



**SENSITIVE**

**EN**

**PART 1/2**

**ANNEX**  
**to the**  
**COMMISSION DECISION**  
**approving a Purchase Agreement on vaccines against COVID-19 and Sars-Cov-2**  
**variants**



EUROPEAN COMMISSION  
Directorate General for Health and Food Safety

PURCHASE AGREEMENT ("PA")<sup>1</sup> for the further development, production,  
purchasing options and supply of COVID-19 Vaccines for EU Member  
States

NUMBER — SANTE/2021/03/020

1. **The European Commission**, acting on behalf and in the name of the Member States set out in Annex III (hereinafter referred to as "Participating Member States")<sup>2</sup>:

being represented for the purposes of the signature of this PA by Ms Stella Kyriakides,  
Commissioner of Health and Food Safety

on the one part and

2. **Pfizer Inc.**

Incorporated in Delaware (Registration Number 0383418) with its registered address at 235  
East 42nd Street

10017 New York City, NY (UNITED STATES)

appointed as the leader of the group by the members of the group that submitted the joint tender  
(hereinafter referred to as "**Pfizer**")

and

**BioNTech Manufacturing GmbH**

Registered with the commercial register of the lower court (*Amtsgericht*) of Mainz, Germany  
under HRB 47548, with its registered address at An der Goldgrube 12

55131 MAINZ, GERMANY  
(hereinafter referred to as "**BioNTech**")

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

<sup>2</sup> As provided for in Article 4(5)(b) of Council Regulation (EU) 2016/369 of 15 March 2016 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.

as a member of the group (collectively '**the Contractor**'), represented for the purposes of the signature of this PA which has the form of a framework contract by [REDACTED]

on the other part,

HAVE AGREED

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

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

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

**Annex III** – Participating Member States

**Annex IV** – Subcontractors

**Annex V** – Participating Contractor Affiliates

Attachment 1 – Specifications

Attachment 2 – Delivery Documentation

Attachment 3 – Delivery Specification

Attachment 4 – Labelling and Packaging Specifications

Attachment 5 – Return and Disposal of Product Materials

which form an integral part of this PA,

In case the Contractor wishes to update the Attachments, [REDACTED]

[REDACTED], the Contractor may do so on communicating the updates to the Commission and to the Participating Member States, and a period of [REDACTED] having passed v [REDACTED]

[REDACTED] For any other proposed amendments, the parties will discuss the impact thereof in good faith and any such shall require the written prior approval of the Commission and the Participating Member States, not to be unreasonably withheld or delayed.

This PA sets out:

1. the procedure and conditions by which the Participating Member States will pay for the services and/or supplies from the Contractor;
2. the provisions that apply to any Vaccine Order Form which the Participating Member States and the Contractor may conclude under this PA; and
3. the obligations of the parties during and after the duration of this PA.

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

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| IN ADDITION, ANY CONTRACTOR AFFILIATE WHICH IS INVOLVED IN THE SALE OR<br>DISTRIBUTION OF PRODUCT WHICH IS RESOLD OR DONATED BY A<br>PARTICIPATING MEMBER STATE SHALL BE DEEMED TO BE A PARTICIPATING<br>CONTRACTOR AFFILIATE. ATTACHMENT 1: SPECIFICATIONS ..... |                                       | 19 |
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## **I. SPECIAL CONDITIONS**

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

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

- (a) The provisions set out in the special conditions and Article 11.6 of the general conditions (Liability) take precedence over those in the other parts of the PA.
- (b) The other provisions set out in the general conditions take precedence over those in the Annexes and Attachments.
- (c) The provisions set out in the PA take precedence over those in the Vaccine Order Forms.

### **I.2 DEFINITIONS**

The following definitions shall apply to this PA:

**'Additional Order'**: has the meaning set forth in Article 1.6.2;

**'Additional Product'**: has the meaning set forth in Article 1.6.2;

**'Affiliate'**: means in relation to a body corporate, any other entity which directly or indirectly Controls, is Controlled by, or is under direct or indirect common Control of that body corporate from time to time;

**'Authorisation'**: means a Conditional Marketing Authorisation and/or Marketing Authorisation that permits the Products to be placed on the market in the European Economic Area;

**"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));

**'Conditional Marketing Authorisation'**: means a conditional marketing authorisation granted by the European Commission, as amended or varied from time to time, as referred to in Article 14-a of Regulation (EC) No 726/2004;

**'Confidential Information'**: means any information disclosed to or obtained by one party to the other party, either directly or indirectly, or which the disclosing party indicates in writing at the time of disclosure to, or receipt by, the recipient is to be considered confidential or proprietary, or which such recipient knows or ought reasonably to know is information of a

confidential or proprietary nature, including the terms of this PA and any Vaccine Order Form. Confidential Information shall not include any information (i) the receiving party can prove was known to it prior to the date of disclosure; (ii) the receiving party can prove was lawfully obtained from a third party without any obligation of confidentiality; (iii) is or becomes part of the public domain other than through any act or omission of the receiving party; or (iv) is independently developed by the receiving party without use of or reference to the disclosing party's Confidential Information, as evidenced by the receiving party's records;

**'Conflict of interest'**: a situation where the impartial and objective *Implementation of the PA* by the Contractor is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the Commission, the Participating Member State or any third party related to the subject matter of the PA;

**'Contracted Doses'**: has the meaning set forth in Article 1.6.2;

**'Control'**: means the possession by a person or an entity, directly or indirectly, of the power to direct or cause the direction of the management and policies of the other person or entity (whether through the ownership of voting shares, by contract or otherwise) and **"Controls"** and **"Controlled"** shall be interpreted accordingly;

**"COVAX Facility"** means the COVID-19 Vaccines Global Access procurement initiative led by Gavi, UNICEF, the Vaccine Alliance, the World Health Organization (WHO) and the Coalition for Epidemic Preparedness Innovations (CEPI), for the procurement and delivery of doses of approved vaccine for COVID-19;

**'Delivery Price'**: has the meaning set forth in Article 1.8.2;

**'Delivery Schedule'**: has the meaning set forth in Article 1.6.3, as such may be modified by agreement of the parties pursuant to the provisions in Articles 1.6.2 and 1.6.3;

**'Effective Date'**: has the meaning set forth in Article 1.4.1;

**'Force majeure'**: any unforeseeable, exceptional situation or event beyond the reasonable control of the parties that prevents either of them from fulfilling any of their obligations under the PA, such as acts of God, natural disasters, flood, severe storm, earthquake, civil disturbance, lockout, riot, order of any court or administrative body, embargo, acts of government (other than the Commission or a Participating Member State, which may not rely on their own acts as being Force majeure), war (whether or not declared), acts of terrorism or the impact on a party of an outbreak of any disease or an epidemic or pandemic or other similar causes subject to the clarification set out below. The situation or event must not be attributable to error or negligence on the part of the parties or on the part of their subcontractors and must prove to be inevitable despite their exercising due diligence. Defaults of service, defects in equipment or material or delays in making them available, labour disputes, strikes and financial difficulties may not be invoked as *Force majeure*, unless they stem directly from a relevant case of *Force majeure*. For the avoidance of doubt, (i) failure to make payment cannot be qualified as *Force majeure*



and (ii) the parties agree that, although the current COVID-19 crisis is in itself no longer an 'unforeseeable' situation, it may still result in circumstances which are unforeseeable and beyond the reasonable control of the parties and therefore within the definition of *Force majeure*;

**'Formal notification'** (or 'formally notify'): form of communication between the parties made in writing by mail or email, which provides the sender with compelling evidence that the message was delivered to the specified recipient;

**'Fraud'**: an act or omission committed in order to make an unlawful gain for the perpetrator or another by causing a loss to the Union's financial interests, and relating to: i) the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds or assets from the Union budget, ii) the non-disclosure of information in violation of a specific obligation, with the same effect or iii) the misapplication of such funds or assets for purposes other than those for which they were originally granted, which damages the Union's financial interests, it being understood that the Union's financial interests are impacted within the framework of this PA as the Union is engaging resources into the coordination and preparation of the PA, resulting from Decision C(2020) 4192 final of 18 June 2020 which approved the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States ("the Decision"), this agreement being 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>3</sup> ("the ESI Regulation") ;

**'Good Manufacturing Practice'**: means the current practices for manufacture required by the standards, rules, principles and guidelines set out in Directive 2001/83/EC (as amended by Directive 2004/27/EC), Directive 2017/1572, 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";

**'Implementation of the PA'**: the purchase of services or supplies envisaged in the PA through the signature and *performance* of Vaccine Order Forms;

**'Indemnified Persons'**: has the meaning set forth in Article I.12.1;

**'Irregularity'**: any infringement of a provision of Union law resulting from an act or omission by the Contractor within the meaning of Article 1(2) of the Council (EC, Euratom) Regulation 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (in OJ 23.12.95, L 312/1) , which has, or would have, the effect of prejudicing the Union's budget, it being understood that the Union's financial interests are impacted within the framework of this PA, as the Union is engaging resources into the coordination and preparation of the PA, resulting from the Decision which approved the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States, this agreement being based on Article 4(5)(b) of the ESI Regulation;

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<sup>3</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.

**“Jurisdiction”** means the sovereign territory of a Participating Member State as well as an embassy, consulate or armed forces installation of the Participating Member State outside its sovereign territory but subject to its jurisdiction;

**“Key Supply/ies”**: means those critical components, services and other critical input items required for the development, production and supply of the Vaccine pursuant to this PA, for which a delay in their supply is capable of materially adversely affecting the timely performance of the Contractor's delivery obligations under this PA.

**“Key Supply Interruption”**

**“Late Delivery”**: a late delivery of Vaccine doses as compared with agreed dates in the Delivery Schedule;

**“Late Delivery Time”**: has the meaning set forth in Article 1.6.3;

**“Latent Defect”**: means a defect causing the Product to not conform to the applicable Specifications which could not have been detected by the Participating Member State, its designee, or their personnel at delivery through visual inspection;

**“Law(s)”**: means, collectively, all applicable supranational, national and local laws, common laws, statutes, ordinances, codes, rules, regulations, orders, decrees or other pronouncements of any government, administrative or judicial authority having the effect of law;

**“Losses”**: has the meaning set forth in Article 1.12.1;

**“Marketing Authorisation”**: means the marketing authorisation (other than Conditional Marketing Authorisation), in respect of the Product granted by the European Commission, as amended or varied from time to time, that allows the Product to be placed on the market in the European Economic Area according to applicable Law;

**“New Countries”**: has the meaning set forth in Article 1.6.3;

**“Non-Complying Product”**: has the meaning set forth in Article 1.6.14;

**“Non-EU Key Supply/ies”**: means Key Supply/ies for which, at the time of production of the Vaccine pursuant to this PA, no supplier exists in the European Union that could provide the component, service and other input item from the territory of the EU.

[REDACTED]

**'Notification'** (or 'notify'): form of communication between the parties made in writing including by electronic means;

**'Participating Contractor Affiliate'**: means an Affiliate of Pfizer or BioNTech as identified in Annex V;

**"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);

[REDACTED]

**'Product'**: means the Vaccine;

**'Product Materials'**: means all packaging materials and components needed for delivery of the Product;

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

**'Record'**: means books, documents, and other data, of all matters relating to performance of obligations under this PA;

**'Related person'**: any natural or legal person who is a member of the administrative, management or supervisory body of the Contractor, or who has powers of representation, decision or control with regard to the Contractor;

**"Shortage"**: has the meaning set forth in Article I.6.3;

**"Shortfall"**: has the meaning set forth in Article I.6.3;

**'Specifications'**: means the specifications for the manufacture, testing and testing procedures, and supply of the Product as set out in Attachment 1 (Specifications), and as such specifications may be amended, supplemented or otherwise modified by the Contractor and communicated to the Commission;

**'Taxes'**: has the meaning set forth in Article II.18.1;

**'Term'**: means the term of the PA set out in Article I.4.2 of the PA;

[REDACTED]

**'Thermal Shipper'**: has the meaning set forth in Article I.6.8;

**'Third Party Claim'**: has the meaning set forth in Article I.12.4.

**'Vaccine'**: the medicinal product, being BNT162b2, a nucleoside-modified messenger RNA (mRNA) vaccine that encodes an optimized SARS-CoV-2 full-length spike glycoprotein (S) for which Authorisation has been granted, in multi-dose presentation.

**'Vaccine IP Rights'**: has the meaning set forth in Article I.11;

**'Vaccine Order Form'**: has the meaning set forth in Article I.5.2; and

Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this PA in its entirety and not to any particular provision hereof, (g) all references herein to Articles, Annexes or Attachments shall be construed to refer to Articles, Annexes or Attachments of this PA, and references to this PA include all Annexes and Attachments hereto, (h) the word "notice" means notice in writing or by email (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this PA, (i) provisions that require that a party or parties "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (including e-mail). (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof.

### **I.3 SUBJECT MATTER**

The subject of the call for tenders SANTE/2021/03/020 is securing the purchase of certain vaccine doses for the Participating Member States.

Following the Decision, taken in accordance with Article 4(5)(b) of the ESI Regulation, the Commission is running procurement procedures on behalf of Participating Member States, with

a view to signing EU-level Advance Purchase Agreements and Purchase Agreements with vaccine manufacturers.

An APA between the Parties was signed on 20 November 2020 ("APA"). Subsequently, a PA between the Parties was signed on 17 February 2021 ("PA.1").

In compliance with Article 164(1)(d) as well as Annex I, Points 11.1(b)(ii) and 11.1(c) of the Financial Regulation, the Commission launched on 9 April 2021 a negotiated procedure without prior publication of a contract notice for the procurement of additional doses of vaccines. This procedure was justified by the need to urgently secure an exceptionally high amount of additional doses of vaccines to address the pandemic within a reasonable period of time, as well as by the absence of competition for technical reasons. This PA is for such additional doses, and while it is organised following the Decision, it is entirely separate from the APA and from the PA.1 between the Parties.

In view of its importance, this PA will be approved for signature on behalf and in the name of the Participating Member States by a separate individual Commission decision.

The Conditional Marketing Authorisation for the Vaccine was granted on 21 December 2020.

The Commission, on behalf of the Participating Member States, wishes to purchase the Vaccine through this PA to ensure the availability in the European Union of sufficient vaccine doses to address the pandemic between December 2021 [REDACTED]

On the basis of this PA, the European Commission commissions the Contractor to commit to produce and deliver 900 million doses of the Vaccine which shall be ordered by the Participating Member States (via specific Vaccine Order Forms) at the price and conditions, including timeframe, agreed under this PA, with the option to obtain a further 900 million doses of the Vaccine subject to the conditions set out in this PA.

The Contractor or a Participating Contractor Affiliate shall supply to the Participating Member States the agreed doses of the Vaccine pursuant to the Vaccine Order Forms.

The Vaccine Order Forms shall be signed by the Contractor and shall incorporate by reference this PA.

#### **I.4 ENTRY INTO FORCE AND DURATION OF THE PA**

- I.4.1 The PA enters into force on the date on which the last party signs it ("Effective Date").
- I.4.2 The PA is concluded for a period of thirty six (36) months with effect from the Effective Date ("Term").
- I.4.3 Contractor and the Participating Member States may not sign any Vaccine Order Form after the PA expires.
- I.4.4 The PA continues to apply to such Vaccine Order Forms after its expiry. The services relating to such Vaccine Order Forms must be performed no later than six months after the expiry of the PA.

#### **1.4.5 Renewal of the PA**

The PA will expire automatically at the end of the Term, unless it is extended in mutual written agreement between the parties. For the avoidance of doubt, if the exercise of the Additional Order involves delivery of doses beyond the Term, the parties shall agree to a renewal until the end of the last month for which deliveries of the Additional Order are foreseen in the relevant delivery schedule. This renewal process will be repeated until all doses have been delivered. Renewal does not change or postpone any existing obligations.

### **1.5 IMPLEMENTATION OF THE PA**

#### **1.5.1 Period of provision of the supplies**

The period for the provision of the supplies starts to run as foreseen in Article 1.6.3.

#### **1.5.2 Implementation of the PA**

The PA shall be implemented following signature between the Commission and the Contractor as follows:

The Contractor agrees to supply an initial total number of 900 million Vaccine doses to Participating Member States collectively, upon their order, in accordance with this PA and the respective Vaccine Order Forms.

The Participating Member States shall place orders for supplies of 900 million Vaccine doses in total in accordance with the allocation communicated by the Commission to the Contractor pursuant to Article 1.6.3, by sending the Contractor a completed copy of Annex 1 (“**Vaccine Order Form**”) in paper format or emailed pdf within 10 business days following the Commission communicating the allocation, which shall be on a pro-rata basis between Participating Member States unless otherwise communicated by the Commission to the Contractor. This Vaccine Order Form shall be signed by an authorised representative of the Participating Member State and the Contractor.

Within 10 business days of receipt of the Vaccine Order Form from a Participating Member State, the Contractor must send back to the Participating Member States the duly signed and dated Vaccine Order Form in paper format or emailed pdf.

### **1.6 SUPPLY OF THE VACCINE**

#### **1.6.1 General**

During the term of this PA, the Contractor shall supply or have supplied the Product to the relevant Participating Member States, and the Participating Member States shall purchase the Product, subject to and in accordance with the terms and conditions of this PA.

#### **1.6.2 Product supply**

At the Effective Date, the Commission orders 900 million doses (“**Contracted Doses**”) of the Product on behalf of the Participating Member States. The Contracted Doses shall be delivered by the Contractor to the Participating Member States in accordance with the allocation provided by the Commission and according to the schedule and in the quantities [REDACTED] as set out in the Delivery Schedule.

### **The Additional Order**

The parties acknowledge that the Commission may wish to place an additional binding order (the "**Additional Order**") for a maximum of up to 900 million doses of the Vaccine, to be exercised (unless otherwise agreed by the parties) in minimum tranches of [REDACTED]

[REDACTED]  
Vaccine to be supplied pursuant to an Additional Order will be "**Additional Product**".  
[REDACTED]

The parties also agree that such Additional Order may be placed by the Commission only after (i) the Contractor confirms whether the doses are available (if the request is for more than the minimum Additional Order volume of [REDACTED] and when they can be delivered (ii) the Commission confirms the required allocation between Participating Member States and (iii) the Contractor confirms the delivery schedule which shall be based on the allocation provided (and which shall not commence earlier than [REDACTED]).

All Additional Orders must be placed by the Commission by [REDACTED]

The Participating Member States participating in one or more tranches of the Additional Order shall be obliged to send an additional Vaccine Order Form for each tranche of the Additional Order in which they participate. All terms and conditions included in this PA, in particular those included in Article 1.6.3 with regard to Deliveries, [REDACTED] shall apply *mutatis mutandis* to the Additional Order.

The Commission shall communicate to the Contractor the allocation of the Contracted Doses supplied pursuant to the initial order and any Additional Product among the Participating Member States.

### **Resale and Donation**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



**Supply of Variant Vaccine**





**Adapted and Paediatric Vaccines**

The following provisions apply other than in relation to the Variant Vaccine as set out above:





These provisions shall apply *mutatis mutandis* as regards the development of an Adapted Vaccine into an upgraded Adapted Vaccine.

### 1.6.3 Supply mechanism

The supply under this PA shall in principle come from [redacted] and shall incorporate RNA produced at [redacted] manufacturing sites, including, subject to necessary permissions being received by Contractor, sites operated by the following sub-contractors:




The parties acknowledge that Contractor is not obliged to use all these sites provided it has sufficient capacity.


Recognising the urgency of the public health crisis and the necessity to hasten/enable supply, (1) the Commission and Participating Member States shall make best reasonable efforts, where appropriate in collaboration with the European Medicines Agency, to expedite any relevant and outstanding authorisations required for supply to commence from the Contractor's controlled manufacturing sites [redacted]

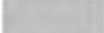





### **Delivery**

The Contracted Doses shall be delivered by the Contractor to the Participating Member States in accordance with the allocation provided by the Commission and according to the schedule and in the quantities  as set out in the following table (the “**Delivery Schedule**”):



Within  following the Effective Date, the Commission shall communicate to the Contractor a table how to allocate the 900 million Vaccine doses amongst the Participating Member States. Each Participating Member State shall have a commitment to purchase the number of Vaccine doses as set out in such allocation table and, to operationalise the ordering of the Vaccine, each Participating Member State will enter into a Vaccine Order Form per Article I.5.2. Each Vaccine Order Form will specify in particular the number of doses that the Participating Member State will purchase from the above-mentioned allocation table, the price of all Vaccine doses pursuant to Article I.7, and the liability and indemnification undertakings by the Participating Member State (which will be incorporated by reference from the PA into the Vaccine Order Form). For the avoidance of doubt, the Contractor shall have no obligation to supply any Vaccine doses to any Participating Member State where there is not a Vaccine Order Form, including provisions related to liability and indemnity (which will be incorporated by reference from the PA into the Vaccine Order Form executed by the Participating Member



State and the Contractor). It is agreed that the Contractor may discharge its obligations under the Vaccine Order Form acting with one or more Participating Contractor Affiliates.

The Delivery Schedule and logistics will be further refined into a weekly schedule by the Contractor in accordance with provisions below, after the execution of the Vaccine Order Form for that Participating Member State.

To operationalise the Vaccine Order Forms, [REDACTED]

For the avoidance of doubt, the Delivery Schedule is firm and no adjustments can be made without the written agreement of the parties. This is without prejudice to the ability of the Contractor to accelerate supply with the consent of the respective Participating Member State.

**Late Delivery**

In this context, the Contractor acknowledges the strong interest of the Participating Member States in the current pandemic situation to receive the Vaccine doses in accordance with the Delivery Schedule. [REDACTED]

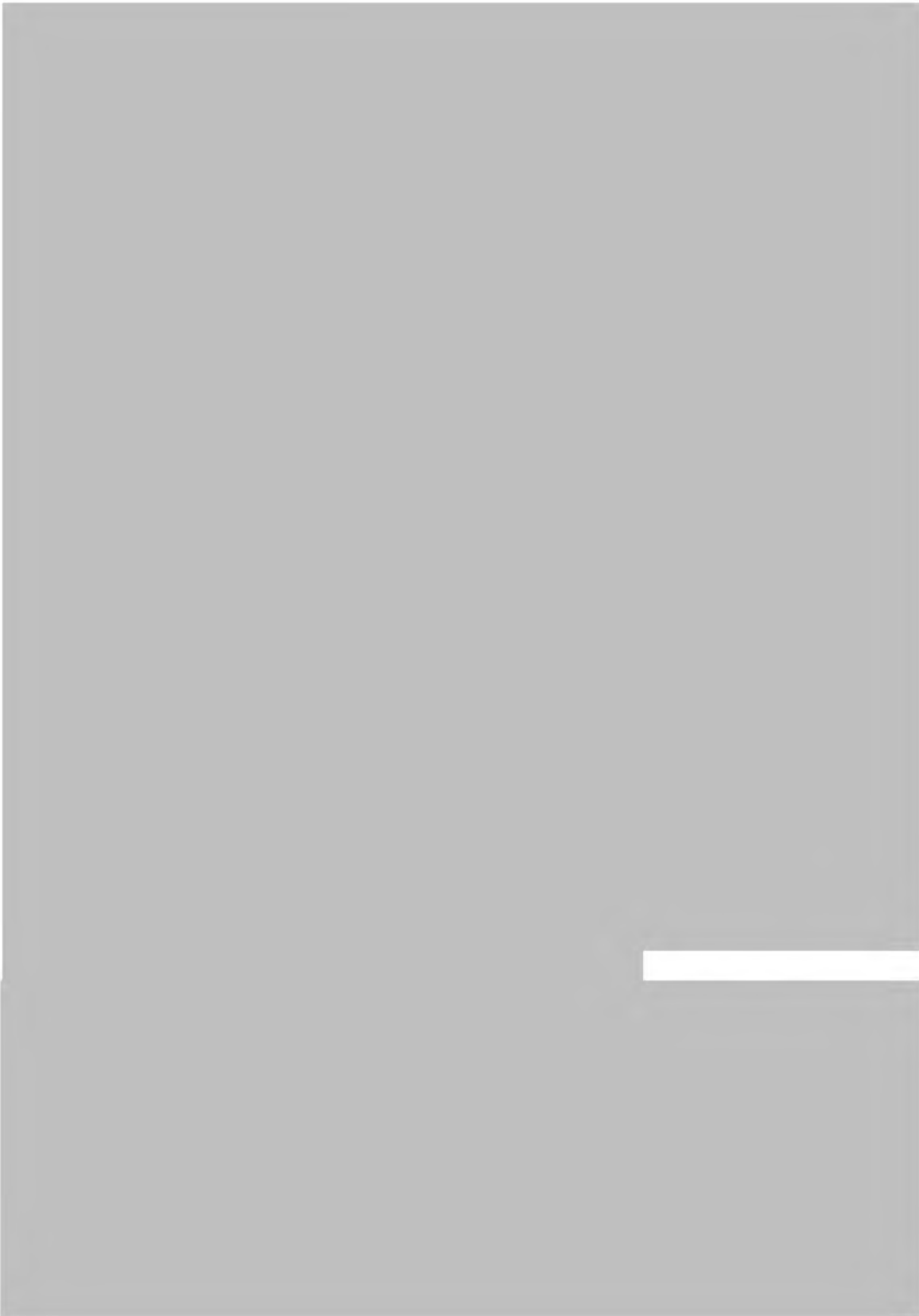
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]







[REDACTED]

In the event of an anticipated or actual shortage of Product, the Contractor shall be entitled to [REDACTED] supply of a different formulation of Product (provided it is authorised for use in the European Union) to the Participating Member State to meet its delivery obligations [REDACTED]

[REDACTED]

#### **1.6.4 Manufacturing**

The Contractor warrants that it will have sufficient available manufacturing capacity in the European Union to be capable of manufacturing the finished Vaccine and drug substance, and supplying the Vaccine, to the Participating Member States in accordance with the provisions of this PA.

The Contractor confirms that it is in possession of all necessary manufacturing authorisations to undertake the manufacturing of the Vaccine.

The Contractor also warrants that, in respect of Contracted Doses and any Additional Product which is the subject of a confirmed order from the Commission, at the time of production of such Vaccine doses it will have, [REDACTED]

[REDACTED]

For the purpose of fulfilling its obligation to manufacture the Vaccine [REDACTED] the Contractor shall, in principle, procure all Key Supplies [REDACTED]

[REDACTED]

[REDACTED]

For each such Key Supply [REDACTED] the Contractor commits that it will have in place, when producing the Vaccine doses covered by this PA, an effective supply management system that includes an early alert system, sufficient safety inventories [REDACTED] [REDACTED] so as to ensure supply of the Contracted Doses in [REDACTED]

[REDACTED]

compliance with the Delivery Schedule. Any additional supply source(s) do not have to be located within the European Union.

#### **1.6.5 Legal and regulatory filings and requests**

The Contractor shall ensure that all Product is properly labelled and packaged in accordance with the provisions of Article 1.6.8 and Good Manufacturing Practice and in accordance with the applicable EU legislation on information on packaging (Title V of Directive 2001/83/EC).

Notwithstanding the above, prior to delivery, the Contractor shall comply with all conditions (in the relevant timescales) set out in the Authorisation (where applicable), subject to any exemption, exception or waiver of requirements for the Product granted or permitted by the Participating Member State (including but not limited to serialization).

[REDACTED]

[REDACTED]

[REDACTED]

It is recommended that the Contractor obtains scientific advice from the European Medicines Agency on the details of the development programmes for Adapted Vaccines.

#### **1.6.7 Waiver**

The Commission and Participating Member States acknowledge and agree that the following remedies:

- [REDACTED]
- [REDACTED]

[REDACTED]

[REDACTED]

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

are reasonable and constitute the Commission's and the Participating Member States' remedies for the Contractor's [REDACTED] and are the [REDACTED] remedies for non-compliance with the [REDACTED] or for Late Delivery. [REDACTED]

Any failure to deliver doses in accordance with the Delivery Schedule shall not give the Participating Member States any right to cancel orders for any quantity of Products except as expressly set forth in Article I.17.1.

#### **I.6.8 Packaging, labelling and shipping**

At the date of execution of this PA, the Vaccine is expected to be supplied in a thermal shipping box in accordance with Attachment 4 (Labelling and Packaging Specifications) ("Thermal Shipper"). [REDACTED] The costs of packaging, packing materials, addressing, labelling, loading and delivery to the agreed Participating Member States' delivery point of the Vaccine shall be borne by the Contractor.

All deliveries shall be accompanied by the documentation specified in Attachment 2 (Delivery Documentation) (which may be updated from time to time by the Contractor upon notice to the Commission), and shall be in accordance with, and subject to, the delivery specification set forth in Attachment 3 (Delivery Specification). The Product shall be labelled and packaged in accordance with the packaging specifications set forth in Attachment 4 (Labelling and Packaging Specifications).

Final specifications including package size and labels will be communicated to the Commission and to the Participating Member States prior to delivery. All specifications shall be consistent with any conditions set out in the Authorisation and applicable Law.

#### **I.6.9 Storage, transport and product acceptance**

[REDACTED]

[REDACTED]

[REDACTED] Final storage specifications, based on the Authorisation received, will be communicated to the Participating Member State prior to delivery.

[REDACTED]

#### **1.6.10 Delivery**

The Contractor will deliver the doses ordered by each of the Participating Member States to one or more locations selected by the Participating Member State in accordance with the procedure set out in this Article 1.6.10 and the Vaccine Order Form. The Participating Member States can decide whether they wish to have the Vaccine delivered to a reasonable number of sites where the Vaccine will be directly used and administered or to one or several central hubs per Participating Member State from which Participating Member States will ensure themselves the further delivery to the sites of use of the Vaccine. For the avoidance of doubt, the Participating Member States shall bear all costs and expenses for operating these distribution hubs and for use of the Vaccine, including, but not limited to, those for storage and distribution of the Vaccine after delivery, local duties and local QA testing.

The Participating Member States must have all appropriate facilities and personnel in place to enable the timely receipt of delivered doses. The duly authorised representative of the Participating Member State shall sign to confirm receipt of delivery (the current proposed format of which is as set out in Attachment 2 (Delivery Documentation)). The person signing for receipt must ensure the contents of the delivery match the accompanying shipping documentation proof of receipt.

The Contractor shall deliver the Product [REDACTED] to the location agreed pursuant to this Article 1.6.10.

The Contractor and the Participating Member State shall agree the location(s) for delivery of shipments of the Product; provided that (i) each location meets the requirements set forth in Attachment 3 (Delivery Specification), and (ii) all locations which are additional to those approved in advance by the Contractor prior to the Effective Date shall be agreed upon by the Contractor and the Participating Member State at least eight (8) weeks prior to shipment of the Product [REDACTED]

The Contractor shall have the ability, acting reasonably, to restrict the number of locations where shipments of Product shall be delivered, provided that it is still agreed to deliver to a reasonable number of sites where the Vaccine will be directly used and administered or to one

[REDACTED]

or several central hubs per Participating Member State from which Participating Member States will ensure themselves the further delivery to the sites of use of the Vaccine.

All shipments of Product shall have a minimum volume as specified in Attachment 3 (Delivery Specification), or such other amount as notified to the Commission from time to time by the Contractor in accordance with the terms of this PA.

#### **1.6.11 Product handling**

Upon delivery of the Product, the Participating Member State shall store and handle the Product in the manner set forth in the Specifications set forth in Attachment 1 (Specifications), the instructions in Attachment 3 (Delivery Specification) and the instructions provided by the Contractor to ensure stability and integrity of the Product.

The Participating Member States shall be solely responsible and liable for the proper storage, handling, distribution, transportation, administration, use and disposal of the Product in their Jurisdiction following delivery of the Product to the Participating Member State or its designee. Without prejudice to the generality of the foregoing, the Participating Member States shall ensure that: (a) recipients of the Product shall follow the return and disposal instructions in Attachment 5 (Return and Disposal of Product Materials) when disposing of open and unused Product and its packaging components; and (b) such return and disposal complies with Laws regarding pharmaceutical waste, medical waste, or hazardous waste, as appropriate.

Participating Member States shall be responsible for and shall ensure that any equipment used to deliver the Product, for example [REDACTED] are stored in an appropriate clean and secure location to protect and maintain the functionality of such equipment (in controlled conditions, with no exposure to weather or pests, etc). Within [REDACTED] of receipt of the Product, subject to Article L6.14, the Participating Member State shall take the necessary measures to enable the collection by the Contractor of all such equipment, including [REDACTED] in accordance with the Contractor's instructions, consistent with the provisions of Attachment 5 (Return and Disposal of Product Materials).

The Contractor may provide Safety Data Sheets and other agreed information to Participating Member States to assist them to develop processes and procedures, including training, to handle the Product and Product Materials in a safe manner and in compliance with Laws, including occupational health and safety Laws. While the Contractor is responsible for the content of such training materials and proposals for handling procedures, Participating Member States acknowledge that it is their responsibility to implement such training programs and procedures to enable proper handling of the Product and Product Materials in a safe and lawful manner.

#### **1.6.12 Title to Product and risk of loss**

Title to the Product and risk of loss or damage shall pass to the Participating Member State on delivery pursuant to Article 1.6.10 and Participating Member States shall be responsible for the unloading of such Product from the transportation carrier. For the sake of clarity, the Contractor's liability shall cease, and risk of loss or damage shall transfer, upon carrier's arrival at the point of delivery and immediately prior to the unloading of the Product. Without prejudice to the generality of the foregoing, following delivery of the Product to Participating Member States, the latter shall be fully responsible for and liable in relation to any Product wastage, and for ensuring appropriate disposal in accordance with the relevant provisions of this PA.

The Participating Member States acknowledge that the Contractor or the Participating Contractor Affiliate will not, [REDACTED] accept any returns of Product (or any dose). In particular, following receipt of the Product in accordance with this paragraph, no Product returns may take place [REDACTED] (inclusive of future changes in stock, changes in Product allocation, delivery, demand or new product launch).

#### **1.6.13 Quality tests and checks**

#### **1.6.14 Rejection of Product; Disposal of rejected shipments**

A Participating Member State must visually inspect the Product within [REDACTED] of delivery following the instructions set out in Attachment 3 (Delivery Specification) and may reject any specific delivery of the Product or doses therein that does not conform to [REDACTED] ("Non-Complying Product") by providing notice to Pfizer Customer Service following an agreed protocol: (i) [REDACTED] after delivery of such Non-Complying Product to the Participating Member State for any issues [REDACTED] or (ii) [REDACTED] after its first knowledge of a Latent Defect. The Contractor shall respond to any rejection and notice of such Non-Complying Product from the Participating Member State in a timely manner. For clarity, the Participating Member State shall not be entitled to notify rejection of any Product based on service complaints unless a Product in its view does not conform [REDACTED]

The Contractor shall conduct an analysis of the causes of any such quality-related complaint, and shall report to the Participating Member State on any corrective action taken. If the Contractor's inspection and testing reveals, to the Contractor's reasonable satisfaction, that such items of the Product are Non-Complying Product and that any such non-conformity or defect has not been caused or contributed to by any abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress,

abnormal environmental conditions or use by the Participating Member State contrary to any instructions issued by the Contractor in accordance with this PA, the Contractor shall (i)

and/or (ii)

issue a credit for such Non-Complying Product, or if there are no amounts payable or additional invoices due to be issued by Contractor for Product, Contractor shall issue a refund for such Non-Complying Product. In such circumstances, the Contractor will further arrange for reverse logistics for Product collection and manage the destruction of the Non-Complying Product. Until collection, the Participating Member State shall store and maintain the relevant Non-Complying Product in appropriately secure locations and in accordance with the manufacturers' specifications.

Without prejudice to the right to refer the matter to the dispute resolution procedure set out in Article I.13.2 and the provision on replacement of Non-Complying Product or credit note/refund shall be the Participating Member State's sole and exclusive remedy for Non-Complying Product (as defined in this Article I.6.14). The provisions of this Article I.6.14 shall survive termination or expiration of this PA.

#### **I.6.15 Maintenance and retention of Records**

Each party shall maintain detailed Records with respect to its activities under this PA as required by Laws.

The Participating Member State will maintain a quality system for receipt, inspection, storage, traceability to further delivery points, and recall activities. If the Participating Member State does not have a quality system for the activities defined, the Contractor may share details of a proposed quality system for the Participating Member State's compliance.

#### **I.6.16 Diversion issues**

All Product delivered to a Participating Member State shall be: (a) stored securely by the Participating Member State; and (b) without prejudice to Article I.6.2, distributed by the Participating Member State in a secure manner appropriate to the transportation route and destination, in each case (a) and (b) to guard against and deter theft, diversion, tampering, substitution (with, for example, counterfeits) or unauthorised resale or export out of the Participating Member State, and to protect and preserve the integrity and efficacy of the Product.



[REDACTED]

## **1.7 PRICES**

The price of the Vaccine to the Commission and the Participating Member States for the 900 million Contracted Doses and any Additional Order will be [REDACTED]

## **1.8 PAYMENT ARRANGEMENTS**

### **1.8.1 No Advance Payment**

There is no advance payment to be made by the Commission under this PA.

### **1.8.2 Delivery Price**

The Delivery Price for the Contracted Doses and any Additional Order is to be paid by the Participating Member State to the Participating Contractor Affiliate [REDACTED]

[REDACTED]

The Participating Contractor Affiliate may claim the payment of the Delivery Price in accordance with this Article 1.8.2. The Participating Contractor Affiliate must send an invoice in paper format or emailed pdf for payment of the balance due under a Vaccine Order Form for each provision of supplies to the Participating Member States.

Invoices shall be established by the Participating Contractor Affiliate for a given order of supplies and for an identified delivery scheduled within the Vaccine Order Form.

The Participating Contractor Affiliate may not send an invoice to a Participating Member State before it receives from the Participating Member State concerned the [REDACTED] as referenced in Article 1.6.10 and Attachment 2 (Delivery Documentation) notifying [REDACTED] in respect of which such invoice is established, which [REDACTED] shall not be unreasonably withheld or delayed and in any event be provided [REDACTED]

[REDACTED]

The Participating Contractor Affiliate must send an invoice in paper format or emailed pdf or by electronic systems for payment due under the Vaccine Order Form accompanied by the following:

- [REDACTED]

Each invoice must contain the following information:

- Name of the Participating Member State concerned
- PA and Vaccine Order Form number/reference
- Order reference
- Billing address
- Product [REDACTED]
- Quantity [REDACTED]
- [REDACTED] reference and date
- Price
- Any applicable taxes, transportation charges or other charges provided for in the Vaccine Order Form
- The ship-to destination
- [REDACTED]
- Participating Contractor Affiliate name and bank account.

The Participating Member States must approve the submitted documents or deliverables as conforming to the above requirements and pay [REDACTED] from receipt of the invoice. Any payment which falls due on a date which is not a business day may be made on the next succeeding business day. Any dispute by a Participating Member State of an invoice shall be provided to the Participating Contractor Affiliate in writing (along with substantiating documentation and a reasonably detailed description of the dispute) [REDACTED] from the date of such invoice. A Participating Member State will be deemed to have accepted all invoices for which the Participating Contractor Affiliate does not receive timely notification of disputes, and shall pay all undisputed amounts due under such invoices within the period set forth in this Article 1.8.2. The parties shall seek to resolve all such disputes expeditiously and in good faith.

In addition to all other remedies available under this PA or at Law, if a Participating Member State fails to pay any undisputed amounts when due under this PA, the Contractor may (i) suspend the delivery of the Product to that Participating Member State or (ii) terminate the relevant Vaccine Order Form if the payment has not been made [REDACTED]

The Commission and the Participating Member States shall not, and acknowledge that they will have no right, under this PA, any Vaccine Order Form, any order, any other agreement, document or Law, to withhold, offset, recoup or debit any amounts owed (or to become due and owing) to the Participating Contractor Affiliate, against any other amount owed (or to become due and owing) to it by the Contractor or an Affiliate.

To avoid doubt, if any Participating Member States [REDACTED] in accordance with the provisions of this PA, the Contractor shall be entitled to invoice such Participating Member States for the balance of the price of the [REDACTED]

### **1.8.3 Bank account**

Payments by the Commission must be made to 1

### **1.9 COMMUNICATION DETAILS**

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

If to the Commission:

European Commission

Directorate-General for Health and Food Safety

E-mail: [SANTE-PROCUREMENT@ec.europa.eu](mailto:SANTE-PROCUREMENT@ec.europa.eu)

If to a Participating Member State – See details in Vaccine Order Form

By derogation from this Article 1.9, different contact details for the Commission, the Participating Member States or the Contractor may be provided in Vaccine Order Form.

### **1.10 PROJECT MANAGEMENT**

Pfizer, BioNTech and the Commission will each nominate a project manager that will be the sole contact point for and responsible for managing the overall relationship between the parties. Each Participating Member State shall in addition appoint an expert to work on PA

implementation at Participating Member State level. Project meetings with the Commission and Participating Member State experts will be held regularly on a timeframe to be determined following execution of the PA to report, amongst other things, on progress of clinical studies, licensing activities, manufacturing status, forecast and deliveries. Details specific to each Participating Member State such as logistics and payments shall be handled directly by the respective Participating Member State experts.

#### **1.11 EXPLOITATION OF THE RESULTS OF THE PA**

The Commission acknowledges and agrees that the Contractor shall be the sole owner of all intellectual property rights generated during the development, manufacture, and supply of the Vaccine or otherwise related to the Vaccine, including all know-how (collectively, the **"Vaccine IP Rights"**).

All rights not expressly granted by the Contractor hereunder are reserved by the Contractor.

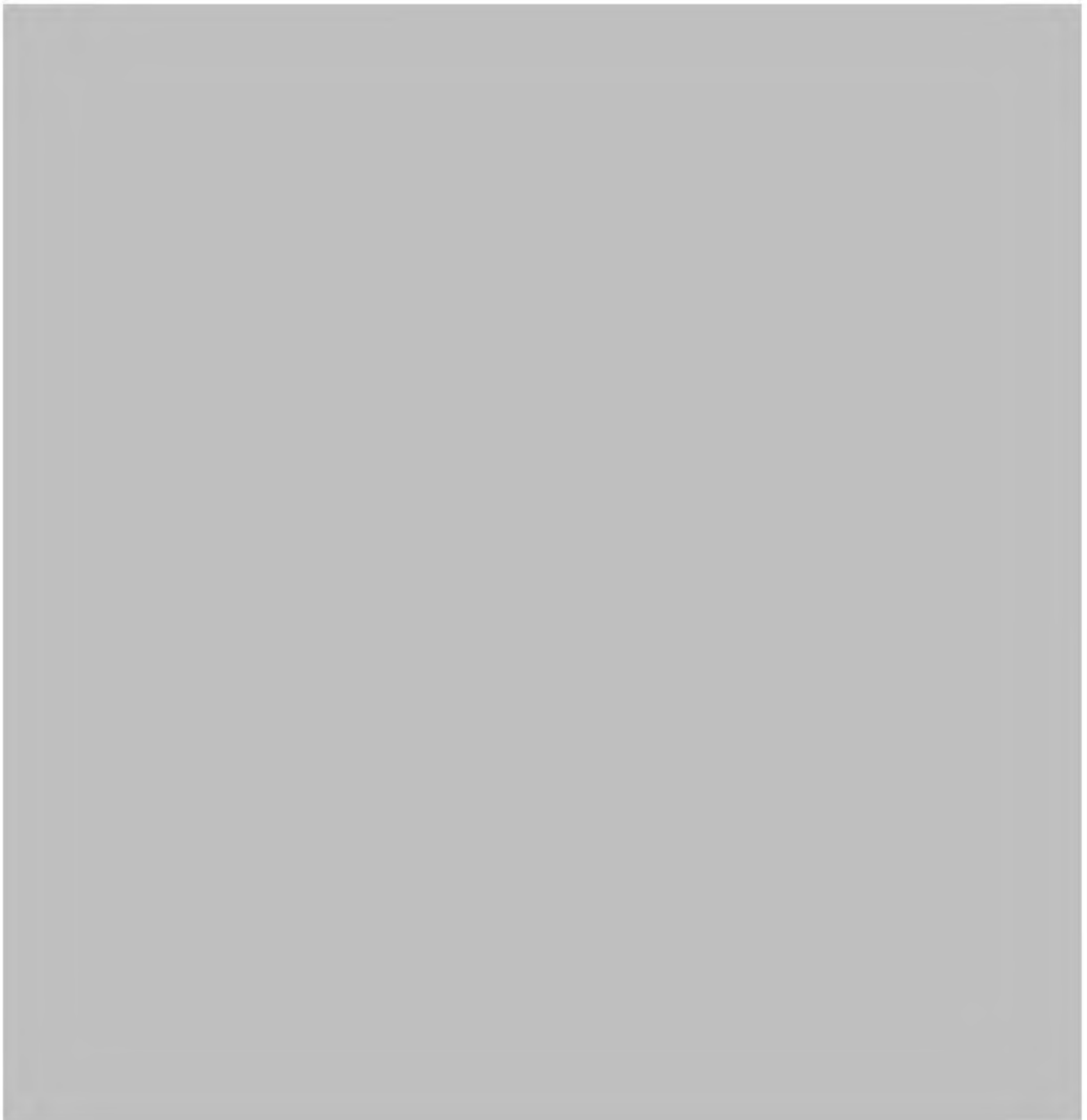
#### **1.12 INDEMNIFICATION**

1.12.1 The Commission, on behalf of the Participating Member States, declares that the use of Vaccines produced under this PA will happen under epidemic conditions requiring such use, and that the administration of Vaccines will therefore be conducted under the sole responsibility of the Participating Member States. Hence, each Participating Member State shall indemnify and hold harmless the Contractor,

(together, the **"Indemnified Persons"**) from and against any and all liabilities incurred,

in the defence of Third Party Claims

relating to harm, damages and losses as defined in Article 1.12.2 (together, the **"Losses"**) arising from or relating to the use and deployment of the Vaccines in question.



[REDACTED]

[REDACTED]

[REDACTED]

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

1.13.1 This PA shall be governed by the laws of Belgium.

#### **1.13.2 Dispute Resolution**

- (a) In the event of a dispute arising under this PA or the Vaccine Order Forms, as applicable, between the parties, the parties shall first refer such dispute to informal dispute resolution discussions between their respective representatives. The Contractor or the Commission on behalf of itself or of the Participating Member States may initiate such informal dispute resolution by sending written notice of the dispute to the other party, and, within ten (10) days of such notice, the representatives shall meet and attempt to resolve the dispute by good faith negotiations.
- (b) The Commission, the Participating Member States and the Contractor each irrevocably submit to the exclusive jurisdiction of the courts located in Brussels, Belgium to settle any dispute or claim which may arise under or in connection with this PA or the legal relationships established by this PA or any Vaccine Order Form.

### **1.14 OTHER SPECIAL CONDITIONS**

The Contractor shall keep the Commission and the Participating Member States informed about any significant safety signal detected during the pharmacovigilance or vaccine monitoring programmes in relation to the Vaccines which are the object of this PA [redacted] from notifying the European Medicines Agency.

### **SIGNATURES**

For the Contractor,

[redacted signature area]

Signature:

Done at [place], [date]

In duplicate in English.

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

[forename/surname/position]

[redacted signature area]

Signature:

Done at [place], [date]

[redacted signature area]

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

### **II.1 DEFINITIONS**

All definitions are contained in Article I.2 or in the relevant provisions of this PA.

### **II.2 ROLES AND RESPONSIBILITIES IN THE EVENT OF A JOINT TENDER**

In the event of a joint tender submitted by a group of economic operators and where the group does not have legal personality or legal capacity, one member of the group is appointed as leader of the group.

### **II.3 SEVERABILITY**

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

### **II.4 PROVISION OF SERVICES AND SUPPLIES**

II.4.1 All periods specified in the PA are calculated in calendar days, unless otherwise specified.

II.4.2 The Contractor must immediately inform the Commission of any changes in the exclusion situations as declared, according to Article 137(1) of Regulation (EU) 2018/1046.

### **II.5 COMMUNICATION BETWEEN THE PARTIES**

#### **II.5.1 Form and means of communication**

Any formal notification under the PA must:

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

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

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



### **II.5.2 Date of communications by mail and email**

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

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

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

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

## **II.6 LIABILITY**

II.6.1 During the term of this PA,



II.6.2



II.6.3 The Commission and the Participating Member States shall use commercially reasonable efforts to mitigate both (1) the damages that would otherwise be recoverable from the other or the Contractor pursuant to this PA and the Vaccine Order Forms, and (2) any costs, fees, expenses or losses that may be incurred by the Commission or the Participating Member State, or for which the Contractor may be responsible, under this PA and/or any Vaccine Order Form, by taking appropriate and reasonable actions to reduce or limit the amount of such damages, costs, fees, expenses or losses.

### **II.6.4 Limits on liability**

- (i) Taking into account the unprecedented nature of the current COVID-19 situation and the exceptional circumstances under which the Vaccine shall be delivered, the parties explicitly agree that



[REDACTED]

(ii)

[REDACTED]

(iii) The Contractor shall not be liable for any breach or non-compliance of this PA solely and exclusively towards the Participating Member State or any third parties acting on its behalf, whenever that Participating Member State or third parties acting on its behalf acted in breach of the Participating Member State's obligations under this PA or any Vaccine Order Form;

(iv) The aggregate liability of the Contractor and its Affiliates towards the Commission arising out of or relating to this PA and/or the Vaccine Order Forms (whether arising contractually or extra-contractually), shall not exceed [REDACTED]

(v) The liability of the Contractor and its Affiliates towards the Participating Member States arising out of or relating to this PA and/or any Vaccine Order Form concluded with a Participating Member State (whether arising contractually or extra contractually), shall not exceed [REDACTED]

[REDACTED] To avoid doubt this limitation of liability applies in respect of [REDACTED]

(vi) For the avoidance of doubt, this provision does not in any way affect the rights of an injured third party (excluding the Commission or any Participating Member State) to claim damages under the applicable Law.

#### **II.6.5 No limitation of liability**

Nothing in this PA excludes or limits the liability of either party for:

- (a) wilful intent, fraud or fraudulent misrepresentation;
  - (b) any breach of Article II.9 (Confidentiality);
  - (c) in the case of a Participating Member State, failure to pay the price for the Product or any other sums properly owing to the Contractor or a Participating Contractor Affiliate under this PA and Vaccine Order Form;
- [REDACTED]



#### **II.6.6 Waiver of sovereign immunity**

Each Participating Member State represents that it has adequate statutory or regulatory authority and adequate funding appropriation to undertake and completely fulfil the indemnification obligations pursuant to Article I.12 of this PA.

#### **II.6.7 Recall**

In the event of a recall of the Vaccine, the Participating Member States shall be responsible for all costs of any recall or market withdrawal of the Vaccine, including reasonable costs incurred by or on behalf of the Contractor and its Affiliates, 



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

II.7.1 The Contractor must take all the necessary measures to prevent any situation of *conflict of interest or professional conflicting interest*.

II.7.2 The Contractor must *notify* the Commission in writing as soon as possible of any situation that could constitute a *conflict of interest or a professional conflicting interest* during the Implementation of the PA. The Contractor must immediately take action to rectify the situation.

The Commission may do any of the following:

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

II.7.3 The Contractor must pass on all the relevant obligations in writing to:

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

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



## **11.8 Representations and warranties**

### **11.8.1 Mutual representations and warranties**

The parties each represent and warrant to each other the following:

- (i) **Organization and authority.** They have full right, power and authority to enter into this PA and to perform their respective obligations under this PA;
- (ii) **No conflicts or violations.** The execution and delivery of this PA by such party and the performance of such party's obligations hereunder (i) do not conflict with or violate any laws existing as of the date of entry into force of the PA and applicable to such party and (ii) do not and will not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any [REDACTED] contractual obligations of such party; for the avoidance of doubt, the parties warrant that they have not undertaken and [REDACTED] contractual obligations that would hinder or impede the rights and obligations under the present PA; and
- (iii) **Valid execution.** Such party is duly authorised to execute and deliver this PA, and the person executing this PA on behalf of such party is duly authorised to execute and bind such party to the terms set forth herein.

The above warranties shall also be given by the Participating Member States in respect of the Vaccine Orders Forms and their obligations contained therein.

### **11.8.2 Warranties of either party**

The Contractor warrants to the Commission and the Participating Member States that:

- (i) at the time of delivery, the Vaccine (except for any non-compliance or failure to meet the relevant standard or requirement that could not be reasonably discovered given the state of medical, scientific or technical knowledge at the time when the Contractor delivered the Vaccine):



- (ii) subject to the Contractor's disclaimer of non-infringement of intellectual property rights of a third party, it has good title to the Contracted Doses and any Additional Order delivered to the Participating Member States pursuant to this PA and shall pass such title to the Participating Member States free and clear of any security interests, liens, or other encumbrances.

The Contractor also grants the warranties set out in Articles 1.6.3 and 1.6.4.

In the event of any breach of the Contractor's warranties or undertakings relating to the Vaccine, the Commission's and the Participating Member States' sole and exclusive remedy will be those mentioned in Article 1.6.7.



The Commission and the Participating Member State warrant that the PA is awarded and each Vaccine Order Form is concluded in accordance with applicable Laws.

The parties warrant that they shall not, and not attempt to, circumvent, bypass, avoid, obviate, or undermine any of their obligations or warranties under this PA.

### **II.8.3 Anti-bribery/anti-corruption**

The parties represent and warrant that, beyond the mutual consideration set forth in this PA, neither they nor their agents have provided or requested, or will provide or request, any additional incentive or benefit to or from the other party or its agents to induce either party to enter into this PA or perform any part of this PA.

The Contractor has not made, and will not make, in the performance of this PA directly or indirectly any payment, offer, promise, or authorisation of payment of money or anything of value to a government official, political party, candidate for political office, or any other person, and has not sought and will not seek improperly or corruptly to influence any government official, political party, candidate for political office, or any other person, in order to gain an improper business advantage.

### **II.8.4 No other warranty**

Except to the extent set out expressly in this PA, all conditions, warranties or other terms which might have effect between the parties or be implied or incorporated into this PA (whether by statute, common law or otherwise) are hereby excluded to the fullest extent permitted by applicable Law.

## **II.9 CONFIDENTIALITY**

II.9.1 Neither the Commission, a Participating Member State nor the Contractor shall, at any time, without the disclosing party's prior written consent, disclose to any third party any of the other party's Confidential Information.

II.9.2 The Commission, the Participating Member State and the Contractor shall:

- (a) use such Confidential Information solely for the purposes for which it was provided;
- (b) take all reasonable precautions to prevent any unauthorised use or disclosure;
- (c) not disclose or distribute any Confidential Information to any third party except as and to the extent authorised in writing to do so by the disclosing party.

II.9.3 The receiving party shall be permitted to disclose Confidential Information that is required or requested to be disclosed by a governmental authority pursuant to applicable law in connection with any other legal or administrative proceeding, provided that it (i)

notifies the disclosing party of any such disclosure requirement or request as soon as practicable and (ii) furnishes only that portion of the Confidential Information which, in the opinion of the receiving party or their legal counsel, is responsive to such requirement or request and (iii) asks the court or other public body, if applicable, to treat the Confidential Information as confidential.

11.9.4 The receiving party shall disclose Confidential Information only to such of its representatives who have a need to know such Confidential Information to fulfil its obligations under this PA; provided, however, before any disclosure of Confidential Information, the receiving party shall bind its representatives receiving such Confidential Information to a written agreement of confidentiality at least as restrictive as contained in this PA; and prior to any disclosure, the receiving party shall instruct its representatives of the confidential nature of, and to maintain the confidentiality of, the Confidential Information. The receiving party shall be responsible for all actions of its representatives, including any breach of the terms hereof, regardless of whether or not such representatives remain employed or in contractual privity with the receiving party.

11.9.5 Notwithstanding the foregoing, in all cases, [REDACTED]

[REDACTED] the Contractor may disclose Confidential Information to their Affiliates without prior written consent of the Participating Member States.

11.9.6 The confidentiality obligations set out in this Article 11.9 are binding on the Commission, the Participating Member State and the Contractor during the Implementation of the PA and for as long as the information or documents remain confidential unless:

- (a) the disclosing party agrees to release the receiving party from the confidentiality obligation earlier;
- (b) the Confidential Information or documents become public through other means than a breach of the confidentiality obligation;
- (c) the applicable Law requires the disclosure of the Confidential Information or documents.

11.9.7 The Contractor must obtain from any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the Implementation of the PA a commitment that they will comply with this Article. At the request of the Commission, the Contractor must provide a document providing evidence of this commitment.


11.9.8 Neither this PA nor the performance by either party hereunder shall transfer to the receiving party any proprietary right, title, interest or claim in or to any of the disclosing party's Confidential Information (including, but not limited to, any intellectual property rights subsisting therein) or be construed as granting a license in its Confidential Information.

**II.9.9** The provisions of this Article II.9 shall survive the termination or expiration of this PA for a period of ten (10) years, except with respect to any information that constitutes a trade secret (as defined by the applicable Law), in which case the recipient of such information will continue to be bound by its obligations under this Article II.9 for so long as such information continues to constitute a trade secret, but in no event for a period of less than the ten (10)-year period specified above.

**II.9.10** The Contractor acknowledges that the Commission is subject to requirements laid down under Regulation (EC) 1049/2001. The Commission commits that it will consult with the Contractor on any disclosure request concerning documents containing Confidential Information as provided for in Article 4(4) of said Regulation.

## **II.10 ANNOUNCEMENTS AND PUBLICITY**

The parties shall consult together on the timing, contents and manner of any press release relating to the execution of this PA. Other than the foregoing, no party shall make, or permit any person to make, any public announcement concerning the existence, subject matter or terms of this PA or a Vaccine Order Form, the wider transactions contemplated by them, or the relationship between the parties, without the prior written consent of the other party (such consent not to be unreasonably withheld or delayed), except (i) as required by law, any governmental or regulatory authority (including, without limitation, any relevant securities exchange), any court or other authority of competent jurisdiction; or (ii) on terms that are consistent and do not go further than the matters covered in any agreed press release. For clarity, unless consent is granted pursuant to this Article II.10, no announcement or disclosure will (i) include or infer




A party shall not use the name, trade name, service marks, trademarks, trade dress or logos of the other party in publicity releases, advertising or any other publication, without the other party's prior written consent in each instance, provided, however, that consent is granted for public announcements pursuant to above sub-clause (ii) in this Article II.10.

## **II.11 PROCESSING OF PERSONAL DATA**

### **II.11.1 Processing of personal data by the Commission**

Any personal data included in or relating to the PA, including its implementation, shall be processed in accordance with Regulation (EU) 2018/1725. Such data shall be processed solely for the purposes of the implementation, management and monitoring of the PA by the data controller. For the purpose of this provision, the data controller for the Commission shall be the Director-General of the European Commission's Directorate-General for Health and Food Safety. The data protection notice is available at [https://ec.europa.eu/info/data-protection-public-procurement-procedures\\_en](https://ec.europa.eu/info/data-protection-public-procurement-procedures_en).

The Contractor or any other person whose personal data is processed by the data controller in relation to this PA has specific rights as a data subject under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, rectify or erase their personal data



and the right to restrict or, where applicable, the right to object to processing or the right to data portability.

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

#### **II.11.2 Processing of personal data by the Contractor**

The processing of personal data by the Contractor shall meet the requirements of Regulation (EU) 2016/679 and be processed solely for the purposes set out by the controller.

#### **II.12 SUBCONTRACTING**

II.12.1 The Contractor may not subcontract and have the PA implemented by third parties beyond the third parties already mentioned in its tender without prior written notification to the Commission. For the avoidance of doubt, it is agreed that the entities mentioned under points a) to f) of section 2.4.2 of the Commissions' tender specifications shall not be considered subcontractors for the purpose of this Article II.12 and that they can be involved in the service delivery by the Contractor.

II.12.2 In the case of subcontracting, the Contractor remains bound by its contractual obligations and is solely responsible for the *Implementation of the PA*.

II.12.3 The Contractor must ensure that the subcontract does not affect the rights of the Commission and the Participating Member States under this PA.

#### **II.13 AMENDMENTS**

II.13.1 Any amendment to the PA or a Vaccine Order Form must be made in writing before all contractual obligations have been fulfilled. A Vaccine Order Form does not constitute an amendment to the PA.

II.13.2 No amendment can make changes to the PA or a Vaccine Order Form that might alter the initial conditions of the procurement procedure or result in unequal treatment of tenderers or contractors.

#### **II.14 ASSIGNMENT**

Neither this PA nor any interest hereunder will be assignable by a party without the prior written consent of the other party, except as follows:

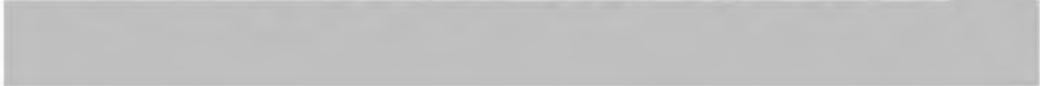




## **II.15 FORCE MAJEURE**

II.15.1 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.15.2 A party is not liable for any delay or failure to perform its obligations under the PA or Vaccine Order Form if that delay or failure is a *result of Force majeure*.



II.15.3 The parties must take all necessary measures to limit any damage due to *Force majeure* and shall use commercially reasonable efforts to avoid or minimize the delay in performance of their respective obligations affected by *Force majeure*.

## **II.16 SUSPENSION OF THE IMPLEMENTATION OF THE PA**

### **II.16.1 Suspension by the Contractor**


If the Contractor or a Participating Contractor Affiliate is affected by *Force majeure*, it may suspend the provision of the services under a Vaccine Order Form.

The Contractor or the Participating Contractor Affiliate must immediately *notify* the Commission of the suspension. The *notification* must include a description of the *Force majeure* and state when the Contractor or the Participating Contractor Affiliate expects to resume the provision of services.

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

### **II.16.2 Suspension by the Commission or the Participating Member State**

Pursuant to the Financial Regulation, the Commission or the Participating Member State may suspend the Implementation of the PA or performance of a Vaccine Order Form or any part of it:



- (a) if the procedure for awarding the PA or a Vaccine Order Form or the Implementation of the PA proves to have been subject to Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations;
- (b) in order to verify whether the presumed Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations have actually occurred.

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

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


- (a) it is lifting the suspension; or
- (b) it intends to terminate the PA or a Vaccine Order Form under Article II.17.1. (f) or (i).

The Contractor is not entitled to compensation for suspension of any part of the PA or a Vaccine Order Form. For the avoidance of doubt, the Contractor shall not be under any obligation to deliver any Contracted Doses or the Additional Order during the suspension period, and the Delivery Schedule shall be adjusted to take into account the period of such suspension. Equally for the avoidance of doubt, the Contractor shall complete the delivery of any Contracted Doses or Additional Order that were already in transit on the date of the formal notification or at the later date indicated in the formal notification.

## **II.17 TERMINATION OF THE PA**

### **II.17.1 Grounds for termination by the Commission**

The Commission may terminate the PA or the Participating Member State may terminate any on-going Vaccine Order Form (depending on whether the event affects the PA or the Vaccine Order Form) solely in the following circumstances:

- (a) 
- (b) if the Contractor does not implement the PA or perform the Vaccine Order Form in accordance with material aspects of the PA or the Vaccine Order Form (as applicable) or is otherwise in material breach of another substantial contractual obligation;
- (c) if the Contractor repeatedly refuses to sign Vaccine Order Forms without cause. Termination of three or more Vaccine Order Forms in these circumstances also constitutes grounds for termination of the PA;
- (d) if the Contractor or any person that assumes unlimited liability for the debts of the Contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation<sup>5</sup>;
- (e) if the Contractor or any Related person is in one of the situations provided for in points (c) to (h) of Article 136(1) or Article 136(2) of the Financial Regulation;

<sup>5</sup> Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 281/2014, 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>

- (f) if the procedure for awarding the PA or the Implementation of the PA proves to have been subject to Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations;
- (g) if the Contractor is in a situation that does constitute a Conflict of interest or a Professional conflicting interest which would have a material adverse impact on the performance of the PA;
- (h) in case of 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;
- (i) in the event of *Force majeure*, where either resuming implementation is impossible or the necessary ensuing amendments to the PA or a Vaccine Order Form would mean that this PA is no longer fulfilled to a substantial degree or result in a substantially unequal treatment of tenderers or contractors.

#### **II.17.2 Grounds for termination by the Contractor**

The Contractor may terminate the PA or any on-going Vaccine Order Form solely in the following circumstances:

- (a) if the Commission or the Participating Member State does not implement the PA or does not perform the Vaccine Order Form in accordance with material aspects of the PA or the Vaccine Order Form (as applicable) or is otherwise in material breach of another substantial contractual obligation, including the Commission's obligation to communicate the allocation of the Contracted Doses or any Additional Order, the Participating Member States' obligation to submit a duly completed Vaccine Order Form in accordance with the allocation, the Participating Member States' obligation to accept delivery of the Contracted Doses or any Additional Order, the Participating Member States' obligation to pay the price of the Contracted Doses or any Additional Order, and, in respect only of the Vaccine Order Form with the relevant Participating Member State, that Participating Member State's obligation to comply with the donation and resale provisions set out in Article I.6.2.

#### **II.17.3 Procedure for termination**

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

The other party has [REDACTED] following the date of receipt to submit observations, including the measures it has taken or will take to continue fulfilling its contractual obligations. Failing that, the decision to terminate becomes enforceable the day after the time limit for submitting observations has elapsed in the event the grounds giving rise to termination have not been cured.

If the other party submits observations, the party intending to terminate must *formally notify* it.

#### **II.17.4 Effects of termination**

[REDACTED] of the date of termination, the Contractor must submit any invoice required for services that were provided before the date of termination.

The termination or expiration of this PA shall not affect the survival and continuing validity of Articles I.1, I.2, I.4, I.6.2 (so far as it concerns resale and donation), I.6.7, I.6.9, I.6.11, I.6.12, I.6.14, I.6.16, I.7 to I.9, I.11 to I.14, II.3, II.5, II.6, II.8.2, II.8.4, II.9 to II.11, II.15, II.17.4, II.18 to II.28, Attachment 3 (Delivery Specification) and Attachment 5 (Return and Disposal of Product Materials) or of any other provision which is expressly or by implication intended to continue in force after such termination or expiration.

Expiry or termination of this PA for any reason shall be without prejudice to either party's other rights and remedies or to any accrued rights and liabilities as the date of such expiry or termination; provided that the Contractor shall have no liability for any future failure to deliver the Contracted Doses or Additional Order in accordance with any delivery dates set forth herein.

## **II.18 INVOICES, VALUE ADDED TAX AND E-INVOICING**

### **II.18.1 Invoices and value added tax**

Invoices must contain the Contractor's or the Participating Contractor Affiliate's (or leader's in the case of a joint tender) identification data, the amount, the currency and the date, as well as the PA reference and reference to the Vaccine Order Form.

Invoices must indicate the place of taxation of the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) for value added tax (VAT) purposes and must specify separately amounts not including VAT and amounts including VAT.

It is understood and agreed between the parties that any prices stated under this PA and Vaccine Order Form are exclusive of any VAT or similar tax and all other taxes which are incurred as a result of manufacturing and supplying the Product (including custom duties, levies and charges and all local taxes) ("Taxes"), which shall be added thereon as applicable. Where Taxes are properly chargeable on any amounts payable under this PA or Vaccine Order Form, the party making the payment will pay the amount of Taxes, as specified on the invoice, in accordance with the laws and regulations of the country in which the Taxes are chargeable.

In the event any payments made pursuant to this PA become subject to withholding taxes under the laws or regulation of any jurisdiction, the party making such payment shall deduct and withhold the amount of such taxes for the account of the payee to the extent required by applicable laws or regulations and such amounts payable to the payee shall be reduced by the amount of taxes deducted and withheld. Any such withholding taxes required under applicable laws or regulations to be paid or withheld shall be an expense of, and borne solely by, the payee.

## **II.19 PAYMENTS AND GUARANTEES**

### **II.19.1 Date of payment**

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

### **II.19.2 Currency**

Payments are made in euros or, for non-Eurozone countries, the local functional currency of the Participating Member State. For non-Eurozone countries, the Vaccine Order Form shall set

forth the Delivery Price in the local functional currency converted from euro at the exchange rate existing one (1) day prior to the Effective Date of the PA as of 4:00pm London time published in Bloomberg FX Fixings (BFIX), such rates being found via Bloomberg or the website [www.bloomberg.com/markets/currencies/fix-fixings](http://www.bloomberg.com/markets/currencies/fix-fixings).

#### **11.19.3 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) the Contractor or the Participating Contractor Affiliate bears the costs of receipt charged by its bank;
- (c) the party causing repetition of the transfer bears the costs for repeated transfer.

#### **11.19.4 Suspension of the time allowed for payment**

The Commission or the Participating Member State in question may suspend the payment periods specified in Article 1.8 at any time by *notifying* the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) that its invoice cannot be processed. The reasons the Commission or the Participating Member State in question may cite for not being able to process an invoice are:

The Commission or the Participating Member State in question must notify the Contractor or the Participating Contractor Affiliate (or leader in the case of joint tender) as soon as possible of any such suspension, giving the reasons for it. In cases b) and c) referred above, the Commission or the Participating Member State in question shall notify the Contractor or the Participating Contractor Affiliate (or leader in case of a joint tender) the time limits to submit additional information or corrections or a new version of the documents or deliverables.

Suspension takes effect on the date the Commission or the Participating Member State in question sends the *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.

#### **11.19.5 Interest on late payment**

On expiry of the payment periods specified in Article 1.8, the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) is entitled to interest on late payment at the higher of (a) the rate applied by the European Central Bank for its main refinancing

operations in euros (the reference rate) [REDACTED] or such centralized bank reference rate set forth in the Vaccine Order Form) and (b) [REDACTED]. The reference rate is the rate in force, as published in the C series of the *Official Journal of the European Union*, on the first day of the month in which the payment period ends.

Suspension of the payment period as provided for in Article II.19.4 is not considered as giving rise to late payment.

Interest on late payment covers the period running from the day following the due date for payment up to and including the date of payment as defined in Article II.19.1.

## **II.20 RECOVERY**

### **II.20.1 Recovery procedure**

In all cases where the recovery procedure as described in the Financial Regulation applies, the parties shall follow the procedure set out in this Article.

Before recovery, the Commission or the Participating Member State in question must formally notify the Contractor of its intention to recover the amount it claims, specifying the amount due and the reasons for recovery and inviting the Contractor to make any observations within [REDACTED] of receipt.

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

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

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

### **II.20.2 Interest on late payment**

If the Contractor does not honour the obligation to pay the amount due by the date set by the Commission or the Participating Member State in question, the amount due bears interest at the rate indicated in Article II.19.5. Interest on late payments will cover the period starting on the day after the due date for payment and ending on the date when the Commission or the Participating Member State in question receives the full amount owed.

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

## **II.21 CHECKS AND AUDITS**

II.21.1 The Commission and the European Anti-Fraud Office may check or require an audit on the Implementation of the PA. This may be carried out either by OLAF's own staff or

by any outside body authorised to do so on its behalf, provided that the auditor may not be a competitor of the Contractor.

Such checks and audits may be initiated at any moment during business hours during the provision of the services and up to five years starting from the payment of the balance of the last specific contract issued under this PA.

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

II.21.2 The Contractor must keep all original documents stored on any appropriate medium, including digitised originals if authorised under national law, for a period of five years starting from the payment of the balance of the last specific contract issued under this PA.

II.21.3 The Contractor must grant the appropriate right of access to sites and premises where the PA is implemented, [REDACTED] needed to conduct such checks and audits. The Contractor must ensure that the information is readily available at the moment of the check or audit and, if so requested, that information is handed over in an appropriate format. The auditor must, insofar possible, comply with all applicable and reasonable security measures notified to Commission by the Contractor subject to this not creating any material obstacles for the performance of the auditor's tasks.

II.21.4 On the basis of the findings made during the audit, a provisional report is drawn up. The Commission or its authorised representative must send it to the Contractor, who has 30 days following the date of receipt to submit observations. The Contractor must receive the final report within 60 days following the expiry of the deadline to submit observations.

On the basis of the final audit findings, the Participating Member State in question may recover all or part of the payments made in accordance with Article II.20 and may take any other measures which it considers necessary.

II.21.5 In accordance with Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities and Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office, the European Anti-Fraud Office may carry out investigations, including on the spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity under the contract affecting the financial interests of the Union. Findings arising from an investigation may lead to criminal prosecution under national law.

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

II.21.6 The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/19398 ('the EPPO') have the same rights as the

Commission, particularly right of access, for the purpose of checks, audits and investigations.

#### **II.22 RELATIONSHIP OF THE PARTIES**

The relationship hereby established between the Contractor and the Commission is solely that of independent contractors. Neither party has authority to act or make any agreements or representations on behalf of the other party. This PA is not intended to create, and shall not be construed as creating, between the parties, the relationship of principal and agent, employer and employee, joint venturers, co-partners, or any other such relationship, the existence of which is expressly denied.

#### **II.23 WAIVER**

A waiver by any party of any term or condition of this PA in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach thereof. All remedies specified in this PA shall be cumulative and in addition to any other remedies provided at Law or in equity, except where expressly otherwise agreed.

#### **II.24 FURTHER DOCUMENTS**

Each party hereto agrees to execute such further documents and take such further steps as may be reasonably necessary or desirable to effectuate the purposes of this PA.

#### **II.25 HEADINGS**

Headings of Articles or other parts of this PA are included herein for convenience of reference only and shall not constitute a part of this PA or change the meaning of this PA.

#### **II.26 ELECTRONIC DELIVERY AND STORAGE**

Delivery of a signed PA by reliable electronic means, including facsimile or email (with receipt electronically confirmed), shall be an effective method of delivery of the executed PA. This PA may be stored by electronic means and either an original or an electronically stored copy of this PA can be used for all purposes, including in any proceeding to enforce the rights or obligations of the parties to this PA.

#### **II.27 ENTIRE AGREEMENT**

This PA, together with any Annexes and Attachments, which are hereby incorporated by reference, constitute the entire agreement of the parties with respect to its subject matter and merges and supersedes all prior discussions and writings with respect to thereto.

#### **II.28 COSTS**

Each party will bear its own legal costs in preparing and concluding this PA.



## ANNEX I: VACCINE ORDER FORM

This Vaccine Order Form is submitted by:

[The Government of [•]] (the “**Participating Member State**”), represented for the purposes of signing this Vaccine Order Form by [forename, surname, function, department of authorising officer],

to:

Pfizer Inc, incorporated in Delaware (Registration Number 0383418) with its registered address at 235 East 42nd Street, 10017 New York City, NY (UNITED STATES) (“**Pfizer**”);

and

BioNTech Manufacturing GmbH, registered with the commercial register of the lower court (Amtsgericht) of Mainz, Germany under HRB 47548, with its registered address at An der Goldgrube 12, 55131 Mainz, Germany (“**BioNTech**”).

(Pfizer and BioNTech together the “**Contractor**”, represented for the purposes of signing this Vaccine Order Form by [REDACTED])

The Participating 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 a Purchase Agreement for the purchase and supply of Contractor’s Vaccine for EU Member States dated [•] 2021 (the “**PA**”), the terms of which are binding on the Participating Member States and must be read in conjunction with this Vaccine Order Form.

The PA provides that each Participating Member State will submit to Contractor a Vaccine Order Form through which Contractor shall make available and deliver to the relevant Participating Member State a proportion of the Contracted Doses or Additional Order as applicable, in accordance with the allocation provided by the Commission pursuant to Article I.6.3 of the PA and at the price and conditions as set out in the PA.

- In accordance with Article I.5.2 and I.6.2 of the PA, the Participating Member State hereby places its order for its full allocated portion of the Contracted Doses or Additional Order (as applicable).

## **Article I**

### **Subject matter**

1. This Vaccine Order Form is submitted by the Participating Member State to Contractor in accordance with the terms of the PA, and forms an integral part of the PA. The terms and conditions of the PA are incorporated into this Vaccine Order Form by reference. In the event of contradiction between this Vaccine Order Form and the PA, the terms of the PA prevail regardless of any provision to the contrary. Any capitalised terms in this Vaccine Order Form will have the meaning attributed to them in the definitions list included in Article I.2 of the PA.

2.

This Vaccine Order Form relates to the order for the Participating Member State's full allocated portion of the Contracted Doses or the relevant Additional Order (as applicable) as set out in the allocation provided by the Commission to Contractor pursuant to Article I.6.2 of the PA. The submission of this signed Vaccine Order Form by the Participating Member State to Contractor constitutes a binding order by the Participating Member State for the purchase of its full allocated portion of the Contracted Doses or the relevant Additional Order (as applicable) in accordance with the details set out in the Appendix to this Vaccine Order Form

3. By signature of this Vaccine Order Form, the undersigned Participating Member State warrants to Contractor that:
  - a it is irrevocably and unconditionally bound by the terms of the PA (as concluded by the Commission on behalf and in the name of the Participating Member States), including the indemnification obligations and the liability, limitation of liability and exclusions terms set out therein;
  - b the provisions of the PA are enforceable against it in accordance with its terms;
  - c it shall indemnify the Indemnified Persons in accordance with Article I.12 (*Indemnification*) of the PA;
  - d it has full right, power and authority to enter into this Vaccine Order Form and to perform its respective obligations under it;
  - e the person executing this Vaccine Order Form is duly authorized to execute and bind the undersigned Participating Member State to the terms set forth herein and incorporated by reference.



5.

The Participating Member State represents and warrants that all necessary permissions and approvals have been or will be obtained prior to the time for performance by the Participating Member State, to authorise performance of all of the obligations contained herein.

6. Any change to the Appendix to this Vaccine Order Form requires to be agreed by the parties in writing or by email.

## **Article II**

### **Delivery, Supply**

1. Delivery Address. The Delivery Address(es) for the Participating Member State is as set out in the Appendix to this Vaccine Order Form.

2. **Supply of the Products**


The Contractor shall supply the Products as further described in the PA: [Note: Include any additional details concerning the supply here.]

## **Article III**

### **Invoices; Notices**

1. Invoice and Payments. Contractor shall invoice the Participating Member State in accordance with the terms of the PA. All payments to Contractor or its designated Affiliate shall be made in accordance with the terms of the PA.

Payment shall be made in the currency set out in the Appendix to this Vaccine Order Form.

2. **Notice**. Any notice given under this Vaccine Order Form must a) be made in writing in English in paper or electronic format; b) bear the PA number and the number of this Vaccine Order Form; c) be made using the relevant communication details set out in the Appendix to this Vaccine Order Form with respect to the Participating Member State and Contractor (as applicable); d) be sent by mail and email:
- 

#### **Article IV.**

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

1. This Vaccine Order Form shall enter into force on the date of signature by the Parties and will remain into force until termination of the PA, or if the PA expires, until the last delivery of Product which in any event must take place within 6 months of such expiry.

#### **Article V.**

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

1. For the avoidance of doubt, Article 1.13 (*Applicable Law and Settlement of Disputes*) of the PA shall apply to any dispute arising out of the implementation of or in connection with this Vaccine Order Form and the Participating Member State irrevocably agrees to be bound by the provisions set out therein.

## Appendix

### Order Details

- a. Participating Member State will purchase [insert amount] number of doses of [Contracted Doses] [Additional Order] of the Vaccine, on the basis of the following delivery schedule:

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  |  |  |
|  |  |  |  |  |

- b. The price of [Contracted Doses] [Additional Order] is

The total amount payable by the Participating Member State for the [Contracted Doses] [Additional Order] is [insert amount],

- c. The Delivery Address(es) are as follows:

[insert]

- d. Payment shall be made in the following currency pursuant to the provisions of Article II.19.2 of the PA: [to be completed].

- e. Details for notices

Participating Member State:

*[Name of Participating Member State]*

*[Full official address of Participating 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:

[Add details]

(Signature page follows)

## SIGNATURES

For the **Participating Member State**,

*[forename'surname'position]*

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

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

For acceptance of the Vaccine Order Form,

Contractor,

\_\_\_\_\_

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

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

The invoice will be paid only once the **Contractor** has returned the signed Vaccine Order Form.



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

**Agreement**

**Preamble**

Having regard to Article 4(5)(b) of Council regulation (EU) 2016/369 on the provision of emergency support within the Union (as amended by Council regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak (hereinafter "ESI" or "ESI regulation"  
.....

\*\*\*

The European Commission ("the Commission")

and

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

Together referred to as "the Parties"

Agree on the Following:

**Article 1: Objective and mandate of the Commission**

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

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

**Article 2: Acquisition of vaccine doses**

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

**Article 3: APAs containing a right to acquire vaccine doses**

Where the Commission concludes an APA in conformity with the present agreement that provides the right for the Participating Member States to acquire vaccine doses, the use of such a right shall take place by means of the conclusion of contracts between the Participating Member States and the vaccine manufacturers. There shall be no obligation for any Participating Member State to conclude such a contract on the basis of the APA. The APA shall contain a clause to this end.

**Article 4: APAs containing an obligation to acquire vaccine doses**

Where the Commission intends to conclude, in conformity with the present agreement, an APA containing an obligation to acquire vaccine doses, it shall inform the Participating Member States of such intention and the detailed terms. In case a Participating Member State does

not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the Commission within 5 working days after the Commission has communicated its intention to conclude the APA. All Participating Member States not having opted out within the period of 5 working days are deemed to have authorised the Commission to negotiate and conclude the APA with the vaccine manufacturer in their name and on their behalf.

#### **Article 5: The legally binding nature of APAs**

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

#### **Article 6: Responsibility and liability**

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

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

Participating Member States acquiring a vaccine shall be responsible for the deployment and use of the vaccines under their national vaccination strategies, and shall bear any liability associated with such use and deployment. This shall extend to and include any indemnification of vaccine manufacturers under the terms and conditions of the relevant APA for liability related to the use and deployment of vaccines normally borne by such manufacturer.

#### **Article 7: Obligation not to negotiate separately**

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

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

### **Annex**

#### **Initial considerations**

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

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

#### **Structure and purpose of the procurement**

Work on a COVID-19 vaccine is challenging for many reasons: the shortened development timeframe, the large upfront costs for manufacturers, the high failure rate during clinical trials. If vaccine producers follow their usual practice of making investments in production capacity



only when they are sure of a viable product, this will result in considerably longer waiting times for a vaccine. Investments need to be made now in order to ensure that vaccines are being produced at the scale required as early as possible.

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

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

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

#### **Process and governance**

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

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

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

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

Should financing under ESI be insufficient, Participating Member States can decide to top up ESI funding to make up the gap to finance all packages. In such a case where there are opportunities to conclude further APAs but money from ESI is no longer sufficient, Participating Member States will

have the opportunity to express their interest in such opportunities. If at least four Participating Member States express interest, those Participating Member States will make use of the possibility of a voluntary contribution to ESI to the required amount allowing the Commission to proceed with signing the APA only on behalf of those Member States that have expressed interest and contributed the funds to ESI.

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

#### **Advanced Purchase Agreements and conditions**

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

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

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

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

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

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

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

and

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

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

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

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

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

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

### **ANNEX III: PARTICIPATING MEMBER STATES**

Federal Republic of Germany

French Republic

Italian Republic

Kingdom of Spain

Republic of Austria

Hellenic Republic

Republic of Cyprus

Republic of Malta

Kingdom of Denmark

Kingdom of Sweden

Republic of Finland

Ireland

Portuguese Republic

Kingdom of Belgium

Grand Duchy of Luxembourg

Kingdom of the Netherlands

Republic of Poland

Romania

Republic of Bulgaria

Republic of Slovenia

Republic of Croatia

Czech Republic

Slovak Republic

Republic of Lithuania

Republic of Latvia

Republic of Estonia

#### **ANNEX IV: SUBCONTRACTORS**



# **ANNEX V – PARTICIPATING CONTRACTOR AFFILIATES**

| <b>Country</b> | <b>Participating Contractor Affiliate</b>        |
|----------------|--|
| Germany        | BioNTech Europe GmbH                             |
| France         | Pfizer SAS                                       |
| Italy          | Pfizer S.r.l.                                    |
| Spain          | Pfizer S.L.U.                                    |
| Austria        | Pfizer Corporation Austria GmbH                  |
| Greece         | Pfizer Hellas SA                                 |
| Cyprus         | Pfizer Export B.V.                               |
| Malta          | Pfizer Export B.V.                               |
| Denmark        | Pfizer ApS                                       |
| Sweden         | Pfizer Innovations AB                            |
| Finland        | Pfizer Finland Oy                                |
| Ireland        | Pfizer Healthcare Ireland                        |
| Portugal       | Pfizer Biofarmacêutica Sociedade Unipessoal, Lda |
| Belgium        | Pfizer SA  |
| Luxembourg     | Pfizer Luxembourg S.A.R.L.                       |
| Netherlands    | Pfizer B.V.                                      |
| Poland         | Pfizer Export B.V. and Trading Polska sp. z o.o. |
| Romania        | Pfizer Romania SRL                               |
| Bulgaria       | Pfizer Export B.V.                               |
| Slovenia       | Pfizer Export B.V.                               |
| Croatia        | Pfizer Export B.V.                               |
| Czech Republic | Pfizer, spol. s r.o.                             |
| Slovakia       | Pfizer Export B.V.                               |
| Lithuania      | Pfizer Export B.V.                               |
| Latvia         | Pfizer Export B.V.                               |
| Estonia        | Pfizer Export B.V.                               |

In addition, any Contractor Affiliate which is involved in the sale or distribution of Product which is resold or donated by a Participating Member State shall be deemed to be a Participating Contractor Affiliate.

pages 71-the end ' have been  
deleted as they are entirely  
protected by Article 4(2) first  
indent of Regulation 1049/2001