COUNTRY SIDE LETTER - COVAX SUPPLY OF PFIZER VACCINE

This Side Letter to the Indemnification Agreement is entered into by [country] (the "**COVAX Participant**") and Pfizer Overseas LLC ("**Pfizer**") on [date] in relation to the access to Pfizer's Comirnaty® vaccine through the COVAX Facility. The Side Letter sets out the terms relating to Product acceptance, storage and handling as well as liability limitation that apply to the COVAX Participant's access to the Product.

Article I - Requirements for Product Delivery, Storage, Handling, Return and Disposal, Confidentiality

The COVAX Participant shall be responsible for and liable for its respective obligations set out in Schedule 1 (*Product Handling Requirements, Confidentiality*).

Article II - Limitation of Liability

Neither Pfizer, nor any Pfizer affiliate, and their respective officers, directors, employees and representatives, shall be liable to the COVAX Participant, whether in tort, for breach of contract or otherwise, for (i) any direct or indirect damages, or (ii) any liabilities of the COVAX Participant to any third party, in each case arising out of or relating to the supply of the Product to the COVAX Participant through the COVAX Facility, and to the maximum extent permitted by applicable Law.

Without prejudice to the COVAX Participant's obligations pursuant to the Indemnification Agreement executed with Pfizer, the COVAX Participant shall not be liable to Pfizer, under or in relation to this Side Letter, for any indirect or consequential loss or damage.

Article III No implied terms

The parties acknowledge that the COVAX Participant's access to the Product and Vaccine is subject to the terms and conditions of its agreement with Gavi and that Pfizer is supplying the Product under terms agreed with Gavi and with the procurement agency. The parties therefore also acknowledge and agree that (i) this Side letter does not constitute a supply agreement between Pfizer and the COVAX Participant, (ii) Pfizer provides no warranties to the COVAX Participant regarding the Product, and (iii) all other terms which might be implied or incorporated into this Side Letter (whether by statute, common law or otherwise), and the United Nations Convention on the International Sale of Goods, are excluded to the fullest extent permitted by applicable Laws.

Article IV - Governing Law; Disputes

This Side Letter and any non-contractual obligations arising out of or in connection with it shall be governed by English law. All disputes arising out of or in connection with this Side Letter shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three arbitrators appointed in accordance with the said Rules.

For the **COVAX Participant**,	For **Pfizer,**
[*forename/surname/position*]	[*forename/surname/position*]
Signature:_____	Signature: _____

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

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

Schedule 1 - Product Handling Requirements, Confidentiality

Each COVAX Participant confirms that it has read and understood the requirements listed below in relation to the storage, handling, distribution and disposal of the Product and confidentiality, and further acknowledges that Pfizer is under no obligation to replace any Product to the extent it has been compromised as a direct result of a failure by that COVAX Participant to comply with such obligations.

Each COVAX Participant shall comply with the following requirements reproduced from the supply agreement concluded between Pfizer and the procurement agency (the "**Supply Agreement**") and adapted only to the extent required for the purpose of context in this Side Letter):

1. DELIVERY LOCATIONS

1.1 The COVAX Participant shall be responsible for working with the procurement agency in:

1.1.1 ensuring that each delivery location: (i) meets the requirements set forth in Annex 1, (ii) is serviced by a contracted transportation carrier of Pfizer, and (iii) holds all appropriate authorizations under applicable Laws to receive the Product or Vaccine;

1.1.2 presenting evidence of satisfaction of the above conditions to Pfizer in an official format reasonably acceptable to Pfizer; and

1.1.3 providing any additional information, as reasonably requested by Pfizer in advance of delivery, to verify such authorization.

2. PRODUCT HANDLING

2.1 Upon delivery of Product or Vaccine to the COVAX Participant shall:

2.1.1 store and handle the Product or Vaccine in the manner set forth in the Specifications, instructions on Annex 1 and any instructions as may be provided by Pfizer to ensure stability and integrity of the Product or Vaccine;

2.1.2 bear all expenses for use of the Product or Vaccine upon transfer from Pfizer at the agreed upon location in-country, including, but not limited to, those for storage of the Product or Vaccine and distribution and administration of the Product or Vaccine (if applicable) in their country.

2.1.3 be solely responsible and liable for the proper storage, handling, distribution, transportation, administration, use and disposal of the Product or Vaccine in their country following delivery of the Product or Vaccine;

2.1.4 follow the return and disposal instructions in Annex 2 (which may be updated from time to time by Pfizer upon notice to the procurement agency and the COVAX Participant) when disposing of open and unused Product or Vaccine and its packaging components;

2.1.5 ensure that any return and disposal of Products or Vaccines complies with Laws regarding pharmaceutical waste, medical waste, or hazardous waste, as appropriate;

2.1.6 ensure that any equipment used to deliver the Product or Vaccine, for example the shipper(s) and monitoring device(s), is stored by such country in an appropriate clean and secure location to protect and maintain the functionality of such equipment (in controlled conditions, with no exposure to weather or pests, etc.); and

2.1.7 within thirty (30) days of receipt of the Product or Vaccine, subject to Section 4.2, organize safe return of all such equipment, including the shipper and monitoring device, in accordance with Pfizer's reasonable instructions; and

2.1.8 ensure that all recipients of the Product, Vaccine and Product Materials have the requisite expertise to develop and implement appropriate procedures and training programs to enable proper handling of the Product or Vaccine and Product Materials in a safe and lawful manner.

3. TITLE TO PRODUCT, RISK OF LOSS

3.1 Title to the Product or Vaccine shall pass to the COVAX Participant at the first point of entry of the Products into its territory before customs clearance. Risk of loss or damage to the Product or Vaccine shall pass to the COVAX Participant at the delivery location specified for delivery in-country and agreed in writing with the procurement agency.

3.2 The COVAX Participant shall be the sole importer of record in front of the relevant customs authorities in their territory and shall be responsible to obtain any import license or other official authorization and carry out all customs formalities for the import in the territory, including having responsibility to pay, where applicable, all duties, taxes and other charges relating to the import of the Products.

3.3 The COVAX Participant accepts responsibility for the unloading of such Product or Vaccine from the transportation carrier and accepts title and risk of loss will pass to it as set out in Section 3.1. For the sake of clarity, Pfizer's liability shall cease, and risk of loss or damage shall transfer, upon carrier's arrival at the point of delivery and immediately prior to the unloading of the Product or the Vaccine. Without prejudice to the generality of the foregoing, following delivery of the Product or the Vaccine to the COVAX Participant, the COVAX Participant takes full responsibility for and is liable in relation to any Product or Vaccine wastage, and for ensuring appropriate disposal in accordance with Sections 2.1.2 and 2.1.6.

3.4 Without prejudice to Section 4, the COVAX Participant acknowledges that Pfizer will not, in any circumstances, accept any returns of Product or Vaccine (or any dose). In particular, following receipt of the Product or Vaccine in accordance with this Section 3, no Product or Vaccine returns may take place under any circumstances (inclusive of future changes in stock, changes in Product or Vaccine allocation, delivery, demand or new product launch).

4. REJECTION OF PRODUCT OR VACCINE; DISPOSAL OF REJECTED SHIPMENTS

4.1 Without prejudice to Section 7, where the COVAX Participant wishes to reject any Product or Vaccine that does not materially conform to Specifications or cGMP ("**Non-Complying Product**"), it shall provide written notice of rejection to Pfizer, setting out detailed reasons for such rejection: (i) immediately (and in no event more than 24 hours) upon delivery of such Non-Complying Product in accordance with this Side Letter; or (ii) immediately and in no event more than 24 hours upon its first knowledge of a Latent Defect. For clarity, the COVAX Participant shall not be entitled to reject any Product or Vaccine supplied through the COVAX Facility based on service complaints unless a Product or Vaccine does not materially conform to Specifications or cGMP or is deemed no longer EUL listed. Other than as set out above, the COVAX Participant shall not be entitled to reject any Product or Vaccine supplied through the COVAX Facility.

4.2 The COVAX Participant shall store and maintain the relevant Non-Complying Product in appropriately secure locations and in accordance with the manufacturers' reasonable specifications.

5. MAINTENANCE AND RETENTION OF RECORDS.

5.1 The COVAX Participant shall maintain a quality system for receipt, inspection, storage, traceability to further delivery points, and recall activities.

6. DIVERSION ISSUES.

6.1 The COVAX Participant shall ensure that all Product or Vaccine delivered through the COVAX Facility shall be: (a) stored securely by the COVAX Participant; and (b) distributed by the COVAX Participant only in its country in a secure manner appropriate to the transportation route and destination, in each case (a) and (b) to guard against and deter theft, diversion, tampering, substitution (with, for example, counterfeits) resale or export out of the COVAX Participant's territory, and to protect and preserve the integrity and efficacy of the Product or Vaccine. The COVAX Participant shall notify the procurement agency of any suspected diversion issues.

7. RECALLS.

7.1 Pfizer shall be entitled to recover from the COVAX Participant all reasonable costs of any recall or market withdrawal of the Product or Vaccine, save where such recall or market withdrawal arises from circumstances that would constitute an exception to the provision of an indemnity to Pfizer for patient claims under the Indemnification Agreement, in which event Pfizer will be responsible solely for: (a) any reasonable and documented out of pocket expenses directly incurred by the COVAX Participant in implementing such recall or market withdrawal; and (b) replacing, at Pfizer's expense, the Product or Vaccine which has to be recalled.

8. CONFIDENTIALITY.

8.1 Non-Use and Non-Disclosure.

8.1.1 The COVAX Participant shall, and shall cause its Representatives which have access to Pfizer's Confidential Information to, maintain in strict confidence, and shall not disclose to any third party, all Confidential Information observed by or disclosed to it by or on behalf of Pfizer or the procurement agency pursuant to this Side Letter. The COVAX Participant shall not use or disclose such Confidential Information except to its Representatives as strictly necessary in order to operationalise the supply of Products or Vaccines and in accordance with the terms of this Side Letter. The COVAX Participant shall safeguard the confidential and proprietary nature of Pfizer's Confidential Information with at least the same degree of care as it holds its own confidential or proprietary information of like kind, which shall be no less than a reasonable degree of care. The COVAX Participant and its Representatives may use, copy, and make extracts of Pfizer's Confidential Information only as strictly necessary in order to operationalise the supply of Products or Vaccines and in accordance with the terms of this Side Letter and, without limiting the foregoing, shall not use the Confidential Information for the benefit of the COVAX Participant or any of its Representatives, or for the benefit of any other person. In the event that the COVAX Participant becomes aware of any breach of the obligations contained in this Section 8.1.1 (Confidential Information) by it or its Representatives, the COVAX Participant shall promptly notify Pfizer in writing of such breach and all facts known to the COVAX Participant regarding same. In addition, if the COVAX Participant is required to disclose Pfizer's Confidential Information in connection with any court order, statute or government directive or requirement under any Law, the COVAX Participant shall (to the extent permitted by such court order, statute or government directive or requirement under any Law) give Pfizer notice of such request, as soon as practicable, before such Confidential Information is disclosed so that Pfizer may seek an appropriate protective order or other remedy, or waive compliance with the relevant provisions of this Side Letter. If Pfizer seeks a protective order or other remedy, the COVAX Participant shall promptly cooperate with and reasonably assist Pfizer (at Pfizer's cost) in such efforts. If Pfizer fails to obtain a protective order or waives compliance with the relevant provisions of this Side Letter, the COVAX Participant shall disclose only that portion of Confidential Information which its legal counsel determines it is required to disclose. Neither this Side Letter nor the performance by either party hereunder shall transfer to the COVAX Participant any proprietary right, title, interest or claim in or to any of Pfizer's Confidential Information (including, but not limited to, any intellectual property rights subsisting therein) or be construed as granting a license in its Confidential Information.

8.1.2 In order to comply with the obligations contained in this Section 8.1.2 (Confidential Information), the COVAX Participant shall take at least the following precautions: (a) the COVAX Participant shall exercise all reasonable efforts to prevent unauthorized employees and unauthorized third parties from gaining access to Confidential Information (and in no event less than reasonable care); (b) the COVAX Participant shall disclose Confidential Information only to such of its Representatives who have a need to know such Confidential Information as strictly necessary in order to operationalise the supply of Products or Vaccines and in accordance with the terms of this Side

Letter; provided, however, before any disclosure of Confidential Information, the COVAX Participant shall bind its Representatives receiving such Confidential Information to a written agreement of confidentiality at least as restrictive as this Side Letter; and (c) prior to any disclosure, the COVAX Participant shall instruct its Representatives of the confidential nature of, and to maintain the confidentiality of, the Confidential Information. The COVAX Participant shall be responsible for all actions of its Representatives, including, without limitation, any breach of the terms hereof, regardless of whether or not such Representatives remain employed or in contractual privity with the COVAX Participant.

8.1.3 The provisions of Section 8 shall not prohibit disclosure or use of Confidential Information if Pfizer has given prior written approval to the disclosure.

8.2 Return of Confidential Information

Upon the written request of Pfizer, the COVAX Participant shall promptly return or, at the COVAX Participant's option, delete or destroy all Confidential Information of Pfizer (including, without limitation, all copies in whatever medium provided to, or made by, such recipient); provided, however, that, subject to the terms of this Side Letter, (i) the COVAX Participant shall be entitled to retain one archival copy of such Confidential Information for purposes of determining its obligations under this Side Letter; and (ii) the COVAX Participant shall not be required to destroy any computer files stored securely by the COVAX Participant that are created during automatic system back up, or retained for legal purposes by the legal division of the COVAX Participant, provided that such retained Confidential Information shall remain subject to the terms of this Side Letter. Notwithstanding the COVAX Participant's return or destruction of Confidential Information, the COVAX Participant shall continue to be bound by its obligation of confidentiality and non-use under this Side Letter.

8.3 Survival

The provisions of this Section 8 (Confidential Information) shall survive for a period of ten (10) years from the date of this Side Letter, except with respect to any information that constitutes a trade secret (as defined under applicable Law), in which case the recipient of such information will continue to be bound by its obligations under this Section 8 (Confidential Information) for so long as such information continues to constitute a trade secret, but in no event for a period of less than the ten (10) year period specified above.

9. OTHER PROVISIONS

Each COVAX Participant acknowledges that:

9.1 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 COVAX Participant

9.2 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; and

9.3 the Product or Vaccine shall not be serialized.

10. DEFINITIONS

As used in this Side Letter, the following terms shall have the meanings set forth below:

10.1 "**Agency-Procuring Countries**" means all Self-Financing Participants who choose to procure the Vaccine via the procurement agency;

10.2 "**Confidential Information**" means all confidential or proprietary information, other than Exempt Information, in any form, directly or indirectly disclosed to the COVAX Participant or its Representatives by or on behalf of Pfizer or the procurement agency pursuant to this Side Letter, regardless of the manner in which such information is disclosed, delivered, furnished, learned, or observed, either marked "Confidential" or, if oral, declared to be confidential when disclosed and confirmed in writing within thirty (30) days of disclosure. Confidential Information includes, without limitation, the terms and conditions of this Side Letter and the Supply Agreement, and the price paid for the Product or Vaccine. Failure to mark Confidential Information disclosed in writing hereunder as "Confidential" shall not cause the information to be considered non-confidential, with the burden on Pfizer to prove such information clearly should have been known by a reasonable person with expertise on the subject matter, based on the nature of the information and the circumstances of its disclosure, to be Confidential Information, provided that Pfizer has otherwise made good faith efforts to clearly mark Confidential Information as such.

10.3 "**COVAX Facility**" means the global COVID-19 vaccine facility created by the vaccine pillar of the Access to COVID-19 Tools Accelerator, through which countries can work together to share risk by accessing a wide portfolio of vaccine candidates.

10.4 "**Current Good Manufacturing Practices**" or "**cGMP**" means the current good manufacturing, distribution and storage practices set out in the EU Directive 2001/83/EC (as amended by Directive 2004/27/EC), Directive 2017/1572, Directive 2003/94/EC and EudraLex - Volume 4 of the Rules Governing Medicinal Products in the EU.

10.5 "**Emergency Use Listing**" or "**EUL**" means a risk-based procedure developed by the WHO for assessing and listing candidate in vitro diagnostics, therapeutics and vaccines for use during public health emergencies.

10.6 "**Exempt Information**" means information that: (a) the COVAX Participant or any of its Representatives lawfully possessed, as demonstrated by competent proof, before Pfizer or the procurement agency disclosed such information under this Side Letter; or (b) was already generally available and in the public domain at the time of disclosure, or becomes public (other than as a result of breach of this Side Letter by the COVAX Participant or its Representatives); (c) the COVAX Participant or any of its Representatives lawfully obtains from a person not in breach of any confidentiality obligation (or other prohibition from disclosing the information) to Pfizer with respect to such information (and the COVAX Participant has made reasonable enquiry with respect thereto); or (d) the COVAX Participant evidences to the reasonable satisfaction of Pfizer is independently developed by or on behalf of the COVAX Participant or its Representatives without the use of, reference to, aid from, or reliance on, the

Confidential Information. In clarification of the foregoing, a general disclosure in the public domain will not cause more specific (but related) information to be deemed Exempt Information under one of the above exceptions; similarly, a combination of several pieces of information, which individually would be deemed Exempt Information, will not be deemed Exempt Information unless the combination itself is in the public domain, independently developed by the COVAX Participant or its Representatives or otherwise lawfully in the possession of the COVAX Participant or any of its Representatives.

10.7 "**Gavi**" means Gavi, the Vaccine Alliance.

10.8 "**Indemnification Agreement**" shall mean the indemnification agreement entered into between the COVAX Participant and Pfizer.

10.9 "**Latent Defect**" means a defect causing the Product or Vaccine to not conform to the applicable Specifications that the COVAX Participant can show was present at the time of Pfizer's delivery of the Product or Vaccine to the COVAX Participant and which could not have been detected by the COVAX Participant, its designee, or their personnel at delivery through diligent inspection.

10.10 "**Law/s**" means, collectively, all applicable national and local laws, common laws, statutes, ordinances, codes, rules, regulations, orders, decrees or other pronouncements of any government, administrative or judicial authority having the effect of law.

10.11 "**Non-Complying Product**" shall have the meaning set forth in Section 4.1.

10.12 "**Product**" means the medicinal product, being BNT162b2, a nucleoside-modified messenger RNA (mRNA) vaccine that encodes an optimized SARS-CoV-2 full-length spike glycoprotein for which Initial Approval has been granted, manufactured, in whole or in part, or supplied, directly or indirectly, by or on behalf of Pfizer or BioNTech or any of their Affiliates pursuant to the Supply Agreement.

10.13 "**Product Materials**" means all packaging materials and components needed for delivery of the Product or Vaccine.

10.14 "**Representatives**" means the COVAX Participant's officers, employees, agents, contractors, consultants, advisors and representatives who (a) are subject to an obligation of confidentiality protecting the Confidential Information on terms no less restrictive than those contained in this Side Letter; and (b) have a need to know the Confidential Information in connection with this Side Letter.

10.15 "**Specifications**" means the material specifications for the manufacture, processing, packaging, labeling, testing and testing procedures, shipping and supply of the Product or Vaccine as set out in Annexes 3, 4 and 6, as such specifications may be amended, supplemented or otherwise modified by Pfizer from time to time.

10.16 "**Vaccine**" means (a) the medicinal product, being BNT162b2, a nucleoside-modified messenger RNA (mRNA) vaccine that encodes an optimized SARS-CoV-2 full-length spike glycoprotein for which initial approval has been granted, manufactured, in whole or in part, or supplied, directly or indirectly, by or on behalf of Pfizer or any of their

affiliates pursuant to the Supply Agreement; and (b) the diluent used in the administration of such vaccine.

Annex 1 - Product Delivery, Storage & Handling Specifications

Shipments will arrive in a long-distance thermal shipping container as provided by Pfizer in accordance with the Labelling and Packaging Specifications set forth in Annex 3 ("**Thermal Shipper**"). At this time, the minimum package in any shipment shall be one (1) tray with 195 vials or 1170 doses of Product.

The COVAX Participant ensures 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:

(a) transfer the Product to:
  (i) a -75 ^{o}C (+/- 15 ^{o}C) ultra-low temperature ("**ULT**") freezer; or
  (ii) a 2-8 ^{o}C refrigerator; or

(b) maintain the Product with sufficient supply of dry ice in accordance with the protocols for re-icing set forth below with such initial re-icing to occur no later than 24 hours from signature of acceptance of delivery.

The COVAX Participant acknowledges the following stability timelines as of the date of this Side Letter:

- The Product has a shelf-life of up to 6 months when stored at a constant a -75 ^{o}C (+/- 15 ^{o}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 30 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 COVAX Participant, and the COVAX Participant shall ensure that all locations where any Product is delivered by, or on behalf of the COVAX Participant, shall comply with the requirements set forth in this Attachment D and shall meet the standards set forth herein.

Protocols for Unpacking Product and Re-icing: See Exhibits 1 and 2 of Annex 1

Requirements of Delivery Location:

1. EUA/EUL, Pre-approval, Post-approval vaccination points with -75 ^{o}C (+/- 15 ^{o}C) ULT freezer
2. EUA/EUL, Pre-approval, Post-approval vaccination points with sufficient access and supply of dry-ice
3. EUA/EUL, Pre-approval, Post-approval vaccination points with 2-8^{o}C refrigerator

Exhibit 1 – Unpacking and Re-icing: Softbox Thermal Shipper

1. OVERVIEW

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 with side shields).

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

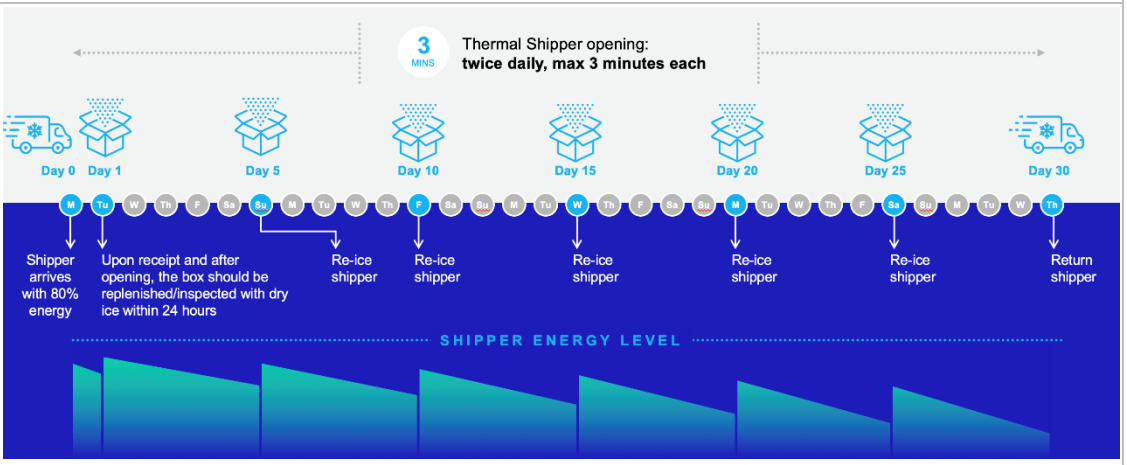
2. GENERAL REQUIREMENTS

2.1 Materials

Specification Number	Description
N/A	Waterproof Thermal Gloves
N/A	Safety Glasses with Side Shields
N/A	Carton Sealing Tape
N/A	Dry Ice Pellets (10 to 16 mm)

2.2 High Level Requirements (Using Thermal Shipping Container as Temporary Storage)

- The thermal shipping container is qualified with a minimum of 20 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 stored at 15° to 25° C (59° to 77° F).
- 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 **3 minutes** at a time. If that is followed, the thermal shipping container should then be re-iced every **5 days**.



- **Remember:** 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 and Controlant monitor must be returned within the allowable time allotted for use.

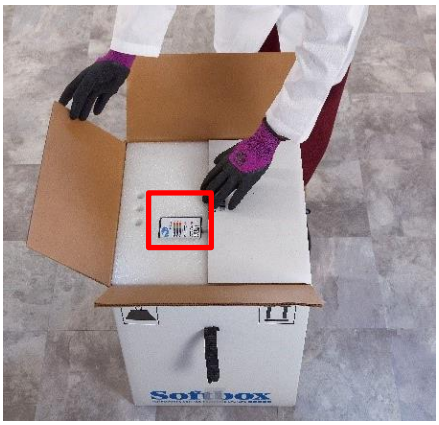
3. UNPACKAGING AND RE-ICING OVERVIEW

3.1 Unpackaging

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.

3. When you open the thermal shipping container, you will see a temperature monitoring device embedded in the foam lid. The temperature monitoring device continuously tracks the temperature during shipment to ensure the frozen vaccine product has been maintained at the required temperatures during transport.



Press and hold the stop button for 5 seconds on the Controlant Monitor. Do not remove the Controlant monitor from the foam lid or container because it must be returned with the thermal shipping container after use.

Note: In cases where the thermal shipping container contains a Sensitech TempTale Ultra Temperature Monitor press and hold the Stop button for 1-3 seconds.

Sites are responsible for continuing to monitor the product storage conditions.

4. 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.

5. While wearing insulated (thermal) gloves, take out the Dry Ice Pod.

6. Remove the Payload Box from the thermal shipper by carefully pulling directly upwards with the handles.
   CAUTION: During the unpacking process, you might feel resistance when trying to remove the box that holds the vial trays. Do not apply force to remove the box. Use the band(s) wrapped around each vial tray to remove the trays from the thermal shipping container.

7. Immediately store vial trays in an ultra-low temperature (ULT) freezer. Remember, do not open the vial trays until you are ready to remove vials for thawing or use.

*If an ULT Freezer is not available, the thermal shipping container may be used as temporary storage. Refer to 2.2 High Level Requirements Section (Using Thermal Shipping Container as Temporary Storage) and then immediately process to Re-Icing Section of this procedure for further details on using the thermal shipping container as temporary storage.

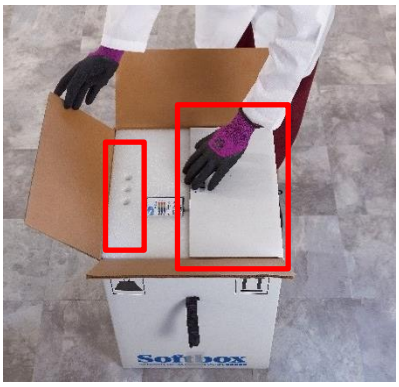
8. If not using the thermal shipping container as temporary storage, insert all components back into the thermal shipping container for return.

   Dry ice must be discarded in a well ventilated area before considering returning the thermal shipping container.

3.2 RE-ICING

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. Below is an overview of the components within the thermal shipping container for re-icing activities.

3. In a well-ventilated area, open the Outer Corrugated Shipper by cutting the tape on the outside and open the lid using the three holes.



4. The dry ice pod is visible. While wearing waterproof thermal gloves, take out the Dry Ice Pod.


5. Fill the sides of the payload sleeve with dry ice until it's equal with the corrugated structure.


6. Reinsert the Dry Ice Pod and fill with dry ice leaving room between dry ice level and sides of shipper.

7. Close the Lid, the Outer Corrugated Shipper and reseal with tape and store back in a well ventilated location.

Exhibit 2 – Unpacking and Re-icing: Aerosafe Thermal Shipper

Important Note: Please read the following ancillary documents included with the Thermal Shipper before performing the unpacking and/or re-icing procedure:
1. Guidelines for Safe, Storage, Use
2. Handling of Dry Ice and Carbon Dioxide, Dry Ice Safety Data Sheet

Unpacking Thermal Shipper A

Step	Picture
1. Open outer corrugated Shipper.	
2. The shipment contains a data logger.	
3. Remove the lid carefully as the probe is connected to the payload box.	 
4. Remove the Dry Ice Tray.	

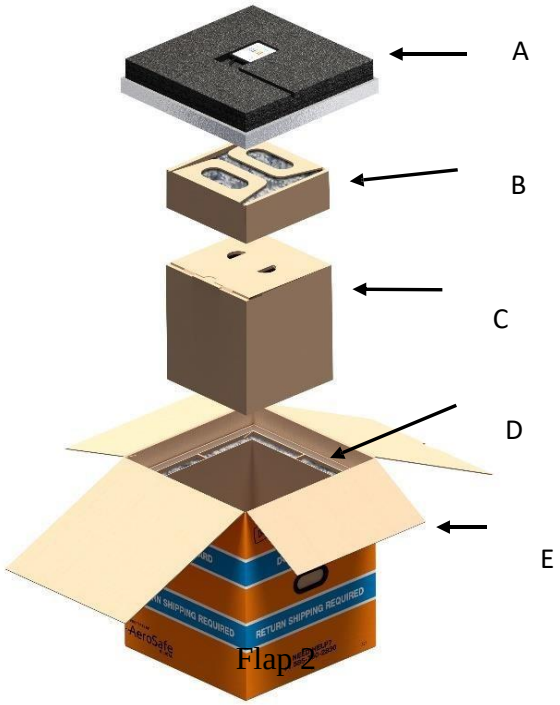
Step	Picture
	
5. Remove the payload box from the Shipper.	 
6. Open the payload box and remove the vial trays.	
7. If using the Thermal Shipper as a temporary storage for the remainder of the vial trays until use, close the payload box. Place back into the insulated Shipper.	

Step	Picture
8. Place the dry ice tray back on the payload box.	
9. Place the Shipper lid back onto the scaffolding tray.	
10. Tape the Shipper closed.	

Re-icing Instructions Thermal Shipper A

1. Open the outer corrugated Shipper (E) and take off the VIP Lid (A).
2. Take out the Dry Ice Tray (B) and set aside.
3. Fill the Scaffolding (D) of the Shipper with dry ice to the top of the scaffolding.
4. Reinsert the Dry Ice Tray (B) on top of the Payload Box (C).
5. Fill the Dry Ice Tray (B) with dry ice.
6. Close the Shipper with the VIP Lid (A).
7. Fold the outer corrugate flaps and reseal Shipper (E) with tape.

	Description
A	VIP Lid
B	Dry Ice Tray
C	Payload Box
D	Corner Dry Ice
E	47L/ Shipper



Recommendations:

- Thermal Shipper keeps ultra-low temperatures up to 10 days if stored at 15°C to 25°C temperatures without opening when packed with 23 kgs of dry ice pellets. Opening sequence and duration effect the Thermal Shipper's thermal performance.
- If Thermal Shipper will be used as temporary storage, Thermal Shipper should be re-iced immediately after delivery.
- Recommendation is to re-ice Thermal Shipper every five days at a minimum.
- Recommended Dry Ice Pellet size: 9 to 16 mm
- Temperature monitoring is to be used if the Thermal Shipper is used as temporary storage. Sites are responsible for obtaining their own temperature monitoring devices to monitor temperatures when using the Thermal Shipper as temporary storage. Temperature monitors capable of being in a dry ice environment to be used and placed in the location of the vial tray within the Thermal Shipper.

Vaccine Preparation & Administration Instructions

Removing the Vials to Thaw

- From storage, remove 1 vial for every 6 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.
- After dilution, vials of COMIRNATY contain six doses of 0.3 mL of vaccine. In order to extract six doses from a single vial, low dead-volume syringes and/or needles should be used. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microliters. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

Preparing the Dose

- **Draw up <u>0.3 mL</u> 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.

Annex 2 Return and Disposal of Product Materials

1. 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 30 days following delivery of the Product to the COVAX Participant. 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 returned within such 30 days; or (b) the **Logistics Delivery Equipment** (or any part thereof), is damaged in any way (determined in Pfizer's sole discretion), Pfizer shall be entitled to charge the COVAX Participant $450 (exclusive of VAT) per Thermal Shipper and temperature data logger/monitoring device; which the COVAX Participant shall pay within 30 days of the date of any invoice for such amount(s). The COVAX Participant acknowledges that such amount represents a reasonable pre-estimate of replacement cost such Logistics Delivery Equipment as a result of the COVAX Participant's default, act or omission.

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 centers.

Annex 3 - Specifications

3.2.P.5. CONTROL OF DRUG PRODUCT

3.2.P.5.1. SPECIFICATION(S)

The specification for BNT162b2 drug product at release and throughout shelf life is provided in Table 3.2.P.5.1-1. For all quality attributes tested on stability except for RNA integrity, the acceptance criteria for release and stability testing throughout shelf life are the same.

Table 3.2.P.5.1-1. BNT162b2 Drug Product Specifications

Quality Attribute	Analytical Procedure[a]	Procedure Number(s)	Acceptance Criteria
Composition and Strength			
Appearance	Appearance (Visual)	TM100010539	White to off-white suspension
Appearance (Visible Particulates)	Appearance (Particles) *(Ph Eur. 2.9.20, USP <790>, JP 6.06)*	TM100010539	May contain white to off-white opaque, amorphous particles
Subvisible Particles	Subvisible Particulate Matter[b] *(USP <787>, light obscuration method)*	TM100010541	Particles ≥10 µm: ≤6000 per container
			Particles ≥ 25 µm: ≤600 per container
pH	Potentiometry *(Ph. Eur. 2.2.3, USP <791>)*	TM100010538	6.9 – 7.9
Osmolality	Osmometry[c, d] *(USP <785>)*	TM100010540	425 - 625 mOsmol/kg
LNP Size	Dynamic Light Scattering (DLS)	TM100010649	40 to 120 nm
LNP Polydispersity	Dynamic Light Scattering (DLS)	TM100010649	≤ 0.3
RNA Encapsulation	Fluorescence assay	TM100010402	≥ 80%
RNA content	Fluorescence assay	TM100010402	0.50 ± 0.13 mg/mL
ALC-0315 content	HPLC-CAD	TM100010322	4.50 to 9.25 mg/mL
ALC-0159 content	HPLC-CAD		0.55 to 1.20 mg/mL
DSPC content	HPLC-CAD		0.90 to 2.05 mg/mL
Cholesterol content	HPLC-CAD		1.80 to 3.90 mg/mL
Vial content (volume)	Container content[d]	TM100011129	Not less than 0.406 mL
Identity			
Lipid identities	HPLC-CAD[d]	TM100010322	Retention times consistent with references (ALC-0315, ALC-0159, Cholesterol, DSPC)
Identity of encoded RNA sequence	RT-PCR[d]	TM100010407	Identity confirmed
Potency			
In Vitro Expression	Cell-based flow cytometry	TM100010380	≥ 30% Cells Positive
Purity			
RNA Integrity	Capillary Gel Electrophoresis	TM100010392	≥ 55% intact RNA (release) ≥ 50% intact RNA (stability)
Adventitious Agents			
Bacterial Endotoxin	Endotoxin (LAL) *(Ph. Eur. 2.6.14, USP <85>, JP 4.01)*	LAB-36816 (Puurs)	≤ 12.5 EU/mL

Table 3.2.P.5.1-1. BNT162b2 Drug Product Specifications

Quality Attribute	Analytical Procedure[a]	Procedure Number(s)	Acceptance Criteria
Sterility	Sterility *(Ph. Eur. 2.6.1, USP <71>, JP 4.06)*	LAB-37166 (Puurs)	No Growth Detected
Container Closure Integrity	Dye incursion[c]	TM100010635	Pass

a. All assays performed on stability unless otherwise noted.
b. Aligned with upcoming (Jan 2021) revision of Ph. Eur. 2.9.19
c. In accordance with Ph. Eur. 2.2.35, with minor difference in instrument calibration
d. Assay not performed on stability.
e. Tested at release and on stability for stability batches only
Abbreviations: LNP = Lipid nanoparticles; CAD = charged aerosol detector; RT-PCR = reverse transcription polymerase chain reaction; FACS = fluorescence activated cell sorter; ddPCR = droplet digital PCR; qPCR = quantitative PCR; dsRNA = double stranded RNA; LAL = Limulus amebocyte lysate; EU = endotoxin unit

Annex 4 – Labelling and Packaging Specifications

Product Labelling Specifications

Product labels for primary, secondary and tertiary packaging will be shared closer to country 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
- 6 doses per vial

Secondary Packaging "**Single Tray**"

- Single tray holds 195 vials
- 1170 doses per tray
- Tray (white box) dimensions: 229 X 229 x 40 mm

Tertiary Container: Thermal Shipper (Softbox)

- Minimum 1 tray (1170 doses) or up to 5 trays (max 5850) 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

Annex 5 - 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. European Union Conditional Marketing Authorization (EU CMA) Fact Sheets/Leaflets – One (1) EU CMA package leaflet (in English) inside each vaccine tray

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 thermal shipper containers are empty (not containing dry ice)

3. Return Shipping Label – One (1)

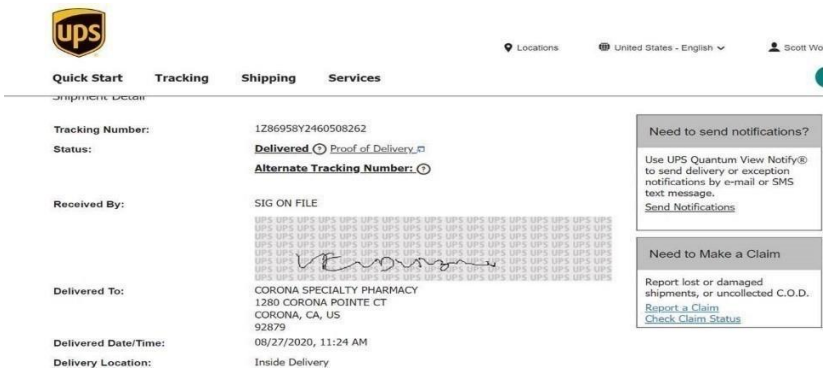
4. Outbound Shipping Label – One (1), standard label on thermal shipper

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, Pfizer 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.