CONTRATOS DE TERCEIRO

Processo nº 20000 (2700)2020-SC

CONTRATO QUE ENTRE SI CELEBRAM A UNIÃO, POR INTERMÉDIO DO DEPARTAMENTO DE LIGAÇÕES E ORÇAMENTO - DLO, E A EMPRESA CONSTRUTORA ALTO DESENVOLVIMENTO LTDA. E COMPRA DÍVIDA CONFIANÇA.

Aos 31 de março de 2020, a UNIÃO, por intermédio do Departamento de Ligações e Orçamento da Secretaria de Governo do Município de São Paulo, inscrito no CNPJ sob o nº 08.234.568/0001-71, com sede na Avenida ... neste ato representado pelo Senhor ..., portador da Cédula de Identidade RG nº ..., e CPF nº ..., nomeado pela Portaria nº ..., de ..., publicada no ..., doravante denominada simplesmente CONTRATANTE, e, de outro lado a empresa **PEDRA EQUIPAMENTOS**, com endereço na Alameda Rio Negro, 585, CEP 06454-000, em Barueri/SP, Bairro Alphaville, doravante denominada VENDEDORA, neste ato representada por **LORENZO ANTONIO MARCHESINI DE ALBUQUERQUE**, ..., de acordo com o disposto no Decreto Municipal nº 56.475, de 05/10/2015, e suas alterações, e demais legislações aplicáveis, e considerando o constante do Termo Aditivado de Ajuste de Conduta, celebrado em 30/09

Transporte e Pessoal prestado ao Fabricante e não se inclui no contrato de transportadora como prestação de serviços.

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ANEXO II - ESPECIFICAÇÃO DE EMBALAGEM - Especificações de Estiragem, Armazenamento e Manuseio do Produto

Os Produtos devem ser embalados de acordo com as especificações do Fabricante e de acordo com as Boas Práticas de Fabricação e Especificações de Engenharia e Embalagem previstas no Anexo II ("**Recipiente Tensionado**"). Nesse tensionado, a embalagem sofrerá um processo de estiramento e/ou tensionamento.

O Recipiente gerado pelo seu tensionamento deve atender os itens abaixo:

- Deve ser capaz de suportar a pressão interna de 2 bar (2 kgf/cm²) sem ocorrer deformação permanente ou ruptura, sendo que seu rompimento só deverá ocorrer no mínimo em 20 (vinte e quatro) horas de armazenamento de acordo com o item 2.1 abaixo e quatro horas de estiragem de acordo com o item 2.2 abaixo;

Plant shall perform all bulk welding, stainless, manufacturing, tube, stainless, including, but not limited to, sand blasting, painting and shipping solutions, and attached all equipment, fittings, and accessories, and shall provide all labor, materials, and equipment required to complete the work in accordance with the plans and specifications and in accordance with the Contract Documents.

1.02 Statement of Work: Thermal Chemical Shipment

Contractor shall supply the Thermal Chemical Shipment Vessel, Thermal Chemical Shipment Vessel Support Structure, Thermal Chemical Shipment Vessel Ancillary Equipment, Thermal Chemical Shipment Vessel Support Structure Ancillary Equipment, and

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.

Attachment D – Delivery Specification

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 Attachment E ("**Thermal Shipper**"). At this time, the minimum package in any shipment shall be one (1) tray with 195 vials or 1170 doses of Product.

Purchaser ensures that at the expected time of arrival at the Place of Destination a dedicated person will be available to receive the Product, sign acceptance for delivery, and, immediately, no later than twenty-four (24) hours of delivery, switch off the temperature logger located in the Thermal Shipper, and:

1. transfer the Product to:
   1. a -75 ºC (+/- 15 ºC) ultra-low temperature ("**ULT**") freezer; or
   2. a 2-8 ºC refrigerator; or
2. 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 twenty-four (24) hours from signature of acceptance of delivery.

Purchaser acknowledges the following stability timelines as of the Effective Date:

- The Product has a shelf-life of up to six (6) months when stored at a constant -75 ºC (+/- 15 ºC)
- The Thermal Shipper can be used as temporary storage for up to thirty (30) days, as long as dry ice is replenished upon receipt and at least every five (5) days per Pfizer's guidelines.
- The Product has an effective life of up to five (5) days when stored at refrigerator temperatures 2-8ºC
- Once the Product is defrosted and reconstituted it can be retained for up to six (6) hours at standard ambient room temperatures (2-30ºC)

Any further shipment or distribution of the Product by Purchaser from the Place(s) of Destination shall be through a certified shipping service, or use of its own logistics system, that will ensure next day delivery from the Place(s) of Destination to point of use of the Product; and Purchaser shall be liable for ensuring continual compliance with the cold chain requirements for any further distribution following delivery to a Place of Destination that is not a point of use of the Product. In all cases, Purchaser shall ensure that all Product is transported in (a) the Thermal Shipper with re-icing performed in accordance with the Protocols for re-icing set forth below; or (b) an alternate shipper purchased by Purchaser, in each case in a manner to maintain the temperature requirements set forth below. All costs associated with receiving, handling, storing and further delivery of the Product shall be the responsibility of Purchaser, and Purchaser shall ensure that all locations where any Product is delivered by, or on behalf of Purchaser, 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 Attachment D

Requirements of Delivery Location:

1. Conditional Approval, Pre-approval, Post-approval vaccination points with -75 ºC (+/- 15 ºC) ULT freezer
2. Conditional Approval, Pre-approval, Post-approval vaccination points with sufficient access and supply of dry-ice
3. Conditional Approval, Pre-approval, Post-approval vaccination points with 2-8ºC refrigerator

Attachment D – Delivery Specification

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

Attachment D – Delivery Specification

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

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.

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 2-30ºC (36-86ºF).
- A single 30 mcg/0.3 mL dose is followed by a second dose 21 (+- 2) days later.

Attachment E – 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
- Six (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 one (1) tray (1170 doses) or up to five (5) trays (max 5850 doses) 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 F – Return and Disposal of Product Materials

1. **Return**

- 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 thirty (30) days following delivery of the Product to the Purchaser's recipient at the Place(s) of Destination. 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 (i) delivered to the return carrier within thirty (30) days following delivery of the Product or (ii) received by Pfizer within five (5) days following the date of Purchaser's return shipment; 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 Purchaser $450 (exclusive of Taxes) per Thermal Shipper and temperature data logger/monitoring device; which Purchaser shall pay within 30 days of the date of any invoice for such amount(s). Purchaser acknowledges that such amount represents a reasonable pre-estimate of replacement cost such Logistics Delivery Equipment as a result of Purchaser's default, act or omission.

2. **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.

Attachment G – Form of Purchase Order

The Parties agree that all Purchase Orders shall include, at a minimum, the following information:

-Name of Purchaser (The Purchase Order shall be presented to Pfizer on Purchaser's official letterhead)
- Fiscal Code
- Purchaser address
- Purchaser e-mail and phone number
- Purchase Order number
- Delivery Place information (name/address and contact person)
- Product description
- Product quantity
- Product price
- Total price of Purchase Order
- Contract reference
- Issuance date of Purchase Order
- Due date of Purchase Order

DOCUMENTO SEI (0019624455) – ANEXOS E APÊNDICES DO CONTRATO Nº 52/2021.

SEI DOCUMENT (0019624455) - ANNEXES AND APPENDICES TO CONTRACT NO. 52/2021.

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Documento assinado eletronicamente por **Roberto Ferreira Dias**, **Diretor(a) do Departamento de Logística**, em 18/03/2021, às 20:59, conforme horário oficial de Brasília, com fundamento no art. 6º, § 1º, do Decreto nº 8.539, de 8 de outubro de 2015; e art. 8º, da Portaria nº 900 de 31 de Março de 2017.

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