



# health

Department:

Health

**REPUBLIC OF SOUTH AFRICA**

## **REQUEST FOR PROPOSALS**

**[HP17-2021TWDV]**

**THE PROVISION OF IMPORTATION SERVICES (PART A),  
AND LOGISTICS SERVICES (PART B) FOR COVID-19  
VACCINES TO THE NATIONAL DEPARTMENT OF HEALTH  
FOR THE PERIOD 01 APRIL 2021 TO 31 DECEMBER 2022**

**BID VALIDITY PERIOD: 120 DAYS**

**CLOSING DATE AND TIME OF BID:  
22 FEBRUARY 2021 AT 11H00**

**TABLE OF CONTENTS**

<b>1.</b>	<b>DEFINITIONS AND INTERPRETATION .....</b>	<b>3</b>
<b>2.</b>	<b>ABBREVIATIONS .....</b>	<b>7</b>
<b>3.</b>	<b>INTRODUCTION.....</b>	<b>9</b>
<b>4.</b>	<b>STRUCTURE OF THE RFP.....</b>	<b>11</b>
<b>5.</b>	<b>SECTION 1: SCOPE OF SERVICES .....</b>	<b>12</b>
<b>6.</b>	<b>SECTION 2: BID PHASES .....</b>	<b>25</b>
<b>7.</b>	<b>SECTION 3: GENERAL REQUIREMENTS AND BID RULES.....</b>	<b>40</b>
<b>8.</b>	<b>SECTION 4: SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT ....</b>	<b>48</b>
	<b>Annex 1: Standard Bidding Documents.....</b>	<b>49</b>
	<b>Annex 2: General Conditions of Contract.....</b>	<b>71</b>
	<b>Annex 3: Importation Services Agreement.....</b>	<b>87</b>
	<b>Annex 4: Logistics Services Agreement.....</b>	<b>129</b>

## 1. DEFINITIONS AND INTERPRETATION

1.1 In this RFP, except as otherwise defined herein, and except where the context requires otherwise, words and expressions which are defined in the Agreement shall have the same meanings when used in this RFP. In this RFP, the following terms shall have the following meanings:

1.1.1 **Affiliate:** In relation to a Bidder or Service Provider, any direct or indirect holding company or subsidiary company of that Bidder or Service Provider, or any subsidiary company of any such holding company.

1.1.2 **Agreement:** The non-negotiable agreement to be entered into by the Department and the Service Provider/s for the provision of the Importation and/or Logistics Services, as the case may be. The Importation Services Agreement and the Logistics Agreement are annexed to this RFP.

1.1.3 **Authorised Delivery Site:** A Delivery Site that the Department notifies the Service Provider in writing has been authorised to place orders for the Products directly with the Service Provider.

1.1.4 **Bidder:** A person or entity that submits a Bid Response to the Department in respect of this tender.

1.1.5 **Bid Response:** Any bid submitted by a Bidder in response to the invitation contained in this RFP.

1.1.6 **Briefing Note:** Any document issued in writing by the Department that amends or supplements this RFP in any way. These notes shall be consecutively numbered in the order in which they are issued.

1.1.7 **Business Day:** Any day other than a Saturday, Sunday or gazetted national public holiday in the Republic of South Africa. All "**days**" referred to in the RFP refer to Business Days.

1.1.8 **Change in Control:** In respect of a Service Provider, means any direct or indirect change in Control of that Service Provider.

1.1.9 **Cold chain:** All of the materials, equipment, processes and procedures used to maintain the Products within the required temperature range from the time of manufacture until the Products are administered to individuals.

- 1.1.10 **Cold chain solutions:** This RFP contemplates the provision of the Importation and Logistics Services at three cold chain ranges for different types of Products—between 2–8 °C (cold chain solution 1), at –20°C (cold chain solution 2) and at –70°C (cold chain solution 3).
- 1.1.11 **Companies Act:** The Companies Act, 71 of 2008.
- 1.1.12 **Contract Period:** From 01 April 2021 until 31 December 2022.
- 1.1.13 **Control:** The possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of an entity, whether through the ability to exercise voting power, by contract or otherwise.
- 1.1.14 **Delivery Sites:** Public and private sector vaccination sites, provincial pharmaceutical depots and other approved storage sites. These sites may change during the course of the contract period.
- 1.1.15 **Department:** The Department of Health of the Republic of South Africa or any successor department designated by the Government of the Republic of South Africa from time to time.
- 1.1.16 **Entity or person:** Any natural or artificial person, association, business, close corporation, company, concern, enterprise, partnership, joint venture, trust, undertaking, voluntary association, body corporate, and any entity similar to any of the foregoing.
- 1.1.17 **Importation Services:** The services provided by the Service Provider in relation to the Products including, but not limited to, collection from the manufacturer's site of delivery, transportation to the nearest international airport loading, international carriage to the Republic of South Africa, off-loading, transportation to a centralised warehouse, arranging of export and import documentation, foreign airport charges, insurance and customs clearance (where applicable).
- 1.1.18 **Incoterms:** The International Chamber of Commerce rules for the use of domestic and international trade terms published in 2020, and which are applicable to the purchase agreement concluded or to be concluded between the Department and the manufacturers or suppliers of the Products.
- 1.1.19 **Lead Time:** The time from the date of receipt of an order for a Product by the Service Provider thereof, to the date of receipt of the Product at the Delivery

Site or the Logistics Service Providers' warehouse/storage facility in respect of such Product.

- 1.1.20 **Logistics Services:** The services provided by Service Provider/s in relation to the Products in South Africa including, but not limited to, customs clearance (where applicable), collection and transportation, warehousing, inventory control, material handling, order and batch order processing and administration, packaging, batch tracking and tracing, cold chain storage, data processing, the communications network necessary for effective management and delivery to the Delivery Sites. It includes all activities related to physical distribution, as well as the return of goods.
- 1.1.21 **Medicines Act:** The Medicines and Related Substances Act, 101 of 1965.
- 1.1.22 **PFMA:** The Public Finance Management Act, 1 of 1999.
- 1.1.23 **Pharmacy Act:** The Pharmacy Act, 53 of 1974.
- 1.1.24 **PPPFA:** The Preferential Procurement Policy Framework Act, 5 of 2000.
- 1.1.25 **Preferential Procurement Regulations:** The Preferential Procurement Regulations published under the PPPFA in Government Notice R32, *Government Gazette* 40553 on 20 January 2017.
- 1.1.26 **Product:** The Covid-19 vaccines as authorised for use in the Republic of South Africa by the South African Health Products Regulatory Authority (SAHPRA), and procured by the Department during the contract period.
- 1.1.27 **Related:** A relationship formed on the basis of any one or more of (i) family (including spouses and in-laws), (ii) friendship, (iii) business acquaintance, (iv) professional engagement, or (v) employment.
- 1.1.28 **Responsive Bids:** A Bid Response that the Department assesses to have met the criteria in 6.1 and 6.2 (i.e. the Administrative and Technical Evaluation).
- 1.1.29 **RFP:** This Request for Proposal document and all annexes, schedules and other appendices to it.
- 1.1.30 **Service Provider:** The name of the person or entity awarded a contract to provide the Importation and/or Logistics Services, as the case may be.
- 1.1.31 **Validation:** Establishing documented evidence, which provides a high degree of assurance that a specific packaging process performed will consistently

produce a result that meets the temperature control requirements for the cold chain solution required.

1.1.32 **VAT:** Value-added tax levied in terms of the Value-added Tax Act, 89 of 1991.

1.2 In this RFP:

1.2.1 references to a statutory provision include any subordinate legislation made from time to time under that provision and include that provision as modified or re-enacted from time to time;

1.2.2 words importing the masculine gender include the feminine and neuter genders and vice versa;

1.2.3 the singular includes the plural and vice versa;

1.2.4 natural persons include artificial persons and vice versa;

1.2.5 references to a "**person**" include a natural person, company, close corporation or any other juristic person or other corporate entity, a charity, trust, partnership, joint venture, syndicate, or any other association of persons;

1.2.6 references to a "**subsidiary**" or a "**holding company**" shall be references to a subsidiary or holding company as defined in the Companies Act;

1.2.7 any definition, wherever it appears in this RFP, shall bear the same meaning and apply throughout this RFP unless otherwise stated;

1.2.8 the rule of construction that if general words or terms are used in association with specific words or terms which are a species of a particular genus or class, the meaning of the general words or terms shall be restricted to that same class (i.e. the *eiusdem generis* rule) shall not apply, and whenever the word "*including*" is used followed by specific examples, such examples shall not be interpreted so as to limit the meaning of any word or term to the same genus or class as the examples given; and

1.2.9 unless otherwise specified, all references to any time shall be to the time of day in Johannesburg, South Africa.

1.3 The expiration or termination of this RFP shall not affect such of the provisions of this RFP which are expressly provided to operate after any such expiration or termination, or which of necessity must continue to have effect after such expiration or termination, notwithstanding that the relevant provisions themselves do not provide for this.

## 2. ABBREVIATIONS

2.1	B-BBEE	: Broad-Based Black Economic Empowerment
2.2	CD	: Compact Disk
2.3	CIPC	: Companies and Intellectual Property Commission
2.4	CIPRO	: Companies and Intellectual Property Registration Office
2.5	CPA	: Contract price adjustment
2.6	CSD	: Central Supplier Database
2.7	ERP	: Enterprise Resource Planning
2.8	FEFO	: First Expiry First Out
2.9	GCC	: General Conditions of Contract
2.10	GMP	: Good Manufacturing Practice
2.11	GWP	: Good Wholesaling Practice
2.12	KPI	: Key Performance Indicator
2.13	MHPL	: Master Health Product List
2.14	NCL	: National Control Laboratory
2.15	NDoH	: National Department of Health
2.16	POD	: Proof of Delivery
2.17	QMS	: Quality Management System
2.18	SAHPRA	: South African Health Products Regulatory Authority
2.19	SAPC	: South African Pharmacy Council
2.20	SARS	: South African Revenue Service
2.21	SBD	: Standard Bidding Document
2.22	SOP	: Standard Operating Procedure
2.23	SRCC	: Special Requirements and Conditions of Contract in this RFP

2.24 WHO : World Health Organisation

2.25 ZAR : South African Rand

### 3. INTRODUCTION

- 3.1 The rapid spread of the infectious coronavirus (SARS-CoV-2) disease has caused a global pandemic. In response to the pandemic, pharmaceutical manufacturers have developed new COVID-19 vaccines to protect against the spread of the disease. This was done within a short period of time and, as a result, these vaccines have not yet been registered with SAHPRA. In the meantime, however, the Department has, on an urgent basis, developed a COVID-19 vaccination programme which aims to promote access to safe and effective COVID-19 vaccines for all eligible members of the population on a suitably prioritised basis.
- 3.2 There are essentially four legs to the COVID-19 vaccination programme: procurement, importation, distribution and administration of the vaccines. The global demand for COVID-19 vaccines far exceeds availability, resulting in the programme's development of a phased vaccine introduction plan and multiple procurement strategies to access adequate quantities of COVID-19 vaccine to achieve the programme's desired outcome. To this end, the COVID-19 vaccination programme will make use of centralised procurement and distribution of the vaccine to the Delivery Sites. To reach the population, an increased number of accessible vaccination sites will be identified and or established. These vaccination sites may include existing public and private health establishments, occupational health sites, temporary outreach sites, community pharmacies and general practitioners.
- 3.3 At this stage, it is envisaged that most of the vaccines are to be imported. These will be stored centrally, and distributed to the Delivery Sites on instruction from the Department. Allocation to the sites will be based on equitable access to vaccines, aligned with the government's phased implementation plan that is linked to identified priority population groups.
- 3.4 Implementing the programme will require a carefully coordinated effort across public and private health sectors. Having regard to this, this RFP constitutes the formal invitation to Bidders to submit a detailed Bid Response to supply either or both Importation Services or Logistics Services in respect of one or more cold chain solutions as detailed in this document.
- 3.5 At the time of publishing this RFP, the manufacturers and other organisations with whom the Department is liaising for purposes of procuring the vaccines have not confirmed the exact volumes of the vaccines to be procured (and imported), the locations from where they will be imported or the exact timing of the importation.

- 3.6 Given these uncertainties, the Department adopts a bifurcated approach in thisRFP:
- 3.6.1 for purposes of the **Importation Services (Part A)**, the Department calls for proposals in order to establish a panel of suitably qualified Service Providers. As such, the Bidders who wish to bid for those services must demonstrate as part of their Bid Response their capability to perform the Importation Services (and the cold chain solution to which their Bid Response applies). Once a consignment of vaccines is available for importation, and depending on the cold chain solution required to transport those vaccines, panellists will be approached to furnish quotations for the Services. Bidders will, for the purposes of Incoterms, be made aware of the specific Incoterm rule, such as FOB, EX Works, CIF, etc, the place of collection of the Products and the port of destination of the Products which are applicable to the quotation, and they will need to make provision in their quotation for this. Prices therefore need not be included in the Bid Responses pertaining to the Importation Services.
- 3.6.2 for purposes of the **Logistics Services (Part B)**, the Department calls for proposals from the Bidders for the appointment of a single Service Provider to perform the Services nationwide in respect of each cold chain solution. Bidders who wish to bid for both services (i.e. the Importation, and Logistics Services) or only for the Logistics Services will therefore need to include their firm prices as part of their Bid Responses.
- 3.7 Bidders are entitled to bid for the provision of **any or all** of the Services and cold chain solutions as part of one Bid Response. The Bid Response must make it clear, however, on the covering page for which Service/s and solution/s the Bidder is bidding. Further detail on this is set out in the section on *General Requirements and Bid Rules*. Each Bid Response will be evaluated and scored separately (per Service and cold chain solution). This is because the Department will be awarding a contract, on a national basis, per service and per cold chain storage solution.
- 3.8 Bidders will, once appointed, be required to sign the applicable Agreement within two (2) days from receipt of the Award letter.
- 3.9 **Please note:** the Department estimates that the Product volumes in respect of each cold chain solution is as follows: between 2–8 °C (6 million vials), at –20°C (2 million vials) and at –70°C (4 million vials).

#### **4. STRUCTURE OF THE RFP**

4.1 For ease of reference, the structure of this RFP is as follows:

4.1.1 *Section 1: Scope of Services*

4.1.1.1 Part A: Importation Services

4.1.1.2 Part B: Logistics Services

4.1.2 *Section 2: Bid Phases*

4.1.2.1 Phase 1: Administrative Qualification

4.1.2.2 Phase 2: Technical Evaluation

4.1.2.3 Phase 3: Financial and Preference Points Adjudication

4.1.2.4 Phase 4: Contract Award

4.1.3 *Section 3: General Requirements and Bid Rules*

4.1.4 *Section 4: Special Requirements and Conditions of Contract*

4.1.5 *Annex 1: Bid Documents*

4.1.6 *Annex 2: GCC*

4.1.7 *Annex 3: Importation Services Agreement*

4.1.8 *Annex 4: Logistics Services Agreement*

## 5. SECTION 1: SCOPE OF SERVICES

### 5.1 Part A: Importation Services

- 5.1.1 Importation requires that the Product be handled and transported in accordance with international regulatory requirements, at controlled temperatures and with efficiency to ensure the quality of the Product.
- 5.1.2 The Department will procure the Products, in terms of agreements concluded with various manufacturers around the world. The Incoterms contained in the purchase agreements with manufacturers or suppliers determine the services required from Service Providers to bring the Product from country of origin to South Africa.
- 5.1.3 Subject to the applicable Incoterm rule, the Service Provider/s will be required to perform the following Importation Services in respect of the Products as detailed below.
- 5.1.3.1 Receiving from manufacturer's site of delivery in the country of Product origin.
- 5.1.3.2 Loading and transportation, including transportation to the nearest suitable international airport, loading of cargo, and international carriage via air to South Africa (the principal port of entry will be O.R. Tambo International Airport, although there might be instances when the Cape Town International Airport and/or King Shaka International Airport will be used).
- 5.1.3.3 Preparation of air cargo and export documentation, including customs clearance.
- 5.1.3.4 Transport of the Product to Distributor in South Africa.
- 5.1.3.5 Cold chain management aligned to manufacturer's recommendations throughout the process.
- 5.1.4 A quotation will be requested from all Service Providers on the panel for specified Importation Services aligned to the specific manufacturer's Incoterm rules in the contract.
- 5.1.5 The Department will provide the Service Provider with the details of the consignments to be transported to South Africa in the request for quotation.

- 5.1.6 Once a quotation is accepted by the Department and subject to the applicable Incoterm rule, an order will be given to the successful Service Provider to arrange the requisite import and export documentation, customs clearances, duties, taxes, terminal and other clearing charges. The Service Provider will, subject to the applicable Incoterm rule, be responsible for managing all import formalities for customs clearing.
- 5.1.7 The Service Provider must provide the expected Lead Time for the required mode of transport, which is air cargo.
- 5.1.8 The Service Provider will ensure that the Product is managed with the appropriate skill and expertise. Appropriate continuous temperature monitoring and shipment tracking must be provided.
- 5.1.9 The Service Provider will be responsible to ensuring secure delivery of cleared products to the warehouse or storage facility of the relevant Logistics Service Provider. This will include ensuring that appropriate transportation is used to maintain the safety and quality of the products. Appropriate security measures are to be provided to ensure safe passage of the products to the warehouse or storage facility. The Service Provider may be required to coordinate with national security and/or police services to ensure the security of the Products.
- 5.1.10 The Service Provider must provide a full detail of all clearing and transport charges for clearing air cargo at airports.
- 5.1.11 The Service Provider must have in place all required authorisations in order to import the Products.
- 5.1.12 The Service Provider may not amend an order from the Department without prior written consent.

## **5.2 Part B: Logistics Services**

- 5.2.1 Pharmaceutical distribution forms part of the supply chain responsible for effective, efficient, and safe, storage and transportation of health products, ensuring that the quality and identity of these products are maintained throughout the supply chain.
- 5.2.2 The Service Provider must be capable of providing one or more of the cold chain solutions. The Service Provider will be required to perform the following Logistics Services as detailed below.

- 5.2.3 The Service Provider is required to acknowledge receipt of all orders received from the Department, in a manner to be stipulated by the Department.
- 5.2.4 Instructions must be processed and executed as per the orders appearing on the official Department instruction document.
- 5.2.5 Changes to any quantities as per original order may only be made upon receipt of an amended order from the Department.

#### **5.2.6 Warehousing and Storage**

- 5.2.6.1 The Service Provider will be responsible for all warehousing of the Products from initial receipt until delivery to the Delivery Site/s.
- 5.2.6.2 All warehousing facilities must be appropriately licenced in terms of the Medicines Act as pharmaceutical warehouses.
- 5.2.6.3 The warehouse must have at least three zones: receiving, storage and dispatch. Recalled or damaged Products must be stored in a quarantine area.
- 5.2.6.4 The Service Provider must provide storage capacity to effectively distribute the estimated volumes, plus ten (10) per cent additional capacity, per cold chain solution forming the subject of the Bid Response.
- 5.2.6.5 The temperature of the storage areas and warehouse must be validated, controlled, monitored and recorded daily. Monitoring and recording are to be done 1) physically twice daily and manually recorded, and 2) through an electronic system daily.
- 5.2.6.6 The storage of the Products must comply with the manufacturers' specifications for the relevant Products.
- 5.2.6.7 The storage areas and warehouse, including cold chain storage, must have a backup emergency power supply to operate during power failures which must be detailed in the risk management strategy.
- 5.2.6.8 Products must be removed from the transportation container or cooler box prior to storage to prevent temperature deviation, as per the manufacturer's instructions, unless otherwise indicated, depending on the relevant cold chain solution.

## **5.2.7 Inventory management**

5.2.7.1 The Service Provider must have a qualified Enterprise Resource Planning (ERP) system for inventory management. The ERP must show all records of transactions including receipts, issue-vouchers, stock adjustments and proof of delivery. The ERP must be capable of tracking product by batch and expiry date, and manufacturing date, where applicable.

5.2.7.2 The Service Provider will implement a cycle counting program, whereby all Products are counted weekly. Stock must be counted and balanced by batch and expiry date. The Service Provider must produce a cumulative report on all count discrepancies for the preceding week, by the first working day of the following week. The report must reflect variances by Product, batch and expiry date.

5.2.7.3 A stocktake is required twice in a financial year i.e. September and March. The Service Provider must invite the Department and independent auditors to all stocktake activities.

5.2.7.4 The Service Provider will inform the Department of any other stock variances and explain any stock adjustments. The Department retains the right to authorise stock adjustments in writing.

5.2.7.5 The Service Provider will provide a signed-off stock count report, including variances, to the Department within seven (7) days of the stocktake event.

5.2.7.6 The Service Provider will provide daily reports at the end of the work day on the transactions that have taken place.

5.2.7.7 The Service Provider will provide the Department with live access to their on-line stock management systems.

## **5.2.8 Receiving**

5.2.8.1 The Service Provider must sign for receipt of the delivery by completing and stamping the delivery documentation, noting the name of the person receiving the consignment, the date and time of receipt.

5.2.8.2 The Service Provider must receive the Products in a temperature-controlled environment, conducive to maintaining the integrity of the Product.

- 5.2.8.3 Temperature data loggers, refrigeration tags, freezer tags, log tags or cold chain monitoring cards that comply with specifications as per the required cold chain solution must be checked to ensure the temperature history of the Product being received, was maintained within the appropriate limits.
- 5.2.8.4 Damage, tampering or temperature deviations must be recorded on the supplier's delivery documentation. Photographic or documentary evidence of the damage, tampering or temperature deviations must be sent to the Department together with a copy of the signed delivery documentation. These incidents must be communicated to the Department within 12 hours of receipt.
- 5.2.8.5 The Service Provider is to perform fine checks of all consignments against the delivery documentation, checking the product description, quantity, batch and expiry date. All fine check discrepancies must be reported, in writing, to the Department within 24 hours of receipt. In addition, the Service Provider is to furnish a vaccine arrival report to the Department in a format to be provided, and in accordance with a time-period to be stipulated, by the Department.
- 5.2.8.6 All Products must be received in a quarantine status pending quality assurance approval and NCL release. The Service Provider is to remove samples for quality assurance testing as per 5.2.9 below.
- 5.2.8.7 All inbound shipments must be checked and captured on the Service Provider's enterprise resource planning (ERP) system within 24 hours of receipt.
- 5.2.8.8 Risk in respect of the Products transfers to the Service Provider once the consignment has been received by that Service Provider.

## **5.2.9 Sampling for quality assurance testing**

- 5.2.9.1 Products supplied to the Service Provider will be subject to batch testing procedures before batches are available for distribution to the Delivery Sites.
- 5.2.9.2 The Department will provide details of the sample quantity per product per batch and per receipt. The Department shall provide details of the NCL where samples will be sent for testing.

- 5.2.9.3 Samples are to be packed per manufacturer instructions using validated packaging to maintain the temperature while in transit to the laboratory.
- 5.2.9.4 Samples must be delivered to the NCL within two (2) days (48 hours) of receipt by the Service Provider.
- 5.2.9.5 The Service Provider is to update the Department on the progress of the release process.
- 5.2.9.6 The designated pharmacist at the Service Provider will inform the Department once the batch has been approved for release by the NCL. At that time, the designated pharmacist may release the batch from quarantine status.
- 5.2.9.7 Batches that fail the quality assurance tests must remain in a quarantine status.

#### **5.2.10 Order management**

- 5.2.10.1 Only orders using an official, authorised format issued by the Department or Authorised Delivery Sites are valid.
- 5.2.10.2 Supply without a valid order is not permitted and the Department will not be responsible for any loss to the Service Provider and will not entertain any demand/claim relating to such supply.
- 5.2.10.3 Order(s) will be sent to the Service Provider by the Department or Authorised Delivery Sites as and when required during the contract period. An order may contain a request to deliver Products to one or more Delivery Sites.
- 5.2.10.4 The Service Provider is required to acknowledge receipt of all orders received from the Department or Authorised Delivery Sites, in a manner to be stipulated by the Department.
- 5.2.10.5 Orders must be processed and executed as per the instructions appearing on the official order document referred to in 5.2.10.1.
- 5.2.10.6 The Service Provider must liaise with the Department Authorised Delivery Site that placed the relevant order before processing an order that appears to be irrational or misaligned with previous orders per site.

5.2.10.7 The Service Provider may not amend an order without prior written consent from the Department or the Authorised Delivery Site that placed such order.

5.2.10.8 Changes to any quantities in the initial order may only be made upon receipt of an amended order from the Department or the Authorised Delivery Site that placed the initial order.

## **5.2.11 Picking and packing**

5.2.11.1 Picking instructions must be generated as per FEFO principles.

5.2.11.2 Products must be picked and packed per the manufacturers' storage and temperature requirements.

5.2.11.3 The Products should be picked in a temperature-controlled environment, conducive to maintaining the integrity of the product.

5.2.11.4 The packaging systems used for the delivery of the Products must be validated to fulfil the manufacturers' temperature requirements for the product. Validation must be performed by person/s with the necessary education, background, training, experience and qualification, as detailed in the validation programme submitted as part of this Bid Response.

5.2.11.5 Products must be packed in containers or packaging capable of maintaining the Product's storage temperature, for the duration of the trip to the delivery point and back to the Service Provider, i.e. two times the duration of the trip.

5.2.11.6 The packaging should withstand the mechanical hazards of handling and transportation, prevent leakage, and provide an appropriate level of protection from environmental conditions.

5.2.11.7 Each shipper pack or repacked container distributed by the Service Provider will carry a label with the following information:

5.2.11.7.1 Shipment, invoice or delivery note number;

5.2.11.7.2 Name of the Delivery Site;

5.2.11.7.3 Number of the carton;

5.2.11.7.4 Total number of cartons in the shipment;

- 5.2.11.7.5 Name of Product in the carton;
- 5.2.11.7.6 Quantity of the Product in the carton; and
- 5.2.11.7.7 Batch and expiry date,
- 5.2.11.8 There must be clear, visible labelling on the packaging with instructions regarding storage conditions, special precautions, and warnings.
- 5.2.11.9 The information on invoices and documents must comply with the minimum data requirements as provided, in writing, by the Department to Service Providers from time to time.
- 5.2.11.10 The Product's batch number and expiry date must appear on the invoice. The Service Provider must ensure that the batch number appearing on the unit packs tallies with the batch number shown on the invoice. Any deviation may lead to the Products not being accepted at the Delivery Site.
- 5.2.11.11 Invoices and documents (including packing slips and credit notes) must reflect both the "proprietary name" (brand name/trade name) which is unique to a particular product, and which is the name approved in terms of section 15(4) of the Medicines Act (provided the medicines have been registered), and the product description as it appears in the MHPL.
- 5.2.11.12 Deliveries which are not accompanied by the required documentation will not be accepted.

## **5.2.12 Transportation and deliveries**

- 5.2.12.1 Temperature data loggers, refrigeration tags, freezer tags or log tags that comply with the applicable WHO specifications must monitor the temperature of the loaded area of the transportation throughout the trip and the validated packaging must have at least a temperature monitoring device that complies or meets with WHO specifications.
- 5.2.12.2 The Service Provider must deliver directly to all identified Delivery Sites without compromising the quality and safety of the Products.
- 5.2.12.3 Transportation of the Products must be in such a way that it is secure and the temperature is maintained to product specifications.

- 5.2.12.4 Products must be delivered in accordance with the delivery instructions stipulated on the Department order forms.
- 5.2.12.5 Two (2) copies of the invoice must accompany the delivery and must include:
- 5.2.12.5.1 Invoice number;
  - 5.2.12.5.2 Instruction number;
  - 5.2.12.5.3 Dispatch or invoice date; and
  - 5.2.12.5.4 List of Products with quantities, batch numbers and expiry dates.
- 5.2.12.6 The maximum delivery Lead Time from receipt of the order is three (3) days. Failure to comply with the contractual Lead Time may result in penalties being enforced as set out in the SRCC, without prejudice to any other remedies available to the Department in terms of the Agreement or applicable law.
- 5.2.12.7 Should the delivery date, as per the contractual Lead-Time, fall on a Saturday, Sunday or public holiday, the delivery should be completed by no later than the next working day after the Saturday, Sunday or public holiday.
- 5.2.12.8 The Department retains the right to request urgent deliveries.
- 5.2.12.9 Vehicles used for distribution should be suitable for their purpose and appropriately equipped to prevent theft and exposure of products to conditions that will affect their stability and integrity. The condition of cartons or containers must be acceptable to the recipient at the point of delivery.
- 5.2.12.10 The Service Provider must ensure that only authorised persons receive the delivery and that a signed and stamped copy of the delivery note is available as the POD. Delivery is deemed to have occurred upon signature of receipt by the authorised person.
- 5.2.12.11 The POD and signed invoice must be scanned and stored on the Service Provider's ERP system for easy retrieval.
- 5.2.12.12 The Service Provider shall collect all packaging material post-delivery.

5.2.12.13 Discrepancies between the invoice and the physical Product, or damaged, defective, expired or otherwise unusable Products, will be reported to the Service Provider within 48 hours of delivery.

5.2.12.14 Service Providers will be responsible for collecting product delivered erroneously, or which are damaged, defective, expired or otherwise unusable within 48 hours of delivery, at the Service Provider's own cost.

### **5.2.13 Security**

5.2.13.1 The Service Provider must ensure appropriate security levels and access control to the warehouse and other storage sites under the control of the Service Provider. These must include, but not be limited to, physical and electronic security (for example, closed circuit television monitoring).

5.2.13.2 The Service Provider must ensure that all deliveries are actively tracked and monitored with an appropriate tracking system.

5.2.13.3 The Service provider should perform appropriate risk assessments to inform their decision to use armed escorts as necessary.

5.2.13.4 The Service provider may be required to coordinate with national security and/or police services to ensure the security of vaccines.

### **5.2.14 Returns**

5.2.14.1 No Product must be accepted for return from any Delivery Site unless such return is instructed in writing by the Department.

5.2.14.2 All returned Products must be accompanied by a record of the continuous cold chain maintenance and monitoring collected from the site.

5.2.14.3 All returned Products must be placed in quarantine pending instruction from the Department.

### **5.2.15 Product Recalls**

5.2.15.1 In the event of a product recall, the Service Provider must provide the Department with a report detailing the quantity of the applicable Product distributed, the Delivery Sites and the dates to which it was delivered. The report must be provided within 24 hours of the request.

5.2.15.2 The Department will meet with the Service Provider to plan any recall activities as per the manufacturers' specifications.

5.2.15.3 All recalled Products must be placed in quarantine and stored in a segregated area according to the manufacturer's specification in the Service Provider's warehouse, until such time the Department provides instructions to dispose.

## 5.2.16 Disposal

5.2.16.1 The disposal of the Product may only be initiated upon written instruction from the Department and must be done in accordance with the applicable legislation.

5.2.16.2 The Service Provider must provide the Department with a certificate of disposal within 30 calendar days.

## 5.2.17 Quality Management System (QMS)

5.2.17.1 The Service Provider must have a QMS that describes the procedures that are in place in the organisation.

5.2.17.2 The Department reserves the right to verify the existence and validity of the QMS.

5.2.17.3 The QMS must include the following areas and sections as a minimum:

Area	Sections
General	Code of conduct Anti-fraud policy Functional organisational chart
Process	Internal process quality control
Legal	Copies of all required documents
Risk management	Pharmaceutical risk management Emergency planning and prevention
Management Information Systems	Pharmaceutical supply information

Area	Sections
Administration	Contacts Keys and access management Security and guarding of premises Management of assets
Human Resources	Staff contracts and job descriptions Working conditions Hygiene and security (Safety of workplace) Training registers and records
Information Technology	Hardware installation and maintenance Software qualification, updates and daily maintenance IT security & organisation of back-up
Archiving	Paper and electronic archiving
Pharmaceutical management	Applicable norms and standards Copies of all forms and notes
Storage	Receipt merchandise Quantitative check receipt merchandise Reporting process (quantitative issues) Inventory Back-order management Customer service, the return of products Management of expired, damaged products Batch tracking Product or batch recall Quarantined stock and returned stock
Thermolabile product management	Validation certificates for packaging and storage Qualification documentation Packing protocols
Stocktake	Stocktake process Variances report and reconciliation
Transport	Transport conditions: safe & secure Delivery and supply documentation Fleet management

## 5.2.18 Reporting

- 5.2.18.1 Service Providers will be required to submit the following information in a specified format and via a mechanism to be determined by the Department:
- 5.2.18.1.1 All transactional data including quantity issued per Product, issue voucher number, batch number, expiry date and recipient.
  - 5.2.18.1.2 Status of outstanding deliveries.
  - 5.2.18.1.3 Details on receipts: supplier name, Product name, quantity, batch number and expiry date.
  - 5.2.18.1.4 Stock on hand quantity per Product, batch number, expiry date.
  - 5.2.18.1.5 Stock on hand quantity awaiting quality assurance release per Product, batch number, expiry date.
  - 5.2.18.1.6 Stock adjustment details including Product, batch, expiry, quantity and reason code.
  - 5.2.18.1.7 Quantities of obsolete Products expired, damaged or otherwise unusable.
- 5.2.18.2 The Department may, from time to time and within reason, add to the required reporting requirements of Service Providers. Any changes to reporting requirements or the reporting mechanism will be communicated in writing to Service Providers.

**6. SECTION 2: BID PHASES**

<b>Phase 1</b>	<b>Phase 2</b>	<b>Phase 3</b>	<b>Phase 4</b>
<p><u>Administrative Evaluation</u></p> <p>Bidders will be assessed for compliance with the mandatory administrative qualification criteria</p>	<p><u>Technical Evaluation</u></p> <p>Acceptable bids will be evaluated (scored) against the stipulated functionality criteria.</p> <p>Responsive Bids for the provision of the Logistics Services (scoring a minimum of 70/100 for functionality) will proceed to the Financial and Preference Points Adjudication Phase</p> <p>Responsive Bids for the provision of Importation Services (scoring 4+ for each functionality criterion) will proceed to the contract award phase</p>	<p><u>Financial and Preference Points Adjudication</u></p> <p>Responsive Bids for the provision of the Logistics Services will be adjudicated against the 90/10 Preferential Point System (price and B-BBEE)</p>	<p><u>Contract Award</u></p> <p>Successful Bidder/s for the provision of the Logistics Services will sign the Logistics Services Agreement</p> <p>Successful Bidders for the provision of Importation Services will sign the Importation Services Agreement</p>

## 6.1 Phase 1: Administrative Evaluation (Part A and Part B)

6.1.1 Bid Responses not complying with one or more of the requirements stipulated below may be deemed non-responsive and may not be considered for evaluation.

### 6.1.2 Mandatory Bid Documents

6.1.2.1 All the documents contained in the table below (collectively "**the Bid Documents**") must be submitted as a compulsory pre-qualification requirement in the Bidder's Bid Response, unless it is not applicable to the Bidder, in which case that must be specified by marking "N/A" in the checklist.

6.1.2.2 Each Bid Document must be signed, and submitted in the exact compilation sequence as contained in the tabulated checklist and in the formats stipulated in 7.10.2 below.

DOCUMENT NAME	YES	NO
<b><i>For both Parts A and B</i></b>		
SBD 1: Invitation to bid		
SBD 4: Declaration of interest		
SBD 6(1): Preference Points Claimed (B-BBEE)		
B-BBEE Status Level Verification Certificate (where preference points are claimed) (Original or Certified Copy)		
SBD 8: Declaration of Past Supply Chain Management (SCM) Practices		
SBD 9: Certificate of Independent Bid Determination		
PBD 4: Contact Details of Bidder		
PBD 8: Declaration of compliance with Special Requirements and Conditions of Contact		

DOCUMENT NAME	YES	NO
<b><i>For both Parts A and B</i></b>		
Central Supplier Database supplier number and security code		
Tax Clearances		
Registration certificate with CIPC/CIPRO and proof of ownership/shareholding		
Entity profile which includes but is not limited to: name, structure, names and identity numbers of all directors, chief operating officers and responsible pharmacist/s		
Testimonials from at least two previous contractors/clients (testimonials must relate to, amongst others, the provision of similar cold chain solutions)		
Proposed project implementation plan		
Document detailing relevant cold chain capabilities/experience, and the technical experience, roles and responsibilities of main team members		
Document detailing Importation/Logistics management processes (as applicable)		
Validation programme		
Details of communication strategy		
Details regarding information management system, monitoring and reporting requirements		

DOCUMENT NAME	YES	NO
<b><i>For both Parts A and B</i></b>		
Details of risk management strategy and template of risk management plan		
Stamped original bank rating letter with grading		
<b><i>For Part A - Importation Services</i></b>		
Certified copies of all authorisations to import and distribute medicines, and all annexures, including:		
A pharmacy premises licence issued in terms of the Pharmacy Act		
Certificates issued by SAPC for owner, responsible pharmacist, pharmacy premises and to carry on the business of a pharmacy		
Licences to act as an importer as well as a wholesaler/distributor issued in terms of the Medicines Act <b>or</b> applications that have been submitted to SAHPRA for licences to act as an importer and wholesaler/distributor		
<b><i>For Part B - Logistics Services</i></b>		
Pricing Schedule		
Declaration of compliance with Good Wholesaling Practice (GWP)		
Certified copies of all authorisations to warehouse and distribute medicines, and all annexures, including:		
A pharmacy premises licence issued in terms of the Pharmacy Act		
Certificates issued by SAPC for owner, responsible pharmacist,		

DOCUMENT NAME	YES	NO
<b><i>For both Parts A and B</i></b>		
pharmacy premises and to carry on the business of a pharmacy		
The licence to act as a wholesaler/distributor issued in terms of the Medicines Act		
Subcontracting agreements		
Proof of the Bidder having Goods in Transit and Liability insurance from a reputable insurer. Such insurance shall cover the replacement cost and cost of logistics while the Product is in the Service Providers custody Such proof must include a confirmation that the policy is not endorsed for Covid-19 related activities		

**6.2 Phase 2: Technical Evaluation**

**6.2.1 Functionality**

6.2.1.1 The Bid Response must contain sufficient information to illustrate that the Bidder is capable of providing the services to which the bid relates and sufficient information to enable the Department to make an effective comparison between bids.

6.2.1.2 All submissions should include a comprehensive explanation of any similar service provided and how the business model could be adapted (if necessary) to provide the relevant services. Examples of current practice, copies of standard operating procedures, photographs, illustrations, diagrams etc. must be provided.

6.2.1.3 The functionality of the Bid Response will be assessed separately in respect of Importation Services and Distribution Services and in respect of each cold chain solution to which the bid relates (with a particular cold chain solution in respect of Importation Services (Part A) being considered

separately from the same cold chain solution in respect of Logistics Services (Part B)). Accordingly, if a bid is submitted for both Importation and Logistics Services and for more than one cold chain solution, the information contemplated in 6.2.1.1 and 6.2.1.2 must include information in respect of each of such Services and each such cold chain solution.

*Part A – Importation Services*

6.2.1.4 For Importation Services (Part A), Bidders must score 4+ in each of the functionality criterion contained in the table below.

Criteria	Scoring Criteria
<p><b>Relevant experience</b></p> <p>Bidder to provide details of relevant cold chain capabilities and experience.</p> <p>Bidder to be assessed on the basis of:</p> <ul style="list-style-type: none"> <li>• Volume of cold chain importation per annum</li> <li>• Range of cold chain products imported</li> <li>• Cold chain importation solutions employed i.e. validated packaging, validated containers</li> <li>• Available cold chain capacity for the relevant cold chain solution forming the subject of the Bid Response, stated in number of pallet locations (pallet dimensions to be provided).</li> <li>• Years' experience.</li> <li>• Provide validation reports or certificates</li> <li>• Validation programme</li> </ul>	<p>No information = 0                      Poor = 1                      Below average = 2                      Average = 3                      Good = 4                      Excellent = 5</p>
<p><b>Proposed implementation plan</b></p> <p>Bidder to provide proposed implementation plan with indicative timelines.</p> <p>Bidder to be assessed on the basis of:</p> <ul style="list-style-type: none"> <li>• Activities in pre-project implementation phase</li> <li>• Activities during project implementation phase</li> <li>• Activities during project close out</li> <li>• Project management</li> </ul>	<p>No information = 0                      Poor = 1                      Below average = 2                      Average = 3                      Good = 4                      Excellent = 5</p>

Criteria	Scoring Criteria
<ul style="list-style-type: none"> <li>Technical experience and roles and responsibilities of main team members</li> </ul>	
<p><b>Importation management</b></p> <p>Bidder to provide details of core importation management processes.</p> <p>Bidder to be assessed on the basis of:</p> <ul style="list-style-type: none"> <li>Proposed importation/distribution management processes <ul style="list-style-type: none"> <li>Damaged stock</li> <li>Storage (interim) and transport</li> <li>Cold chain management, , including the ability to comply with the <i>Minimum Requirements for the Procurement, Storage and Distribution of Thermolabile Products as stated in the Rules relating to Good Pharmacy Practice (GPP, SAPC)</i></li> <li>Managing temperature excursion</li> </ul> </li> </ul>	<p>No information = 0</p> <p>Poor = 1</p> <p>Below average = 2</p> <p>Average = 3</p> <p>Good = 4</p> <p>Excellent = 5</p>
<p><b>Risk management</b></p> <p>Bidder to provide proposed risk management plan.</p> <p>Bidder to be assessed on the basis of:</p> <ul style="list-style-type: none"> <li>Description of risk management approach, i.e. processes, techniques, tools, and team roles and responsibilities</li> <li>Types of risk to be managed and proposed mitigation plan</li> <li>Template of plan to be used for risk management</li> </ul>	<p>No information = 0</p> <p>Poor = 1</p> <p>Below average = 2</p> <p>Average = 3</p> <p>Good = 4</p> <p>Excellent = 5</p>
<p><b>Financial stability</b></p> <p>Bidder to provide stamped original bank rating letter with grading</p>	<p>No information = 0</p> <p>Category C = 3</p> <p>Category B = 4</p> <p>Category A = 5</p>

**Part B: Logistics Services (Warehousing and Distribution)**

6.2.1.5 For Logistics Services (Part B), Bidders must achieve a minimum functionality score of 70% (70/100) to progress to Phase 3 of the evaluation.

6.2.1.6 Bidders will be scored according to the following weighted criteria:

Criteria	Weighted %	Scoring Criteria
<p><b>Relevant experience</b></p> <p>Bidder to provide details of relevant cold chain capabilities and experience.</p> <p>Bidder to be assessed on the basis of:</p> <ul style="list-style-type: none"> <li>• Volume of cold chain distribution per annum</li> <li>• Range of cold chain products distributed per solution</li> <li>• Cold chain distribution solutions employed i.e. validated packaging, validated containers</li> <li>• Available cold chain capacity for the relevant cold chain solution forming the subject of the Bid Response, stated in number of pallet locations (pallet dimensions to be provided).</li> <li>• Years' experience.</li> <li>• Provide validation reports or certificates</li> <li>• Validation programme</li> </ul>	20%	<p>No information = 0            Poor = 1            Below average = 2            Average = 3            Good = 4            Excellent = 5</p>
<p><b>Proposed implementation plan</b></p> <p>Bidder to provide proposed implementation plan with indicative timelines.</p> <p>Bidder to be assessed on the basis of:</p> <ul style="list-style-type: none"> <li>• Activities in pre-project implementation phase</li> <li>• Activities during project implementation phase</li> <li>• Activities during project close out</li> <li>• Project management</li> <li>• Technical experience and roles and responsibilities of main team members.</li> </ul>	15%	<p>No information = 0            Poor = 1            Below average = 2            Average = 3            Good = 4            Excellent = 5</p>

Criteria	Weighted %	Scoring Criteria
<p><b>Logistics management</b></p> <p>Bidder to provide details of core logistics management processes.</p> <p>Bidder to provide details of QMS (as above)</p> <p>Bidder to be assessed on the basis of:</p> <ul style="list-style-type: none"> <li>• Proposed distribution management processes <ul style="list-style-type: none"> <li>○ Ordering and receipt</li> <li>○ Stock rotation</li> <li>○ Expired/damaged stock</li> <li>○ Storage and transport</li> <li>○ Stocktake</li> <li>○ Return of stock</li> <li>○ Cold chain management, including the ability to comply with the <i>Minimum Requirements for the Procurement, Storage and Distribution of Thermolabile Products as stated in the Rules relating to Good Pharmacy Practice (GPP, SAPC)</i></li> <li>○ Managing temperature excursion</li> <li>○ Product recalls</li> </ul> </li> </ul>	25%	<p>No information = 0</p> <p>Poor = 1</p> <p>Below average = 2</p> <p>Average = 3</p> <p>Good = 4</p> <p>Excellent = 5</p>
<p><b>Information management system, monitoring and reporting requirements</b></p> <p>Bidder to provide information on:</p> <ul style="list-style-type: none"> <li>• Information management system</li> <li>• Proposed monitoring</li> <li>• Proposed reporting</li> </ul> <p>Bidder to be assessed on the basis of:</p> <ul style="list-style-type: none"> <li>• Information management systems available</li> <li>• Ability to interface or provide data to Department systems</li> <li>• Data management processes</li> <li>• Record keeping</li> </ul>	15%	<p>No information = 0</p> <p>Poor = 1</p> <p>Below average = 2</p> <p>Average = 3</p> <p>Good = 4</p> <p>Excellent = 5</p>
<p><b>Risk management</b></p> <p>Bidder to provide proposed risk management and mitigation plan.</p>	15%	<p>No information = 0</p> <p>Poor = 1</p> <p>Below average = 2</p>

Criteria	Weighted %	Scoring Criteria
Bidder to be assessed on the basis of: <ul style="list-style-type: none"> <li>• Description of risk management approach, i.e. processes, techniques, tools, and team roles and responsibilities</li> <li>• Types of risk to be managed</li> <li>• Mitigation plans for each risk identified</li> <li>• Template of plan to be used for risk management</li> <li>• Business Continuity and Disaster Recovery plan</li> </ul>		Average = 3 Good = 4 Excellent = 5
<b>Financial stability</b>  Bidder to provide stamped original bank rating letter with grading	10%	No information = 0 Category C = 5 Category B = 7 Category A = 10

## 6.2.2 Due diligence

6.2.2.1 The Department reserves the right to conduct a Bidder due diligence prior to final award or at any time during the contract period. This may include site visits to assess whether the site complies with the requirements as set out in the scope of work.

## 6.3 Phase 3: Financial and Preference Point Adjudication

6.3.1 Bids for the provision of the Logistics Services scoring 70% or more in Phase 2 (Responsive Bids) will proceed Phase 3 in accordance with the following preference points system.

6.3.2 Please note that each Service and each cold chain solution will be scored separately, and awarded separately.

### 6.3.3 Preference Points System

6.3.3.1 In terms of regulation 7 of the Preferential Procurement Regulations, responsive bids will be adjudicated by the Department on the 90/10-preference point system in terms of which points are awarded to bidders on the basis of:

6.3.3.1.1 The bid price (maximum 90 points); and

6.3.3.1.2 B-BBEE status level of contributor (maximum 10 points).

6.3.3.2 Bidders are required to complete the preference claim form (SBD 6.1), and submit their original and valid B-BBEE status level verification certificate or a certified copy thereof at the closing date and time of the bid in order to claim B-BBEE status level points.

### 6.3.3.3 Price evaluation

6.3.3.3.1 The Bidder must provide a price for each of the cold chain solutions for which a bid has been submitted:

Option 1 (2– 8°C) Price:

Option 2 (–20°C) Price

Option 3 (–70°C) Price

6.3.3.3.2 All prices must be quoted:

6.3.3.3.2.1 in ZAR;

6.3.3.3.2.2 inclusive of VAT;

6.3.3.3.2.3 per vial of the Product (regardless of size, dose and number of Delivery Sites) for the specific cold chain solution.

6.3.3.3.3 The following formula will be used to calculate the points for price:

$$P_s = 90 \times \left( 1 - \frac{P_t - P_{\min}}{P_{\min}} \right)$$

Where:

$P_s$  = Points scored for comparative price of bid under consideration

$P_t$  = Comparative price of bid under consideration

$P_{\min}$  = Comparative price of lowest acceptable bid



# health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA

**HP17-2021TWDV:  
THE PROVISION OF PHARMACEUTICAL TRANSPORT, WAREHOUSING AND  
DISTRIBUTION SERVICES FOR COVID-19 VACCINES**

**PRICING SCHEDULE**

**PART B:**

LOGISTICS SERVICES	PRICE PER VIAL (IN RANDES INC VAT)
Option 1 2-8°C	
Option 2 -20°C	
Option 3 -70°C	

### 6.3.3.4 B-BBEE point allocation

6.3.3.4.1 A maximum of 10 points may be allocated to a Bidder for their B-BBEE status level of contributor in accordance with the table below (where such level is claimed and proof is submitted):

B-BBEE Status Level of Contributor	Number of Points
1	10
2	9
3	6
4	5
5	4
6	3
7	2
8	1
0	Non-compliant contributor

6.3.3.4.2 Only Bidders who have completed and signed the declaration part of the preference claim form and who have submitted a B-BBEE status level certificate issued by a registered auditor, accounting officer (as contemplated in section 60(4) of the Close Corporation Act, 1984 (Act No. 69 of 1984)) or an accredited verification agency will be considered for preference points.

6.3.3.4.3 If the bidder fails to comply with paragraph 6.3.3.4.2 above, the bidder will be deemed not to have claimed preference points for B-BBEE status level of contribution and will therefore be allocated a zero (0). The Department may, before a bid is adjudicated or at any time, require a Bidder to substantiate claims it has made with regards to preference.

### 6.3.3.5 Total points

6.3.3.5.1 The points scored by a Bidder in respect of the level of B-BBEE contribution will be added to the points scored for price.

6.3.3.5.2 The points scored will be rounded off to the nearest two (2) decimals.

6.3.3.5.3 Subject to regulation 7(9) of the Preferential Procurement

Regulations, the contract will be awarded to the Bidder scoring the highest number of points.

- 6.3.3.5.4 In the event that two (2) or more bids have scored equal total points, the contract will be awarded to the Bidder scoring the highest number of preference points for B-BBEE. If functionality is part of the evaluation process and two (2) or more tenders score equal total points and equal preference points for B-BBEE, the contract will be awarded to the Bidder that scored the highest points for functionality.
- 6.3.3.5.5 Should two or more bids be equal in all respects, the award shall be decided by the drawing of lots.
- 6.3.3.5.6 A contract may be awarded to a Bidder that did not score the highest number of points if the Department is not satisfied that the Bidder which did score the most points on more than one Service or cold chain solution has the capacity to perform under each of the Services and cold chain solutions, simultaneously.

#### **6.3.4 Phase 4: Contract Award**

##### **6.3.4.1 Contract Award for Importation Services (Part A)**

- 6.3.4.1.1 Bidders who submitted Responsive Bids in respect of one or more cold chain solutions for Importation Services will be preferred Bidders and will be placed on a panel of Service Providers in respect of those cold chain solutions if they enter into the Importation Services Agreement within a period of two (2) days after being notified that they are a preferred Bidder. If a Bidder is appointed as the preferred Bidder in respect of more than one cold chain solution, it must enter into a single Importation Services Agreement which covers all such cold chain solutions.
- 6.3.4.1.2 When the Department requires Products to be imported from time to time, it will approach the panel for written quotations in respect of the relevant cold chain solution.
- 6.3.4.1.3 The written quotations of those panellists who are able to provide the Importation Services in respect of the relevant Products within the requisite time frame, will then be assessed using the formula set out above in 6.3.3 for price and B-BBEE.

6.3.4.1.4 The order will be placed, in writing, with the panellist that scores the most points in accordance with the points system set out in 6.3.3.

6.3.4.1.5 If the preferred Bidder with whom the order is placed in terms of 6.3.4.1.4 does not execute the order timeously, the Department may, in its sole discretion, withdraw the order and place it with the panellist that scored the second most points in accordance with the points system set out in 6.3.3.

#### **6.3.4.2 Contract Award for Logistics Services (Part B)**

6.3.4.2.1 The contract in respect of each cold chain solution for the Logistics Services (i.e. the Logistics Services Agreement) will be awarded on a national basis.

6.3.4.2.2 The Department reserves the right to appoint a preferred Bidder and a reserve Bidder per cold chain solution.

6.3.4.2.3 The preferred Bidder/s will be notified of the award by means of an Award Letter issued by the Department.

6.3.4.2.4 Pursuant to making of the award, and within two (2) days thereof, the preferred Bidder/s must enter into the Logistics Services Agreement. If a Bidder is appointed as the preferred Bidder in respect of more than one cold chain solution, it must enter into a single Logistics Services Agreement which covers all such cold chain solutions.

6.3.4.2.5 If, for whatever reason, it transpires that the preferred Bidder does not, in the reasonable discretion of the Department, have the capacity to perform the relevant Services in full (i.e. in respect of the volumes contemplated in the each cold chain solution in respect of which that Bidder was the preferred Bidder), the reserve bidder will, by means of a Reserve Award Letter, be notified of the contract award to that bidder in respect of one or more cold chain solutions as determined by the Department.

6.3.4.2.6 Pursuant to making of the award contemplated in 6.3.4.2.5, and within two (2) days thereof, the reserve Bidder must enter into the Logistics Services Agreement in respect of the relevant cold chain solutions.

## 7. SECTION 3: GENERAL REQUIREMENTS AND BID RULES

### 7.1 General bid rules

7.1.1 The RFP is open to the general public.

7.1.2 The Department may seek advice from suitably qualified experts in the evaluation of the bid.

7.1.3 The Department reserves the right not to make an award.

### 7.2 Non-Eligible Persons

7.2.1 Bid Responses will only be considered by the Department, in its sole discretion, if the Bidder submitting the relevant Bid Response has the necessary expertise and relevant experience, and specifically if the Bidder satisfies the minimum requirements specified in *Administrative and Technical Evaluations* sections of this RFP.

7.2.2 Bidders are required to declare if any individual who is a director, officer, employee or shareholder of the Bidder is or is Related to any employee of the Department by completing and submitting SBD 8 (*Declaration of Interest Form*) annexed to this RFP.

7.2.3 If any Bidder includes in its Bid Response the involvement of any person:

7.2.3.1 blacklisted by the office of National Treasury; or

7.2.3.2 blacklisted by such person's professional body (if applicable); or

7.2.3.3 who is or who is Related to any employee of the Department; or

7.2.3.4 who is or who is Related to any other Government official or person directly involved in the Covid-19 vaccination programme, who may be involved or have been involved with the evaluation of the Bid Responses and, any person with the ability to influence or to have influenced the decision of the Department with respect to the appointment of Preferred Bidders; or

7.2.3.5 who or which has been found guilty in a court of law of fraud or corruption-related crimes,

such Bidder may, in the sole discretion of the Department, be disqualified by the Department.

## **7.5 No Collusion**

7.5.1 The attention of each of the Bidders, as well as their advisors and agents is drawn to Section 4(1)(b)(iii) of the Competition Act, 89 of 1998, which prohibits collusive bidding.

7.5.2 In submitting a Bid Response, each of the Bidders and all other participants in any Bid Response certifies that:

7.5.2.1 its Bid Response has been prepared without consultation, communication or agreement for restricting competition with any other Bidder or participant in another Bid Response, or any other competitor or potential competitor;

7.5.2.2 its Bid Response has not been disclosed, nor will it be disclosed to any other Bidder or participant in another Bid Response, or any competitor or potential competitor;

7.5.2.3 no attempt has been made or will be made by it to induce any other person not to submit or participate in a Bid Response for the purpose of restricting competition; and

7.5.2.4 no attempt has been made or will be made by it to induce any other person to alter the form or contents of its participation in any Bid Response for the purpose of restricting competition.

7.5.3 If the Department becomes aware of or is of the opinion that any of the activities detailed in clause 7.5.2 have been undertaken by any Bidder, the Department shall be entitled to disqualify such Bidder.

## **7.6 Fronting**

7.6.1 The Department supports the spirit of B-BBEE and recognises the real empowerment can only be achieved through individuals and businesses conducting themselves in accordance with the Constitution and in an honest, fair, equitable, transparent and legally compliant manner. Against this background, the Department condemns any form of fronting.

- 7.6.2 The Department in ensuring that bidders conduct themselves in an honest manner will, as part of the bid evaluation processes, conduct or initiate then necessary enquiries/investigations to determine the accuracy of the representation made in bid documents. Should any of the fronting indicators as contained in the Guidelines on Complex Structures and Transactions and Fronting, issued by the Department of Trade and Industry, be established during such enquiry/investigation, the onus will be on the Bidder to prove that fronting does not exist. Failure to do so within a period of fourteen (14) days from the date of notification may invalidate the bid / Agreement and may also result in the restriction of the Bidder to conduct business with the public sector for the period not exceeding ten (10) years, in addition to any other remedies the Department may have against the Bidder concerned.

## **7.7 Contact policy**

- 7.7.1 The Department will communicate on matters related to the RFP with the person identified in SBD 1 as the person appointed by the Bidder to undertake all contact with the Department.
- 7.7.2 Any Bidder may only communicate with the Department through such person/s and the Department shall be entitled, at its sole discretion, to disregard any communication from a Bidder, that does not come from such contactperson/s.
- 7.7.3 All queries and requests for clarification in respect of this RFP are to be addressed, in writing, to the following email: tenders@health.gov.za.

## **7.8 Time for requests and clarifications**

The Bidder may request clarification on any item contained within this RFP by no later than five (5) days before the bid closing date (Bid closing date being: 22 February 2021).

## **7.9 Requests and responses to requests**

- 7.9.1 All requests and queries from Bidders must be in writing sent to the email referred to in 7.7.3. Oral requests and queries will not be entertained and will not receive a response.
- 7.9.2 The Department will endeavour in good faith to respond to all reasonable written queries and requests for clarification raised by the Bidders by email distributed to the Bidder and published by way of a Briefing Note on the Department's website. In general, all such written queries and responses will be published by

way of a Briefing Note on the Department's website. The Department reserves the right not to answer or respond to any particular question, query or request.

7.9.3 No response given to a question or request for clarification will not have any status or impact on the RFP, save to the extent that such response is subsequently reflected in Briefing Notes to the RFP.

7.9.4 It is the responsibility of a Bidder to identify in its queries or requests for clarification which information it deems to be confidential to its Bid Response and which it does not wish to have communicated to other Bidders, and the Bidder must give written grounds for requesting such information be treated as confidential. The Bidder's attention is drawn to the requirements of the Constitution of the Republic of South Africa, 1996; the PFMA; the Promotion of Access to Information Act, 2 of 2000 and the Promotion of Administrative Justice Act, 3 of 2000, all of which are relevant to the determination whether the Department shall be entitled to respect the Bidder's request for confidentiality.

## **7.10 Single Bid Response**

A Bidder is entitled to submit one Bid Response for either or both the Importation and the Logistics Services, and in respect of one or more of the cold chain storage solutions. The Bid Response must clearly indicate which aspect of the Services is being offered as well as the relevant cold chain solution/s.

### **7.10.1 Subcontracting**

7.10.1.1 Bidders bidding for the provision of Logistics Services are required to stipulate the following where any subcontractor relationship will be entered into for the delivery of any component of the Services:

7.10.1.1.1 Description of the goods and/or services to be provided by the subcontractor;

7.10.1.1.2 The registered name of the subcontractor;

7.10.1.1.3 The B-BBEE contributor level of the subcontractor, incl. whether they are a Qualifying Small Enterprises (QSE) or Exempted Micro Enterprise (EME), or whether this is not applicable (N/A).

7.10.1.2 Bidders bidding for the provision of Logistics Services are required to include copies of the applicable subcontracting agreement as part of their Bid Response. Bidders may not subcontract any aspect of the Logistics

Services without prior approval from the Department for the subcontracting arrangement.

- 7.10.1.3 Bidders appointed to the panel for the provision of Importation Services will be required to furnish details as set out in the Importation Services Agreement if they intend subcontracting any aspect of the Importation Services (and will require prior approval from the Department for the subcontracting arrangement).

## 7.10.2 Registration on Central Supplier Database

- 7.10.2.1 It is a compulsory requirement that all bidders are registered on the Central Supplier Database (CSD) managed by National Treasury at the closing time of the bid (date and hour specified in the bidding documents). Suppliers must provide the unique supplier number and security code allocated to them as part of the bid document.

- 7.10.2.2 For information regarding registration on the CSD, go to [www.csd.gov.za](http://www.csd.gov.za).

## 7.11 Format and copies of Bid Response

- 7.11.1 Bidders must submit **three (3)** sets of the entire Bid Response according to the following instructions:

- 7.11.2 **Set 1:** Hard copy (constitutes the legally binding bid document)

- 7.11.2.1 All SBD and Bid Response forms must be completed in black typescript. All fields must be completed. Where no electronic entry field is provided, bidders must complete the forms in black ink, handwritten in capital letters. Where information as requested is not relevant, this should be indicated with N/A. After completion, the full PDF document and the Bid Response document must be printed. Bidders must submit their complete bid in hard copy format (paper document).

- 7.11.2.2 The duly authorised designee of the entity submitting the bid must attach his/her official signature where indicated on the documents. All pages in the bid submission must be initialled by the same person with black ink. The use of correction fluid is not acceptable. Any change/s must be clearly indicated and initialled. Where certified copies of documents are required, the person certifying such documents must not be associated with the bidder in any way.

- 7.11.2.3 The signed hard copy of the Bid Response will serve as the legal bid document.
- 7.11.3 **Set 2:** Scanned version of Set 1. (i.e. scanned complete hard copy)
- 7.11.3.1 Bidders **must** submit a PDF version of the entire signed hardcopy bid, including all certificates and documents requested.
- 7.11.4 **Set 3:** Electronic version of bid documents
- 7.11.4.1 Bidders **must** submit the electronic versions of all bidding documents to facilitate data extraction. The PDF document must be submitted as editable PDF
- 7.11.5 Set 2 and Set 3 must be included on a CD and submitted in a **sealed** package with Set 1. The full name and address of the bidder, the bid number and the closing date of the bid must be clearly indicated on the package.
- 7.11.6 All three (3) sets of Bid Responses must be submitted before the closing time of the bid (22 February 2021 at 11H00).
- 7.11.7 Each copy of the Bid Response and all the documents contained therein, whether in hard or soft copy form, must be:
- 7.11.7.1 provided and compiled in accordance with the order set out in the table at 6.1.2 of the RFP;
- 7.11.7.2 complete, comprehensive, clear and legible (and in relation to the soft copies, readable and capable of being opened); and
- 7.11.7.3 identical to and consistent with all other copies of the Bid Response.
- 7.12 Submission of Bid Response and Extension of Bid Submission Date**
- 7.12.1 Bid Responses are to be submitted by 22 February 2021 by 11H00 at the address set out in SBD 1.
- 7.12.2 The Department may, in its sole discretion, extend the Bid Submission Date by publication on the Department's website.

**7.13 Late Submissions**

Bid Responses reaching the Department later than the specified cut-off time on the original or extended Bid Submission Date (as the case may be) may, in the Department's sole discretion, be rejected without further consideration.

**7.14 Changes to Bid Response**

No change is permitted by a Bidder to any aspect of a Bid Response after submission of a Bid Response.

**7.15 Bid Validity**

All Bid Responses constitute an irrevocable binding offer by the Bidder to the Department. Bid Responses must remain valid and binding for 120 calendar days from the relevant Bid Submission Date.

**7.16 Extension of Bid Validity Period**

If the Department requests the Bidder to extend the Bid Validity Period of its Bid Response for any reason, the Bidder must issue its response to the Department in writing within the time-period specified in the applicable letter of request from the Department.

**7.17 Opening of Bid Responses**

The Department will open the Bid Responses after the relevant Bid Submission Date following receipt of the Bid Responses.

**7.18 Bid Response Rejection**

The Department shall be entitled to accept or reject any Bid Response or to waive any failure to comply with the requirements set out in this RFP at any time.

**7.19 Disqualification**

Any material failure on the part of a Bidder to comply with any of the terms of this RFP may result in the Bidder, and other persons associated in any relevant way with the Bidder, being disqualified from participating in the bidprocess.

**7.20 Due diligence**

The Department reserves the right to conduct supplier due diligence prior to final award or at any time during the contract period. This may include site visits

**7.21 Price negotiations**

The Department reserves the right to conduct price negotiations, where deemed necessary.

**8. SECTION 4: SPECIAL REQUIREMENTS AND CONDITIONS OF CONTRACT**

- 8.1 This RFP and the Agreements will be subject to the Medicines Act and the Pharmacy Act.
- 8.2 The SRCC and the Agreements are supplementary to the General Conditions of Contract (GCC) issued in accordance with Treasury Regulation 16A published in terms of the PFMA. Where, however, the SRCC or the Agreement(s) is/are in conflict with the GCC, the SRCC or the Agreement(s) shall prevail.
- 8.3 The SRCC attaching to the contract are set out in the non-negotiable Agreements (annexed to this RFP). In the event of a conflict, the relevant Agreement prevails over the GCC.

# **Annexure 1**

## **Standard Bidding Documents**

## PART A INVITATION TO BID

<b>YOU ARE HEREBY INVITED TO BID FOR REQUIREMENTS OF THE (NAME OF DEPARTMENT/ PUBLIC ENTITY)</b>					
BID NUMBER:	HP17-2021TWDV	CLOSING DATE:	22 FEBRUARY 2021	CLOSING TIME:	11:00
DESCRIPTION	THE PROVISION OF PHARMACEUTICAL TRANSPORT, WAREHOUSING AND DISTRIBUTION SERVICES FOR COVID-19 VACCINES				
<b>BID RESPONSE DOCUMENTS MAY BE DEPOSITED IN THE BID BOX SITUATED AT (STREET ADDRESS)</b>					
NATIONAL DEPARTMENT OF HEALTH					
CIVITAS BUILDING- MAIN ENTRANCE IN THABO SEHUME STREET					
LARGE BROWN WOODEN TENDER BOX ONLY. DO NOT USE THE SMALLER GREEN BOX					
CIVITAS RECEPTION AREA					
<b>BIDDING PROCEDURE ENQUIRIES MAY BE DIRECTED TO</b>			<b>TECHNICAL ENQUIRIES MAY BE DIRECTED TO:</b>		
CONTACT PERSON		CONTACT PERSON			
TELEPHONE NUMBER		TELEPHONE NUMBER			
FACSIMILE NUMBER		FACSIMILE NUMBER			
E-MAIL ADDRESS	tenders@health.gov.za	E-MAIL ADDRESS		tenders@health.gov.za	
<b>SUPPLIER INFORMATION</b>					
NAME OF BIDDER					
POSTAL ADDRESS					
STREET ADDRESS					
TELEPHONE NUMBER	CODE		NUMBER		
CELLPHONE NUMBER					
FACSIMILE NUMBER	CODE		NUMBER		
E-MAIL ADDRESS					
VAT REGISTRATION NUMBER					
SUPPLIER COMPLIANCE STATUS	TAX COMPLIANCE SYSTEM PIN:		OR	CENTRAL SUPPLIER DATABASE No:	MAAA
B-BBEE STATUS LEVEL VERIFICATION CERTIFICATE	TICK APPLICABLE BOX]		B-BBEE STATUS LEVEL SWORN AFFIDAVIT	[TICK APPLICABLEBOX]	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No		<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>[A B-BBEE STATUS LEVEL VERIFICATION CERTIFICATE/ SWORN AFFIDAVIT (FOR EMES &amp; QSEs) MUST BE SUBMITTED IN ORDER TO QUALIFY FOR PREFERENCE POINTS FOR B-BBEE]</b>					
ARE YOU THE ACCREDITED REPRESENTATIVE IN SOUTH AFRICA FOR THE GOODS /SERVICES /WORKS OFFERED?	<input type="checkbox"/> Yes <input type="checkbox"/> No [IF YES ENCLOSE PROOF]		ARE YOU A FOREIGN BASED SUPPLIER FOR THE GOODS /SERVICES /WORKS OFFERED?	<input type="checkbox"/> Yes <input type="checkbox"/> No [IF YES, ANSWER THE QUESTIONNAIRE BELOW ]	
<b>QUESTIONNAIRE TO BIDDING FOREIGN SUPPLIERS</b>					
IS THE ENTITY A RESIDENT OF THE REPUBLIC OF SOUTH AFRICA (RSA)?				<input type="checkbox"/> YES <input type="checkbox"/> NO	
DOES THE ENTITY HAVE A BRANCH IN THE RSA?				<input type="checkbox"/> YES <input type="checkbox"/> NO	
DOES THE ENTITY HAVE A PERMANENT ESTABLISHMENT IN THE RSA?				<input type="checkbox"/> YES <input type="checkbox"/> NO	
DOES THE ENTITY HAVE ANY SOURCE OF INCOME IN THE RSA?				<input type="checkbox"/> YES <input type="checkbox"/> NO	
IS THE ENTITY LIABLE IN THE RSA FOR ANY FORM OF TAXATION?				<input type="checkbox"/> YES <input type="checkbox"/> NO	
<b>IF THE ANSWER IS "NO" TO ALL OF THE ABOVE, THEN IT IS NOT A REQUIREMENT TO REGISTER FOR A TAX COMPLIANCE STATUS SYSTEM PIN CODE FROM THE SOUTH AFRICAN REVENUE SERVICE (SARS) AND IF NOT REGISTER AS PER 2.3 BELOW.</b>					

Bidder Signature \_\_\_\_\_ Date \_\_\_\_\_

## PART B TERMS AND CONDITIONS FOR BIDDING

<b>1. BID SUBMISSION:</b>
<p>1.1. BIDS MUST BE DELIVERED BY THE STIPULATED TIME TO THE CORRECT ADDRESS. LATE BIDS WILL NOT BE ACCEPTED FOR CONSIDERATION.</p> <p>1.2. <b>ALL BIDS MUST BE SUBMITTED ON THE OFFICIAL FORMS PROVIDED--(NOT TO BE RE-TYPED) OR IN THE MANNER PRESCRIBED IN THE BID DOCUMENT.</b></p> <p>1.3. THIS BID IS SUBJECT TO THE PREFERENTIAL PROCUREMENT POLICY FRAMEWORK ACT, 2000 AND THE PREFERENTIAL PROCUREMENT REGULATIONS, 2017, THE GENERAL CONDITIONS OF CONTRACT (GCC) AND, IF APPLICABLE, ANY OTHER SPECIAL CONDITIONS OF CONTRACT.</p> <p>1.4. <b>THE SUCCESSFUL BIDDER WILL BE REQUIRED TO FILL IN AND SIGN A WRITTEN CONTRACT FORM(SBD7).</b></p>

<b>2. TAX COMPLIANCE REQUIREMENTS</b>
<p>2.1 BIDDERS MUST ENSURE COMPLIANCE WITH THEIR TAX OBLIGATIONS.</p> <p>2.2 BIDDERS ARE REQUIRED TO SUBMIT THEIR UNIQUE PERSONAL IDENTIFICATION NUMBER (PIN) ISSUED BY SARS TO ENABLE THE ORGAN OF STATE TO VERIFY THE TAXPAYER'S PROFILE AND TAX STATUS.</p> <p>2.3 APPLICATION FOR TAX COMPLIANCE STATUS (TCS) PIN MAY BE MADE VIA E-FILING THROUGH THE SARS WEBSITE WWW.SARS.GOV.ZA.</p> <p>2.4 BIDDERS MAY ALSO SUBMIT A PRINTED TCS CERTIFICATE TOGETHER WITH THE BID.</p> <p>2.5 IN BIDS WHERE CONSORTIA / JOINT VENTURES / SUB-CONTRACTORS ARE INVOLVED, EACH PARTY MUST SUBMIT A SEPARATE TCS CERTIFICATE / PIN / CSD NUMBER.</p> <p>2.6 WHERE NO TCS PIN IS AVAILABLE BUT THE BIDDER IS REGISTERED ON THE CENTRAL SUPPLIER DATABASE (CSD), A CSD NUMBER MUST BE PROVIDED.</p> <p>2.7 NO BIDS WILL BE CONSIDERED FROM PERSONS IN THE SERVICE OF THE STATE, COMPANIES WITH DIRECTORS WHO ARE PERSONS IN THE SERVICE OF THE STATE, OR CLOSE CORPORATIONS WITH MEMBERS PERSONS IN THE SERVICE OF THE STATE."</p>

**NB: FAILURE TO PROVIDE / OR COMPLY WITH ANY OF THE ABOVE PARTICULARS MAY RENDER THE BID INVALID.**

SIGNATURE OF BIDDER: .....

CAPACITY UNDER WHICH THIS BID IS SIGNED: .....

(Proof of authority must be submitted e.g. company resolution)

DATE: .....

## SBD 4

### DECLARATION OF INTEREST

1. Any legal person, including persons employed by the state<sup>1</sup>, or persons having a kinship with persons employed by the state, including a blood relationship, may make an offer or offers in terms of this invitation to bid (includes a price quotation, advertised competitive bid, limited bid or proposal). In view of possible allegations of favouritism, should the resulting bid, or part thereof, be awarded to persons employed by the state, or to persons connected with or related to them, it is required that the bidder or his/her authorised representative declare his/her position in relation to the evaluating/adjudicating authority where-

- the bidder is employed by the state; and/or
- the legal person on whose behalf the bidding document is signed, has a relationship with persons/a person who are/is involved in the evaluation and or adjudication of the bid(s), or where it is known that such a relationship exists between the person or persons for or on whose behalf the declarant acts and persons who are involved with the evaluation and or adjudication of the bid.

**2. In order to give effect to the above, the following questionnaire must be completed and submitted with the bid.**

2.1 Full Name of bidder or his or her representative: .....

2.2 Identity Number: .....

2.3 Position occupied in the Company (director, trustee,shareholder<sup>2</sup>): .....

2.4 Company Registration Number: .....

2.5 Tax Reference Number: .....

2.6 VAT Registration Number: .....

2.6.1 The names of all directors / trustees / shareholders / members, their individual identity numbers, tax reference numbers and, if applicable, employee / persal numbers must be indicated in paragraph 3 below.

<sup>1</sup>“State” means –

- (a) any national or provincial department, national or provincial public entity or constitutional institution within the meaning of the Public Finance Management Act, 1999 (Act No. 1 of 1999);
- (b) any municipality or municipal entity;
- (c) provincial legislature;
- (d) national Assembly or the national Council of provinces; or
- (e) Parliament.

<sup>2</sup>“Shareholder” means a person who owns shares in the company and is actively involved in the management of the enterprise or business and exercises control over the enterprise.

### SBD 4

2.7 Are you or any person connected with the bidder presently employed by the state? **YES / NO**

2.7.1 If so, furnish the following particulars:

Name of person / director / trustee / shareholder/ member: .....  
Name of state institution at which you or the person connected to the bidder is employed : .....  
Position occupied in the state institution: .....

Any other particulars:  
.....  
.....  
.....

2.7.2 If you are presently employed by the state, did you obtain the appropriate authority to undertake remunerative work outside employment in the public sector? **YES / NO**

2.7.2.1 If yes, did you attached proof of such authority to the bid document? **YES / NO**

(Note: Failure to submit proof of such authority, where applicable, may result in the disqualification of the bid.

2.7.2.2 If no, furnish reasons for non-submission of such proof:

.....  
.....  
.....

2.8 Did you or your spouse, or any of the company's directors / trustees / shareholders / members or their spouses conduct business with the state in the previous twelve months? **YES / NO**

2.8.1 If so, furnish particulars:

.....  
.....  
.....

2.9 Do you, or any person connected with the bidder, have any relationship (family, friend, other) with a person employed by the state and who may be involved with the evaluation and or adjudication of this bid? **YES / NO**

### SBD 4

2.9.1 If so, furnish particulars.

.....  
 .....  
 .....

**2.10** Are you, or any person connected with the bidder, **YES/NO**  
 aware of any relationship (family, friend, other) between  
 any other bidder and any person employed by the state  
 who may be involved with the evaluation and or adjudication  
 of this bid?

**2.10.1** If so, furnish particulars.  
 .....  
 .....  
 .....

**2.11** Do you or any of the directors / trustees / shareholders / members **YES/NO**  
 of the company have any interest in any other related companies  
 whether or not they are bidding for this contract?

2.11.1 If so, furnish particulars:  
 .....  
 .....  
 .....

**3 Full details of directors / trustees / members / shareholders.**

Full Name	Identity Number	Personal Tax Reference Number	State Employee Number / Persal Number

# SBD 4

## 4 DECLARATION

I, THE UNDERSIGNED (NAME).....

CERTIFY THAT THE INFORMATION FURNISHED IN PARAGRAPHS 2 and 3 ABOVE IS CORRECT. I ACCEPT THAT THE STATE MAY REJECT THE BID OR ACT AGAINST ME IN TERMS OF PARAGRAPH 23 OF THE GENERAL CONDITIONS OF CONTRACT SHOULD THIS DECLARATION PROVE TO BE FALSE.

.....  
Signature

.....  
Date

.....  
Position

.....  
Name of bidder

**SBD 6.1****PREFERENCE POINTS CLAIM FORM IN TERMS OF THE PREFERENTIAL  
PROCUREMENT REGULATIONS 2017**

This preference form must form part of all bids invited. It contains general information and serves as a claim form for preference points for Broad-Based Black Economic Empowerment (B-BBEE) Status Level of Contribution

**NB: BEFORE COMPLETING THIS FORM, BIDDERS MUST STUDY THE GENERAL CONDITIONS, DEFINITIONS AND DIRECTIVES APPLICABLE IN RESPECT OF B-BBEE, AS PRESCRIBED IN THE PREFERENTIAL PROCUREMENT REGULATIONS, 2017.**

**1. GENERAL CONDITIONS**

1.1 The following preference point systems are applicable to all bids:

- the 80/20 system for requirements with a Rand value of up to R50 000 000 (all applicable taxes included); and
- the 90/10 system for requirements with a Rand value above R50 000 000 (all applicable taxes included).

1.2

- a) The value of this bid is estimated to exceed ~~not exceed~~ R50 000 000 (all applicable taxes included) and therefore the 90/10. preference point system shall be applicable; or
- b) Either the 80/20 or 90/10 preference point system will be applicable to this tender (*delete whichever is not applicable for this tender*).

1.3 Points for this bid shall be awarded for:

- (a) Price; and
- (b) B-BBEE Status Level of Contributor.

1.4 The maximum points for this bid are allocated as follows:

	POINTS
<b>PRICE</b>	90
<b>B-BBEE STATUS LEVEL OF CONTRIBUTOR</b>	10
<b>Total points for Price and B-BBEE must not exceed</b>	<b>100</b>

1.5 Failure on the part of a bidder to submit proof of B-BBEE Status level of contributor together with the bid, will be interpreted to mean that preference points for B-BBEE status level of contribution are not claimed.

1.6 The purchaser reserves the right to require of a bidder, either before a bid is adjudicated or at any time subsequently, to substantiate any claim in regard to preferences, in any manner required by the purchaser.

## 2. DEFINITIONS

- (a) **“B-BBEE”** means broad-based black economic empowerment as defined in section 1 of the Broad-Based Black Economic Empowerment Act;
- (b) **“B-BBEE status level of contributor”** means the B-BBEE status of an entity in terms of a code of good practice on black economic empowerment, issued in terms of section 9(1) of the Broad-Based Black Economic Empowerment Act;
- (c) **“bid”** means a written offer in a prescribed or stipulated form in response to an invitation by an organ of state for the provision of goods or services, through price quotations, advertised competitive bidding processes or proposals;
- (d) **“Broad-Based Black Economic Empowerment Act”** means the Broad-Based Black Economic Empowerment Act, 2003 (Act No. 53 of 2003);
- (e) **“EME”** means an Exempted Micro Enterprise in terms of a code of good practice on black economic empowerment issued in terms of section 9 (1) of the Broad-Based Black Economic Empowerment Act;
- (f) **“functionality”** means the ability of a tenderer to provide goods or services in accordance with specifications as set out in the tender documents.
- (g) **“prices”** includes all applicable taxes less all unconditional discounts;
- (h) **“proof of B-BBEE status level of contributor”** means:
- 1) B-BBEE Status level certificate issued by an authorized body or person;
  - 2) A sworn affidavit as prescribed by the B-BBEE Codes of Good Practice;
  - 3) Any other requirement prescribed in terms of the B-BBEE Act;
- (i) **“QSE”** means a qualifying small business enterprise in terms of a code of good practice on black economic empowerment issued in terms of section 9 (1) of the Broad-Based Black Economic Empowerment Act;
- (j) **“rand value”** means the total estimated value of a contract in Rand, calculated at the time of bid invitation, and includes all applicable taxes;

## 3. POINTS AWARDED FOR PRICE

### 3.1 THE 80/20 OR 90/10 PREFERENCE POINT SYSTEMS

A maximum of 80 or 90 points is allocated for price on the following basis:

$$P_s = 80 \left( 1 - \frac{P_t - P_{\min}}{P_{\min}} \right) \quad \text{or} \quad P_s = 90 \left( 1 - \frac{P_t - P_{\min}}{P_{\min}} \right)$$

Where

$P_s$  = Points scored for price of bid under consideration

$P_t$  = Price of bid under consideration

$P_{\min}$  = Price of lowest acceptable bid

## 4. POINTS AWARDED FOR B-BBEE STATUS LEVEL OF CONTRIBUTOR

- 4.1 In terms of Regulation 6 (2) and 7 (2) of the Preferential Procurement Regulations, preference points must be awarded to a bidder for attaining the B-BBEE status level of contribution in accordance with the table below:

B-BBEE Status Level of Contributor	Number of points (90/10 system)	Number of points (80/20 system)
1	10	20
2	9	18
3	6	14
4	5	12
5	4	8
6	3	6
7	2	4
8	1	2
Non-compliant contributor	0	0

**5. BID DECLARATION**

5.1 Bidders who claim points in respect of B-BBEE Status Level of Contribution must complete the following:

**6. B-BBEE STATUS LEVEL OF CONTRIBUTOR CLAIMED IN TERMS OF PARAGRAPHS 1.4 AND 4.1**

6.1 B-BBEE Status Level of Contributor: . = .....(maximum of 10 or 20 points)  
 (Points claimed in respect of paragraph 7.1 must be in accordance with the table reflected in paragraph 4.1 and must be substantiated by relevant proof of B-BBEE status level of contributor.

**7. SUB-CONTRACTING**

7.1 Will any portion of the contract be sub-contracted?

*(Tick applicable box)*

YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
-----	--------------------------	----	--------------------------

7.1.1 If yes, indicate:

- i) What percentage of the contract will be subcontracted.....%
- ii) The name of the sub-contractor.....
- iii) The B-BBEE status level of the sub-contractor.....
- iv) Whether the sub-contractor is an EME or QSE

*(Tick applicable box)*

YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
-----	--------------------------	----	--------------------------

v) Specify, by ticking the appropriate box, if subcontracting with an enterprise in terms of Preferential Procurement Regulations,2017:

<b>Designated Group: An EME or QSE which is at last 51% owned by:</b>	<b>EME</b> √	<b>QSE</b> √
Black people		
Black people who are youth		
Black people who are women		
Black people with disabilities		
Black people living in rural or underdeveloped areas or townships		
Cooperative owned by black people		

Black people who are military veterans		
<b>OR</b>		
Any EME		
Any QSE		

**8. DECLARATION WITH REGARD TO COMPANY/FIRM**

8.1 Name \_\_\_\_\_ of  
company/firm:.....

8.2 VAT \_\_\_\_\_ registration  
number:.....

8.3 Company \_\_\_\_\_ registration  
number:.....

**8.4 TYPE OF COMPANY/ FIRM**

- Partnership/Joint Venture / Consortium
  - One person business/sole propriety
  - Close corporation
  - Company
  - (Pty) Limited
- [TICK APPLICABLE BOX]

**8.5 DESCRIBE PRINCIPAL BUSINESS ACTIVITIES**

.....  
 .....  
 .....  
 .....  
 .....

**8.6 COMPANY CLASSIFICATION**

- Manufacturer
  - Supplier
  - Professional service provider
  - Other service providers, e.g. transporter, etc.
- [TICK APPLICABLE BOX]

8.7 Total number of years the company/firm has been in business:.....

8.8 I/we, the undersigned, who is / are duly authorised to do so on behalf of the company/firm, certify that the points claimed, based on the B-BBE status level of contributor indicated in paragraphs 1.4 and 6.1 of the foregoing certificate, qualifies the company/ firm for the preference(s) shown and I / we acknowledge that:

- i) The information furnished is true and correct;
- ii) The preference points claimed are in accordance with the General Conditions as indicated in paragraph 1 of this form;
- iii) In the event of a contract being awarded as a result of points claimed as shown in paragraphs 1.4 and 6.1, the contractor may be required to furnish documentary proof to the satisfaction of the purchaser that the claims are correct;
- iv) If the B-BBEE status level of contributor has been claimed or obtained on a

fraudulent basis or any of the conditions of contract have not been fulfilled, the purchaser may, in addition to any other remedy it may have –

- (a) disqualify the person from the bidding process;
- (b) recover costs, losses or damages it has incurred or suffered as a result of that person’s conduct;
- (c) cancel the contract and claim any damages which it has suffered as a result of having to make less favourable arrangements due to such cancellation;
- (d) recommend that the bidder or contractor, its shareholders and directors, or only the shareholders and directors who acted on a fraudulent basis, be restricted by the National Treasury from obtaining business from any organ of state for a period not exceeding 10 years, after the *audi alteram partem* (hear the other side) rule has been applied; and
- (e) forward the matter for criminal prosecution.

WITNESSES

1. ....

2. ....

.....  
SIGNATURE(S) OF BIDDERS(S)

DATE: .....

ADDRESS .....

.....

.....

**SBD 8****DECLARATION OF BIDDER'S PAST SUPPLY CHAIN MANAGEMENT PRACTICES**

- 1 This Standard Bidding Document must form part of all bids invited.
- 2 It serves as a declaration to be used by institutions in ensuring that when goods and services are being procured, all reasonable steps are taken to combat the abuse of the supply chain management system.
- 3 The bid of any bidder may be disregarded if that bidder, or any of its directors have-
  - a. abused the institution's supply chain management system;
  - b. committed fraud or any other improper conduct in relation to such system; or
  - c. failed to perform on any previous contract.
- 4 **In order to give effect to the above, the following questionnaire must be completed and submitted with the bid.**

Item	Question	Yes	No
4.1	Is the bidder or any of its directors listed on the National Treasury's Database of Restricted Suppliers as companies or persons prohibited from doing business with the public sector? <b>(Companies or persons who are listed on this Database were informed in writing of this restriction by the Accounting Officer/Authority of the institution that imposed the restriction after the <i>audi alteram partem</i> rule was applied).</b>  The Database of Restricted Suppliers now resides on the National Treasury's website( <a href="http://www.treasury.gov.za">www.treasury.gov.za</a> ) and can be accessed by clicking on its link at the bottom of the home page.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4.1.1	If so, furnish particulars:		
4.2	Is the bidder or any of its directors listed on the Register for Tender Defaulters in terms of section 29 of the Prevention and Combating of Corrupt Activities Act (No 12 of 2004)? <b>The Register for Tender Defaulters can be accessed on the National Treasury's website (<a href="http://www.treasury.gov.za">www.treasury.gov.za</a>) by clicking on its link at the bottom of the home page.</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4.2.1	If so, furnish particulars:		
4.3	Was the bidder or any of its directors convicted by a court of law (including a court outside of the Republic of South Africa) for fraud or corruption during the past five years?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4.3.1	If so, furnish particulars:		
4.4	Was any contract between the bidder and any organ of state terminated during the past five years on account of failure to perform on or comply with the contract?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

4.4.1	If so, furnish particulars:
-------	-----------------------------

**SBD 8**

**CERTIFICATION**

**I, THE UNDERSIGNED (FULL NAME).....  
CERTIFY THAT THE INFORMATION FURNISHED ON THIS DECLARATION  
FORM IS TRUE AND CORRECT.**

**I ACCEPT THAT, IN ADDITION TO CANCELLATION OF A CONTRACT,  
ACTION MAY BE TAKEN AGAINST ME SHOULD THIS DECLARATION PROVE  
TO BE FALSE.**

.....  
**Signature**

.....  
**Date**

.....  
**Position**

.....  
**Name of Bidder**

**SBD 9****CERTIFICATE OF INDEPENDENT BID DETERMINATION**

- 1 This Standard Bidding Document (SBD) must form part of all bids<sup>1</sup> invited.
- 2 Section 4 (1) (b) (iii) of the Competition Act No. 89 of 1998, as amended, prohibits an agreement between, or concerted practice by, firms, or a decision by an association of firms, if it is between parties in a horizontal relationship and if it involves collusive bidding (or bid rigging).<sup>2</sup> Collusive bidding is a *pe se* prohibition meaning that it cannot be justified under any grounds.
- 3 Treasury Regulation 16A9 prescribes that accounting officers and accounting authorities must take all reasonable steps to prevent abuse of the supply chain management system and authorizes accounting officers and accounting authorities to:
  - a. disregard the bid of any bidder if that bidder, or any of its directors have abused the institution's supply chain management system and or committed fraud or any other improper conduct in relation to such system.
  - b. cancel a contract awarded to a supplier of goods and services if the supplier committed any corrupt or fraudulent act during the bidding process or the execution of that contract.
- 4 This SBD serves as a certificate of declaration that would be used by institutions to ensure that, when bids are considered, reasonable steps are taken to prevent any form of bid-rigging.
- 5 In order to give effect to the above, the attached Certificate of Bid Determination (SBD 9) must be completed and submitted with the bid:

<sup>1</sup> Includes price quotations, advertised competitive bids, limited bids and proposals.

<sup>2</sup> Bid rigging (or collusive bidding) occurs when businesses, that would otherwise be expected to compete, secretly conspire to raise prices or lower the quality of goods and / or services for purchasers who wish to acquire goods and / or services through a bidding process. Bid rigging is, therefore, an agreement between competitors not to compete.

**SBD 9****CERTIFICATE OF INDEPENDENT BID DETERMINATION**

I, the undersigned, in submitting the accompanying bid:

---

(Bid Number and Description)

in response to the invitation for the bid made by:

---

(Name of Institution)

do hereby make the following statements that I certify to be true and complete in every respect:

I certify, on behalf of: \_\_\_\_\_ that:

(Name of Bidder)

1. I have read and I understand the contents of this Certificate;
2. I understand that the accompanying bid will be disqualified if this Certificate is found not to be true and complete in every respect;
3. I am authorized by the bidder to sign this Certificate, and to submit the accompanying bid, on behalf of the bidder;
4. Each person whose signature appears on the accompanying bid has been authorized by the bidder to determine the terms of, and to sign the bid, on behalf of the bidder;
5. For the purposes of this Certificate and the accompanying bid, I understand that the word "competitor" shall include any individual or organization, other than the bidder, whether or not affiliated with the bidder, who:
  - (a) has been requested to submit a bid in response to this bid invitation;
  - (b) could potentially submit a bid in response to this bid invitation, based on their qualifications, abilities or experience; and
  - (c) provides the same goods and services as the bidder and/or is in the same line of business as the bidder

Bidder Signature \_\_\_\_\_ Date \_\_\_\_\_

**SBD 9**

6. The bidder has arrived at the accompanying bid independently from, and without consultation, communication, agreement or arrangement with any competitor. However communication between partners in a joint venture or consortium<sup>3</sup> will not be construed as collusive bidding.
7. In particular, without limiting the generality of paragraphs 6 above, there has been no consultation, communication, agreement or arrangement with any competitor regarding:
  - (a) prices;
  - (b) geographical area where product or service will be rendered (market allocation)
  - (c) methods, factors or formulas used to calculate prices;
  - (d) the intention or decision to submit or not to submit, a bid;
  - (e) the submission of a bid which does not meet the specifications and conditions of the bid; or
  - (f) bidding with the intention not to win the bid.
8. In addition, there have been no consultations, communications, agreements or arrangements with any competitor regarding the quality, quantity, specifications and conditions or delivery particulars of the products or services to which this bid invitation relates.
9. The terms of the accompanying bid have not been, and will not be, disclosed by the bidder, directly or indirectly, to any competitor, prior to the date and time of the official bid opening or of the awarding of the contract.

<sup>3</sup> Joint venture or Consortium means an association of persons for the purpose of combining their expertise, property, capital, efforts, skill and knowledge in an activity for the execution of a contract.

**SBD 9**

10. I am aware that, in addition and without prejudice to any other remedy provided to combat any restrictive practices related to bids and contracts, bids that are suspicious will be reported to the Competition Commission for investigation and possible imposition of administrative penalties in terms of section 59 of the Competition Act No 89 of 1998 and or may be reported to the National Prosecuting Authority (NPA) for criminal investigation and or may be restricted from conducting business with the public sector for a period not exceeding ten (10) years in terms of the Prevention and Combating of Corrupt Activities Act No 12 of 2004 or any other applicable legislation.

.....  
Signature

.....  
Date

.....  
Position

.....  
Name of Bidder



# health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA

<b>PBD4.1</b>
---------------

Private Bag X828, PRETORIA, 0001. Civitas Building Cnr Thabo Sehume & Struben Streets, PRETORIA 0001  
Directorate: Access to Affordable Medicines Tel: (012) 395 8130 Fax: (012) 395 8823/4

**CONTRACT NUMBER:** HP17-2021TWDV

### SUPPLIER DETAILS:

Note that Provincial Departments of Health will require separate registration of suppliers on their Databases & could request completion of Province-specific documents.

If a contract is awarded, full detail for supplier registration or verification will be requested.

Should any of the detail provided below change, please advise the National Department of Health immediately in writing with detail of such change(s).

### CONTACT DETAIL

<b>1. Supplier Registered Name</b> <i>Legal entity / corresponding with banking detail</i>			
<b>2. Contact person regarding contract enquiries (to be printed on contract cover)</b>			
Name & Surname		e-mail	
Telephone		Fax	
Cell		Other	
<b>3. Contact regarding orders</b>			
Address for posting of orders		Fax	
		Tel (confirmation)	
		EDI	<input type="checkbox"/>
<b>Order enquiries</b>	Name & surname:	Tel	
		e-mail	
<b>4. National key Account Manager (or Tender Manager)</b>			
Name		e-mail	
Telephone		Cell	

**SIGNATURE FOR PBD4.1**

I / we, the undersigned, herewith certify that all of the above information is correct at the time of completion. I / we furthermore certify that I / we have the appropriate authority to furnish the above-mentioned information on behalf of our employer.

Name:	Signature
Designation:	Date

Name:	Signature
Designation:	Date

**PBD5.1**

**PBD5.1 DECLARATION OF COMPLIANCE WITH GOOD WHOLESALING PRACTICE (GWP)**

**To be signed by the Chief Executive Officer of the Company in terms of this bid.**

I,.....

(Full name) being the Chief Executive Officer

Of.....

(Organisation name) hereby certify that to the best of my knowledge all reasonable steps have been taken to ensure that:

- a) There are no outstanding or impending GWP or legal matters that may have a material impact on the Company’s ability to perform in terms of this contract.
- b) In terms of this declaration, I undertake to inform the Department of Health at first knowledge of any circumstances that may result in interrupted supply.
- c) (Organisation name)..... has complied with all the legal requirements as stipulated in terms of Medicines and Related Substances Act 101 of 1965, as amended, for such products offered.

.....

Full Name of Chief Executive Officer

.....

Full Identity Number/or equivalent of the Chief Executive Officer

.....

Signature of Chief Executive Officer

.....

Signature of Witness

.....

Signed

at

Date

**PBD 8: DECLARATION OF COMPLIANCE WITH THE SPECIAL REQUIREMENTS  
AND CONDITIONS OF CONTRACT**

**To be signed by the Chief Executive Officer of the Company in terms of this bid.**

I,.....(Full name)  
being the Chief Executive Officer

of..... (Organisation name)  
hereby declare that to the best of my knowledge all reasonable steps have been taken to ensure  
that:

- a) (Organisation name)..... has complied  
with all the legal requirements as provided in the Medicines and Related Substances Act  
101 of 1965, as amended, for such products offered;
- b) There are no outstanding or impending matters (including GMP or legal) that may have a  
material impact on the Company’s ability to perform in terms of this contract

In terms of this declaration, I undertake to inform the Department of Health at first knowledge of any  
circumstances that may result in interrupted supply of product if the contract is awarded.

I further declare that  
.....(Organisation name)  
will comply with the requirements and conditions as stipulated in the Special Requirements and  
Conditions of Contract

.....  
Full Name of Chief Executive Officer

.....  
Full Identity Number/or equivalent of the Chief Executive Officer

.....  
Signature of Chief Executive Officer

.....  
Signature of Witness

Date Signed ..... at .....

# **Annexure 2**

## **General Conditions of Contract**

# THE NATIONAL TREASURY

Republic of South Africa



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## GOVERNMENT PROCUREMENT: GENERAL CONDITIONS OF CONTRACT

July 2010

**GOVERNMENT PROCUREMENT**  
**GENERAL CONDITIONS OF CONTRACT**  
**July 2010**

**NOTES**

The purpose of this document is to:

- (i) Draw special attention to certain general conditions applicable to government bids, contracts and orders; and
- (ii) To ensure that clients be familiar with regard to the rights and obligations of all parties involved in doing business with government.

In this document words in the singular also mean in the plural and vice versa and words in the masculine also mean in the feminine and neuter.

- The General Conditions of Contract will form part of all bid documents and may not be amended.
- Special Conditions of Contract (SCC) relevant to a specific bid, should be compiled separately for every bid (if applicable) and will supplement the General Conditions of Contract. Whenever there is a conflict, the provisions in the SCC shall prevail.

## TABLE OF CLAUSES

1. Definitions
2. Application
3. General
4. Standards
5. Use of contract documents and information; inspection
6. Patent rights
7. Performance security
8. Inspections, tests and analysis
9. Packing
10. Delivery and documents
11. Insurance
12. Transportation
13. Incidental services
14. Spare parts
15. Warranty
16. Payment
17. Prices
18. Contract amendments
19. Assignment
20. Subcontracts
21. Delays in the supplier's performance
22. Penalties
23. Termination for default
24. Dumping and countervailing duties
25. Force Majeure
26. Termination for insolvency
27. Settlement of disputes
28. Limitation of liability
29. Governing language
30. Applicable law
31. Notices
32. Taxes and duties
33. National Industrial Participation Programme (NIPP)
34. Prohibition of restrictive practices

## General Conditions of Contract

### 1. Definitions

1. The following terms shall be interpreted as indicated:
  - 1.1 “Closing time” means the date and hour specified in the bidding documents for the receipt of bids.
  - 1.2 “Contract” means the written agreement entered into between the purchaser and the supplier, as recorded in the contract form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.
  - 1.3 “Contract price” means the price payable to the supplier under the contract for the full and proper performance of his contractual obligations.
  - 1.4 “Corrupt practice” means the offering, giving, receiving, or soliciting of any thing of value to influence the action of a public official in the procurement process or in contract execution.
  - 1.5 "Countervailing duties" are imposed in cases where an enterprise abroad is subsidized by its government and encouraged to market its products internationally.
  - 1.6 “Country of origin” means the place where the goods were mined, grown or produced or from which the services are supplied. Goods are produced when, through manufacturing, processing or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.
  - 1.7 “Day” means calendar day.
  - 1.8 “Delivery” means delivery in compliance of the conditions of the contract or order.
  - 1.9 “Delivery ex stock” means immediate delivery directly from stock actually on hand.
  - 1.10 “Delivery into consignees store or to his site” means delivered and unloaded in the specified store or depot or on the specified site in compliance with the conditions of the contract or order, the supplier bearing all risks and charges involved until the supplies are so delivered and a valid receipt is obtained.
  - 1.11 "Dumping" occurs when a private enterprise abroad market its goods on own initiative in the RSA at lower prices than that of the country of origin and which have the potential to harm the local industries in the

RSA.

- 1.12 "Force majeure" means an event beyond the control of the supplier and not involving the supplier's fault or negligence and not foreseeable. Such events may include, but is not restricted to, acts of the purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions and freight embargoes.
- 1.13 "Fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of any bidder, and includes collusive practice among bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the bidder of the benefits of free and open competition.
- 1.14 "GCC" means the General Conditions of Contract.
- 1.15 "Goods" means all of the equipment, machinery, and/or other materials that the supplier is required to supply to the purchaser under the contract.
- 1.16 "Imported content" means that portion of the bidding price represented by the cost of components, parts or materials which have been or are still to be imported (whether by the supplier or his subcontractors) and which costs are inclusive of the costs abroad, plus freight and other direct importation costs such as landing costs, dock dues, import duty, sales duty or other similar tax or duty at the South African place of entry as well as transportation and handling charges to the factory in the Republic where the supplies covered by the bid will be manufactured.
- 1.17 "Local content" means that portion of the bidding price which is not included in the imported content provided that local manufacture does take place.
- 1.18 "Manufacture" means the production of products in a factory using labour, materials, components and machinery and includes other related value-adding activities.
- 1.19 "Order" means an official written order issued for the supply of goods or works or the rendering of a service.
- 1.20 "Project site," where applicable, means the place indicated in bidding documents.
- 1.21 "Purchaser" means the organization purchasing the goods.
- 1.22 "Republic" means the Republic of South Africa.
- 1.23 "SCC" means the Special Conditions of Contract.
- 1.24 "Services" means those functional services ancillary to the supply of the goods, such as transportation and any other incidental services, such as installation, commissioning, provision of technical assistance, training, catering, gardening, security, maintenance and other such

obligations of the supplier covered under the contract.

1.25 “Written” or “in writing” means handwritten in ink or any form of electronic or mechanical writing.

## **2. Application**

2.1 These general conditions are applicable to all bids, contracts and orders including bids for functional and professional services, sales, hiring, letting and the granting or acquiring of rights, but excluding immovable property, unless otherwise indicated in the bidding documents.

2.2 Where applicable, special conditions of contract are also laid down to cover specific supplies, services or works.

2.3 Where such special conditions of contract are in conflict with these general conditions, the special conditions shall apply.

## **3. General**

3.1 Unless otherwise indicated in the bidding documents, the purchaser shall not be liable for any expense incurred in the preparation and submission of a bid. Where applicable a non-refundable fee for documents may be charged.

3.2 With certain exceptions, invitations to bid are only published in the Government Tender Bulletin. The Government Tender Bulletin may be obtained directly from the Government Printer, Private Bag X85, Pretoria 0001, or accessed electronically from [www.treasury.gov.za](http://www.treasury.gov.za)

## **4. Standards**

4.1 The goods supplied shall conform to the standards mentioned in the bidding documents and specifications.

## **5. Use of contract documents and information; inspection.**

5.1 The supplier shall not, without the purchaser’s prior written consent, disclose the contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the purchaser in connection therewith, to any person other than a person employed by the supplier in the performance of the contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.

5.2 The supplier shall not, without the purchaser’s prior written consent, make use of any document or information mentioned in GCC clause 5.1 except for purposes of performing the contract.

5.3 Any document, other than the contract itself mentioned in GCC clause 5.1 shall remain the property of the purchaser and shall be returned (all copies) to the purchaser on completion of the supplier’s performance under the contract if so required by the purchaser.

5.4 The supplier shall permit the purchaser to inspect the supplier’s records relating to the performance of the supplier and to have them audited by auditors appointed by the purchaser, if so required by the purchaser.

## **6. Patent rights**

6.1 The supplier shall indemnify the purchaser against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the goods or any part thereof by the purchaser.

**7. Performance security**

- 7.1 Within thirty (30) days of receipt of the notification of contract award, the successful bidder shall furnish to the purchaser the performance security of the amount specified in SCC.
- 7.2 The proceeds of the performance security shall be payable to the purchaser as compensation for any loss resulting from the supplier's failure to complete his obligations under the contract.
- 7.3 The performance security shall be denominated in the currency of the contract, or in a freely convertible currency acceptable to the purchaser and shall be in one of the following forms:
- (a) a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the purchaser's country or abroad, acceptable to the purchaser, in the form provided in the bidding documents or another form acceptable to the purchaser; or
  - (b) a cashier's or certified cheque
- 7.4 The performance security will be discharged by the purchaser and returned to the supplier not later than thirty (30) days following the date of completion of the supplier's performance obligations under the contract, including any warranty obligations, unless otherwise specified in SCC.

**8. Inspections, tests and analyses**

- 8.1 All pre-bidding testing will be for the account of the bidder.
- 8.2 If it is a bid condition that supplies to be produced or services to be rendered should at any stage during production or execution or on completion be subject to inspection, the premises of the bidder or contractor shall be open, at all reasonable hours, for inspection by a representative of the Department or an organization acting on behalf of the Department.
- 8.3 If there are no inspection requirements indicated in the bidding documents and no mention is made in the contract, but during the contract period it is decided that inspections shall be carried out, the purchaser shall itself make the necessary arrangements, including payment arrangements with the testing authority concerned.
- 8.4 If the inspections, tests and analyses referred to in clauses 8.2 and 8.3 show the supplies to be in accordance with the contract requirements, the cost of the inspections, tests and analyses shall be defrayed by the purchaser.
- 8.5 Where the supplies or services referred to in clauses 8.2 and 8.3 do not comply with the contract requirements, irrespective of whether such supplies or services are accepted or not, the cost in connection with these inspections, tests or analyses shall be defrayed by the supplier.
- 8.6 Supplies and services which are referred to in clauses 8.2 and 8.3 and which do not comply with the contract requirements may be rejected.
- 8.7 Any contract supplies may on or after delivery be inspected, tested or

analyzed and may be rejected if found not to comply with the requirements of the contract. Such rejected supplies shall be held at the cost and risk of the supplier who shall, when called upon, remove them immediately at his own cost and forthwith substitute them with supplies which do comply with the requirements of the contract. Failing such removal the rejected supplies shall be returned at the suppliers cost and risk. Should the supplier fail to provide the substitute supplies forthwith, the purchaser may, without giving the supplier further opportunity to substitute the rejected supplies, purchase such supplies as may be necessary at the expense of the supplier.

8.8 The provisions of clauses 8.4 to 8.7 shall not prejudice the right of the purchaser to cancel the contract on account of a breach of the conditions thereof, or to act in terms of Clause 23 of GCC.

## **9. Packing**

9.1 The supplier shall provide such packing of the goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit, and open storage. Packing, case size and weights shall take into consideration, where appropriate, the remoteness of the goods' final destination and the absence of heavy handling facilities at all points in transit.

9.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the contract, including additional requirements, if any, specified in SCC, and in any subsequent instructions ordered by the purchaser.

## **10. Delivery and documents**

10.1 Delivery of the goods shall be made by the supplier in accordance with the terms specified in the contract. The details of shipping and/or other documents to be furnished by the supplier are specified in SCC.

10.2 Documents to be submitted by the supplier are specified in SCC.

## **11. Insurance**

11.1 The goods supplied under the contract shall be fully insured in a freely convertible currency against loss or damage incidental to manufacture or acquisition, transportation, storage and delivery in the manner specified in the SCC.

## **12. Transportation**

12.1 Should a price other than an all-inclusive delivered price be required, this shall be specified in the SCC.

## **13. Incidental services**

13.1 The supplier may be required to provide any or all of the following services, including additional services, if any, specified in SCC:

- (a) performance or supervision of on-site assembly and/or commissioning of the supplied goods;
- (b) furnishing of tools required for assembly and/or maintenance of the supplied goods;
- (c) furnishing of a detailed operations and maintenance manual for each appropriate unit of the supplied goods;

- (d) performance or supervision or maintenance and/or repair of the supplied goods, for a period of time agreed by the parties, provided that this service shall not relieve the supplier of any warranty obligations under this contract; and
- (e) training of the purchaser's personnel, at the supplier's plant and/or on-site, in assembly, start-up, operation, maintenance, and/or repair of the supplied goods.

13.2 Prices charged by the supplier for incidental services, if not included in the contract price for the goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the supplier for similar services.

#### **14. Spare parts**

14.1 As specified in SCC, the supplier may be required to provide any or all of the following materials, notifications, and information pertaining to spare parts manufactured or distributed by the supplier:

- (a) such spare parts as the purchaser may elect to purchase from the supplier, provided that this election shall not relieve the supplier of any warranty obligations under the contract; and
- (b) in the event of termination of production of the spare parts:
  - (i) Advance notification to the purchaser of the pending termination, in sufficient time to permit the purchaser to procure needed requirements; and
  - (ii) following such termination, furnishing at no cost to the purchaser, the blueprints, drawings, and specifications of the spare parts, if requested.

#### **15. Warranty**

15.1 The supplier warrants that the goods supplied under the contract are new, unused, of the most recent or current models, and that they incorporate all recent improvements in design and materials unless provided otherwise in the contract. The supplier further warrants that all goods supplied under this contract shall have no defect, arising from design, materials, or workmanship (except when the design and/or material is required by the purchaser's specifications) or from any act or omission of the supplier, that may develop under normal use of the supplied goods in the conditions prevailing in the country of final destination.

15.2 This warranty shall remain valid for twelve (12) months after the goods, or any portion thereof as the case may be, have been delivered to and accepted at the final destination indicated in the contract, or for eighteen (18) months after the date of shipment from the port or place of loading in the source country, whichever period concludes earlier, unless specified otherwise in SCC.

15.3 The purchaser shall promptly notify the supplier in writing of any claims arising under this warranty.

15.4 Upon receipt of such notice, the supplier shall, within the period specified in SCC and with all reasonable speed, repair or replace the defective goods or parts thereof, without costs to the purchaser.

15.5 If the supplier, having been notified, fails to remedy the defect(s) within the period specified in SCC, the purchaser may proceed to take

such remedial action as may be necessary, at the supplier's risk and expense and without prejudice to any other rights which the purchaser may have against the supplier under the contract.

- 16. Payment**
- 16.1 The method and conditions of payment to be made to the supplier under this contract shall be specified in SCC.
- 16.2 The supplier shall furnish the purchaser with an invoice accompanied by a copy of the delivery note and upon fulfillment of other obligations stipulated in the contract.
- 16.3 Payments shall be made promptly by the purchaser, but in no case later than thirty (30) days after submission of an invoice or claim by the supplier.
- 16.4 Payment will be made in Rand unless otherwise stipulated in SCC.
- 17. Prices**
- 17.1 Prices charged by the supplier for goods delivered and services performed under the contract shall not vary from the prices quoted by the supplier in his bid, with the exception of any price adjustments authorized in SCC or in the purchaser's request for bid validity extension, as the case may be.
- 18. Contract amendments**
- 18.1 No variation in or modification of the terms of the contract shall be made except by written amendment signed by the parties concerned.
- 19. Assignment**
- 19.1 The supplier shall not assign, in whole or in part, its obligations to perform under the contract, except with the purchaser's prior written consent.
- 20. Subcontracts**
- 20.1 The supplier shall notify the purchaser in writing of all subcontracts awarded under this contracts if not already specified in the bid. Such notification, in the original bid or later, shall not relieve the supplier from any liability or obligation under the contract.
- 21. Delays in the supplier's performance**
- 21.1 Delivery of the goods and performance of services shall be made by the supplier in accordance with the time schedule prescribed by the purchaser in the contract.
- 21.2 If at any time during performance of the contract, the supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the goods and performance of services, the supplier shall promptly notify the purchaser in writing of the fact of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the supplier's notice, the purchaser shall evaluate the situation and may at his discretion extend the supplier's time for performance, with or without the imposition of penalties, in which case the extension shall be ratified by the parties by amendment of contract.
- 21.3 No provision in a contract shall be deemed to prohibit the obtaining of supplies or services from a national department, provincial department, or a local authority.
- 21.4 The right is reserved to procure outside of the contract small quantities or to have minor essential services executed if an emergency arises, the

supplier's point of supply is not situated at or near the place where the supplies are required, or the supplier's services are not readily available.

21.5 Except as provided under GCC Clause 25, a delay by the supplier in the performance of its delivery obligations shall render the supplier liable to the imposition of penalties, pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Clause 21.2 without the application of penalties.

21.6 Upon any delay beyond the delivery period in the case of a supplies contract, the purchaser shall, without canceling the contract, be entitled to purchase supplies of a similar quality and up to the same quantity in substitution of the goods not supplied in conformity with the contract and to return any goods delivered later at the supplier's expense and risk, or to cancel the contract and buy such goods as may be required to complete the contract and without prejudice to his other rights, be entitled to claim damages from the supplier.

## **22. Penalties**

22.1 Subject to GCC Clause 25, if the supplier fails to deliver any or all of the goods or to perform the services within the period(s) specified in the contract, the purchaser shall, without prejudice to its other remedies under the contract, deduct from the contract price, as a penalty, a sum calculated on the delivered price of the delayed goods or unperformed services using the current prime interest rate calculated for each day of the delay until actual delivery or performance. The purchaser may also consider termination of the contract pursuant to GCC Clause 23.

## **23. Termination for default**

23.1 The purchaser, without prejudice to any other remedy for breach of contract, by written notice of default sent to the supplier, may terminate this contract in whole or in part:

- (a) if the supplier fails to deliver any or all of the goods within the period(s) specified in the contract, or within any extension thereof granted by the purchaser pursuant to GCC Clause 21.2;
- (b) if the Supplier fails to perform any other obligation(s) under the contract; or
- (c) if the supplier, in the judgment of the purchaser, has engaged in corrupt or fraudulent practices in competing for or in executing the contract.

23.2 In the event the purchaser terminates the contract in whole or in part, the purchaser may procure, upon such terms and in such manner as it deems appropriate, goods, works or services similar to those undelivered, and the supplier shall be liable to the purchaser for any excess costs for such similar goods, works or services. However, the supplier shall continue performance of the contract to the extent not terminated.

23.3 Where the purchaser terminates the contract in whole or in part, the purchaser may decide to impose a restriction penalty on the supplier by prohibiting such supplier from doing business with the public sector for a period not exceeding 10 years.

23.4 If a purchaser intends imposing a restriction on a supplier or any

person associated with the supplier, the supplier will be allowed a time period of not more than fourteen (14) days to provide reasons why the envisaged restriction should not be imposed. Should the supplier fail to respond within the stipulated fourteen (14) days the purchaser may regard the intended penalty as not objected against and may impose it on the supplier.

- 23.5 Any restriction imposed on any person by the Accounting Officer / Authority will, at the discretion of the Accounting Officer / Authority, also be applicable to any other enterprise or any partner, manager, director or other person who wholly or partly exercises or exercised or may exercise control over the enterprise of the first-mentioned person, and with which enterprise or person the first-mentioned person, is or was in the opinion of the Accounting Officer / Authority actively associated.
- 23.6 If a restriction is imposed, the purchaser must, within five (5) working days of such imposition, furnish the National Treasury, with the following information:
- (i) the name and address of the supplier and / or person restricted by the purchaser;
  - (ii) the date of commencement of the restriction
  - (iii) the period of restriction; and
  - (iv) the reasons for the restriction.

These details will be loaded in the National Treasury's central database of suppliers or persons prohibited from doing business with the public sector.

- 23.7 If a court of law convicts a person of an offence as contemplated in sections 12 or 13 of the Prevention and Combating of Corrupt Activities Act, No. 12 of 2004, the court may also rule that such person's name be endorsed on the Register for Tender Defaulters. When a person's name has been endorsed on the Register, the person will be prohibited from doing business with the public sector for a period not less than five years and not more than 10 years. The National Treasury is empowered to determine the period of restriction and each case will be dealt with on its own merits. According to section 32 of the Act the Register must be open to the public. The Register can be perused on the National Treasury website.

**24. Anti-dumping  
and countervailing  
duties and rights**

- 24.1 When, after the date of bid, provisional payments are required, or anti-dumping or countervailing duties are imposed, or the amount of a provisional payment or anti-dumping or countervailing right is increased in respect of any dumped or subsidized import, the State is not liable for any amount so required or imposed, or for the amount of any such increase. When, after the said date, such a provisional payment is no longer required or any such anti-dumping or countervailing right is abolished, or where the amount of such provisional payment or any such right is reduced, any such favourable difference shall on demand be paid forthwith by the contractor to the State or the State may deduct such amounts from moneys (if any) which may otherwise be due to the contractor in regard to supplies or services which he delivered or rendered, or is to deliver or render in terms of the contract or any other contract or any other amount which

may be due to him

**25. Force Majeure**

25.1 Notwithstanding the provisions of GCC Clauses 22 and 23, the supplier shall not be liable for forfeiture of its performance security, damages, or termination for default if and to the extent that his delay in performance or other failure to perform his obligations under the contract is the result of an event of force majeure.

25.2 If a force majeure situation arises, the supplier shall promptly notify the purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the purchaser in writing, the supplier shall continue to perform its obligations under the contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the force majeure event.

**26. Termination for insolvency**

26.1 The purchaser may at any time terminate the contract by giving written notice to the supplier if the supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the supplier, provided that such termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to the purchaser.

**27. Settlement of Disputes**

27.1 If any dispute or difference of any kind whatsoever arises between the purchaser and the supplier in connection with or arising out of the contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.

27.2 If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the purchaser or the supplier may give notice to the other party of his intention to commence with mediation. No mediation in respect of this matter may be commenced unless such notice is given to the other party.

27.3 Should it not be possible to settle a dispute by means of mediation, it may be settled in a South African court of law.

27.4 Mediation proceedings shall be conducted in accordance with the rules of procedure specified in the SCC.

27.5 Notwithstanding any reference to mediation and/or court proceedings herein,

- (a) the parties shall continue to perform their respective obligations under the contract unless they otherwise agree; and
- (b) the purchaser shall pay the supplier any monies due the supplier.

**28. Limitation of liability**

28.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 6;

- (a) the supplier shall not be liable to the purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the supplier to pay penalties and/or damages to the purchaser; and

ility of the supplier to the purchaser, whether under the contract, in tort or otherwise, shall not exceed the total contract price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.

- 29. Governing language**
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- 29.1 The contract shall be written in English. All correspondence and other documents pertaining to the contract that is exchanged by the parties shall also be written in English.
- 30. Applicable law**
- 30.1 The contract shall be interpreted in accordance with South African laws, unless otherwise specified in SCC.
- 31. Notices**
- 31.1 Every written acceptance of a bid shall be posted to the supplier concerned by registered or certified mail and any other notice to him shall be posted by ordinary mail to the address furnished in his bid or to the address notified later by him in writing and such posting shall be deemed to be proper service of such notice
- 31.2 The time mentioned in the contract documents for performing any act after such aforesaid notice has been given, shall be reckoned from the date of posting of such notice.
- 32. Taxes and duties**
- 32.1 A foreign supplier shall be entirely responsible for all taxes, stamp duties, license fees, and other such levies imposed outside the purchaser's country.
- 32.2 A local supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted goods to the purchaser.
- 32.3 No contract shall be concluded with any bidder whose tax matters are not in order. Prior to the award of a bid the Department must be in possession of a tax clearance certificate, submitted by the bidder. This certificate must be an original issued by the South African Revenue Services.
- 33. National Industrial Participation (NIP) Programme**
- 33.1 The NIP Programme administered by the Department of Trade and Industry shall be applicable to all contracts that are subject to the NIP obligation.
- 34 Prohibition of Restrictive practices**
- In terms of section 4 (1) (b) (iii) of the Competition Act No. 89 of 1998, as amended, an agreement between, or concerted practice by, firms, or a decision by an association of firms, is prohibited if it is between parties in a horizontal relationship and if a bidder (s) is / are or a contractor(s) was / were involved in collusive bidding (or bid rigging).
- 34.2 If a bidder(s) or contractor(s), based on reasonable grounds or evidence obtained by the purchaser, has / have engaged in the restrictive practice

referred to above, the purchaser may refer the matter to the Competition Commission for investigation and possible imposition of administrative penalties as contemplated in the Competition Act No. 89 of 1998.

34.3 If a bidder(s) or contractor(s), has / have been found guilty by the Competition Commission of the restrictive practice referred to above, the purchaser may, in addition and without prejudice to any other remedy provided for, invalidate the bid(s) for such item(s) offered, and / or

terminate the contract in whole or part, and / or restrict the bidder(s) or contractor(s) from conducting business with the public sector for a period not exceeding ten (10) years and / or claim damages from the bidder(s) or contractor(s) concerned.

Js General Conditions of Contract (revised July 2010)

**Annexure 3**  
**IMPORTATION SERVICES AGREEMENT**

**IMPORTATION AGREEMENT**

**between**

**THE GOVERNMENT OF THE REPUBLIC OF SOUTH AFRICA THROUGH ITS  
NATIONAL DEPARTMENT OF HEALTH**  
(hereinafter referred to as “**the NDoH**”)

herein represented by **Dr SSS Buthelezi**  
in his capacity as **DIRECTOR-GENERAL** and duly authorised.

**and**

**THE SERVICE PROVIDER AS SET OUT IN ANNEXE A**  
(hereinafter referred to as “**the Service Provider**”)

**Regarding**

**The importation and transportation of COVID-19 Vaccines into and  
within the Republic of South Africa**

## Table of Contents

	<b>Page No</b>
1. Preamble .....	2
2. Definitions and interpretation.....	3
3. Purpose / Objectives of Agreement.....	8
4. Duration.....	8
5. Appointment .....	9
6. Applicability of other documents.....	9
7. Services by the Service Provider.....	10
8. Obligations of the Service Provider .....	12
9. Roles and Responsibilities of the NDoH.....	14
10. Service level management and reporting .....	14
11. Terms of payment and invoices .....	15
12. Audits and inspections .....	16
13. Indemnity.....	17
14. Performance and penalties .....	17
15. Business continuity.....	18
16. Liability for damages, loss or destruction of the Product.....	18
17. Insurance.....	18
18. Assignment, cession and delegation .....	19
19. Subcontracting .....	19
20. Intellectual property .....	20
21. Confidentiality .....	22
22. Force Majeure .....	24
23. Breach and termination .....	25
24. Settlement of Disputes .....	26
25. Amendment of the Agreement .....	29
26. Fraud and corruption .....	29
27. Domicilia and notices .....	30
28. General.....	31
29. Governing law .....	31
30. Authority .....	32
31. Jurisdiction of South African courts .....	32
32. Counterpart signing of the Agreement .....	32
 Annexe A The Services – the process of exportation and importation of the Products..	 34

## 1. Preamble

**WHEREAS** the NDoH is in the process of sourcing and procuring vaccines from global manufacturers against SARS-CoV-2 that would be utilised to fight the current Covid-19 pandemic (the “**Covid-19 Vaccines**”) and will conclude procurement agreements for the Product with the various manufacturers around the world in terms of which the NDoH owns the Products (as that term is defined below) to be exported from various foreign countries and imported into the Republic of South Africa by the Service Provider. The Incoterms contained in the purchase agreements with Manufacturers or Suppliers determine the services required from the Service Provider to bring the Product from the country of origin to South Africa.

**AND WHEREAS** to the extent that the Products are not registered, the Products will be supplied through an authorisation in terms of section 21 of the Medicines and Related Substances Act No. 101 of 1965 as there are currently no Covid-19 Vaccines registered by the South African Health Products Regulatory Authority (“**SAHPRA**”).

**AND WHEREAS** on or about 5 February 2021 the NDoH issued a request for proposals for the provision of importation, warehouse and distribution services for the Covid-19 Vaccines to the NDoH, in terms of which, amongst others, the successful bidder/s would be required to, amongst others, attend to (i) the exportation of the Covid-19 Vaccines (where required) from the country of manufacture; (ii) the importation of the Covid-19 Vaccines (where required) into the Republic of South Africa; and (iii) the transport of the Covid-19 Vaccines (where required) to the warehouse and storage facilities of the Logistics Service Provider/s (as defined below).

**AND WHEREAS** the Service Provider has been identified as a panellist that may be eligible to submit written quotations as and when the NDoH requests quotations for the provision of the Services (as this term is defined below). Should the Service Provider be selected as a successful panellist, the NDoH will issue a purchase order to the Service Provider for the provision of the Services, the terms of which will be regulated by this agreement.

**AND WHEREAS** the NDoH confirms the appropriateness of the procurement process and compliance with all relevant policies, regulations and prescripts governing emergency government procurement.

**NOW THEREFORE** the Parties wish to enter into this importation agreement to formalise the obligations and duties of the Parties:

## **2. Definitions and interpretation**

2.1 In this Agreement, the following words shall, unless otherwise stated or inconsistent with the context in which they appear, bear the following meanings and other words derived from the same origins as such words (that is, cognate words) shall bear corresponding meanings:

2.1.1 "**Agreement**" means this importation agreement, including the Annexes as amended from time to time;

2.1.2 "**Annexe[s]**" means the annexe[s] attached to this Agreement;

2.1.3 "**Business Day**" means any day other than a Saturday, Sunday or gazetted national public holiday in the Republic of South Africa;

2.1.4 "**Cold Chain**" means all of the materials, equipment, facilities, vehicles, processes and procedures used to maintain the Products within the required temperature range from the time of manufacture until the Products are administered to individuals;

2.1.5 "**Cold Chain Solutions**" means the three cold chain ranges for different types of Products– (i) between 2–8°C (cold chain solution 1); (ii) at –20°C (cold chain solution 2); and (iii) at –70°C (cold chain solution 3);

2.1.6 "**Commencement Date**" means the date on which this Agreement will come into effect being the date on which this Agreement is signed by the Service Provider;

2.1.7 "**Country of Export**" means the country other than the Republic of South Africa where the Product has been manufactured;

2.1.8 "**Director-General**" means a person appointed as the accounting officer of the NDoH;

2.1.9 "**Fees**" means the fees to be charged by the Service Provider for the Services, as provided in terms of a quote and approved in writing by the NDoH before commencement of the Services;

- 2.1.10 **"Force Majeure"** means any circumstances or causes beyond the reasonable control of either Party, that prevents either Party from performing its obligations assumed in this Agreement, including, but not limited to, acts of God, acts, regulations action, inaction, laws or restrictions of any government, terrorism, war, riot, civil commotion, strikes, lock-outs, destruction of production facilities or materials by flood, fire, earthquake or storm, labour and/or civil disturbances, epidemic and failure of public utilities or common carriers, excluding however the SARS-CoV-2 pandemic or Covid-19 and any quarantine or lockdown that may be implemented by the government of South Africa or any regulatory authority in South Africa;
- 2.1.11 **"Freight Forwarding"** means those specific services which are or may be performed by a Subcontractor in the country of manufacture of the Products and which relate to the arranging of space on an air carrier, and to the extent required the storage, transportation and delivery of the Products. To the extent required in the Incoterms applicable, these services may also include those of a clearing agent in the country of manufacture and/or South Africa;
- 2.1.12 **"GDP"** means the guidelines of good distribution practice as set out in the South African Good Wholesaling Practice for Wholesalers document issued by the then Medicines Control Council together with the NDoH dated July 2016;
- 2.1.13 **"Inbound Logistics"** means all logistics for the importation, receipt and delivery of the Products from the time when the Products are received by the Service Provider at the premises of the Manufacturer or Supplier, to the time they are given into the possession of the Logistics Service Provider in terms of this Agreement, which may include the Freight Forwarding services;
- 2.1.14 **"Incoterms"** means the International Chamber of Commerce rules for the use of domestic and international trade terms published in 2020 and which are applicable to the purchase agreement concluded or to be concluded between the NDoH and the Manufacturers or Suppliers (as the case may be) of the Products;
- 2.1.15 **"Initial Term"** has the meaning set out in clause 4.1 (*Duration*) below;
- 2.1.16 **"Lead Time"** means the time from the date of receipt of a purchase order by the Service Provider, to the date of receipt of the Product at the Warehouses;

- 2.1.17           **"Logistics Phase"** means the stage following the Services provided in this Agreement, which includes services to be provided by the Logistics Service Providers in relation to the Products in South Africa including, but not limited to, customs clearance (where applicable), collection and transportation, warehousing, inventory control, material handling, order and batch order processing and administration, packaging, batch tracking and tracing, cold chain storage, data processing, the communications network necessary for effective management and delivery to the Delivery Sites. It includes all activities related to physical distribution, as well as the return of the Products (where applicable);
- 2.1.18           **"Logistics Service Providers"** means the successful bidders for the Logistics Phase of the Tender for the relevant Cold Chain Solution;
- 2.1.19           **"Manufacturer"** means the manufacturer of the Products;
- 2.1.20           **"NDoH"** means the Department of Health of the Republic of South Africa;
- 2.1.21           **"Parties"** means the NDoH and the Service Provider and **"Party"** shall mean either one of them, as the context requires;
- 2.1.22           **"POD"** means proof of delivery documents which includes a delivery note and documents that acknowledge and prove delivery and receipt of the Products by the Logistics Service Provider at the Warehouse in the correct condition and specific quantities;
- 2.1.23           **"Products"** means the Covid-19 vaccines as authorised for use by the SAHPRA for use in the Republic of South Africa and procured by the NDoH during the contract period in respect of which the NDoH may require the Service Provider to provide the Services;
- 2.1.24           **"Services"** mean the scope of the importation and transport services to be performed and rendered by the Service Provider to the NDoH in relation to the Products including, but not limited to, all Freight Forwarding services collection from the Manufacturer's or Supplier's site of delivery, Transportation to the nearest suitable international airport loading, international carriage to South Africa, off-loading, Transportation to a centralised warehouse or delivery/handover to the Logistics Service Provider, arranging of export and import documentation, foreign airport

charges, insurance and customs clearance (where applicable) in South Africa, as more fully described in Annexe A;

- 2.1.25        **"Subcontractor"** means any person appointed as a subcontractor to perform the Services or part thereof on behalf of the Service Provider in accordance with the provisions of this Agreement;
- 2.1.26        **"Supplier"** means the relevant entity acting as supplier for the Products and/or any other supplier of the Products;
- 2.1.27        **"Tender"** means the tender issued by the NDoH for the provision of importation and logistics services for the Covid-19 Vaccines to the NDoH for the period of 1 April 2021 to 31 December 2022 under request for proposals, HP17-2021TWDV;
- 2.1.28        **"Transport" or "Transportation"** means the entire transportation system, including loading, unloading, storing, handling and any and all other services whatsoever undertaken by the Service Provider in relation to the Products;
- 2.1.29        **"Warehouses"** means the warehouse/s of the Logistics Service Providers or the warehouse/s of the Service Provider, should the Service Provider also be a successful bidder in relation to the Logistics Phase of the Tender;
- 2.1.30        **"VAT"** means value-added tax levied in terms of the Value-added Tax Act, 89 of 1991, as amended; and
- 2.1.31        **"WHO"** means the World Health Organisation.

2.2            In this Agreement:

- 2.2.1            references to a statutory provision include any subordinate legislation made from time to time under that provision and include that provision as modified or re-enacted from time to time;
- 2.2.2            words importing the masculine gender include the feminine and neuter genders and vice versa; the singular includes the plural and vice versa; and natural persons include artificial persons and vice versa;
- 2.2.3            references to a "person" include a natural person, company, close corporation or any other juristic person or other corporate entity, a charity,

trust, partnership, joint venture, syndicate, or any other association of persons;

- 2.2.4 references to a "subsidiary" or a "holding company" shall be references to a subsidiary or holding company as defined in the Companies Act;
- 2.2.5 if a definition imposes substantive rights and obligations on a Party, such rights and obligations shall be given effect to and shall be enforceable, notwithstanding that they are contained in a definition;
- 2.2.6 any definition, wherever it appears in this Agreement, shall bear the same meaning and apply throughout this Agreement unless otherwise stated or inconsistent with the context in which it appears;
- 2.2.7 if there is any conflict between any definitions in this Agreement then, for purposes of interpreting any clause of the Agreement or paragraph of any Annexe, the definition appearing in that clause or paragraph shall prevail over any other conflicting definition appearing elsewhere in the Agreement;
- 2.2.8 where any number of days is prescribed, those days shall be reckoned exclusively of the first and inclusively of the last day unless the last day falls on a day which is not a Business Day, in which event the last day shall be the next succeeding Business Day;
- 2.2.9 where the day upon or by which any act is required to be performed is not a Business Day, the Parties shall be deemed to have intended such act to be performed upon or by the next succeeding Business Day;
- 2.2.10 any provision in this Agreement which is or may become illegal, invalid or unenforceable in any jurisdiction affected by this Agreement shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability and shall be treated as having not been written (ie *pro non scripto*) and severed from the balance of this Agreement, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction;
- 2.2.11 the use of any expression covering a process available under South African law (such as but not limited to a winding-up) shall, if any of the Parties is subject to the law of any other jurisdiction, be interpreted in relation to that

Party as including any equivalent or analogous proceeding under the law of such other jurisdiction;

2.2.12 references to any amount shall mean that amount inclusive of VAT, unless the amount expressly excludes VAT;

2.2.13 the rule of construction that if general words or terms are used in association with specific words or terms which are a species of a particular genus or class, the meaning of the general words or terms shall be restricted to that same class (ie the *eiusdem generis* rule) shall not apply, and whenever the word "*including*" is used followed by specific examples, such examples shall not be interpreted so as to limit the meaning of any word or term to the same genus or class as the examples given.

2.3 The expiration or termination of this Agreement shall not affect such of the provisions of this Agreement which are expressly provided to operate after any such expiration or termination, or which of necessity must continue to have effect after such expiration or termination, notwithstanding that the relevant provisions themselves do not provide for this.

### 3. Purpose / Objectives of Agreement

The purpose of this Agreement is to regulate the relationship between the NDoH and the Service Provider by ensuring that the objectives of the NDoH for the effective exportation and importation of the Products, and the provision of the Services in relation to the Products, are met including in respect of one or more Cold Chain Solutions as detailed in this Agreement.

### 4. Duration

4.1 This Agreement shall become effective on the Commencement Date and shall endure until 31 December 2022 ("**Initial Term**"). Unless otherwise terminated in accordance with this Agreement, this Agreement shall terminate on 31 December 2022 ("**Termination Date**"), subject to the provisions of clause 4.2 below.

4.2 The NDoH reserves the right to extend this Agreement with the Service Provider for a further period of six months as required ("**Extended Term**") on the same terms and conditions as set out in this Agreement, or terminate in terms of the provisions of this Agreement. In the case of an extension, the NDoH shall provide

a written notice of extension to the Service Provider at least one month prior to the Termination Date.

## **5. Appointment**

- 5.1 Should the Service Provider submit a quotation for the performance of the Services that is subsequently accepted by the NDoH, the NDoH will appoint the Service Provider on a non-exclusive basis to provide the Services reflected in this Agreement and its Annexes, subject to the terms and conditions set out herein and the Service Provider shall provide the Services reflected in this Agreement and its Annexes.
- 5.2 When the Service Provider submits a quotation in response to a request for quotation from the NDoH, the necessary proof of insurance in accordance with the provisions of clause 17 shall be furnished and such insurance shall comply with the applicable Incoterm rule. The Service Provider will, for purposes of Incoterms, be made aware of the specific Incoterm rule, such as FOB, Ex Works, CIF, etc. when the request for quotation is issued and provision will need to be made for this in their quotation, the quotation shall be aligned to the specific Manufacturer or Supplier's Incoterm rules.
- 5.3 This Agreement is binding on the successors in title, assignees and administrators of the respective Parties.
- 5.4 The Parties expressly agree that nothing in this Agreement shall affect, or be interpreted to affect the NDoH's rights to appoint and use any other third party service providers to import and export the Products or any other Covid-19 Vaccines at any time.

## **6. Applicability of other documents**

- 6.1 All Annexes and the delivery schedules shall be an integral part of this document and are incorporated as Annexes to this Agreement.
- 6.2 In the event of conflict between the provisions of any of the Annexures and this Agreement, the provisions of this Agreement shall take precedence over the provisions of such Annexe.

## 7. Services by the Service Provider

- 7.1 The Service Provider shall, upon receipt of a purchase order, provide the Services as detailed in Annexe A and in the below clauses within the stipulated time frames.
- 7.2 The Service Provider shall take delivery of the Products at a loading venue ("**Designated Loading Venue**") to be determined by the Manufacturer or Supplier (as the case may be), which loading area will be communicated in writing to the Service Provider by the NDoH five Business Days' before the export of the Products is to take place.
- 7.3 Following receipt of the Products from the Manufacturer or Supplier (as the case may be) the Service Provider shall, whilst complying with all requirements so stipulated and ensuring that the Cold Chain is not broken, Transport the Products to a designated international airport within the Country of Export that is suitable for the purposes of Transport.
- 7.4 Following arrival and receipt of the Products in South Africa, the Service Provider will Transport the Products to the designated Warehouses.
- 7.5 During Transport of the Products from the Designated Loading Venue to South Africa and from South Africa to the designated Warehouses, the Service Provider shall be solely responsible, at its own costs, for securing the Products, maintaining Cold Chain of the Products as well as ensuring compliance with applicable legislation (including GDP) and any other standard international protocols which apply to products the same as or substantially similar to the Products.
- 7.6 The Service Provider shall be solely responsible for the Transportation of the Products from (i) the Country of Export to South Africa; and (ii) in South Africa to the designated Warehouses. Any deterioration in the quality of the said Products due to incorrect handling and/or Cold Chain and/or Cold Chain Solution or any other related activities shall be solely for the Service Provider's account.
- 7.7 The Service Provider shall monitor the Cold Chain Solution as provided for in clauses 7.5 and 7.6, which shall be ensured by using temperature monitoring devices of international standard that complies or meets the WHO specifications or recommendations.
- 7.8 The Service Provider will be required to arrange the requisite import and export documentation, customs clearance, pay airport and other clearing charges in the

Country of Export and in South Africa. The Service Provider will, subject to the applicable Incoterm rule, be responsible for managing all export formalities in the Country of Export and all import formalities for customs clearing in South Africa.

- 7.9 The Products supplied will meet the specifications as provided and directed by the NDoH. The Service Provider shall conduct an inspection of each consignment of the Products delivered at O R Tambo International Airport (which shall be the principal port of entry although not the exclusive port of entry), or such other site as notified by the NDoH, for shortfalls, damages, losses or defects, other than the latent defect in the Products. To the extent that the Service Provider is involved with Transportation of the Product from OR Tambo International Airport or other location where the Products are brought into South Africa, such inspection shall be conducted either:
- 7.9.1 at the airport site prior to transfer and delivery to the Warehouses designated by the Logistics Service Provider for storage; or
  - 7.9.2 at the Warehouses designated by the Logistics Service Provider immediately following Transport from the airport; or
  - 7.9.3 at such other venue as designated by the NDoH.
- 7.10 Upon receipt of the Products at airport in South Africa, authorised personnel of the Service Provider shall check all parameters such as total quantity received, any damages, losses or defects other than latent defects, and audit temperature monitoring devices to ascertain if requisite Cold Chain Solution was maintained throughout the supply chain, i.e. from the Designated Loading Venues where the Products were collected in the Country of Export to O R Tambo International Airport (or any other designated airport within the Republic of South Africa). The Service Provider shall confirm this information to the NDoH in writing in terms of the standard UNICEF Vaccine Arrival Report.
- 7.11 Any claims under clauses 7.9 and 7.10, other than in respect of latent defects, shall be communicated to the NDoH by the Service Provider within 12 hours of receipt of each consignment of Products, and in the event of any difference of opinion with respect to the above, then the Parties will agree that the same be referred to an independent third party for assessment of the said claim and the Parties agree to accept the third party's decision.

- 7.12 Claims of the Service Provider shall be communicated to the NDoH in writing within seven days after discovery of such defects. The NDoH shall address the concerns directly with the Manufacturer or Supplier (as the case may be) and the Service Provider shall cooperate and support the NDoH with this process.

## **8. Obligations of the Service Provider**

- 8.1 Upon receipt of a purchase order from the NDoH, following approval of the quotation, the Service Provider shall be responsible for the following, subject to the applicable Incoterm rule:
- 8.1.1 receiving the Product from the Manufacturer's or the Supplier's Designated Loading Venue in the Country of Export;
  - 8.1.2 the provision or arrangement for the provision of Freight Forwarding;
  - 8.1.3 fulfilling and facilitating the Inbound Logistics of the Products into and within the Republic of South Africa;
  - 8.1.4 loading and Transportation, including transportation to the nearest suitable international airport, loading of cargo, and international carriage via air to South Africa (the principle port of entry will be O.R. Tambo International Airport, although there might be instances when the Cape Town International Airport and/or King Shaka International Airport will be used);
  - 8.1.5 preparation of any documentation required for air cargo, exportation and importation of the Products, including customs clearance;
  - 8.1.6 payment of all fees, taxes, duties relating to the export of the Products;
  - 8.1.7 providing all security up to the loading of the Products onto the aircraft transporting them;
  - 8.1.8 Cold Chain management and ensuring that at all times the Cold Chain Solution and Cold Chain of the Products are maintained in accordance and in alignment with the Manufacturer's instructions throughout the process as well as ensuring compliance with applicable legislation (including GDP) and any other standard international protocols which apply to products the same as or substantially similar to the Products;

- 8.1.9 if required in terms of the Incoterms applicable to this Agreement and confirmed by the NDoH, the role of clearing agent so as to clear the Products at South African customs;
- 8.1.10 any required storage and Transport of the Products until delivery to the Logistics Service Provider at the Warehouse;
- 8.1.11 the Transport and delivery of the Products having been imported into South Africa, to the Logistics Service Provider at the designated Warehouses;
- 8.1.12 prompt payment to all third party Subcontractors that may participate in and assist the Service Provider in the provision of any of the Services (such as Freight Forwarding) in this Agreement, e.g. delivery companies;
- 8.1.13 application and receipt of the necessary authorisations under the Medicines and Related Substances Act, 101 of 1965 and the Pharmacy Act, 53 of 1974, to the extent required.
- 8.2 A quotation will be requested from the Service Provider (together with any other successful bidders that are on the panel) for specified Services (which may be the full Services or a portion thereof) aligned to the specific Manufacturer's Incoterms in the contract with the Manufacturer or the Supplier of the Products.
- 8.3 The NDoH will provide the Service Provider with the details of the consignments to be transported to South Africa in the request for quotation.
- 8.4 If a quotation from the Service Provider is accepted by the NDoH, a purchase order will be given to the Service Provider to arrange the requisite import and export documentation, customs clearances, duties, taxes, terminal and other clearing charges. The Service Provider will, subject to the applicable Incoterm rule, be responsible for managing all import formalities for customs clearing.
- 8.5 The Service Provider must provide the expected Lead Time for the required mode of transport, which is air cargo.
- 8.6 The Service Provider will ensure that the Products are at all times managed with the appropriate skill and expertise expected of an expert logistics provider who is providing all of the Services contemplated in this Agreement. Appropriate continuous temperature monitoring and shipment tracking must be provided.

- 8.7 The Service Provider will be responsible for ensuring secure delivery of cleared Products to the Warehouse. This will include ensuring that the Transportation used is appropriate to maintain the safety and quality of the Products. Appropriate security measures are to be provided to ensure safe passage of the Products to the Warehouse. The Service Provider may be required to coordinate with national security and/or police services to ensure the security of the Products.
- 8.8 The Service Provider must provide full details of all clearing and transport charges for clearing air cargo at airports.
- 8.9 The Service Provider will be responsible for processing and securing all required authorisations to import the Products.
- 8.10 The Service Provider may not amend a purchase order from the NDoH without prior written consent.

## **9. Roles and Responsibilities of the NDoH**

The NDoH shall retain ownership of the Products and shall be responsible for the following:

- 9.1 the acquisition (negotiation, terms and payment) of the Products from the Manufacturers or Suppliers (as the case may be);
- 9.2 requesting quotations from the successful panellists including the Service Provider from time to time;
- 9.3 providing the Service Provider with the purchase orders in relation to the Products;
- 9.4 coordinating between the Manufacturer or Supplier (as the case may be) and the Service Provider to arrange for the Service Provider to collect the Products from the Manufacturer or Supplier in the Country of Export; and
- 9.5 coordinating between the Logistics Service Providers and the Service Provider regarding the Transport of the Products by the Service Provider to the Logistics Service Provider's Warehouses.

## **10. Service level management and reporting**

- 10.1 The Parties shall meet at least once a week to review the progress regarding the implementation of this Agreement. Such meeting shall be held in person or by way

of a Microsoft Teams or Zoom meetings as the Parties may agree. Minutes of the meeting will be taken, recorded and distributed to the NDoH within five (5) business days following the meeting.

- 10.2 The Service Provider will submit a final written report to the NDoH within two weeks of the end of the Initial Term and/or the Extended Term, as the case may be.
- 10.3 The Products shall always remain the property of the NDoH and shall at no time become the property of the Service Provider.

## **11. Terms of payment and invoices**

- 11.1 The payments to be made by the NDoH to the Service Provider for the provision of the Services will be as set out in the purchase order issued by the NDoH to the Service Provider.
- 11.2 The Service Provider shall generate a valid tax invoice for Fees, with supporting documentation (which shall include signed invoices and PODs), and submit same to the NDoH within 5 (five) Business Days' of the completion by the Service Provider of a purchase order issued by the NDoH.
- 11.3 The NDoH shall effect payment within 30 (thirty) calendar days after the receipt of the valid tax invoice for Fees and any supporting documentation (which shall include signed invoices and PODs) subject to the satisfactory performance of the Services in accordance with this Agreement.
- 11.4 The amounts to be paid are inclusive of VAT.
- 11.5 The total number of vials to be managed in accordance with the Agreement will be as set out in each purchase order.
- 11.6 Unless prior written approval has been obtained from the NDoH, the quotation as approved by the NDoH may not be adjusted.
- 11.7 The Service Provider shall retain all data and documents pertaining to the Agreement and the Services as well as all transactions undertaken in accordance with the applicable guidelines published by SARS (South African Revenue Services) and applicable law, including GDP.

## 12. Audits and inspections

- 12.1 The Parties agree that NDoH may, through their internal or external auditors, or other experts retained by NDoH, undertake a physical inspection of the Warehouses of the Service Provider, at any time, to ensure compliance with all storage requirements, including Cold Chain specifications.
- 12.2 Any cost related to such investigations and the provision of audit certificates on request, where necessary, shall be borne by the Service Provider if the audit and/or inspection indicates that the Service Provider is guilty of any wrong-doing including negligence.
- 12.3 The Service Provider shall retain all records that may be required for auditing for the periods prescribed by law.
- 12.4 The audit shall be conducted with access to the Service Provider's servers, electronic records and otherwise any of the Service Provider's systems or tools as reasonably required. The NDoH and its representatives performing the audit shall only refer and review hard copies and electronic copies specific to the Agreement for the audit.
- 12.5 The audit may be performed at the Service Provider's premises or elsewhere as determined by the NDoH.
- 12.6 The Parties acknowledge that auditors or other experts envisaged in this clause may not be competitors of the Service Provider.
- 12.7 In the event that NDoH engages a third party to undertake the audit, NDoH shall ensure that such third party, prior to undertaking the audit, signs an irrevocable and unconditional confidentiality and non-disclosure undertaking in favour of the Service Provider on terms and conditions acceptable to the NDoH.
- 12.8 The NDoH may also conduct quality assurance in accordance with clause 3.2 of Annexe A. In such case the representatives of the NDoH shall always be accompanied by authorised representatives of the Service Provider
- 12.9 This clause shall survive termination of this Agreement.

### **13. Indemnity**

- 13.1 The Service Provider will be responsible for any and all liabilities arising from the Service Provider's acts or omissions relating to the Service Provider's provision of the Services.
- 13.2 The Service Provider hereby indemnifies and shall hold harmless and defend the NDoH from and against any and all claims, suits, losses, damages, costs and expenses of any nature whatsoever and however arising out of any respective individual or collective wilful or negligent act or omission by the Service Provider or any Subcontractor.
- 13.3 The Service Provider shall indemnify, hold harmless and defend the NDoH and its officers, directors, employees and agents from and against any claims, suits, losses, damages, costs, fees and expenses (including court costs and reasonable attorney's fees) which result from breach of a representation, warranty or obligations of the Service Provider in this Agreement.
- 13.4 The Parties shall not be liable to each other for any indirect, special and consequential damages arising out of or in connection with this Agreement, including for the use or sale of the Product.

### **14. Performance and penalties**

- 14.1 The Service Provider agrees to perform the Services in accordance with the service standards outlined in this Agreement and to the satisfaction of the NDoH during the Initial Term and any Extended Term of this Agreement.
- 14.2 All Services not conforming to the requirements and standards set out in this Agreement and/or the Tender, including any substitutions and alterations not properly approved and authorized by the NDoH, shall be deemed to be defective.
- 14.3 The NDoH shall be entitled to impose penalties for a proven breach of the Service Provider's obligations resulting in either a late or defective performance by the Service Provider of any Service. In this regard, the NDoH shall deduct 20% (twenty percent) of the service fee per consignment as reflected in the purchase order issued by the NDoH.

## 15. Business continuity

- 15.1 The Service Provider must inform the NDoH at first knowledge of any circumstances that may result in interrupted supply, including but not limited to:
- 15.1.1 regulatory action which may impact on the licensing and registration of the Service Provider or that of entities on which it is reliant;
  - 15.1.2 industrial action;
  - 15.1.3 supply of electricity or water to any of the Warehouses of the Service Provider;
  - 15.1.4 any other service delivery challenges.
- 15.2 All official written communication must include detail of corrective actions taken, or to be taken, by the contracted Service Provider to ensure continuity of supply.

## 16. Liability for damages, loss or destruction of the Product

The Service Provider will be responsible and assumes all responsibility and liability for any damage, loss or destruction of the Products whilst in its possession or under its care and control.

## 17. Insurance

- 17.1 Subject to the proviso to this clause 17.1, the Service Provider shall, at its own cost, effect and maintain adequate insurance cover at its own expense with a reputable insurer, so as to insure the Products and cover the risks undertaken by it in terms of this Agreement, in accordance with prudent insurance practice, for loss, damage or injury incidental to the Services and/or which may be suffered by the NDoH as a result of the Service Provider's fault or omission in rendering the Services envisaged in this Agreement. Such insurance shall include its having procured Goods in Transit and Liability insurance from a reputable insurer. Such insurance shall cover the replacement cost of the Products and cost of logistics while the Products are in the Service Providers' custody. Such proof must include a confirmation that the policy is not endorsed for Covid-19 related activities. Insofar as the Service Provider self-insures, then it shall provide to NDoH- i) proof of the fact that it does so in the normal and ordinary course of its business; ii) a bank guarantee provided by its corporate bankers in favour of the NDoH guaranteeing to pay all losses incurred by NDoH from all risks emanating from this Agreement.

- 17.2 Subject to the proviso to clause 17.1, the insurance must be taken out and become fully effective at the Commencement Date.
- 17.3 The Service Provider shall not take any action or fail to take any action, or (in so far as is reasonably within its power) permit anything to occur in relation to it, which would:-
- 17.3.1 entitle any insurer to refuse to pay any claim under the policy applying to any of the insurances relating to the Services; or
- 17.3.2 result in the banking institution contemplated in clause 17.1 failing to honour the guarantee which might have been provided.
- 17.4 Subject to the proviso to clause 17.1, true and complete certificates of all the insurances (together with any other information reasonably requested by the NDoH relating to such policies) shall be made available to the NDoH on request and the NDoH shall be entitled to inspect the originals during ordinary business hours.
- 17.5 Subject to the proviso to clause 17.1, satisfactory evidence that the premiums due and payable under any such policies have been paid and that the insurances are in full force and effect in accordance with the requirements of this clause shall be provided to the NDoH on request.
- 17.6 Subject to the proviso to clause 17.1, the Service Provider shall, as and when required pursuant to the terms of the relevant insurance, renew each insurance for so long as any risk covered thereby exists and shall furnish the NDoH with true and complete copies of each certificate of renewal for such insurance as soon as possible but in any event no less than at least 10 (ten) Business Days before the relevant renewal date.

## **18. Assignment, cession and delegation**

The Parties herein shall not assign, cede or delegate any right and /or obligations under this Agreement to a third party without each other's prior written approval.

## **19. Subcontracting**

- 19.1 The Service Provider shall be entitled to subcontract part of the Services or any of its obligations in terms of this Agreement to Subcontractors, provided that the Service Provider provides for same in its quotation to be submitted to the NDoH. In such quotation, the Service Provider must state what part of the Services will be

subcontracted and to whom the Services will be subcontracted to. The Service Provider shall require the prior written consent of the NDoH, which consent shall not be unreasonably withheld or delayed.

19.2 Where any subcontractor relationship will be entered into for the delivery of any component of the Services, the Service Provider is required to stipulate the following, where any subcontractor relationship will be entered into for the delivery of any component of the Services:

19.2.1 description of the goods and/or services to be provided by the Subcontractor;

19.2.2 the registered name of the Subcontractor;

19.2.3 the B-BBEE contributor level of the Subcontractor, including whether they are a Qualifying Small Enterprises (QSE) or Exempted Micro Enterprise (EME), or whether this is not applicable;

19.2.4 the value of the subcontractor relationship as a percentage of the overall approved quote and corresponding Fees.

19.3 The Service Provider shall remain fully responsible and liable for the actions and omissions of any Subcontractor and for the performance of its obligations under this Agreement and the Service Provider shall procure that the Subcontractor complies with the obligations of the Service Provider under this Agreement as if it were a party to this Agreement.

## 20. Intellectual property

20.1 The Parties agree and record that the Manufacturer and/or the Supplier of the Products to the NDoH owns and shall continue to own and/or control all right, title and interest in the said Product, including all rights, title and interest in any discovery, data, improvements, inventions, know-how, findings, processes, systems etc. in relation to the Manufacturer's and the Supplier's development, manufacturing and commercialization of the said Product ("**Owner's IP**"). The NDoH has the right to use the Owner's IP in its control for the duration of the Agreement.

20.2 All statutory and other proprietary right, title and interest (including rights to require information to be kept confidential) in respect of know-how, trade secrets, trade mark(s), copyrights, designs, patents and inventions, including the rights to apply

for such rights and all applications and registrations therefor, which pertain to the Products, including the dossier, literature, technical data and information for the Products, do not vest with the Service Provider.

- 20.3 Material or information made available to or obtained directly by the Service Provider from the NDoH or in connection with or as a result of the rendering of the Services and in respect of which the intellectual property rights vest in the NDoH shall remain the property of the NDoH (the "**NDoH's Intellectual Property**"). No rights therein shall vest or pass to the Service Provider. Notwithstanding what is set out above, each Party will retain ownership of all rights, titles and interests in its pre-existing products, methodologies, templates, tool kits, know-hows, software and tools, training materials, proprietary data and programs (and changes, additions and enhancements thereto that constitute derivative works thereof) and all of the intellectual property rights therein, including, without limitation, copyright, trade secrets and patent rights.
- 20.4 All and any material, information or the NDOH's Intellectual Property made available to or obtained by the Service Provider from or in connection with or as a result of this Agreement shall remain the property of the NDoH. No rights therein shall vest or pass to the Service Provider and it may not be used in any manner or form unless the Service Provider has obtained written consent from the NDoH.
- 20.5 The Service Provider shall not acquire any rights, title or interest of any kind in any information and / or the Owner's IP and/or the NDoH's Intellectual Property. If called upon to do so by the NDoH, the Service Provider shall sign a user agreement in respect of any intellectual property with the owner thereof.
- 20.6 Any intellectual property created pursuant to this Agreement belongs to the NDoH. All and any material, information or NDoH Intellectual Property made available to or obtained by the Service Provider from or in connection with or as a result of this Agreement shall remain the property of the NDoH. No rights therein shall vest or pass to the Service Provider and it may not be used in any manner or form unless the Service Provider has obtained written consent from the NDoH.
- 20.7 The Products are distributed by and on behalf of the NDoH in South Africa under the Manufacturer's or the Supplier's trademarks as may be designated for the said Product ("**Trade Marks**") and the Service Provider shall extend all co-operation in securing and protecting the Trade Marks.

20.8 Upon expiry or termination of this Agreement, the Trade Marks shall not be utilized by the Service Provider, whether directly or indirectly, for any purpose whatsoever.

20.9 This clause shall survive termination of this Agreement.

## 21. Confidentiality

21.1 For the purposes of this clause, "**Confidential Information**" shall mean any and all data and information, whether oral, written or electronic, irrespective of its form owned, possessed or controlled or passed on by the NDoH, before or after execution of this Agreement, to the Service Provider and/or accessed through the provision of the Services, including, without limitation, technical or scientific or clinical trial data, standard operating procedures, quality management systems, unpublished records, know-how, formulas, product specifications, quality control process, clinical trials, flow charts, operating policies and procedures, transactions, data and information, manuals, patterns, patents, trademarks, copyrights and other intellectual property related matters, designs, sequences, drawings, commercial, manufacturing, information relating to costs, strategic plans, processes, techniques, technologies, ideas, improvements, studies, products and any other information disclosed in relation to this Agreement.

21.2 The Service Provider is bound to protect the confidentiality of all Confidential Information and shall not disclose or use any Confidential Information other than in fulfillment of the Services. The Service Provider shall not during the term of the Agreement nor after its expiry or termination, disclose any information relating to the Confidential Information, the Products, any patients, the NDoH and the Services, or government in any other sphere, or any government institution or organ of state, to anyone other than those persons who are connected to the NDoH and/or the Service Provider and who are required or authorised to have access to such information.

21.3 All information and data received and accessed through this Agreement or the Tender shall automatically be deemed to be Confidential Information and shall only be used to meet the objectives of this Agreement as outlined in the Tender and this Agreement, namely the provision of the Services.

21.4 Any Confidential Information disclosed by the NDoH shall be strictly confidential and shall not be used, shared with or disclosed to, directly or indirectly, with any third party by the Service Provider. The absence of any marking or legend

indicating that any particular information disclosed by the NDoH is to be treated as confidential shall not limit or diminish the obligation of the Service Provider to treat such information as Confidential Information.

21.5 The Service Provider shall:

21.5.1 use the Confidential Information only for the purpose of rendering the Services;

21.5.2 treat and safeguard the Confidential Information as private and confidential; and

21.5.3 ensure proper and secure storage of all Confidential Information.

21.6 The NDoH shall become the sole owner of the data, information, documents and reports collated and compiled by the Service Provider in the execution of this Agreement.

21.7 The copyright of the data, documents and reports compiled by the Service Provider will belong to the NDoH and none of the data, documents and reports may be made available and reproduced or distributed to third parties in any way without the prior written approval of the NDoH.

21.8 Any documents or records (including written instructions, notes or memoranda) relating to the Services which are to be provided to the Service Provider or which come into the Service Provider's possession during the currency of this Agreement, are deemed to be the property of the NDoH and shall be surrendered to the NDoH on demand, and in the event of the expiry or termination of this Agreement, the Service Provider will not retain any copies thereof or extracts therefrom without obtaining the prior written permission of the NDoH. The provisions of clause 21.6 shall not apply to the extent that Service Provider is obliged to retain any Confidential Information in terms of any applicable law, rule or regulation or by any competent judicial, governmental, supervisory or regulatory body or in accordance with reasonable internal policy.

21.9 The Service Provider agrees to keep confidential and not to disclose to third parties any information provided by the NDoH or its employees in the course of performance of the Services pursuant to this Agreement unless the Service Provider has received the prior written consent of the NDoH to make such disclosure.

- 21.10 The NDoH reserves the right to request copies or delivery of any relevant information or documentation at any time during the term of the Agreement.
- 21.11 The NDoH reserves all rights to any remedies, whether under the law to remedy any unauthorized use or disclosure by the Service Provider.
- 21.12 The Service Provider may not issue any press release or any other public document or make any public statement in each case relating to or connected with or arising out of this Agreement or the matters contained herein (save for any such release, announcement or documents which is required to be given, made or published by law or any relevant stock exchange and/or any other regulatory authority) without obtaining the prior written approval of the NDoH to the contents thereof and the manner of its presentation and publication, provided that such approval shall not unreasonably be withheld or delayed.
- 21.13 In the case of a release, announcement or document which is required to be given, made or published by law or under the rules of any relevant stock exchange and/or any other regulatory authority, the Service Provider shall give to the NDoH as much advance warning thereof as is reasonable in the circumstances together with drafts or a copy thereof as soon as it is at liberty to do so.
- 21.14 This clause shall survive the termination of this Agreement.

## **22. Force Majeure**

- 22.1 Each of the Parties shall not be liable to the other for any non-performance (either wholly or in part) or delay in performance of its obligations, shall be excused from the fulfilment of any of its obligations under this Agreement and shall not be considered to be in breach or default in the event that such performance is prevented or delayed by Force Majeure, provided that each of the Parties shall use its best efforts to complete such performance by other means. The Party relying on a Force Majeure event shall promptly notify the other Party accordingly in writing together with such evidence of a Force Majeure event as it can reasonably give and also specifying the period for which it is estimated that the preventions or delay will continue.
- 22.2 In this regard the party relying on a Force Majeure event must prove that:
- 22.2.1 the failure was due to an impediment wholly beyond its control;

- 22.2.2 on the Commencement Date, it could not reasonably have foreseen the effect that the impediment would have upon its ability to perform; and
- 22.2.3 it could not reasonably have avoided or overcome the impediment or at least its effects.
- 22.3 On the occurrence of a Force Majeure event, and notification thereof to the other Party, the obligation to perform shall be suspended until such time as it can be resumed. The NDoH shall be entitled to exercise step-in rights from the date on which notification from the Service Provider is received and shall be entitled to appoint any other third party to act as a service provider and perform the Services. If the NDoH does appoint another third party to act as a service provider and perform the Services, then the Service Provider shall on request by the NDoH forthwith give up possession of all Products under its control to such person as the NDoH may specify.
- 22.4 If the performance by either Party of any of its obligations under this Agreement is prevented or delayed by a Force Majeure for 7 (seven) days or more, consecutively or cumulatively, during the Initial Term or the Extended Term of this Agreement, then either the NDoH or the Service Provider shall in its discretion have the right to terminate this Agreement forthwith upon written notice.
- 22.5 However, if any payments are due or outstanding for the Product and/or Services prior to such termination, then such payments shall be effected by NDoH without regard to any existing cause of Force Majeure.

### **23. Breach and termination**

- 23.1 Should any Party fail to comply with an obligation under this Agreement, the other Party shall send a notice of breach to such Party.
- 23.2 A notice of breach shall:
- 23.2.1 indicate clearly the nature and extent of such breach;
- 23.2.2 contain a demand that the Party concerned remedy the breach within 14 (fourteen) days after receiving such notice; and
- 23.2.3 draw the attention of the Party concerned to the remedies the aggrieved party may have if such demand is not attended to.

- 23.3 If such breach is not remedied by the date and to the extent stipulated in the notice of breach, the aggrieved party may, without prejudice to any of this other right under this Agreement or common law:
- 23.3.1 cancel this Agreement and claim damages;
  - 23.3.2 continue this Agreement and claim specific performance; or
  - 23.3.3 avail itself of any other remedy that is legally available upon of the breach of contract.
- 23.4 Either Party may terminate this Agreement by giving 30 (thirty) days written notice to the other Party, provided that if the NDoH terminates this Agreement, the NDoH shall remunerate the Service Provider for any unpaid amounts relating to the Services already rendered to the satisfaction of the NDoH.
- 23.5 Should the Parties not reach agreement where the Agreement requires that a decision should be taken in consultation, the NDoH shall have the right to forthwith terminate the Agreement.
- 23.6 In the event that notice contemplated in clause 23.2 has been given by the NDoH and irrespective of whether it is contested or not, the Service Provider shall forthwith give up possession of any Products under its control to such person as the NDoH may specify.

## **24. Settlement of Disputes**

- 24.1 This clause is a separate, divisible agreement from the rest of this Agreement and shall:
- 24.1.1 not be or become void, voidable or unenforceable by reason only of any alleged misrepresentation, mistake, duress, undue influence, impossibility (initial or supervening), illegality, immorality, absence of consensus, lack of authority or other cause relating in substance to the rest of the Agreement and not to this clause. The Parties intend that all disputes, including the issues set forth above, be and remain subject to arbitration in terms of this clause; and
  - 24.1.2 remain in effect even if the Agreement expires or terminates for any reason whatsoever.

24.2 Save as may be expressly provided for elsewhere in this Agreement for the resolution of particular disputes, any dispute arising out of or in connection with this Agreement or the subject matter of this Agreement, including without limitation, any dispute concerning:

- 24.2.1 the existence of the Agreement apart from this clause;
- 24.2.2 the interpretation, application and effect of any provisions in the Agreement;
- 24.2.3 the Parties' respective rights or obligations under the Agreement;
- 24.2.4 the rectification of the Agreement;
- 24.2.5 any alleged misrepresentation, mistake, duress, undue influence, impossibility (initial or supervening), illegality, immorality, absence of consensus, lack of authority or other cause relating to or in any way connected with the Agreement or any part or portion thereof;
- 24.2.6 the breach, expiry, termination or cancellation of the Agreement or any matter arising out of the breach, expiry, termination or cancellation; and
- 24.2.7 any claims in delict, compensation for unjust enrichment or any other claim,

whether or not the rest of the Agreement apart from this clause is valid and enforceable, shall be referred, in the first instance, to negotiation as set out in clause 24.3 failing which to arbitration as set out in clause 24.4.

### **24.3 Negotiation**

- 24.3.1 The Parties will endeavour to resolve any dispute arising from the interpretation, application or implementation of this Agreement amicably and through consultation and negotiation between the Parties.
- 24.3.2 Should a deadlock or dispute of whatever nature arise from or in connection with any provision of this Agreement, conduct arising from the Agreement and/or information furnished in pursuit of its objectives, the Parties shall convene as soon as possible after the dispute/deadlock arises at the offices of the NDoH to negotiate a solution. Such negotiations shall be conducted in good faith.

## **24.4 Arbitration**

- 24.4.1 If the Parties are unable to resolve the deadlock or dispute in question within 30 (thirty) days after the commencement of the negotiations referred to above, then the deadlock or dispute shall be referred to confidential arbitration in terms of the expedited rules of the Arbitration Foundation of South Africa ("**AFSA**"). This clause shall not preclude either party from obtaining interim relief on an urgent basis from a court of competent jurisdiction pending the decision of the arbitrator.
- 24.4.2 The arbitration shall be held in Pretoria subject to the provisions of the Arbitration Act No. 42 of 1965 with the procedure followed being as simple and inexpensive as possible.
- 24.4.3 The decision of the Arbitrator shall be final in all respects and such an arbitration decision can be made an order of the Court if either of the Parties applies for this. The cost of any such arbitration shall be allocated by the Arbitrator.
- 24.4.4 The Arbitrator shall be appointed in accordance with the AFSA rules for expedited arbitrations.
- 24.5 Provisions of this clause constitute (once agreed) an irrevocable consent by the Parties to any arbitration proceedings in terms hereof and neither Party shall be entitled to withdraw there from or claim at any such proceedings that it is not bound by such provisions.

## **24.6 Confidentiality**

The existence and content of arbitration proceedings as well as any ruling, award or outcome shall be treated as confidential by the Parties as well as the members of the arbitral tribunal. This will apply unless:

- 24.6.1 the Parties will require disclosure to the extent that it is required by a Party to fulfil a legal duty, protect or pursue a legal right, or enforce or challenge an award in *bona fide* legal proceedings before a court, forum or tribunal;
- 24.6.2 the Parties consent in writing to the disclosure of certain information;
- 24.6.3 the information is needed for the preparation or presentation of a claim or defence in the arbitration;

- 24.6.4 the information is already in the public domain without any Party breaching this clause; or
- 24.6.5 the arbitral tribunal has ordered that it be disclosed upon application by a Party.

## **25. Amendment of the Agreement**

No addition to or variation, consensual cancellation or novation of this Agreement shall be of any force or effect unless reduced to writing and signed by both Parties or their duly authorized representatives.

## **26. Fraud and corruption**

- 26.1 The Service Provider warrants that the performance of its obligations shall in no way constitute an infringement or other violation of any laws of South Africa, and in particular, it will under no circumstances engage in any activities which may constitute corruption or corrupt activities within the ambit of the Prevention and Combating of Corrupt Activities Act, 2004, such activities to include:
- 26.1.1 accepting or agreeing, or offering to accept or give or offer any gratification to any person in order to influence such other person to act in a manner that amounts to the illegal dishonest exercise or performance of any power, duty, statutory, contractual or other legal obligation; or
- 26.1.2 to procure that any person, directly or indirectly, accepts or agrees or offers to accept any gratification from another person or gives or agrees or offers to give to any other person any gratification in order to improperly influence the conclusion or performance of its obligations in terms of this Agreement.
- 26.2 The Service Provider warrants that it shall conduct its business in compliance with all applicable laws (including anti-corruption laws), its business is in compliance with all laws, including applicable anti-corruption laws, and it has instituted and maintained, as at the Commencement Date, policies and procedures designed to promote and achieve compliance with these laws.
- 26.3 Should it be found at any stage of this Agreement, including in negotiations prior to or subsequent to the Commencement Date as well as upon and after termination of this Agreement, that any Party to this Agreement and/or any third party involved directly or indirectly in this Agreement, has performed or contemplated performing

an act of fraud or corruption, either in the award of this Agreement or any past or current or future endeavours involving the Parties to this Agreement, which resulted in either Party suffering loss, injury/or damage including to its reputation, the Agreement shall terminate at the instance of the innocent party, notwithstanding anything to the contrary contained herein, and nothing contained herein shall prevent the innocent Party from invoking the remedies available to it contained in this Agreement as well as to proceed against any and all individuals in their personal capacity who performed the corrupt act.

26.4 This clause shall survive termination of this Agreement.

## 27. Domicilia and notices

27.1 The NDoH chooses as its *domicilia citandi et executandi* for all purposes arising from this Agreement, the addresses specified below:

Attention: Dr SSS Buthelezi

Physical: Civitas Building  
Corner Thabo Sehume and Struben Streets  
Pretoria

Postal: Private Bag X828,  
PRETORIA,  
0001

Email dg@health.gov.za and Khadija K. Jamaloodien  
Khadija.Jamaloodien@health.gov.za.

27.2 The Service Provider chooses as its *domicilia citandi et executandi* for all purposes arising from this Agreement, the addresses specified in Annexe A.

27.3 Either Party may amend its *domicilium citandi et executandi* by means of written notice to the other Party, provided that such domicilium shall be a physical address within the Republic of South Africa.

27.4 Any notice, request, consent or communication made between Parties pursuant to this Agreement shall be in writing and shall be delivered by hand or sent by prepaid registered post or by email.

- 27.5 A notice, request, consent or communication is presumed unless the contrary is proven, to have been given:
- 27.5.1 if hand delivered during business hours on a Business Day, on the day of delivery;
- 27.5.2 if posted by prepaid registered post, 5 (five) Business Days after the date of posting thereof; *or*
- 27.5.3 if sent by email, on the first Business Day following the day of sending of such email.
- 27.6 Notwithstanding anything to the contrary contained or implied in this Agreement, a written notice or communication actually received by one of the Parties from another shall be adequate written notice or communication to such Party.

## **28. General**

- 28.1 This Agreement, in two signed originals, constitutes the sole record of the agreement between the Parties in regard to the subject matter hereof. Each Party shall retain one of the two signed originals and the Parties shall exchange copies of the countersigned Agreement.
- 28.2 No Party shall be bound by any representations, express or implied, warranties, promises or the like, not recorded herein, incorporated as an Annexe or otherwise reduced to writing and signed by or on behalf of the Parties.
- 28.3 This Agreement supersedes and replaces prior commitments, undertakings or representations, whether oral or written, between the Parties in respect of the subject matter hereof.
- 28.4 No relaxation of the terms of this Agreement and no indulgence which one Party may grant to the other will in any way operate as an estoppel against the former Party or be deemed to be a waiver of its rights, or in any other way limit, alter or prejudice those rights.

## **29. Governing law**

This Agreement is governed by the laws of the Republic of South Africa.

**30. Authority**

Each person signing this Agreement for and on behalf of a Party hereto hereby warrants in his or her official capacity that he or she is duly authorised by such Party to do so.

**31. Jurisdiction of South African courts**

The Parties consent to the non-exclusive jurisdiction of the High Court of South Africa, Gauteng Division, Pretoria for any proceedings arising out of or in connection with this Agreement.

**32. Counterpart signing of the Agreement**

The Parties agree that this Agreement may be signed at different times and in different places, and in copy provided the content of the Agreement and signatures are exact replicas (counterparts) of the originals when put together. The signed Agreement's when put together shall constitute a binding agreement between the Parties.

**THUS DONE AND SIGNED** on behalf of the **PARTIES** by their duly authorised representatives, in the presence of the undersigned witnesses, at the places appearing in the appropriate spaces below, on the dates as specified.

For the NDoH: Full Names and Surname:	For the Service Provider: Full Names and Surname:
Designation:	Designation:
Signature:	Signature:
Date:	Date:
Place:	Place:
AS WITNESSES (Full Names and Surname):	AS WITNESSES (Full Names and Surname):
1. _____	1. _____
2. _____	2. _____

**Annexe A**

**The Services – the process of exportation and importation of the Products**

**1. General**

1.1 Commencement Date: Signature Date.

1.2 The Service Provider is:\_\_\_\_\_.

1.3 The Service Provider will be represented by:\_\_\_\_\_.

1.4 The NDoH will be represented by: Marione Schonfeldt.

1.5 The Country of Export: as specified in the request for quotation.

1.6 Product specifics: as specified in the request for quotation.

1.7 The Service Provider chooses as its *domicilia citandi et executandi* for all purposes arising from the Agreement, the addresses specified below:

Attention: \_\_\_\_\_

Physical: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Postal: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Tel: \_\_\_\_\_

Email \_\_\_\_\_

## **2. Operations**

### **2.1 Receiving and Product verification:**

#### **2.1.1 Minimum requirements for the Service Provider to receive the Products**

The NDoH will provide the Service Provider with the following:

- 2.1.1.1 a purchase order detailing the Product description, quantity and any other pertinent details to the shipment;
- 2.1.1.2 an electronic notification, as soon as possible, but in any event no later than the date for collection of the Products from the Manufacturer or Supplier by the Service Provider, detailing at a minimum the following:
  - 2.1.1.2.1 date for collection of the Products from the Manufacturer or Supplier (as the case may be);
  - 2.1.1.2.2 the Product description;
  - 2.1.1.2.3 the Batch number of the Products;
  - 2.1.1.2.4 the expiry date of the Products;
  - 2.1.1.2.5 the quantity of the Products;
  - 2.1.1.2.6 airwaybill;
  - 2.1.1.2.7 packing list or pallet configuration sheet;
  - 2.1.1.2.8 temperature monitor device configuration/ detail sheet;
  - 2.1.1.2.9 quality documents where applicable; and
  - 2.1.1.2.10 Certificate of Delivery/ Vaccine Arrival Report where applicable and any other pertinent details to the shipment.

#### **2.1.2 Receipt of the Products**

The Service Provider will receive the Products from the Manufacturer or the Supplier (as the case may be) in the Country of Export.

### **2.1.3 Transport of the Products**

2.1.3.1 The Service Provider will Transport the Products to the designated airport (which shall be a suitable international airport) in the Country of Export, where the Service Provider will attend to the loading of the Products on the designated cargo flight for Transport, subject to the applicable Incoterm rule. The Service Provider shall be responsible for the necessary preparations for Transportation via air cargo and for obtaining the requisite export documentation (including customs clearance), subject to the applicable Incoterm rule.

2.1.3.2 The Service Provider shall ensure that the Cold Chain management is aligned to the Manufacturer's instructions throughout the Transportation process up until delivery of the Product to the Logistics Service Provider in South Africa.

### **2.1.4 Delivery of the Products**

The Service Provider will take delivery of the Products immediately upon arrival of the Products at the designated airport in South Africa.

### **2.1.5 Clearing of Products**

The Service Provider will be responsible for the clearing of the Products through customs.

## **2.2 Shipment verification**

2.2.1 The Service Provider's appointed representative shall conduct a visual inspection of each consignment of the Products at (i) the Designated Loading Venue for the collection of the Products in the Country of Export; (ii) the designated airport in the Country of Export; and (iii) at the designated airport in South Africa, for shortfalls, damages, losses or defects, other than the latent defect in the Products.

2.2.2 The Service Provider shall, upon receipt of the Products, only confirm the number of pallets and the Manufacturer or Supplier cartons (subject to the requirements of the shipment documentation) and that the contents are received "unchecked". Such confirmation shall be made on the shipment

documentation of the Service Provider. In addition, the Service Provider shall check the shipment for visible damages and tampering and shall endorse the shipment documentation accordingly.

### **2.3 Delivery turnaround times**

- 2.3.1 Only purchase orders using an official, authorised order format issued by the NDoH are valid.
- 2.3.2 The Service Provider may not amend a purchase order from the NDoH without the prior written consent of the NDoH, which consent will not be unreasonably withheld.
- 2.3.3 Once a purchase order is issued to the Service Provider, the Service Provider will be required to arrange the requisite import and export documentation, customs clearance, airport and other clearing charges as well as any taxes in South Africa. The Service Provider will be responsible for managing all import formalities for customs clearing in South Africa.
- 2.3.4 The Service Provider must provide and update the NDoH on the expected Lead Time for the required mode of transport, which is air cargo.
- 2.3.5 The Service Provider will ensure that the Products are at all times managed with the appropriate skill and expertise expected of an expert logistics provider. Appropriate continuous temperature monitoring and shipment tracking must be provided.
- 2.3.6 The Service Provider will be responsible for ensuring secure delivery of cleared Products to the Warehouse. This will include ensuring that appropriate Transportation is used to maintain the safety and quality of the Products. Appropriate security measures are to be provided to ensure safe passage of the Products to the Warehouse. The Service Provider may be required to coordinate with national security and/or police services to ensure the security of the Products.
- 2.3.7 The Service Provider must provide full details of all clearing and Transport charges for clearing air cargo at airports.

- 2.3.8 The Service Provider will be responsible for processing and procuring all required authorisations to import the Products.
- 2.3.9 The Service Provider must liaise with the NDoH before processing a purchaser order that appears to be irrational or misaligned with estimates.
- 2.3.10 The NDoH will instruct the Service Provider to deliver the Products to the Warehouses identified and specified with the allocations for delivery, the NDoH may select multiple Warehouses per purchase order.

## **2.4 Transportation and Deliveries**

- 2.4.1 All delivery vehicles shall have tracking devices.
- 2.4.2 Transportation of the Products must be in such a way that it is secure and the temperature is maintained to the Product specifications.
- 2.4.3 The Products and related documentation must be delivered in accordance with the terms, conditions and delivery instructions stipulated in the purchase order.
- 2.4.4 The Products must be delivered in accordance with the appropriate conditions of storage as per the Products' condition of registration/authorisation.
- 2.4.5 All temperature data loggers, refrigeration tags, freezer tags and log tags shall comply with and meet WHO specifications or recommendations. All temperature data loggers, refrigeration tags, freezer tags and log tags must monitor the temperature of the loaded area of the transportation throughout the trip and the validated shipper must have at least a continuous temperature monitoring device that complies or meets with WHO specifications or recommendations.
- 2.4.6 Once the delivery has been completed the Service Provider will submit signed invoices and POD to the NDoH electronically as well as hand deliver the originals.

## **2.5 Authorisations**

- 2.5.1 All requisite regulatory authorisations for the provision of the Services must be maintained by the Service Provider for the full period of the Agreement. Non-compliance with this special condition shall result in cancellation of the Agreement.
- 2.5.2 Any change in the status of any of the authorisations during the period of the Agreement must be reported in writing within 7 (seven) days of receipt of such notice from the applicable regulator to the NDoH for the attention of Khadija Jamaloodien using email address: Khadija.jamaloodien@health.gov.za.

## **2.6 Post award evaluation**

- 2.6.1 The NDoH will monitor the performance of the Service Provider for compliance to the terms of the Agreement.
- 2.6.2 The performance will be measured, monitored and discussed with the Service Provider on a regular basis. The underperformance may affect the contractual relationship between the NDoH and the Service Provider.
- 2.6.3 The NDoH may, at any time, carry out inspections, either using the NDoH personnel and/or through contracted auditors.

## **3. Quality Assurance**

### **3.1 Premises, equipment and processes**

The Service Provider shall, at all times, manage and monitor its nominated premises, processes and equipment to ensure compliance with all applicable laws including GDP.

### **3.2 Quality assurance audits**

- 3.2.1 NDoH may conduct quality assurance inspections, provided that the Service Provider shall be notified of such intended audit. The Service Provider will address any inspection deviations noted by the Service Provider within 15 (fifteen) calendar days of the inspection.

- 3.2.2 The Service Provider will notify the NDoH of any inspection of its facilities by the SAHPRA or any other regulatory authority if this inspection will involve the Products.

#### **4. Administration**

##### **4.1 Document retention**

The Service Provider will retain data and documents pertaining to the transactions as detailed in the Agreement for a period of 5 (five) years.

##### **4.2 Security**

- 4.2.1 The Service Provider must ensure appropriate security levels and access control to the Warehouses and other storage sites under the control of the Service Provider. These must include, but not be limited to, physical and electronic security (for example, closed circuit television monitoring).
- 4.2.2 The Service Provider must ensure that all deliveries are actively tracked and monitored with an appropriate tracking system.
- 4.2.3 The Service Provider should perform appropriate risk assessments to inform their decision to use armed escorts as necessary.
- 4.2.4 The Service Provider may be required to coordinate with national security and/or police services to ensure the security of the Products.

**Annexure 4**  
**LOGISTICS SERVICES AGREEMENT**

**LOGISTICS SERVICES AGREEMENT**

**between**

**THE GOVERNMENT OF THE REPUBLIC OF SOUTH AFRICA THROUGH ITS NATIONAL  
DEPARTMENT OF HEALTH**

(hereinafter referred to as “**the NDoH**”)

herein represented by **Dr SSS Buthelezi**  
in his capacity as **DIRECTOR-GENERAL** and duly authorised.

**and**

**THE SERVICE PROVIDER AS SET OUT IN ANNEXE A**

(hereinafter referred to as “**the Service Provider**”)

**Regarding**

**The Warehousing and Distribution of COVID-19 Vaccines**

## Table of Contents

	<b>Page No</b>
1. Preamble.....	4
2. Definitions .....	5
3. Purpose / Objectives of Agreement .....	10
4. Duration .....	11
5. Appointment.....	11
6. Applicability of other documents .....	11
7. Services by the Service Provider .....	12
8. Obligations of the Service Provider.....	13
9. Roles and responsibilities of the NDoH.....	15
10. Service level management, reporting and product recalls .....	16
11. Terms of payment and invoices .....	17
12. Audits and inspections .....	19
13. Indemnity .....	20
14. Performance and penalties .....	20
15. Business continuity .....	21
16. Liability for damages, loss or destruction of the Product.....	21
17. Insurance .....	21
18. Assignment, cession and delegation .....	22
19. Subcontracting .....	23
20. Intellectual property.....	23
21. Confidentiality .....	25
22. Force majeure.....	27
23. Breach and termination .....	28
24. Settlement of disputes .....	29
25. Domicilia and notices .....	32
26. Amendment of this Agreement .....	33
27. Fraud and corruption.....	33
28. General .....	34

29. Governing law ..... 34

30. Authority ..... 34

31. Jurisdiction of South African courts ..... 35

32. Counterpart signing of the Agreement ..... 35

Annexe A      The Services - The Process of Warehousing and Distribution of the Products .....36

Annexe B      Fee Schedule ..... 54

## 1. Preamble

**WHEREAS** the NDoH is in the process of sourcing and procuring vaccines from global manufacturers against SARS-CoV-2 that would be utilised to fight the current Covid-19 pandemic (the “**Covid-19 Vaccines**”) and will conclude procurement agreements for the Product with the various manufacturers around the world in terms of which the NDoH owns the Products (as that term is defined below) to be distributed and warehoused by the Service Provider.

**AND WHEREAS** to the extent that the Products are not registered, the Products will be supplied through an authorisation in terms of section 21 of the Medicines Act (as defined below) as there are currently no Covid-19 Vaccines registered by the South African Health Products Regulatory Authority (“**SAHPRA**”). The rollout of the Covid-19 Vaccines is intended to be in a phased manner.

**AND WHEREAS** on or about 5 February 2021 the NDoH issued a request for proposals for the provision of logistics, warehouse and distribution management services for the Covid-19 Vaccines to the NDoH, in terms of which, amongst others, the successful bidder/s would be required to, amongst others, (i) be responsible for all warehousing of the Products following receipt thereof from the Importation Service Provider (as that term is defined below); and (ii) be responsible for the transport and delivery of the Product to Delivery Sites (as defined below).

**AND WHEREAS** the Service Provider was a successful bidder and, accordingly, the NDoH has appointed the Service Provider, in order to achieve the abovementioned objectives, the terms of which will be regulated by this agreement.

**AND WHEREAS** the NDoH confirms the appropriateness of the procurement process and compliance with all relevant policies, regulations and prescripts governing emergency government procurement.

**AND WHEREAS** the NDoH is desirous of entering into this Agreement with the Service Provider and the Service Provider has the capacity and wishes to achieve the abovementioned objectives in terms of this agreement wherein the Products contemplated in this Agreement would be warehoused and distributed by the Service Provider.

**NOW THEREFORE** the Parties wish to enter into this logistics services agreement to formalise the obligations and duties of the Parties.

## 2. Definitions

- 2.1. In this Agreement, the following words shall, unless otherwise stated or inconsistent with the context in which they appear, bear the following meanings and other words derived from the same origins as such words (that is, cognate words) shall bear corresponding meanings:
- 2.1.1. "**Agreement**" means this logistics services agreement, including the Annexes as amended and varied from time to time;
- 2.1.2. "**Annexes**" means the annexes attached to this Agreement;
- 2.1.3. "**Authorised Delivery Site**" means a Delivery Site that the NDoH notifies the Service Provider in writing has been authorised to place and receive purchase orders for the Products directly with the Service Provider;
- 2.1.4. "**Business Day**" means any day other than a Saturday, Sunday or gazetted national public holiday in the Republic of South Africa;
- 2.1.5. "**Cold Chain**" means all of the materials, equipment, facilities, vehicles, processes and procedures used to maintain the Products within the required temperature range from the time of manufacture until the Products are administered to individuals;
- 2.1.6. "**Cold Chain Solutions**" means the three cold chain ranges for different types of Products– (i) between 2–8°C (cold chain solution 1); (ii) at –20°C (cold chain solution 2); and (iii) at –70°C (cold chain solution 3);
- 2.1.7. "**Commencement Date**" means the date on which this Agreement will come into effect, which is the date of signature of the Party signing last;
- 2.1.8. "**Country of Export**" means the country other than the Republic of South Africa where the Product has been manufactured;
- 2.1.9. "**CPI**" means the consumer price inflation index published by Statistics South Africa from time to time;
- 2.1.10. "**Delivery Sites**" means public and private sector vaccination sites, provincial pharmaceutical depots and other approved storage sites. These sites may change from time to time during the term of the Agreement and notification of any such change shall be notified to the Service Provider;

- 2.1.11. **"Designated Facilities"** means the designated sites, storage facilities and warehouses that the Service Provider uses for storage of the Products, which shall be agreed in advance with the NDoH from time to time;
- 2.1.12. **"Designated Participants"** means any party that NDoH wishes for the Service Provider to deliver to including, but not limited to, provinces government and private sector providers;
- 2.1.13. **"Director-General"** means a person appointed as the Accounting Officer of the NDoH;
- 2.1.14. **"Fees"** means the fees to be charged by the Service Provider for the Services, as approved in writing by the NDoH as part of the award of the contract, before commencement of the Services and as detailed in clause 11;
- 2.1.15. **"Extended Term"** has the meaning set out in clause 4.2 (*Duration*) below;
- 2.1.16. **"Force Majeure"** means any circumstances or causes beyond the reasonable control of either Party, that prevents either Party from performing its obligations assumed in this Agreement, including, but not limited to, acts of God, Acts, regulations action, inaction, laws or restrictions of any government, terrorism, war, riot, civil commotion, strikes, lock-outs, destruction of production facilities or materials by flood, fire, earthquake or storm, labour and/or civil disturbances, epidemic and failure of public utilities or common carriers, excluding however the SARS-CoV-2 pandemic or Covid-19 and any quarantine or lockdown that may be implemented by the government of South Africa or any regulatory authority in South Africa;
- 2.1.17. **"GDP"** means the guidelines of good distribution practice as set out in the South African Good Wholesaling Practice for Wholesalers document issued by the then Medicines Control Council together with the NDoH dated July 2016;
- 2.1.18. **"GMP"** means the guidelines of good manufacturing practice as set out in the South African Good Manufacturing Practice for Medicines document issued by the SAHPRA together with the NDoH dated July 2019;

- 2.1.19. **"Importation Service Provider"** means a successful bidder selected by the NDoH as a panellist and appointed from time to time to provide the Importation Services;
- 2.1.20. **"Importation Services"** means the services to be provided by a successful bidder in relation to the Products including, but not limited to, freight forwarding services, collection from the Manufacturer's site of delivery, transportation to the nearest suitable international airport loading, international carriage to the Republic of South Africa, off-loading, transportation to the Designated Facilities, arranging of export and import documentation, foreign airport charges, insurance and customs clearance (where applicable);
- 2.1.21. **"Inbound Logistics"** means for the receipt and storage of the Products in South Africa including the forward and reverse movement, handling, and storage of the Products from the time when the Products arrive at the Designated Facilities where the Service Provider takes possession, to the time they are delivered to the Delivery Sites, and the reverse movement thereof to the extent that is so required, in terms of this Agreement as set out in more detail in clause 11 (*Terms of Payment and Invoice*);
- 2.1.22. **"Initial Term"** has the meaning set out in clause 4.1 (*Duration*) below;
- 2.1.23. **"Lead Time"** means the time from the date of receipt of a purchase order by the Service Provider, to the date of receipt of the Product at the Delivery Site;
- 2.1.24. **"Manufacturer"** means the manufacturer of the Products;
- 2.1.25. **"Medicines Act"** means the Medicines and Related Substances Act, 101 of 1965;
- 2.1.26. **"NDoH"** means the National Department of Health;
- 2.1.27. **"NCL"** means the South African National Control Laboratory;
- 2.1.28. **"Parties"** means the NDoH and the Service Provider and **"Party"** shall mean either one of them, as the context requires;
- 2.1.29. **"POD"** means proof of delivery documents which includes a delivery note and documents that acknowledge and prove delivery of the Products by the

Service Provider at the Delivery Site in the correct condition and specific quantities;

- 2.1.30. **“Products”** means the Covid-19 Vaccines as authorised for use by the SAHPRA for use in the Republic of South Africa and procured by the NDoH during the period of the Agreement, in respect of which the NDoH may require the Service Provider to provide the Services, as the case may be;
- 2.1.31. **“Services”** mean the services to be performed and rendered by the Service Provider to the NDoH in relation to the Products in South Africa, including, but not limited to, Inbound Logistics (where applicable), customs clearance (where applicable), collection and Transportation, warehousing, inventory control, material handling, purchase order and batch order processing and administration, packaging, batch tracking and tracing, Cold Chain Solution, data processing, the communications network necessary for effective management and delivery to and from the Delivery Sites. It includes all activities related to physical distribution, as well as the return of the Products, as more fully described in Annexe A;
- 2.1.32. **“Subcontractor”** means any person appointed as a subcontractor to perform the Services or part thereof on behalf of the Service Provider in accordance with the provisions of this Agreement;
- 2.1.33. **“Supplier”** means the relevant entity acting as supplier of the Products and/or any other supplier of the Products;
- 2.1.34. **“Tender”** means the tender issued by the NDoH for the provision of importation and logistics services for the Products to the NDoH for the period of 1 April 2021 to 31 December 2022 under request for proposals, HP17-2021TWDV;
- 2.1.35. **“Transport”** or **“Transportation”** means the entire transportation system including loading, unloading, handling and any and all other services whatsoever undertaken by the Service Provider in relation to the Products;
- 2.1.36. **“VAT”** means value-added tax levied in terms of the Value-added Tax Act, 89 of 1991, as amended; and
- 2.1.37. **“WHO”** means the World Health Organisation.

2.2. In this Agreement:

- 2.2.1. references to a statutory provision include any subordinate legislation made from time to time under that provision and include that provision as modified or re-enacted from time to time;
- 2.2.2. words importing the masculine gender include the feminine and neuter genders and *vice versa*; the singular includes the plural and vice versa; and natural persons include artificial persons and vice versa;
- 2.2.3. references to a "person" include a natural person, company, close corporation or any other juristic person or other corporate entity, a charity, trust, partnership, joint venture, syndicate, or any other association of persons;
- 2.2.4. references to a "subsidiary" or a "holding company" shall be references to a subsidiary or holding company as defined in the Companies Act;
- 2.2.5. if a definition imposes substantive rights and obligations on a Party, such rights and obligations shall be given effect to and shall be enforceable, notwithstanding that they are contained in a definition;
- 2.2.6. any definition, wherever it appears in this Agreement, shall bear the same meaning and apply throughout this Agreement unless otherwise stated or inconsistent with the context in which it appears;
- 2.2.7. if there is any conflict between any definitions in this Agreement then, for purposes of interpreting any clause of the Agreement or paragraph of any Annexe, the definition appearing in that clause or paragraph shall prevail over any other conflicting definition appearing elsewhere in the Agreement;
- 2.2.8. where any number of days is prescribed, those days shall be reckoned exclusively of the first and inclusively of the last day unless the last day falls on a day which is not a Business Day, in which event the last day shall be the next succeeding Business Day;
- 2.2.9. where the day upon or by which any act is required to be performed is not a Business Day, the Parties shall be deemed to have intended such act to be performed upon or by the next succeeding Business Day;

- 2.2.10. any provision in this Agreement which is or may become illegal, invalid or unenforceable in any jurisdiction affected by this Agreement shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability and shall be treated as having not been written (ie *pro non scripto*) and severed from the balance of this Agreement, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction;
- 2.2.11. the use of any expression covering a process available under South African law (such as but not limited to a winding-up) shall, if any of the Parties is subject to the law of any other jurisdiction, be interpreted in relation to that Party as including any equivalent or analogous proceeding under the law of such other jurisdiction;
- 2.2.12. references to any amount shall mean that amount inclusive of VAT, unless the amount expressly excludes VAT;
- 2.2.13. the rule of construction that if general words or terms are used in association with specific words or terms which are a species of a particular genus or class, the meaning of the general words or terms shall be restricted to that same class (ie the *eiusdem generis* rule) shall not apply, and whenever the word "*including*" is used followed by specific examples, such examples shall not be interpreted so as to limit the meaning of any word or term to the same genus or class as the examples given.
- 2.3. The expiration or termination of this Agreement shall not affect such of the provisions of this Agreement which are expressly provided to operate after any such expiration or termination, or which of necessity must continue to have effect after such expiration or termination, notwithstanding that the relevant provisions themselves do not provide for this.

### **3. Purpose / Objectives of Agreement**

The purpose of this Agreement is to regulate the relationship between the NDoH and the Service Provider by ensuring that the objectives of the NDoH for the effective provision of the Services in relation to the Products, are met including in respect of one or more Cold Chain Solutions as detailed in this Agreement.

#### 4. Duration

- 4.1. This Agreement shall become effective on the Commencement Date and shall endure until 31 December 2022 ("**Initial Term**"). Unless otherwise terminated in accordance with this Agreement, this Agreement shall terminate on 31 December 2022 ("**Termination Date**"), subject to the provisions of clause 4.2 below.
- 4.2. The NDoH reserves the right to extend the Agreement with the Service Provider for a further 6 (six) months, in the event that any deliveries to be made under this Agreement are required to continue for a limited period after the Initial Term ("**Extended Term**"). In the case of an extension, such extension will be on the same terms and conditions as this Agreement and the NDoH shall provide a written notice of extension to the Service Provider at least one month prior to the Termination Date.

#### 5. Appointment

- 5.1. The Service Provider submitted a successful bid in response to the Tender. Accordingly, the NDoH hereby appoints the Service Provider on a non-exclusive basis to provide the Services, subject to the terms and conditions set out herein and the Service Provider shall provide the Services.
- 5.2. This Agreement is binding on the successors in title, assignees and administrators of the respective Parties.
- 5.3. The Parties expressly agree that nothing in this Agreement shall affect, or be interpreted to affect, the NDoH's rights to appoint and use any other third party service providers to store and distribute the Products or any other Covid-19 Vaccines at any time.

#### 6. Applicability of other documents

- 6.1. All Annexes shall form an integral part of this Agreement and are incorporated as Annexes to this Agreement.
- 6.2. In the event of conflict between the provisions of any of the Annexes and this Agreement, the provisions of this Agreement shall take precedence over the provisions of such Annexe.

## **7. Services by the Service Provider**

- 7.1. The Service Provider shall, in accordance with and in response to purchase orders received from the NDoH, provide the Services as detailed in Annexe A and in the below clauses of this Agreement, within the stipulated time frames.
- 7.2. The Service Provider shall take delivery of the Products from the Importation Service Provider immediately upon arrival of the Products at the Service Provider's Designated Facilities.
- 7.3. The Service Provider shall be solely responsible for (i) the storage of the Products at the Designated Facilities; (ii) the handling of the Products (including all other related activities) as per the NDoH's instructions; and (iii) the Transport of the Products to the Delivery Sites. Any deterioration in the quality of the said Products due to incorrect handling and/or Cold Chain and/or Cold Chain Solution or any other related activities shall be solely for the Service Provider's account.
- 7.4. The Service Provider shall be solely responsible, at its own costs, for maintaining Cold Chain and/or Cold Chain Solution and other standard international protocols (i) at the Service Provider's Designated Facilities; and (ii) during the Transport of the Products from the Service Provider's Designated Facilities to the Delivery Site(s).
- 7.5. During Transport of the Products from the Designated Facilities to the Delivery Sites, the Service Provider shall be solely responsible, at its own costs, for securing the Products, maintaining Cold Chain of the Products as well as ensuring compliance with applicable legislation (including GWP and GDP) and any other standard international protocols which apply to products the same as or substantially similar to the Products.
- 7.6. The Service Provider shall monitor the Cold Chain Solution as provided in clause 7.3, clause 7.4 and clause 7.5, which shall be ensured by using temperature monitoring devices of international standard that complies with or meets the WHO specifications or recommendations.
- 7.7. The Products supplied will meet the specifications as provided and directed by the NDoH. When the Service Provider takes delivery of the Products at the Designated Facility, the Service Provider shall immediately conduct a final inspection of each consignment of the Products delivered for shortfalls, damages, losses or defects, other than the latent defect in the Products. The final inspection shall be conducted by the Service Provider either:

- 7.7.1. at the Designated Facilities immediately following Transport of the Products from O R Tambo International Airport (or any other designated airport within the Republic of South Africa); or
- 7.7.2. at such other venue as designated by the NDoH.
- 7.8. Upon receipt of the Products at the Designated Facilities, authorised personnel of the Service Provider shall check and inspect all parameters such as total quantity received, any damages, losses or defects other than latent defects, and audit temperature monitoring devices to ascertain if requisite Cold Chain Storage was maintained throughout the supply chain, i.e. from the Country of Export where the Products were collected by the Importation Service Provider to O R Tambo International Airport (or any other designated airport within the Republic of South Africa) and/or the Designated Facilities. The Service Provider shall confirm this information to the NDoH in writing in terms of the standard UNICEF Vaccine Arrival Report. However, the NDoH shall not be liable for any claim on shortfalls, damages or defects or Cold Chain Storage breakage if the Service Provider fails to notify the NDoH in the said format after receipt of any consignment of Product at the Designated Facilities within 24 (twenty-four) hours of such receipt.
- 7.9. Any claims under clauses 7.7 and 7.8, other than in respect of latent defects, shall be communicated to the NDoH by the Service Provider within 24 (twenty four) hours of receipt of each consignment of Products (unless otherwise specified),
- 7.10. The Service Provider shall ensure proper Cold Chain conditions for the Products (i) at the Designated Facilities; and (ii) during the Transportation process from the Designated Facilities to regional Delivery Sites in South Africa (and vice versa), including maintaining at all times the requisite applicable temperatures ranges and ensuring that it's Designated Facilities shall have adequate space to accommodate the quantity of Products initially and in relation to any subsequent consignments.

## **8. Obligations of the Service Provider**

- 8.1. In respect of each and every purchase order and consignment, the Service Provider shall be responsible for the following:
- 8.1.1. supporting the NDoH with the section 21 application, where and to the extent applicable;

- 8.1.2. fulfilling the SAHPRA approval conditions applicable to the Service Provider, where and to the extent applicable;
- 8.1.3. acknowledging receipt of all purchase orders received from the NDoH, in a manner to be stipulated by the NDoH;
- 8.1.4. fulfilling and facilitating the Inbound Logistics of the Products within the Republic of South Africa;
- 8.1.5. ensuring that all of the Designated Facilities are appropriately licenced in terms of the Medicines Act as pharmaceutical warehouses;
- 8.1.6. ensuring that the Designated Facilities must have at least three zones: receiving, storage and dispatch. Recalled or damaged Products must be stored in a quarantine area;
- 8.1.7. ensuring that the Designated Facilities have sufficient storage capacity to meet the estimated volumes plus 10 (ten) per cent additional capacity;
- 8.1.8. ensuring that the Designated Facilities have a backup emergency power supply to operate during power failures;
- 8.1.9. ensuring that the temperature of the Designated Facilities are validated, controlled, monitored and recorded daily. Monitoring and recording are to be done (i) physically twice daily and manually recorded; and (ii) through an electronic system daily;
- 8.1.10. ensuring at all times the Cold Chain Solution and Cold Chain of the Products are maintained in accordance and in alignment with the Manufacturer's or Supplier's (as the case may be) specifications throughout the process as well as ensuring compliance with applicable legislation (including GDP and GMP) and any other standard international protocols which apply to products the same as or substantially similar to the Products;
- 8.1.11. receiving and warehousing the Products in accordance with GDP and GMP, including provision of additional security at the Designated Facilities;
- 8.1.12. sampling and shipment of the Products to the NCL;
- 8.1.13. managing a call centre capable of handling and resolving queries related to purchase orders managed and delivered by the Service Provider. Queries

outside of the terms of this Agreement shall be referred to the designated NDoH representative;

- 8.1.14. distribution of the Products to the nine provinces in accordance with the GDP, including provision of security for bulk distribution points; and
  - 8.1.15. prompt payment to all third party Subcontractors that may participate in and assist the Service Provider in the provision of any of the Services in this Agreement.
- 8.2. The Service Provider may make reasonable amendments to the operating procedures and the service levels of Services detailed in this Agreement only for the purposes of, inter alia, process improvement, cost efficiency, achievement of economies and enhancing the Service Provider and customer service, and it shall ensure to update the NDoH on any amendments in the weekly meetings, which weekly meetings are outlined in clauses 10.1 and 10.2.
- 8.3. The Service Provider's obligations will be limited to the point of handover to the Designated Participants. This handover point is where the Designated Participants sign off on acceptance of receipt of stock at the Delivery Site. This may include the Designated Participants collecting stock at Service Provider Designated Facilities or if the NDoH and its Designated Participants so require for the Service Provider to deliver at points of delivery outside of healthcare facilities i.e. airports/airbases.
- 8.4. The Service Provider must provide and update the NDoH on the expected Lead Time for Transportation to the Delivery Sites.
- 8.5. The Service Provider may not amend a purchase order from the NDoH without prior written consent.

## **9. Roles and responsibilities of the NDoH**

- 9.1. The NDoH shall retain ownership of the Products and shall be responsible for the following:
- 9.1.1. the procurement of the Products from the Manufacturers or Suppliers (as the case may be);
  - 9.1.2. providing the Service Provider with the purchase orders in relation to the Products;

- 9.1.3. fulfilment of any approval conditions by the SAHPRA;
  - 9.1.4. facilitating the logistics of the Products into and within the Republic of South Africa, including the facilitation of any additional security requirements and provisions by state organs at the Service Provider's Designated Facilities or for onward delivery;
  - 9.1.5. coordinating between the Importation Service Provider and the Service Provider to advise of the arrival of the Products at the Service Provider's Designated Facilities;
  - 9.1.6. coordinating between the various nine provinces and the Service Provider to ensure quantity, the Delivery Sites and delivery date are communicated; and
  - 9.1.7. coordinating between the SAHPRA (including NCL) and the Service Provider regarding Products and samples.
- 9.2. It is recorded that the NDoH shall, to the extent required, provide all such assistance as may be reasonably required to the Service Provider in respect of the obligations set out in clauses 8.1.1 and 8.1.2.

## **10. Service level management, reporting and product recalls**

- 10.1. The Parties shall meet at least once a week to review the progress regarding the implementation of this Agreement. Such meeting shall be held in person or by way of a Microsoft Teams or Zoom meeting as the Parties may agree. Minutes of the meeting shall be taken, recorded and distributed to the NDoH within 5 (five) Business Days following the meeting.
- 10.2. The Service Provider will submit daily reports on the progress with implementation of the Agreement to the NDoH, in the format approved by the NDoH.
- 10.3. The Service Provider shall submit a final written report to the NDoH within 2 (two) weeks of the end of the Initial Term and/or the Extended Term, as the case may be.
- 10.4. The Products shall always remain the property of the NDoH and shall at no time become the property of the Service Provider.

### **10.5. Product Recalls**

- 10.5.1. If, for any reason, it shall become necessary to trace back or recall any particular batch of the Products in accordance with the regulatory guidelines of South Africa, or to identify the customer or customers or end users to whom the Products from such consignment batch will have been delivered, the NDoH shall take all necessary steps to trace back or recall such batch of the said Products and send the said details to the Service Provider in accordance with the procedure established for the said purpose.
- 10.5.2. The NDoH undertakes and agrees to notify the Service Provider of any change or modification in the regulatory provisions or guidelines applicable to the Products in South Africa.
- 10.5.3. The Service Provider will not recall the Products from the market without obtaining the NDoH's prior written consent, such consent shall not be unreasonably withheld. In the event of a recall mandated by SAHPRA, then the NDoH shall immediately notify the Service Provider of this requirement before such recall and the Service Provider shall cooperate and provide its full support to the NDoH in ensuring the Products are timeously and completely recalled.
- 10.5.4. The Service Provider shall be solely responsible at its own cost and expenses for recall of the Products at any time, if such recall is due to any of the Services provided including defective storage by the Service Provider or handling of the Products before or during delivery/transfer to the Delivery Sites designated by the NDoH, and the Service Provider shall accept any liability arising from or due to such recall.

## **11. Terms of payment and invoices**

- 11.1. The Fees to be paid by the NDoH to the Service Provider for the provision of the Services, in terms of this Agreement and in accordance with the table annexed hereto as Annexe B, will be as set out in the purchase order issued by the NDoH to the Service Provider.
- 11.2. The Service Provider shall generate a valid tax invoice for Fees, with supporting documentation (which shall include signed invoices and PODs), and submit same to the NDoH on a monthly basis (and by no later than the 7<sup>th</sup> (seventh) day of the next month) following the completion by the Service Provider of the deliveries made in respect of any purchase order issued by the NDoH during that month.

- 11.3. The NDoH shall effect payment within 30 (thirty) days after the receipt of the valid tax invoice for the Fees and any supporting documentation (which shall include signed invoiced and PODs), subject to the satisfactory performance of the Services in accordance with this Agreement.
- 11.4. The amounts to be paid are inclusive of VAT.
- 11.5. The total number of vials to be managed in accordance with the Agreement will be as set out in each purchase order, unless otherwise agreed between the Parties in writing.
- 11.6. The NDoH shall make payments to the Service Provider for the provision of the Services in accordance with the terms of this Agreement and the table annexed as Annexe B (the "**Fee Schedule**").

**11.7. Price**

- 11.7.1. Unless prior written approval has been obtained from the NDoH, the Fees as approved by the NDoH may not be adjusted.
- 11.7.2. Price adjustments according to CPI will be performed annually, with the first being 12 (twelve) months after the Commencement Date.
- 11.7.3. Price adjustments will be performed on the price, including VAT.
- 11.7.4. The Service Provider is required to apply for the annual price adjustments by 28th February of each year, which adjustment will be effective from the 1<sup>st</sup> April of the following year.
- 11.7.5. Scanned copies of signed applications for price adjustments must be received by the NDoH prior to 28th February of each year.
- 11.7.6. Eligibility for favourable contract price adjustments may be rejected by NDoH in light of evidence of poor compliance by the Service Provider with this Agreement or the Tender.
- 11.8. The Service Provider shall retain all data and documents pertaining to the Agreement and the Services as well as all transactions undertaken in accordance with the applicable guidelines published by the SARS (South African Revenue Services) and applicable law, including GDP and GWP.

## 12. Audits and inspections

- 12.1. The Parties agree that NDoH may, through their internal or external auditors, or other experts retained by NDoH:
  - 12.1.1. undertake a complete audit of the Service Provider's physical financial records pertaining to this Agreement to confirm the accuracy of transactions, and/or the inflow of payments to or from various sources and calculation of reserves;
  - 12.1.2. undertake a physical inspection of the Designated Facilities of the Service Provider, at any time, to ensure compliance with all storage requirements, including Cold Chain specifications; and
  - 12.1.3. from time to time carry out an inspection of relevant statistics and information relating to the funds transferred to the Service Provider by means of electronic systems and manually.
- 12.2. Any cost related to such investigations and the provision of audit certificates on request, where necessary, shall be borne by the Service Provider if the audit and/or inspection indicates that the Service Provider is guilty of any wrong-doing including negligence.
- 12.3. The Service Provider shall retain all records that may be required for auditing for the periods prescribed by law.
- 12.4. The audit shall be conducted with access to the Service Provider's servers, electronic records and otherwise any of the Service Provider's systems or tools as reasonably required. The NDoH and its representatives performing the audit shall only refer and review hard copies and electronic copies specific to the Agreement for the audit.
- 12.5. The audit may be performed at the Service Provider's premises or elsewhere as determined by the NDoH.
- 12.6. The Parties acknowledge that auditors or other experts envisaged in this clause may not be competitors of the Service Provider.
- 12.7. In the event that NDoH engages a third party to undertake the audit, NDoH shall ensure that such third party, prior to undertaking the audit, signs an irrevocable and unconditional confidentiality and non-disclosure undertaking in favour of the Service Provider on terms and conditions acceptable to the NDoH.

12.8. The NDoH may also conduct quality assurance in accordance with clause 3 of Annexe A. In such case the representatives of the NDoH shall always be accompanied by authorised representatives of the Service Provider

12.9. This clause shall survive termination of this Agreement.

### **13. Indemnity**

13.1. The Service Provider will be responsible for any and all liabilities arising from the Service Provider's acts or omissions relating to the Service Provider's provision of the Services.

13.2. The Service Provider hereby indemnifies and shall hold harmless and defend the NDoH from and against any and all claims, suits, losses, damages, costs and expenses of any nature whatsoever and however arising out of any respective individual or collective wilful or negligent act or omission by the Service Provider or any Subcontractor.

13.3. The Service Provider shall indemnify, hold harmless and defend the NDoH and its officers, directors, employees and agents from and against any claims, suits, losses, damages, costs, fees and expenses (including court costs and reasonable attorney's fees) which result from breach of a representation, warranty or obligations of the Service Provider in this Agreement.

13.4. The Parties shall not be liable to each other for any indirect, special and consequential damages, arising out of or in connection with this Agreement, including for the use or sale of the Product.

### **14. Performance and penalties**

14.1. The Service Provider agrees to perform the Services in accordance with the service standards outlined in this Agreement and to the satisfaction of the NDoH during the Initial Term and any Extended Term of this Agreement.

14.2. All Services not conforming to the requirements and standards set out in the Agreement, including any substitutions and alterations not properly approved and authorized by the NDoH, shall be deemed to be defective.

14.3. The NDoH shall be entitled to impose penalties for a proven breach of the Service Provider's obligations resulting in either a late or defective performance by the Service

Provider of any Service. In this regard, the NDoH shall deduct 20% (twenty percent) of the service fee per vial as reflected in the purchase order issued by the NDoH.

## **15. Business continuity**

- 15.1. The Service Provider must inform the NDoH at first knowledge of any circumstances that may result in interrupted supply, including but not limited to:
- 15.1.1. regulatory action which may impact on the licensing and registration of the Service Provider or that of entities on which it is reliant;
  - 15.1.2. industrial action;
  - 15.1.3. supply of electricity or water to any of the warehouses of the Service Provider; or
  - 15.1.4. any other service delivery challenges.
- 15.2. All official written communication must include detail of corrective actions taken, or to be taken, by the contracted Service Provider to ensure continuity of supply.

## **16. Liability for damages, loss or destruction of the Product**

The Service Provider will be responsible and assumes all responsibility and liability for any damage, loss or destruction of the Products whilst in its possession or under its care and control.

## **17. Insurance**

- 17.1. Subject to the proviso to this clause 17.1, the Service Provider shall, at its own expense, effect and maintain adequate insurance cover at its own expense with a reputable insurer, so as to cover the Products and cover the risks undertaken by it in terms of this Agreement, in accordance with prudent insurance practice, for loss, damage or injury incidental to the Services and/or which may be suffered by the NDoH as a result of the Service Provider's fault or omission in rendering the Services envisaged in this Agreement. Such insurance shall include its having procured Goods in Transit and Liability insurance from a reputable insurer. Such insurance shall cover the replacement cost of the Products and cost of logistics while the Products are in the Service Providers' custody. Such proof must include a confirmation that the policy is not endorsed for Covid-19 related activities. Insofar as the Service Provider self-insures, then it shall provide to NDoH: i) proof of the fact that it does so in the normal and ordinary course of its business; and ii) a bank guarantee provided by its corporate

bankers in favour of the NDoH guaranteeing to pay all losses incurred by NDoH from all risks emanating from this Agreement.

- 17.2. Subject to the proviso to clause 17.1, the insurance must be taken out and become fully effective at the Commencement Date.
- 17.3. The Service Provider shall not take any action or fail to take any action, or (in so far as is reasonably within its power) permit anything to occur in relation to it, which would:
  - 17.3.1. entitle any insurer to refuse to pay any claim under the policy applying to any of the insurances relating to the Services; or
  - 17.3.2. result in the banking institution contemplated in clause 17.1 failing to honour the guarantee which might have been provided.
- 17.4. Subject to the proviso to clause 17.1, true and complete certificates of all the insurances (together with any other information reasonably requested by the NDoH relating to such policies) shall be made available to the NDoH on request and the NDoH shall be entitled to inspect the originals during ordinary business hours.
- 17.5. Subject to the proviso to clause 17.1, satisfactory evidence that the premiums due and payable under any such policies have been paid and that the insurances are in full force and effect in accordance with the requirements of this clause shall be provided to the NDoH on request.
- 17.6. Subject to the proviso to clause 17.1, the Service Provider shall, as and when required pursuant to the terms of the relevant insurance, renew each insurance for so long as any risk covered thereby exists and shall furnish the NDoH with true and complete copies of each certificate of renewal for such insurance as soon as possible but in any event no less than at least 10 (ten) Business Days before the relevant renewal date.
- 17.7. The Service Provider shall provide the NDoH with a certificate of insurance confirming the insurance cover bi-annually and as and when requested by the NDoH.

## **18. Assignment, cession and delegation**

The Parties herein shall not assign, cede or delegate any right and /or obligations under this Agreement to a third party without each other's prior written approval.

## 19. Subcontracting

- 19.1. The Service Provider shall be entitled to subcontract any part of the Services or any of its obligations in terms of this Agreement to the Subcontractors, provided that the Service Provider has obtained the prior written consent of the NDoH, which consent shall not be unreasonably withheld or delayed.
- 19.2. Where any subcontractor relationship will be entered into for the delivery of any component of the Services, the Service Provider, in requesting the NDoH's approval, is required to stipulate the following where any subcontractor relationship will be entered into for the delivery of any component of the Services:
- 19.2.1. description of the goods and/or services to be provided by the Subcontractor;
- 19.2.2. the registered name of the Subcontractor;
- 19.2.3. the B-BBEE contributor level of the Subcontractor, including whether they are a Qualifying Small Enterprises (QSE) or Exempted Micro Enterprise (EME), or whether this is not applicable; and
- 19.2.4. the value of the subcontractor relationship as a percentage of the overall approved quote and corresponding Fees.
- 19.3. The Service Provider shall remain fully responsible and liable for the actions and omissions of any Subcontractor and for the performance of its obligations under this Agreement and the Service Provider shall procure that the Subcontractor complies with the obligations of the Service Provider under this Agreement as if it were a party to this Agreement.

## 20. Intellectual property

- 20.1. The Parties agree and record that the Manufacturer and/or the Supplier of the Products to the NDoH owns and shall continue to own and/or control all right, title and interest in the said Product, including all rights, title and interest in any discovery, data, improvements, inventions, know-how, findings, processes, systems etc. in relation to the Manufacturer's and the Supplier's development, manufacturing and commercialization of the said Product ("**Owner's IP**"). The NDoH has the right to use the Owner's IP in its control for the duration of the Agreement.

- 20.2. All statutory and other proprietary right, title and interest (including rights to require information to be kept confidential) in respect of know-how, trade secrets, trade mark(s), copyrights, designs, patents and inventions, including the rights to apply for such rights and all applications and registrations therefor, which pertain to the Products, including the dossier, literature, technical data and information for the Products, do not vest with the Service Provider.
- 20.3. Material or information made available to or obtained directly by the Service Provider from the NDoH or in connection with or as a result of the rendering of the Services and in respect of which the intellectual property rights vest in the NDoH shall remain the property of the NDoH (the "**NDoH's Intellectual Property**"). No rights therein shall vest or pass to the Service Provider. Notwithstanding what is set out above, each Party will retain ownership of all rights, titles and interests in its pre-existing products, methodologies, templates, tool kits, know-hows, software and tools, training materials, proprietary data and programs (and changes, additions and enhancements thereto that constitute derivative works thereof) and all of the intellectual property rights therein, including, without limitation, copyright, trade secrets and patent rights.
- 20.4. All and any material, information or the NDoH's Intellectual Property made available to or obtained by the Service Provider from or in connection with or as a result of this Agreement shall remain the property of the NDoH. No rights therein shall vest or pass to the Service Provider and it may not be used in any manner or form unless the Service Provider has obtained written consent from the NDoH.
- 20.5. The Service Provider shall not acquire any rights, title or interest of any kind in any information and/or the Owner's IP and/or the NDoH's Intellectual Property. If called upon to do so by the NDoH, the Service Provider shall sign a user agreement in respect of any intellectual property with the owner thereof.
- 20.6. Any intellectual property created pursuant to this Agreement belongs to the NDoH. All and any material, information or NDoH Intellectual Property made available to or obtained by the Service Provider from or in connection with or as a result of this Agreement shall remain the property of the NDoH. No rights therein shall vest or pass to the Service Provider and it may not be used in any manner or form unless the Service Provider has obtained written consent from the NDoH.
- 20.7. The Products are distributed by and on behalf of the NDoH in South Africa under the Manufacturer's or the Supplier's trademarks as may be designated for the said Product

("Trade Marks") and the Service Provider shall extend all co-operation in securing and protecting the Trade Marks.

- 20.8. Upon expiry or termination of this Agreement, the Trade Marks shall not be utilized by the Service Provider, whether directly or indirectly, for any purpose whatsoever.
- 20.9. This clause shall survive termination of this Agreement.

## 21. Confidentiality

- 21.1. For the purposes of this clause, "**Confidential Information**" shall mean any and all data and information, whether oral, written or electronic, irrespective of its form owned, possessed or controlled or passed on by the NDoH, before or after execution of this Agreement, to the Service Provider, including, without limitation, technical or scientific or clinical trial data, standard operating procedures, quality management systems, unpublished records, know-how, formulas, product specifications, quality control process, clinical trials, flow charts, operating policies and procedures, transactions, data and information, manuals, patterns, patents, trademarks, copyrights and other intellectual property related matters, designs, sequences, drawings, commercial, manufacturing, information relating to costs, strategic plans, processes, techniques, technologies, ideas, improvements, studies, products and any other information disclosed in relation to this Agreement.
- 21.2. The Service Provider is bound to protect the confidentiality of all Confidential Information and shall not disclose or use any Confidential Information other than in fulfillment of the Services. The Service Provider shall not, during the term of the Agreement and thereafter, without the prior written consent of the NDoH, disclose any information relating to the Confidential Information, the Products, any patients, the NDoH and the Services, or government in any other sphere, or any government institution or organ of state, to anyone other than those persons who are connected to the NDoH and/or the Service Provider and who are required or authorised to have access to such information.
- 21.3. Notwithstanding the foregoing, any Confidential Information disclosed during a tour of any premises or visit to a Delivery Site shall automatically be deemed as Confidential Information for purposes of this Agreement.
- 21.4. All information and data received and accessed through this Agreement or the Tender shall automatically be deemed to be Confidential Information and shall only be used

to meet the objectives of this Agreement as outlined in the Tender and this Agreement, namely the provision of the Services.

- 21.5. Any Confidential Information disclosed by the NDoH shall be strictly confidential and shall not be used, shared with or disclosed to, directly or indirectly, with any third party by the Service Provider. The absence of any marking or legend indicating that any particular information disclosed by the NDoH is to be treated as confidential shall not limit or diminish the obligation of the Service Provider to treat such information as Confidential Information.
- 21.6. The Service Provider shall:
- 21.6.1. use the Confidential Information only for the purpose of rendering the Services;
  - 21.6.2. treat and safeguard the Confidential Information as private and confidential; and
  - 21.6.3. ensure proper and secure storage of all Confidential Information.
- 21.7. The NDoH shall become the sole owner of the data, information, documents and reports collated and compiled by the Service Provider in the execution of this Agreement.
- 21.8. The copyright in the data, documents and reports compiled by the Service Provider will belong to the NDoH and none of the data, documents and reports may be made available and reproduced or distributed to third parties in any way without the prior written approval of the NDoH.
- 21.9. Any documents or records (including written instructions, notes or memoranda) relating to the Services which are to be provided to the Service Provider or which come into the Service Provider's possession during the currency of this Agreement, are deemed to be the property of the NDoH and shall be surrendered to the NDoH on demand, and in the event of the expiry or termination of this Agreement, the Service Provider will not retain any copies thereof or extracts therefrom without obtaining the prior written permission of the NDoH. The provisions of clause 21.7 shall not apply to the extent that Service Provider is obliged to retain any Confidential Information in terms of any applicable law, rule or regulation or by any competent judicial, governmental, supervisory or regulatory body or in accordance with reasonable internal policy.

- 21.10. The Service Provider agrees to keep confidential and not to disclose to third parties any information provided by the NDoH or its employees in the course of performance of the Services pursuant to this Agreement unless the Service Provider has received the prior written consent of the NDoH to make such disclosure.
- 21.11. The NDoH reserves the right to request copies or delivery of any relevant information or documentation at any time during the term of the Agreement.
- 21.12. The NDoH reserves all rights to any remedies, whether under the law to remedy any unauthorized use or disclosure by the Service Provider.
- 21.13. The Service Provider may not issue any press release or any other public document or make any public statement in each case relating to or connected with or arising out of this Agreement or the matters contained herein (save for any such release, announcement or documents which is required to be given, made or published by law or any relevant stock exchange and/or any other regulatory authority) without obtaining the prior written approval of the NDoH to the contents thereof and the manner of its presentation and publication, provided that such approval shall not unreasonably be withheld or delayed.
- 21.14. In the case of a release, announcement or document which is required to be given, made or published by law or under the rules of any relevant stock exchange and/or any other regulatory authority, the Service Provider shall give to the NDoH as much advance warning thereof as is reasonable in the circumstances together with drafts or a copy thereof as soon as it is at liberty to do so.
- 21.15. This clause shall survive the termination of this Agreement.

## **22. Force majeure**

- 22.1. Each of the Parties shall not be liable to the other for any non-performance (either wholly or in part) or delay in performance of its obligations, shall be excused from the fulfilment of any of its obligations under this Agreement and shall not be considered to be in breach or default in the event that such performance is prevented or delayed by Force Majeure, provided that each of the Parties shall use its best efforts to complete such performance by other means. The Party relying on a Force Majeure event shall promptly notify the other Party accordingly in writing together with such evidence of a Force Majeure event as it can reasonably give and also specifying the period for which it is estimated that the preventions or delay will continue.

- 22.2. In this regard the party relying on a Force Majeure event must prove that:
- 22.2.1. the failure was due to an impediment wholly beyond its control;
  - 22.2.2. on the Commencement Date, it could not reasonably have foreseen the effect that the impediment would have upon its ability to perform; and
  - 22.2.3. it could not reasonably have avoided or overcome the impediment or at least its effects.
- 22.3. On the occurrence of a Force Majeure event, and notification thereof to the other Party, the obligation to perform shall be suspended until such time as it can be resumed. The NDoH shall be entitled to exercise step-in rights from the date on which notification from the Service Provider is received and shall be entitled to appoint another third party to act as a service provider and perform the Services. If the NDoH does appoint another third party to act as a service provider and perform the Services, then the Service Provider shall on request by the NDoH forthwith give up possession of all Products under its control to such person as the NDoH may specify.
- 22.4. If the performance by either Party of any of its obligations under this Agreement is prevented or delayed by a Force Majeure for 7 (seven) days or more, consecutively or cumulatively, during the Initial Term or the Extended Term of this Agreement, then either the NDoH or the Service Provider shall in its discretion have the right to terminate this Agreement forthwith upon written notice.
- 22.5. However, if any payments are due or outstanding for the Product and/or Services prior to such termination, then such payments shall be effected by NDoH without regard to any existing cause of Force Majeure.

### **23. Breach and termination**

- 23.1. Should any Party fail to comply with an obligation, under this Agreement, the other Party shall send a notice of breach to such Party.
- 23.2. A notice of breach shall:
- 23.2.1. indicate clearly the nature and extent of such breach;
  - 23.2.2. contain a demand that the Party concerned remedy the breach within 14 (fourteen) days after receiving such notice; and

- 23.2.3. draw the attention of the Party concerned to the remedies the aggrieved party may have if such demand is not attended to.
- 23.3. If such breach is not remedied by the date and to the extent stipulated in the notice of breach, the aggrieved party may, without prejudice to any of this other right under this Agreement or common law:
- 23.3.1. cancel this Agreement and claim damages;
- 23.3.2. continue this Agreement and claim specific performance; or
- 23.3.3. avail itself of any other remedy that is legally available upon of the breach of contract.
- 23.4. Either Party may terminate this Agreement by giving 30 (thirty) days written notice to the other Party, provided that if the NDoH terminates this Agreement, the NDoH shall remunerate the Service Provider for any unpaid amounts relating to the Services already rendered to the satisfaction of the NDoH.
- 23.5. Should the Parties not reach agreement where the Agreement requires that a decision should be taken in consultation, the NDoH shall have the right to forthwith terminate the Agreement.
- 23.6. In the event that notice contemplated in clause 23.2 has been given by the NDoH and irrespective of whether it is contested or not, the Service Provider shall forthwith give up possession of any Products under its control to such person as the NDoH may specify.

## **24. Settlement of disputes**

- 24.1. This clause is a separate, divisible agreement from the rest of this Agreement and shall:
- 24.1.1. not be or become void, voidable or unenforceable by reason only of any alleged misrepresentation, mistake, duress, undue influence, impossibility (initial or supervening), illegality, immorality, absence of consensus, lack of authority or other cause relating in substance to the rest of the Agreement and not to this clause. The Parties intend that all disputes, including the issues set forth above, be and remain subject to arbitration in terms of this clause; and

24.1.2. remain in effect even if the Agreement expires or terminates for any reason whatsoever.

24.2. Save as may be expressly provided for elsewhere in this Agreement for the resolution of particular disputes, any dispute arising out of or in connection with this Agreement or the subject matter of this Agreement, including without limitation, any dispute concerning:

24.2.1. the existence of the Agreement apart from this clause;

24.2.2. the interpretation, application and effect of any provisions in the Agreement;

24.2.3. the Parties' respective rights or obligations under the Agreement;

24.2.4. the rectification of the Agreement;

24.2.5. any alleged misrepresentation, mistake, duress, undue influence, impossibility (initial or supervening), illegality, immorality, absence of consensus, lack of authority or other cause relating to or in any way connected with the Agreement or any part or portion thereof;

24.2.6. the breach, expiry, termination or cancellation of the Agreement or any matter arising out of the breach, expiry, termination or cancellation; and

24.2.7. any claims in delict, compensation for unjust enrichment or any other claim,

whether or not the rest of the Agreement apart from this clause is valid and enforceable, shall be referred, in the first instance, to negotiation as set out in clause 24.3 failing which to arbitration as set out in clause 24.4.

### **24.3. Negotiation**

24.3.1. The Parties will endeavour to resolve any dispute arising from the interpretation, application or implementation of this Agreement amicably and through consultation and negotiation between the Parties.

24.3.2. Should a deadlock or dispute of whatever nature arise from or in connection with any provision of this Agreement, conduct arising from the Agreement and/or information furnished in pursuit of its objectives, the Parties shall convene as soon as possible after the dispute/deadlock arises at the offices of the NDoH to negotiate a solution. Such negotiations shall be conducted in good faith.

#### **24.4. Arbitration**

- 24.4.1. If the Parties are unable to resolve the deadlock or dispute in question within 30 (thirty) days after the commencement of the negotiations referred to above, then the deadlock or dispute shall be referred to confidential arbitration in terms of the expedited rules of the Arbitration Foundation of South Africa ("**AFSA**"). This clause shall not preclude either party from obtaining interim relief on an urgent basis from a court of competent jurisdiction pending the decision of the arbitrator.
- 24.4.2. The arbitration shall be held in Pretoria subject to the provisions of the Arbitration Act No. 42 of 1965 with the procedure followed being as simple and inexpensive as possible.
- 24.4.3. The decision of the Arbitrator shall be final in all respects and such an arbitration decision can be made an order of the Court if either of the Parties applies for this. The cost of any such arbitration shall be allocated by the Arbitrator.
- 24.4.4. The Arbitrator shall be appointed in accordance with the AFSA rules for expedited arbitrations.
- 24.4.5. Provisions of this clause constitute (once agreed) an irrevocable consent by the Parties to any arbitration proceedings in terms hereof and neither Party shall be entitled to withdraw there from or claim at any such proceedings that it is not bound by such provisions.

#### **24.5. Confidentiality**

The existence and content of arbitration proceedings as well as any ruling, award or outcome shall be treated as confidential by the Parties as well as the members of the arbitral tribunal. This will apply unless:

- 24.5.1. the Parties will require disclosure to the extent that it is required by a Party to fulfil a legal duty, protect or pursue a legal right, or enforce or challenge an award in *bona fide* legal proceedings before a court, forum or tribunal;
- 24.5.2. the Parties consent in writing to the disclosure of certain information;
- 24.5.3. the information is needed for the preparation or presentation of a claim or defence in the arbitration;

- 24.5.4. the information is already in the public domain without any Party breaching this clause; or
- 24.5.5. the arbitral tribunal has ordered that it be disclosed upon application by a Party.

## 25. Domicilia and notices

- 25.1. The NDoH chooses as its *domicilia citandi et executandi* for all purposes arising from this Agreement, the addresses specified below:

Attention: Dr SSS Buthelezi  
 Physical: Civitas Building  
 Corner Thabo Sehume and Struben Streets  
 Pretoria  
 Postal: Private Bag X828,  
 PRETORIA,  
 0001

Email dg@health.gov.za and Khadija K. Jamaloodien  
 Khadija.Jamaloodien@health.gov.za.

- 25.2. The Service Provider chooses as its *domicilia citandi et executandi* for all purposes arising from this Agreement, the addresses specified in Annexe A.
- 25.3. Either Party may amend its *domicilium citandi et executandi* by means of written notice to the other Party, provided that such domicilium shall be a physical address within the Republic of South Africa.
- 25.4. Any notice, request, consent or communication made between Parties pursuant to this Agreement shall be in writing and shall be delivered by hand or sent by prepaid registered post or by email.
- 25.5. A notice, request, consent or communication is presumed unless the contrary is proven, to have been given:
- 25.5.1. if hand delivered during business hours on a Business Day, on the day of delivery;
- 25.5.2. if posted by prepaid registered post, 5 (five) Business Days after the date of posting thereof; or

- 25.5.3. if sent by email, on the first Business Day following the day of sending of such email.
- 25.6. Notwithstanding anything to the contrary contained or implied in this Agreement, a written notice or communication actually received by one of the Parties from another shall be adequate written notice or communication to such Party.

## **26. Amendment of this Agreement**

No addition to or variation, consensual cancellation or novation of this Agreement shall be of any force or effect unless reduced to writing and signed by both Parties or their duly authorized representatives.

## **27. Fraud and corruption**

- 27.1. The Service Provider warrants that the performance of its obligations shall in no way constitute an infringement or other violation of any laws of South Africa, and in particular, it will under no circumstances engage in any activities which may constitute corruption or corrupt activities within the ambit of the Prevention and Combating of Corrupt Activities Act, 2004, such activities to include:
- 27.1.1. accepting or agreeing, or offering to accept or give or offer any gratification to any person in order to influence such other person to act in a manner that amounts to the illegal dishonest exercise or performance of any power, duty, statutory, contractual or other legal obligation; or
- 27.1.2. to procure that any person, directly or indirectly, accepts or agrees or offers to accept any gratification from another person or gives or agrees or offers to give to any other person any gratification in order to improperly influence the conclusion or performance of its obligations in terms of this Agreement.
- 27.2. The Service Provider warrants that it shall conduct its business in compliance with all applicable laws (including anti-corruption laws), its business is in compliance with all laws, including applicable anti-corruption laws, and it has instituted and maintained, as at the Commencement Date, policies and procedures designed to promote and achieve compliance with these laws.
- 27.3. Should it be found at any stage of this Agreement, including in negotiations prior to or subsequent to the Commencement Date as well as upon and after termination of this Agreement, that any Party to this Agreement and/or any third party involved directly or

indirectly in this Agreement, has performed or contemplated performing an act of fraud or corruption, either in the award of this Agreement or any past or current or future endeavours involving the Parties to this Agreement, which resulted in either Party suffering loss, injury/or damage including to its reputation, the Agreement shall terminate at the instance of the innocent party, notwithstanding anything to the contrary contained herein, and nothing contained herein shall prevent the innocent Party from invoking the remedies available to it contained in this Agreement as well as to proceed against any and all individuals in their personal capacity who performed the corrupt act.

27.4. This clause shall survive termination of this Agreement.

## **28. General**

28.1. This Agreement, in two signed originals, constitutes the sole record of the agreement between the Parties in regard to the subject matter hereof. Each Party shall retain one of the two signed originals and the Parties shall exchange copies of the countersigned Agreement.

28.2. No Party shall be bound by any representations, express or implied, warranties, promises or the like, not recorded herein, incorporated as an Annexe or otherwise reduced to writing and signed by or on behalf of the Parties.

28.3. This Agreement supersedes and replaces prior commitments, undertakings or representations, whether oral or written, between the Parties in respect of the subject matter hereof.

28.4. No relaxation of the terms of this Agreement and no indulgence which one Party may grant to the other will in any way operate as an estoppel against the former Party or be deemed to be a waiver of its rights, or in any other way limit, alter or prejudice those rights.

## **29. Governing law**

This Agreement is governed by the laws of the Republic of South Africa.

## **30. Authority**

Each person signing this Agreement for and on behalf of a Party hereto hereby warrants in his or her official capacity that he or she is duly authorised by such Party to do so.

**31. Jurisdiction of South African courts**

The Parties consent to the non-exclusive jurisdiction of the High Court of South Africa, Gauteng Division, Pretoria for any proceedings arising out of or in connection with this Agreement.

**32. Counterpart signing of the Agreement**

The Parties agree that this Agreement may be signed at different times and in different places, and in copy provided the content of the Agreement and signatures are exact replicas (counterparts) of the originals when put together. The signed Agreement's when put together shall constitute a binding agreement between the Parties.

**THUS DONE AND SIGNED** on behalf of the **PARTIES** by their duly authorised representatives, in the presence of the undersigned witnesses, at the places appearing in the appropriate spaces below, on the dates as specified.

For the NDoH: Full Names and Surname:	For the Service Provider: Full Names and Surname:
Designation:	Designation:
Signature:	Signature:
Date:	Date:
Place:	Place:
AS WITNESSES (Full Names and Surname): 1. _____	AS WITNESSES (Full Names and Surname): 1. _____
2. _____	2. _____

**Annexe A**

**The Services - The Process of Warehousing and Distribution of the Products**

**1. General**

1.1 Commencement Date: Signature Date.

1.2 The Service provider is \_\_\_\_\_.

1.3 The Service Provider will be represented by:\_\_\_\_\_.

1.4 The NDoH will be represented by: Marione Schonfeldt.

1.5 Product specifics: as specified in the purchase order.

1.6 The Service Provider chooses as its *domicilia citandi et executandi* for all purposes arising from the Agreement, the addresses specified below:

Attention: \_\_\_\_\_

Physical: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Postal: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Tel: \_\_\_\_\_

Email \_\_\_\_\_

**2. Operations**

**2.1 Purchase Orders**

2.1.1. Only purchase orders using an official, authorised format issued by the NDoH or the Authorised Delivery Sites are valid.

2.1.2. Supply without a valid purchase order is not permitted and the NDoH will not be responsible for any loss to the Service Provider and will not entertain any demand/claim relating to such supply.

- 2.1.3. Purchase order(s) will be sent to the Service Provider by the NDoH or the Authorised Delivery Sites as and when required during the term of this Agreement. A purchase order may contain a request to deliver Products to one or more Delivery Sites.
- 2.1.4. The Service Provider is required to acknowledge receipt of all purchase orders received from the NDoH or the Authorised Delivery Sites, in a manner to be stipulated by the NDoH.
- 2.1.5. Purchase orders must be processed and executed as per the instructions appearing on the official purchase order document.
- 2.1.6. The Service Provider must liaise with the NDoH or the Authorised Delivery Site that placed the relevant purchase order before processing a purchase order that appears to be irrational or misaligned with previous purchase orders per Delivery Site.
- 2.1.7. The Service Provider may not amend a purchase order without prior written consent from the NDoH or the Authorised Delivery Site that placed such purchase order.
- 2.1.8. Changes to any quantities in the initial purchase order may only be made upon receipt of an amended purchase order from the NDoH or the Authorised Delivery Site that placed the initial purchase order.

## **2.2 Receiving and Product verification:**

### **2.2.1 Minimum requirements for the Service Provider to receive the Product:**

The NDoH will provide the Service Provider with the following:

- (a) a purchase order;
- (b) pre-notification, detailing the Product description, quantity and any other pertinent details to the shipment;
- (c) the pre-notification may be sent to the Service Provider prior to shipment arriving as far as this is reasonably possible; and
- (d) notification as soon as possible is to be submitted to the Service Provider electronically, detailing at a minimum the following:
  - (i) estimated date of arrival of the Products in the Republic of South Africa;
  - (ii) the Product description;

- (iii) the batch number of the Products;
- (iv) the expiry date of the Products;
- (v) the quantity of the Products;
- (vi) packing list or pallet configuration sheet;
- (vii) temperature monitor device configuration/ detail sheet;
- (viii) quality documents where applicable; and
- (ix) certificate of Delivery/ Vaccine Arrival Report where applicable and any other pertinent details to the shipment.

### **2.3 Receiving of Products**

- 2.3.1 The Service Provider must receive the Products from the Importer Service Provider at the Designated Facility.
- 2.3.2 The Service Provider must sign for receipt of the Products by completing and stamping the delivery documentation, noting the name of the person receiving the consignment, the date and time of receipt.
- 2.3.3 The Service Provider must receive the Products in a temperature-controlled environment, conducive to maintaining the integrity of the Product.
- 2.3.4 All temperature data loggers, refrigeration tags, freezer tags and log tags shall comply with and meet the WHO specifications and/or recommendations. All temperature data loggers, refrigeration tags, freezer tags and log tags must be checked to ensure the temperature history of the Products being received, have been maintained within the appropriate limits.
- 2.3.5 Damage, tampering or temperature deviations must be recorded on the Manufacturer or Supplier's delivery documentation. Photographic or documentary evidence of the damage, tampering or temperature deviations must be sent to the NDoH together with a copy of the signed delivery documentation. These incidents must be communicated to the NDoH within 24 (twenty-four) hours of receipt.

- 2.3.6 The Service Provider is to perform fine checks of all consignments against the delivery documentation, checking the Product description, quantity, batch and expiry date. All fine check discrepancies must be reported, in writing, to the NDoH within 24 (twenty-four) hours of receipt. In addition, the Service Provider is to furnish a vaccine arrival report to the NDoH in a format to be provided, and in accordance with a time-period to be stipulated, by the NDoH.
- 2.3.7 All Products must be received in a quarantine status pending quality assurance approval and the NCL release. The Service Provider is to remove samples for quality assurance testing.
- 2.3.8 All inbound shipments must be checked and captured on the Service Provider's enterprise resource planning (ERP) system within 24 (twenty-four) hours of receipt.
- 2.3.9 Risk in respect of the Products transfers to the Service Provider once the consignment has been received by that Service Provider.
- 2.3.10 Picking and packing**
- 2.3.10.1 Picking instructions must be generated as per FEFO principles.
- 2.3.10.2 Products must be picked and packed per the Manufacturers' storage and temperature requirements.
- 2.3.10.3 The Products should be picked in a temperature-controlled environment, conducive to maintaining the integrity of the Product.
- 2.3.10.4 The packaging systems used for the delivery of the Products must be validated to fulfil the Manufacturers' temperature requirements for the Product. Validation must be performed by person/s with the necessary education, background, training, experience and qualification, as detailed in the validation programme submitted as part of the Tender.
- 2.3.10.5 Products must be packed in containers or packaging capable of maintaining the Product's storage temperature, for the duration of the trip to the delivery point and back to the Service Provider, i.e. two times the duration of the trip.

- 2.3.10.6 The packaging should withstand the mechanical hazards of handling and transportation, prevent leakage, and provide an appropriate level of protection from environmental conditions.
- 2.3.10.7 Each shipper pack or repacked container distributed by the Service Provider will carry a label with the following information:
- 2.3.10.7.1 Shipment, invoice or delivery note number;
  - 2.3.10.7.2 Name of the Delivery Site;
  - 2.3.10.7.3 Number of the carton;
  - 2.3.10.7.4 Total number of cartons in the shipment;
  - 2.3.10.7.5 Name of Product in the carton;
  - 2.3.10.7.6 Quantity of the Product in the carton; and
  - 2.3.10.7.7 Batch and expiry date,
- 2.3.10.8 There must be clear, visible labelling on the packaging with instructions regarding storage conditions, special precautions, and warnings.
- 2.3.10.9 The information on invoices and documents must comply with the minimum data requirements as provided, in writing, by the NDoH to Service Providers from time to time.
- 2.3.10.10 The Product's batch number and expiry date must appear on the invoice. The Service Provider must ensure that the batch number appearing on the unit packs tallies with the batch number shown on the invoice. Any deviation may lead to the Products not being accepted at the Delivery Site.
- 2.3.10.11 Invoices and documents (including packing slips and credit notes) must reflect both the "proprietary name" (brand name/trade name) which is unique to a particular product, and which is the name approved in terms of section 15(4) of the Medicines Act (provided the medicines have been registered), and the product description as it appears in the MHPL.

2.3.10.12 Deliveries which are not accompanied by the required documentation will not be accepted.

### **2.3.11 Delivery of Products:**

The Service Provider will take delivery of the Products at the Service Provider's Designated Facilities.

## **2.4 Shipment verification**

2.4.1 The Service Provider shall, upon receipt of the Products, only confirm the number of pallets and the Manufacturer cartons (subject to the requirements of the shipment documentation) and that the contents are received "unchecked". In addition, the Service Provider shall check the shipment for visible damages and tampering and shall endorse the shipment documentation accordingly.

2.4.2 The Service Provider shall examine the consignment against the Manufacturer Shipping documents and pre-notification prior to packing the Product away and place the Products in quarantine until such time as quality assurance release (NCL) is available is complete and the product is available for distribution. This check shall involve a count of the cartons per pallet, a spot check of the contents of cartons and a review of the condition of the shipment and compliance with special storage requirements during the delivery process. The Service Provider shall notify the NDoH in accordance with clause 2.4.4. The Service provider shall require the authorisation of the named applicant of the Products prior to the release of any Product. The Service Provider shall check and obtain the approval from such applicant, whether the Manufacturer or the NDoH, as the case may be, before release.

2.4.3 Upon receipt of each consignment of the Product, the Service Provider will check all parameters, such as total quantity received, any damages, losses or defects other than latent defects, and audit temperature monitoring devices to ascertain if the requisite Cold Chain was maintained throughout the supply chain, i.e. from receipt of the Products from the Importation Service Provider to the Designated Facilities.

2.4.4 The Service Provider will notify the NDoH in writing within 24 (twenty-four) hours of receipt of the Product as to the status of the Product, i.e. if all in good order

or of any discrepancies or storage or quality assurance deviations at the time of receipt.

## **2.5 Storage**

- 2.5.1 The Service Provider will be responsible for all warehousing of the Products from initial receipt until delivery to the Delivery Site/s.
- 2.5.2 The Service Provider shall comply with the following, per Cold Chain Solution:
- 2.5.2.1 All of the Designated Facilities must be appropriately licenced in terms of the Medicines Act as pharmaceutical warehouses. In addition, the Products will be stored in compliance with the GDP and the GMP in so far as they apply to the Products, the Service Provider and the provision of the Services.
- 2.5.2.2 The Designated Facilities must have at least three zones: receiving, storage and dispatch. Recalled or damaged Products must be stored in a quarantine area.
- 2.5.2.3 The Service Provider must provide storage capacity to effectively distribute the estimated volumes, plus 10 (ten) per cent additional capacity, per Cold Chain Solution.
- 2.5.2.4 The temperature of the storage areas and Designated Facilities must be validated, controlled, monitored and recorded daily. Monitoring and recording are to be done: 1) physically twice daily and manually recorded; and 2) through an electronic system daily.
- 2.5.2.5 The storage of the Products must comply with the Manufacturers' specifications for the relevant Products.
- 2.5.2.6 The storage areas and Designated Facilities, including Cold Chain Solution, must have a backup emergency power supply to operate during power failures which must be detailed in the risk management strategy.
- 2.5.2.7 Products must be removed from the transportation container or cooler box prior to storage to prevent temperature deviation, as per the Manufacturer's instructions, unless otherwise indicated, depending on the relevant Cold Chain Solution.

2.5.2.8 The Service Provider will ensure that the Designated Facilities comply with the requirements of all applicable laws. If any additional storage facility is required, the Service Provider will notify the NDoH. The Service Provider will ensure that the alternative facility meets the conditions set out in this Agreement and obtain approval from NDoH before distributing or storing the Product at an alternative facility.

2.5.2.9 The way in which the Products and related products are handled by the Service Provider must be in accordance with the Minimum Requirements for The Procurement, Storage And Distribution Of Thermolabile Products As Stated In Rules Relating To Good Pharmacy Practice (GPP, SAPC): The minimum requirements include the following:

- 2.5.2.9.1 Storage Area;
- 2.5.2.9.2 Distribution;
- 2.5.2.9.3 Transport;
- 2.5.2.9.4 Receiving;
- 2.5.2.9.5 Documentation; and
- 2.5.2.9.6 Personnel.

## **2.6 Stock Control**

### **Security procedures – stock management**

The Service Provider shall implement such procedures and measures, which may be amended from time to time, as may be necessary to manage the risks associated with the Transport, storing and distribution of the Products including but not limited to:

- 2.6.1 Monitoring by camera;
- 2.6.2 Access control;
- 2.6.3 Segregation of duties;
- 2.6.4 Authorisation levels;
- 2.6.5 Employee scanning procedures; and

2.6.6 Segregated and secure storage areas.

## **2.7 Inventory management**

2.7.1 The Service Provider must have a qualified Enterprise Resource Planning ("ERP") system for inventory management. The ERP must show all records of transactions including receipts, issue-vouchers, stock adjustments and proof of delivery. The ERP must be capable of tracking Product by batch and expiry date, and manufacturing date, where applicable.

2.7.2 The Service Provider will implement a cycle counting program, whereby all Products are counted weekly. Stock must be counted and balanced by batch and expiry date. The Service Provider must produce a cumulative report on all count discrepancies for the preceding week, by the first Business Day of the following week. The report must reflect variances by Product, batch and expiry date.

2.7.3 The Service Provider will inform the NDoH of any other stock variances and explain any stock adjustments. The NDoH retains the right to authorise stock adjustments in writing.

2.7.4 The Service Provider will provide a signed-off stock count report, including variances, to the NDoH within seven (7) days of the stocktake event.

2.7.5 The Service Provider will provide daily reports at the end of the Business Day on the transactions that have taken place.

2.7.6 The Service Provider will provide NDoH with live access to their on-line stock management systems.

2.7.7 A stocktake is required twice in a financial year i.e. September and March. The Service Provider must invite the NDoH and independent auditors to all stocktake activities.

## **2.8 Delivery Turnaround Times**

2.8.1 The Service Provider will utilise existing validated routes and methods for the transportation of the Product. Any requests from NDoH to utilise alternative modes of transportation, will be done in writing and NDoH will be responsible

for any deviation to the Service Providers mode and methods of transportation including the liability and insurance thereof.

- 2.8.2 NDoH will submit purchase orders to the Service Provider for processing and/or delivery in accordance with the delivery schedule, approved by NDoH and to be attached hereto as an Annexure.
- 2.8.3 All purchase orders will be distributed within 72 hours from receipt of purchase order to the Delivery Site, according to the NDoH approved delivery schedule.
- 2.8.4 The NDoH will instruct the Service Provider to deliver the Products to the specific Delivery Sites identified and specified with the allocations for delivery, the NDoH may select multiple Delivery Sites per purchase order.
- 2.8.5 If the need arises for emergency distribution of purchase orders (that is any demand/need for Product or any request for the Products that is out of the ordinary and normal course of distribution), the Service Provider will process such emergency orders, and deliver them within 24 (twenty-four) hours from receipt of the purchase order, if requested by the NDoH.
- 2.8.6 The Service Provider will either call or send an e-mail alert to the delivery Site (and NDoH) at least 24 (twenty-four) hours before the expected delivery to ensure sufficient cold storage capacity at the facility and to ensure that the delegated official will be available to accept delivery. Where the Service provider calls the delivery Site, such call will be confirmed in writing by means of a follow up email.

## **2.9 Deliveries**

- 2.9.1 All delivery vehicles shall have tracking devices.
- 2.9.2 Deliveries must be planned in accordance with the NDoH approved delivery schedule.
- 2.9.3 The NDoH including, Designated Participants, shall ensure that deliveries outside of normal working hours will be permitted and that provisions (including personnel availability) are catered for.
- 2.9.4 Products and related documentation must be delivered in accordance with the terms, conditions and delivery instructions stipulated in the purchase order.

- 2.9.5 The delegated official at the delivery point must sign original invoices and proof of delivery. The NDoH shall provide a circular to communicate that this is done.
- 2.9.6 Products must be delivered in accordance with the appropriate conditions of storage as per Products' condition of registration/authorisation.
- 2.9.7 Temperature data loggers that comply with the WHO specification must monitor the temperature of the loaded area of the transportation throughout the trip and the validated shipper must have at least a continuous temperature monitoring device that complies or meets with the WHO specifications or recommendations.
- 2.9.8 The Service Provider must deliver directly to all identified Delivery Sites without compromising the quality and safety of the Products.
- 2.9.9 Transportation of the Products must be in such a way that it is secure and the temperature is maintained to Manufacturer specifications.
- 2.9.10 Products must be delivered in accordance with the delivery instructions stipulated on the NDoH order forms.
- 2.9.11 2 (two) copies of the invoice must accompany the delivery and must include:
- 2.9.11.1 Invoice number;
  - 2.9.11.2 Instruction number;
  - 2.9.11.3 Dispatch or invoice date; and
  - 2.9.11.4 List of Products with quantities, batch numbers and expiry dates.
- 2.9.12 The maximum delivery Lead Time from receipt of the purchase order is 3 (three) days. Failure to comply with the contractual Lead Time may result in penalties being enforced as set out in the SRCC, without prejudice to any other remedies available to the NDoH in terms of the Agreement or applicable law.
- 2.9.13 Should the delivery date, as per the contractual Lead Time, fall on a Saturday, Sunday or public holiday, the delivery should be completed by no later than the next working day after the Saturday, Sunday or public holiday.
- 2.9.14 The NDoH retains the right to request urgent deliveries or emergency orders.

- 2.9.15 Vehicles used for distribution should be suitable for their purpose and appropriately equipped to prevent theft and exposure of products to conditions that will affect their stability and integrity. The condition of cartons or containers must be acceptable to the recipient at the point of delivery.
- 2.9.16 The Service Provider must ensure that only authorised persons receive the delivery and that a signed and stamped copy of the delivery note is available as the POD. Delivery is deemed to have occurred upon signature of receipt by the authorised person.
- 2.9.17 The POD and signed invoice must be scanned and stored on the Service Provider's ERP system for easy retrieval.
- 2.9.18 The Service Provider shall collect all packaging material post-delivery.
- 2.9.19 Discrepancies between the invoice and the physical Product, or damaged, defective, expired or otherwise unusable Products, will be reported to the Service Provider within 48 (forty-eight) hours of delivery.
- 2.9.20 Service Providers will be responsible for collecting Product delivered erroneously, or which are damaged, defective, expired or otherwise unusable within 48 (forty-eight) hours of delivery, at the Service Provider's own cost.

## **2.10 Back orders**

- 2.10.1 In the event of back order situations or special requests including vaccination campaigns, additional service levels will be required, and this will be specified by the NDoH.
- 2.10.2 In cases where the purchase order has not been delivered within the contacted Lead Time due to stock-outs or supply constraints, the Service Provider will inform NDoH of the revised delivery schedule.

## **3. QUALITY ASSURANCE**

### **3.1 Premises, equipment and processes**

The Service Provider shall, at all times, manage and monitor its nominated premises, processes and equipment to ensure compliance with all applicable laws including GDP and GMP.

### **3.2 Quality assurance audits**

3.2.1 NDoH may conduct quality assurance inspections, provided that the Service Provider shall be notified of such intended audit. The Service Provider will respond to and resolve any inspection deviations noted by the Service Provider within 15 (fifteen) calendar days of the inspection.

3.2.2 The Service Provider will notify the NDoH of any inspection of its facilities by the SAHPRA or any other regulatory authority if this inspection will involve the Products.

### **3.3 Quarantined stock on receipt**

3.3.1 The Service Provider will quarantine the Products upon receipt, which may not have to be stored separately from distributable Products. However, such quarantined Product shall be clearly marked "quarantined", as per the Service Provider's procedures as well as on the Service Provider's ERP system.

3.3.2 Products will remain "unavailable for distribution" until released by the Service Provider's representative on the instruction of the NDoH and will be released on the Service Provider's ERP system by the Service Provider's representative within 24 (twenty-four) hours upon receipt of a written instruction/release certificate by the Service Provider.

3.3.3 NDoH will be notified at least 24 (twenty-four) hours before the expected release by the Service Provider from the ERP system.

### **3.4 Sampling for quality assurance testing**

3.4.1 Products supplied to the Service Provider will be subject to batch testing procedures before batches are available for distribution to the Delivery Sites.

3.4.2 The NDoH will provide details of the sample quantity per Product per batch and per receipt. The NDoH shall provide details of the NCL where samples will be sent for testing.

3.4.3 Samples are to be packed per Manufacturer instructions using validated packaging to maintain the temperature while in transit to the laboratory.

3.4.4 Samples must be delivered to the NCL within 2 (two) days (48 hours) of receipt by the Service Provider.

- 3.4.5 The Service Provider is to update the NDoH on the progress of the release process.
- 3.4.6 The designated pharmacist at the Service Provider will inform the NDoH once the batch has been approved for release by the NCL. At that time, the designated pharmacist may release the batch from quarantine status.
- 3.4.7 Batches that fail the quality assurance tests must remain in a quarantine status.
- 3.4.8 All samples remain under the ownership of the NDoH.

### **3.5 Returns**

- 3.5.1 No Product must be accepted for return from any Delivery Site unless such return is instructed in writing by the NDoH.
- 3.5.2 All returned Products must be accompanied by a record of the continuous Cold Chain maintenance and monitoring collected from the Delivery Site.
- 3.5.3 All returned Products must be placed in quarantine pending instruction from the NDoH.
- 3.5.4 All returned Products remain under the ownership of the NDoH.

### **3.6 Product Recalls**

- 3.6.1 In the event of a Product recall, the Service Provider must provide the NDoH with a report detailing the quantity of the applicable Product distributed, the Delivery Sites and the dates on which the Product was delivered. The report must be provided within 24 (twenty-four) hours of the request.
- 3.6.2 The NDoH will meet with the Service Provider to plan any recall activities as per the Manufacturers' specifications.
- 3.6.3 All recalled Products must be placed in quarantine and stored in a segregated area according to the Manufacturer's specification in the Service Provider's warehouse, until such time as the NDoH provides instructions to dispose.

### **3.7 Disposal**

- 3.7.1 The disposal of the Product may only be initiated upon written instruction from the NDoH and must be done in accordance with the applicable legislation and in accordance with the directions of NDoH.
- 3.7.2 The cost of the disposal shall be determined by NDoH depending as to the reason for the disposal, and notified to the Service Provider.
- 3.7.3 The Service Provider must provide the NDoH with a certificate of disposal within 30 (thirty) calendar days.

#### 4. Quality Management System (QMS)

- 4.1.1 The Service Provider must have a QMS that describes the procedures that are in place in the organisation.
- 4.1.2 The NDoH reserves the right to verify the existence and validity of the QMS.
- 4.1.3 The QMS must comply with requirements of GWP – 2016 and must include the following areas and sections as a minimum:

Area	Sections
General	Code of conduct Anti-fraud policy Functional organisational chart
Process	Internal process quality control
Legal	Copies of all required documents
Risk management	Pharmaceutical risk management Emergency planning and prevention
Management Information Systems	Pharmaceutical supply information
Administration	Contacts Keys and access management Security and guarding of premises Management of assets

<b>Area</b>	<b>Sections</b>
Human Resources	Staff contracts and job descriptions Working conditions Hygiene and security (Safety of workplace) Training registers and records
Information Technology	Hardware installation and maintenance Software qualification, updates and daily maintenance IT security & organisation of back-up
Archiving	Paper and electronic archiving
Pharmaceutical management	Applicable norms and standards Copies of all forms and notes
Storage	Receipt merchandise Quantitative check receipt merchandise Reporting process (quantitative issues) Inventory Back-order management Customer service, the return of Products Management of expired, damaged Products Batch tracking Product or batch recall
Thermolabile product management	Validation certificates for packaging and storage Qualification documentation Packing protocols
Stocktake	Stocktake process Variances report and reconciliation
Transport	Transport conditions: safe & secure Delivery and supply documentation Fleet management

## 5. ADMINISTRATION

### 5.1 Documentation retention

The Service Provider will retain data and documents pertaining to the transactions as detailed in the Agreement for a period of 5 (five) years.

## **5.2 Call Centre**

The Service Provider shall constitute and manage a call centre capable of handling and resolving queries related to orders managed and delivered by the Service Provider. Queries outside of the terms of the Agreement shall be referred to the designated NDoH representative.

## **6. SECURITY**

6.1 The Service Provider must ensure appropriate security levels and access control to the warehouse and other storage sites under the control of the Service Provider. These must include, but not be limited to, physical and electronic security (for example, closed circuit television monitoring).

6.2 The Service Provider must ensure that all deliveries are actively tracked and monitored with an appropriate tracking system.

6.3 The Service Provider should perform appropriate risk assessments to inform their decision to use armed escorts as necessary.

6.4 The Service Provider may be required to coordinate with national security and/or police services to ensure the security of the Products.

## **7. REPORTING**

7.1 The Service Provider will be required to submit the following information in a specified format and via a mechanism to be determined by the NDoH:

7.1.1 All transactional data including quantity issued per Product, issue voucher number, batch number, expiry date and recipient;

7.1.2 Status of outstanding deliveries;

7.1.3 Details on receipts: supplier name, Product name, quantity, batch number and expiry date;

7.1.4 Stock on hand quantity per Product, batch number, expiry date;

- 7.1.5 Stock on hand quantity awaiting quality assurance release per Product, batch number, expiry date;
  - 7.1.6 Stock adjustment details including Product, batch, expiry, quantity and reason code; and
  - 7.1.7 Quantities of obsolete Products expired, damaged or otherwise unusable.
- 7.2 The NDoH may, from time to time and within reason, add to the required reporting requirements of Service Providers. Any changes to reporting requirements or the reporting mechanism will be communicated in writing to Service Providers.

**Annexe B****Fee Schedule**

<b>LOGISTICS</b>	<b>PRICE PER VIAL (IN RANDS INC VAT)</b>
Option 1 2-8°C	
Option 2 -20°C	
Option 3 -70°C	

The total amount for the Products as at the Signature Date will be R\_\_\_\_\_ per vial, payable as per the Fee Schedule.