

**DRAFT 11 FEBRUARY 2021  
CONFIDENTIAL  
FOR DISCUSSION PURPOSES ONLY  
SUBJECT TO FURTHER INTERNAL REVIEW BY PFIZER  
NDOH COMMENTS 23.02.2021**

**MANUFACTURING AND SUPPLY AGREEMENT**

**BETWEEN**

**PFIZER LABORATORIES PROPRIETARY LIMITED**

**AND**

**THE GOVERNMENT OF THE REPUBLIC OF SOUTH AFRICA ACTING THROUGH  
THE NATIONAL DEPARTMENT OF HEALTH OF SOUTH AFRICA ( "NDOH" )**

**DATED AS OF**

**XXX February 2021**

[TOC to be inserted]

## MANUFACTURING AND SUPPLY AGREEMENT

**THIS MANUFACTURING AND SUPPLY AGREEMENT** dated as of **[Insert date]** 2021 (the “**Effective Date**”) is made by and between PFIZER LABORATORIES (PROPRIETARY) LIMITED with offices at 85 Bute Lane, Sandton, Johannesburg, South Africa (hereinafter “**Pfizer**”) and the Government of the Republic of South Africa acting through the National Department of Health of South Africa, together with its agents, subcontractors and Affiliates (“**NDOH**”), with offices at [ ] (hereinafter “**Purchaser**”). Purchaser and Pfizer may be referred to herein individually as a “**Party**” or collectively as the “**Parties**”.

WHEREAS, Pfizer Inc. (“**Pfizer US**”) and BioNTech SE, a company organized and existing under the laws of Germany (“**BioNTech**”), are collaborating to develop a vaccine to address the global COVID-19 pandemic;

WHEREAS, subject to clinical success, Pfizer US and BioNTech shall be responsible for all requirements of the processes of approval of the clinical trials and the marketing authorization of the Product;

WHEREAS, Purchaser desires to purchase the Product for use in South Africa (the “**Territory**”), and subject to clinical success and regulatory approval, Pfizer desires to manufacture and supply such Product to Purchaser; and

WHEREAS, the Parties are willing to carry out the foregoing pursuant to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of these premises and the covenants and agreements set forth herein, the sufficiency of which is hereby acknowledged and agreed, and intending to be legally bound thereby, the Parties hereby agree as follows:

### 1. DEFINITIONS.

As used in this Agreement, the following terms shall have the meanings set forth below.

- 1.1 “**Adjusted Delivery Schedule**” shall have the meaning set forth in Section 2.4(c)2.4(f).
- 1.2 “**Advance Payment**” shall have the meaning set forth in Section Error! Reference source not found.3.2(a).
- 1.3 “**Affiliate(s)**” means, with respect to each Party or, if applicable, BioNTech, any corporation, firm, partnership or other entity or Person which directly or indirectly controls or is controlled by or is under common control with the named Party, including without limitation Pfizer US, or, if applicable, BioNTech. For purposes of this definition, “control” (including, with correlative meaning, the terms “controlled by” and “under common control with”) shall be presumed to exist if one of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors of such corporate entity or any direct or indirect parent of such corporate entity, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity

**Commented [MS1]:** Note to NDOH:

Please confirm NDOH will be the SELL TO/Invoiced Entity – kindly confirm the exact address details as it will be required in Pfizer system set-up

**Commented [DoH2]:** We confirm that NDoH will be the sell to entity.

We are currently in the process of moving offices and will confirm at a later stage with the new address.

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interest with the power to direct the management and policies of such non-corporate entities.

- 1.4 “**Agreement**” means this Manufacturing and Supply Agreement and all Attachments hereto as the same may be amended, amended and restated, supplemented or otherwise replaced from time to time.
- 1.5 “**Allocation**” shall have the meaning set forth in Section 2.5(a).
- 1.6 “**Authorization**” means the Conditional Approval or Marketing Authorization.
- 1.7 “**Batch**” shall have the meaning set forth in Attachment B.
- 1.8 “**BioNTech**” shall have the meaning set forth in the recitals.
- 1.9 “**Binding Term Sheet**” means the binding term sheet entered into by and between the Parties on [15 January 2021].
- 1.10 “**Business Day**” means any day other than Saturday, Sunday or a public holiday in New York, New York or Johannesburg.
- 1.11 “**Commercially Reasonable Efforts**” means with respect to the efforts to be expended by Pfizer to achieve the relevant objective, the activities and degree of effort that a similarly situated party (with respect to size, resources and assets) in the pharmaceutical industry would use to accomplish a similar objective in its own commercial interests under similar circumstances and considering the relevant risks, uncertainties, limitations and challenges of the development, manufacture, commercialization and distribution of a novel COVID-19 vaccine product, taking into account the following factors: actual and potential issues of safety and efficacy, novelty, product profile, the proprietary position, the then current competitive environment for such Product, the likely timing of the Product’s entry into the market, the regulatory environment and status of the Product, compliance with Laws, past performance of the Product and other similar products, the ability to produce or obtain adequate supply of the Product or any components or materials used in the manufacture of the Product and other relevant scientific, technical, operational and commercial factors, in each case as measured by the facts and circumstances at the time such efforts are due.
- 1.12 “**Conditional Approval**” means a conditional marketing authorization for the Product granted by the South African Health Products Regulatory Authority (“SAHPRA”), that allows the Product to be placed on the market in South Africa.
- 1.13 “**Confidential Information**” means all confidential or proprietary information, other than Exempt Information, in any form, directly or indirectly disclosed to Recipient or its Representatives by or on behalf of the Disclosing Party pursuant to this Agreement, 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 Agreement. Failure to mark Confidential Information disclosed in writing hereunder as “Confidential”

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shall not cause the information to be considered non-confidential, with the burden on the Disclosing Party 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 the Disclosing Party has otherwise made good faith efforts to clearly mark Confidential Information as such.

- 1.14 “**Contracted Doses**” shall have the meaning set forth in Section 2.3(a).
- 1.15 “**Covax Facility**” means the global procurement mechanism for the procurement and delivery of doses of approved vaccine for COVID-19.
- 1.16 “**Current Good Manufacturing Practices**” or “**cGMP**” means applicable Good Manufacturing Practices as specified in the United States Code of Federal Regulations and/or the EU Good Manufacturing Guidelines, and any successor legislation from time to time, prevailing at the time of the manufacture of the Product.
- 1.17 “**Delivery Price**” shall have the meaning set forth in Section 3.2(a).
- 1.18 “**Delivery Specifications**” shall have the meaning set forth in Section 2.4(d).
- 1.19 “**Disclosing Party**” means the Party or any of its Affiliates that discloses, or causes to be disclosed, Confidential Information to the other Party or any of its Affiliates.
- 1.20 “**Effective Date**” shall have the meaning set forth in the preamble.
- 1.21 “**Exempt Information**” means information that: (a) the Recipient or any of its Representatives lawfully possessed, as demonstrated by competent proof, before the Disclosing Party disclosed such information under this Agreement; 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 Agreement by the Recipient or its Representatives); (c) the Recipient 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 the Disclosing Party with respect to such information (and Recipient has made reasonable enquiry with respect thereto); or (d) the Recipient evidences to the reasonable satisfaction of the Disclosing Party is independently developed by or on behalf of the Recipient 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 Recipient or its Representatives or otherwise lawfully in the possession of the Recipient or any of its Representatives.
- 1.22 “**Facilities**” means Pfizer’s manufacturing sites in Kalamazoo (Michigan) and Puurs, Belgium and BioNTech’s two manufacturing sites, in Mainz and Idar Oberstein in

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Germany or such other manufacturing site used in connection with the manufacture of the Product supplied by Pfizer hereunder.

- 1.23 “**Force Majeure Event**” shall have the meaning set forth in Section 12.8.
- 1.24 “**Forms**” shall have the meaning set forth in Section 12.12.
- 1.25 “**Government**” means all levels and subdivisions of government (i.e., local, regional, national, provincial, federal, administrative, legislative, or executive) of South Africa.
- 1.26 “**ICC**” shall have the meaning set forth in Section 12.2.
- 1.27 “**Indemnified Claims**” shall have the meaning set forth in Section 8.2.
- 1.28 “**Indemnitees**” shall have the meaning set forth in Section 8.1.
- 1.29 “**Interim Delivery Schedule**” shall have the meaning set forth in Section 2.4(d).
- 1.30 “**Intellectual Property**” means (a) any processes, trade secrets, inventions, industrial models, designs, methodologies, drawings, discoveries, result, materials, formulae, procedures, techniques, clinical data or technical or other information or data, manufacturing, engineering and technical drawings, including proprietary rights in any of the foregoing, and (b) registered trademarks, trade mark applications, unregistered marks, trade dress, copyrights, know-how, patents, patent applications, and any and all provisionals, divisions, continuations, continuations in part, extensions, substitutions, renewals, registrations, revalidations, reissues or additions, including certificates of supplementary protection, of or to any of the aforesaid patents and patent applications, and all foreign counterparts of any, or to any, of the aforesaid patents and patent applications.
- 1.31 “**Labelling and Packaging Specifications**” shall have the meaning set forth in Section 2.4(e).
- 1.32 “**Latent Defect**” means a defect causing the Product to not conform to the applicable Specifications that Purchaser can show was present at the time of Pfizer’s delivery of the Product to Purchaser and which could not have been detected by Purchaser, its designee, or their Personnel at delivery through diligent inspection.
- 1.33 “**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.
- 1.34 “**Losses**” shall have the meaning set forth in Section 8.1.
- 1.35 “**Marketing Authorization**” means the marketing authorization, or such other permission having similar effect, in respect of the Product granted by South African Health Products Regulatory Authority, as amended or varied by the South African Health Products Regulatory Authority from time to time, that allows the Product to be placed on the market in South Africa according to Law.

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- 1.36 **“Non-Complying Product”** shall have the meaning set forth in Section 4.4(a).
- 1.37 **“Party”** or **“Parties”** shall have the meaning set forth in the preamble.
- 1.38 **“Person”** means any natural person, entity, corporation, general partnership, limited partnership, limited liability partnership, joint venture or similar entity or organization, joint stock company, proprietorship, other business organization, trust, union, association or Government.
- 1.39 **“Personnel”** means all Affiliates, subcontractors, or other third parties, and employees and agents of each of them, used by either Party in the performance of services or obligations or in connection with this Agreement.
- 1.40 **“Pfizer”** shall have the meaning set forth in the preamble.
- 1.41 **“Pfizer US”** shall have the meaning set forth in the preamble.
- 1.42 **“Price”** shall have the meaning set forth in Section 3.1.
- 1.43 **“Privileges and Immunities”** means any privileges, immunities, or legislation in the Republic of South Africa, including, without limitation, no-fault vaccine compensation programs, pandemic insurance programs, immunities from suit or liability, or any protections, defenses, or limitations-of-liability (whether statutory, regulatory, common law or otherwise), existing or future, that may separately protect Indemnitees from Losses.
- ~~1.43~~ ~~1.44~~ **“Programme”** means the Purchaser's national COVID-19 vaccine procurement and roll-out programme.
- ~~1.44~~ ~~1.45~~ **“Product”** means the medicinal product being BNT162b2, a nucleoside-modified messenger RNA (mRNA) vaccine that encodes an optimised SARS-CoV-2 full length spike glycoprotein (S) in an unpreserved frozen multi-dose vial that must be diluted, for which Authorisation has been granted or is being sought, for the prevention of COVID-19, including any subsequent non-material variations as reasonably determined by Pfizer and approved by the relevant regulatory authority. For the avoidance of doubt, changes to the active substance or antigenic characteristics of BNT162b2 encoding a variant or new strain of SARS-CoV-2 as well as any new formulation of BNT162b2 are explicitly excluded from the scope of the “Product” as defined here, as are any other significant product changes as Pfizer may reasonably determine.
- ~~1.45~~ ~~1.46~~ **“Product Materials”** means all packaging materials and components needed for delivery of the Product.
- ~~1.46~~ ~~1.47~~ **“Purchase Order”** means a written or electronic order form submitted by Purchaser to Pfizer in accordance with the terms of this Agreement authorizing the manufacture and supply of the Product, in substantially the form attached as Attachment G (as may be updated from time to time by Pfizer upon notice to Purchaser).
- ~~1.47~~ ~~1.48~~ **“Purchaser”** shall have the meaning set forth in the preamble.

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1.481.49 **“Recipient”** means the Party who receives Confidential Information from the other Party.

1.491.50 **“Records”** means books, documents, and other data, of all matters relating to performance of obligations under this Agreement.

1.501.51 **“Representatives”** means, with respect to Recipient, its Affiliates and its and their respective directors, officers, and 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 Agreement; and (b) have a need to know the Confidential Information in connection with this Agreement.

1.511.52 **“Specifications”** means the material specifications for the manufacture, processing, packaging, labeling, testing and testing procedures, shipping, storage and supply of the Product as will be set out in Attachment A following the Effective Date (and in any event before supply in accordance with the agreed Interim Delivery Schedule), and as such specifications may be amended, supplemented or otherwise modified by Pfizer and communicated to Purchaser.

1.521.53 **“Taxes”** shall have the meaning set forth in Section 3.4.

1.531.54 **“Term”**, with respect to this Agreement, shall have the meaning set forth in Section 6.1.

1.541.55 **“Third Party Beneficiary”** or **“Third Party Beneficiaries”** shall have the meaning set forth in Section 12.5(a).

1.551.56 **“USD”** means the lawful currency of the United States of America.

1.561.57 **“Vaccine”** shall include (a) all vaccines manufactured, in whole or in part, or supplied, directly or indirectly, by or on behalf of Pfizer or BioNTech or any of their Affiliates that are intended for the prevention of the human disease COVID-19 or any other human disease, in each case which is caused by any of the virus SARS-CoV-2, and/or any or all related strains, mutations, modifications or derivatives of the foregoing that are procured by Purchaser, its Affiliates or agents by any means ~~(whether pursuant to the Agreement or by way of any purchase or donation from any third party or otherwise, whether or not authorized pursuant to Section 2.1) or that are administered within the Territory, and whether procured or administered prior to or following execution of this Agreement.~~ (b) any device, technology, or product used in the administration of or to enhance the use or effect of, such vaccine, (c) any component or constituent material of (a) or (b), or (d) any use or application of any product referred to in (a)-(b).

1.571.58 **“VAT”** means Value Added Tax.

Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words “include”.

Commented [DoH5]: Definition and purview to be confirmed.

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“includes” and “including” shall be deemed to be followed by the phrase “without limitation”. (c) the word “will” shall be construed to have the same meaning and effect as the word “shall”, (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person’s successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Attachments shall be construed to refer to Sections or Attachments of this Agreement, and references to this Agreement include all Attachments hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof and (j) the term “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or”.

**2. SUPPLY OF PRODUCT.**

**2.1 Agreement to Supply.**

(a) It is recorded that contemporaneously with this Agreement, Purchaser will have concluded an agreement with COVAX Facility to acquire the same or similar products contemplated in this Agreement and that these are to be viewed as mutually separate from this Agreement.

**Commented [u6]:** Reword so that Covax volumes must compliment these volumes in this agreement

(a)(b) During the Term, Pfizer shall use Commercially Reasonable Efforts to supply or have supplied the Product to Purchaser, and Purchaser shall purchase the Product, subject to and in accordance with the terms and conditions of this Agreement.

(b)(c) Purchaser acknowledges and agrees that (i) Pfizer’s efforts to develop and manufacture the Product are aspirational in nature and subject to significant risks and uncertainties, and (ii) the fact that any other drug or vaccine to prevent, treat or cure COVID-19 infection is successfully developed or granted authorization earlier than the granting of Authorization for the Product shall not change the current situation of urgent needs for prevention of the spread of the COVID-19 infection that poses serious threats to and harmful effects on the lives and health of the general public.

(e)(d) Notwithstanding the efforts and any estimated dates set forth in the Interim Delivery Schedule, the Parties recognize that the Product has completed Phase 2b/3 clinical trials and that, despite the efforts of Pfizer in research, and development and manufacturing, the Product may not be successful due to technical, clinical, regulatory, manufacturing, shipping, storage, or other challenges or failures.

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~~(d)(c)~~ Accordingly, Pfizer and its Affiliates shall have no liability for any failure by Pfizer or its Affiliates to develop or obtain Authorization of the Product in accordance with the estimated dates described in this Agreement. Even if the Product is successfully developed and obtains Authorization, Pfizer shall have no liability for any failure to deliver doses in accordance with any estimated delivery dates set forth herein (other than as expressly set out in this Agreement), nor shall any such failure give Purchaser any right to cancel orders for any quantities of Product, save in the case of gross negligence or willful misconduct on the part of Pfizer or its Affiliates. Further, Pfizer shall have no obligation to deliver the Product to Purchaser unless and until the Indemnification Agreement is executed between the Parties in accordance with Section 8 (Indemnification). To the extent that there is a delay in terms of the delivery of any quantities of Product, Pfizer shall notify Purchaser in writing as soon as possible of any such first knowledge of such possible delays.

**Commented [DoH7]:** To be discussed please. There needs to be a time limit on this. We suggest that should Pfizer not have delivered the Products within four weeks of the delivery date the Purchaser shall have a right to cancel. We also suggest that "any failure" should be limited to Pfizer being liable for fault-based failures.

~~(e)(f)~~ Pfizer shall keep Purchaser apprised of the progress of the material development of the Product and shall provide Purchaser with such information regarding that development as Purchaser reasonably requests.

~~(g)~~ Purchaser, including any related Person or any agents of Purchaser, covenants to exclusively obtain all of its supply of any vaccine of Pfizer, BioNTech or their respective Affiliates intended for the prevention of the human disease COVID-19 (including the Product) either (i) directly from Pfizer or from Pfizer through the COVAX Facility, or (ii) from a Third Party, whether by donation, resale or otherwise, only if Purchaser has obtained Pfizer's prior written consent, which consent shall not be unreasonably delayed or withheld. Any breach of this Section 2.1(f) shall be deemed an incurable material breach of this Agreement, and Pfizer may immediately terminate this Agreement pursuant to Section 6.2. For clarity, nothing in this Section 2.1(f) shall prevent Purchaser from purchasing competing vaccine products of any Third Party.

**Commented [DoH8]:** Please see alternative to "g" as "h" below

**Commented [DoH9]:** There would appear to be a drafting error in as much as the clause provides that Pfizer's consent is required in order to buy from Pfizer itself or the Covax Facility.

~~(h)~~ Alternative to G

~~(i)~~ Purchaser, including any related Person or any agents of Purchaser, covenants, subject to h(ii), to exclusively obtain all of its supply of any vaccine of Pfizer, BioNTech or their respective Affiliates intended for the prevention of the human disease COVID-19 (including the Product) directly from Pfizer or from Pfizer through the COVAX Facility or another multilateral facility such as that established by the African Union.

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~~(ii)~~ Purchaser, including any related Person or any agents of Purchaser may obtain supply of any vaccine of Pfizer, BioNTech or their respective Affiliates intended for the prevention of the human disease COVID-19 (including the Product) from a Third Party, whether by donation, resale or otherwise, only if Purchaser has obtained Pfizer's prior written consent, which consent shall not be unreasonably delayed or withheld.



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2.2 Capacity.

Pfizer shall use Commercially Reasonable Efforts to build or obtain manufacturing capacity to be capable of manufacturing and supplying the Product to Purchaser in accordance with the provisions of this Agreement.

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2.3 Purchase Orders.

(a) ~~On the Effective Date, Purchaser shall submit to Pfizer a legally binding and irrevocable Purchase Order(s) for Twenty million one thousand one hundred fifty (20,001,150) doses ("Contracted Doses") of the Product. Subject to Section 2.4(c) of this Agreement, Pfizer shall have the right, at its sole discretion, to update the Contracted Doses to the nearest possible number that is divisible by the Minimum Order Quantity.~~

Commented [u10]: Volumes need to be discussed

(b) ~~The Purchase Order shall be provided together with Purchaser's order number, VAT number (if applicable), and invoice address. Pfizer shall accept the Purchase Order conforming to the terms set forth in this Agreement in writing, and the confirmed Purchase Order shall be binding upon the Parties and subject to the terms and conditions set out in this Agreement.~~

(a) ~~The Purchaser may request additional doses during the Term of the Agreement through a legally binding and irrevocable Purchase Order(s), but only upon being advised that: On the Effective Date, Purchaser shall submit to Pfizer a legally binding and irrevocable Purchase Order(s) for Twenty million one thousand one hundred fifty (20,001,150) doses ("Contracted Doses") of the Product. Subject to Section 2.4(c) of this Agreement, Pfizer shall have the right, at its sole discretion, to update the Contracted Doses to the nearest possible number that is divisible by the Minimum Order Quantity.~~

Commented [DoH11]: To be discussed. Alternative construction to be considered please, where we submit a purchase order 30 days before the next quarter with prepayment 5 days after purchaser order accepted by Pfizer.

(b) ~~The Purchase Order shall be provided together with Purchaser's order number, VAT number (if applicable), and invoice address. Pfizer shall accept the Purchase Order conforming to the terms set forth in this Agreement in writing, and the confirmed Purchase Order shall be binding upon the Parties and subject to the terms and conditions set out in this Agreement.~~

Commented [DoH12]: NDoH is not registered for VAT in SA and will therefore not have a VAT registration number.

(c) ~~The Purchaser may request additional doses during the Term of the Agreement through a legally binding and irrevocable Purchase Order(s), but only upon being advised that: (i) Pfizer has availability of supply of such additional requested doses (the "Additional Order") and (ii) Pfizer agrees, in its sole discretion, to allocate such Additional Order to Purchaser. Each Additional Order will be subject to the same terms and conditions set forth in the Agreement (and any subsequent amendments thereto), as applicable; provided such Additional Order must be placed during the Term of the Agreement. In such event, the doses subject to the accepted Additional Order shall be Contracted Doses. After submission to, and acceptance by, Pfizer of an Additional Order, Purchaser shall pay Pfizer such~~

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additional advance payment as agreed within thirty (30) days of the approval of purchase order of such Additional Order in accordance with the terms of Section 3.2 (“**Additional Advance Payment**”), provided that requisite Authorization has been obtained. Purchaser shall pay such Additional Advance Payment, and Pfizer shall provide an updated Attachment B to reflect such Additional Order. Full payment of the Additional Advance Payment is a condition to supply any doses subject to the Additional Order. If any failure by Purchaser to pay Pfizer for the Additional Advance Payment results in a delay in delivery, the undelivered doses will be at the sole risk of Purchaser, and Pfizer shall have no liability to Purchaser regarding such delay or further inability to supply by Pfizer.

(e)

2.4 Delivery Schedule.

- (a) Pfizer shall deliver the Product Delivery at Place (“**DAP**”) Incoterms 2020.
- (b) The Parties shall reasonably agree, in writing, on the location(s) (including number of locations) for delivery of shipments of Product (“**Place(s) of Destination**”) within five (5) Business Days from the Effective Date for the first expected shipment of Product, and for any subsequent delivery, at least eight (8) weeks prior to shipment of the Product; provided that, in each case: (i) each Place of Destination meets the requirements set forth in Attachment D, and (ii) the Place(s) of Destination are serviced by a contracted transportation carrier of Pfizer, and (iii) each Place of Destination is an authorized location to receive the Product, evidence of which shall be presented to Pfizer on Purchaser’s official letterhead and Purchaser shall provide any additional information, as reasonably requested by Pfizer in advance of delivery, to verify such authorization (“**Shipping Agent**”). Pfizer shall have the ability, acting reasonably, to restrict the number of Places of Destination where shipments of Product shall be delivered. However, the Parties agree that Purchaser shall have full liability and responsibility for any further transportation and distribution following delivery to Place of Destination that is not a point of use of the Product, including but not limited to ensuring compliance with Attachment D. For the purposes of this Section 2.4(b), Pfizer agrees that it shall provide the Purchaser with such information as Pfizer considers necessary for the Purchaser to comply with the provisions of this section: to the extent in Pfizer’s control and/or possession at the time, including details on the proposed Shipping Agent as part of Pfizer’s logistics planning information. Notwithstanding Pfizer agreeing that it shall provide the Purchaser with such information as it considers necessary, Pfizer shall always provide the Purchaser with no less than what is required of it in terms of DAP Incoterms 2020, as published by the ICC, Paris, France.
- (c) All shipment of Product shall be comprised of quantity of Product in increments of 195 vials/1170 doses (“**Minimum Order Quantity**”). Pfizer shall have the right to update such Minimum Order Quantity at its sole discretion from time to time upon advance written notice to Purchaser.

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- (d) Pfizer may deliver the Product by separate installments and shall use Commercially Reasonable Efforts to meet the estimated delivery schedule set out in Attachment B (the “**Interim Delivery Schedule**”), provided that no Product shall be shipped until Authorization is received and Purchaser is compliant, in Pfizer’s discretion, with the terms and conditions of this Agreement. All deliveries shall be accompanied by the documentation specified in Attachment C (which may be updated from time to time by Pfizer upon notice to Purchaser), and shall be in accordance with, and subject to, the delivery specifications to be set forth in Attachment D (as may be updated from time to time by Pfizer upon notice to Purchaser) (“**Delivery Specifications**”).
- (e) The Product shall be labelled and packaged in accordance with the packaging specifications to be set forth in Attachment E (which shall be populated following the Effective Date, but in any event before supply in line with the agreed Interim Delivery Schedule, and as may be updated from time to time by Pfizer upon notice to Purchaser) (“**Labelling and Packaging Specifications**”).
- (f) If an Authorization is granted after [15 February 2021] but before 30 September 2021, then the Interim Delivery Schedule will be revised to add the period of time between [15 February 2021] and the date of the Authorization (“**Adjusted Delivery Schedule**”). In the event that the Authorization is granted prior to [15 February 2021], Pfizer has no obligation to accelerate shipment of Product.
- (g) If Authorization is received by 30 September 2021, but Pfizer is unable to deliver any Contracted Doses for technical or other reasons from the Facilities intended to produce the Contracted Doses under this Agreement, Pfizer agrees to use Commercially Reasonable Efforts to obtain supply of the Product from another location, subject to availability of supply.
- (h) If Authorization is received by 30 September 2021, but by 31 March 2022 Pfizer is unable to manufacture or deliver any Contracted Doses for technical or other reasons from any Facilities, Pfizer will have no obligation to deliver against the Interim Delivery Schedule, Adjusted Delivery Schedule or a Purchase Order.

Commented [u13]: To be aligned to the new authorization date

2.5 Product Shortages.

- (a) If Authorization is received but there is insufficient supply to deliver the full number of Contracted Doses on the Interim Delivery Schedule (including the Adjusted Delivery Schedule), including to the extent any shortage is due to a requirement of Pfizer to divert available supply of the Product to another market, Pfizer shall work collaboratively to provide notice (and manage any communications associated with any Product shortages). Following receipt of such notification, Purchaser shall execute any instructions set out in the notice in a timely fashion (and in no event longer than 24 hours). Subject to the foregoing, including any requirement by Pfizer to divert Product to another market, Pfizer shall decide

Commented [u14]: Who gives this authorization - for clarification?



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on necessary adjustments to the number of Contracted Doses and Interim Delivery Schedule due to the Purchaser to reflect such shortages based on principles to be determined by Pfizer under the then existing circumstances (“**Allocation**”) which shall be set out in such notice. Purchaser shall be deemed to agree to any revision.

- (b) Purchaser hereby waives all rights and remedies that it may have at Law, in equity or otherwise, arising from or relating to: (i) any failure by Pfizer to develop or obtain Authorization of the Product in accordance with the estimated dates described in this Agreement; or (ii) any failure by Pfizer to deliver the Contracted Doses in accordance with the Interim Delivery Schedule. In the event of an inconsistency between the provisions of this Section 2.5 (Product Shortages) and those of other sections of this Agreement, the provisions of this Section 2.5 (Product Shortages) shall control and supersede over those of other sections of this Agreement to the extent of such inconsistency.

Commented [u15]: Needs re-alignment

2.6 Delivery Delays.

Should Pfizer be delayed in making a delivery for a quarter (being a period of three months) for whatsoever reason, including for the reasons referred to in Section 2.5, Purchaser shall be entitled to cancel the relevant delivery of Product, and be reimbursed for such volume of Vaccine not delivered. Under no circumstances will Pfizer be subject to or liable for any late delivery penalties to the extent that any payment has been made and Purchaser shall be entitled to submit orders to obtain a vaccine from any third party without requiring the prior consent of Pfizer.

2.7 Product Handling.

- (a) Pfizer shall use Commercially Reasonable Efforts to assure the Product is manufactured in accordance with material Specifications and cGMP.
- (b) Upon delivery of Product to Purchaser at the Place(s) of Destination and, to the extent applicable, for any onward distribution and/or transportation to a Place of Destination that is not a point of use of the Product, Purchaser shall store and handle the Product in the manner set forth in the Specifications, instructions on Attachment D and the instructions provided by Pfizer to ensure stability and integrity of the Product.
- (c) For the avoidance of doubt, Purchaser shall bear all expenses for use of the Product upon delivery by Pfizer at the Place(s) of Destination, including, but not limited to, those for storage of the Product and distribution and administration of the Product (if applicable) in South Africa.
- (d) Purchaser shall be solely responsible and liable for the proper storage, handling, distribution, transportation, administration, use and disposal of the Product in South Africa following delivery of the Product to Purchaser or its designee at the Place(s) of Destination. Without prejudice to the generality of the foregoing, Purchaser shall

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ensure that: (a) recipients of the Product shall follow the return and disposal instructions in Attachment F (which may be updated from time to time by Pfizer upon notice to Purchaser) when disposing of open and unused Product and its packaging components; and (b) such return and disposal complies with Laws regarding pharmaceutical waste, medical waste, or hazardous waste, as appropriate. Attachment F provides the ability for Pfizer to charge Purchaser for the cost of such packaging components, without limiting any other remedies available to Pfizer, in the event that Purchaser fails to comply with the return requirement set forth in Attachment F.

- (e) Purchaser shall be ~~responsible for and shall~~ use its reasonable commercial endeavours to ensure that any equipment used to deliver the Product, for example the shipper(s) and monitoring device(s), are stored in an appropriate clean and secure location to protect and maintain the functionality of such equipment (in controlled conditions, with no exposure to weather or pests, etc.). Within thirty (30) days of delivery of the Product at the Place(s) of Destination, subject to Section 4.4(b), ~~Purchaser~~ Pfizer shall collect, or organize for the collection of, and the safe return of, all such equipment, including the shipper and monitoring device, in accordance with Attachment F.
- (f) Pfizer ~~shall~~ may provide Safety Data Sheets and other information to Purchaser to assist Purchaser to develop processes and procedures, including training, to handle the Product and Product Materials in a safe manner and in compliance with Laws, including occupational health and safety Laws. Purchaser represents and warrants that Purchaser has and shall ensure that all recipients of the Product and Product Materials have the requisite expertise to develop and implement appropriate procedures and training programs to enable proper handling of the Product and Product Materials in a safe and lawful manner.

**Commented [DoH16]:** We recommend the safe storage of the shippers and monitoring devices but will not be held liable for any loss or damage of such shipper or monitoring devices. This was not the position presented to the Minister where a solution was offered. Clause to be discussed.

2.8 Title to Product, Risk of Loss.

- (a) Title to the Product, and risk of loss or damage shall pass to Purchaser at the Place(s) of Destination in accordance with Section 2.4(b). Pfizer reserves the right to change any supply point (being the point from which Pfizer shall supply the Product) by giving Purchaser adequate notice as acceptable under the Laws. Prices are quoted on DAP Place(s) of Destination basis in effect at the time and Place(s) of Destination. For purposes of this Agreement, the terms DAP shall have the meaning ascribed thereto in INCOTERMS 2020 as published by the ICC, Paris, France.
- (b) Pfizer shall be the importer of the Product in front of the relevant customs authorities in the Territory ("**Importer of Record**") and shall be responsible to obtain, where applicable, any import license or other official authorization and to carry out all customs formalities for the import of the Product in South Africa. Pfizer shall also be responsible to pay, where applicable, all duties, taxes and other charges, as well as the costs of carrying out customs formalities payable upon import of the Products. Given the nature of the Product, Purchaser undertakes to

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support Pfizer and its appointed Shipping Agent to swiftly clear the Product from the relevant customs authorities within twenty four (24) hours from the arrival of the Product at the customs authorities, and to obtain any waivers required; and Purchaser acknowledges that any delay in such clearance process might affect the overall shelf-life of the Products. Both Parties confirm that the required documents for customs clearance of the Product are indicated in Attachment H of this Agreement. Without prejudice to the generality of the foregoing, Purchaser undertakes to take appropriate measures and exercise its reasonable efforts to ensure the smooth and efficient passage of the Product through the port of entry in accordance with applicable Laws of South Africa.

- (c) Purchaser shall be responsible for the unloading of such Product from the transportation carrier. For the sake of clarity, Purchaser shall be responsible for unloading the Product from the transportation carrier and Pfizer's liability shall cease, and risk of loss or damage shall transfer, upon carrier's arrival at the Place(s) of Destination and immediately prior to the unloading of the Product. Without prejudice to the generality of the foregoing, following delivery of the Product to Purchaser, Purchaser shall be fully responsible for and liable in relation to any Product wastage, and for ensuring appropriate disposal in accordance with Sections 2.7(d) and 2.7(e). Pfizer will not be liable for any risks of loss or damage to the Product after delivering the Product at the Place(s) of Destination, including without limitation, temperature excursions, theft, or damages of any kind to the Product.

Commented [u17]: Not the norm – but ok

- (-) ~~Without prejudice to Section 4.4, Purchaser acknowledges that Pfizer will not, in any circumstances, accept any returns of Product (or any dose). In particular, following receipt of the Product in accordance with this Section 2.8, no Product returns may take place under any circumstances (inclusive of future changes in stock, expired Products, changes in Product allocation, delivery, demand or new product launch).~~

Commented [DoH18]: This is in direct conflict with clause 4.4(b).

#### 4.3. PRICE AND PAYMENT.

##### 4.3.1 Purchase Price.

Purchaser shall purchase the Product from Pfizer at the price per dose set out in Attachment B, ~~excluding inclusive of VAT (the "Price")~~ and in accordance with the terms of this Agreement. ~~The Price as reflected in the Purchase Order shall be the agreed Price and shall include all of Pfizer's internal costs associated with the manufacturing and delivery of the Product to the Place(s) of Destination in accordance with this Agreement. The Price shall be firm for the Term.~~

Commented [DoH19]: There is uncertainty whether Pfizer will manufacture the vaccine in SA or will manufacture outside SA and thereafter import and supply to NDoH in SA. This aspect of the draft agreement needs to be clarified as there will be VAT implications. Depending on the position, certain amendments will be needed.

##### 4.3.2 Invoices and Payment.

- (a) In partial consideration of the Contracted Doses, ~~on or as soon as possible after the Effective Date, following receipt of the Purchase Order, Pfizer shall invoice Purchaser in line with the details contained in the Purchase Order, and Purchaser~~

Commented [u20]: Pfizer to complete SBD4 form, and be registered on CSD and provide of good tax standing.



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shall pay Pfizer, on condition that the requisite Authorization has been obtained from SAHPRA, an upfront payment of Forty Million two thousand three hundred US Dollars (USD 40,002,300) (calculated as two (2) USD per dose multiplied by the Contracted Doses) ~~an upfront payment of Forty Million two thousand three hundred US Dollars (USD 40,002,300) (calculated as two (2) USD per dose multiplied by the Contracted Doses)~~ (the "Advance Payment"). Purchaser shall pay the Advance Payment on the later of within thirty (30) days from the Effective Date or as soon as the requisite Authorization is received; provided, however, that Pfizer shall have no obligation to deliver any Product until receipt of the Advance Payment by Pfizer. All amounts due hereunder shall be converted to South African Rand which shall be determined based on the exchange rate used by Bloomberg BFIX at the close of business on the day prior to the invoice date ~~date on which the Purchase Order is to be placed~~ 4:00 pm London time.

- (b) Pfizer shall invoice Purchaser for the remainder of the Price for the Contracted Doses (the "Delivery Price") in advance of each calendar quarter during the Term in advance of the expected Delivery Date. Purchaser shall pay all undisputed (in good faith) amounts on the first (1<sup>st</sup>) Business Day of the first (1<sup>st</sup>) month of each calendar quarter ~~for after delivery of the Batch of Contracted Doses to be delivered in such calendar quarter, or in the case of Batch 1, within five (5) Business Days of the issuance of Conditional Approval. All such amounts shall be due prior to delivery of the volume of anticipated doses to be delivered in such delivery, which Delivery Price shall be equal to the difference of the Price for the number of the Contracted Doses being delivered in such delivery and an apportionment of the Advance Payment based on the number of Contracted Doses (being whatever is remaining of the doses in the Batch multiplied by the doses in the Batch to be received in the next quarter) in such delivery. Full payment of each prior shipment is a condition to Pfizer's obligation to supply any future shipment. If any failure by Purchaser to pay Pfizer for the Contracted Doses results in a delay in delivery, the undelivered doses will be at the sole risk of Purchaser, and Pfizer shall have no liability to Purchaser regarding such delay or further inability to supply by Pfizer.~~
- (c) Invoices shall be provided to [NTD: Insert Purchaser invoicing details]. Pfizer shall include the following information on all invoices: the Purchase Order number and billing address; and shall also include, where applicable, the type description, part number (if any) and number of Contracted Doses delivered; the delivery date; the actual date of shipment; the Price; any applicable taxes or other charges provided for in the Purchase Order; and the ship-to destination.

(e)(d)

4.3.3 Method of Payment.

- (a) All amounts due under this Agreement shall be paid by the Purchaser to Pfizer in accordance with the provisions of Section 3.2(a) and 3.2(b). Payment shall be remitted by wire ~~electronic~~ transfer in immediately available funds to the Pfizer bank account indicated below. Any payment which falls due on a date which is not

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Commented [MS21]: Note to NDOH – just to avoid any shipment delay, this period may become shorter in case the supply agreement is concluded on a date that is close to the shipping date.

Commented [DoH22]: Our payments don't work like this – purchase order must be created using this number, then there are internal sign-off processes, then invoice from Pfizer then payment – will take longer than one day.

Commented [u23]: NDOH process for generating a PO

Commented [DoH24]: We have included formula wording for this.

Commented [MS25]: Note to NDOH - Please confirm the SELL To/Invoiced Entity – Any amounts shall be transacted to Pfizer from the SELL To/Invoiced Entity

Commented [DoH26]: See comment above on how payment are made by Government.

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a Business Day may be made on the next succeeding Business Day. Any dispute by Purchaser of an invoice shall be provided to Pfizer in writing (along with substantiating documentation and a reasonably detailed description of the dispute) within five (5) Business Days from the date of such invoice. Purchaser will be deemed to have accepted all invoices for which Pfizer does not receive timely notification of disputes, and shall pay all undisputed amounts due under such invoices within the period set forth in this Section 3.3(a). The Parties shall seek to resolve all such disputes expeditiously and in good faith.

<b>BANK NAME:</b>	<b>Citibank</b>
<b>BRANCH:</b>	<b>Johannesburg</b>
<b>BRANCH NUMBER:</b>	<b>350005</b>
<b>CURRENCY:</b>	<b>ZAR</b>
<b>ACCOUNT NUMBER:</b>	<b>0201700086</b>
<b>SWIFT CODE:</b>	<b>CITIZAJX</b>

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- (b) Any amount required to be paid by a Party hereunder which is not paid on the date due shall bear interest, to the extent permitted by law, at five percent (5%) above South African Reserve Bank Repo Rate (or any successor to such rate) effective for the date such payment was due, as reported in the Wall Street Journal (<https://www.wsj.com/market-data/bonds>). Such interest shall be computed on the basis of a year of three hundred sixty (360) days for the actual number of days payment is delinquent. In addition to all other remedies available under this Agreement or at Law, if Purchaser fails to pay any undisputed amounts when due under this Agreement, Pfizer may (i) suspend the delivery of the Product or (ii) terminate this Agreement.
- (c) Purchaser shall not, and acknowledges that it will have no right, under this Agreement, in respect of any Purchase Order, any other agreement, document or Law, to withhold, offset, recoup or debit any amounts owed (or to become due and owing) to Pfizer, whether under this Agreement or otherwise, against any other amount owed (or to become due and owing) to it by Pfizer or a Pfizer Affiliate.

**Commented [DoH27]:** To be discussed. There is an obligation on the NDoH, when it enters into agreements, in respect of fruitless and wasteful expenditure, to try and recoup losses.

4.4.4 Taxes

The importation of the Products into South Africa is VAT exempt. It is understood and agreed between the Parties that any payments made and other consideration provided under this Agreement are therefore exclusive-free of any VAT or similar tax and all other taxes which are incurred as a result of manufacturing and supplying the Product (including, without limitation, custom duties, levies and charges and all local taxes) ("Taxes"), which shall be added thereon as applicable. Where Taxes are properly chargeable on a payment made or consideration provided under this Agreement, the Party making the payment or providing the consideration will pay the amount of Taxes in accordance with the laws and regulations of the country in which the Taxes are chargeable.

**Commented [DoH28]:** Wording to be discussed and confirmed in light of VAT. If Pfizer is registered for VAT in SA (which in all probability is the case), then the price in respect of the supply/sale of the vaccine must include VAT at the standard rate of 15%. If VAT is payable on the supply it will be added to the price. Depending on the position re VAT and importation this wording may need to be amended.



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In the event any payments made pursuant to this Agreement 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 Law and such amounts payable to the payee shall be reduced by the amount of taxes deducted and withheld. Any such withholding taxes required under Law to be paid or withheld shall be an expense of, and borne solely by, the payee.

5.4. MANUFACTURING STANDARDS AND QUALITY ASSURANCE.

5.14.1 Manufacturing Standards.

Pfizer shall manufacture and supply the Product in material accordance with the Specifications and cGMP. Such Specifications may be revised through written notification by Pfizer to Purchaser to conform to the Authorization or changes to the manufacturing or distribution of the Product.

5.24.2 Legal and Regulatory Filings and Requests.

- (a) Pfizer shall (a) comply with all Laws, including, but not limited to all regulatory or government licenses and permits, and (b) comply with all cGMP with respect to its manufacturing and packaging processes, the Facilities or otherwise, to permit the performance of its obligations hereunder.
- (b) Pfizer shall ensure that all Product is properly labelled and packaged in accordance with the applicable Authorization, Specifications and material cGMP standards.
- (c) Prior to delivery, Pfizer shall comply with all conditions (in the relevant timescales) set out in the Authorization and all Laws; provided, however, that Purchaser shall grant to the extent that it is able to do this, or, using its best efforts to obtain facilitate on Pfizer's behalf, all exemptions, exceptions, and waivers of country specific requirements for the Product granted or permitted by the Government authority (including but not limited to serialization, applicable laboratory or quality testing and/or marketing information form submission and approval), which requirements, absent an exemption, exception or waiver, would prevent Pfizer from supplying and releasing the Product in South Africa upon receipt of the Authorization. Purchaser acknowledges the Product will be supplied without serialization. Purchaser agrees to exercise its best efforts to cause the relevant Government authorities to facilitate the issuance of appropriate waivers and/or approvals in case of active serialization, track & trace, and/or 2D coding mandates within 24 hours. In order to maintain an efficient supply chain for the manufacture, release and supply of the Product, Pfizer will be solely responsible for determination of manufacturing and testing locations and will conduct testing in accordance with the Authorization. The Parties have agreed that Pfizer will not be required to respond to, or provide Product or method transfer in connection with, requests for —local testing, requests for lot release protocols or requests for registration samples in this Agreement or in subsequent amendments or extensions of this Agreement.

**Commented [DoH29]:** To be confirmed and discussed given risk with the lack of barcoding to protect Pfizer and DOH from counterfeiting.

**Commented [DoH30]:** Please confirm whether SAHPRA agreed to this exemption. We do not have the authority to agree to this unless SAHPRA has cleared this.

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- (d) Due to the current pandemic situation and the fact that any anticipated Authorization will be initially under a Conditional Approval in conjunction with the agreement that Pfizer will only supply the Purchaser directly, the Purchaser agrees to the below conditions as a condition precedent to supply of the Product. Purchaser will issue to the extent that it is able to do this, or use its best efforts to facilitate that make any other Government authority ~~to~~ issues, any necessary approvals to ensure enforceability of the same:
- i. During the Term, Pfizer will not be required by the Purchaser or any other Government authority to appoint a local agent or distributor, including without limitation, for purposes of selling or supplying the Product or applying for the Authorization, unless Pfizer, in its discretion during the Term, appoints a local agent or distributor. For the avoidance of doubt, Purchaser also agrees that as of the Effective Date (1) Pfizer or any of its Affiliates will be the entity applying and submitting any regulatory files required for issuance of the Conditional Approval; and (2) the Conditional Approval will be issued under Pfizer's or any of its Affiliates name.
  - ii. During the Term, Pfizer will not be required by the Purchaser or any other Government authority to submit a price reference certificate for purposes of applying for the Conditional Approval or otherwise.
  - iii. In the event that during the Term a third party is the applicant or holder of the Authorization, any obligation on Pfizer under this Agreement shall be taken as a requirement on Pfizer to use Commercially Reasonable Efforts to procure the compliance of such third party Authorization applicant or holder with such obligations to the extent necessary to ensure the relevant obligation is fully met.

Commented [DoH31]: Position to be discussed.

Commented [DoH32]: Government cannot force SAHPRA to issue an authorization.

Commented [DoH33]: What is this? What is the reason for this? Why is it required? We do not have the authority to agree to this as we are not responsible for regulating the prices.

5.34.3 Quality Tests and Checks.

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

5.44.4 Rejection of Product: Disposal of Rejected Shipments.

- (a) Purchaser may reject any Product that does not materially conform to Specifications or cGMP ("**Non-Complying Product**") by providing written notice of rejection to Pfizer and setting out detailed reasons for such rejection: ~~(i) immediately (and in no event more than 24 hours) upon delivery of such Non-Complying Product to Purchaser; or (ii) immediately and in no event more than 24 hours upon its first knowledge of a Latent Defect~~ within 48 (forty eight) hours of receipt of notice reporting that such Product is defective in the case of a material defect and within

Commented [DoH34]: This is so as to comply with the Government importation and logistics agreements.

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seven days of first knowledge (be it by notice or otherwise) of a Latent Defect. Pfizer shall respond to any rejection and notice of Non-Complying Product from Purchaser in a ~~timely~~ prompt manner. For clarity, Purchaser shall not be entitled to reject any Product based on service complaints unless a Product does not materially conform to Specifications or cGMP.

- (b) Pfizer shall conduct an analysis of the causes of any such quality-related complaint, and shall report to Purchaser on any corrective action taken. If Pfizer's inspection and testing reveals, to Pfizer's reasonable satisfaction, that such items of the Product are Non-Complying Product and that any such non-conformity or defect has not been caused or contributed to by any abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Pfizer, Pfizer shall use Commercially Reasonable Efforts to replace such Non-Complying Product as soon as practicable at no additional charge to Purchaser. In such circumstances, Pfizer will further arrange for reverse logistics for Product collection and manage the destruction of the Non-Complying Product. Until collection, Purchaser shall store and maintain the relevant Non-Complying Product in appropriately secure locations and in accordance with the manufacturers' specifications. Notwithstanding any other provision of this Agreement, this Section 4.4(b) contains Purchaser's sole and exclusive remedy for Non-Complying Product. The provisions of this Section 4.4 (Rejection of Product; Disposal of Rejected Shipments) shall survive termination or expiration of this Agreement.

5.74.5 Maintenance and Retention of Records.

- (a) Each Party shall maintain detailed Records with respect to its activities under this Agreement as required by Laws.
- (b) Purchaser will maintain a quality system for receipt, inspection, storage, traceability to further delivery points, and recall activities. If Purchaser does not have a quality system for the activities defined, Pfizer may share details of a proposed quality system for Purchaser's compliance.

5.84.6 Diversion Issues.

Purchaser shall be entitled to sell or donate Product within the Territory. All Product delivered to Purchaser shall be: (a) stored securely by Purchaser; and (b) distributed by Purchaser only in South Africa 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 out of South Africa or export out of South Africa, and to protect and preserve the integrity and efficacy of the Product. Purchaser shall promptly notify Pfizer Quality Department ProductComplaintsZAF@pfizer.com and Pfizer Adverse Events Reporting by email



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ZAF.AEReporting@pfizer.com within forty-eight (48) hours (with follow up in writing in line with the notice provisions of this Agreement) in the event of any severe or serious event if at any time Purchaser believes that any of the Product has been stolen, diverted, tampered with, substituted, or otherwise subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Pfizer. Where the event is minor, Purchaser shall notify within 7 days after first becomes aware or receives notice thereof. The notice shall provide all information relating to the Product diversion, including, but not limited to, detailed information including the date, time, location, number, batch number(s), expiration date, circumstances, and contact person(s) information. Purchaser shall cooperate with Pfizer or its designee, upon Pfizer's request, to cooperate in connection with such Product diversion. Purchaser shall not directly or indirectly resell, export, transfer, donate, or otherwise distribute Product outside of the Territory without Pfizer's prior written consent, which consent shall not be unreasonably withheld.

**Commented [DoH35]:** 48 hours is fine for serious events, but for minor events this will need to be 7 days after receipt at the NDOH. This is inline with the NDOH's existing agreement with SAHPRA.

It is specifically recorded that to the extent that Purchaser determines that the Product is no longer cost effective and/or no longer efficacious in South Africa, but that it is or will be efficacious elsewhere in the world, then Purchaser shall be entitled to sell or donate the Product in question outside of the Territory, with written approval from Pfizer, which will not be unreasonably withheld.

5.04.7 Recalls.

Purchaser shall be responsible for all costs of any recall or market withdrawal of the Product in South Africa, including, without limitation, reasonable costs incurred by or on behalf of Pfizer and its Affiliates or BioNTech and its Affiliates, except to the extent that such recall or market withdrawal results from willful misconduct (being a wrongful act, willingly and knowingly committed without legal or factual justification, with the intent to cause the harmful effects) on the part of, Pfizer or any of its Affiliates or any of their respective Personnel, in which event Pfizer will be responsible solely for: (a) any reasonable and documented out of pocket expenses directly incurred by Purchaser to third parties in implementing such recall or market withdrawal; and (b) replacing, at Pfizer's expense, the Product which has to be recalled.

**Commented [u36]:** What about recall of vaccine following latent defects?  
For discussion

8.5. **REPRESENTATIONS & WARRANTIES.**

8.15.1 **Mutual Representations and Warranties.** Pfizer and Purchaser each represents and warrants to each other the following:

- (a) **Organization and Authority.** It has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement, including, in the case of Purchaser, that all necessary authorizations and approvals have been obtained by Purchaser to authorize its performance of all of its



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obligations contained herein, that Purchaser has the authority to bind the Republic of South Africa and that Purchaser has exercised that authority to bind the Republic of South Africa as to each of the provisions and terms and conditions set forth in this Agreement;

- (b) No Conflicts or Violations. The execution and delivery of this Agreement by such Party and the performance of such Party's obligations hereunder (i) do not conflict with or violate any Laws existing as of the Effective Date and applicable to such Party and (ii) do not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any contractual obligations of such Party existing as of the Effective Date; and
- (c) Valid Execution. Such Party is duly authorized to execute and deliver this Agreement, and the Person executing this Agreement on behalf of such Party is duly authorized to execute and bind such Party to the terms set forth herein.

8.25.2 Warranties of Pfizer.

Pfizer warrants to Purchaser that:

- (a) At the time of delivery, the Product (except for any non-compliance or failure to meet the relevant standard or requirement that could not be reasonably discovered given the state of medical, scientific or technical knowledge at the time when Pfizer delivered the Product):
  - (i) complies in a material manner with the relevant Specifications;
  - ~~(ii)~~ complies with all Laws and any failure to comply with applicable Laws, SAHPRA or the Authorizations or any deviations therefrom shall not constitute a breach by Purchaser; and
  - ~~(iii)~~ has been manufactured in material accordance with current Good Manufacturing Practices.
- (b) Subject to Pfizer's disclaimer of non-infringement of Intellectual Property rights of a third party (at Section 5.4(a) and (b) below), it has good title to the Product delivered to Purchaser pursuant to this Agreement and shall pass such title to Purchaser free and clear of any security interests, liens, or other encumbrances.
- (c) The execution, delivery and performance of this Agreement by Pfizer will not violate any agreement or instrument to which Pfizer is a party.
- ~~(e)~~(d) The shelf life of the Product, as at the date on which the specific doses of the Product are delivered to Purchaser, shall be at least 80% of the total shelf life of the Products, such that the expiry date of the Product shall be no earlier than 46 (sixfour) months after the Product is received by Purchaser.

Commented [u37]: What is the shelf life based on latest stability studies.

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8.35.3 Anti-Bribery/Anti-Corruption and Global Trade Controls.

- (a) The Parties represent and warrant that, beyond the mutual consideration set forth in this Agreement, neither they nor their agents have provided or requested, or will provide or request, any additional incentive or benefit to or from the other Party or its agents to induce either Party to enter this Agreement or perform any part of this Agreement.
- (b) Pfizer has not made, and will not make, in the performance of this Agreement directly or indirectly any payment, offer, promise, or authorization of payment of money or anything of value to a Government official, political party, candidate for political office, or any other Person, and has not sought and will not seek improperly or corruptly to influence any Government official, political party, candidate for political office, or any other Person, in order to gain an improper business advantage.
- (c) The Parties will comply with applicable economic sanctions, import, and export control laws, regulations, and orders in the performance of this Agreement.
- (d) Activities performed under this Agreement will not involve Restricted Parties (defined as the list of sanctioned parties maintained by the United Nations; the Specially Designated Nationals List and the Sectoral Sanctions Identifications List, as administered by the U.S. Department of the Treasury Office of Foreign Assets Control; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; the entities subject to restrictive measures and the Consolidated List of Persons, Groups and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy; and similar lists of restricted parties maintained by relevant governmental entities).
- (e) Notwithstanding any other provision of this Agreement, Pfizer shall not be required to take or refrain from taking any action prohibited or penalized under the laws of the United States or any applicable non-United States jurisdiction, including, without limitation, the antiboycott laws administered by the U.S. Commerce and Treasury Departments.

8.45.4 No Other Warranty.

Except to the extent set out expressly in this Agreement, all conditions, warranties or other terms which might have effect between the Parties or be implied or incorporated into this Agreement (whether by statute, common law or otherwise) are hereby excluded to the fullest extent permitted by Law. Without prejudice to the general nature of the previous sentence, unless this Agreement specifically states otherwise and to the maximum extent permitted by Law, Pfizer expressly disclaims any representations or warranties with respect to the Product, including, but not limited to, any representation, warranties or undertaking as to (a) non-infringement of Intellectual Property rights of any third party, (b) that there is no requirement to obtain a license of third party Intellectual Property rights to enable the

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use or receipt of the Product, (c) merchantability, or (d) fitness for a particular purpose.

8-55.5 Purchaser Acknowledgement.

Purchaser 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 Purchaser under this Agreement. Purchaser 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, Purchaser acknowledges that the Product shall not be serialized.

Commented [DoH38]: Should this not refer to Product?

9.6. TERM; TERMINATION.

9.16.1 Term of Agreement.

This Agreement shall commence on the Effective Date and shall continue until the later of (a) delivery of the Contracted Doses of the Product under the accepted Purchase Order submitted on the Effective Date, and (b) twenty-four (24) months from the Effective Date, unless extended or terminated pursuant to this Section 6 (Term: Termination) or the mutual written agreement of the Parties ("**Term**").

9.26.2 Termination for Cause.

Either Party may terminate this Agreement immediately upon written notice to the other Party in the event of a material breach by the other Party of any term of this Agreement, which breach remains uncured for thirty (30) days following written notice to the other Party of such material breach. Notwithstanding the foregoing, if such material breach, by its nature, cannot be cured, the terminating Party may terminate this Agreement immediately upon written notice to the other Party. In the event that this Agreement is terminated by Pfizer under this Section 6.2, Purchaser shall pay within thirty (30) days of the date of notice of termination of this Agreement the full Price for all Contracted Doses less amounts already paid to Pfizer as of such date. In the event that this Agreement is terminated by Purchaser under this Section 6.2, Pfizer shall reimburse Purchaser with the Advance Payment and all other payments made by Purchaser within thirty (30) days of the date of notice of termination of this Agreement.

9.36.3 Mutual Termination Rights.

- (a) In the event: (i) the Authorization has not been obtained in the Territory by 30 September 2021 ~~(except in a case where such event is mainly or solely attributable to Purchaser or any ministry or secretary of the Government of the Republic of South Africa)~~ and Pfizer has supplied to Purchaser no doses of Product by 30 September 2021, subject to the extensions set forth in Section 2.4 (Delivery Schedule), or (ii) Pfizer is unable to supply all of the Contracted Doses by December 31, 2021<sup>2</sup>, then either Party may terminate this Agreement upon written notice to the other Party. Purchaser may invoice Pfizer for a refund of ~~fifty percent (50%)~~ of the Advance Payment for the Contracted Doses not delivered (as



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determined ratably for the doses not delivered) except for cases where the cause of the termination is mainly or solely attributable to Purchaser. In the event this Agreement is terminated pursuant to this Section 6.3, the return of fifty percent (50%) the Advance Payment shall be Purchaser's sole and exclusive remedy for the failure to deliver any Contracted Doses.

9.46.4 Termination in Event of Insolvency.

In the event that Pfizer: (a) becomes insolvent, or institutes or has instituted against it a petition for bankruptcy or is adjudicated bankrupt; or (b) executes a bill of sale, deed of trust, or a general assignment for the benefit of creditors; or (c) is dissolved or transfers a substantial portion of its assets to a third party (excluding any of Pfizer's Affiliates); or (d) has a receiver appointed for the benefit of its creditors, or has a receiver appointed on account of insolvency; then Pfizer shall immediately notify Purchaser of such event and Purchaser shall be entitled to terminate this Agreement.

9.56.5 Effect of Termination.

- (a) Upon expiry or termination of this Agreement for any reason:
  - (i) ~~Purchaser shall pay any sums owed to Pfizer pursuant to this Agreement within thirty (30) days of the date of invoice for the same; and~~
  - ~~(ii)~~(i) each Party shall use Commercially Reasonable Efforts to mitigate both (1) the damages that would otherwise be recoverable from the other pursuant to this Agreement, and (2) any costs, fees, expenses or losses that may be incurred by a Party, or for which a Party may be responsible, under this Agreement, by taking appropriate and reasonable actions to reduce or limit the amount of such damages, costs, fees, expenses or losses.
- (b) The termination or expiration of this Agreement shall not affect the survival and continuing validity of [Sections \_\_\_\_]<sup>1</sup> or of any other provision which is expressly or by implication intended to continue in force after such termination or expiration.
- (c) Expiry or termination of this Agreement 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 (i) Pfizer shall have no liability for any failure by Pfizer to develop or obtain Authorization of the Product in accordance with the estimated dates described in this Agreement and (ii) even if the Product is successfully developed and Pfizer obtains Authorization, Pfizer shall have no liability for any failure to deliver Contracted Doses in accordance with any estimated delivery dates set forth herein.

**Commented [DoH39]:** 6.2 and 6.3 already contemplate the payment mechanisms on breach.

**Commented [MS40]:** To be confirmed

10.7. INTELLECTUAL PROPERTY.

<sup>1</sup>Note to Draft: To be inserted closer to finalization of Agreement.

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Pfizer US will be the sole owner of all Intellectual Property it generates during the development, manufacture, and supply of the Product or otherwise related to the Product. Neither Party will gain any rights of ownership to or use of any property or Intellectual Property owned by the other (whether by virtue of this Agreement, by implication or otherwise).

11.8. **INDEMNIFICATION.**

11.18. Indemnification by Purchaser. For the Term of this Agreement and solely in relation to the Batches of Vaccines provided in terms of this Agreement or until such time as the Vaccines are registered with SAHPRA (which ever event occurs first), the pPurchaser hereby agrees to indemnify, defend and hold harmless Pfizer, BioNTech, each of their Affiliates, contractors, sub-contractors, licensors, licensees, sub-licensees, distributors, contract manufacturers, services providers, clinical trial researchers, third parties to whom Pfizer or BioNTech or any of their respective Affiliates may directly or indirectly owe an indemnity based on the research, development, manufacture, distribution, commercialization or use of the Vaccine, and each of the officers, directors, employees and other agents and representatives, and the respective predecessors, successors and assigns of any of the foregoing (“**Indemnitees**”), from and against any and all suits, claims, actions, demands, losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys’ and other counsels’ fees and other expenses of an investigation or litigation), whether sounding in contract, tort (delict), intellectual property, or any other theory, and whether legal, statutory, equitable or otherwise by any natural or legal person (collectively, “**Losses**”) caused by, arising out of, relating to, or resulting from the Vaccine, including but not limited to any stage of ~~design, development, investigation, formulation, testing, clinical testing, manufacture, labeling, packaging, transport, storage, distribution, marketing, promotion, sale, purchase, licensing, donation, dispensing, prescribing, administration, provision, or use of the Vaccine, any information, instructions, advice or guidance provided by Pfizer, or BioNTech or any of their respective Affiliates and relating to the use of the Vaccine (provided that the requisite Authorization for the Vaccine has not been withdrawn), but only to the extent that these activities, actions, processes and other operations referred to are not solely under the knowledge, responsibility and/or control of the Indemnitee/s to the exclusion of Purchaser, or any processing or transfer of anyone’s personal information processed and transferred by Purchaser to the Indemnitees (“**Covered Activities**”).~~ The indemnification right under this section will not be available to the Indemnitees to the extent that their Losses result directly from the willful misconduct or failure to comply with the cGMP and other applicable Laws of such Indemnitees and/or where the necessary Authorization has been withdrawn or was not in place at the relevant time.

**Commented [DoH41]:** We would wish for the clause to be limited to those issues where the Purchaser is responsible for the loss, rather than purely indemnifying Pfizer against all losses that are or were under the control of Pfizer.

8.2 Pfizer further undertakes and agrees that to the extent that Pfizer or its Affiliates conclude any agreement with a third party in South Africa to procure and/or supply to them within the Territory any vaccine of Pfizer, BioNTech or their respective Affiliates intended for the prevention of the human disease COVID-19 (including the Product) either (i) directly from Pfizer or from Pfizer through the COVAX Facility; or (ii) from a Third Party, whether by donation, sale or otherwise, then the indemnification granted by Purchaser and this Section 8 shall cease to be of any further force or effect.

**Commented [DoH42]:** Given that Vaccines aren’t barcoded, it will be impossible to identity, track and trace any vaccine products within the country and/or to allocate liability.



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8.3 Both Parties undertake and endeavour to use their best commercial endeavours to fulfil their responsibilities in terms of applicable Law and requirements and this Agreement and to act with the utmost good faith in all dealings with each other, third parties and SAHPRA in connection with this Agreement, and in a manner that minimises the risk of any Indemnified Claim (defined below). Losses or liability arising in respect of Purchaser.

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11.28.4 **Assumption of Defense by Purchaser.** The Indemnitee(s) shall notify Purchaser of Losses for which it is seeking indemnification pursuant hereto ("**Indemnified Claims**"). Upon such notification, the Indemnitee(s) shall have the option to conduct and control the defense or to require Purchaser to promptly assume conduct and control of the defense of such Indemnified Claims with counsel acceptable to Indemnitee(s), whether or not the Indemnified Claim is rightfully brought; provided, however, that Purchaser shall provide advance notice in writing of any proposed compromise or settlement of any Indemnified Claim and in no event may Purchaser compromise or settle any Indemnified Claim without Indemnitee(s)'s prior written consent, such consent not to be unreasonably withheld. Indemnitee(s) shall reasonably cooperate with Purchaser in the defense of any Indemnified Claims conducted and controlled by Purchaser. Pfizer shall, at all times, including where a potential Indemnified Claim might arise, fulfil its obligations in a reasonable manner and in accordance with all Law and ensure its uses its best efforts to mitigate any Losses, liability or risk which might arise for Purchaser, to the extent reasonably possible.

11.38.5 **Participation Rights.** Each Indemnitee shall have the right to retain its own counsel and to participate in Purchaser's defense of any Indemnified Claim, at its own cost and expense except as set forth below. A failure by the Indemnitee(s) to give notice of Indemnified Claims or to offer to tender the defense of the action or suit pursuant to this Section 8.58.3 (Participation Rights) shall not limit the obligation of Purchaser under this Section 8 (Indemnification), except and only to the extent Purchaser is actually prejudiced thereby.

11.48.6 **Assumption of Defense.** Notwithstanding the foregoing and without prejudice to Section 12.5, Pfizer, directly or through any of its Affiliates or through BioNTech, may elect to assume control of the defense of an Indemnified Claim (a) within thirty (30) days of Indemnitee's notice to Purchaser of the Indemnified Claim or (b) at any time if, in Pfizer's sole reasonable discretion: (i) Purchaser fails to timely assume the defense of or reasonably defend such Indemnified Claim(s) in good faith to the satisfaction of Pfizer (or Pfizer's Affiliates and BioNTech); or (ii) Pfizer believes (or any of Pfizer's Affiliates or BioNTech believe) in good faith that a bona fide conflict exists between Indemnitee(s) and Purchaser with respect to an Indemnified Claim hereunder. Upon written notice of such election, Pfizer shall have the right to assume control of such defense (directly or through either one of its Affiliates or BioNTech), and Purchaser shall pay (as incurred and on demand), all Losses, including, without limitation, the reasonable attorneys' fees and other expenses incurred by Indemnitee(s), in connection with the Indemnified Claim. In all events, Purchaser shall cooperate with Indemnitee(s) in the defense, settlement or compromise of the Indemnified Claim.

11.58.7 **Privileges and Immunities.** Purchaser acknowledges that its indemnification obligations under this Agreement are (a) expressly in addition to, and not limited by, any Privileges



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and Immunities, and (b) do not waive or relinquish Indemnitees' rights to any Privileges and Immunities.

~~11.68.8~~ Costs. To the extent that Pfizer validly assumes the defense as is contemplated in Section 8.5, then ~~Costs~~-costs and expenses, including, without limitation, fees and disbursements of counsel, incurred by the Indemnitee(s) in connection with any Indemnified Claim shall be reimbursed on a quarterly basis by Purchaser, without prejudice to Purchaser's right to refund in the event that Purchaser is ultimately held in a final, non-appealable judgment or award to be not obligated to indemnify the Indemnitee(s).

~~12.9.~~ **INSURANCE AND LIABILITY.**

~~12.9.1~~ Insurance.

During the Term, Pfizer or its Affiliates shall self-insure or procure and maintain such types and amounts of general liability insurance to cover liabilities related to its activities under this Agreement as is normal and customary in the pharmaceutical industry generally for companies that are similarly situated and providing similar manufacturing and supply services. For absolute clarity, this shall not include, nor constitute, product liability insurance to cover any third party/patients claims and such general liability insurance shall be without prejudice to Purchaser's indemnification obligation as set out in this Agreement.

~~12.9.2~~ Limits on Liability.

- (a) Subject to the exclusions set forth in Section 9.3, in no circumstances shall (i) either Party be liable to the other Party or its Affiliates, whether arising in tort (including, without limitation, negligence), contract or otherwise, for any indirect, special, consequential, incidental or punitive damages, whether in contract, warranty, tort, negligence, strict liability or otherwise arising out of or relating to this Agreement, the transactions contemplated therein or any breach thereof (whether or not reasonably foreseeable and even if the first Party had been advised of the possibility of the other Party incurring such loss or type of loss), and (ii) in the case of Pfizer and its Affiliates, in no event shall Pfizer be liable to Purchaser for any direct damages except to the extent such direct damages were a result of a material breach of a representation or warranty by Pfizer under this Agreement that directly and solely caused the damage. In no instance shall Pfizer and its Affiliates be liable to Purchaser (whether arising in warranty, tort (including, without limitation, negligence), contract, strict liability or otherwise) for any liabilities of Purchaser to any third party, including, without limitation, through contribution, indemnity, or for any claim for which Purchaser would have to indemnify Pfizer if that claim were brought directly against Pfizer.
- (b) The aggregate liability of Pfizer and its Affiliates (whether arising in warranty, tort (including, without limitation, negligence, contract, strict liability or otherwise) arising out of, under or in connection with this Agreement shall not exceed a sum

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equivalent to one hundred percent (100%) of the total Price actually received by Pfizer under this Agreement for the Contracted Doses.

12.39.3 Excluded Liability.

Nothing in this Agreement excludes or limits the liability of either Party for:

- (i) fraud or fraudulent misrepresentation;
- (ii) any breach of Section 10 (Confidential Information);
- (iii) in the case of Purchaser, the indemnity given by it under Section 8 (Indemnification); or
- ~~(iv)~~ (iv) in the case of Purchaser, failure to pay the Price for the Product or any other sums properly owing to Pfizer under this Agreement; ~~or:~~
- ~~(iv)(v)~~ (v) in the case of Pfizer, failure to repay any sums properly owing to Purchaser under this Agreement.

12.49.4 Waiver of Sovereign Immunity. Purchaser, on behalf of itself and the Republic of South Africa, expressly and irrevocably waives any right of immunity which either it or its assets may have or acquire in the future (whether characterized as sovereign immunity or any other type of immunity), including any assets controlled by any agency, instrumentality, central bank, or monetary authority of the Republic of South Africa as specified ~~and applicable by 28 U.S.C. § 1611~~ in respect of any arbitration pursuant to Section 12.2 (Arbitration) or any other legal procedure initiated to confirm or enforce any arbitral decision, order or award, or any settlement in connection with any arbitration pursuant to Section 12.2 (Arbitration), whether in the Republic of South Africa or any other foreign jurisdiction, including but not limited to immunity against service of process, immunity of jurisdiction, immunity against any judgment rendered by a court or tribunal (including any interim award or decision), immunity against any order to enforce the judgment, and immunity against precautionary seizure of any of its assets. Purchaser, on behalf of itself and the Republic of South Africa, further covenants and agrees not to assert any such immunity in any proceeding in connection with this Agreement. Purchaser, on behalf of itself and the Republic of South Africa expressly and irrevocably submits to the jurisdiction of the courts of ~~New York~~ England and Wales, or any other court of competent jurisdiction, for the purposes of enforcing any arbitral decision, order or award, or any settlement in connection with any arbitration pursuant to Section 12.2 and represents and warrants that the person signing this Agreement on its behalf has actual authority to submit to such jurisdiction. Purchaser also expressly and irrevocably waives the application of any Law in any jurisdiction that may otherwise limit or cap its obligation to pay damages arising from or in connection with any Indemnified Claims. Purchaser represents and warrants that the person signing this Agreement on its behalf has actual authority to waive such immunity and bind Purchaser and the Republic of South Africa to the limitations of liability and liability waivers set forth herein.

12.59.5 Vaccine Compensation Program.



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- (a) Purchaser represents, warrants and covenants to Pfizer that commits to undertake the necessary processes to establish, as soon as reasonably possible after the Effective Date, a no fault compensation program that provides, amongst other matters, a system of compensation to individuals who have been vaccinated with the Batches of the Vaccine(s) provided in terms of this Agreement and who suffer serious physical injury or death caused by the Vaccine, without the need to demonstrate a defect in the Vaccine or any fault by a person, injuries arising out of, relating to, or resulting from administration or use of the Vaccine shall be within the scope of, and eligible for compensation under [Insert Name of Applicable Compensation, Immunity, or Insurance Program or Fund], in accordance with the procedures set forth in [Applicable Laws/Regulations].
- (b) The no fault compensation program referred to in Section 9.5(a), once established, will be maintained for a period sufficient to cover indemnity in respect of claims in relation to the Batches of Vaccines provided in terms of this Agreement or until such time as the Vaccines are registered by SAHPRA (whichever event occurs first), as referred to in Section 8.1. Pfizer undertakes to actively prosecute the Authorization in terms of section 15 of the Medicines and Related Substances Act as soon as possible after the Effective Date, and by no later than [insert].

12.69.6 Conditions Precedent to Execution of Agreement and Supply.

- (a) Purchaser represents that it has and will undertake the development and processing of necessary legislation and regulatory measures in order to have and continue to have adequate statutory or regulatory authority and adequate funding appropriation to undertake and completely fulfil the indemnification obligations as specified and for the term provided in Section 9.5 and provide adequate protection to Pfizer and all Indemnitees from liability for claims and all Losses arising out of or in connection with the Vaccine or its uses specified in that section.
- (b) Purchaser hereby covenants and acknowledges and agrees that a condition precedent for execution of this Agreement and the supply of the Product hereunder:
  - (i) Purchaser shall undertake necessary legislative and other processes referred to in Sections 9.5 and 9.6(a) to implement and maintain in effect such statutory or regulatory requirements or funding appropriation sufficient to meet its obligations in this Agreement prior to supply of the Product by Pfizer and thereafter shall maintain such statutory and regulatory requirement and funding appropriation, each as applicable, for so long as necessary to meet all of Purchaser's obligations under this Agreement, including, without limitation, any such obligations that, pursuant to Section 6.5, survive expiration or termination of this Agreement;
  - (ii) Purchaser must demonstrate, in a manner reasonably satisfactory to Pfizer, that Pfizer and its affiliates will have adequate protection, as determined in Pfizer's sole reasonable discretion, from liability for claims arising out of or in connection with the Vaccine or its use for the period specified in

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Commented [MS46]: Note to NDOH - Subject to further assessment depending on information from government on funding of indemnity. We understand there is discussion of funding the indemnity through some type of reserve account. We need to understand this is greater detail and it may be appropriate to include more specific CPs relating to the financial backstop.

Commented [DoH47]: Should this not refer to Products?



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~~Section 9.5 and, including but not limited to, that the Republic of South Africa will continue funding the No Fault Compensation System contemplated in 9.5 [INSERT FUND NAME] to meet any and all its indemnification obligations for the period specified in Section 9.5, and will provide as a condition precedent to the signing of this Agreement and supply of doses, documentation showing authorization for the indemnification obligations and a guarantee of payment of any such claims from the Republic of South Africa, satisfactory in Pfizer's sole discretion, [a true and correct copy of which is attached as Attachment I].~~

~~(-) Purchaser shall agree to provide additional terms and guarantees as required by Pfizer to ensure that Purchaser will undertake and completely fulfil the indemnification obligations and provide adequate protection to Pfizer and all Indemnitees, such additional terms and guarantees (which may include, but are not limited to, guarantees of third-party financial institutions) to be determined in Pfizer's sole discretion. For clarity, the sufficiency of such statutory or regulatory requirements or funding appropriation shall be in Pfizer's sole discretion, including the sufficiency of any guarantee.~~

~~(c) Purchaser acknowledges that (a) Pfizer's supply of Product hereunder is in reliance (without any duty of investigation or confirmation by or on behalf of Pfizer or its Affiliates), *inter alia*, on Purchaser's representations and covenants under this Section 9.6, Purchaser implementing and maintaining in effect the requirements and funding appropriation described in this Section 9.6 and the other representations and warranties made by Purchaser under this Agreement, and (b) in assessing the cost and pricing of the Vaccine pursuant to this Agreement, Pfizer took into account the above-mentioned indemnity and liability protections and accordingly consider such indemnity and liability protection as fundamental elements of this Agreement.~~

~~(d) For the avoidance of doubt, each of the requirements under this Section 9.6 must be satisfied before supply or continued supply of the Vaccine. The satisfaction of all such conditions precedent shall be determined by Pfizer, at its sole discretion. If any condition precedent is not satisfied, Pfizer may nonetheless elect to supply doses, at its sole discretion. Pfizer's partial performance under this Agreement, including any elective supply under this Section 9.6(d) shall not constitute waiver. If Pfizer determines in its sole discretion that fulfilment of any condition under this Section 9.6 lapses or otherwise becomes unsatisfactory, then Pfizer shall not be obligated to supply any further Vaccine~~

**43-10. CONFIDENTIAL INFORMATION.**

**43-10.1 Non-Use and Non-Disclosure.**

~~Subject to provisions of section 10.4, each Recipient shall, and shall cause its~~

**Commented [MS48]:** Note to NDOH – please insert details

**Commented [DoH49]:** Given the legal complexity relating to the implementation of the No Fault Compensation System contemplated in 9.5 and the time it will take to implement this, the Purchaser has provided its commitment in 9.5 above. Moreover, the Purchaser will be transparent with Pfizer in relation to the process which is undertaken so as to implement the No Fault Compensation System.

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Representatives which have access to the Disclosing Party'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 the Disclosing Party pursuant to this Agreement. Each Recipient shall not use or disclose such Confidential Information except as permitted by this Agreement. Each Recipient shall safeguard the confidential and proprietary nature of the Disclosing Party'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 Recipient and its Representatives may use, copy, and make extracts of the Disclosing Party's Confidential Information only in connection with fulfilling its obligations under this Agreement and, without limiting the foregoing, shall not use the Confidential Information for the benefit of the Recipient or any of its Representatives, or for the benefit of any other Person. In the event that Recipient becomes aware of any breach of the obligations contained in this Section 10 (Confidential Information) by it or its Representatives, Recipient shall promptly notify the Disclosing Party in writing of such breach and all facts known to Recipient regarding same. In addition, if Recipient is required to disclose the Disclosing Party's Confidential Information in connection with any court order, statute or Government directive or requirement under any Law, Recipient shall give the Disclosing Party notice of such request, as soon as practicable, before such Confidential Information is disclosed so that the Disclosing Party may seek an appropriate protective order or other remedy, or waive compliance with the relevant provisions of this Agreement. If the Disclosing Party seeks a protective order or other remedy, Recipient shall promptly cooperate with and reasonably assist the Disclosing Party (at the Disclosing Party's cost) in such efforts. If the Disclosing Party fails to obtain a protective order or waives compliance with the relevant provisions of this Agreement, Recipient shall disclose only that portion of Confidential Information which its legal counsel determines it is required to disclose. If the Disclosing Party does not respond to the Recipient within three (3) Business Days of notice by the Recipient, the Disclosing Party shall be deemed to have waived compliance with the Agreement and consented to the disclosure. Neither this Agreement nor the performance by either Party hereunder shall transfer to the Recipient any proprietary right, title, interest or claim in or to any of the Disclosing Party's Confidential Information (including, but not limited to, any Intellectual Property rights subsisting therein) or be construed as granting a license in its Confidential Information. [three days.] Notwithstanding the foregoing, in all cases, ~~(a) Purchaser may not disclose any of the financial or indemnification provisions contained in this Agreement, including, without limitation, the price per dose of Product or refundability of the Advance Payment or any information that could reasonably ascertain the price per dose of Product, without the prior written consent of Pfizer, and (b) Pfizer may disclose (i) Confidential Information to its Affiliates and BioNTech without prior written consent of Purchaser, and (ii) upon foreign government request, financial information relating to this Agreement, including cost per dose.~~

**Commented [DOH50]:** We need to be able to disclose and be accountable.

13.210.2 Recipient Precautions.

Subject to provisions of section 10.4, in order to comply with the obligations contained in this Section 10 (Confidential Information), Recipient shall take at least the following precautions: (a) Recipient shall exercise all reasonable efforts to prevent unauthorized

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employees and unauthorized third parties from gaining access to Confidential Information (and in no event less than reasonable care); (b) Recipient shall disclose Confidential Information only to such of its Representatives who have a need to know such Confidential Information to fulfill its obligations under this Agreement; provided, however, before any disclosure of Confidential Information, Recipient shall bind its Representatives receiving such Confidential Information to a written agreement of confidentiality at least as restrictive as this Agreement; and (c) prior to any disclosure, Recipient shall instruct its Representatives of the confidential nature of, and to maintain the confidentiality of, the Confidential Information. Recipient 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 Recipient.

### 13.310.3 Return of Confidential Information.

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

### 10.4 Permitted Disclosures of Confidential Information

- (a) Pfizer acknowledges and agrees that any disclosure by Purchaser to the Auditor-General, Parliament or in compliance with existing legislation of any information regarding its Programme, the Product and/or the Vaccine or this Agreement, including all Confidential Information, shall not constitute a violation of the provisions of this Section 10 and Purchaser is accordingly authorised to provide to the office of the Auditor-General and/or Parliament all information sought by the Auditor-General and/or Parliament, as the case may be, without obtaining Pfizer's prior approval nor having to follow the steps set out in the section.
- (b) Pfizer acknowledges and agrees that the Purchaser may face any of the circumstances below in which event the Purchaser may desire to disclose certain information regarding its Programme, the Product and/or the Vaccine or this Agreement which may constitute Confidential Information, namely that:
  - (i) the Purchaser believes transparency as regards the Programme is important to garner public trust and confidence in and support for the Programme; so as to encourage maximum public uptake of the Vaccines, or



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- (ii) during the course of the Programme, the Purchaser considers it possible that emergency situations may arise which necessitates expeditious disclosure of Confidential Information in order to protect public safety; or
- (iii) the Government Purchaser intends selling or donating any of the Products to other purchasers.
- (c) Accordingly, if the Purchaser believes that any of the circumstances envisioned in section 10.4 (a) exist, (bi) the Purchaser shall provide notice of such circumstances to Pfizer which describes the circumstances, the Purchaser's desired disclosures and an identification of the portion of such disclosure which constitutes Pfizer's Confidential Information; and (bii) Pfizer and the Purchaser shall generally co-operate with one another in good faith with respect reaching a mutually agreeable approach to such disclosure. As part of such cooperation, the Parties will discuss, among other things:
  - (i) the value of disclosure of Pfizer Confidential Information toward resolution of the circumstances in section 10.4 (a);
  - (ii) the commercial, regulatory, scientific, strategic or other value of the Pfizer Confidential Information to Pfizer, and, the extent to which, if disclosed or otherwise made available to the public, would result in significant competitive prejudice and undue loss to Pfizer and its Affiliates;
  - (iii) the extent to which similar information of other vaccine manufacturers has been disclosed (or has not been disclosed) by the Purchaser;
  - (iv) the extent to which similar information has been disclosed (or has not been disclosed) by Pfizer in other countries; and
  - (v) redaction, partial or selective disclosure (whether as to content or audience) or other mechanisms by which appropriate disclosure may be made while providing reasonable assurances that confidential treatment will be accorded to the Confidential Information.

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43.410.5 Survival.

The provisions of this Section 10 (Confidential Information) shall survive the termination or expiration of the this Agreement for a period of ~~ten-two (102)~~ years, except with respect to any information that constitutes a trade secret (as defined under Law), in which case the recipient of such information will continue to be bound by its obligations under this Section 10 (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-two (102)~~-year period specified above.

**Commented [DoH51]:** The resolution of the World Health Assembly on transparency related to pharmaceutical procurement requires that countries share information relating to essential medicines procured. The USA, amongst other countries, is a signatory to this resolution.

14.11. **NOTICES.**

Any notice required to be given hereunder shall be in writing and deemed to have been sufficiently

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given, (a) when delivered in person, (b) on the next Business Day after mailing by overnight courier service, or, where overnight courier service is unavailable, by other expedited delivery provided by a recognized express courier, or (c) when delivered via e-mail, provided the original is delivered via one of the preceding methods on or prior to the fifth (5th) Business Day after transmission of the e-mail, to the addresses specified below. Each notice shall specify the name and date of and parties to this Agreement.

If to Purchaser:

The National Department of Health,  
Republic of South Africa

~~Purchaser notice information~~

[●]

South Africa

Attention the Director General Dr SSS,

Buthelezi

sandile.buthelezi@health.gov.za

With a copy (which shall not constitute  
notice) \_\_\_\_\_ to

khadija.jamaloodien@health.gov.za

With a copy (which shall not constitute notice) to:

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton

Johannesburg

South Africa

2196

Attention: Legal Director

Email [●]

If to Pfizer:

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton

Johannesburg

South Africa

2196

Attention: Country Manager

Email [●]

Either Party may, by notice to the other Party, change the addresses and names given above.

**15.12. MISCELLANEOUS.**

**15.12.1 Negotiations of Dispute.**

Prior to commencing any arbitration with respect to any controversy, claim, counterclaim, dispute, difference or misunderstanding arising out of or relating to the interpretation or application of any term or provisions of this Agreement, a Party shall provide written notice to the other Party of the existence of such dispute. The Parties shall for a period of thirty (30) days following such notice enter into good faith discussions and negotiations in an attempt to resolve such dispute. If, by the end of such thirty (30) day period, unless such period is extended by mutual written agreement of the Parties, the Parties have been unable to resolve such dispute, either Party may initiate arbitration in accordance with the procedures set forth in Section 12.2 (Arbitration). The procedures specified in this Section 12.1 (Negotiations of Dispute) are a precondition to the initiation of arbitration by a Party, in connection with disputes between the Parties arising from or related to this Agreement

**Commented [DoH52]:** As mentioned in an earlier comment, we are in the process of moving and will provide updated details as soon as possible.

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or a Purchase Order; provided, however, that a Party may seek a preliminary injunction or other preliminary judicial relief, without attempting to resolve such dispute as provided in this Section 12.1 (Negotiations of Dispute), if in its judgment such action is necessary to avoid irreparable harm. The Parties expressly and irrevocably submit to the jurisdiction of the courts of ~~England and Wales~~~~New York, New York, U.S.A.~~ for any such injunctive relief. Further, the requirement to attempt to resolve a dispute in accordance with this Section 12.1 (Negotiations of Dispute) does not affect a Party's right to terminate this Agreement as provided in Section 6 hereof, and neither Party shall be required to follow these procedures prior to terminating the Agreement. The failure of either Party to participate in good faith discussions and negotiations in an attempt to resolve such dispute shall not delay the date by which the other Party may initiate arbitration under this Section 12.1 (Negotiations of Dispute).

45.312.2 Arbitration.

Any dispute, controversy, or claim arising out of, relating to, or in connection with this Agreement, including with respect to the formation, applicability, breach, termination, validity or enforceability thereof, or relating to arbitrability or the scope and application of this Section 12.2 (Arbitration), shall be finally resolved by arbitration. The arbitration shall be conducted by three arbitrators, in accordance with the Rules of Arbitration of the International Chamber of Commerce ("ICC"). The claimant shall nominate an arbitrator in its request for arbitration. The respondent shall nominate an arbitrator within thirty (30) days of the receipt of the request for arbitration. The two (2) arbitrators nominated by the Parties shall nominate a third arbitrator, in consultation with the Parties, within thirty (30) days after the confirmation of the later-nominated arbitrator. The third arbitrator shall act as chair of the tribunal. If any of the three (3) arbitrators are not nominated within the time prescribed above, then the ICC shall appoint the arbitrator(s). The seat of the arbitration shall be ~~New York, New York, U.S.A.~~~~London, England~~ and it shall be conducted in the English language. The Parties undertake to maintain confidentiality as to all aspects of the arbitration, including its existence, content and result, and as to all submissions, correspondence and evidence relating to the arbitration proceedings. The foregoing sentence shall survive the termination of the arbitral proceedings. Notwithstanding the foregoing, a Party may disclose information relating to the arbitration proceedings to the extent that disclosure is required to protect or pursue a legal right related to the arbitration; enforce or challenge an award in bona fide legal proceedings; respond to a bona fide compulsory order or request for information of a governmental or regulatory body; make a disclosure required by securities laws, rules of a securities exchange, or other similar laws, regulations, or rules; or seek legal, accounting, or other professional services. The costs of the arbitration, including, without limitation, the Parties' reasonable legal fees, shall be borne by the unsuccessful Party or Parties. However, the arbitral tribunal may apportion such costs between the Parties if it determines that apportionment is reasonable, taking into account the circumstances of the case. The arbitration award shall be final and binding on the Parties, and the parties undertake to carry out any award without delay. Judgment upon the award may be entered by any court having jurisdiction of the award or having jurisdiction over the relevant party or its assets.

45.312.3 Publicity.



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A Party shall not use the name, trade name, service marks, trademarks, trade dress or logos of the other Party in publicity releases, advertising or any other publication, without the other Party's prior written consent in each instance, which consent shall not be unreasonably withheld. For the purposes of transparency, the Parties shall however agree on a standard format containing the names and logos of the other which might be used generically in publicity releases, advertising or any other publications.

45.412.4 Governing Law.

All disputes shall be governed by the Laws of England and Wales the State of New York, USA, without regard to conflict of Law principles other than Section 5-1401 of the New York General Obligations Law, except that any dispute regarding the arbitrability or the scope and application of this Section shall be governed by the Federal Arbitration Act of the United States.

45.512.5 Third Party Rights.

- (a) Purchaser agrees the applicable rights granted or provided to Pfizer under this Agreement are also granted or provided to Pfizer's Affiliates or to BioNTech to the extent that those rights relate to such Affiliates or BioNTech, including but not limited to the indemnification in Section 8(a) (each a "**Third Party Beneficiary**" and together the "**Third Party Beneficiaries**"). Each Third Party Beneficiary shall be entitled to enforce the terms of this Agreement; provided that, to the extent permissible by Law and where reasonably practicable, any claims, demands or actions from any Third Party Beneficiary shall be brought by Pfizer itself on behalf of the relevant Third Party Beneficiary.
- (b) Any Losses suffered by a Third Party Beneficiary will not be treated as being indirect solely because it has been suffered by a Third Party Beneficiary and not by Pfizer directly.

45.612.6 Relationship of the Parties.

The relationship hereby established between Purchaser and Pfizer 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 Agreement is not intended to create, and shall not be construed as creating, between Pfizer and Purchaser, 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.

45.712.7 Assignment; Binding Effect.

- (a) Neither Purchaser nor Pfizer shall assign any of its rights or delegate or subcontract any of its duties and obligations under this Agreement without the prior written consent of the other Party, which may not be unreasonably be withheld at such Party's discretion, provided that Pfizer, without Purchaser's consent, may assign.

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delegate or subcontract any of its duties and obligations under this Agreement to an Affiliate of Pfizer, BioNTech or an Affiliate of BioNTech. Any such attempted assignment of rights or delegation or subcontracting of duties without the required prior written consent of the other Party shall be void and ineffective. Any such assignment, delegation or subcontracting consented to by a Party in writing shall not relieve the other Party of its responsibilities and liabilities hereunder and such assigning Party shall remain liable to other Party for the conduct and performance of each permitted assignee, delegate and subcontractor hereunder. This Agreement shall apply to, inure to the benefit of and be binding upon the Parties hereto and their respective successors and permitted assigns. The Parties agree that this Agreement is not intended by either Party to give any benefits, rights, privileges, actions or remedies to any Person or entity, partnership, firm or corporation as a third-party beneficiary or otherwise under any theory of Law.

(b) Where, subsequent to the Effective Date of this Agreement, the Vaccine is found not to be efficacious in the vaccination against SARS-CoV-2/COVID-19, the Purchaser may novate or assign and delegate its rights and obligations under this Agreement to another party who may be willing to receive and/or purchase the Vaccines from the Purchaser, and all Vaccines which have not as yet been delivered to the Purchaser shall, subject to appropriate arrangements and warranties being in place between the Purchaser and the assignee, and the obtaining of the consent of Pfizer, which consent shall not be unreasonably withheld or delayed, be delivered to the assignee.

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15.812.8 Force Majeure.

Neither Party shall be liable for any failure to perform or any delays in performance, and neither Party shall be deemed to be in breach or default of its obligations set forth in this Agreement, if, to the extent and for so long as, such failure or delay is due to any causes that are beyond its reasonable control and not to its acts or omissions, including, without limitation, such causes as acts of God, natural disasters, flood, severe storm, earthquake, civil disturbance, lockout, riot, order of any court or administrative body, embargo, acts of Government (other than Purchaser), war (whether or not declared), acts of terrorism, the impact on a Party of an outbreak of any disease or an epidemic or pandemic or other similar causes ("Force Majeure Event"). Failure or inability to pay shall not be a basis for a Force Majeure Event under this Agreement. In the event of a Force Majeure Event, the Party prevented from or delayed in performing shall promptly give notice to the other Party and shall use Commercially Reasonable Efforts to avoid or minimize the delay.

Commented [DoH53]: This must be subject to a time limitation.

15.912.9 Severability.

If and solely to the extent that any court or tribunal of competent jurisdiction holds any provision of this Agreement to be unenforceable in a final non-appealable order, such unenforceable provision shall be stricken and the remainder of this Agreement shall not be affected thereby. In such event, the Parties shall in good faith attempt to replace any unenforceable provision of this Agreement with a provision that is enforceable and that comes as close as possible to expressing the intention of the original provision.

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15.1012.10 Non-Waiver; Remedies.

A waiver by any Party of any term or condition of this Agreement 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 Agreement shall be cumulative and in addition to any other remedies provided at Law or in equity.

15.1112.11 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 Agreement.

15.1212.12 Forms.

The Parties recognize that, during the Term, a Purchase Order acknowledgment form or similar routine document (collectively, "**Forms**") may be used to implement or administer provisions of this Agreement. The Parties agree that the terms of this Agreement shall prevail in the event of any conflict between terms of this Agreement and the terms of such Forms, and any additional or different terms contained in such Forms shall not apply to this Agreement.

15.1312.13 Headings.

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

15.1412.14 Counterparts.

This Agreement may be executed in two or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement, and shall become effective when signed by each of the Parties hereto and delivered to the other Party in accordance with the means set forth in Section 11 (Notices) or by reliable electronic means (with receipt electronically confirmed).

15.1512.15 Electronic Delivery and Storage.

Delivery of a signed Agreement by reliable electronic means, including facsimile or email (with receipt electronically confirmed), shall be an effective method of delivery of the executed Agreement. This Agreement may be stored by electronic means and either an original or an electronically stored copy of this Agreement can be used for all purposes, including in any proceeding to enforce the rights or obligations of the Parties to this Agreement.

15.1612.16 Entire Agreement; Amendments.

This Agreement, together with any attachments and amendments (and as such attachments may be amended, amended and restated or replaced from time to time), which are hereby



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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, including the Binding Term Sheet. Except as otherwise set out herein: no modification or alteration of this Agreement shall be binding upon the Parties unless contained in a writing signed by a duly authorized agent for each respective Party and specifically referring hereto or thereto.

15.17 12.17 Rule of Construction.

The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event that an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.

15.18 12.18 English Language.

This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

15.19 12.19 Legal Costs.

Each Party will bear its own legal costs in preparing and concluding this Agreement.

**13. GOVERNMENT SIGNATORIES**

13.1 This Agreement is required by the national state of disaster as an emergency response to deal with the immediate risk to health caused by the Covid-19 pandemic and is signed by:

~~13.1 The Minister of Health accounting officer of Purchaser in that capacity to authorise the expenditure and to approve the issue of the indemnity in terms of clause 8 of the Agreement under section 66 of the Public Finance Management Act, 1999 (PFMA).~~

~~13.2 The Minister of Health approving and giving directions to the accounting officer of the National Department of Health for emergency procurement in terms of this Agreement and as authorised by the PFMA and its subordinate legislation.~~

~~13.3 The accounting officer of the National Department of Health who signs and approves this Agreement and the emergency procurement in their capacity as accounting officer and pursuant to the written directions contained in this Agreement for the emergency procurement of the goods and services referred to and the implementation and performance of this Agreement on behalf of the Minister of Health and the Minister of Finance.~~

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Commented [DoH54]: Only accounting officer may authorize expenditure.

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~~13.4~~ The Minister of Finance who signs this Agreement for the use of the funds required for this Agreement in the emergency situation arising from the national state of disaster in terms of section 16 and 63 & 64 of the PFMA, and to give concurrence to the Minister of Health for the issue of the indemnity in terms of clause 8 as required by section 66 of the PFMA, acknowledging that this Agreement provides the Minister of Finance with all relevant information required regarding the issue of the indemnity and the relevant financial commitment as required by section 70(3) of the PFMA.

~~13.25~~ The Government signatories Purchaser undertakes ing to ensure reporting of the procurement in terms of this Agreement to the National Treasury and the Auditor-General within 10 days of the entering into of this Agreement.

*[signature on following page]*

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed and delivered as of the date first written above.

[Redacted]

[Redacted]

[Redacted]  
[Redacted]  
[Redacted]

[Redacted]  
[Redacted]  
[Redacted]



**Attachment A - Specifications**

[To be inserted following the Effective Date (and in any event before supply in line with the agreed Interim Delivery Schedule)]

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**Attachment B - Interim Delivery Schedule and Price**<sub>[u55]</sub>

<u>Quarter</u>	<u>Q1 2021</u>	<u>Q2 2021</u>	<u>Q3 2021</u>	<u>Q4 2021</u>	<u>Total</u>
	<u>Batch 1</u>	<u>Batch 2</u>	<u>Batch 3</u>	<u>Batch 4</u>	
Doses	<u>499,590</u>	<u>4,899,960</u>	<u>7,600,320</u>	<u>7,001,280</u>	<u>20,001,150</u>
Price per dose	<u>\$10</u>	<u>\$10</u>	<u>\$10</u>	<u>\$10</u>	<u>\$200,001,150</u>

**Attachment B - Interim Delivery Schedule and Price**<sub>[u56]</sub>

<u>Quarter</u>	<u>Q1-2021</u>	<u>Q2-2021</u>	<u>Q3-2021</u>	<u>Q4-2021</u>	<u>Total</u>
	<u>Batch-1</u>	<u>Batch-2</u>	<u>Batch-3</u>	<u>Batch-4</u>	
Doses	<u>499,590</u>	<u>4,899,960</u>	<u>7,600,320</u>	<u>7,001,280</u>	<u>20,001,150</u>
Price per dose	<u>\$10</u>	<u>\$10</u>	<u>\$10</u>	<u>\$10</u>	<u>\$200,001,150</u>

**Attachment C- 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. 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, Pfizer intends to use the carrier delivery signal as proof of delivery.

**Commented [DoH57]:** Please advise what this is.

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/1170 doses of Product.

Purchaser ensures that at the expected time of arrival at the Place(s) of Destination 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 °C (+/- 15 °C) ultra-low temperature (“**ULT**”) freezer; or
  - (ii) a 2-8 °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.

Commented [u58]: Include minus 20°C storage

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

- The Product has a shelf-life of up to 6 months when stored at a constant -75 °C (+/- 15 °C)
- The Thermal Shipper can be used as temporary storage for up to 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 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 (2-25°C)

Commented [u59]: Include minus 20C storage

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 Good Distribution Practices (“**GDP**”) including 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 via a GDP qualified shipping system. Purchaser acknowledges that the Thermal Shipper (including Pfizer temperature monitoring devices) shall not be utilized for any in-market transportation and/or distribution by the Purchaser and shall be returned to Pfizer in accordance with Attachment F – Return and Disposal of Product Materials of this Agreement. Subject to the terms of the Agreement, 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.

Commented [DoH60]: As Pfizer previously promised to the Minister.

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

**Requirements of Delivery Location:**

1. Marketing authorization, Pre-approval, Post-approval vaccination points with -75 °C (+/- 15 °C) ULT freezer
2. Marketing authorisation, Pre-approval, Post-approval vaccination points with sufficient access and supply of dry-ice
3. Marketing authorization, Pre-approval, Post-approval vaccination points with 2-8°C refrigerator

**Commented [u61]:** To be discussed. Vaccination sites will not have storage for -70 C. Distribution plan aligned to storage at minus 20C and 2-8C.

**Attachment D – Delivery Specification**

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



Shipper A.pdf

**Attachment D – Delivery Specification**

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



Shipper B.pdf

**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.

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**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 will follow the protocol in the South African vaccinators manual 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.



## **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 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

## Attachment F – 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 ~~collection by Pfizer~~ ~~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.).

~~Collection/Return~~ of the **Logistics Delivery Equipment** to be undertaken by Pfizer within 30 days following delivery of the Product to the Purchaser’s recipient at Place(s) of Destination. Instructions and logistics for ~~collection and return~~ will be attended to by Pfizer in accordance with the ~~provided~~ ~~directions as 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 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 VAT) 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.

### 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 centers.

**Attachment G – Form of Purchase Order**

- Purchase details
- PO Number
- Currency
- Creation Date
- Requested Date
- Incoterm
- Ship-To location details
- Item Description
- Quantity
- Price and Total Value
- Payment terms



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**Attachment H- Customs Clearance Documentation**

1. Shipping Document/Airway Bill "AWB"
2. Commercial Invoice
3. Packing List
4. Copy of the Certificate of Analysis "COA"

During the Term of the Agreement:

- Any other documents not included in the above-mentioned list of documents, including but not limited to import permits, will be waived by the Purchaser or any other Government authority.
- Any notarization, legalization and/or certification of the above-mentioned list of documents will be waived by the Purchaser or any other Government authority.
- ~~Any required analysis to release any of the shipments upon arrival at the port of entry and/or Place(s) of Destination will be waived by the Purchaser or any other Government authority.~~

**Commented [DoH62]:** This is not within our powers to waive.