to meet long stop dates**

If:

- [REDACTED]
- [REDACTED]

(each a "**Potential Termination Event**"), then the Commission and the Participating Member States shall Notify to contractor, [REDACTED] of the Potential Termination Event, whether they consider terminating this APA and the Vaccine Order Forms due to the Potential Termination Event ("**Termination Intent Notice**"). [REDACTED]



[REDACTED]

[REDACTED]



### **II.16.2 Other grounds for termination by the Commission and a Participating Member State**

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

- (a) if the contractor is in material Breach of obligations
- 
- 

- (b) 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 Regulation<sup>5</sup>;
- (c) 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;
- (d) if the procedure for awarding the APA or the Implementation of the APA prove to have been subject to Irregularities, Fraud or Breach of obligations;
- (e) if the contractor is in a situation that constitutes a Conflict of interest or a Professional conflicting interest and the situation is not resolved in accordance with Article II.6.2;
- (f) 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;
- (g) in the event of Force majeure, as provided under Article II.13.4.

### **II.16.3 Grounds for termination by the contractor**

<sup>5</sup> 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>

The contractor may terminate the APA in the following circumstances:

- (a) If the Commission materially fails to comply with its respective obligations
- (b) In the event of *Force majeure*, as provided under Article II.13.4.

The contractor may terminate the Vaccine Order Form of a Participating Member State in the following circumstances:

- (a) If the Participating Member State in question materially fails to comply with its respective obligations
- (b) In the event of *Force majeure*, as provided under Article II.13.4.

#### **II.16.4 Procedure for termination under Articles II.16.2 and II.16.3**

A Party must Formally notify the other Party of its intention to terminate the APA or a Vaccine Order Form and the grounds for termination.

If a Party Formally notifies its intention to terminate under Articles II.16.2(a) to (f), or II.16.3(a), the other Party has [REDACTED] to cure the relevant issue or dispute the existence of such issue by submitting observations, including the measures it has taken or will take to continue fulfilling its contractual obligations.

If the terminating Party confirms that the measures the other Party has taken, or will take, cure such issue [REDACTED], the notice of termination submitted by the terminating Party shall become null and void. If the terminating Party does not provide such confirmation, and the other Party fails to cure the issue [REDACTED], the Party intending to terminate must Formally notify such Party's decision to terminate this APA or a Vaccine Order Form and the grounds for termination. [REDACTED]

[REDACTED], in the event of a dispute of the existence or cure status of the relevant issue, such dispute shall be subject to Article I.10.2 prior to any termination of this APA or of a Vaccine Order Form.

#### **II.16.5 Effects of termination**

In case of termination pursuant to Article II.16.1:

- (a) No liability is incurred by any Party;
- (b) The Down Payment paid to the contractor shall be refundable according to the following procedure:
  - (i) The contractor shall send to the Commission [REDACTED] from Notifying the Commission about the termination of the APA, a financial statement (the "**Financial Statement**"), detailing for which expenses the Down Payment has been used in relation to the purposes as set out in the APA. Expenses to be taken into account include the full amount of internal and/or external expenses which

have been, or will be, incurred as well as such which have been committed by, or relate to commitments made by, the contractor at the time when the contractor Notified the Commission, [REDACTED]

- (ii) In the Financial Statement, the contractor will set out such amounts as well as those amounts of the Down Payment that have neither been incurred nor committed ("**Unspent Amounts**"). Such Unspent Amounts will be reimbursed by the contractor to the Participating Member States [REDACTED] from the receipt of the Financial Statement by the Commission, it being understood that the Financial Statement and the Unspent Amounts shall be final and binding upon all Parties to the extent the Commission has not provided to the contractor a written statement of objections, specifying in reasonable detail the grounds of objections, [REDACTED] from the receipt of the Financial Statement by the Commission. The reimbursement of the Unspent Amounts shall be distributed between the Participating Member States in proportion of each Participating Member State's allocation of Doses under the APA.

- (c) In addition, the contractor will transfer, upon the Commission's request to be provided [REDACTED] after the receipt of Notification about the termination, to the Commission, or a Third Party named by the Commission, any raw materials and primary components paid for with the Down Payment and not used (the "**Refundable Items**"). The contractor will also use its Best Reasonable Efforts to facilitate the discussion of a transfer of reserved capacity with CMOs paid for with the Down Payment to a Third Party selected by the Commission. Any such transfer is subject to the CMOs express agreement and any discussions about financial terms of such transfer will take place between such selected Third Party and the CMO.

[REDACTED]

[REDACTED]

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



[REDACTED], the contractor must submit any report and any invoice for Product doses that were already delivered or in delivery in compliance with the APA at the time of termination.

## **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 information set out in Articles I.8.1 and I.8.3.

## **II.18 PAYMENTS**

### **II.18.1 Date of payment**

The date of payment is deemed to be the date on which contractor receives the relevant sums on its bank account.

### **II.18.2 Costs of transfer**

The costs of the transfer are borne as follows:

- (a) the Commission or the Participating Member State in question bears the costs of dispatch charged by its bank;
- (b) the contractor bears the costs of receipt charged by its bank;
- (c) the Party causing repetition of the transfer bears the costs for repeated transfer.

### **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 Articles I.8.1 and I.8.3 at any time by Notifying the contractor that its invoice cannot be processed. The only reason the Commission or the Participating Member State in question may cite for not being able to process an invoice is because it does not substantially comply with the invoicing process in the APA.


The Commission or the Participating Member State in question must Notify the contractor as soon as possible of any such suspension, giving the reasons for it. The Commission or the Participating Member State in question shall Notify the contractor the time limits to submit additional information or corrections or a new version of the documents.

Suspension takes effect on the date the Commission or the Participating Member State in question sends the Notification. The remaining payment period resumes from the date on which the requested information or revised documents are received. The contractor may request the Commission or the Participating Member State in question to justify the continued suspension.

### **II.18.4 Interest on late payment**

On expiry of the payment periods specified in Article I.8, the contractor is entitled to interest [REDACTED]



 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 recovery, 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 unless contractor disputes such payment.

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, provided that legal conditions for such offsetting are met;
- (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 (OLAF) may check or require an audit on the Implementation of the APA. This may be carried out either by OLAF's own staff or by any outside body authorised to do so on its behalf, provided that the auditor may not be a competitor of the contractor.

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

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.

Audit missions scope applies to the contractor's compliance with applicable regulatory standards insofar as relevant for the Implementation of the APA. Audit missions may not be extended to a broader audit of the contractor's activities or the contractors' contractual relations, which do not involve the Commission or the Participating Member States regarding the purpose of this APA or the Vaccines Order Forms.

**II.20.2** The contractor must keep all original documents stored on any appropriate medium, including digitised originals if allowed 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 APA.

**II.20.3** The contractor must grant the appropriate right of access to sites and premises where the APA is implemented, and to all 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. The auditor must, insofar possible, comply with all applicable and reasonable security measures Notified to Commission by the contractor, and minimize disruption in contractor's operations, subject to this not creating any material obstacles for the performance of the auditor's tasks.

**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.

If, on the basis of the final audit findings, the Commission or a Participating Member State wishes to challenge all or part of the payments made under the APA, and the Parties cannot reach an agreement, any dispute between the Parties in this respect shall be settled under Article I.10.2.

**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 APA affecting the financial interests of the European 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 doses and up to five years starting from the payment of the balance of the last Vaccine Order Form issued under this APA.

**II.20.6** The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939<sup>6</sup> ('the **EPPO**') have the same rights as the Commission, particularly right of access, for the purpose of checks, audits and investigations.

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<sup>6</sup> 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 AND ALLOCATED VOLUMES



## ANNEX II: MODEL FOR VACCINE ORDER FORMS

### 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 in electronic format (PDF by e-mail) for its relevant allocated **Doses** as set out in Annex I (of this APA).
    - *By when (deadline)?* Within 10 days of the date of signature of the APA.
- ✓ *To Whom and how shall the Vaccine Order Form be sent?*
  - To the contractor by email at the following email address: [redacted]@valneva.com, with a copy to [cvdvaxorders@valneva.com](mailto:cvdvaxorders@valneva.com). Please always send the duly completed and signed Vaccine Order Form as a PDF attachment to the email.
- ✓ *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 APA requirements.
- ✓ *Whom to contact in case of questions re. how to complete this Vaccine Order Form?*
  - Commission representatives:
    - Commission will confirm the name after signature. Please copy all communications to [EC-VACCINES@ec.europa.eu](mailto:EC-VACCINES@ec.europa.eu)
  - Contractor's representatives:
    - [redacted]@valneva.com, with a copy to [cvdvaxorders@valneva.com](mailto:cvdvaxorders@valneva.com)



*[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:

**Valneva Austria GmbH**, a limited liability company (“Gesellschaft mit beschränkter Haftung”) incorporated under [REDACTED], whose registered office is at [REDACTED] 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 an Advance Purchase Agreement for the purchase and supply of the contractor’s COVID-19 vaccine for EU Member States SANTE/2020/C3/054 (the “**APA**”), the terms of which are binding on the Participating Member States.

The APA provides that each Participating Member State will submit to the contractor a Vaccine Order Form through which the contractor shall (subject to the terms and conditions of the APA) deliver to the relevant Participating Member State a proportion of the Doses at the price and conditions as set out in the APA.

- In accordance with Article I.4, the Member State hereby places its order for its allocation of Doses.

#### Article I

##### Definitions

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

#### 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 APA, and forms an integral part of the APA. The terms and conditions of the APA are incorporated into this Vaccine Order Form by reference. In the event of contradiction between this Vaccine Order Form and the APA, the terms of the APA prevail regardless of any provision to the contrary.
2. This Vaccine Order Form relates to the order for the Member State's full allocated Doses as set out in Annex I of the APA. 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 Doses at the Price.

### **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 APA.

### **Article IV**

#### **Invoices; Notices**

1. Invoice and Payments. The contractor shall invoice the Member State in accordance with the terms of the APA. All payments to the contractor shall be made in accordance with the terms of the APA.
2. Notice. Any notice given under this Vaccine Order Form must be made in writing in English in paper or electronic format; bear the APA 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 email:

#### **Member State:**

[Name of Member State]

[Full official address of Member State]

[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:

**Valneva Austria GmbH**

To the attention of: [REDACTED]

Mail address: [REDACTED]

Email address: [REDACTED]@valneva.com

with a copy sent, in any case, by email to: [cvdvaxorders@valneva.com](mailto:cvdvaxorders@valneva.com)

#### **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 the APA.
2. This Vaccine Order Form shall automatically expire upon delivery of the Member State's full allocated Doses as set out in the APA.
3. Expiry of the Vaccine Order Form shall be without prejudice to Article I.3.4 of the APA (*Surviving Provisions*).

#### **Article VI.**

##### **Applicable Law and Settlement of Disputes**

Article I.10 (*Applicable Law and Settlement of Disputes*) of the APA 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: TARGET PRODUCT PROFILE

At the date of signature of the APA, the current target Product profile is set out below, and can be varied by contractor during the APA as and when the Product is being developed in accordance with Article I.4.2 of the APA. For the avoidance of doubt, the final Product and related Marketing Authorisation (and notably the Product indication) will depend on the clinical trial data and acceptability of the Marketing Authorisation application by the EMA.

Vaccine Properties