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. 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		

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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	PF-07305885 COVID-19 Vaccine mRNA Drug Substance
LIMS Product Name	DS-001426 Initial Specifications (Section 3.0) DS-001477 PPQ Specifications (Section 4.0)
BNT Vaccine Code	BNT162b2
BNT RNA Code	RBP020.2
Plasmid PF# (BNT Plasmid Code)	PF-07305883 (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

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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

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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

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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

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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

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

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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; 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

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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					

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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.

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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

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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

090177e194990286\Approved\Approved On: 07-Aug-2020 22:37 (GMT)

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)

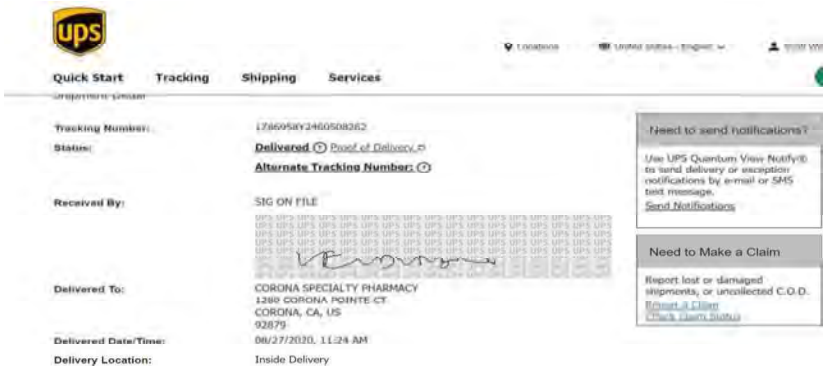
4. Outbound Shipping Label – One (1), standard label on Thermal Shipper

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

Pfizer	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 Marci-Ann Ando 21 Oct 2020 18:48:024-0400 REASON: I approve this document as author. 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

Appendix A: Instructions
(11 Pages)

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

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.

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. • The thermal shipping container should be stored at 15° to 25° Celsius, which is 59° to 77° Fahrenheit. • 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. • The thermal shipping container should be re-iced every 5 days.   • 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.
 	
• 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.
 	
• The thermal shipping container should be returned within 20 business days of delivery, including temperature data logger.
  • If you receive a Controlant Real-Time Temperature Monitor, it must be returned with the thermal shipping container.
  • 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.

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

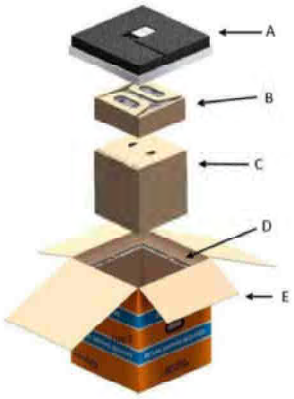
Responsible Role	Action Step
	 
	3. Remove the VIP Lid carefully as the temperature monitor probe is connected to the Payload Box. Care should be taken to not disconnect the probe from the Payload Box. 
	4. While wearing insulated (thermal) gloves, take out the Dry Ice Tray.

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. *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

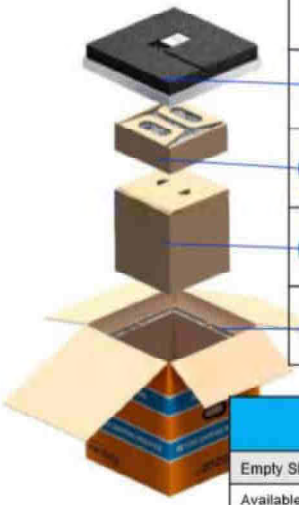
Version	History of Changes
01	Initial version
02	Updated formatting and pictures for clarity.

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

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

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

	Logistics Solutions & Compliance | Technical Assessment 2020TA021 v2.0	Page 1 of 2
Pfizer	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 Marci-Ann Ando 21 Oct 2020 18:47:044-0400 REASON: I approve this document as author. 0a1fb5f4-f692-45e0-8d06-8eb5d9529e8f
Logistics Solutions and Compliance | Sr. Manager Transport Validation & Innovation				
Approved:	Name	James Jean	Sign/Date	James E Jean James E Jean 21 Oct 2020 19:11:006-0400 REASON: I approve this document. 524412a2-6820-4b64-8cc4-a43540e06a26

Appendix A: Instructions
(12 Pages)

DocUUID : 93d2c072-1193-449d-b8fa-ef78b87c0f19

2020TA021 v2.0

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

Table Of Content

DocUUID : 93d2c072-1193-449d-b8fa-ef78b87c0f19

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. • The thermal shipping container should be stored at 15° to 25° Celsius, which is 59° to 77° Fahrenheit. • 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. • The thermal shipping container should be re-iced every 5 days.   • 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.

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

Recommendations (Using Thermal Shipping Container as Temporary Storage)

• Local dry ice suppliers should be used for re-icing the thermal shipping container.
 	
• 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.
 	
• The thermal shipping container should be returned within 20 business days of delivery, including temperature data logger.
  • If you receive a Controlant Real-Time Temperature Monitor, it must be returned with the thermal shipping container.
  • 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.

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

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.  Once the lid is opened the dry ice pod will be seen as illustrated below. 
	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.  **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.

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

Responsible Role	Action Step
	 *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. 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.

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

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.  Once the lid is opened the dry ice pod will be seen as illustrated below. 
	4. While wearing insulated (thermal) gloves, take out the Dry Ice Pod.

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. 
	7. Close the Dry Ice Pod. 
	8. Close the Lid, the Outer Corrugated Shipper and reseal with tape.

Responsible Role	Action Step
	 

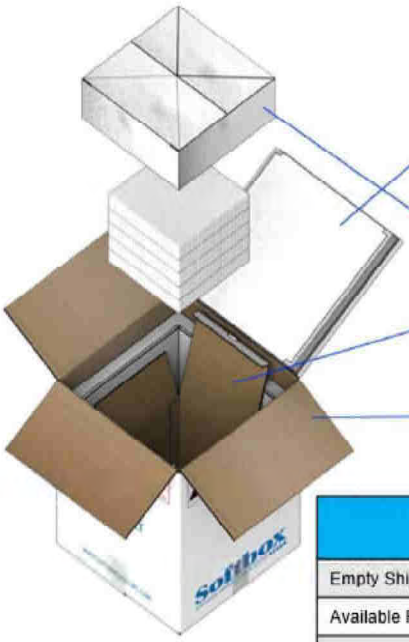
6. History of changes

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

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

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.