SENSITIVE

EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

ADVANCE PURCHASE AGREEMENT ("APA")[1] for the development, production, priority-purchasing options and supply of a successful COVID-19 vaccine for EU Member States

SANTE/2020/C3/043 - SI2.838335

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"),[2]:

being represented for the purposes of the signature of this APA 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"**)

as a member of the group (collectively '**the Contractor'**), represented for the purposes of the signature of this APA which has the form of a framework contract by Nanette Cocero, President of Vaccines, Pfizer Inc.

on the other part,

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

2 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.

HAVE AGREED

to the **special conditions and the general conditions of this APA** 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 APA.

The full content of the Attachments will be provided as soon as possible after Authorisation has been obtained and prior to the first shipment and may be updated by the Contractor and communicated to the Participating Member States from time to time, it being understood that any changes made will be of a practical nature and will not materially alter the risk, cost or liability of the parties. In case any substantial amendments are sought to be made, the parties will discuss the impact thereof in good faith.

This APA sets out:

1. the procedure and conditions by which the Commission and 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 APA; and

3. the obligations of the parties during and after the duration of this APA.

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 APA. In all circumstances, in the event of contradiction between this APA and documents issued by the Contractor, this APA prevails, regardless of any provision to the contrary in the Contractor's documents.

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I. SPECIAL CONDITIONS

I.1 ORDER OF PRIORITY OF PROVISIONS

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

(a) The provisions set out in the special conditions and Article II.6 of the general conditions (Liability) take precedence over those in the other parts of the APA.

(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 APA take precedence over those in the Vaccine Order Forms.

I.2 DEFINITIONS

The following definitions shall apply to this APA:

'Additional Order': has the meaning set forth in Article I.6.2;

'Additional Product': has the meaning set forth in Article I.6.2;

'Adjusted Delivery Schedule': has the meaning set forth in Article I.6.3(ii);

'Advance Payment': has the meaning set forth in Article I.8.1

'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;

'Best Reasonable Efforts': means, with respect to the efforts to be expended by the Contractor to achieve the objective, the activities and degree of effort that a similarly situated party (with respect to size, resources and assets) in the pharmaceutical industry would use to accomplish a similar objective in similar circumstances, in particular taking into account the following factors: current urgency of the COVID-19 crisis and the Contractor's desire to address the crisis; the COVID-19 vaccine landscape; the novelty, safety and efficacy of the Vaccine; the costs, liabilities and any external and internal resources reasonably necessary or useful to achieve the relevant objective; the specific challenges of developing, manufacturing and supplying this novel Vaccine; and all other relevant risks, uncertainties, limitations and challenges. The Commission acknowledges and agrees, and Best Reasonable Efforts does not

require, that the Contractor be obliged to take any action prejudicial to the Contractor to meet such "Best Reasonable Efforts" standard, and the Contractor in turn acknowledges and shares the Commission's desire that the Vaccine be made available to help address the pandemic;

'Conditional Marketing Authorisation': means a conditional marketing authorisation granted by the European Commission 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 APA 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 APA* by the Contractor is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the Commission, the Participating Member State or any third party related to the subject matter of the APA;

'Contracted Doses': has the meaning set forth in Article I.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;

'Delivery Price': has the meaning set forth in Article I.8.2;

'Delivery Schedule': means the Interim Delivery Schedule or the Adjusted Delivery Schedule, as applicable;

'Effective Date': has the meaning set forth in Article I.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 APA, 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), 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 the subcontractors and must prove to be inevitable despite their exercising due diligence. Defaults of service, defects in equipment or material or delays in making them available, labour disputes, strikes and financial difficulties 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 under this APA only by reason of the Advance Payment;

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

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

'Interim Delivery Schedule': has the meaning set forth in Article I.6.3;

'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 under this APA only by reason of the Advance Payment;

'Latent Defect': means a defect causing the Product to not conform to the applicable Specifications that the relevant Participating Member State can show was present at the time of delivery of the Product and 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 I.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;

'Non-Complying Product': has the meaning set forth in Article I.6.14;

'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;

'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 APA 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 APA;

'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;

'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 APA set out in Article I.4.2 of the APA;

'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': BNT162b2, a nucleoside-modified messenger RNA (modRNA) vaccine that encodes an optimized SARS-CoV-2 full-length spike glycoprotein (S) for which a rolling submission for BNT162b2 has been initiated with the European Medicines Agency;

'Vaccine IP Rights': has the meaning set forth in Article **Error! Reference source not f ound.**; and

'Vaccine Order Form: has the meaning set forth in Article I.5.2I.3.

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 APA 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 APA, and references to this APA 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 APA, (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/2020/C3/043 is securing the purchase of certain vaccine doses for the Participating Member States.

By Decision C(2020) 4192 final of 18 June 2020, the Commission approved the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States ("the Decision"). This agreement is based on Article 4(5)(b) of Regulation (EU) 2016/369 of 15

March 2016 on the provision of emergency support within the Union[3] ("the ESI Regulation") which provides that the Commission may grant emergency support in the form of procurement on behalf of the Member States based on an agreement between the Commission and Member States. In order to implement such action, the Commission is running procurement procedures on behalf of Participating Member States, with a view to signing EU-level APAs with vaccine manufacturers. In view of its importance, this APA will be approved for signature on behalf and in the name of the Participating Member States by a separate individual Commission decision.

The Contractor is currently in Phase 3 clinical development of the Vaccine and is using its Best Reasonable Efforts to secure Authorisation of such vaccine candidate by the Commission, expected at the earliest in December 2020.

The Commission, on behalf of the Participating Member States, wishes to purchase the Vaccine during the pandemic period through this APA. It acknowledges that the clinical development might not be successful or regulatory approval may not be obtained and subsequently an authorised Vaccine may not be available.

On the basis of this APA, the European Commission commissions the Contractor to commit to produce and deliver in priority 200 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 APA.

In case the Contractor succeeds to develop a safe and effective Vaccine according to the terms laid down in this APA, the Contractor or an Affiliate of the Contractor 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 APA.

I.4 ENTRY INTO FORCE AND DURATION OF THE APA

I.4.1 The APA enters into force on the date on which the last party signs it (**"Effective Date"**).

I.4.2 The APA is concluded for a period of 24 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 APA expires.

The APA 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 APA.

[3] 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.

I.4.4 Renewal of the APA

The APA will expire automatically at the end of the Term, unless it is extended in mutual written agreement between the parties. Renewal does not change or postpone any existing obligations.

I.5 IMPLEMENTATION OF THE APA

I.5.1 Period of provision of the supplies

The period for the provision of the supplies starts to run as foreseen in Article I.6.3.

I.5.2 Implementation of the APA

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

In order to guarantee the right of the Participating Member States to acquire Vaccine doses in a given timeframe and at a certain price and conditions, the Commission will pay the Advance Payment.

The Contractor shall use Best Reasonable Efforts to build manufacturing capacity or utilise existing capacity to be capable of manufacturing and supplying the Product to the Commission in accordance with the provisions of this APA.

The Contractor agrees to supply an initial total number of 200 million Vaccine doses to Participating Member States collectively, upon their order, in accordance with this APA and the respective Vaccine Order Forms.

The Participating Member States shall place orders for supplies of 200 million Vaccine doses in total in accordance with the allocation communicated by the Commission to the Contractor pursuant to Article I.6.3, by sending the Contractor a completed copy of Annex I ("**Vaccine Order Form**") in paper format or emailed pdf within 10 business days following the Commission communicating the allocation. 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.

I.6 SUPPLY OF THE VACCINE

I.6.1 Creation of the Vaccine

During the term of this APA, and subject to the successful development and authorisation of the Vaccine as set out in this APA, the Contractor shall use Best Reasonable Efforts to 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 APA.

I.6.2 Product supply

At the Effective Date, the Commission orders 200 million doses (**"Contracted Doses"**) of the Product on behalf of the Participating Member States to be delivered if the Contractor succeeds to develop a safe and effective Vaccine according to the terms laid down in this APA.

The parties acknowledge that the Commission may wish to place an additional binding order (the **"Additional Order"**) for a maximum of up to 100 million doses of the Vaccine. The parties also agree that such Additional Order may be placed by the Commission only after (i) being advised by the Contractor that the Contractor has availability of supply of such additional requested doses at the time of the proposed Additional Order (the **"Additional Product"**) (ii) the Contractor agrees, in its sole discretion, to allocate the Additional Product to the Commission (iii) the Contractor confirms how many doses can be delivered and by when (iv) the Commission confirms the required allocation between Participating Member States and (v) the Contractor confirms the delivery schedule based on a pro-rata split of the available doses across the Participating Member States who wish Additional Product. The Additional Order will be placed by way of an additional Vaccine Order Form and, as such, be subject to the same terms and conditions set forth in this APA.

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 governments of the Participating Member States. Each Participating Member State will have the right to resell or donate them to in need third countries or public institutions, contributing to a global and fair access to the Vaccine across the world. The right to resell or donate excess doses under the preceding sentence shall be subject to the Contractor's consent and be contingent in particular on receipt of (i) written indemnification by the recipient third country or public institution of the Contractor on terms satisfactory to the Contractor, and (ii) written confirmation that the Participating Member States and the receiving third countries or public institutions as the case may be shall, to the extent relevant to their actions in respect of such resale or donation, comply with applicable storage, transport and product acceptance requirements, as well as conditions of further resale or donation, to the satisfaction of the Contractor. Notwithstanding the foregoing, excess doses may be resold or re-allocated by the Participating Member States to other EU Member States or resold to EEA Member States provided, as the case may be, that any receiving EU Member State has executed a Vaccine Order Form and shall agree in writing to be bound by the same terms for such reallocated doses and that any EEA Member State has executed an agreement equivalent to a Vaccine Order Form in case of direct delivery from the Contractor, and shall (i) agree in writing to be bound by the indemnification clause in Article I.12 and (ii) provide a written confirmation that it shall comply with applicable storage, transport and product acceptance requirements, as well as conditions of further resale or donation, to the satisfaction of the Contractor for such resold doses. Any such resale by a Participating Member State shall be at a price no higher than it paid the Contractor. The parties acknowledge that should resale to any third country take place, the Participating Member State reselling doses has an obligation to reimburse the Commission the Advance Payment per dose paid by the Commission to the Contractor.

I.6.3 Supply mechanism

Vaccine supply in Europe will primarily come from Pfizer's manufacturing site in Puurs, Belgium and shall incorporate RNA produced at BioNTech controlled manufacturing sites including sites operated by the following sub-contractors in Germany:

- Polymun Scientific Immunbiologische Forschung GmbH
- Dermapharm AG
- Rentschler Biopharma SE;

however the Contractor may manufacture at and supply from facilities outside Europe, where appropriate to hasten supply, with prior written notice to the Commission, and subject to the Contractor obtaining any necessary regulatory approval.

Subject to points (i) to (v) below, it is estimated that the order will be delivered as set out in the table below (the **"Interim Delivery Schedule"**) assuming Authorisation being granted by 15 December 2020. The Interim Delivery Schedule and logistics will be further refined into a monthly schedule by the Contractor after the Commission has communicated how to apportion the 200 million Vaccine doses amongst the Participating Member States pursuant to the provisions of this Article I.6.3.

The Interim Delivery Schedule is as follows (subject to the limitations set forth below):

Quarter	Q4 2020	Q1 2021	Q2 2021	Q3 2021
Doses (million)	25	40	60	75

(i) No doses will be shipped to the Member States prior to the Contractor receiving Authorisation.

(ii) If Authorisation is received after 15 December 2020 then the Interim Delivery Schedule will shift accordingly and be adjusted to reflect the delay between 15 December 2020 and the date of Authorisation (**"Adjusted Delivery Schedule"**).

(iii) If Authorisation is not received by 15 August 2021, the Commission and the Contractor will have the right to terminate the APA.

(iv) If Authorisation is received prior to 15 August 2021, and the Contractor is able to manufacture and deliver a certain number of the Contracted Doses, but there is insufficient supply to deliver the full amount of Contracted Doses on the Interim Delivery Schedule or the Adjusted Delivery Schedule, then the Contractor will abide by allocation guidelines based on fair and equitable principles under the then existing circumstances, taking into account, among other things, the contracted volumes and the estimated or adjusted delivery dates across all commitments of the Contractor and its Affiliates. The Contractor will demonstrate its allocation according to the fair and equitable principles mentioned before to the Commission, specifying in particular the available European production capacity in the relevant time-period, the Contractor's and its Affiliates' aggregate dose commitments and estimated delivery dates for doses from such European facilities during the relevant time period and a summary explanation of corresponding delivery timeline adjustments.

(v) If Authorisation is received by 15 August 2021, but by 15 November 2021 the Contractor is unable to deliver any Contracted Doses for technical or other reasons, the Commission and the Contractor will have the right to terminate the APA.

(vi) In the event the Contractor is unable to deliver the full amount of the Contracted Doses by 31 May 2022, the Commission and the Contractor will have the right to terminate the APA.

For the avoidance of doubt, the Participating Member States will not have the right to terminate the Vaccine Order Forms in scenarios (iii), (v) or (vi) above in the event that the Commission has not exercised its right to terminate the APA.

If the Vaccine is successfully developed and obtains Authorisation in the foreseen time-line (between 15 December 2020 and 15 August 2021), the Contractor shall use Best Reasonable Efforts to ensure that the doses are supplied in accordance with the Interim Delivery Schedule, or if applicable, the Adjusted Delivery Schedule. Allocations shall be made pursuant to Article I.6.3(iv) in case of insufficient supply to deliver the full amount of Contracted Doses.

Within 20 days following the Effective Date, the Commission shall communicate to the Contractor a table how to allocate the 200 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 the above-mentioned allocation table and to sign a Vaccine Order Form to this effect as set out below.

To operationalise the ordering of the Vaccine, each Participating Member State will enter into a Vaccine Order Form. 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 APA into the Vaccine Order Form). Deliveries of doses to each Participating Member State shall be done on a pro-rata basis throughout the delivery period. 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 APA 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.

I.6.4 Manufacturing

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

I.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 I.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).

I.6.6 Clinical trials and licensure

The Contractor will use Best Reasonable Efforts to obtain Authorisation. If this is a Conditional Marketing Authorisation, thereafter the Contractor also commits to use Best Reasonable Efforts to seek the Marketing Authorisation once all necessary additional data and other information is available.

I.6.7 Waiver

The Commission acknowledges and agrees that the Contractor's efforts to develop and manufacture the Vaccine are aspirational in nature and subject to significant risks and uncertainties. Notwithstanding the efforts and any estimated dates set forth in this APA, the parties recognize that the Vaccine is in Phase 3 clinical trials at the date of signature of this APA and that, despite the diligent efforts of the Contractor in research, and development and manufacturing, the Vaccine may not obtain Authorisation or may not be delivered (despite the Contractor's obligation to use Best Reasonable Efforts pursuant to Articles I.6.1 and 1.6.6 of this APA) due to technical, clinical, regulatory or manufacturing, shipping, storage or other challenges or failures.

Accordingly, the Commission and Participating Member States acknowledge and agree that, in such circumstances, the following remedies:

- obtaining replacement Products pursuant to Articles I.6.14;
- payment or reimbursement of the costs as provided for in Article II.6.7;
- the right to terminate given by Article II.17; and
- the right to a refund of the Advanced Payment pursuant to Article I.8.1

are reasonable and constitute the Commission's and the Participating Member States' remedies for the Contractor's failure to obtain or procure the obtaining of Authorisation or to manufacture, supply or deliver the Products in compliance with this APA or Vaccine Order Forms, for whatever reason. Notwithstanding the foregoing, the parties explicitly agree that the Contractor is liable if found by a court of competent jurisdiction to have breached its obligation to use Best Reasonable Efforts as set out in this APA within the limits of Article II.6. In addition, the provision on no limitation of liability set out in II.6.5 prevails.

Any failure to deliver doses in accordance with the estimated delivery dates as set out above 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.6.3.

I.6.8 Packaging, labelling and shipping

At the date of execution of this APA, the Vaccine is expected to be supplied in a thermal shipping box in accordance with Schedule 4 (Labelling and Packaging Specifications) (**"Thermal Shipper"**) containing up to 5 trays of multidose 2ml vials. Each tray will contain

195 vials. Each vial contains multiple doses of formulated Vaccine. 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

Based on current knowledge and subject to updating based on Authorisation, the Vaccine is expected to be a two dose regimen in a concentration liquid formulation that needs to be stored frozen at temperatures between -75 °C (+/- 15 °C). The Vaccine must be thawed on the day of administration and stored at 2-8 °C until administration. The concentrate will need to be diluted at point of use prior to dosing. Vaccinators will need to obtain locally sourced 0.9% Sodium Chloride Injection (Normal Saline) for dilution, syringes and needles, as the Contractor will not be supplying such items with the Vaccine.

The non-preserved multidose vial must be discarded after 6 hours of use. To ensure cold chain compliance the Contractor will utilize a GPS enabled temperature monitoring device until the point of delivery. The Participating Member State will switch off the temperature monitoring device when opening the delivery package (which must occur within the timeframe set out in Attachment 3 (Delivery Specification)), and upon request by the Participating Member State prior to the end of such timeframe the Contractor will provide conformation of the temperature data from the temperature monitoring device and shall in any event inform the Participating Member State about any temperature non-compliance that occurred prior to delivery. If there has been any temperature non-compliance, the Participating Member State shall reject the Product in accordance with the provisions of Article I.6.14. Final storage specifications, based on the Authorisation received, will be communicated to the Participating Member State prior to delivery.

I.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 I.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 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 DAP Incoterm 2020 to the location agreed pursuant to this Article I.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 shall be agreed upon by the Contractor and the Participating Member State at least eight (8) weeks prior to shipment of the Product noting that the Contractor will look to expedite these timescales where it can do so, and, in particular, may be able to shorten the eight (8) week lead time to four (4) weeks or sooner for locations that have been proposed by the relevant Participating Member State in early dialogue with the Contractor hence allowing the Contractor to pre-plan deliveries. 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 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 of 975 doses (one tray).

I.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), 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 country 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 ensure that: (a) recipients of the Product shall follow the return and disposal instructions in Attachment 5 (Return and Disposal of Product Materials) (as updated by the Contractor and communicated to the Participating Member State from time to time) 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 the Thermal Shipper(s) and monitoring device(s), 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 20 business days of receipt of the Product, subject to Article I.6.14, the Participating Member State shall take the necessary measures to enable the collection by the Contractor of all such equipment, including the Thermal Shipper and temperature monitoring device, 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.

I.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 I.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 APA.

The Participating Member States acknowledge that the Contractor or the Participating Contractor Affiliate will not, other than as provided in Article I.6.14, 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 other than as provided in Article I.6.14 (inclusive of future changes in stock, changes in Product allocation, delivery, demand or new product launch).

I.6.13 Quality tests and checks

The Contractor shall perform all bulk holding stability, manufacturing trials, validation (including, but not limited to, method, process and equipment cleaning validation), raw material, in-process, bulk finished product and stability (chemical or microbial) tests or checks required to assure the quality of the Product and tests or checks required by the Specifications and Good Manufacturing Practice.

I.6.14 Rejection of Product; Disposal of rejected shipments

A Participating Member State must visually inspect the Product within 24 hours 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 Specifications or Good Manufacturing Practice (**"Non-Complying Product"**) by providing notice to Pfizer Customer Service following an agreed protocol: (i) within 48 hours after delivery of such Non-Complying Product to the Participating Member State for any issues which would be apparent on visual inspection of the Product; or (ii) within 5 business days 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 to Specifications or Good Manufacturing Practice.

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 APA, the Contractor shall replace such Non-Complying Product as soon as practicable at no additional charge to the Participating Member State. 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.

If the Participating Member State disputes the Contractor's finding and this cannot be resolved with the Contractor, upon the Participating Member State's request, a sample of the rejected Product will be sent to a third party lab (which will be selected by mutual agreement between the Contractor and the Participating Member State) for analysis and the parties agree that they will use reasonable efforts to discuss an appropriate resolution on the basis of the third party lab's analysis. For the avoidance of doubt, the foregoing is without prejudice to either party's right to refer to the dispute resolution procedure set out in Article I.13.2 in order to establish whether any of the delivered Product constitutes Non-Complying Product.

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 no limitations on liability under Article II.6.5, replacement of Non-Complying Product 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 APA.

I.6.15 Maintenance and retention of Records

Each party shall maintain detailed Records with respect to its activities under this APA 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. The Participating Member State shall promptly notify the Contractor in writing (and in any event within 5 business days) if at any time the Participating Member State believes or

becomes aware that any of the Product has been stolen, diverted, tampered with, substituted, or otherwise subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by the Contractor. The notice shall provide all information relating to the Product diversion, including, but not limited to, detailed information including the date, time, location, number, batch number(s), expiration date, circumstances, and contact person(s) information.

I.7 PRICES

The price of the Vaccine to the Commission and the Participating Member States for the 200 million Contracted Doses will be €15,50 per dose excluding VAT.

The unit price for each dose of the Vaccine is volume-based as set out in the following table:

Volume tier (doses)	1-100 million	101-200 million
Total price per dose within each volume tier, excluding VAT	€17,50	€13,50

To the extent that, contrary to the commitments set out in Article I.6.2 and in the table set out in Article I.6.3, fewer than 200 million doses are ordered under this APA, then the price per dose of the Vaccine will be adjusted accordingly. For example, if the APA is for 150 million doses, the average price will be: ((100 million x €17.50) + (50 million x €13.50)) / 150 million = €16.17 per dose. As another example, if the APA is for 70 million doses, the average price will be: (70 million x €17.50)/70 million = €17.50 per dose.

In addition, if an Additional Order is requested by the Commission and agreed to by the Contractor, the price of the Additional Product will be:

i. €15,50 per dose for any Additional Order placed and agreed by the Contractor within three (3) months of the date that the Contractor first obtains Authorisation;

ii. €17,50 per dose for any Additional Order placed and agreed by the Contractor thereafter but prior to termination of the APA.

I.8 PAYMENT ARRANGEMENTS

I.8.1 Advance Payment

The Commission agrees to pay an upfront payment of €700 million (calculated as €3.50 per dose multiplied by 200 million doses) to the Contractor (the **"Advance Payment"**). The Advance Payment shall be a down payment to secure the volume ordered as per Article I.5.2, and shall be counted as a payment towards the Delivery Price as defined below.

The Commission shall pay to Contractor the Advance Payment, on behalf of the Participating Member States, within 20 business days after the date of Contractor's invoice in respect thereof.

The parties agree that, as a sole and exclusive remedy for the Commission and all Participating Member States, one-hundred percent (100%) of the Advance Payment will be refunded to the

Commission if either party terminates the APA pursuant to Article I.6.3 (iii) and (v), and one-hundred percent (100%) of the Advance Payment for Contracted Doses not delivered will be refunded to the Commission if either party terminates the APA pursuant to Article I.6.3 (vi). For the avoidance of doubt, unless expressly stated in the APA, the Advance Payment will not be refunded in any other case.

I.8.2 Delivery Price

After the Advance Payment is made, the remainder of the contracted price per dose (the **"Delivery Price"**) for the Contracted Doses is to be paid by the Participating Member State to the Participating Contractor Affiliate upon delivery. The Delivery Price is equal to €15,50 excluding VAT per dose (assuming a purchase of 200 million doses) minus the Advance Payment per dose, multiplied by the number of doses supplied in the relevant timeframe.

The full contracted price per dose for any Additional Order (as set out in Article I.7 above) is to be paid to the Participating Contractor Affiliate upon delivery.

If the Contractor is unable to manufacture and deliver any Contracted Doses, the Delivery Price and/or the price for any Additional Product would not be payable or due to the Participating Contractor Affiliate for the undelivered doses.

The Participating Contractor Affiliate may claim the payment of the balance in accordance with Article I.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 proof of delivery as referenced in Article I.6.10 and Attachment 2 (Delivery Documentation) notifying acceptance of the delivery in respect of which such invoice is established, which proof of delivery shall not be unreasonably withheld or delayed and in any event be provided within a term of five (5) business days from delivery.

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:

- Proof of delivery of the supplies to the places of delivery indicated by the Participating Member State in accordance with Article I.6.10.

Each invoice must contain the following information:

- Name of the Participating Member State concerned
- APA and Vaccine Order Form number/reference
- Order reference
- Billing address
- Product delivered

- Quantity delivered
- Delivery reference and date
- Price
- Any applicable taxes, transportation charges or other charges provided for in the Vaccine Order Form
- The ship-to destination
- Actual date of shipment
- 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 within thirty (30) days 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) within ten (10) days 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 I.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 APA or at Law, if a Participating Member State fails to pay any undisputed amounts when due under this APA, 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 within an additional 30 days.

The Commission and the Participating Member States shall not, and acknowledge that they will have no right, under this APA, 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 do not accept delivery of any ordered Vaccine doses in accordance with the provisions of this APA, the Contractor shall be entitled to invoice such Participating Member States for the balance of the price of the ordered doses not so accepted.

I.8.3 Bank account

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

Name of bank: Citibank Dublin
Exact denomination of account holder: Pfizer, Inc. EUR Account
Full account number including bank codes: Account 24208001
IBAN: IE85CITI99005124208001
Swift: CITIIE2X

I.9 COMMUNICATION DETAILS

For the purpose of this APA, 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

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

If to Pfizer:

Janine Small

IDM Vaccines Regional President

Pfizer Inc.

E-mail: Janine.small@pfizer.com

By derogation from this Article I.9, different contact details for the Commission, the Participating Member States or the Contractor may be provided in Vaccine Order Form.

I.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 APA 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 APA 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.

I.11 EXPLOITATION OF THE RESULTS OF THE APA[4]

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"**). The Contractor shall be entitled to exclusively exploit any such Vaccine

[4] This article must be adapted with care. In particular where the FWC is in essence only a licence on pre-existing materials (with no actual production of new materials specifically for the Union), as is the case for instance for a subscription contract to a database service provider, this article must be adapted accordingly. All information is in the Explanatory note on IPR on: http://myintracomm.ec.testa.eu/budgweb/EN/imp/procurement/Documents/ipr-note-en.pdf.

IP Rights. Except as expressly set forth in this APA, the Contractor does not grant to the Commission by implication, estoppel or otherwise, any right, title, license or interest in the Vaccine IP Rights. All rights not expressly granted by the Contractor hereunder are reserved by the Contractor.

I.12 INDEMNIFICATION

I.12.1 The Commission, on behalf of the Participating Member States, declares that the use of Vaccines produced under this APA 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, their Affiliates, sub-contractors, licensors and sub-licensees, and officers, directors, employees and other agents and representatives of each (together, the **"Indemnified Persons"**) from and against any and all liabilities incurred, settlements as per Article I.12.6, and reasonable direct external legal costs incurred in the defence of Third Party Claims (including reasonable attorney's fees and other expenses) relating to harm, damages and losses as defined in Article I.12.2 (together, the **"Losses"**) arising from or relating to the use and deployment of the Vaccines in the jurisdiction of the Participating Member State in question. This Article I.12 applies to Losses which arise from or relate to the Vaccines supplied in accordance with this APA during the initial duration of this APA of 24 months (for the avoidance of doubt, regardless whether the Use of the Vaccine or Losses occur within or after such initial duration). In the event that additional doses of the Vaccine are supplied under this APA following its renewal, the parties will discuss in good faith whether the grounds justifying the existence of this clause are still present. If this is not the case, the indemnification provisions will cease to apply to doses supplied pursuant to and after that renewal agreement. If those grounds are still (partially) present, the parties will discuss in good faith whether any amendment to this clause is warranted. Such indemnification will not be available to the Indemnified Persons to the extent that (i) the Losses were caused by the Wilful Misconduct, as defined in Article I.12.3, of such Indemnified Person; or (ii) the Losses were caused by a material breach of Good Manufacturing Practice (as applied at the time of manufacture) before certification of batch-release of the Vaccine according to the requirements set out in Title IV of Directive 2001/83/EC, leading to a Quality Defect in the Vaccine at the time of each delivery and resulting in a determination by the competent regulatory authority to recall or suspend the supply of the Vaccine, or in a withdrawal or suspension of the Authorisation by the European Commission. The Participating Member State shall, notwithstanding the competency and responsibility of the competent regulatory authority, involve the CHMP of the European Medicines Agency (the "EMA") in any case of a recall or suspension of supply of the Vaccine because of suspected GMP failure, and shall seek without delay a scientific opinion of the CHMP whether a recall or suspension of supply of the Vaccine by the competent regulatory authority was justified, and shall submit all necessary information to the CHMP. The Contractor shall be involved in the process in accordance with the applicable procedures. For the purposes of applying the provisions under point (ii) above, regard shall be had to the CHMP opinion. For the avoidance of doubt, indemnification under the conditions laid down in this Article I.12 includes Losses arising from or related to actions or omissions of any person receiving the Vaccine directly or indirectly after Indemnified Persons deliver the Vaccine to Participating

Member States or their designated carriers, including, but not limited to, any transport, storage, distribution, handling, use, administration, or change in the condition of the Vaccine.

I.12.2 Indemnification pursuant to Article I.12.1 will only be available for the following losses suffered by a third party: death, physical injury, mental or emotional injury, illness, disability, property loss or damage, economic losses or business interruption.

I.12.3 For the purpose of this Article I.12, the following terms shall be defined as follows:

(i) "Wilful Misconduct" shall mean: any wrongful act, willingly and knowingly committed, with the intent to cause harmful effects;

(ii) "Quality Defect" shall have the meaning defined in Volume 4 of the EU Rules governing medicinal products - EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use.

I.12.4 If any Indemnified Person incurs any Losses as defined in Article I.12.1, the Indemnified Person(s) shall notify the Participating Member State in question promptly in writing, describing such Losses in reasonable detail, including the amount or estimated amount, if known or reasonably capable of estimation. If any action is instituted or claim is asserted by a third party with respect to which an Indemnified Person intends to seek indemnification for any Losses that may ultimately be incurred (**"Third Party Claim"**), the Contractor shall notify the Participating Member State in question promptly in writing, stating the nature and basis of such Third Party Claim. Any delay or deficiency of the Contractor in informing the Participating Member State of such Third Party Claim shall not limit the right to indemnification pursuant to Article I.12.1, unless such failure materially prejudiced the Participating Member State. Where permission from a third person is necessary to share certain information with the Participating Member States, the Contractor will use reasonable efforts to obtain such permission.

I.12.5 The Participating Member State shall be allowed to utilize an independent expert to evaluate any notice or information provided under Article I.12.4. In that case, the Participating Member State shall notify the relevant Indemnified Person in advance of its intention to use an expert and the identity of such expert. The Indemnified Person shall be allowed to object to the use of an expert within thirty (30) business days counted from such notification, if it puts forward reasonable grounds on the basis of which the specific expert in question should not be permitted access to such information, such as conflict of interest. In such case, the Participating Member State shall be allowed to appoint a new independent expert and shall provide the identity of that expert to the Indemnified Person who will have the right to object to the use of that expert in accordance with this Article I.12.5.

I.12.6 The Contractor shall ensure that the Indemnified Person(s) control the defense against the Third Party Claim, using legal counsel chosen by the Indemnified Person(s) and approved by the Participating Member State(s), such consent not to be unreasonably withheld. For the avoidance of doubt, the Indemnified Person(s)' control of the defense or the outcome of the claim shall not affect their right to indemnification for legal costs as provided in Article I.12.1. The Indemnified Person(s) may compromise or settle the

Third Party Claim, provided that the Indemnified Person(s) shall give the Participating Member State reasonable advance notice in writing of any proposed compromise or settlement and seek the Participating Member State's consent, such consent not to be unreasonably withheld. The Contractor shall ensure that the Indemnified Person(s) provide reasonable updates to the Participating Member State concerning the defense of the Third Party Claim either directly, or if the Participating Member State so chooses, through counsel chosen by the Participating Member State, provided that the fees and expenses of such counsel shall be borne by the Participating Member State. The Participating Member State shall cooperate with the Indemnified Person(s) for access to documents and other information required for the defense of any Third Party Claim, using reasonable efforts. The Participating Member State(s) may further cooperate in the defense of any Third Party Claim where appropriate, through its own counsel.

I.12.7 The parties explicitly and irrevocably agree that each of the Indemnified Persons, to the extent that such person is not a party, is a third-party beneficiary (within the meaning of Article 1121 of the Belgian Civil Code) of this Article I.12 and shall be entitled to invoke and exercise all rights, claims and waivers under this Article I.12 against any of the Participating Member States.

I.12.8 The parties explicitly agree that:

(i) any warranties given by the Contractor, whether express or implied, under this APA as regards compliance with Good Manufacturing Practice or conformity of the Product with the Specifications shall be without prejudice to the provisions of this Article I.12, which shall apply independently of and prevail over such warranties, including any (claimed) breach of such warranty; and

(ii) a Participating Member State does not have the right to suspend and/or otherwise not perform its obligations under this clause I.12 except where the Participating Member State puts forward reasonable evidence that one of the situations listed in this Article I.12.1(i) and (ii) is applicable and the matter is brought for dispute resolution under Article I.13, in which case the Participating Member State's obligation to make any indemnity payment which is the subject of such dispute resolution shall be suspended until the resolution of such dispute; and the amounts paid by a Participating Member State under this Article I.12 are not recoverable from the Contractor (irrespective of whether or not the Third Party Claim resulted from a contractual breach by the Contractor) based on a claim of breach by the Contractor of the provisions of this APA or of a Vaccine Order Form except where there is final adjudication by competent courts that no indemnification is available to the Contractor pursuant to this Article I.12, in which case any corresponding indemnification already paid by a Participating Member State shall be fully reimbursed by the Contractor.

I.13 APPLICABLE LAW AND SETTLEMENT OF DISPUTES

I.13.1 This APA shall be governed by the laws of Belgium.

I.13.2 Dispute Resolution

(a) In the event of a dispute arising under this APA 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 twenty (20) days of such notice, the representatives shall meet and attempt to resolve the dispute by good faith negotiations.

(b) The Commission, the Participating Member States and the Contractor 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 APA or the legal relationships established by this APA or any Vaccine Order Form.

I.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 APA within 5 business days from notifying the European Medicines Agency.

(Signature page follows)