**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 found.**; 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.

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[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)

**SIGNATURES**

| For the Contractor, | For the Commission, on behalf and in the name of the Participating Member States, |
|---|---|
| Nanette Cocero | Stella Kyriakides |
| Global President, Vaccines,<br>Pfizer Biopharmaceuticals Group, Pfizer Inc. | Commissioner of Health and Food Safety |
| Signature:  | Signature:  |
| Done at 20 of November, 2020 | Done at , |

In duplicate in English.

# II. GENERAL CONDITIONS FOR THE FRAMEWORK CONTRACT FOR SERVICES

## II.1 DEFINITIONS

All definitions are contained in Article I.2

## 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 APA is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable to any extent, it must be severed from the remainder of the APA. This does not affect the legality, validity or enforceability of any other provisions of the APA, which continue in full force and effect. The illegal, invalid or unenforceable provision must be replaced by a legal, valid and enforceable substitute provision which corresponds as closely as possible with the actual intent of the parties under the illegal, invalid or unenforceable provision. The replacement of such a provision must be made in good faith between the parties. The APA 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 APA 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 communication of information, notices or documents under the APA must:

(a) be made in writing in paper or electronic format in the language of the contract;

(b) bear the APA number and, if applicable, the Vaccine Order Form number;

(c) be made using the relevant communication details set out in Article I.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 APA refers to the date when the communication was sent.

E-mail is deemed to have been received by the receiving party on the day of dispatch of that e-mail, provided that it is sent to the e-mail address indicated in Article I.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 APA, the Contractor or its Affiliates shall self-insure or procure and maintain such types and amounts of insurance to cover liabilities related to its activities under this APA as is normal and customary in the pharmaceutical industry generally for companies that are similarly situated and providing similar manufacturing and supply services. For absolute clarity, this shall not include, nor constitute, product liability insurance to cover any third party/patients claims and such general insurance shall be without prejudice to the Participating Member States' indemnification obligation as set out in this APA.

II.6.2 Pfizer and BioNTech are jointly and severally liable to the Commission or the Participating Member State for the Implementation of the APA.

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 pursuant to this APA 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 APA 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 the Contractor and its Affiliates cannot be held liable for any damages except for proven damages which are

suffered by the Commission or the Participating Member States as a direct consequence of a breach by the Contractor or its Affiliates of its obligations under this APA or a Vaccine Order Form, and that the Contractor and its Affiliates shall in any case not be liable for late deliveries (subject to the Contractor's obligation to use Best Reasonable Efforts as contained in Article I.6.3), loss of revenue, loss of anticipated savings, loss of business, loss of profit, loss of goodwill, reputational damages, loses from economic disruption or cost of alternative supply.

(ii) Taking into account the Participating Member States' indemnification obligation as set out in this APA, the parties also explicitly agree that the Contractor shall have no liability to the Commission or the Participating Member States in respect of losses or damages suffered by the Commission or the Participating Member States as a result of any claim by a third party relating to the distribution or use of the Vaccine, save in circumstances where the Contractor would not have been entitled to indemnification under Article I.12, had such claim by a third party been made against the Contractor.

(iii) The aggregate liability of the Contractor and its Affiliates towards the Commission arising out of or relating to this APA and/or the Vaccine Order Forms (whether arising contractually or extracontractually), shall not exceed a sum equivalent to the Advance Payment actually received by the Contractor.

(iv) The aggregate liability of the Contractor and its Affiliates towards any of the Participating Member States arising out of or relating to this APA and/or the Vaccine Order Form concluded with that Participating Member State (whether arising contractually or extracontractually), shall not exceed a sum equivalent to 50% of the sums actually received by the Contractor under the Vaccine Order Form concluded with that Participating Member State.

(v) 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**

(i) Nothing in this APA 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 the Commission, failure to pay the Advance Payment;

(d) 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 APA and Vaccine Order Form;

(e) in the case of a Participating Member State, the indemnity given by it under Article I.12;

(f) in the case of Contractor the circumstances in which the indemnity under Article I.12 is not available.

### 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 APA.

### 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, except to the extent that such recall or market withdrawal results from one of the situations described in points (i) and (ii) of Article I.12.1 of this APA, in which event the Contractor 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 Commission and Participating Member States.

## 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 APA. The Contractor must immediately take action to rectify the situation.

The Commission may do any of the following:

(a) verify that the Contractor's action is appropriate;

(b) require the Contractor to take further action within a specified deadline;

(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 APA;

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

(c) third parties involved in the Implementation of the APA, including subcontractors.

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

## II.8 Representations and warranties

### II.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 APA and to perform their respective obligations under this APA;

(ii) No conflicts or violations. The execution and delivery of this APA 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 APA and applicable to such party and (ii) do not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any contractual obligations of such party existing as of the date of entry into force of the APA; and

(iii) Valid execution. Such party is duly authorised to execute and deliver this APA, and the person executing this APA 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.

### II.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):

(a) complies with the Specifications;

(b) has been manufactured in accordance with current Good Manufacturing Practice; and

(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 delivered to the Participating Member States pursuant to this APA and shall pass such title to the Participating Member States free and clear of any security interests, liens, or other encumbrances.

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 for the Contractor to deliver replacement Vaccine in the circumstances provided in Article I.6.14.

The Commission warrants that the APA is awarded and each Vaccine Order Form is concluded in accordance with applicable Laws.

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

The parties represent and warrant that, beyond the mutual consideration set forth in this APA, 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 APA or perform any part of this APA.

The Contractor has not made, and will not make, in the performance of this APA 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 APA, all conditions, warranties or other terms which might have effect between the parties or be implied or incorporated into this APA (whether by statute, common law or otherwise) are hereby excluded to the fullest extent permitted by applicable Law. Without prejudice to the general nature of the previous sentence, unless this APA specifically states otherwise and to the maximum extent permitted by applicable Law, the Contractor expressly disclaims any representations or warranties with respect to the Vaccine, including, but not limited to, any warranties or undertaking as to non-infringement of intellectual property rights of a third party.

## 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.

II.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 APA; 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 APA; 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.

II.9.5 Notwithstanding the foregoing, in all cases, (a) the Participating Member States may not disclose any of the financial or indemnification provisions contained in this APA, including the price per dose of Vaccine or refundability of the Advance Payment or any information that could reasonably ascertain the price per dose of Vaccine, without the prior written consent of the Contractor, and (b) the Contractor may disclose Confidential Information to their Affiliates without prior written consent of the Participating Member States.

II.9.6 The confidentiality obligations set out in this Article II.9 are binding on the Commission, the Participating Member State and the Contractor during the Implementation of the APA and for as long as the information or documents remain confidential unless:

(a) the disclosing party agrees to release the receiving party from the confidentiality obligation earlier;

(b) the Confidential Information or documents become public through other means than a breach of the confidentiality obligation;

(c) the applicable Law requires the disclosure of the Confidential Information or documents.

II.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 APA 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.

II.9.8 Neither this APA 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 APA 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 APA. 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 APA 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 clause II.10, no announcement or disclosure will include or infer the price per dose or the Q4 2020 volumes agreed in the Delivery Schedule or contain information that would be material to the Contractor.

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

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

Should the Contractor or any other person whose personal data is processed in relation to this APA have any queries concerning the processing of its personal data, it shall address itself to the data controller. They may also address themselves to the Data Protection Officer of the data

controller. They have the right to lodge a complaint at any time to the European Data Protection Supervisor.

### II.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 APA 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 APA*.

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 APA.

II.12.4 The Commission may request the Contractor to replace a subcontractor found to be in a situation provided for in points (d) and (e) of Article II.16.1.

## II.13 AMENDMENTS

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

II.13.2 No amendment can make changes to the APA 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 APA nor any interest hereunder will be assignable by a party without the prior written consent of the other party, except as follows: (a) Pfizer may assign its rights and obligations under this APA by way of sale of itself or the sale of the portion of its business to which this APA relates, through merger, sale of assets and/or sale of stock or ownership interest, provided that the assignee will expressly agree to be bound by Pfizer's obligations under this APA and that such sale is not primarily for the benefit of its creditors, (b) Pfizer may assign its rights and obligations under this APA to any of its Affiliates, provided that the assignee will expressly agree to be bound by Pfizer's obligations under this APA and that the Contractor will remain liable for all of its rights and obligations under this APA. In addition, the Contractor may assign its rights and obligations under this APA to a third party where the Contractor or its Affiliate is required, or makes a good faith determination based on advice of counsel, to divest a Product in order to comply with Law or the order of any governmental

authority as a result of a merger or acquisition, provided that the assignee will expressly agree to be bound by the Contractor's obligations under this APA. The Contractor will promptly notify the Commission of any assignment or transfer. This APA will be binding upon the successors and permitted assigns of the parties and the name of a party appearing herein will be deemed to include the names of such party's successors and permitted assigns to the extent necessary to carry out the intent of this APA. For the purposes of this Article II.14, any references to "the Contractor" shall be interpreted as references to "Pfizer and/or BioNTech". For the purposes of the Vaccine Order Form, any references to the "APA" in this Article II.14 shall be interpreted as references to the "Vaccine Order Form".

## 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 APA or Vaccine Order Form if that delay or failure is a *result of Force majeure*. If the Contractor is unable to fulfil its contractual obligations owing to *Force majeure*, it has the right to remuneration only for the services actually provided.

II.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 APA

### 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 APA 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 APA or performance of a Vaccine Order Form or any part of it:

(a) if the procedure for awarding the APA or a Vaccine Order Form or the Implementation of the APA proves to have been subject to Irregularities, 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 APA 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 APA or a Vaccine Order Form. For the avoidance of doubt, the Contractor shall not be under any obligation to deliver any Contracted Doses 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 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 APA

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

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

(a) in the event any of the circumstances referred to in Articles I.6.3(iii), I.6.3(v) or I.6.3(vi) occur;
(b) if the Contractor does not implement the APA or perform the Vaccine Order Form in accordance with material aspects of the APA or the Vaccine Order Form (as applicable) or is otherwise in material breach of another substantial contractual obligation;
(c) if the Contractor repeatedly refuse 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 APA;
(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[5];
(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;

[5] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193 of 30.7.2018, p.1 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1544791836334&uri=CELEX:32018R1046

(f) if the procedure for awarding the APA or the Implementation of the APA prove 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 APA;

(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 APA or a Vaccine Order Form would mean that this APA 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 APA 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 APA or perform the Vaccine Order Form in accordance with material aspects of the APA 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, the Commission's obligation to pay the Advance Payment, 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, and the Participating Member States' obligation to pay the price of the Contracted Doses; or

(b) in the event any of the circumstances referred to in Articles I.6.3(iii), I.6.3(v) or I.6.3(vi) occur.

**II.17.3 Procedure for termination**

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

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

Within 60 days of the date of termination, the Contractor must submit any invoice required for services that were provided before the date of termination. The Advance Payment will be refunded to the Commission if either party terminates the APA pursuant to Article I.6.3(iii) or

Article I.6.3(v), and 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).

The termination or expiration of this APA shall not affect the survival and continuing validity of Articles I.1, I.2, I.4, 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 APA 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 failure to deliver the Contracted Doses in accordance with any estimated 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 APA 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.

The Commission is exempt from all taxes and duties, including VAT, in accordance with Articles 3 and 4 of the Protocol 7 of the Treaty on the Functioning of the European Union on the privileges and immunities of the European Union.

It is understood and agreed between the parties that any prices stated under this APA 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 APA 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 APA 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 APA 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/fx-fixings.

### II.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.

### II.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 I.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:

(a) because it does not comply with the APA or Vaccine Order Form;
(b) because the Contractor or the Participating Contractor Affiliate has not produced the appropriate documents or deliverables; as required by the APA or a Vaccine Order Form; or
(c) because the Commission or the Participating Member State in question has reasonable observations on the documents or deliverables submitted with the invoice as not complying with the APA or Vaccine Order Form.

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. Where the suspension period exceeds two months, the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) may request the Commission or the Participating Member State in question to justify the continued suspension.

### II.19.5 Interest on late payment

On expiry of the payment periods specified in Article I.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) plus five points (or such centralized bank reference rate set forth in the Vaccine Order Form) and (b) 2%. 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 thirty (30) days of receipt.

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

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

(a) by offsetting them against any amounts owed to the Contractor by the Commission or the Participating Member State in question;
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 APA. This may be carried out either by OLAF's own staff or by any outside body authorised to do so on its behalf, provided that the auditor may not be a competitor of the Contractor.

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

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

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 APA.

II.21.3 The Contractor must grant the appropriate right of access to sites and premises where the APA is implemented, and to all information, including information in electronic format, needed to conduct such checks and audits. The Contractor must ensure that the information is readily available at the moment of the check or audit and, if so requested, that information is handed over in an appropriate format. The auditor must, insofar possible, comply with all applicable and reasonable security measures notified to Commission by the Contractor 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 Commission or 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 APA.

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 APA 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 APA 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 APA 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 APA.

## II.25 HEADINGS

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

## II.26 ELECTRONIC DELIVERY AND STORAGE

Delivery of a signed APA by reliable electronic means, including facsimile or email (with receipt electronically confirmed), shall be an effective method of delivery of the executed APA.

This APA may be stored by electronic means and either an original or an electronically stored copy of this APA can be used for all purposes, including in any proceeding to enforce the rights or obligations of the parties to this APA.

### II.27 ENTIRE AGREEMENT

This APA, 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 APA.

## 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:

[Add details for Contractor]

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 an Advance Purchase Agreement for the purchase and supply of Contractor's Vaccine for EU Member States dated [•] 2020 (the "**APA**"), the terms of which are binding on the Participating Member States and must be read in conjunction with this Vaccine Order Form.

— The APA 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 APA and at the price and conditions as set out in the APA.

— In accordance with Article I.5.2 of the APA, the [name of 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 [name of the Participating Member State] to Contractor in accordance with the terms of the APA, and forms an integral part of the APA. The terms and conditions of the APA are incorporated into this Vaccine Order Form by reference. In the event of contradiction between this Vaccine Order Form and the APA, the terms of the APA prevail regardless of any provision to the contrary. 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 APA.

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 APA. The submission of this signed Vaccine Order Form by the Member State to Contractor constitutes a binding order by the Member State for the purchase of its full allocated portion of the Contracted Doses or the relevant Additional Order (as applicable) as follows

    a. [Name of the 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: [insert details of quarterly allocation].

    b. The Delivery Price of Contracted Doses is [insert price here] euros per dose excl. VAT.

    The total amount payable by the Participating Member State for the [Contracted Doses] [Additional Order] is [insert amount], excluding [insert applicable percentage]% VAT.

3. By signature of this Vaccine Order Form, the undersigned Member State warrants to Contractor that:

    a it is irrevocably and unconditionally bound by the terms of the APA (as 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 APA 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 APA;

    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.

4. The Participating Member State acknowledges that the Vaccine and materials related to the Vaccine, and their components and constituent materials are being rapidly developed due to the emergency circumstances of the COVID-19 pandemic and will continue to be studied after provision of the Vaccine to the Participating Member States under the APA. The Participating Member State further acknowledges that the long-

term effects and efficacy of the Vaccine are not currently known and that there may be adverse effects of the Vaccine that are not currently known. Further, to the extent applicable, the Participating Member State acknowledges that the Vaccine shall not be serialized.

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.

**Article II**

**Delivery, Supply**

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

   [• - *Member State to enter location of its distribution hub*]

2. Supply of the Products

   The Contractor shall supply the Products as further described in the APA: [**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 APA. All payments to Contractor or its designated Affiliate shall be made in accordance with the terms of the APA.

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

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 APA number and the number of this Vaccine Order Form; c) be made using the relevant communication details set out below with respect to the Member State and Contractor (as applicable); d) be sent by mail and email:

   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]

**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 APA, or if the APA 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 I.13 (*Applicable Law and Settlement of Disputes*) of the APA 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.

(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],

[*forename/surname/position*]

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 Union1as 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 Participation 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

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

## ANNEX IV: SUBCONTRACTORS

| |
|---|
| Polymun Scientific Immunbiologische Forschung GmbH, Donaustrasse 99, Klosterneuburg, Niederoesterreich 3400, Austria |
| Dermapharm AG, Lil-Dagover-Ring 7, 82031 Grünwald, Germany |
| Rentschler Biopharma SE (Rentschler), located at Erwin-Rentschler-Str. 21, 88471 Laupheim, Germany |

## ANNEX V – PARTICIPATING CONTRACTOR AFFILIATES

| Country | Participating Contractor Affiliate |
|---|---|
| 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 Hellas SA |
| Malta | Pfizer Hellas SA |
| 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 BV |
| Poland | Pfizer 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 PFE, spol. s r.o.<br>After 1/12 shall be merged into Pfizer, spol. s r.o. |
| Hungary | Pfizer Gyógyszerkereskedelmi Kft. |
| Slovakia | Pfizer Export B.V. |
| Lithuania | Pfizer Export B.V. |
| Latvia | Pfizer Export B.V. |
| Estonia | Pfizer Export B.V. |

# ATTACHMENT 1: SPECIFICATIONS

**Biotherapeutics Pharmaceutical Sciences**
**Specification Review Team**
**INX100421728, Version 4**

**To:** David Cirelli

**From:** Jeff Ryczek

**Date:** 14-Aug-2020

**Subject:** Specification Report for PF-07305885 COVID-19 Vaccine BNT162b2 mRNA Drug Substance

**CC:** Margaret Ruesch, Justin Sperry, Amy St Charles, Susan John, Mary Denton, Specification Review Team

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## 1.0 Notification of Changes

This report has been updated to add process performance qualification (PPQ) drug substance specifications. Table 2-1 has been amended to add the LIMS Product Name for the PPQ drug substance. Initial drug substance specifications are retained in Section 3.0 and remain unchanged versus version 3 of this document. PPQ drug substance specifications are added as Section 4.0. Minor changes to text and table headers were made in order to differentiate the initial and PPQ drug substance specification sections.

A summary of changes between the initial and the PPQ specifications is captured in Table 1-1.

**Table 1-1: Changes to DS Specifications from Initial to PPQ**

| | Analytical Procedure | Quality Attribute | Acceptance Criteria | Procedure Number | Release, Stability, or Both | Rationale for Change | Date of Change |
|---|---|---|---|---|---|---|---|
| Previous Version | RP-HPLC | 5'-Cap | Report Results | TM100010578 | Both | Method elevated from additional test to registered test with endorsed acceptance criteria. | 14-Aug-2020 |
| Current Version | RP-HPLC | 5'-Cap | ≥ 50% 5'-Cap | TM100010578 | Both | | |
| Previous Version | ddPCR | Poly (A) Tail | Report Results | TM100010379 | Both | Method elevated from additional test to registered test with endorsed acceptance criteria. | 14-Aug-2020 |
| Current Version | ddPCR | Poly (A) Tail | ≥ 70% Poly (A) Tail | TM100010379 | Both | | |
| Previous Version | ddPCR | RNA Integrity | Report Results | TM100010379 | Both | ddPCR for RNA Integrity removed as additional test. | 14-Aug-2020 |
| Current Version | N/A | N/A | N/A | N/A | N/A | | |

| **Impact assessment** |
|---|
| Supplies in inventory:<br>☒ These Specification changes have **no impact** on approved supplies in inventory<br>☐ These Specification changes **impact** the following lots in inventory: _____<br>Regulatory commitments:<br>☒ These Specification changes have **no impact** on regulatory submissions<br>☐ These Specification changes **may impact** regulatory submissions |

## 2.0 PRODUCT INFORMATION

A brief description of the product and other information relevant to establishing the specification are provided in Table 2-1.

**Table 2-1: General Product Description**

| Product Information | |
|---|---|
| Product Name | PF-07305885 COVID-19 Vaccine mRNA Drug Substance |
| LIMS Product Name | DS-001426 Initial Specifications (Section 3.0)<br>DS-001477 PPQ Specifications (Section 4.0) |
| BNT Vaccine Code | BNT162b2 |
| BNT RNA Code | RBP020.2 |
| Plasmid PF#<br>(BNT Plasmid Code) | PF-07305883<br>(pST4-1525) |
| General Properties | |
| mRNA Type | modRNA |
| Modified NTP | N1-Methylpseudourodine-5'-triphosphate (m1ΨTP) |
| 5' Cap Analog | $m_2^{7,3'-O}Gppp(m_1^{2'-O})ApG$ |
| Encoded Antigen | Full Spike Protein, S-P2 Variant |
| mRNA Length | 4,283 nt |
| Theoretical Molecular Weight | 1,388,651 g/mol |
| Specific Absorption Coefficient at 260 nm | 25.0 mL/(mg*cm) |
| Manufacturing, Formulation, Dose | |
| Manufacturing Process | In vitro transcription and tangential flow filtration (IVT/TFF) |
| Formulation | 10 mM HEPES 0.1 mM EDTA pH 7.0 |
| Maximum dose | 30 μg flat dose |

### 3.0 INITIAL SPECIFICATIONS FOR DRUG SUBSTANCE

Analytical test methods contained in this section were chosen to ensure the quality, identity, and purity of the PF-07305885 drug substance throughout the manufacturing process and during long term storage under recommended storage conditions. The initial release specifications for PF-07305885 drug substance (LIMS Product Name DS-001426) are provided in Table 3-1. These are the analytical requirements for batch release listed in LIMS as the Drug Substance Specification. Analytical procedures and acceptance criteria applicable to the PF-07305885 drug substance stability program are noted in the table.

**Table 3-1: Initial Drug Substance Specification**

| Analytical Procedure | Quality Attribute | Acceptance Criteria | LIMS Target | Procedure Number | Stability Protocol |
|---|---|---|---|---|---|
| Composition and Strength | | | | | |
| Appearance (Clarity) | Clarity | ≤ 6 NTU | ≤ 3 NTU | TM100010539 | Yes |
| Appearance (Coloration) | Coloration | Not more intensely colored than level 7 of the brown (B) color standard. | | TM100010539 | Yes |
| Potentiometry | pH | 7.0 ± 0.5 | | TM100010538 | Yes |
| UV Spectroscopy | Content (RNA Concentration) | 2.00 2.50 mg/mL | | TM100010308 | Yes |
| Identity | | | | | |
| RT-PCR | Identity of Encoded RNA Sequence | Identity confirmed | | TM100010407 | No |
| Product Purity | | | | | |
| Capillary Gel Electrophoresis | RNA Integrity | ≥ 50 % intact RNA | | TM100010392 | Yes |
| Product-Related Impurities | | | | | |
| qPCR | Residual DNA Template | ≤ 330 ng DNA / mg RNA | | TM100010388 | No |
| Immunoblot | Residual Double Stranded RNA (dsRNA) | ≤ 1000 pg dsRNA / µg RNA | | TM100010474 | No |
| Adventitious Agents | | | | | |
| Endotoxin (LAL) | Bacterial Endotoxins | ≤ 12.5 EU/mL | | TM100001884 | Yes |
| Bioburden | Bioburden | ≤ 1 CFU / 10 mL | | TM100002094 | Yes |

Additional analytical tests as listed in Table 3-2 are performed for each drug substance batch to gain further information about the normal range of drug substance manufacturing process variation, to evaluate new methods, or to monitor the significance of the attribute(s) measured by these tests.

**Table 3-2: Initial Additional Tests for Drug Substance**

| Analytical Procedure | Quality Attribute | Acceptance Criteria | LIMS Target | Procedure Number | Stability Protocol |
|---|---|---|---|---|---|
| Appearance (visual) | Visible particulates | NA (information only) | Report Results | TM100010539 | Yes |
| Osmolality | Osmolality | NA (information only) | Report Results | TM100010540 | No |
| Agarose Gel Electrophoresis | Identity: RNA length | NA (information only) | Report Results | TM100010316 | No |
| | Identity: as RNA | NA (information only) | Report Results | | No |
| RP-HPLC | 5'-Cap | NA (information only) | Report Results | TM100010578 | Yes |
| ddPCR | RNA Integrity | NA (information only) | Report Results | TM100010379 | Yes |
| | Poly(A) Tail | NA (information only) | Report Results | | Yes |

Table 3-3 lists the analytical method(s) that will be performed for characterization purposes.

**Table 3-3: Initial Characterization Tests for Drug Substance**

| Analytical Procedure | Quality Attribute | Procedure Number | Stability Protocol |
|---|---|---|---|
| RP-HPLC | Poly(A) Tail: Length and Distribution | TM100010391 | Yes |

## 4.0 PPQ SPECIFICATIONS FOR DRUG SUBSTANCE

Analytical test methods contained in this section were chosen to ensure the quality, identity, and purity of the PF-07305885 drug substance throughout the manufacturing process and during long term storage under recommended storage conditions. The process performance qualification (PPQ) release specifications for PF-07305885 drug substance (LIMS Product Name DS-001477) are provided in Table 4-1. These are the analytical requirements for batch release listed in LIMS as the Drug Substance Specification. Analytical procedures and acceptance criteria applicable to the PF-07305885 drug substance stability program are noted in the table.

**Table 4-1: PPQ Drug Substance Specification**

| Analytical Procedure | Quality Attribute | Acceptance Criteria | LIMS Target | Procedure Number | Stability Protocol |
|---|---|---|---|---|---|
| Composition and Strength | | | | | |
| Appearance (Clarity) | Clarity | ≤ 6 NTU | ≤ 3 NTU | TM100010539 | Yes |
| Appearance (Coloration) | Coloration | Not more intensely colored than level 7 of the brown (B) color standard. | | TM100010539 | Yes |
| Potentiometry | pH | 7.0 ± 0.5 | | TM100010538 | Yes |
| UV Spectroscopy | Content (RNA Concentration) | 2.00 2.50 mg/mL | | TM100010308 | Yes |
| Identity | | | | | |
| RT-PCR | Identity of Encoded RNA Sequence | Identity confirmed | | TM100010407 | No |
| Product Purity | | | | | |
| Capillary Gel Electrophoresis | RNA Integrity | ≥ 50 % intact RNA | | TM100010392 | Yes |
| RP-HPLC | 5'-Cap | ≥ 50% 5'-Cap | | TM100010578 | Yes |
| ddPCR | Poly (A) Tail | ≥ 70% Poly (A) Tail | | TM100010379 | Yes |
| Product-Related Impurities | | | | | |
| qPCR | Residual DNA Template | ≤ 330 ng DNA / mg RNA | | TM100010388 | No |
| Immunoblot | Residual Double Stranded RNA (dsRNA) | ≤ 1000 pg dsRNA / µg RNA | | TM100010474 | No |

| Analytical Procedure | Quality Attribute | Acceptance Criteria | LIMS Target | Procedure Number | Stability Protocol |
|---|---|---|---|---|---|
| Adventitious Agents | | | | | |
| Endotoxin (LAL) | Bacterial Endotoxins | ≤ 12.5 EU/mL | | TM100001884 | Yes |
| Bioburden | Bioburden | ≤ 1 CFU / 10 mL | | TM100002094 | Yes |

Additional analytical tests as listed in Table 4-2 are performed for each clinical drug substance batch to gain further information about the normal range of drug substance manufacturing process variation, to evaluate new methods, or to monitor the significance of the attribute(s) measured by these tests.

**Table 4-2: PPQ Additional Tests for Drug Substance**

| Analytical Procedure | Quality Attribute | Acceptance Criteria | LIMS Target | Procedure Number | Stability Protocol |
|---|---|---|---|---|---|
| Appearance (visual) | Visible particulates | NA (information only) | Report Results | TM100010539 | Yes |
| Osmolality | Osmolality | NA (information only) | Report Results | TM100010540 | No |
| Agarose Gel Electrophoresis | Identity: RNA length | NA (information only) | Report Results | TM100010316 | No |
| | Identity: as RNA | NA (information only) | Report Results | | No |

## Document Approval Record

| | |
|---|---|
| **Document Name:** | INX100421728 |
| **Document Title:** | Specification Report for PF-07305885 COVID-19 Vaccine BNT162b2 mRNA Drug Substance |

| Signed By: | Date(GMT) | Signing Capacity |
|---|---|---|
| Ryczek, Jeff S | 14-Aug-2020 17:03:40 | Business Line Approver |

`

**Biotherapeutics Pharmaceutical Sciences**
**Specification Review Team**
**INX100422573, Version 1**

**To:** David Cirelli

**From:** Rebekah Ward

**Date:** 07-Aug-2020

**Subject:** Specification Report for BNT162b2 (PF-07302048) COVID-19 Vaccine Lipid Nanoparticle (LNP) Drug Product to support Emergency Use Authorization

**CC:** Lavinia Lewis, Mary Denton, Justin Sperry, Fanyu Meng

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## 1.0 Notification of Changes

A summary of changes reflected throughout the document with associated rationale.

**Table 1-1: Changes to DP Specifications**

| | Analytical Procedure | Quality Attribute | Acceptance Criteria | Procedure Number | Release, Stability, or Both | Rationale for Change | Date of Change |
|---|---|---|---|---|---|---|---|
| Previous Version | NA | NA | NA | NA | NA | Initial specification | Aug 2020 |
| Current Version | New | New | New | New | New | | |

**Impact assessment**

Supplies in inventory:
☒ These Specification changes have **no impact** on approved supplies in inventory
☐ These Specification changes **impact** the following lots in inventory: _____
Regulatory commitments:
☒ These Specification changes have **no impact** on regulatory submissions
☐ These Specification changes **may impact** regulatory submissions

## 2.0 PRODUCT INFORMATION

A brief description of the product and other information relevant to establishing the specification are provided in Table 2-1.

**Table 2-1: General Product Description**

| **Product Information** | |
|---|---|
| Product name | BNT162b2 (PF-07302048) COVID-19 Vaccine Lipid Nanoparticle (LNP) Drug Product |
| Clinical indication(s) | Vaccine |
| Drug Product (Lipid Nanoparticle Suspension) | DMID #D2000091, BNT162b2 Vaccine (SARS CoV 2 full spike protein S-P2 variant) |
| BNT Vaccine Code | BNT162b2 |
| BNT RNA Code | RBP020.2 |
| **General Properties** | |
| mRNA Type | modRNA |
| Encoded Antigen | Full Spike Protein, S-P2 Variant |
| mRNA Length | 4,283 nt |
| Specific Absorption Coefficient[a] | 25.0 $(mg/mL)^{-1}$ $cm^{-1}$ |
| Manufacturing Process and Formulation | Product specific process involving co-mixing of lipids and mRNA drug substance, followed by TFF, dilution and fill;<br>Formulated in 0.75X PBS, 300 mM Sucrose |
| Novel Raw Materials and Excipients | ALC-0315, ALC-0159 |
| Stage of Development | Emergency Use Authorization (EUA) |
| Maximum Dose | 30 µg flat dose |

## 3.0 SPECIFICATIONS FOR DRUG PRODUCT

Analytical test methods contained in this section were chosen to ensure the quality, identity, purity, and potency of the BNT162b2 (PF-07302048) drug product throughout the manufacturing process and during long term storage under recommended storage conditions. The release specification for BNT162b2 drug product EUA is provided in **Table 3-1**. These are the batch release analytical requirements listed in LIMS as the Drug Product Specification. Analytical procedures and acceptance criteria applicable to the BNT162b2 drug product stability program are noted in the table. Drug product lots are additionally required to undergo 100% and acceptable quality limit visual inspections as part of product release.

**Table 3-1: Drug Product Specification**

**Table 3-1: Drug Product Specification**

| Quality Attribute | Analytical Procedure | Acceptance Criteria | LIMS Target | Procedure Number | Stability Protocol |
|---|---|---|---|---|---|
| **Composition and Strength** | | | | | |
| Appearance | Appearance (Visual) | White to off-white suspension | | TM100010539 | Yes |
| Appearance (Visible Particulates) | Appearance(Particles) | Essentially free from visible particulates | | TM100010539 | |
| Subvisible particles | Subvisible particulate matter | Meets compendial requirements | | USP<787> TM100010541 | Yes |
| pH | Potentiometry | 7.4 ± 0.5 | | TM100010538 | Yes |
| Osmolality | Osmometry | 525 ± 100 mOsmol/kg | | TM100010540 | No |
| LNP Size | Dynamic Light Scattering (DLS) | ≤ 200 nm | | TM100010649 | Yes |
| LNP Polydispersity | Dynamic Light Scattering (DLS) | ≤ 0.3 | | TM100010649 | Yes |
| RNA Encapsulation | Fluorescence assay | ≥ 80% | | TM100010402 | Yes |
| RNA Content | Fluorescence assay | 0.50 ± 0.13 mg/mL | | TM100010402 | Yes |
| ALC-0315 content | HPLC-CAD | Report Result: mg/mL | Record Result: % Relative (molar), N/P Ratio | TM100010322 | Yes |
| ALC-0159 content | HPLC-CAD | Report Result: mg/mL | Record Result: % Relative (molar) | TM100010322 | Yes |
| DSPC content | HPLC-CAD | Report Result: mg/mL | Record Result: % Relative (molar) | TM100010322 | Yes |
| Cholesterol content | HPLC-CAD | Report Result: mg/mL | Record Result: % Relative (molar) | TM100010322 | Yes |
| Container content for injections | Volume of injections in containers | Not less than stated dose | | USP<697> TM100010614 | No |
| **Identity** | | | | | |

**Table 3-1: Drug Product Specification**

| Quality Attribute | Analytical Procedure | Acceptance Criteria | LIMS Target | Procedure Number | Stability Protocol |
|---|---|---|---|---|---|
| Lipid identities | HPLC-CAD | Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC) | | TM100010322 | No |
| Identity of encoded RNA sequence | RT-PCR | Identity confirmed | | TM100010407 | No |
| **Product Purity** | | | | | |
| RNA Integrity | Capillary Gel Electrophoresis | ≥ 50% intact RNA | | TM100010392 | Yes |
| **Adventitious Agents** | | | | | |
| Bacterial Endotoxins | Endotoxin (LAL) | ≤ 12.5 EU/mL | | USP <85> LAB-36816 (Puurs) | Yes |
| Sterility | Sterility | No growth detected | | USP<71>; Ph.Eur. 2.6.1 | Yes |
| Container Closure Integrity[a] | Dye incursion | Pass | | TM100010635 | Yes |

a. Tested at release and on stability for stability batches only

Additional analytical tests listed in **Table 3-2** are performed for each clinical drug product lot to gain further information about the normal range of drug product manufacturing process variation or to monitor the significance of the attribute(s) measured by this test.

**Table 3-2: Additional Tests for Drug Product**

| Quality Attribute | Analytical Procedure | Acceptance Criteria | Procedure Number | Stability Protocol |
|---|---|---|---|---|
| 5'- Cap | RP-HPLC | Report results | TM100010578 | Yes |
| In Vitro Expression | Cell-based FACS | Report results | TM100010380 | Yes |
| Poly(A) Tail | ddPCR | Report results | TM100010379 | Yes |
| Residual Ethanol | GC | ≤ 5000 ppm | TM100010581 | No |
| Content | Uniformity of dosage units | Meets compendial requirements | TM100010647 | No |

Routine in-process tests are listed in **Table 3-3** and are performed for each clinical drug product lot. These methods may be performed at a variety of stages in the process.

**Table 3-3: In-Process Tests for Drug Product**

| Quality Attribute | Analytical Procedure | Stage | Target | Procedure Number |
|---|---|---|---|---|
| Bioburden | Bioburden | Prefiltration Bioburden | ≤2 CFU/20mL | LAB-12943 (Puurs) |

**Table 3-4** lists the analytical method(s) that will be performed for characterization purposes.

**Table 3-4: Characterization Tests for Drug Product**

| Quality Attribute | Analytical Procedure | Acceptance Criteria | Procedure Number | Stability Protocol |
|---|---|---|---|---|
| Poly A Tail: Length and Distribution | RP-HPLC | Report results | TM100010391 | Yes |
| RNA Integrity | ddPCR | Report results | TM100010379 | Yes |

## Document Approval Record

| | |
|---|---|
| **Document Name:** | INX100422573 |
| **Document Title:** | Specification Report for BNT162b2 (PF-07302048) COVID-19 Vaccine Lipid Nanoparticle (LNP) Drug Product |

| Signed By: | Date(GMT) | Signing Capacity |
|---|---|---|
| Ward, Rebekah Mary | 07-Aug-2020 22:37:18 | Author Approval |

# ATTACHMENT 2: DELIVERY DOCUMENTATION

## Documentation and Delivery Notes

## Thermal Shipper Documentation

It is currently envisaged that the following will be provided with each shipment of the Products:

1. Authorisation Fact Sheets/Leaflets – Five (5) fact sheets folded 3x2" in a plastic bag

2. Pfizer Brochure – One (1) per Thermal Shipper container containing product storage and handling information including:
   - Dry Ice Handling Insert
   - Safety Data Sheet (SDS) for Dry Ice
   - Return instructions for GPS loggers and thermal shipping system
   - A stand-alone SDS for Dry Ice
   - Blank label – purpose of the blank label: for carriers to mark out the dry ice label to indicate that the Thermal Shipper containers are empty (not containing dry ice)

3. Return Shipping Label – One (1)

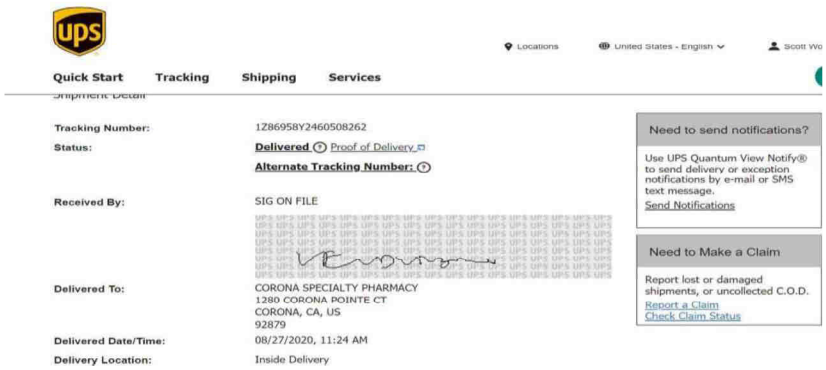
4. Outbound Shipping Label – One (1), standard label on Thermal Shipper

5. Contents Label – One (1) label on inside flap, picking label details how many carton trays are in Thermal Shipper

## Proof of Delivery Documentation

Currently, the Contractor intends to use the carrier delivery signal as proof of delivery.

Proof of delivery document that can be accessed online based on track and trace number. See UPS example* below:




*The above proof of delivery image is an example only. Please note that the transport carrier selection will be based on the detail agreed in the Vaccine Order Form between the Contractor and the relevant Participating Member State.

## ATTACHMENT 3: DELIVERY SPECIFICATION

### Product Delivery, Storage & Handling Specifications

Product delivery, storage and handling specifications are captured below specific to the distribution model: direct shipping from the Contractor manufacturing sites direct to point of use (POU) locations or shipping 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.

Shipments will arrive in a long distance Thermal Shipper as provided by the Contractor in accordance with Attachment 4 (Labelling and Packaging Specifications). At this time, the minimum order quantity in any shipment shall be one (1) tray with 195 vials or 975 doses of Product. The Contractor is investigating the viability of fewer than 195 vial count SKUs and expects to determine feasibility of an alternative shipping configuration by 1H2021. The Contractor will determine order quantities for future pack sizes.

The Participating Member State shall ensure that at the expected time of arrival a dedicated person will be available to receive the Product, sign acceptance for delivery, and immediately, no later than 24 hours of delivery, switch off the temperature logger located in the Thermal Shipper, and:

1. immediately transfer the Product to:
    1. a -75 °C (+/- 15 °C) ultra-low temperature ("**ULT**") freezer; or
    2. a 2-8 °C refrigerator; or
2. maintain the Product in accordance with product storage and handling guideline captured in Pfizer's brochure and website (e.g. unpacking, storage, re-icing).

The Participating Member State acknowledges the following storage guidelines:

- As at the Effective Date, the Product has a shelf-life of up to 6 months when stored at a constant -75°C(±15°C)

- Provided the re-icing protocols are followed and re-icing occurs within 24 hours of delivery and every 5 days thereafter, the Product may be stored in the Thermal Shipper for up to 15 days

- The Product has an effective life of up to 5 days when stored at refrigerator temperatures 2-8°C

- Once the Product is defrosted and reconstituted it can be retained for up to 6 hours at standard ambient room temperatures (19-25°C)

All costs associated with receiving, handling, storing and further delivery of the Product shall be the responsibility of the Participating Member State, and the Participating Member State shall ensure that all locations where any Product is delivered shall comply with the product storage and handling specifications set forth in this Attachment 3 and shall meet the standards set forth herein.

**Protocols for Unpacking Product and Re-icing:** See Exhibits 1 and 2 of Attachment 3

**Requirements of Delivery Location:**

1. Vaccination points with -75°C (+/- 15 °C) ULT freezer
2. Vaccination points with sufficient access and supply of dry-ice
3. Vaccination points with 2-8°C refrigerator

**Vaccine Preparation & Administration Instructions**

**Removing the Vials to Thaw**

- From storage, remove 1 vial for every 5 recipients according to planned vaccinations schedule.
- Vials may be stored in the refrigerator for 5 days (120 hours).

**Diluting the Vaccine**

- Obtain 0.9% Sodium Chloride Injection, for use as a diluent. Do not use any alternate diluents.
- Dilute the thawed vial by adding **1.8 mL of 0.9% Sodium Chloride Injection** into the vial.
- Ensure vial pressure is equalized by **withdrawing 1.8 mL air** into the empty diluent syringe before removing the needle from the vial.

**Preparing the Dose**

- **Draw up 0.3 mL of the diluted dosing solution** into a new sterile dosing syringe with a needle appropriate for intramuscular injection.
- For each additional dose, use a new sterile syringe and needle and ensure the vial stopper is cleansed with antiseptic before each withdrawal.

**Vaccine Administration**

- Diluted vials must be used within 6 hours from the time of dilution and stored between 2-25 °C (35-77°F).
- A single 30 mcg/0.3 mL dose is followed by a second dose 21 days later.

## Exhibit 1 to Attachment 3 – Unpacking and Re-icing: Thermal Shipper A

| | | |
|---|---|---|
| | Icing Instructions of the AeroSafe 47L7 ULT Parcel Shipper | CONFIDENTIAL |

1. **Purpose**

Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 ULT Parcel Shipper with version control.

2. **Appendices**

| Appendix ID | Title |
|---|---|
| Appendix A | Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 ULT Parcel Shipper |

3. **Change History**

| Issue Number | Description of Change(s) | Reason for Change(s) |
|---|---|---|
| 1.0 | Initial Release | Initial Release |
| 2.0 | Updated formatting and pictures for clarity. | Updated formatting and pictures for clarity. |

4. **Approvals:**

| Logistics Solutions and Compliance\| Transport Qualification and Compliance Manager | | | | |
|---|---|---|---|---|
| Author: | Name | Marci-Ann Ando | Sign/Date | Marci-Ann Ando<br>Marci-Ann Ando 21 Oct 2020 18:48:024-0400<br>REASON: I approve this document as author.<br>0a1fb5f4-f692-45e0-8d06-8eb5d9529e8f |
| Logistics Solutions and Compliance \| Sr. Manager Transport Validation & Innovation | | | | |
| Approved: | Name | James Jean | Sign/Date | |

DocUUID : 6ef8ea33-14ef-44c3-a1be-429f0db02480

| | | |
|---|---|---|
| Pfizer | Logistics Solutions & Compliance \| Technical Assessment<br>2020TA022 v2.0 | Page **2** of **2** |
| | Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 ULT Parcel Shipper | CONFIDENTIAL |

# Appendix A: Instructions
(11 Pages)

2020TA022 v2.0

Unpackaging and Re-Icing Instructions of the AeroSafe 47L7 ULT Parcel Shipper

Table Of Content





DocUUID : 6ef8ea33-14ef-44c3-a1be-429f0db02480

## 1. Purpose

The purpose of this controlled document is to provide unpackaging and re-icing requirements on the AeroSafe 47L7 Parcel Shipper with Dry Ice.

**CAUTION:** Use of dry ice in confined spaces (small rooms or walk-in coolers) and/or poorly ventilated areas can result in depletion of oxygen resulting in asphyxiation. Exposed skin should be protected from contact with dry ice. Eye protection is recommended (for example, safety glasses).

Appropriate training to be been conducted for personnel handling dry ice and documented within their relevant training system as required.

## 2. Scope

This controlled document is applicable to unpackaging and re-icing requirements using the AeroSafe 47L7 ULT Parcel Shipper with Dry Ice.



DocUUID : 6ef8ea33-14ef-44c3-a1be-429f0db02480

## 3. Reference Documents

| Document Number | Description |
|---|---|
| N/A | Safe Handling Guidelines for Dry Ice |
| N/A | Safety Data Sheet Dry Ice |

## 4. General Requirements

4.1. Materials

| Specification Number | Description |
|---|---|
| CD-86218 | SPEC – AeroSafe 47L7 Small Parcel Shipper |
| N/A | Insulated (Thermal) Gloves |
| N/A | Safety Glasses |
| N/A | Carton Sealing Tape |
| N/A | Dry Ice Pellets (10 to 16 mm) |

4.2. Recommendations

| Recommendations (Using Thermal Shipping Container as Temporary Storage) |
|---|
| • The thermal shipping container is a passive (non-compressor) device that contains dry ice as the energy source to maintain the required temperatures when maintained properly as defined by Pfizer instructions. The dry ice in the thermal shipper will deplete over a number of days (duration will vary depending on use and care), which will impact how long the shipper holds the temperatures. This differs from an ultra-low-temperature freezer, an active (electronically powered, compressor-driven) device, which when plugged in, is designed to maintain ultra-low temperatures indefinitely. The longer the thermal shipping container remains closed, the longer it will take for the dry ice to deplete.<br>• The thermal shipping container should be stored at 15° to 25° Celsius, which is 59° to 77° Fahrenheit.<br>• The thermal shipping container is qualified with a minimum of 22 kgs of dry ice pellets (10 mm – 16 mm pellets). Upon receipt and after opening, the box should be replenished/inspected with dry ice within 24 hours by adding dry ice to the maximum within the payload insert areas and dry ice pod.<br>• The thermal shipping container should be re-iced every 5 days.<br>  • This can help maintain the level of dry ice and the temperature of the vaccine product. It is recommended that the thermal shipping container **not be opened more than 2 times a day, and shouldn't be opened for** more than 1 minute at a time. If that is followed, the thermal shipping container should then be re-iced every 5 days. |

| Recommendations (Using Thermal Shipping Container as Temporary Storage) |
|---|
| • Local dry ice suppliers should be used for re-icing the thermal shipping container.<br><br>• Temperature monitoring devices to be used if thermal shipping container is used as temporary storage. Sites are responsible for obtaining their own temperature monitoring devices to monitor temperatures when using the thermal shipping container as temporary storage. Temperature monitoring devices (probe or probeless) capable of being in a dry ice environment to be used and placed in the location of the vial tray payload area within the thermal shipping container.<br><br>• The thermal shipping container should be returned within 20 business days of delivery, including temperature data logger.<br>  • If you receive a Controlant Real-Time Temperature Monitor, it must be returned with the thermal shipping container.<br>  • If you receive a Sensitech Temperature Monitor, it does not need to be returned. |

## 5. Procedure

5.1. Unpackaging

| Responsible Role | Action Step |
|---|---|
| Operator | 1. Before opening the thermal shipping container, make sure the area in which you are working has proper ventilation. Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, can result in depletion of oxygen, resulting in asphyxiation. |
| | 2. In a well-ventilated area, open the Outer Corrugated Shipper by cutting the tape on the outside. |

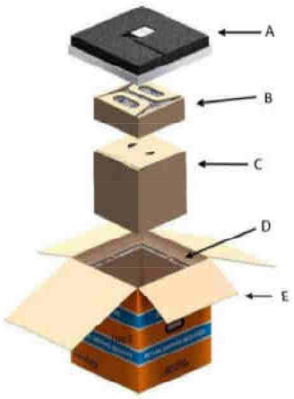
| Responsible Role | Action Step |
|---|---|
| |   |
| | 3. Remove the VIP Lid carefully as the temperature monitor probe is connected to the Payload Box. Care should be taken to not disconnect the probe from the Payload Box.  |
| | 4. While wearing insulated (thermal) gloves, take out the Dry Ice Tray. |

| Responsible Role | Action Step |
|---|---|
| |  |
| | 5. Remove the Payload Box from the thermal shipper by carefully pulling directly upwards. Care should be taken to not disconnect the probe from the Payload Box.  |
| | 6. Open the Payload Box and remove the vial tray. |
| | 7. Take out the product for inspection and immediately (within one minute of opening) store in an ultra-low temperature freezer or prepare for use. If shipper will be used as temporary storage for remaining vials within tray, immediately re-insert the tray with vials within one minute of opening and follow the re-icing instructions.<br><br>*Refer to Recommendations section of this procedure for further details on using the thermal shipping container as temporary storage. |
| | 8. If not using the thermal shipping container as temporary storage, insert all components back into the thermal shipping container for return. |

| Responsible Role | Action Step |
|---|---|
| | Dry ice must be discarded in a well ventilated area before considering returning the thermal shipping container. |

5.2. Re-Icing

| | Description |
|---|---|
| A | VIP Lid |
| B | Dry Ice Tray |
| C | Payload Box |
| D | Corner Dry Ice Scaffold |
| E | 47L7 Shipper |




| Responsible Role | Action Step |
|---|---|
| Operator | 1. Before opening the thermal shipping container, make sure the area in which you are working has proper ventilation. Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, can result in depletion of oxygen, resulting in asphyxiation. |
| | 2. In a well-ventilated area, open the Outer Corrugated Shipper by cutting the tape on the outside. |

| Responsible Role | Action Step |
|---|---|
| |   |
| | 3. Remove the VIP lid, Item A.  |
| | 4. While wearing insulated (thermal) gloves, take out the Dry Ice Tray, Item B as required to get better access to the Scaffolding to begin re-icing. |
| | 5. Fill the Scaffolding, Item D of the shipper with dry ice to the top of the scaffolding. |

| Responsible Role | Action Step |
|---|---|
| | 6. Reinsert the Dry Ice Tray, Item B on top of the Payload Box, Item C. Fill the Dry Ice Tray, Item B with dry ice to the top.  |
| | 7. Add the VIP Shipper Lid, Item A back on top.  |
| | 8. Fold the outer corrugated flaps and reseal shipper with tape.  |

## 6. History of changes

| Version | History of Changes |
|---|---|
| 01 | Initial version |
| 02 | Updated formatting and pictures for clarity. |

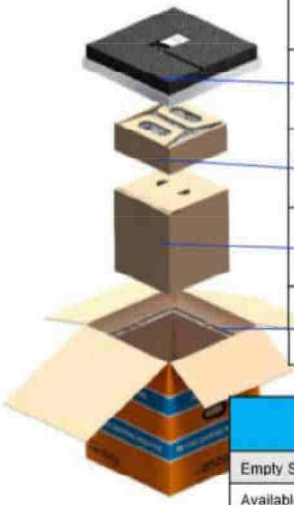


DocUUID : 6ef8ea33-14ef-44c3-a1be-429f0db02480

## 7. Appendix

### 7.1 Appendix 1: AeroSafe 47L7 ULT Parcel Shipper

**Note:** Approximate weights are based on maximum configuration of dry ice.



| ITEM | DESCRIPTION |
|---|---|
| 1 | VIP LID |
| 2 | DRY ICE TRAY |
| 3 | PAYLOAD BOX (Takes 1 vial tray) |
| 4 | 47L7 THERMAL SHIPPER |

| Aerosafe 47L7 Weights and Dimension | |
|---|---|
| Empty Shipper Weight | 9.4 kgs |
| Available Payload Space | 9.75" x 9.75" x 9.75" |
| External Dimension | 17.5" x 17.5" x 21.5" |
| Amount of Dry Ice | 22 kgs |
| Tare Weight w/ Dry Ice | 31.4 kgs |
| Total weight w/ 1 vial tray | 32.5 kgs |

| | |
|---|---|
| Weight of Vial Tray | 1.038 kgs |



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## Exhibit 2 of Attachment 3 – Unpacking and Re-icing: Thermal Shipper B

| | Logistics Solutions & Compliance \| Technical Assessment 2020TA021 v2.0 | Page 1 of 2 |
|---|---|---|
| | Unpackaging and Re-Icing Instructions of the Softbox Medium ULT Parcel Shipper | CONFIDENTIAL |

1. **Purpose**

Unpackaging and Re-Icing Instructions of the Softbox Medium ULT Parcel Shipper with version control.

2. **Appendices**

| Appendix ID | Title |
|---|---|
| Appendix A | Unpackaging and Re-Icing Instructions of the Softbox Medium ULT Parcel Shipper |

3. **Change History**

| Issue Number | Description of Change(s) | Reason for Change(s) |
|---|---|---|
| 1.0 | Initial Release | Initial Release |
| 2.0 | Updated formatting and pictures for clarity. | Updated formatting and pictures for clarity. |

4. **Approvals:**

| Logistics Solutions and Compliance\| Transport Qualification and Compliance Manager | | | | |
|---|---|---|---|---|
| Author: | Name | Marci-Ann Ando | Sign/Date | Marci-Ann Ando<br>Marci-Ann Ando 21 Oct 2020 18:47:044-0400<br>REASON: I approve this document as author.<br>0a1fb5f4-f692-45e0-8d06-8eb5d9529e8f |
| Logistics Solutions and Compliance \| Sr. Manager Transport Validation & Innovation | | | | |
| Approved: | Name | James Jean | Sign/Date | James E Jean<br>James E Jean 21 Oct 2020 19:11:006-0400<br>REASON: I approve this document.<br>524412a2-6820-4b64-8cc4-a43540e06a26 |

# Appendix A: Instructions
(12 Pages)

2020TA021 v2.0

Unpackaging and Re-Icing Instructions of the Softbox Medium ULT Parcel Shipper

Table Of Content

## 1. Purpose

The purpose of this controlled document is to provide unpackaging and re-icing requirements on the Softbox Medium ULT Parcel Shipper with Dry Ice.

**CAUTION:** Use of dry ice in confined spaces (small rooms or walk-in coolers) and/or poorly ventilated areas can result in depletion of oxygen resulting in asphyxiation. Exposed skin should be protected from contact with dry ice. Eye protection is recommended (for example, safety glasses).

Appropriate training to be been conducted for personnel handling dry ice and documented within their relevant training system as required.

## 2. Scope

This controlled document is applicable to unpackaging and re-icing requirements using the Softbox Medium ULT Parcel Shipper with Dry Ice.



DocUUID : 93d2c072-1193-449d-b0fa-ef78b87c0f19

## 3. Reference Documents

| Document Number | Description |
|---|---|
| N/A | Safe Handling Guidelines for Dry Ice |
| N/A | Safety Data Sheet Dry Ice |

## 4. General Requirements

4.1. Materials

| Specification Number | Description |
|---|---|
| CD-88557 | SPEC – Softbox Medium ULT Parcel Shipper |
| N/A | Insulated (Thermal) Gloves |
| N/A | Safety Glasses |
| N/A | Carton Sealing Tape |
| N/A | Dry Ice Pellets (10 to 16 mm) |

4.2. Recommendations

| Recommendations (Using Thermal Shipping Container as Temporary Storage) |
|---|
| • The thermal shipping container is a passive (non-compressor) device that contains dry ice as the energy source to maintain the required temperatures when maintained properly as defined by Pfizer instructions. The dry ice in the thermal shipper will deplete over a number of days (duration will vary depending on use and care), which will impact how long the shipper holds the temperatures. This differs from an ultra-low-temperature freezer, an active (electronically powered, compressor-driven) device, which when plugged in, is designed to maintain ultra-low temperatures indefinitely. The longer the thermal shipping container remains closed, the longer it will take for the dry ice to deplete.<br>• The thermal shipping container should be stored at 15° to 25° Celsius, which is 59° to 77° Fahrenheit.<br>• The thermal shipping container is qualified with a minimum of 23 kgs of dry ice pellets (10 mm – 16 mm pellets). Upon receipt and after opening, the box should be replenished/inspected with dry ice within 24 hours by adding dry ice to the maximum within the payload insert areas and dry ice pod.<br>• The thermal shipping container should be re-iced every 5 days.<br>  • This can help maintain the level of dry ice and the temperature of the vaccine product. It is recommended that the thermal shipping container **not be opened more than 2 times a day, and shouldn't be opened for** more than 1 minute at a time. If that is followed, the thermal shipping container should then be re-iced every 5 days. |



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| Recommendations (Using Thermal Shipping Container as Temporary Storage) |
|---|
| • Local dry ice suppliers should be used for re-icing the thermal shipping container.<br><br>• Temperature monitoring devices to be used if thermal shipping container is used as temporary storage. Sites are responsible for obtaining their own temperature monitoring devices to monitor temperatures when using the thermal shipping container as temporary storage. Temperature monitoring devices (probe or probeless) capable of being in a dry ice environment to be used and placed in the location of the vial tray payload area within the thermal shipping container.<br><br>• The thermal shipping container should be returned within 20 business days of delivery, including temperature data logger.<br>  • If you receive a Controlant Real-Time Temperature Monitor, it must be returned with the thermal shipping container.<br>  • If you receive a Sensitech Temperature Monitor, it does not need to be returned. |

## 5. Procedure

5.1. Unpackaging

| Responsible Role | Action Step |
|---|---|
| Operator | 1. Before opening the thermal shipping container, make sure the area in which you are working has proper ventilation. Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, can result in depletion of oxygen, resulting in asphyxiation. |
| | 2. In a well-ventilated area, open the Outer Corrugated Shipper by cutting the tape on the outside. |



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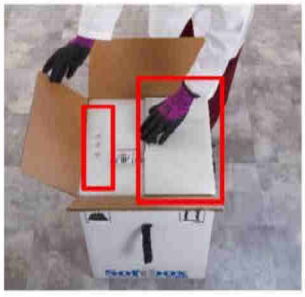
| Responsible Role | Action Step |
|---|---|
| |  |
| | 3. Open the lid. **Note:** One side of the thermal shipping container is permanently affixed so it is recommended to use the three finger hole die-cut on the foam.<br>  <br>Once the lid is opened the dry ice pod will be seen as illustrated below.<br>  |
| | 4. While wearing insulated (thermal) gloves, take out the Dry Ice Pod. |

| Responsible Role | Action Step |
|---|---|
| |  |
| |  |
| | 5. Access the payload sleeve, which is on top of a thin layer of dry ice and open it.<br>  <br>**Note:** The payload sleeve does not have a bottom, so do not pull it out of the thermal shipping container. |
| | 6. Take out the product for inspection and immediately (within one minute of opening) store in an ultra-low temperature freezer or prepare for use. If shipper will be used as temporary storage for remaining vial trays, immediately re-insert the trays within one minute of opening and follow the re-icing instructions. |

| Responsible Role | Action Step |
|---|---|
| |  <br>*Refer to Recommendations section of this procedure for further details on using the thermal shipping container as temporary storage. |
| | 7. If not using the thermal shipping container as temporary storage, insert all components back into the thermal shipping container for return.<br><br>Dry ice must be discarded in a well ventilated area before considering returning the thermal shipping container. |

5.2. Re-Icing

| Responsible Role | Action Step |
|---|---|
| Operator | 1. Before opening the thermal shipping container, make sure the area in which you are working has proper ventilation. Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, can result in depletion of oxygen, resulting in asphyxiation. |
| | 2. In a well-ventilated area, open the Outer Corrugated Shipper by cutting the tape on the outside. |



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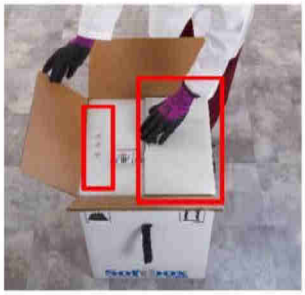
| Responsible Role | Action Step |
|---|---|
| |  |
| | 3. Open the lid. **Note:** One side of the thermal shipping container is permanently affixed so it is recommended to use the three finger hole die-cut on the foam.<br>  <br>Once the lid is opened the dry ice pod will be seen as illustrated below.<br>  |
| | 4. While wearing insulated (thermal) gloves, take out the Dry Ice Pod. |



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| Responsible Role | Action Step |
|---|---|
| |   |
| | 5. Fill the sides of the payload sleeve with dry ice until it's equal with the corrugated structure.  |

| Responsible Role | Action Step |
|---|---|
| |  |
| | 6. Reinsert the Dry Ice Pod and fill with dry ice leaving room between dry ice level and sides of shipper.<br>  |
| | 7. Close the Dry Ice Pod.<br>  |
| | 8. Close the Lid, the Outer Corrugated Shipper and reseal with tape. |



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| Responsible Role | Action Step |
|---|---|
| |   |

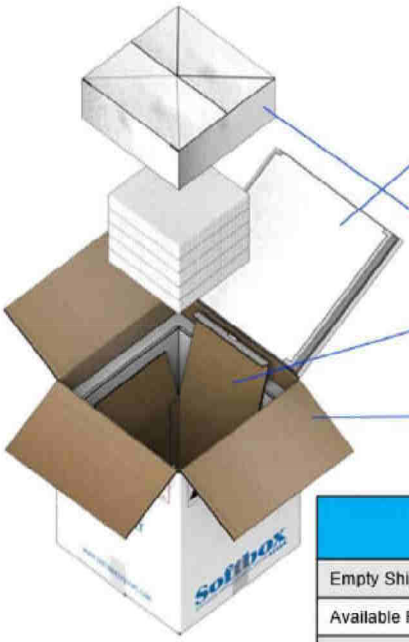
## 6. History of changes

| Version | History of Changes |
|---|---|
| 01 | Initial version |
| 02 | Updated formatting and pictures for clarity. |

## 7. Appendix

### 7.1 Appendix 1: Softbox Medium ULT Parcel Shipper

**Note:** Approximate weights are based on maximum configuration of dry ice.




| ITEM | DESCRIPTION |
|---|---|
| 1 | VIP LID |
| 2 | DRY ICE POD |
| 3 | PAYLOAD SLEEVE (Takes 1 to 5 vial trays) |
| 4 | MEDIUM ULT THERMAL SHIPPER |

| Softbox Medium ULT Weights and Dimension | |
|---|---|
| Empty Shipper Weight | 8.5 kgs |
| Available Payload Space | 9.65" x 9.65" x 9.49" |
| External Dimension | 15.75" x 15.75" x 22.04" |
| Amount of Dry Ice | 23 kgs |
| Tare Weight w/ Dry Ice | 31.5 kgs |
| Total Weight w/ 1 Vial Tray | 32.6 kgs |
| Total Weight w/ 5 Vial Trays | 36.7 kgs |

| | |
|---|---|
| Weight of Vial Tray | 1.038 kgs |



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## ATTACHMENT 4 : LABELLING AND PACKAGING SPECIFICATIONS

**Product Labelling Specifications**

Product labels for primary, secondary and tertiary packaging will be shared closer to regulatory filings.

It is currently envisaged that the following will be part of the initial product artwork:

**Primary Packaging (Vial):**

- Linear barcode: Scans as the Global Trade Item Number (GTIN) that includes the human-readable National Drug Code (NDC) number.

**Secondary Packaging (Carton Tray):**

- Linear barcode: Scans as the GTIN number that includes the human-readable NDC number.
- QR code: When scanned, this code links to a landing page where a copy of the Fact Sheets for the Healthcare Provider, patient/recipient, and Emergency Use Authorization Product Insert (i.e. e-leaflet) will be available.
- 2D GS1 DataMatrix: Scan of the 2D code will include the GTIN number, lot and expiry information.

**Product Packaging Specifications**

**Primary Packaging**

- 2 mL type 1 glass preservative free multi-dose vial (MDV)
- MDV has 0.45 mL frozen liquid drug product
- 5 doses per vial

**Secondary Packaging "Single Tray"**

- Single tray holds 195 vials
- 975 doses per tray
- Tray (white box) dimensions: 229 X 229 x 40 mm

**Tertiary Container: Thermal Shipper (Softbox)**

- Minimum 1 tray (975 doses) or up to 5 trays (max 4875) stacked in a payload area of the shipper
- Payload carton submerged in 23 Kg of dry ice pellets (9 mm – 16 mm pellets)
- Thermal shipper dimensions:
    - Internal Dimensions: 245mm X 245mm X 241mm
    - External Dimensions: 400mm X 400mm X 560mm

## ATTACHMENT 5: RETURN AND DISPOSAL OF PRODUCT MATERIALS

**A. Return**

"**Logistics Delivery Equipment**" refers to the long-distance thermal shipping container ("**Thermal Shipper**") used for shipping and the temperature data logger/monitoring device attached to such Thermal Shipper.

Once dry ice is no longer needed, open the **Logistics Delivery Equipment** and leave it at room temperature in a well-ventilated area. The dry ice will readily sublime from a solid to a gas. DO NOT leave dry ice unattended.

Store the empty **Logistics Delivery Equipment** until return in an appropriate clean and secure location to protect and maintain the functionality of the equipment (e.g., do not store outside under uncontrolled conditions, exposed to weather, exposed to pests, etc.).

Return of the **Logistics Delivery Equipment** to be undertaken within 20 business days following delivery of the Product to the Participating Member State's recipient, which will be effected by collection by the Contractor within that time. Instructions and logistics for return will be provided on the interior of the Thermal Shipper and will also be available on Pfizer's website. In the event that either: (a) the **Logistics Delivery Equipment** (or any part thereof), is not made available for collection within such 20 business days; or (b) the **Logistics Delivery Equipment** (or any part thereof), is damaged in any way (determined in the Contractor's sole discretion), the Contractor shall be entitled to charge the Participating Member State $450 (exclusive of VAT) per Thermal Shipper and logger; which the Participating Member State shall pay within 30 days of the date of any invoice for such amount(s). Participating Member State acknowledges that such amount represents a reasonable pre-estimate of replacement cost for such Logistics Delivery Equipment as a result of the Participating Member State's default, act or omission.

**B. Disposal**

"**Primary Container Units**" refers to the vials that contain the Product.

Destruction of the **Primary Container Units** that have been opened or are unused must take place at a facility appropriately licensed to handle and destroy pharmaceutical waste, medical waste, and/or hazardous waste, and destruction must be by means of grinding or incineration.

"**Secondary Cartons**" refers to the immediate boxes that contain the vials of Product.

**Secondary Cartons** must be defaced and destroyed in accordance with local clinical dosing facility waste management services, and **Secondary Cartons** may not be disposed of in routine household waste collection or recycling centres.