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**EUROPEAN COMMISSION**  
Directorate-General for Health and Food Safety

**ADVANCE PURCHASE AGREEMENT (APA) for the purchase and supply of a COVID-19 vaccine  
for EU Member States**

**NUMBER SANTE/2020/C3/047-SI2.836209**

1. The European Commission (hereinafter the **"Commission"**), acting on behalf and in the name of the following EU Member States (hereinafter referred to as **"Participating Member States"** and each individually as a **"Participating Member State"**):

**Republic of Austria (AT)**

**Kingdom of Belgium (BE)**

**Republic of Croatia (HR)**

**Republic of Cyprus (CY)**

**Czech Republic (CZ)**

**Kingdom of Denmark (DK)**

**Republic of Estonia (EE)**

**Republic of Finland (FI)**

**French Republic (FR)**

**Federal Republic of Germany (DE)**

**Hellenic Republic (EL)**

**Hungary (HU)**

**Ireland (IE)**

**Italian Republic (IT)**

**Republic of Latvia (LV)**

**Republic of Lithuania (LT)**

**Grand Duchy of Luxembourg (LU)**

**Republic of Malta (MT)**

**Kingdom of the Netherlands (NL)**

**Republic of Poland (PL)**

**Portuguese Republic (PT)**

**SENSITIVE**

Romania (RO)

Republic of Slovakia (SK)

Republic of Slovenia (SI)

Kingdom of Spain (ES)

Kingdom of Sweden (SE)

being represented for the purposes of the signature of this APA by Ms Stella Kyriakides, Commissioner for Health and Food Safety on the one part;

and

2. Janssen Pharmaceutica NV, a limited liability company (*naamloze vennootschap / société anonyme*) incorporated under the laws of Belgium, with registered address at Turnhoutseweg 30, 2340 Beerse (Belgium) and registered under company number 0403.834.160 (hereinafter referred to as "**Contractor**"), being represented for the purposes of the signature of this APA which has the form of a framework contract by [REDACTED] on the other part.

Contractor is an Affiliate of Janssen Pharmaceuticals Inc. ("**JPI**"). JPI controls or will control the Janssen group's Intellectual Property Rights to supply the Vaccine Volume. Both Contractor and JPI are Affiliates of Johnson & Johnson and are part of the Janssen Pharmaceutical Companies of Johnson & Johnson ("**Janssen group**"). The Janssen group is leveraging its world-wide resources and capabilities in a global exercise to develop the Vaccine Candidate in response to the current COVID-19 pandemic.

The Commission, acting on behalf and in the name of the Participating Member States, and 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** – Definitions, Interpretation and Exhibits

**Annex II** – Model for Vaccine Order Form

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

which form an integral part of this APA.

**Whereas**

- The Janssen group is developing the Vaccine Candidate in response to the current COVID-19 pandemic, leveraging its proprietary AdVac® and high yielding manufacturing platforms, as well as its experience and capabilities from the development of its Ebola vaccine and investigational HIV, RSV and Zika vaccine candidates, with the aim of making available a safe and efficacious vaccine in 2021;

## SENSITIVE

- In response to the current COVID-19 pandemic, and in view of the medical urgency, Contractor is currently executing an accelerated clinical development plan for the Vaccine Candidate, initiating multiple large multi-country studies within highly compressed timelines, based on the outcomes of multiple pre-clinical studies and initial clinical studies performed world-wide;
- In parallel, and in an effort to ensure accelerated availability and deployment, Contractor is at-risk expanding its internal and external global manufacturing network for the Vaccine Candidate, i.e., prior to the generation of the clinical data that is usually available before contemplating such further investment in a candidate, and in parallel to the development of the commercial scale manufacturing process;
- 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 the European Union level;
- The Commission wishes to secure supply of the COVID Vaccine for human use for the Member States adhering to this APA (i.e., the Participating Member States) during the COVID-19 pandemic as promptly as possible;
- 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 has been cleared by the competent regulatory bodies;
- According to the Agreement between the Commission and the Member States referred to in Annex III, 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 that have not opted out in accordance with the Agreement between the Commission and the Member States referred to in Annex III are deemed to have authorised the Commission to negotiate and conclude the APA with the vaccine manufacturer in their name and on their behalf;
- The present APA is such an agreement which the Commission enters into, on behalf and in the name of the Member States which have not opted out of the agreement. These Participating Member States will then have an obligation to acquire the vaccine and a right to be supplied with the respective vaccine doses. While the APA is legally binding upon those Participating Member States, the present APA will be complemented by a Vaccine Order Form between each of the Member States which have not opted out of the APA (i.e., the Participating Member States), and Contractor. A template Vaccine Order Form for the agreement between each of the Participating Member States and Contractor is attached in Annex II;
- Pursuant to the terms and conditions of this APA, access to vaccine doses will be allocated to Participating Member States according to a population distribution key, unless a different allocation is communicated by the Commission to Contractor. The down payments paid by the Commission pursuant to this APA, should be taken into account in equal terms per dose ordered by the Participating Member States as per the terms of this APA;

**SENSITIVE**

- Contractor wishes to help address the ongoing pandemic in the European Union (with the assumption that its Vaccine Candidate will be developed and manufactured successfully) and therefore the Parties now wish to enter into this APA to (1) enable Contractor and its Affiliates to progress its accelerated clinical development plan for the Vaccine Candidate, expand its manufacturing capacity in relation to the manufacturing of the Vaccine Candidate, purchase (and make financial commitments for the purchase of) materials, supplies, components and manufacturing capacity necessary for the manufacture of the Vaccine Candidate, and commence the at-risk production of the Vaccine Candidate, (2) set out the procedure and conditions by which the Commission and the Participating Member States shall advance purchase and pay for the Vaccine Volume from Contractor for the benefit of the Participating Member States; and (3) set out the rights and obligations of the Parties during and after the term of this APA.
- The Parties' intention is that the terms of this APA apply to the Vaccine Volume only (and not to any purchase of any Further Vaccine Volume in excess of the Vaccine Volume or use of the Vaccine Volume for any purpose other than for the Purpose), irrespective of the number of individuals who will ultimately be protected with the Vaccine Volume.
- Contractor and the Commission have thus agreed to collaborate with the aim of achieving the above objective, implementing the principles described hereafter.

In the event of contradiction between this APA (including its Annexes) and other documents unilaterally issued by Contractor, this APA prevails, regardless of any provision to the contrary in Contractor's documents.

## TABLE OF CONTENTS

TABLE OF CONTENTS.....	4
<b>I. Special Conditions.....</b>	<b>6</b>
I.1 Order of priority of provisions .....	6
I.2 Subject matter.....	6
I.3 Entry into force and duration of the APA .....	6
I.4 Implementation of the APA .....	7
I.5 Prices .....	17
I.6 Payment arrangements .....	18
I.7 Bank account .....	21
I.8 Communication details.....	21
I.9 Applicable law and settlement of disputes .....	22
I.10 Other special conditions .....	23
<b>II. General Conditions.....</b>	<b>28</b>
II.1 Definitions and Interpretation .....	28
II.2 Severability .....	28
II.3 Performance .....	28
II.4 Communication between the parties .....	28
II.5 Indemnification .....	29
II.6 Liability.....	31
II.7 Conflict of Interest and Professional Conflicting Interests .....	31
II.8 Confidentiality.....	32
II.9 Processing of personal data .....	33
II.10 Subcontracting.....	34
II.11 Amendments .....	34
II.12 Assignment.....	34
II.13 Intellectual property rights .....	35
II.14 Force majeure.....	35

II.15	Suspension of the implementation of the APA .....	35
II.16	Termination of the APA .....	36
II.17	Invoices, value added tax and e-invoicing .....	37
II.18	Payments and guarantees .....	37
II.19	Checks and audits .....	38
ANNEX I	.....	40
ANNEX II	.....	58
ANNEX III	.....	65

**SENSITIVE**

## **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) Article II.5 (*Indemnification*) takes precedence over those in the other parts of the APA.
- (b) Subject to Article I.1(a), the provisions set out in Article I (*Special Conditions*) take precedence over those in the other parts of the APA.
- (c) Subject to Articles I.1(a) and I.1(b), the provisions set out in Article II (*General Conditions*) take precedence over those in the other parts of the APA.
- (d) Subject to Article I.1(a) to I.1(c), the provisions set out in the APA take precedence over Annex II (Model for Vaccine Order Form).

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

The subject of this APA is securing the purchase of the Vaccine Volume for the Participating Member States.

By Decision C(2020) 4192 final of 18 June 2020, the Commission approved the agreement with the Participating Member States on procuring COVID-19 vaccines on behalf of the Participating Member States, see Annex III. This 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<sup>1</sup> which provides that the Commission may grant emergency support in the form of procurement on behalf of the Participating Member States based on an agreement between the Commission and Participating Member States. In order to implement such action, the Commission is conducting a single central procurement procedure on behalf of Participating Member States, with a view to signing EU-level APAs with vaccine manufacturers.

In exchange for the commitment to make Available the Vaccine Volume, Contractor shall receive from the Commission or the Exercising Member States, as applicable, up-front payments, subject to the terms of this APA, to enable Contractor and its Affiliates to progress its accelerated clinical development plan for the Vaccine Candidate, expand its manufacturing capacity in relation to the manufacturing of the Vaccine Candidate, purchase (and make financial commitments for the purchase of) materials, supplies, components and manufacturing capacity necessary for the manufacture of the Vaccine Candidate, and commence the at-risk production of the Vaccine Candidate. Each Participating Member State shall submit to Contractor (a) Vaccine Order Form(s) (based on the model in Annex II) through which Contractor shall make Available and Deliver to the relevant Participating Member State, a proportion of the Vaccine Volume at the price and conditions, as set out in this APA.

Contractor may perform any and all of its obligations under this APA through any of its Affiliates.

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

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<sup>1</sup> 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.

## SENSITIVE

**1.3.1** The APA enters into force on the date on which the last Party signs it.

**1.3.2** Without prejudice to Article 1.3.4, this APA shall automatically expire (i) in the event the Commission, acting on behalf of the Participating Member States, has not provided an Option Exercise Notice by the Second Option Deadline, upon Delivery by Contractor of the Base Volume Commitment and payment in full of the Price for the Base Volume Commitment by the Commission and/or Participating Member States, as applicable, or (ii) in the event the Commission, acting on behalf of the Participating Member States, has provided an Option Exercise Notice before the First Option Deadline and/or the Second Option Deadline, as applicable, upon Delivery of the Base Volume Commitment and each applicable Additional Volume Commitment, and payment in full of the Price for the Base Volume Commitment and each applicable Additional Volume Commitment, by the Commission, Participating Member States and/or Exercising Member States, as applicable.

**1.3.3** The Participating Member States may not sign any Vaccine Order Form, and Contractor shall not be required to accept any Vaccine Order Form, after the APA expires or has terminated.

**1.3.4** Articles 1.1, 1.3.3, 1.3.4, 1.4.6 and 1.4.7 (to the extent any Vaccine Regimens have been Delivered), 1.5.3, 1.5.4, 1.6 (to the extent any payment obligations are still outstanding), 1.7, 1.8, 1.9, 1.10.3.2, 1.10.3.3, 1.10.4, 11.1, 11.2, 11.4, 11.5, 11.8, 11.9, 11.11, 11.12, 11.13, 11.16.4, 11.18 (to the extent any payment obligations are still outstanding) and 11.19 (for the period stated in 11.19.1) shall survive the termination or expiry of this APA.

## **1.4 IMPLEMENTATION OF THE APA**

### **1.4.1 Purchase Commitments**

#### **1.4.1.1 Base Volume Commitment**

The Commission, on behalf of the Participating Member States, shall advance purchase a volume of 200 million Vaccine Regimens (the "**Base Volume Commitment**") in accordance with Article 1.6, by making the Base Down Payment referred to in Article 1.6.1 that will allow the manufacture of the Base Volume Commitment and the Participating Member States to subsequently purchase their Allocation of the Base Volume Commitment.

#### **1.4.1.2 Additional Volume Commitment**

The Commission, on behalf of the Participating Member States, shall reserve an additional volume of up to 200 million Vaccine Regimens (the "**Additional Volume**") by making a payment for the Reservation Fee referred to in Article 1.6.1 that will give the Participating Member States the option to subsequently elect to advance purchase such further Vaccine Regimens in accordance with this Article 1.4.1.2.

The Commission, on behalf of the Participating Member States or any number of them (the "**Exercising Member States**"), may elect to advance purchase the Additional Volume in two separate tranches of each up to 100 million Vaccine Regimens each (each an "**Additional Volume Commitment**") by providing to Contractor, by no later than: (i) 15 days following the decision by the Commission to grant Regulatory Approval, with respect to the first Additional Volume Commitment (the "**First Option Deadline**"), and (ii) the later of 30 June 2021 or 15 days following the decision by the Commission to grant Regulatory Approval, with respect to the second Additional Volume Commitment (the "**Second Option Deadline**"), a binding notice, in the form of Exhibit C, (each an "**Option Exercise Notice**") to advance purchase such Additional Volume Commitment. The following principles shall apply in respect of any Option Exercise Notice and Additional Volume Commitment:

- (a) The Commission may submit only one Option Exercise Notice for each Additional Volume Commitment.



## SENSITIVE

- (b) The number of Vaccine Regimens to be purchased by the Exercising Member States as part of each Additional Volume Commitment must equal either: (i) twenty-five (25) million Vaccine Regimens; (ii) fifty (50) million Vaccine Regimens; (iii) seventy-five (75) million Vaccine Regimens, or (iv) one hundred (100) million Vaccine Regimens. For clarity, if the Commission, on behalf of the Exercising Member States, elects to purchase less than 100 million Vaccine Regimens in either of the Additional Volume Commitments, the Commission and the Exercising Member States shall have no more right to purchase the remaining proportion of such Additional Volume Commitment.
- (c) The Option Exercise Notice for each Additional Volume Commitment shall specify (i) the number of Vaccine Regimens to be purchased by the Exercising Member States (which shall be one of the four numbers referred to in (b) above), (ii) the Allocation of the Additional Volume Commitment as between the Exercising Member States, as set out in Article 1.4.8.1(h), and (iii) the responsibility, as between the Exercising Member States, for the payment of the First Further Down Payment or Second Further Down Payment (as applicable) as set out in Article 1.4.8.1(b).
- (d) For clarity, the Commission, acting on behalf of the Exercising Member States, may provide an Option Exercise Notice for the second Additional Volume Commitment by the Second Option Deadline even if it has not provided an Option Exercise Notice for the first Additional Volume Commitment by the First Option Deadline. In such cases, the Exercising Member States shall be entitled to purchase an additional volume of up to 100 million Vaccine Regimens.

If the Commission provides an Option Exercise Notice to Contractor:

- (a) on or before the First Option Deadline, the Exercising Member States shall advance purchase the first Additional Volume Commitment in accordance with Article 1.6 by making the First Further Down Payment referred to in Article 1.6.1.2.
- (b) on or before the Second Option Deadline, the Exercising Member States shall advance purchase the second Additional Volume Commitment in accordance with Article 1.6 by making the Second Further Down Payments referred to in Article 1.6.1.3.

If Contractor has not received an Option Exercise Notice by the First Option Deadline and/or the Second Option Deadline, as applicable, the Participating Member States' right to purchase the first Additional Volume Commitment and/or the second Additional Volume Commitment, as applicable, under the terms of this APA shall lapse and Contractor shall be free to take any action it considers appropriate in respect of such additional Vaccine Regimens (including reallocating all or part thereof to any third party of its choice).

For the purposes of this APA, any reference to the Participating Member States made in the context of a reference to any Additional Volume Commitment shall be read, where appropriate, as a reference to the Exercising Member States relevant to that Additional Volume Commitment. Any reference to Participating Member States shall be read as including each Exercising Member State, where the context requires. For the avoidance of doubt, each Exercising Member State is, by definition, a Participating Member State and all rights and obligations of the Participating Member States are also rights and obligations of each Exercising Member State. However, the Exercising Member States may have additional rights and obligations in relation to the first and/or second Additional Volume Commitment that any Participating Member States who are not also Exercising Member States do not have.

### 1.4.1.3 Further Purchases

**SENSITIVE**

The Participating Member States, or any number of them, may, on written notice by the Commission on their behalf to Contractor, request to purchase additional quantities of the Vaccine Regimens, in excess of the Vaccine Volume. Within thirty (30) days of Contractor's receipt of such request, the Parties shall initiate discussions regarding such request and Contractor may, in its sole discretion, agree to make available additional quantities of the Vaccine Regimens in excess of the Vaccine Volume (such additional quantities agreed to be made available, the "Further Vaccine Volume") at such times as may be agreed between the Parties. For clarity, nothing in this APA requires Contractor to agree to Deliver any Further Vaccine Volume.

Any orders for the Further Vaccine Volume, to the extent agreed by Contractor pursuant to this Article, shall require the conclusion of a separate purchase agreement. Such Further Vaccine Volume, if agreed to be made available by Contractor, will be made available at the price applicable at that time (which may be different from the Price set out in this APA for the Vaccine Volume). The terms of this APA apply to the Vaccine Volume only and, unless agreed otherwise by Contractor, shall not apply to any purchase of Further Vaccine Volume or to use of the Vaccine Volume for any purpose other than for the Purpose.

**1.4.2 Conditions**

Contractor's Delivery obligations in respect of the Vaccine Volume to any Participating Member State under this APA shall be subject to and conditional upon the satisfaction of the following cumulative conditions:

- (a) the Commission having granted or issued the Regulatory Approval or, in the event that any Participating Member State authorizes within such Participating Member State the use (under Article 5(2) and (3) of Directive 2001/83 or otherwise) of the Vaccine Candidate prior to the Commission's grant of the Regulatory Approval, such Participating Member State having so authorized the use of the Vaccine Candidate (it being understood that this condition (a) shall then only be deemed to be satisfied in respect of such Participating Member State);
- (b) Contractor having scaled up manufacture and expanded manufacturing capacity of the COVID Vaccine at anticipated scale, it being understood that (i) Contractor relies also on third party CMOs to achieve such effect, (ii) Contractor shall use reasonable best efforts to scale up and expand its manufacturing processes, and (iii) as at the Effective Date, Contractor has not yet scaled up and expanded its manufacturing processes at anticipated mass scale;
- (c) Contractor having received the relevant Vaccine Order Form from the respective Participating Member State following receipt of the Allocation by the Commission;
- (d) to the extent the Vaccine Candidate or COVID Vaccine is regulated as a GMO by a Participating Member State, the Vaccine Candidate or COVID Vaccine, as applicable, being exempted from, or permitted under, the legislation in such Participating Member State (it being understood that this condition shall apply with respect to such Participating Member State only); and
- (e) (i) the Commission having paid the Initial Down Payment, (ii) where applicable, the Exercising Member States having paid the Further Down Payments, and (iii) the Participating Member States having

## SENSITIVE

paid the Price Balance for the relevant Delivery, in accordance with Article 1.6.

### **1.4.3 Vaccine Volume**

1.4.3.1 Contractor shall Deliver the Vaccine Volume to the Participating Member States in accordance with the Allocation and the other terms and conditions of this APA.

1.4.3.2 The Commission, on behalf of the Participating Member States, acknowledges and agrees that:

- (a) Contractor's expectation, as at the Effective Date, based on the current status of development of the Vaccine Candidate, is that to address the current pandemic, and depending on the results generated as part of the overall clinical development plan, each Vaccine Regimen will consist of either, (i) two separate injections of up to  $1 \times 10^{11}$  viral particles (two doses, given with a time interval of a few weeks), or (ii) one single injection of up to  $1 \times 10^{11}$  viral particles (one dose);
- (b) the final total dosage and administration schedule of COVID Vaccine required to protect one (1) individual against COVID-19 has not been determined as of the Effective Date and shall be determined solely by Contractor based on data generated in ongoing clinical trials, the results of which will partially be generated and/or reported after the Effective Date; and
- (c) therefore, as at the Effective Date and depending on the results to be generated as part of the overall clinical development plan, it is uncertain whether the dosage referred to in Article 1.4.3.2(a) will be sufficient to protect one (1) individual against SARS-Cov-2 infection. Contractor shall report on progress made in the clinical development of the Vaccine Candidate as set out in Article 1.10.2 and shall inform the Commission of the final dosage and administration schedule of the Vaccine Candidate as set out Article 1.4.3.3.

1.4.3.3 Once Contractor has determined the final total dosage and administration schedule of the Vaccine Candidate, Contractor shall, as soon as reasonably practicable, inform the Commission of such final total dosage and administration schedule (it being understood that it shall be the Commission's responsibility to further inform the Participating Member States). If, following such information, the Participating Member States (or any number of them) desire to purchase Further Vaccine Volume in excess of the Vaccine Volume, the provisions of Article 1.4.1.3 shall apply.

### **1.4.4 Orders of Vaccine Volume**

#### **1.4.4.1 Vaccine Order Forms**

Each Participating Member State shall place an order for its full Allocated portion of the Base Volume Commitment and, if applicable, for its full Allocated portion of each of the Additional Volume Commitments, by sending Contractor the duly completed and signed Vaccine Order Form (the format of which is set out in Annex II) in paper format (by registered mail) and in electronic format (PDF by e-mail) to Contractor's address specified in the Vaccine Order Form.

Each Vaccine Order Form shall be signed by an authorized representative of the relevant Participating Member State.

## SENSITIVE

Each Participating Member State shall submit a Vaccine Order Form in respect of its Allocated portion of the Base Volume Commitment in writing to Contractor no later than 30 December 2020 (the "**Base Order Form Deadline**"). in order for Contractor to meet the Tentative Availability Schedule (or, as the case may be, the Final Availability Schedule). The Commission, on behalf of the Participating Member States, acknowledges that for any Vaccine Order Forms received by Contractor after the Base Order Form Deadline, the timelines for Availability mentioned in the Tentative Availability Schedule (or, as the case may be, the Final Availability Schedule) may not be met.

Each Exercising Member State shall submit a further Vaccine Order Form in respect of its Allocated portion of each Additional Volume Commitment in writing to Contractor no later than fifteen (15) calendar days after the date of the relevant Option Exercise Notice provided by the Commission to Contractor in accordance with Article 1.4.1.2 (the "**Relevant Additional Order Form Deadline**"). in order for Contractor to meet the Tentative Availability Schedule (or, as the case may be, the Final Availability Schedule). The Commission, on behalf of the Exercising Member States, acknowledges that for any Vaccine Order Form received by Contractor after such Relevant Additional Order Form Deadline, the timelines for Availability mentioned in the Tentative Availability Schedule (or, as the case may be, the Final Availability Schedule) may not be met.

Each Exercising Member State shall pay to Contractor its allocated share of the First Further Down Payment or Second Further Down Payment (as applicable) in accordance with Article 1.6.1.6.

### 1.4.4.2 Placement of orders

This APA constitutes a binding order by the Commission, on behalf of the Participating Member States, and acceptance of such order by Contractor, for the purchase of the Base Volume Commitment by the Participating Member States, such Base Volume Commitment to be made Available and Delivered by Contractor in accordance with Article 1.4.5. The Base Volume Commitment shall be Allocated in accordance with Article 1.4.8.1 and each Participating Member State shall submit a duly completed Vaccine Order Form to Contractor for its full Allocated portion of the Base Volume Commitment.

If the Commission, on behalf of the Exercising Member States, sends an Option Exercise Notice in respect of an Additional Volume Commitment in accordance with Article 1.4.1.2, the provision of such Option Exercise Notice to Contractor shall constitute a binding order by the Commission, on behalf of the Exercising Member States, and acceptance of such order by Contractor, for the purchase of the relevant Additional Volume Commitment by the Exercising Member States, with such Additional Volume Commitment to be made Available and Delivered by Contractor in accordance with Article 1.4.5. The relevant Additional Volume Commitment shall be Allocated in accordance with Article 1.4.8.1 and each Exercising Member State shall submit a duly completed Vaccine Order Form to Contractor for its full Allocated portion of such Additional Volume Commitment.

### 1.4.5 Delivery of Vaccine Volume

#### 1.4.5.1 Availability Schedule

As at the Effective Date, Contractor tentatively expects, and shall use reasonable best efforts, to make Available the Vaccine Volume to the Participating Member States on the schedule and in the quantities as set out in the Tentative Availability Schedule set out in Exhibit A.

After the Effective Date, Contractor intends to refine and update the Tentative Availability Schedule in order to provide the Commission with a final availability schedule (the "**Final Availability Schedule**").

The schedule and quantities set out in the Tentative Availability Schedule are based on Contractor's current assumption that Regulatory Approval will be granted or issued on or prior to 30 April 2021 (the "**Expected Approval Date**"), and Commission acknowledges that if Regulatory Approval is not

## SENSITIVE

granted or issued by the Expected Approval Date, such schedule and quantities may require adjustments as Availability will likely be delayed.

Contractor shall inform the Commission of any expected material change in the Availability of the Vaccine Volume as per the Tentative Availability Schedule or Final Availability Schedule, including any expected material change if the Regulatory Approval is not granted or issued by the Expected Approval Date. In such case, Contractor shall (after prior consultation with the Commission) propose to the Commission an updated schedule with the intention to make Available the Vaccine Volume within a schedule that is as close as reasonably possible to the Tentative Availability Schedule (it being understood that any change in the Availability of the Vaccine Volume as per the Tentative Availability Schedule or Final Availability Schedule shall have no impact on the obligation of the Participating Member States to purchase the Vaccine Volume under the Vaccine Order Forms and no impact on the obligation of Contractor to make Available and Deliver such Vaccine Volume, subject to Article 11.16).

The schedule set out in the Tentative Availability Schedule reflects, and the schedule that will be set out in the Final Availability Schedule shall reflect, the quarter in which Vaccine Volume will be made Available. The Commission and the Participating Member States acknowledge that:

- (i) the exact date of Delivery of the Vaccine Volume to the Delivery Address will depend on various factors and requirements to be satisfied after Vaccine Volume has been quality released by Contractor, including requirements under laws and regulations of the Participating Member States (such as requirements for testing, evaluation and release by OMCLs, obtaining of OCABR certificate, local testing and local release by competent authorities within the Territory, import restrictions, etc.) and shipping time from Contractor's distribution centres to the Delivery Address; and
- (ii) accordingly, Contractor cannot provide any assurance or commitment to the Commission or the Participating Member States as to the exact timing of Delivery of Vaccine Volume to the Delivery Address. The Contractor shall inform the Participating Member States, on a rolling basis, in good time in advance of the expected timing of Delivery of any quantity of Vaccine Volume, following receipt of the Vaccine Order Forms.

The grant or issuance of the Regulatory Approval shall not require Contractor to make Available or Deliver any quantities of the Vaccine Volume ahead of the Tentative Availability Schedule or the Final Availability Schedule. Notwithstanding the foregoing, in the event that any Participating Member State authorizes within such Participating Member State the use (under Article 5(2) and (3) of Directive 2001/83 or otherwise) of the Vaccine Candidate prior to the Commission's grant of the Regulatory Approval, Contractor shall (subject to satisfaction of the conditions in Article 1.4.2) use reasonable efforts to make Available to the relevant Participating Member State in March 2021 the Allocated portion of the Q2 2021 Vaccine Regimens as set forth on Exhibit A.

### 1.4.5.2 Delivery.

The Vaccine Volume shall be Delivered by Contractor to the Participating Member States, and the Participating Member States shall accept Delivery of, the Vaccine Volume, DDP (Delivered Duty Paid) Incoterms 2020, at the Delivery Address. The Participating Member States acknowledge that Contractor will make multiple Deliveries over a period of time, in varying quantities, depending on Availability, and on a non-discriminatory basis as between the Participating Member States having provided a Vaccine Order Form.

Risk of loss and title in the Vaccine Volume shall transfer to the Participating Member States upon Delivery at the Delivery Address.

### 1.4.5.3 Form of Delivery.

## SENSITIVE

Vaccine Volume shall be Delivered in collector boxes, each box currently expected to contain [REDACTED]

[REDACTED] Contractor shall inform the Participating Member States in due course of any specificities of shipment packaging and of ordering of the Vaccine Volume.

The Commission and the Participating Member States acknowledge that:

(a) Contractor's current expectation is that, to address the current pandemic, Regulatory Authorities will require all Vaccine Regimens comprised in a vial to be used within [REDACTED]

and

(h) given the current pandemic and the urgency of required Delivery of the Vaccine Volume, Contractor may not be able to Deliver the Vaccine Volume to the Participating Member States fully in accordance with the usual packaging and labelling requirements for medicinal products approved for commercialization within the Territory (in this respect, Contractor is discussing with EMA to ensure Vaccine Volume will be packaged and labelled in a form that is suitable for usage in the Territory). The Participating Member States shall accept Delivery of any Vaccine Volume packaged and labelled in a form suitable and approved for usage in the Territory.

#### 1.4.5.4 Non-conforming Vaccine Volume

If a Participating Member State alleges that any quantity of Vaccine Volume Delivered to it under a Vaccine Order Form is defective, the provisions of Exhibit D shall apply.

#### 1.4.6 Use of Vaccine Volume

1.4.6.1 Following Delivery in accordance with Article 1.4.5.2, the Participating Member States shall be solely responsible and liable for the allocation, maintenance, distribution, storage, transport, administration, and management of the Vaccine Volume, along with any related follow-on care, and shall use the Vaccine Volume only for the Purpose and in accordance with this APA and applicable Law.

1.4.6.2 The Commission and the Participating Member States acknowledge and agree that, for Vaccine Volume the Participating Member States receive from the Contractor under this APA, each Participating Member State shall establish and maintain a Cold Chain distribution channel in compliance with (i) Good Distribution Practices, (ii) Specifications and (iii) Contractor's reasonable instructions for storage thereof.

1.4.6.3 Contractor may audit the Participating Member States' distribution channels that are used for Vaccine Volume to determine whether such channels are in compliance with Cold Chain requirements, Good Distribution Practices, Specifications, and Contractor's reasonable instructions for storage of the Vaccine Volume. If Contractor finds any material non-compliance during such audit and informs the relevant Participating Member State thereof, the relevant Participating Member State shall cure such non-compliance within the cure period communicated by Contractor (acting reasonably). If by the end of such cure period such non-compliance is not cured, Contractor may (after prior consultation with the relevant Participating Member State, and taking into account reasonable observations of such Participating Member State) take measures and actions it considers reasonably appropriate towards the relevant Participating Member State.

1.4.6.4 The Participating Member States acknowledge and agree that Contractor is selling the Vaccine Volume to the Participating Member States at the Price solely for use by the Participating Member States for the Purpose (and none of the Participating Member States shall use the Vaccine Volume for any purpose other than the Purpose, subject to the extent otherwise permitted under Article 1.4.7).

**SENSITIVE**

**1.4.6.5 The Participating Member States shall:**

- (a) not apply any mark-up or other price differentials to any resale price in the distribution of the Vaccine Volume in the Territory. Nothing in this Article 1.4.6.5(a) shall prevent a Participating Member State from (i) seeking reimbursement from its customers of any additional transport and/or distribution costs it would have incurred in the distribution of the Vaccine Volume in the Territory, and (ii) applying any discounts in the distribution of the Vaccine Volume in the Territory (provided that such discounts are applied uniformly throughout the Territory); and
- (b) in the event the Participating Member States have any unadministered stock of the Vaccine Volume on the Vaccine Expiry Date, promptly notify Contractor thereof and destroy such stock of unadministered Vaccine Volume at the Participating Member State's cost and provide Contractor with a certificate of destruction.

**1.4.7 Resale and Donation**

**1.4.7.1** Notwithstanding any other term of this APA, Participating Member States may resell Vaccine Regimens from their Allocated portion of the Vaccine Volume to:

- (i) a Member State who has opted out of this APA (such Member State, a "Non-PMS") or to any of Norway, Liechtenstein and Iceland, without prior consent of Contractor on the following cumulative conditions:
  - (a) appropriate regulatory approval having been granted or issued for the legal marketing, importation, distribution, sale, administration and use of the Vaccine Candidate in such Non-PMS, Norway, Liechtenstein or Iceland (as applicable);
  - (b) the Participating Member States not selling such Vaccine Regimens at a price per Vaccine Regimen that is higher than the Price (for the avoidance of doubt, net of any value added or similar taxes) paid to Contractor for such Vaccine Regimens (it being understood that this restriction does not affect the possibility for Participating Member States to have any additional transport and distribution costs reimbursed by the receiving state);
  - (c) in case of a Participating Member State reselling such Vaccine Regimens to Norway, Liechtenstein or Iceland (but not to a Non-PMS):
    - (1) such Participating Member State reimbursing the Commission for the part of the Price of such Vaccine Regimens funded by the Initial Down Payment (it being understood that Contractor shall have no obligation towards the Commission in respect of such reimbursement);
    - (2) Contractor and the selling Participating Member State agreeing on the volume of such Vaccine Regimens to be resold, in order to optimize the worldwide allocation of the COVID Vaccine;

**SENSITIVE**


- (d) the recipient government of such Non-PMS, Norway, Lichtenstein or Iceland (as applicable) providing Contractor a valid and binding written confirmation (in a form and substance satisfactory to Contractor) expressly accepting to be bound by, and to comply with, the relevant terms of this APA, including the indemnification provision set forth in Article II.5; and
  - (e) the selling Participating Member State being responsible for all logistics in relation to shipment of the Vaccine Regimens to the recipient government of such Non-PMS, Norway, Lichtenstein or Iceland (including adherence to Cold Chain requirements) and the costs thereof (unless the selling Participating Member State agrees otherwise with the recipient government of such Non-PMS, or Norway, Lichtenstein or Iceland (as appropriate)).
- (ii) another Participating Member State (the "**Buying PMS**"), without the prior written consent of Contractor on the following cumulative conditions:
- (a) appropriate regulatory approval having been granted or issued for the legal marketing, importation, distribution, sale, administration and use of the Vaccine Candidate in such Buying PMS;
  - (b) the selling Participating Member State not selling such Vaccine Regimens to the Buying PMS at a price per Vaccine Regimen that is higher than the Price (for the avoidance of doubt, net of any value added or similar taxes) paid to Contractor for such Vaccine Regimens (it being understood that this restriction does not affect the possibility for Participating Member States to have any additional transport and distribution costs reimbursed by the Buying PMS);
  - (c) the recipient government of such Buying PMS providing Contractor a valid and binding written confirmation (in a form and substance satisfactory to Contractor) expressly accepting to be bound by, and to comply with, the relevant terms of this APA, including the indemnification provision set forth in Article II.5; and
  - (d) the selling Participating Member State being responsible for all logistics in relation to shipment of the sold Vaccine Regimens to the Buying PMS (including adherence to Cold Chain requirements) and the costs thereof (unless the selling Participating Member State agrees otherwise with the Buying PMS).
- (iii) any other third party (other than a Buying PMS, a Non-PMS, Lichtenstein, Norway or Iceland), subject to such Participating Member State informing Contractor of its intention to resell, and Contractor and the Participating Member State (both acknowledging and taking into account the importance of an optimized worldwide allocation of the COVID Vaccine) mutually agreeing on the appropriate terms and conditions of such resale (as the case may be as part of the discussion platform referred to in Article I.10.5).

1.4.7.2 If any Participating Member State contemplates the donation of any of the Vaccine Volume Delivered by Contractor under this APA to any third party, such Participating Member State shall inform Contractor hereof, and Contractor and the Participating Member State shall discuss whether this would be possible (taking into account, among others, the importance of optimized



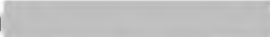
## SENSITIVE

worldwide allocation of the COVID Vaccine) and, if so, mutually agree on the appropriate terms and conditions for such donation, including the following:

- (a) donations being made to supranational/international organizations or governments or non-governmental entities (each a **"Donation Recipient"**) mutually agreed by the donating Participating Member State and Contractor, and Contractor, the Donation Recipient and the donating Participating Member State agreeing on the donation recipient country (which shall be a low income country or lower-middle-income country as per the definitions of the World Bank);
- (b) appropriate regulatory approval having been granted or issued for the COVID Vaccine by the relevant regulatory authorities in each donation recipient country, to the satisfaction of Contractor (to be confirmed in writing by Contractor to the donating Participating Member State prior to any such donation);
- (c) Contractor and the donating Participating Member State agreeing on the volume of Vaccine Regimens to be donated to a Donation Recipient, in order to optimize the worldwide allocation of the COVID Vaccine;
- (d) 
- (e) the donating Participating Member State being responsible for all logistics in relation to shipment of the Vaccine Regimens to the Donation Recipient (including adherence to Cold Chain requirements) and the costs thereof (unless the donating Participating Member State agrees with the Donation Recipient that the latter shall be responsible therefor).

### 1.4.8 Allocation between Participating Member States

#### 1.4.8.1 The Commission shall provide to Contractor in writing:

- (a) at the latest  the allocation for distribution of the Base Volume Commitment among the Participating Member States. Such allocation shall be binding on the Participating Member States and shall be communicated in table format in the form set out in Exhibit E, and shall indicate for each Participating Member State, the precise volume of Vaccine Regimens (expressed as a percentage of the Base Volume Commitment plus as a number of Vaccine Regimens) to be Delivered to each Participating Member State;

## SENSITIVE

(b) together with any Option Exercise Notice provided pursuant to Article 1.4.1.2:

- (1) the allocation for distribution of the relevant Additional Volume Commitment among the Exercising Member States. Such allocation shall indicate for each Exercising Member State, the precise volume of Vaccine Regimens (expressed as a percentage of the relevant Additional Volume Commitment plus as a number of Vaccine Regimens) to be Delivered to each Exercising Member State; and
- (2) the allocation of the First Further Down Payment or Second Further Down Payment (as applicable) among the Exercising Member States; such allocation shall indicate for each Exercising Member State the exact portion of the First Further Down Payment or Second Further Down Payment (as applicable) [REDACTED] to be paid by each Exercising Member State in accordance with Article 1.6.1.6.

The allocations set out in (1) and (2) above shall be binding on the Exercising Member States and shall be communicated by the Commission to Contractor in table format in the form set out in Exhibit E.

1.4.8.2 Contractor shall rely on the allocation table(s) as received from the Commission pursuant to Article 1.4.8.1, and in particular may refuse any Vaccine Order Form which does not comply with the Allocation.

1.4.8.3 The Commission and the Participating Member States acknowledge that if the Commission does not provide the Allocation to Contractor by the timings specified in Article 1.4.8.1, Contractor may not be able to meet the timelines for Availability mentioned in the Tentative Availability Schedule (or, as the case may be, the Final Availability Schedule).

## 1.5 PRICES

### 1.5.1 Price per Vaccine Regimen

The price per single Vaccine Regimen of the Vaccine Volume purchased hereunder shall be [REDACTED] ("Price"). For clarity, the price for the total Vaccine Volume shall be obtained by multiplying the Price by the total number of Vaccine Regimens covered by this APA.

### 1.5.2 Global Not-for-Profit Framework

1.5.2.1 The Commission, on behalf of the Participating Member States, acknowledge that Contractor is developing a framework for determining the global price for its Vaccine Regimen, to strengthen its commitment to making the Vaccine Regimen available on a not-for-profit basis during the emergency pandemic response period. This framework shall be subject to a review process by a third-party audit firm (such framework, the "Global Not-for-Profit Framework"). [REDACTED]

### 1.5.3 Costs

The Price shall be exclusive of any and all costs in relation to the allocation, maintenance, distribution, storage, transport, administration and management of the Vaccine Volume following Delivery, and, for clarity, of VAT and other taxes (as further set out in Article 1.6.8). The Participating Member States shall be solely responsible for any and all costs in relation to the allocation, maintenance, distribution, storage, transport, administration, and management of the Vaccine Volume following Delivery and for payment of VAT and other taxes.

### 1.5.4 Commercial Pricing

The Commission acknowledges that the price payable for any Further Vaccine Volume or for any COVID Vaccine that are for use other than for the Purpose, may be higher than the Price, and that Contractor may transition to commercial pricing for any COVID Vaccines after the emergency pandemic response period.

## 1.6 PAYMENT ARRANGEMENTS

### 1.6.1 Down Payments

1.6.1.1 The Commission shall make an initial down payment of [REDACTED] to Contractor as set out in Exhibit B, consisting of:

- (a) a down payment of [REDACTED] for the Base Volume Commitment ("**Base Down Payment**"); and
- (b) a reservation fee of [REDACTED] for each Additional Volume Commitment (each a "**Reservation Fee**"),

the Base Down Payment and the Reservation Fee are collectively referred to as the "**Initial Down Payment**".

1.6.1.2 To the extent the Commission serves an Option Exercise Notice by the First Option Deadline under Article 1.4.1.2 to inform Contractor that Exercising Member States intend to purchase the first Additional Volume Commitment, the Exercising Member States shall make a further down payment of [REDACTED] per Vaccine Regimen specified in the Option Exercise Notice for the Additional Volume Commitment as set out in Exhibit B (the "**First Further Down Payment**").

1.6.1.3 To the extent the Commission serves an Option Exercise Notice by the Second Option Deadline under Article 1.4.1.2 to inform Contractor that Exercising Member States intend to purchase the second Additional Volume Commitment, the Exercising Member States shall make a further down payment of [REDACTED] per Vaccine Regimen specified in the Option Exercise Notice for the Additional Volume Commitment as set out in Exhibit B (the "**Second Further Down Payment**").

1.6.1.4 The Initial Down Payment plus, if applicable, the First Further Down Payment and the Second Further Down Payment are collectively referred to as the "**Down Payments**", and the First Further Down Payment and the Second Further Down Payment are collectively referred to as the "**Further Down Payments**".

## SENSITIVE

1.6.1.5 The Commission shall pay to Contractor the Initial Down Payment within twenty (20) business days after the Effective Date, in euros for an amount of [REDACTED]

1.6.1.6 Each Exercising Member State shall pay to Contractor its allocated share of the First Further Down Payment and Second Further Down Payment, as applicable, within ten (10) business days after the date of Contractor's invoice in respect thereof (it being understood that Contractor shall be entitled to send such invoice immediately upon receipt of the relevant Option Exercise Notice from the Commission in accordance with Article 1.4.1.2). The Commission, on behalf of the Exercising Member States, acknowledges that if an Exercising Member State fails to pay its allocated share of the First Further Down Payment or Second Further Down Payment in full, as applicable, in accordance with this Article 1.6.1.6, Contractor shall have no obligation to consider the Exercising Member State's Vaccine Order Form for its Allocated portion of the relevant Additional Volume Commitment or to Deliver the Allocated Vaccine Regimens to such Exercising Member State.

### 1.6.2 Credit

Contractor shall credit the Down Payments toward the Price of the Vaccine Volume Delivered by Contractor to the Participating Member States at a rate of [REDACTED] per Vaccine Regimen (such amount, the "Credit"). The Participating Member States (or, where applicable, the Exercising Member States) shall pay, for each Vaccine Regimen, the difference between the Price and the Credit (the "Price Balance") in accordance with Article 1.6.5.

### 1.6.3 Non-exercise of option.

If the Commission, on behalf of the Participating Member States, does not serve an Option Exercise Notice by the First Option Deadline or the Second Option Deadline, as applicable, the relevant Reservation Fee paid pursuant to Article 1.6.1 shall not be refunded (neither to the Commission nor to the Participating Member States) and shall not constitute a credit towards any further purchases of the COVID Vaccine (whether pursuant to this APA or otherwise). Neither the Commission nor the Participating Member States shall have a right to recover any portion of the Reservation Fees if rights to purchase any Additional Volume Commitment under Article 1.4.1.2 are not exercised or are exercised in less than the full entitled amount.

### 1.6.4 Refundability.

1.6.4.1 The Down Payments are deductible from the Price by way of Credit, as set out in Article 1.6.2. Apart from such deduction, the Down Payments shall not be refundable by Contractor to the Commission or the Participating Member States, except if Contractor decides to abandon its development program in respect of the Vaccine Candidate. In such situation, the Parties agree that they shall implement an appropriate mechanism for refund of the Down Payments considering the following principles:

- (a) any cash refund would be limited to such portion of Down Payments already paid by the Commission or the Exercising Member States and which remains unspent or uncommitted by Contractor at the time of its abandoning of the development program (and the Commission and the Participating Member States recognize that Contractor has already made and continues to make significant investment in developing and manufacturing the Vaccine Candidate such that it is probable that the Down Payments shall be fully deployed, spent or committed immediately or shortly after the Down Payments are received by Contractor and shall not be recoverable); in this respect, Contractor shall document such unspent or uncommitted portion of the funds constituting the Down Payments, if any, (the "Unspent Amounts") and will repay such Unspent Amounts (if any) within 30 business days to the Commission;

**SENSITIVE**

- (h) in case Down Payments have been used by Contractor for investment in manufacturing the Vaccine Candidate, the Parties shall discuss possibilities for resale or re-use of such investments made by Contractor with the Down Payments, or for return of a portion of the Down Payments in-kind (e.g., in the form of re-usable materials or capacity at contract manufacturers), as the case may be to a third party named by the Commission; and

(c)

#### **1.6.5 Price Balance.**

Prior to Delivery of any Vaccine Volume and as soon as any Vaccine Volume is Available, Contractor shall invoice the Participating Member States or the Exercising Member States, as applicable, and the Participating Member States or the Exercising Member States, as applicable, shall pay to Contractor the Price Balance for such Vaccine Volume within twenty (20) business days of the receipt of the invoice, in accordance with this APA. Contractor shall send the invoice to the address identified in the Vaccine Order Form, and each invoice must contain the following information:

- (a) Name of the addressee
- (b) APA number
- (c) Contractor name and bank account

#### **1.6.6 Suspension of Vaccine Volume delivery by Payment Default.**

If the Commission or any of the Participating Member States fails to pay (any portion of) the Down Payments or Price Balance (as applicable) for (any quantity of) the Vaccine Volume in accordance with this Article 1.6, Contractor may (i) suspend the Availability of all of the Vaccine Volume (in case of payment default by the Commission) or (ii) suspend the Availability of the Vaccine Volume to which that Participating Member State is entitled to in accordance with the Allocation (in case of payment default by a Participating Member State).

Termination due to payment default is regulated under Article II.1.6.2(a).

#### **1.6.7 Currency.**

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

**SENSITIVE**

**1.6.8 Taxes.**

1.6.8.1 All amounts payable by the Commission or the Participating Member States under this APA, including any Vaccine Order Form, are exclusive of amounts in respect of value added tax chargeable from time to time ("VAT"), sales taxes and all other taxes. The Participating Member States are responsible to pay all such taxes in addition to any payments for the Vaccine Volume under this APA, including any Vaccine Order Form, as required by applicable Laws. Where any taxable delivery for VAT purposes is made under this APA by Contractor, the Participating Member States shall, on receipt of a valid VAT invoice from Contractor, pay to Contractor or directly towards the relevant taxing authorities, in case required by applicable Laws, such additional amounts in respect of VAT as are chargeable on the Delivery of the Vaccine Volume. Where a payment is to be made on account before the Vaccine Volume is Delivered, VAT shall become chargeable on receipt of the payment and on the amount received.

1.6.8.2 Each Participating Member State represents and warrants to Contractor that it is registered for VAT in respect of the supplies to be made under this APA and that each Participating Member State shall provide its VAT number to Contractor promptly on request from Contractor. Each Party therefore acknowledges that the Price (including the Down Payments) shall be treated as consideration for an intra-community supply under Article 138 of Council Directive 2006/112/EC of 28 November 2006 and so subject to reverse charge VAT in the hands of the relevant Participating Member State save in respect of Belgium.

1.6.8.3 For the avoidance of doubt, where legally required, VAT may be charged on any quantity of the Vaccine Volume under the conditions of legislation of Participating Member States. In such cases, the taxable amount shall be the Price (including the respective portion of the Down Payments). Such VAT shall only be included in the invoice to be delivered under 1.6.5 and shall be paid following delivery of such invoice (provided that the invoice complies with applicable VAT legislation consistent with the approach outlined in this Article 1.6.8).

**1.6.9 Set off.**

All amounts due under this APA from the Commission or Participating Member States to Contractor shall be paid in full without any set-off, counterclaim, deduction or withholding (other than any deduction or withholding of tax as required by applicable Laws). If any deductions or withholding of tax is required by applicable Laws to be made from any amounts due under this APA from the Commission or Participating Member States to Contractor, the Commission or Participating Member States (as applicable) shall pay to Contractor such sum as will, after the deduction or withholding has been made, leave Contractor with the same amount as it would have been entitled to receive in the absence of any such requirement to make a deduction or withholding.

**1.7 BANK ACCOUNT**

The Commission or the Participating Member States, as applicable, shall make all payments by wire transfer of immediately available funds to Contractor's bank account, identified as follows:



**SENSITIVE**

## **1.8 COMMUNICATION DETAILS**

For the purpose of this APA, communications between the Parties shall be sent to the following addresses:

European Commission

Directorate-General for Health and Food Safety

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

Contractor:

Janssen Pharmaceutica NV



Communication details between Contractor and the Participating Member States shall be set out in the relevant Vaccine Order Form.

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

### **1.9.1 Governing Law**

This APA and each Vaccine Order Form and all matters relating to or in connection with them shall be governed by the laws of Belgium, excluding, however, its conflicts of laws provisions. The Parties specifically disclaim the UN Convention on Contracts for the International Sale of Goods.

### **1.9.2 Dispute Resolution**

1.9.2.1 In the event of any dispute, controversy or claim arising under or in connection with this APA or any Vaccine Order Form (including any question regarding its existence, validity or termination) (a "Dispute") between the Parties or any Participating Member States, the Parties shall first refer such Dispute to informal dispute resolution discussions between their respective representatives. Contractor or the Commission (on behalf of itself or of the Participating Member States) may initiate such informal dispute resolution by sending written notice of the Dispute to the other Party, and, within twenty (20) days of such notice, the representatives shall meet and attempt to resolve the dispute by good faith negotiations.

1.9.2.2 The Commission, the Participating Member States and 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 relationship established by this APA, and the Commission and the Participating Member States accept the jurisdiction of such courts and waive their immunity of jurisdiction (if any), it being understood however that if a third party, not being a Party, commences proceedings against Contractor in any court of competent jurisdiction, arising out of or in connection with this APA or the COVID Vaccine, nothing in this Article 1.9.2.2 shall impact the provisions of Article II.5.

1.9.2.3 Each Participating Member State hereby expressly and irrevocably waives, to the fullest extent possible, in respect of itself and its assets, any right of immunity under the laws of any jurisdiction on the grounds of sovereignty or otherwise which may now or hereafter exist, and agrees not

## SENSITIVE

to assert any such right or claim in any legal action or proceeding. This waiver includes waiving any right of sovereign immunity as to each Participating Member State and any of its property, including any bank account belonging to any Participating Member State.

### **I.9.3 Service of Proceedings**

Without prejudice to any other mode of service allowed under any relevant law, each Participating Member State shall - for the term of the APA - maintain an agent for service of process in Belgium and to that effect elects domicile with an agent (within the meaning of article 39 of the Belgian Judicial Code - "*elected domicile*" / "*woonstkeuze*"). Such agent shall be the embassy of the Participating Member State. Any writ, summons, judgment or other notice of legal process shall be validly and sufficiently served on any Participating Member State if delivered to the embassy of the Participating Member State at its address. Each Participating Member State undertakes that it shall not revoke the authority of the embassy of the Participating Member State as its agent.

### **I.10 OTHER SPECIAL CONDITIONS**

#### **I.10.1 Regulatory Matters**

I.10.1.1 Contractor shall use reasonable best efforts to submit a marketing authorization application for Regulatory Approval as soon as reasonably practicable after successful development of the Vaccine Candidate, having regard to the estimated time required to secure the Regulatory Approval in order to make Available the Vaccine Volume in accordance with the Tentative Availability Schedule. If, in the process of reviewing the results or progress of its clinical trials with respect to the Vaccine Candidate, Contractor reasonably determines that the ongoing or planned clinical trials are likely to be insufficient for Regulatory Approval, Contractor shall promptly inform the Commission thereof.

I.10.1.2 The Participating Member States shall work with Contractor and Regulatory Authorities to facilitate and expedite the review of all licenses, permits, legislative or regulatory exemptions and activities in relation to the Vaccine Candidate and the COVID Vaccine within the limits of applicable law.

#### **I.10.2 Reporting**

I.10.2.1 Contractor shall on a regular basis provide to the Commission Experts in the context of the operational discussion platform referred to in Article I.10.5, during the Vaccine Candidate development phase, the following information as part of and until its submission for Regulatory Approval:

- (a) summarized key updates on progress made in the clinical development of the Vaccine Candidate;
- (b) key updates on (i) progress, challenges and opportunities on establishment of the supply chain and (ii) the purchasing of materials necessary for the manufacture of the Vaccine Volume;
- (c) final reports of clinical studies and safety evaluations intended for submission to the European Medicines Agency, promptly after submission to the European Medicines Agency; and
- (d) scientific publications and public announcements, after such publications and announcements have been published.



## SENSITIVE

The Commission Experts shall be entitled to inform the PMS Experts of the information received from Contractor pursuant to this Article 1.10.2.1, subject to appropriate confidentiality arrangements being entered into with such PMS Experts pursuant to Article 1.10.2.2.

For the purpose of this APA:

- (i) **"Commission Experts"** means up to three (3) clinical expert individuals employed by, or advising, the Commission in connection with the COVID-19 pandemic, such individuals to be identified by the Commission and communicated to Contractor promptly following the Effective Date (it being understood that if Contractor expresses a reasonable objection to the identity of one or more Commission Experts, the Commission will suggest (an) alternative expert(s)); and
- (ii) **"PMS Experts"** means, in relation to each Participating Member State, one (1) clinical expert employed by, or advising, such Participating Member State in connection with the COVID-19 pandemic, the identity of such individual to be communicated by the Commission to Contractor promptly following the Effective Date (it being understood that if Contractor expresses a reasonable objection to the identity of a PMS Expert, the relevant Participating Member State will suggest an alternative expert).

1.10.2.2 The Commission acknowledges that the information referred to in Article 1.10.2.1 shall only be provided by Contractor to the Commission Experts, and by the Commission Experts to the PMS Experts, if appropriate confidentiality arrangements have been entered into between Contractor and the Commission Experts and respectively the PMS Experts, to ensure the strict confidentiality and non-disclosure of such information. Such confidentiality arrangements shall acknowledge agreement by the Commission Experts and respectively the PMS Experts to the confidentiality and non-disclosure obligations under Article II.8, including in particular Article II.8.6.3

### 1.10.3 Pharmacovigilance and Quality

1.10.3.1 The Parties shall, promptly following the granting of the Regulatory Approval, meet to discuss proper implementation and follow-up of any post-approval monitoring and other requirements that may be linked to such Regulatory Approval, as part of the discussion platform referred to in Article 1.10.5. To the extent required the Parties shall enter into a pharmacovigilance agreement establishing an appropriate pharmacovigilance framework reflecting the responsibilities of Contractor, the Participating Member States and any other relevant parties (as needed), including arrangements around the post-approval monitoring process required by the EMA.

1.10.3.2 Without prejudice to Article 1.10.3.1, each Participating Member State shall inform Contractor of any Adverse Events Following Immunisation and Special Situations following use of the COVID Vaccine (together, if available, with the relevant lot/batch numbers of the relevant COVID Vaccine), within three (3) business days, no later than five (5) calendar days, of the date of first receipt. Such information shall be sent to Contractor in accordance with the method of exchange below:



1.10.3.3 The roles and responsibilities between Contractor and the Participating Member States in relation to quality assurance matters related to the Vaccine Volume are set out in Exhibit F.

**I.10.4 Representations and Warranties**

**I.10.4.1 Each Party represents and warrants to the other Party that:**

- (a) it has the requisite power and authority and the legal right to enter into this APA and to perform its obligations hereunder; and
- (b) this APA has been duly executed and delivered by it and comprises a valid and legally binding obligation enforceable against it in accordance with the terms of this APA.

**I.10.4.2 The Commission warrants to Contractor that:**

- (a) it has the right, on behalf of the Participating Member States, to commit to advance purchase the Vaccine Volume (including payment of the Initial Down Payment) in accordance with any applicable Law, including the applicable provisions of European Union Law;
- (b) it has the right to enter into this APA on behalf of the Participating Member States; and
- (c) by executing this APA on behalf of the Participating Member States, each Participating Member State is irrevocably and unconditionally bound by the terms of this APA (including without limitation the provisions of Article II.5 (*Indemnification*)) and this APA comprises a valid and legally binding obligation enforceable against each Participating Member State in accordance with the terms of this APA.

**I.10.4.3 Each Participating Member State warrants to Contractor that:**

- (a) it has the requisite power and authority and the legal right to order, purchase, allocate, maintain, distribute, store, transport, administer and manage the Vaccine Volume in accordance with the terms of this APA and any applicable Law;
- (b) it is not under any obligation, contractual or otherwise, that conflicts with or is inconsistent in any material respect with the terms of this APA or that would impede the complete fulfillment of its obligations under this APA; and
- (c) it shall comply with all Laws that are applicable to its activities and operations under this APA.

**I.10.4.4 Contractor warrants to the Commission that:**

- (a) the execution and delivery of this APA and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action;
- (b) as at the time of Delivery pursuant to Article I.4.5, it has manufactured, filled, stored, packaged, labelled, released and Delivered the Vaccine Volume in compliance with GMP applicable at the time of Delivery, to the extent that each standard of GMP is or can be applicable, and taking into account any waiver, forbearance or exemption granted or allowed by a Participating Member State or any other applicable

**SENSITIVE**

Regulatory Authority;

- (c) as of the Effective Date, it is not under any contractual obligation to any Third Party in respect of the Vaccine Volume or that conflicts with or is inconsistent in any material respect with the terms of this APA;
- (d) all information, including historic financial information, submitted to the Commission or Participating Member States in relation to this APA is true, complete and accurate in all material respects; and
- (e) it shall comply with all Laws that are applicable to its activities and operations under this APA.

I.10.4.5 Except for the warranties set out in Article I.10.4.4, Contractor disclaims all warranties, express or implied (whether by Law, custom or course of dealing), including the implied warranties of merchantability and fitness for a particular purpose.

#### **I.10.5 Operational discussion platform**

I.10.5.1 The Parties shall, after the Effective Date, set up an informal operational discussion platform to discuss, on an as-needed basis, certain operational matters regarding the implementation of this APA, e.g., to discuss supply chain, logistics, regulatory or other relevant matters.

**SENSITIVE**

**SIGNATURES**

For Janssen Pharmaceutica NV,

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



Mrs. Stella KYRIAKIDES

Commissioner for Health and Food Safety

Signature:



Signature:



Done at [place], [date]



Done at Brussels, 21 October 2020

In duplicate in English.



**SENSITIVE**

## **II. GENERAL CONDITIONS**

### **II.1 DEFINITIONS AND INTERPRETATION**

For the purpose of this APA, the definitions and rules of interpretation in Annex I shall apply.

### **II.2 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.11. The APA must be interpreted as if it had contained the substitute provision as from its entry into force.

### **II.3 PERFORMANCE**

**II.3.1** Contractor shall perform this APA in accordance with its terms.

**II.3.2** All periods specified in the APA are calculated in calendar days, unless otherwise specified.

**II.3.3** Contractor must immediately inform the Commission of any changes in the exclusion situations as declared in its tender, according to Article 137 (1) of Regulation (EU) 2018/1046.

### **II.4 COMMUNICATION BETWEEN THE PARTIES**

#### **II.4.1 Form and means of communication**

**II.4.1.1** 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 1.8; and
- (d) be sent by mail or email.

**II.4.1.2** 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.

**II.4.1.3** The Parties agree that any communication made by email has full legal effect and is admissible as evidence in judicial proceedings.

#### **II.4.2 Date of communications by mail and email**

**II.4.2.1** Any communication is deemed to have been made when the receiving Party receives it, unless this APA contract refers to the date when the communication was sent.

## SENSITIVE

II.4.2.2 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. The sending Party must be able to prove the date of dispatch. In the event that the sending Party receives a non-delivery report, it must make every effort to ensure that the other Party actually receives the communication by email or mail. In such a case, the sending Party is not held in breach of its obligation to send such communication within a specified deadline.

II.4.2.3 Mail sent to the Commission or the Participating Member States is deemed to have been received on the date on which the department responsible referred to in Article I.8 registers it.

II.4.2.4 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.5 INDEMNIFICATION

II.5.1 The Commission, on behalf of the Participating Member States, declares that the administration and use of the COVID Vaccines made Available and Delivered by Contractor under this APA shall happen due to epidemic conditions, and that the administration and use of the COVID Vaccines shall therefore be conducted under the sole responsibility of the Participating Member States.

II.5.2 Each Participating Member State shall indemnify and hold harmless Contractor, its Affiliates, sub-contractors and sub-licensees, all of its partners involved in and contracted for the research, development (including pre-clinical and clinical testing), manufacturing (including contract manufacturers) and deployment of the COVID Vaccine, as well as its and their officers, directors, employees and other agents and representatives (together, the "Indemnified Persons") from any and all (i) damages, (ii) liability, (iii) external legal costs necessary to the defence or resolution (including settlement) of any claim brought by any third party in any legal, civil or similar proceeding (i.e. reasonable attorneys' and other professional advisors' fees) and (iv) procedural costs (such as interest or fines, or taxes on court ordered payments) ((i) to (iv) together, the "Losses") suffered or incurred by the Indemnified Persons in connection with any demands, claims, actions or proceedings:

- (a) involving, relating to, or arising out of or in connection with the use and deployment of the COVID Vaccine (regardless of whether the alleged cause of the damage originates from the design, research, development, testing, manufacture, labelling, packaging, sale, deployment, distribution, storage, administration and/or use of the COVID Vaccine); and
- (b) brought or initiated by or on behalf of:
  - (1) such Participating Member State or any of its agencies, departments, ministries, bodies, governments (local, regional or federal) or other public authorities or social security institutions except in cases under Article II.5.3; or
  - (2) a Vaccinated Individual whose place of permanent home or principal establishment ("Residence") is in such Participating Member State (irrespective of the nationality, citizenship or country of non-principal establishment or incorporation of such Vaccinated Individual); or
  - (3) a Vaccinated Individual who has been administered the COVID Vaccine in such Participating Member State (even if

**SENSITIVE**

such Vaccinated Individual's Residence is not in such Participating Member State); or

- (4) any other person in the courts of competent jurisdiction of such Participating Member State.

**II.5.3** The indemnification right under Article II.5.2 shall not be available to the Indemnified Persons to the extent that

**II.5.4** If any person makes a claim or initiates a demand, action or proceeding (or notifies an intention to do so) against an Indemnified Person, which in the reasonable opinion of Contractor is considered likely to result in indemnification under Article II.5.2 above (a "Claim"), Contractor:

- (a) shall as soon as reasonably practicable, give written notice of the Claim to the relevant Participating Member State, specifying the nature of the Claim in reasonable detail, provided that the failure to promptly provide such notice shall not relieve the relevant Participating Member State of its indemnification obligations under Article II.5.2; and
- (b) either:
  - (1) shall take such actions as it may consider reasonable and appropriate to avoid, dispute, compromise or defend the Claim (with all related costs, fees and expenses, as well as Losses, to be paid by the relevant Participating Member State), provided that (i) Contractor may settle the Claim only with the prior consent of the relevant Participating Member State (such consent not to be unreasonably withheld, conditioned or delayed) and (ii) Contractor may select its counsel and other advisors in its discretion, and at such professional fee rates and costs consistent with its ordinary practices; or
  - (2) may request the relevant Participating Member State, which request shall not be unreasonably denied by the relevant Participating Member State, to assume (with its own counsel and at its own costs) sole control of the defence or settlement of the Claim and where possible the relevant Participating Member State shall then become the defendant, provided that if such request is accepted by the relevant Participating Member State:
    - i. the relevant Participating Member State shall reasonably take into consideration the interests of Contractor and shall not conclude any agreement or make any compromise or settlement with any person in relation to such Claim without the prior written consent of Contractor (such consent not to be unreasonably conditioned, withheld or delayed); and
    - ii. Contractor shall have the right, but not the obligation, to participate in the defence or settlement of the Claim and to retain its own counsel in connection with such Claim at its own expense; and
    - iii. Contractor shall provide assistance and information reasonably required by the relevant Participating Member State in the defence of the Claim (at the expense of such Participating Member State), provided that (a) any information reasonably considered by Contractor as confidential or proprietary information shall be provided by it only if and when satisfactory confidentiality arrangements are put in place, and (b) under no circumstances shall Contractor provide any information (including trade secrets) which it reasonably believes would cause material harm to it if disclosed.

## **SENSITIVE**

**II.5.5** Each of the Indemnified Persons (other than Contractor) shall constitute a third party beneficiary within the meaning of article 1121 of the Belgian Civil Code ("*stipulation pour autrui*" / "*beding ten behoeve van een derde*") in respect of the obligations of the Participating Member States under this Article II.5, so that it may enforce these obligations directly.

**II.5.6** The Participating Member States' obligation to indemnify the Indemnified Persons for Claims under this Article II.5 is not limited by the number of indemnifiable Claims brought against the Indemnified Persons.

**II.5.7** If any payment in satisfaction of the indemnification right under Article II.5.2 is liable to tax in the hands of an Indemnified Person as recipient of such payment (the "payee"), then the payment shall be increased by such additional amount as necessary to ensure that the payee receives a net sum equal to the sum it would have received had the payment not been liable to tax. If and to the extent the relevant tax authority subsequently determines that no liability for tax arose in respect of such payment, then the payee shall re-pay such additional amount to the applicable Participating Member State which made the aforementioned payment in satisfaction of the indemnification right under Article II.5.2.

## **II.6 LIABILITY**

**II.6.1** If required by relevant applicable Law, Contractor shall obtain required insurance against risks and damage or loss relating to the implementation of the APA (which, where permitted by Law, may include self-insurance) and upon request, Contractor must provide evidence of such insurance coverage to the Commission. In no event shall this Article II.6.1 or the existence of any such insurance be deemed to modify, amend, decrease, toll or otherwise adversely impact Contractor's rights under Article II.5.

**II.6.2** If a Third Party brings any action against the Commission or a Participating Member State in connection with the implementation of the APA, including any action for alleged breach of Intellectual Property Rights, Contractor must reasonably assist the Commission or the relevant Participating Member State.

## **II.7 CONFLICT OF INTEREST AND PROFESSIONAL CONFLICTING INTERESTS**

**II.7.1** Contractor must use reasonable commercial efforts to take the measures it considers reasonably necessary to prevent any situation of Conflict of Interest or Professional Conflicting Interest.

**II.7.2** Contractor must notify the Commission in writing as soon as possible of any situation that constitutes a Conflict of Interest or a Professional Conflicting Interest during the Implementation of the APA. Contractor must use commercially reasonable efforts to take action to rectify the situation as soon as possible.

The Commission may do any of the following (acting reasonably):

- (a) verify that Contractor's action is appropriate;
- (b) request Contractor to take further action within a specified deadline.

**II.7.3** Contractor shall ensure that:

- (a) its personnel;
- (b) any natural person with the power to represent it or take decisions on its behalf;



## **SENSITIVE**

- (c) third parties involved in the Implementation of the APA, including subcontractors, are informed of Contractor's undertaking under Article II.7.1.

Contractor shall use reasonable commercial efforts to ensure that the persons referred to above are not placed in a situation which could give rise to Conflicts of Interest.

### **II.8 CONFIDENTIALITY**

**II.8.1** The Commission and the Participating Member States shall treat Contractor's Confidential Information, and Contractor shall treat the Commission's and the Participating Member States' Confidential Information, as confidential and not disclose such Confidential Information except in accordance with the terms of this Article II.8.

**II.8.2** The receiving Party shall:

- (a) not use the disclosing Party's Confidential Information for any purpose other than to perform its obligations or exercise its rights under the APA, including a Vaccine Order Form, without the prior written agreement of the other Party;
- (b) ensure the protection of the disclosing Party's Confidential Information with the same level of protection as its own Confidential Information and in any case with due diligence;
- (c) not disclose, directly or indirectly, Confidential Information to third parties without the prior written agreement of the other Party; and provided that the receiving Party shall be responsible for actions and omissions of such third parties to whom Confidential Information is disclosed pursuant to this Article II.8.2(c), and shall be liable as if such actions or omissions were of the receiving Party.

**II.8.3** The confidentiality obligations set out in this Article II.8 are binding on the Commission, the Participating Member States and 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 becomes public, except as a result of the breach of this Article II.8;
- (c) the applicable Law requires the disclosure of the Confidential Information, including in the case of Contractor, a competent governmental authority, or the rules of any securities exchange to which Contractor or its Affiliates may be subject or under applicable securities Laws; provided that and subject to Article II.8.5 the receiving Party shall (a) unless prohibited by Law, promptly notify the disclosing Party prior to making such disclosure and limit such disclosure and, if permitted, provide the disclosing Party with an opportunity to intervene to protect its Confidential Information, including an opportunity to make representations to the relevant court or governmental authority (as applicable) objecting to disclosure, and (b) use reasonable efforts to obtain assurances that

## **SENSITIVE**

confidential treatment shall be accorded to the Confidential Information to be disclosed pursuant to this Article II.8.

**II.8.4** Notwithstanding Article II.8.2(c), Contractor may disclose the Commission's and Participating Member States' Confidential Information to its employees, consultants, agents, officers, advisers and other representatives, its Affiliates and sub-contractors, on a need to know basis solely for the purpose of performing its obligations and exercising its rights under this APA ("**Representatives**"), provided that such Representatives are subject to customary obligations of confidentiality.

**II.8.5** Neither Party shall issue any press release or make any other public statement disclosing the other Party's Confidential Information without the prior written consent of the disclosing Party, provided that Contractor or its Affiliates may issue any press release or other public statement required under the rules of any securities exchange to which Contractor or its Affiliates may be subject or applicable securities Laws.

### **II.8.6 Freedom of Information**

**II.8.6.1** Without prejudice to Article II.8.6.3, 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>2</sup>, which may require the European Institutions to disclose information to third parties on request.

**II.8.6.2** The Commission acknowledges and agrees that Contractor's Confidential Information (a) constitutes commercial, financial, scientific and/or technical information supplied to Commission in confidence, and (b) is competitively sensitive and proprietary information of Contractor that, if disclosed or otherwise made available to the public, would result in significant competitive prejudice and undue loss to Contractor and its Affiliates. Accordingly, Contractor reserves and relies upon all of its rights under any applicable freedom of information Laws, and the Commission shall assist Contractor in protecting Contractor's Confidential Information and take all other reasonable steps to prevent disclosure of any such Confidential Information under such applicable Laws.

**II.8.6.3** Notwithstanding Article II.8.3(c), in the event that any European Institution receives a request for information under Regulation (EC) 1049/2001, which may relate to Contractor's Confidential Information, prior to making any disclosure of such information it shall notify and consult with Contractor and shall allow Contractor a reasonable opportunity to make representations to such European Institution as to the applicability of any exemptions Contractor believes apply to such information under Regulation (EC) 1049/2001. The European Institutions shall give due consideration to those representations and shall give Contractor ten (10) business days' notice prior to any disclosure of information that contradict Contractor's representations.

## **II.9 PROCESSING OF PERSONAL DATA**

### **II.9.1 Processing of personal data by the Commission**

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<sup>2</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.

## **SENSITIVE**

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 Director-General of the 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).<sup>1</sup>

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 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.9.2 Processing of personal data by Contractor**

To the extent Contractor processes any personal data included in or relating to the APA, including its implementation, that is subject to Regulation (EU) 2018/1725, Contractor shall meet the requirements of Regulation (EU) 2018/1725 and process such personal data solely for the purposes set out by the data controller set out in Article II.9.1 above.

### **II.10 SUBCONTRACTING**

**II.10.1** Contractor may subcontract, perform its obligations and have the APA implemented by third parties, including its Affiliates.

**II.10.2** In the case of subcontracting, Contractor remains bound by its contractual obligations and is solely responsible for the Implementation of the APA.

**II.10.3** Contractor must ensure that the subcontract does not affect the rights of the Commission and the Participating Member States under this APA.

### **II.11 AMENDMENTS**

**II.11.1** Any amendment to the APA or a Vaccine Order Form must be made in writing before all contractual obligations have been fulfilled. A Vaccine Order Form does not constitute an amendment to the APA.

**II.11.2** No amendment can make changes to the APA or a Vaccine Order Form that might alter the initial conditions of the procurement procedure.

### **II.12 ASSIGNMENT**

**II.12.1** Contractor may not assign any of its obligations arising from the APA, without prior written authorisation from the Commission. In such cases, Contractor shall provide the Commission with the identity of the intended assignee. Other than with the written consent of Contractor and except as permitted under Article I.4.7, the Commission or any Participating Member State may not assign, transfer, mortgage, charge, or otherwise grant any other person any interest in, the whole or any part of the benefit of, or any of its rights or obligations or interests under, this APA.

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<sup>1</sup> Last accessed 6 October 2020.

## **SENSITIVE**

**II.12.2** Without prejudice to Article II.12.1 and except as permitted under Article I.4.7, any right or obligation assigned by the Commission or the Participating Member States, without authorisation from Contractor, is not enforceable against Contractor, and any obligation assigned by Contractor without authorization from the Commission, is not enforceable against the Commission.

### **II.13 INTELLECTUAL PROPERTY RIGHTS**

**II.13.1** Nothing in this APA shall grant either Party any rights to the other Party's Intellectual Property Rights. Under no circumstances does Contractor grant to the Commission, the Participating Member States, the Commission Experts, or to any third party by transfer, implication, estoppel or otherwise, any right, title, license or interest in any Intellectual Property Rights it or any of its Affiliates owns or controls in relation to, in connection with or resulting from the Vaccine Candidate, the COVID Vaccine or the Vaccine Volume.

### **II.14 FORCE MAJEURE**

**II.14.1** If a Party is affected by Force Majeure, it must immediately notify the other Party, stating the nature of the circumstances, their likely duration and foreseeable effects.

**II.14.2** 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 or the action(s) of a Third Party governmental entity. If Contractor is unable to fulfil its contractual obligations owing to Force Majeure or the action(s) of a Third Party governmental entity, it has the right to remuneration only for the services actually provided. If and to the extent that Contractor, its Affiliates or sub-contractors are prevented from performing any or all of their obligations under this APA because of any cause which arises from or is attributable to Force Majeure or the action(s) of a Third Party governmental entity, then Contractor shall be excused performance of its obligations to the extent and for the period required by such cause.

**II.14.3** The Parties must take all necessary measures to limit any damage due to Force Majeure.

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

#### **II.15.1 Suspension by Contractor**

**II.15.1.1** If Contractor is affected by Force Majeure, it may suspend performance of its obligations under the APA or a Vaccine Order Form.

**II.15.1.2** Contractor shall promptly notify the Commission of the suspension. The notification must include a description of the Force Majeure and state when Contractor expects to resume the performance of its obligations.

#### **II.15.2 Suspension by the Commission**

**II.15.2.1** The Commission may suspend the Implementation of the APA or Performance of a Vaccine Order Form or any part of it:

- (a) if the procedure for awarding the APA is proven to have been subject to Irregularities or Fraud;
- (b) in order to verify whether the presumed Irregularities, or Fraud have actually occurred.

**II.15.2.2** The Commission must Formally Notify 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.

**SENSITIVE**

**II.15.2.3** The Commission must notify Contractor as soon as the verification is completed whether:

- (a) it is lifting the suspension; or
- (b) it intends to terminate the APA or a Vaccine Order Form under Article II.16.1(e).

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

### **II.16.1 Grounds for termination by the Commission**

The Commission may terminate the APA, and a Participating Member State may terminate any ongoing Vaccine Order Form, in the following circumstances:

- (a) if Contractor is unable, to obtain Regulatory Approval by the Approval Long Stop Date;
- (b) if Contractor fails to comply with its material obligations under this APA (or, in respect of a Participating Member State's termination right, a Vaccine Order Form), [REDACTED]
- (c) if Contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation;<sup>4</sup>
- (d) if Contractor is in one of the situations provided for in points (c) to (h) of Article 136(1) or to Article 136(2) of the Financial Regulation;
- (e) if the procedure for awarding the APA is proven to have been subject to Irregularities, or Fraud;
- (f) if a change to Contractor's financial, or ownership situation substantially affects the Implementation of the APA or substantially modifies the conditions under which the APA was initially awarded or a change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046 that calls into question the decision to award the contract; or
- (g) in the event of Force Majeure, where resuming implementation of the APA (or, in respect of a Participating Member State's termination right, a Vaccine Order Form) is impossible.

### **II.16.2 Grounds for termination by Contractor**

Contractor may terminate the APA or any ongoing Vaccine Order Form in the following circumstances:

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

## **SENSITIVE**

- (a) if the Commission or the Participating Member State fails to comply with its material obligations under this APA or a Vaccine Order Form (in particular, the obligation to provide the information needed for Contractor to Implement the APA or to perform a Vaccine Order Form or any payment obligation under Article 1.6), and such failure is not remedied within ninety (90) calendar days (or, in case of failure to comply with any payment obligation under Article 1.6, thirty (30) calendar days);
- (b) if Contractor abandons its development program in respect of the Vaccine Candidate (including in case of inadequate safety profile);
- (c) if Contractor is unable to obtain Regulatory Approval by 31 December 2021 (the "Approval Long Stop Date"); or
- (d) in the event of Force Majeure, where resuming implementation of the APA or a Vaccine Order Form is impossible.

### **II.16.3 Procedure for termination**

**II.16.3.1** A Party must Formally Notify the other Party of its intention to terminate the APA or a Vaccine Order Form and of the grounds for such termination.

### **II.16.4 Effects of termination**

**II.16.4.1** On termination or expiry of this APA, each Party shall promptly:

- (a) return to the other Party all equipment, materials and property belonging to the other Party that the other Party had supplied to it in connection with the purchase of the Vaccine Volume under or in connection with this APA;
- (b) erase all the other Party's Confidential Information from its computer systems (to the extent possible); and
- (c) on request, certify in writing to the other Party that it has complied with its obligations under this Article II.16.4.

**II.16.4.2** Termination or expiry of this APA shall not affect any rights, remedies, obligations or liabilities of the Parties that have accrued up to the date of termination or expiry, including the right to claim damages in respect of any breach of this APA which existed at or before the date of termination or expiry.

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

**II.17.1** Invoices must contain Contractor's identification data, the amount, the currency and the date, as well as the APA reference and reference to the Vaccine Order Form (to the extent relevant).

**II.17.2** Invoices must indicate the place of taxation of Contractor for value added tax (VAT) purposes and must specify separately amounts not including VAT and amounts including VAT.

## **II.18 PAYMENTS AND GUARANTEES**

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

## **SENSITIVE**

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

### **II.18.2 Currency**

Payments are made as set out in Article I.6.7.

### **II.18.3 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) 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.18.4 Suspension of the time allowed for payment**

**II.18.4.1** If applicable, the Commission or the Participating Member State in question may, acting reasonably, suspend the payment periods specified in Article I.6 at any time by notifying Contractor that the invoice which relates to such payment cannot be processed. The reasons the Commission or the Participating Member State in question may cite for not being able to process an invoice are only because it does not comply with the APA.

**II.18.4.2** The Commission or the Participating Member State in question must notify Contractor immediately of any such suspension, giving the reasons for it.

**II.18.4.3** 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 or the necessary further verification, including on-the-spot checks, is carried out. Where the suspension period exceeds two months, Contractor may request the Commission or the Participating Member State in question to justify the continued suspension.

### **II.18.5 Interest on late payment**

**II.18.5.1** On expiry of the payment periods specified in Article I.6, Contractor, without limiting any of Contractor's remedies, is entitled to interest on late payment at the rate applied by the European Central Bank for its main refinancing operations in euros (the reference rate) plus five points. The reference rate is the rate in force, as published in the C series of the *Official Journal of the European Union*, on the first day of the month in which the payment period ends.

**II.18.5.2** Suspension of the payment period as provided for in Article II.18.4 is not considered as giving rise to late payment.

**II.18.5.3** 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 CHECKS AND AUDITS**

**II.19.1** The Commission and the European Anti-Fraud Office may check or require an audit on the Implementation of the APA. This may be carried out either by Anti-Fraud Office's own staff or by any outside body authorised to do so on its behalf.

## **SENSITIVE**

Such checks and audits may be initiated at any moment during the provision of the services 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 and require appropriate confidentiality arrangements being put in place to ensure the confidential treatment of Contractor's information.

**II.19.2** Contractor must keep all original documents stored on any appropriate medium, including digitised originals if authorised under national law, for a period of five years starting from the payment of the balance of the last Vaccine Order Form issued under this APA.

**II.19.3** Contractor must grant the appropriate right of access to sites and premises where the APA is implemented and to all the information, including information in electronic format, needed to conduct such checks and audits, subject to appropriate confidentiality arrangements being put in place, it being understood that right of access shall be limited to those representatives of the Commission and the European Anti-Fraud Office who strictly require such access. Contractor must ensure that the information is readily available at the moment of the check or audit and, if so requested, that information is handed over in an appropriate format.

**II.19.4** 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 Contractor, who has 30 days following the date of receipt to submit observations. Contractor must receive the final report within 60 days following the expiry of the deadline to submit observations.

**II.19.5** In accordance with Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against Fraud and other Irregularities and Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office, the European Anti-Fraud Office may carry out investigations, including on the spot checks and inspections, to establish whether there has been Fraud, corruption or any other illegal activity under the contract affecting the financial interests of the 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 services and up to five years starting from the payment of the balance of the last Vaccine Order Form issued under this APA.

**II.19.6** The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939<sup>5</sup> have the same rights as the Commission, particularly right of access, for the purpose of checks, audits and investigations.

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



**SENSITIVE**

## **ANNEX I**

### **Definitions, Interpretation and Exhibits**

#### **ALL DEFINITIONS**

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

**"Additional Volume"** has the meaning given to it in Article I.4.1.2;

**"Additional Volume Commitment"** has the meaning given to it in Article I.4.1.2;

**"Adverse Events Following Immunisation"** shall mean any untoward medical occurrence in a patient or a clinical-trial subject following immunisation, which does not necessarily have a causal relationship with usage of the COVID Vaccine. An Adverse Event Following Immunisation can therefore be any unfavourable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this medicinal product;

**"Affiliate"** means, with respect to Contractor, any person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with Contractor. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means:

- (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or
- (b) the ownership, directly or indirectly, of at least fifty per cent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

**"Allocation"** means the allocation of the Vaccine Volume, by the Commission as between the Participating Member States (in respect of the Base Volume Commitment) or, as the case may be, the Exercising Member States (in respect of any Additional Volume Commitment), in accordance with Article I.4.8.1. **"Allocated"** shall be construed accordingly;

**"APA"** means this Advance Purchase Agreement, as amended, supplemented, replaced or novated from time to time in accordance with its terms and conditions;

**"Approval Long Stop Date"** has the meaning given to it in Article II.16.2(c);

**"Authority"** means any national, regional, provincial, or territorial authority, state, canton, governmental community or entity, county, city, town, municipality, district, local government, or subnational component of the European Union or the Participating Member States, including any department, ministry, agency, or other organizational unit thereof;

**"Availability"** means Vaccine Volume at Contractor's central warehouse, quality released by Contractor prior to shipment and Delivery to the Participating Member States; and the terms **"Available"** and **"made Available"** (or any similar construct) shall be construed accordingly;

**"Base Down Payment"** has the meaning given to it in Article I.6.1.1(a);

**"Base Order Form Deadline"** has the meaning given to it in Article I.4.4.1;

**"Base Volume Commitment"** has the meaning given to it in Article I.4.1.1;

**"Buying PMS"** has the meaning given to it in Article I.4.7.1;

**"Claim"** has the meaning given to it in Article II.5.4;

**"Cold Chain"** means, in relation to Vaccine Volume, temperature-controlled such that the temperatures to which such Vaccine Volume are exposed are within the range of 2°C to 8°C;

**"Commission Experts"** has the meaning given to it in Article I.10.2.1;

**"Confidential Information"** means any information or document received by either Party from the other, or accessed by either Party, in the context of and/or related to the APA, including the text of this APA, the negotiation thereof and Implementation of the APA. Confidential Information does not include information or documents which (i) are already lawfully possessed by the receiving Party without any obligations of confidentiality or restrictions on use prior to receiving it from the disclosing Party (whether before, on or after the Effective Date), as documented by prior written records; (ii) is obtained subsequently by the receiving Party from a Third Party, which Third Party is not itself subject to any obligations of confidentiality, or (iii) has been developed by the receiving Party independently of any access to or use of any Confidential Information disclosed hereunder, as documented by the receiving Party's written records. Notwithstanding the foregoing all information that was provided or to be provided by Contractor to the Commission or Participating Member States with regard to the Vaccine Candidate, COVID Vaccines and/or Vaccine Volume, shall be deemed Contractor's Confidential Information;

**"Conflict of Interest"** means a situation where the impartial and objective Implementation of the APA by 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 Vaccine"** means the final drug product form of the Vaccine Candidate, the substance of which has received Regulatory Approval;

**"Credit"** has the meaning given to it in Article I.6.2;

**"Delivery"** means, in respect of any quantity of Vaccine Volume, delivery of that Vaccine Volume by Contractor to the Participating Member States in accordance with the requirements of Article I.4.5, and the terms **"Deliver"** and **"Delivered"** shall be construed accordingly;

**"Delivery Address"** means a single central location (warehouse) for Delivery in each Participating Member State to be communicated by each Participating Member State to Contractor in its Vaccine Order Form;

**"Dispute"** has the meaning given to it in Article I.9.2.1;

**"Down Payments"** has the meaning given to it in Article I.6.1.4;

**"Effective Date"** means the date on which the last Party signs this APA;

**"EMA"** means the European Medicines Agency, or any successor agency thereto;

**“European Institutions”** has the meaning given to it in Article II.8.6;

**“Exercising Member States”** has the meaning given to it in Article I.4.1.2;

**“Expected Approval Date”** has the meaning given to it in Article I.4.5.1;

**“Final Availability Schedule”** has the meaning given to it in Article I.4.5.1;

**“First Further Down Payment”** has the meaning given to it in Article I.6.1.2;

**“First Option Deadline”** has the meaning given to it in Article I.4.1.2;

**“Force Majeure”** means any unforeseeable, exceptional situation or event beyond the control of a Party that prevents such Party from fulfilling any of its obligations under the APA (including, acts of god or nature, war, riot, civil commotion, inability of Contractor and/or its Affiliates to operate manufacturing or development activities (including due to lack of staff as a consequence of a disease, fire, flood or storm)). The situation or event must not be attributable to error or negligence on the part of the Party or on the part of the subcontractors and must prove to be inevitable despite their exercising due diligence;

**“Formal Notification”** (or **“Formally Notify”**) means a form of communication between the Parties made in writing by mail or email, which provides the sender with compelling evidence that the message was delivered to the specified recipient;

**“Fraud”** means an act or omission committed wilfully 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 European 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;

**“Further Vaccine Volume”** has the meaning given to it in Article I.4.1.3;

**“Global Not-for-Profit Framework”** has the meaning given to it in Article I.5.2.1;

**“GMO”** has the meaning given in Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC;

**“GMP”** means the good practices for manufacturing required by the standards, rules, principles and guidelines set out in Directive 2001/83/EC (as amended by Directive 2004/27/EC), Directive 2003/94/EC 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”, in each case as applicable to and at the time of manufacture of the COVID Vaccine;

**“Good Distribution Practices”** means current good distribution practices for medicinal products, as applicable, as set forth in the EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01), as amended and revised from time to time;

**"Implementation of the APA"** means the purchase and making Available of Vaccine Volume envisaged in the APA through the Performance of Vaccine Order Forms. **"Implement the APA"** shall be construed accordingly;

**"Indemnified Persons"** has the meaning given to it in Article II.5.2;

**"Initial Down Payment"** has the meaning given to it in Article I.6.1.1;

**"Intellectual Property Rights"** means patents, utility models, rights to inventions, copyright and neighbouring and related rights, moral rights, trademarks and service marks, business names and domain names, rights in get-up and trade dress, goodwill and the right to sue for passing off or unfair competition, rights in designs, rights in computer software, database rights, rights to use, and protect the confidentiality of, Confidential Information (including know-how and trade secrets) and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world;

**"Irregularities"** means any material infringement of a provision of Union law resulting from an act or omission by Contractor committed by Contractor with the intention to infringe a provision of Union law, which has the effect of materially prejudicing the Union 's budget;

**"Law"** means all civil codes, statutes, regulations, rules of common law, judgments, decrees or orders of any governmental, administrative, supervisory, regulatory or determinative authority, agency, court or other organisation of any jurisdiction, in each case which is established by, or having the authority of, law, and other measures or decisions having the force of law in any jurisdiction from time to time;

**"Losses"** has the meaning given to it in Article II.5.2;

**"Non-PMS"** has the meaning given to it in Article I.4.7.1;

**"OCABR"** means the Control Authority Batch Release;

**"OMCLs"** means the Official Medicines Control Laboratories;

**"Option Exercise Notice"** has the meaning given to it in Article I.4.1.2;

**"Performance of a Vaccine Order Form"** means the making Available of the purchased portion of Vaccine Volume by Contractor to the relevant Participating Member State;

**"PMS Experts"** has the meaning given to it in Article I.10.2.1;

**"Price"** has the meaning given to it in Article I.5.1;

**"Price Balance"** has the meaning given to it in Article I.6.2;

**"Professional Conflicting Interest"** means a situation in which Contractor's ongoing professional activities affect its capacity to implement the APA or to perform a Vaccine Order Form;

## SENSITIVE

**"Purpose"** means use of the Vaccine Volume by the Participating Member States to vaccinate individuals in the Territory, directly (through the Participating Member States) or indirectly (including through a Third Party engaged by the Participating Member State), against COVID-19 during the emergency pandemic response period in accordance with this APA and subject to Article 1.4.7 (*Resale and Donation*), it being understood that in no event shall the Vaccine Volume be used after the Vaccine Expiry Date;

**"Regulatory Approval"** means regulatory approval (conditional or otherwise) for the legal marketing, importation, distribution, sale, administration and use of the Vaccine Candidate in the European Economic Area (excluding the United Kingdom) granted or issued by the Commission pursuant to Regulation (EC) No 726/2004, Directive 2001/83/EC and regulations applicable thereunder;

**"Regulatory Authority"** means the Commission, the European Medicines Agency, OMCLs and the competent authorities of the Participating Member States, or any successor agencies thereto;

**"Relevant Additional Order Form Deadline"** has the meaning given to it in Article 1.4.4.1;

**"Representatives"** has the meaning given to it in Article 11.8.4.

**"Reservation Fee"** has the meaning given to it in Article 1.6.1.1(b);

**"Residence"** has the meaning given to it in Article 11.5.2(b)(2);

**"Second Further Down Payment"** has the meaning given to it in Article 1.6.1.3;

**"Second Option Deadline"** has the meaning given to it in Article 1.4.1.2;

**"Special Situations"** shall mean any special situation, including but not limited to reports of exposure during pregnancy or breastfeeding, overdose, abuse and misuse, medication errors, suspected transmission of any infectious agents, outside of label use, occupational exposure, inadvertent or accidental exposure, failure of expected pharmacological action, unexpected therapeutic or clinical benefit, expired drug use and falsified medicine;

**"Specifications"** means any of the sets of release specifications for Vaccine Volume, as provided by Contractor to the Participating Member States from time to time;

**"Tentative Availability Schedule"** means the Tentative Availability Schedule for the Vaccine Volume as set out in Exhibit A;

**"Territory"** means, with respect to the Participating Member States, the territories of such Participating Member States;

**"Third Party"** means any person other than the Commission, Participating Member States, Contractor, or Contractor's Affiliates, or the Authorities and the Commission Experts;

**"Unspent Amounts"** has the meaning given to it in Article 1.6.4;

**"Vaccinated Individual"** means any individual who has been administered the COVID Vaccine (or, as the case may be, any individual, group, entity or organization purporting to represent, act on behalf of, recover for or in respect of, or seek damages with respect to, any such individual or group of such individuals);

**"Vaccine Candidate"** means Contractor's investigational SARS-CoV-2 vaccine, Ad26.COV2-S, recombinant;

## SENSITIVE

**“Vaccine Expiry Date”** means the date on which the shelf life of the COVID Vaccine ends;

**“Vaccine Order Form”** means the purchase order issued by a Participating Member State to Contractor for the purchase of its Allocated portion of the Vaccine Volume under the framework of the APA, which shall be in the form attached as (and contain the information set out in) Annex II;

**“Vaccine Regimen”** means, with respect to the COVID Vaccine, either (i) two separate injections of up to  $1 \times 10^{11}$  viral particles (two doses, given with a time interval of a few weeks) or (ii) one single injection of up to  $1 \times 10^{11}$  viral particles (one dose);

**“Vaccine Volume”** means the Base Volume Commitment, and, if the Commission has exercised the Option Exercise Notice(s) in accordance with 1.4.1.2, the Additional Volume Commitment(s);



### A1.2. INTERPRETATION

Unless the context otherwise requires, the following rules of interpretation shall apply to this APA:

- (a) words in the singular include the plural and in the plural include the singular;
- (b) use of any gender or neuter includes the other genders and neuter;
- (c) references to a particular statute or statutory provision or other Law shall:
  - (i) include all subordinate legislation made from time to time under that statute, statutory provision or other Law; and
  - (ii) be construed as a reference to such Law as amended, re-enacted, consolidated, supplemented, replaced or renumbered (or as its application or interpretation is changed or affected by other Laws) from time to time and as was, is, or will be (as the case may be) applicable at the time in question;
- (d) references to “Articles” and “Exhibits” are to Articles of, and exhibits to, this APA;
- (e) references to a “day” shall mean a period of twenty four (24) hours running from midnight to midnight and reference to any time or date shall, save where otherwise expressly stated to the contrary, be a reference to the time or date (as the case may be) in Brussels, Belgium;
- (f) references to a “person” shall be construed so as to include:
  - (i) any individual, firm, body corporate, regulatory authority (including any Regulatory Authority), other governmental authorities, joint venture, association, undertaking, partnership or limited partnership (whether or not having separate legal personality); and
  - (ii) a reference to the estate, successors, permitted transferees and permitted assignees of any of such person;

## **SENSITIVE**

(g) the words "include", "including" or "in particular" shall not limit the generality of any preceding words or be construed as being limited to the same class as any preceding words where a wider construction is possible; and

(h) references to "written" or "writing" shall include all data in written form in the English language, whether represented in hand-written, facsimile, printed, electronic or other format (including e-mail, but excluding short-message-service (SMS)).

**SENSITIVE**

**EXHIBIT A**  
**Tentative Availability Schedule**


Based on current assumptions (certain of which are outlined below), Contractor tentatively expects to be able to make Available to the Participating Member States allocations of the Vaccine Volume after grant of the Regulatory Approval as follows:

**(a) Base Volume Commitment**



Contractor is scaling up manufacturing capacity in various European Member States with a view to make available Vaccine Volume from its European manufacturing sites. The Commission and the Participating Member States acknowledge and agree that Contractor will rely on additional capacity established (and to be established) within Contractor's worldwide manufacturing network, in order to support availability of Vaccine Volume under this APA. This applies in particular to the activities in the United States that would in the current plans enable Contractor to provide Vaccine Volume during the initial Deliveries (anticipated to continue until approx. July 2021). Contractor will inform the Commission if other manufacturing capacity outside the European Union Member States will be required for making available the Vaccine Volume.

**(h) Additional Volume Commitment**

 Expected fiscal quarter of Availability and number of Vaccine Regimens per quarter will be communicated by Contractor at the time of exercise of the optional tranches.

**Notes and Assumptions:**

- Commencement of Delivery is dependent on granting or issuance of Regulatory Approval as well as on the local quality release of Vaccine Volume by local competent authorities, and is based on current expectation of timing for granting of Regulatory Approval and process and timing for local quality release of Vaccine Volume by local competent authorities. Should individual jurisdictions obtain regulatory approval prior to or later than the current assumption or should the current expectations regarding process and timing for local quality release of Vaccine Volume by local competent authorities prove to be incorrect, the foregoing allocation may change.
- The foregoing assumes that all contemplated Contractor manufacturing capacity produces at expected volumes and that the jurisdictions of production allow free export of the Vaccine Volume. Should one or more facilities (or portions thereof) fail to come online as expected or should there be any issues with export or transport, this allocation may change.
- The timing reflected in the above table assumes that the Vaccine Volume will be released for sale based solely on Contractor's standard requirements. If importation or sale of the Vaccine



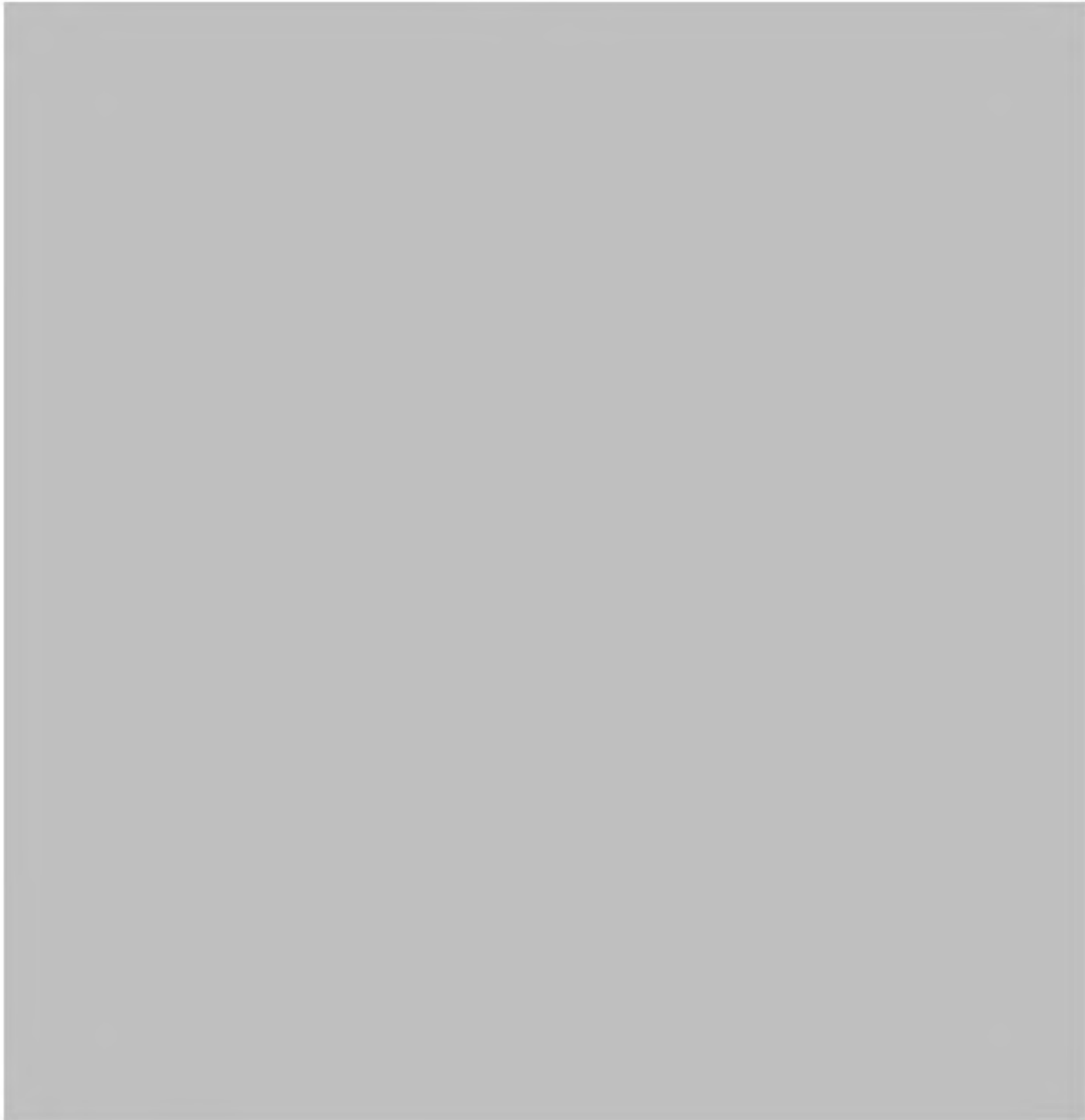
## **SENSITIVE**

Volume is subject to local release testing or other requirements that are in addition to Contractor's standard requirements, Delivery of the Vaccine Volume may take longer than the Availability schedule set forth above.

- Final dose and administration schedule will be determined in clinical studies. If concentration and/or dosing and/or administration schedule changes, this allocation may change.

**SENSITIVE**

**EXHIBIT B**  
**PAYMENT SCHEDULE**



**Base Volume Commitment to consist of a total of 200 million Vaccine Regimens**  
**Each Additional Volume Commitment to consist of a total of up to 100 million Vaccine Regimens**

**SENSITIVE**

**EXHIBIT C**

**OPTION EXERCISE NOTICE TEMPLATE**

***[COMMISSION LETTER HEAD]***

***[Janssen address]***

***[Date]***

Dear **[JANSSEN CONTACT]**,

**[[First] OR [Second]] Option Exercise Notice for Additional Volume Commitment**

We refer to the Advance Purchase Agreement between us dated [●] 2020 ("APA") for the SARS-CoV-2 vaccine. Capitalized terms not defined in this letter shall have the meaning given to them in the APA.

We hereby serve the binding [[First] OR [Second]] Option Exercise Notice for the purchase by the Exercising Member States of the Additional Volume Commitment at the Price [REDACTED] pursuant to Article 1.4.1.2 of the APA.

This Option Exercise Notice relates to the purchase by the Exercising Member States of [●] Vaccine Regimens.<sup>6</sup> Such [●] Vaccine Regimens shall be Allocated between the Exercising Member States as follows:

*[Insert Allocation (as per requirements of the APA (see format in Exhibit E))]*

As between the Exercising Member States, the responsibility for the payment of the [[First] OR [Second]] Further Down Payment shall be as follows:

*[Insert payment responsibilities (including [REDACTED] amount of payment responsibility for each Exercising Member State (see format in Exhibit E))]*

This [[First] OR [Second]] Option Exercise Notice constitutes a binding offer by the Exercising Member States for the purchase of the Additional Volume Commitment under the APA and the terms of the APA shall govern each Party's and Exercising Member States' obligations with respect thereto.

Yours sincerely,

***[Signature]***

***[Name]***

***[Role]***

By signing this [[First] OR [Second]] Option Exercise Notice, I represent and warrant to Janssen Pharmaceutica NV that I have the requisite power and authority and the legal right to serve this [[First] OR [Second]] Option Exercise Notice on behalf of the Exercising Member States to purchase the Additional Volume Commitment in accordance with the APA.

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<sup>6</sup> Note to Option Exercise Notice: this figure must be 25, 50, 75 or 100 million.

**SENSITIVE****EXHIBIT D****Non-conforming Vaccine Volume**

**Section 1.01. Defective COVID Vaccine.** Without prejudice to Article 111 of Directive 2001/83/EC, all COVID Vaccine Delivered to a Participating Member State under this APA may be inspected by such Participating Member State by means of (i) a customary visual inspection of the shipment (without opening secondary packaging) and (ii) by consulting the certificate of analysis accompanying such COVID Vaccine. If any of such inspections referenced above under (i) and (ii) reveal that any COVID Vaccine Delivered to a Participating Member State does not meet the Specifications (any such COVID Vaccine, the “**Nonconforming COVID Vaccine**”), such Participating Member State may reject such Nonconforming COVID Vaccine by delivering a written notice (a “**Rejection Notice**”) to Contractor describing, in reasonable detail, the alleged nonconformity and, if requested by Contractor, providing sample(s) of the alleged Nonconforming COVID Vaccine. If the Participating Member State does not deliver a Rejection Notice within (a) in the case of a visible defect, five (5) business days after Participating Member State’s Delivery of such COVID Vaccine or (b) in the case of a defect not detectable through initial customary visual inspection, within ten (10) business days after the date the Participating Member State discovered or should have reasonably discovered such nonconformity, the received COVID Vaccine shall be deemed to be in compliance with the Specifications and accepted by the Participating Member State. This is without prejudice to the Contractor’s obligations under GDP and GMP as further described in the APA and Article 114 of Directive 2001/83 up until Delivery.

**Section 1.02. Contractor’s Right to Verify Nonconforming COVID Vaccine.** Following receipt of a Rejection Notice pursuant Section 1.01 above, Contractor will have ten (10) business days to inspect the Nonconforming COVID Vaccine and make a reasonable assessment of the alleged nonconformance, provided that the Participating Member State has provided Contractor appropriate sample(s) of the Nonconforming COVID Vaccine or such other reasonably available evidence Contractor may reasonably specify. If Contractor agrees that any Delivery contains Nonconforming COVID Vaccine and that such non-conformance was caused by Contractor or any of Contractor’s suppliers or subcontractors, Contractor shall

**Section 1.03. Disagreements Regarding Nonconforming COVID Vaccine.**

(a) **Independent Third Party Laboratory.** If Contractor disagrees with a Participating Member State’s determination that certain COVID Vaccine Delivered is a Nonconforming COVID Vaccine, then Contractor shall promptly notify the Participating Member State thereof and, if the Parties continue to be in disagreement after a ten (10) business days period following delivery of such notice and the Participating Member State still alleges that such COVID Vaccine Delivered, as applicable, is Nonconforming COVID Vaccine, then sample(s) of such COVID Vaccine Delivered may be submitted for testing to a qualified independent Third Party laboratory mutually agreed to by Contractor and the Participating Member State (“**Third Party Lab**”), for analytical testing to verify the COVID Vaccine Delivered conformance to the Specifications.

(b) **Verification Process.** Without prejudice to Article 1.9 of the APA, the parties agree to submit to a Third Party Lab for verification whether all or part of such COVID Vaccine Delivered is a Nonconforming COVID Vaccine. All costs, fees and expenses of the Third Party Lab testing, as well as any freight and disposition costs of COVID Vaccine and samples sent to the Third Party Lab, and related costs (collectively, “**Third Party Lab Fees**”), shall be paid as follows:

(i) In the event the Third Party Lab determines the COVID Vaccine Delivered not to be Nonconforming COVID Vaccine, (a) all Third Party Lab Fees shall be paid by

**SENSITIVE**

the Participating Member State and (b) the Participating Member State shall accept the applicable Delivery of and, if it has not already done so, pay the applicable Price for such COVID Vaccine, as applicable.

(ii) In the event the Third Party Lab determines the COVID Vaccine Delivered to be Nonconforming COVID Vaccine and such laboratory determines that such non-conformance was caused by Contractor prior to the Delivery of the relevant COVID Vaccine to Participating Member State, (a) all Third Party Lab Fees shall be paid by Contractor and (b) Contractor shall, at Contractor's election,

(iii) In the event the Third Party Lab cannot determine if the COVID Vaccine Delivered is a Nonconforming COVID Vaccine or determines the COVID Vaccine Delivered is a Nonconforming COVID Vaccine but cannot determine the cause of such non-conformance, then (a) all such Third Party Lab Fees shall be equally borne by the Participating Member State and Contractor, and (b) the Participating Member State and Contractor shall attempt to resolve the matter amicably within a period of 15 calendar days and, if they fail to do so, the matter shall be handled in accordance with Article 19.2 of the APA.

(iv) In the event the Third Party Lab determines (i) the COVID Vaccine Delivered to be Nonconforming COVID Vaccine and (ii) such non-conformance was caused by (a) Participating Member State or any of Participating Member State's contractors, or (b) improper handling after the Delivery, then (x) all Third Party Lab Fees shall be borne by Participating Member State and (y) Participating Member State shall accept the Delivery of and, if it has not already done so, pay the Price for such COVID Vaccine, as applicable.

**Section 1.04. Handling of Rejected COVID Vaccine.** Participating Member State shall not destroy any allegedly Nonconforming COVID Vaccine until (i) it receives written notification from Contractor that Contractor does not dispute that the COVID Vaccine Delivered is Nonconforming COVID Vaccine; (ii) following completion of the verification process set forth in Section 1.03(b), where such COVID Vaccine Delivered is determined by the Third Party Lab to be Nonconforming COVID Vaccine and (A) it receives written notification from Contractor that Contractor does not desire return of such Nonconforming COVID Vaccine, (B) it receives written authorization from Contractor to destroy such Nonconforming COVID Vaccine, or (C) it receives no notice, authorization or other instruction from Contractor regarding such Nonconforming COVID Vaccine within ten (10) business days following such completion of the verification process pursuant to Section 1.03(b); or (iii) following completion of the verification process set forth in Section 1.03(b), where the COVID Vaccine Delivered is determined by the Third Party Lab not to be Nonconforming COVID Vaccine, it elects to do so in its sole discretion. Upon the occurrence of any of the foregoing events under (i) through (iii), Participating Member State shall destroy or have destroyed such Nonconforming COVID Vaccine promptly and provide Contractor with certification of such destruction. The expense of such destruction including additional storage expenses shall be borne (1) by Contractor in the event that Contractor does not dispute that the COVID Vaccine is Nonconforming COVID Vaccine or (2) in the event the Parties resort to the verification process, by the party as described in Section 1.03(b).

**Section 1.05. Recalls.**


(a) In the event of an actual or threatened Recall of COVID Vaccine required or recommended by a Regulatory Authority within the Territory, or if a Recall of COVID Vaccine is reasonably deemed advisable by Participating Member State, or jointly deemed advisable by Contractor and Participating Member State due to the COVID Vaccine subject to the Recall is determined to be a Nonconforming COVID Vaccine pursuant Sections 1.01 to 1.03 above, such Recall shall be promptly implemented and administered by Participating Member State in a manner which is appropriate and

## SENSITIVE

reasonable under the circumstances and in conformity with applicable regulatory requirements. Contractor shall assist Participating Member State as requested by Participating Member State to ensure a timely, accurate and complete Recall.

(b) Contractor and Participating Member State shall keep each other fully and promptly informed of any notification, event or other information, whether received directly or indirectly, which might reasonably affect the marketability, safety or effectiveness of COVID Vaccine or might reasonably result in a Recall of COVID Vaccine by a Regulatory Authority.

(c) In the event of any Recall, other than to the extent caused by Participating Member State's, Participating Member State Third Party's or Participating Member State customers' handling of the COVID Vaccines following the Delivery thereof, Contractor shall, at the election of Contractor, either



(d) In the event of any Recall caused by Participating Member State's, Participating Member State Third Party's or Participating Member State customers' handling of the COVID Vaccines following the Delivery thereof, Participating Member State shall pay Contractor's reasonable out-of-pocket expenses incurred in connection with such Recall in accordance with this Section.

For the purpose of this Section 1.05, and without prejudice to the provisions contained in Article 47 of the Directive 2001/83, "Recall" means a recall, correction or market withdrawal relating to COVID Vaccine and shall include any post-sale warning or mailing of information.

**SENSITIVE****EXHIBIT E****Form of Allocation Table****I. Form allocation table for the Base Volume Commitment**

#	Participating Member State	Vaccine Volume	% of Base Volume Commitment
1.	Austria	[•] million Vaccine Regimens	[•] %
2.	Belgium		
3.	Croatia		
4.	Republic of Cyprus		
5.	Czech Republic		
6.	Denmark		
7.	Estonia		
8.	Finland		
9.	France		
10.	Germany		
11.	Greece		
12.	Hungary		
13.	Ireland		
14.	Italy		
15.	Latvia		
16.	Lithuania		
17.	Luxembourg		
18.	Malta		
19.	Netherlands		
20.	Poland		
21.	Portugal		
22.	Romania		
23.	Slovakia		
24.	Slovenia		
25.	Spain		
26.	Sweden		
	<b>TOTAL</b>	<b>200 million Vaccine Regimens</b>	<b>100 %</b>

**SENSITIVE**

## II. Form allocation table for the First and second Additional Volume Commitments

#	Exercising Member State	Vaccine Volume		[First / Second] Further Down Payment	
		Number of Vaccine Regimens	% of [first/second] Additional Volume Commitment	Amount (per Vaccine Regimen)	% of [First/Second] Further Down Payment
1.	Austria	[•] million Vaccine Regimens	[•] %	[•]	[•] %
2.	Belgium				
3.	Croatia				
4.	Rep. of Cyprus				
5.	Czech Republic				
6.	Denmark				
7.	Estonia				
8.	Finland				
9.	France				
10.	Germany				
11.	Greece				
12.	Hungary				
13.	Ireland				
14.	Italy				
15.	Latvia				
16.	Lithuania				
17.	Luxembourg				
18.	Malta				
19.	Netherlands				
20.	Poland				
21.	Portugal				
22.	Romania				
23.	Slovakia				
24.	Slovenia				
25.	Spain				
26.	Sweden				
	<b>TOTAL</b>		<b>100 %</b>		<b>100 %</b>



**SENSITIVE****EXHIBIT F****Quality requirements**

The table below defines the roles and responsibilities between Contractor and the Participating Member States (for the purpose of this Exhibit F, the "PMS") with respect to compliance with applicable quality assurance requirements in respect of the Vaccine Volume and the COVID Vaccine.

<b>1. Notification</b>	<b>Contractor</b>	<b>PMS</b>
Promptly notify Contractor about any regulatory inspections related to COVID Vaccine, while under its control, including observations and actions taken to mitigate those observations.		X
Promptly communicate any untoward incident that occurs after Delivery and while COVID Vaccine is under its control and that impacts COVID Vaccine safety, quality or compliance.		X
Notify Contractor of any instance of suspected counterfeit, tampered or diverted COVID Vaccine within 24h of awareness		X
<b>2. Permits &amp; Regulatory Requirements</b>	<b>Contractor</b>	<b>PMS</b>
Have and maintain or ensure that its contractors have and maintain all necessary licenses, regulatory approvals and certificates required by competent authorities to perform all activities under its control with the COVID Vaccine up until Delivery.	X	
Comply and ensure that its contractors comply with all laws, regulations and policies applicable to the activities performed under its control with COVID Vaccine up until Delivery, including Good Distribution Practices and GMP	X	
Have and maintain or ensure that its contractors have and maintain all necessary licenses, regulatory approvals and certificates required by competent authorities to perform all activities under its control with the COVID Vaccine after Delivery, including but not limited to the receipt, storage, distribution, transport and handling thereof.		X
Comply and ensure that its contractors comply with all laws, regulations and policies applicable to the activities performed under its control with COVID Vaccine after Delivery, including Good Distribution Practices and GMP		X
Ensure distribution of the COVID Vaccine from Delivery up only to entities that have the required licenses, regulatory approvals and certificates as applicable.		X
Unless otherwise authorized by Contractor, ensure that from Delivery up until administration the COVID Vaccine remains in the same form of primary and/or secondary packages as originally Delivered by Contractor without altering the product, nor remove, deface, tamper the primary and/or secondary packages of the COVID Vaccine or affix any logo or words to the product or their primary and/or secondary packages that overwrite or destroy the product lot traceability and product information.		X
Do not sell, trade or donate any expired COVID Vaccine to anyone. Expired COVID Vaccine are not to be used as sales samples		X
<b>3. Facilities and Equipment</b>	<b>Contractor</b>	<b>PMS</b>
Ensure sufficient space, suitable and adequate premises, installations and equipment, so as to ensure proper storage and handling of the Vaccine Volume according to specifications at all times. Premises and facilities must comply with all regulations for performing all agreed activities, including Good Distribution Practices.		X


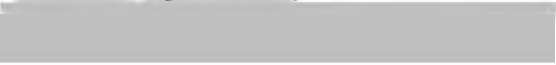

**SENSITIVE**

<b>4. Field Actions</b>	<b>Contractor</b>	<b>PMS</b>
Provide final decision and authority to initiate any field action.	X	
Provide all communications to the competent authority related to field actions.	X	
Assist, adhere to and execute all requested actions from Contractor in a timely manner related to field actions.		X
<b>5. Cold Chain</b>	<b>Contractor</b>	<b>PMS</b>
Ensure that any and all of its contractors involved in receiving, handling, storage, delivery and similar actions with the COVID Vaccine have appropriate procedures in place to handle cold chain products. These procedures shall include handling temperature excursion that may occur		X

## ANNEX II

## Model For Vaccine Order Form

### EXPLANATORY NOTE

- **Who shall send a Vaccine Order Form?**
- Each Participating Member State shall send to Contractor one duly completed and signed Vaccine Order Form in paper format (by registered mail) and in electronic format (PDF by e-mail) for its Allocated portion of the **Base** Volume Commitment (such portion is as communicated by the Commission to Contractor pursuant to Article 1.4.8.1(a) of the APA).
  - **By when (deadline)?** No later than 30 December 2020 (Article 1.4.4.1 of the APA).
  - **What is each Participating Member States' allocated portion?** Please contact the Commission, who is responsible for allocating the Base Volume Commitment among the Participating Member States.
- Each Exercising Member State shall send to Contractor one duly completed and signed Vaccine Order Form in paper format (by registered mail) and in electronic format (PDF by e-mail) for its Allocated portion of each of the **Additional** Volume Commitments (such portion is as communicated by the Commission to Contractor pursuant to Article 1.4.8.1(b)(1) of the APA).
  - **By when (deadline)?** No later than 15 calendar days after the date of the relevant Option Exercise Notice provided by the Commission to Contractor (Article 1.4.4.1 APA).
  - **What is each Exercising Member States' allocated portion?** Please contact the Commission, who is responsible for allocating each Additional Volume Commitment among the Exercising Member States.
- **To Whom and how shall the Vaccine Order Form be sent?**
- To Contractor:
  - (1) by registered mail to the following address:  
Janssen Pharmaceutica NV  

  - and
  - (2) by email at the following address: [janssen\\_covid\\_vaccine\\_supply@its.jnj.com](mailto:janssen_covid_vaccine_supply@its.jnj.com). Please send the duly completed and signed Vaccine Order Form as a PDF attachment to the email.
- **How to complete this Vaccine Order Form?**
- The information highlighted in grey must be completed by each Participating/Exercising Member State.
- Other than completing such information highlighted in grey, **no changes or amendments are permitted** to this model Vaccine Order Form. 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:  

- Contractor representatives:  


<sup>8</sup> **Note to EC:** please provide names of contact persons.



*[Letterhead of Government]*

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:

Janssen Pharmaceutica NV, a limited liability company (*naamloze vennootschap / société anonyme*) incorporated under the laws of Belgium, with registered address at Turnhoutseweg 30, 2340 Beerse (Belgium) and registered under company number 0403.834.160 (hereinafter referred to as “**Contractor**”)

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

#### WHEREAS

- 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 Contractor’s COVID-19 vaccine for EU Member States dated [•] 2020 (the “**APA**”), the terms of which are binding on the Participating Member States.
- The APA provides that:
  - i. each Participating Member State will submit to Contractor a Vaccine Order Form through which Contractor shall (subject to the conditions in Article I.4.2 of the APA) make Available and Deliver to the relevant Participating Member State a proportion of the Base Volume Commitment, and
  - ii. in the event the Commission, acting on behalf of the Exercising Member States, has provided an Option Exercise Notice before the First Option Deadline and/or the Second Option Deadline, as applicable, that each Exercising Member State will submit to Contractor a Vaccine Order Form through which Contractor shall (subject to the conditions in Article I.4.2 of the APA) make Available and Deliver to the relevant Exercising Member State a proportion of the relevant Additional Volume Commitment,

both (i) and (ii) at the price and conditions as set out in the APA.

- In accordance with Article I.4.4.1, the Member State hereby places its order for its full Allocated portion of the Base Volume Commitment or the relevant Additional Volume Commitment (as applicable).

## **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 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 portion of the Base Volume Commitment or the relevant Additional Volume Commitment (as applicable) as set out in the Allocation provided by the Commission to Contractor pursuant to Article I.4.8 of the APA. The provision of this Vaccine Order Form by the Member State to Contractor constitutes a binding order by the Member State for the purchase of its full Allocated portion of the Base Volume Commitment or the relevant Additional Volume Commitment (as applicable) at the Price.
3. By execution of this Vaccine Order Form, the undersigned Member State warrants to Contractor that:
  - a. it is irrevocably and unconditionally bound by the terms of the APA (as executed by the Commission on behalf and in the name of the Participating Member States) as if the Member State had executed the APA itself;
  - b. the provisions of the APA are enforceable against it in accordance with its terms;
  - c. without limiting the generality of paragraph (a) above, it shall indemnify Contractor in accordance with Article II.5 (*Indemnification*) of the APA; and

- d. the warranties set out in Article I.10.4.3(a) to (c) of the APA are true and correct at the date of this Vaccine Order Form.
4. To the extent this Vaccine Order Form relates to an Additional Volume Commitment, the Member State acknowledges that if it fails to pay its allocated share of the First Further Down Payment or Second Further Down Payment (as applicable) in accordance with Article I.6.1.6 of the APA, Contractor shall have no obligation to consider the Member State's Vaccine Order Form for its Allocated portion of the relevant Additional Volume Commitment or to Deliver the Allocated Vaccine Regimens to the Member State.

### **Article III**

#### **Delivery; Quality**

1. Delivery Address. The Delivery Address for the Member State is as follows:  
  
*[\* - Member State to enter location of single central distribution hub]*
2. Quality. The roles and responsibilities between Contractor and the Member States in relation to quality assurance matters related to the Vaccine Volume and the COVID Vaccine are set out in Exhibit F of the APA.

### **Article IV**

#### **Invoices; Notices**

1. Invoice and Payments. Contractor shall invoice the Member State in accordance with the terms of the APA. All payments to 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 Contractor (as applicable); and be sent by mail and email:

#### Member State:

*[Name of Member State]*

*[Full official address of Member State]*

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

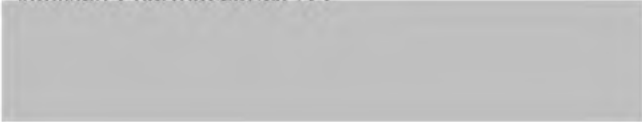
*[Function of addressee physical person (contact person)]*



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

Contractor:

Janssen Pharmaceutica NV



#### **Article V.**

##### **Entry into Force and Duration**

1. This Vaccine Order Form shall become effective upon execution and delivery by the Member State to Contractor in accordance with Article I.4.4.1 of the APA.
2. This Vaccine Order Form shall automatically expire upon Delivery of the Member State's full Allocated portion of the Base Volume Commitment or the relevant Additional Volume Commitment (as applicable) as set out in the Allocation provided by the Commission to Contractor pursuant to Article I.4.8 of 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.9 (*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,

**Janssen Pharmaceutica NV.**

*[forename/surname/position]*

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

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

### **ANNEX III**

#### **Agreement between the Commission and Participating Member States on procuring COVID-19 vaccines on behalf of the Participating 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.