Terms and Conditions for Supply of Health Products and Technologies

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1. INTERPRETATION

1.1 **Definitions**

a) “Conditions” means information contained in this document.
b) "Contract" means Agreement signed between MEDS and Supplier and other documents referred to in the Agreement.
c) “Contract Price” means the price, payable under the Agreement for the full and proper performance of all Supplier’s obligations.
d) "Goods" means all commodities which the Supplier is required to supply under the Agreement
e) “Health Products and Technologies” means products or materials used in the delivery of health care services to namely pharmaceuticals, non-pharmaceuticals, nutraceuticals, vaccines and therapeutic antisera, medical equipment and devices, medial appliances and materials, health technologies, laboratory supplies and reagents, dental materials, hospital consumables and any other material or equipment as may be necessary for the delivery of health care.
f) “Supplier” means the party undertaking supply of Goods

1.2 **Acronyms**

a) “BP” refers to the British Pharmacopoeia
b) “DDP” refers to Delivered Duty Paid
c) “GMP” refers to Good Manufacturing Practices
d) ‘MEDS” refers to Mission for Essential Drugs and Supplies (The Contractor)
e) “USP” refers to the United States Pharmacopoeia
f) “INN” refers to the International Non-Proprietary Name
g) “ISO” refers to the International Organization for Standardization
h) “ITB” refers to Invitation to Tender
i) “RTS” refers to Return to Supplier
j) “WHO” refers to World Health Organization

1.3 **Other**

1.3.1 Unless the context requires otherwise, rules given below shall apply

1.3.2 A reference to **writing** or **written** shall be deemed to mean by letter or electronic means from an official mailing address

2. STANDARDS AND REGULATIONS

2.1 **General**

2.1.1 Supplies should conform to specifications indicated in the Tender Documents and MEDS Purchase Order e.g. strength, unit pack, manufacturer etc. No alterations, unless confirmed in writing prior to delivery of Goods, are acceptable.

2.1.2 Where no specification or standard is stated, products should be supplied in accordance with the relevant ISO Standard or to a recognised national standard in the country of manufacture acceptable to MEDS.

2.1.3 The Supplier shall comply with all applicable statutory and regulatory requirements relating to the manufacture, labelling, packaging, storage, handling and delivery of the Goods, including within the country where the Goods are manufactured and within the End-User’s country.

2.1.4 The supplier shall provide the Goods in accordance with the terms of the Contract.
2.1.5 The Supplier shall at all times maintain all the licences, permits, certificates (including registration and retention certificates for medicines) and authorisations that it needs to carry out its obligations under the Contract.

2.2 **Certification**

2.2.1 Manufacturers of pharmaceuticals should hold WHO or National Certification for Good Manufacturing Practice (GMP) and manufacturing license(s).
2.2.2 Suppliers operating as agents for pharmaceutical manufacturers should be licensed to operate as a pharmaceutical wholesaler by the Pharmacy and Poisons Board.
2.2.3 Where applicable, copies of GMP certificates, Retention Certificates, Certificates of Conformities (CoCs), Certificate of Origins (COOs), Manufacturing and wholesaler's licenses shall be submitted to MEDS.

2.3 **Product Registration and Retention**

2.3.1 Products that require registration for sale in Kenya should have proof of such registration.
2.3.2 Copies of registration and retention certificates shall be submitted to MEDS.
2.3.3 All legal implications pertaining to product registration shall be borne by the supplier.

3. QUALITY

3.1 **General Requirements**

All products supplied under this contract must:

3.1.1 Meet the requirements of manufacturing legislation in the country of origin and be approved for use in that country.
3.1.2 Where applicable, be of BP, USP or International Pharmacopoeia standard
3.1.3 Where applicable, contain a lot or batch number and expiry date on the label of every dispensing unit.
3.1.4 Where applicable, be certified in accordance with the WHO Certification Scheme for Pharmaceuticals Moving in International Commerce. The certificate should be issued by the health authorities of the country of original manufacture.
3.1.5 Be formulations and packages that are stable in the tropical climate (Zone 4b).
3.1.6 Retain stability within the product's shelf-life.
3.1.7 Sourced from the manufacturer, site and country indicated in the supplier's bid documents and as specified on MEDS purchase order.

3.2 **Certificates of Analysis (COA)**

3.2.1 Pharmaceutical products must have a copy of the manufacturer's Certificate of Analysis (CoA) for **each batch** supplied.
3.2.2 The COA should be sent directly to MEDS **prior to shipment/delivery of Goods, or be delivered together with the goods.**
3.2.3 COAs should be in **English**, bear the letter-head of the manufacturer or testing laboratory as stated on the supplier's bid documents and indicate the Pharmacopoeia/Standard used in performing the analysis.

3.2.4 The COA should have the product's generic (non-proprietary) name, strength and unit pack conspicuously displayed and the actual test results indicated against each test specifications. A general indication of the word "complies", or "conforms" is not sufficient.

3.2.5 The analysis of tablets and capsules must include **dissolution test** if the test is specified in **ANY of** the following: BP/USP/International Pharmacopoeia, irrespective of the particular pharmacopoeia standard used for analysis.

3.2.6 MEDS shall reject medicines delivered without a valid COA.

3.3 **Testing**

3.3.1 MEDS may undertake routine quality control testing of supplied Goods and may reject the whole consignment if the samples tested fail to meet the required standards.

3.3.2 Goods that fail to meet MEDS quality control standards or which are defective in any way shall NOT BE ACCEPTED.

3.3.3 Where several batches of a product from the same manufacturer are supplied, MEDS shall analyse a maximum of **three** (3) batches at its own cost; the supplier shall pay for analysis of additional batches.

3.3.4 MEDS will share the results of its routine testing programme with the Ministry of Health when called upon to do so.

3.3.5 The supplier shall give MEDS full credit for rejected stock and MEDS reserves the right to cancel the order balance.

3.3.6 The supplier shall collect from MEDS any rejected goods.

3.3.7 MEDS shall analyse all new brands of products and products that have previously failed quality analysis tests before confirming an order. **The cost of analysis shall be borne by the supplier and shall be paid in full prior to analysis.**

3.4 Communication of changes to products

3.4.1 Supplier shall inform MEDS in writing of any changes to the product or quality management system that may affect the safety, efficacy or quality of the product supplied. The changes to be reported include but are not limited to changes in:

a) Manufacturing process for the product.
b) Site of manufacturing or contract manufacturer (s) for the product.
c) Formulation or composition of the product.
d) Supplier (s) of raw materials, containers or closure/packaging system.
e) Specifications for the product.
f) Shelf-life
g) Artwork

3.4.2 Communication should be addressed to Quality Assurance Manager in the form of an official letter with the company's official letterhead, accompanied with the approved variation report issued by Pharmacy and Poisons Board.

3.4.3 MEDS shall determine and formally communicate actions to be taken following such changes.

4. LABELLING

The following shall apply:

4.1 Unless stated otherwise, the language used **should be English.**

4.2 All internal and external containers should be labelled with the INN of the active ingredient and should contain at least the following additional information: quantity of active ingredient, dosage form, number of units per pack, batch number, date of manufacture, expiry date, pharmacopoeia standard, instructions for storage, name and address of manufacturer, directions for use (where applicable). All non- pharmaceutical products should be labelled with product name, manufacturer details, quantity, number of units per pack, batch number, date of manufacture and expiry date.

4.3 **S**tickers affixed on labels to contain information required under 6.2.2. labels are **NOT** acceptable.

4.4 Batch number, date of manufacture and expiry date must appear on each **individual article** e.g. ampoule/vial for injectable. For preparations in tubes, the information must be inscribed/printed on individual tubes.

4.5 All poisons must be clearly marked international standard marks and the label must give adequate details of the antidote/treatment.

4.6 Products for external use must be clearly marked as such.

4.7 Dilution/reconstitution directions must be shown on labels for each article as necessary e.g. for injectable preparations in powder form. **Note:** Such information is not sufficient if it appears on literature inserts only.

4.8 The labels for sterile medical and surgical items must clearly indicate the date of sterilization, expiry date and method of sterilization.

4.9 All hazardous chemicals must be clearly marked with the relevant standard symbol.

The word 'FRAGILE' must be indicated on cartons whose contents are delicate and require careful handling e.g. vials, ampoules and glass bottles

5. PACKING

5.1 General Requirements

5.1.1 The supplier shall provide such packing as is required to prevent damage to or deterioration of the Goods during transit to and stacking on storage locations as well as facilitate visual quality inspection.

5.1.2 The packing shall be sufficient, without limitation, to withstand rough handling and exposure to extreme temperatures. The cost of such packing shall be included in the Contract Price.

5.1.3 The packing, marking and documentation within and outside the packages shall comply with such special requirements as provided for in the Contract, or in any subsequent instructions and, where appropriate, with any relevant regulations governing the dispatch of hazardous cargo by sea, air or overland.

5.1.4 All packaging must be suitable for use in tropical climate (Zone 4b).

5.1.5 Containers for all pharmaceutical preparations should conform to the latest edition of an internationally recognized pharmacopoeia e.g. BP, USP, International Pharmacopoeia.

5.1.6 The Supplier is responsible for replacing any packages and products found to be damaged at the point of delivery.

5.1.7 All packaging materials should include GS1 compliant barcode to support product identification and traceability.

5.2 Tablets, Capsules and Caplets

5.2.1 Should be packed in sealed, waterproof containers with replaceable lids that protect the contents against light and humidity or blister pack or laminated

aluminium foil, packed in well closed and light resistant containers of appropriate size. The containers should be tamper-proof and sealed.

5.2.2 Containers must have either **"tamper proof"** container seal or have an internal security seal.

5.2.3 For purposes of physical inspection at various points and for added protection against moisture, bulk packs of capsules and tablets should be enclosed in an inner see-through polythene bag or strip-pack.

5.3 Elixirs, Oral Suspensions and Syrups

5.3.1 Elixirs and Syrups should be packed in tamper proof cap, amber-coloured glass or non-transparent plastic bottles.

5.3.1 Suspensions should be packed in see-through/transparent containers unless there is documented evidence of deterioration due to exposure to light.

5.3.2 They should have appropriate dispensing measure in each pack, packed in well-padded strong carton.

5.3.3 Glass bottles should be partitioned appropriately in packaging cartons to avoid breakage during transportation.

5.3.4 Bottles of powder for oral suspension should have a clear marking to show the required volume and or clear direction for reconstitution. The cap and stopper on every bottle should be watertight and leak-proof.

5.4 Ampoules and Vials

5.4.1 Ampoules must be packed in rigid paperboard boxes, strong enough to resist crushing during transportation and storage in units of 5, 10 or similar multiples up to a maximum of 100 (10x10).

5.4.1 All ampoules must have a break line and be easy to break. Alternatively, each minimum unit pack should include an adequate supply of ampoule files to facilitate breaking.

5.4.2 Light-sensitive products e.g. ergometrine should be packed in brown glass Ampoules.

5.4.3 Individual ampoules should be packed in plastic or in cardboard trays and the trays in outer cartons.

5.5 Infusions

5.5.1 The concentration of electrolytes shall be stated on the label in milli-equivalent (Meq), weight or percentage concentration.

5.6 Topical Preparations

5.6.1 Content with less than 50gm shall be packed in leak-proof collapsible metallic or plastic tube, for volumes above 50gm in aluminum foil or plastic jars with close fittings caps or slip on lids.

5.6.2 Each individual tube must be packed in a rigid paper board box and labelled appropriately.

5.7 Suppositories and Pessaries

5.7.1 Shall be packed in ready-to-dispensing patient packs accompanied by suitable applicator for use in administration. Each must be individually sealed and packed.

5.8 Tertiary Packaging

5.8.1 Should be of strong, export quality material able to withstand rough handling and tropical climate during transport and stacking during storage.

5.8.2 Tertiary packaging **MUST** be undertaken in **five-ply** cartons, duly labelled and

marked.

5.8.3 The Primary, Tertiary and Secondary packing should have proper labelling requirements (i.e. Batch Number, Expiry Date, Manufacturer details and quantities of the unit of sale).

5.8.4 The shapes of the cartons must be consistent and complementary to allow stacking.

5.8.5 The cartons must have consistent dimensions of length, width and height.

5.8.6 The size of the carton should be proportional to its content, with the addition of appropriate padding to prevent damage to the product during transport.

5.8.7 All carton flaps must be properly secured and sealed with special gum paper tapes.

5.8.8 The Gross weight of each packed carton delivered to MEDS should not exceed 25kg.

5.8.9 Should contain products with the same expiry date. The date should be printed on both the carton as well as on the immediate containers.

5.8.10 Outer packaging materials shall clearly indicate stacking instructions.

6. SHELF LIFE AND EXPIRY

The following shall apply:

6.1 All items should, where applicable, have **at least 75%** of their shelf life remaining from the date supplies are received at MEDS.

6.2 The supplier shall notify MEDS and seek written approval to supply any Goods that do not meet the requirement in 8.1 above **prior** to delivery of such Goods.

6.3 Expiry dates should be clearly stated on all internal and external containers.

6.4 In the event of reduced demand, MEDS will request suppliers to replace Goods with short remaining shelf-life (at least six months) with longer expiry batches.

7. PRICES AND CURRENCY

The following shall apply:

7.1 Prices shall be quoted in Kenya Shillings unless indicated otherwise on the Tender Requirements Document.

7.2 Contract prices shall apply throughout the contract period for stocked items and corporate discounts on non-stocked items shall apply for a minimum of one year.

7.3 Price changes due to significant currency fluctuations and other verifiable market forces outside a 10% margin within which the price was based will be subject to renegotiation by either party.

7.4 Where applicable, VAT must be included in the quoted prices and the comment "**VAT Inclusive"** made under the 'Remarks' column in the Tender Requirements Document.

8. AWARD OF CONTRACTS

The following shall apply:

8.1 MEDS shall enter into a contract with suppliers whose Bid(s) have been determined to be the best suited Bid(s) based on the organization's award criteria.

8.2 MEDS shall notify the supplier in writing regarding acceptance of bid for specific item(s).

8.3 The Bidder shall acknowledge receipt of notification in writing.

8.4 The Contract shall become effective when the notice of award is dispatched to the successful Bidder.

8.5 The notification will be subsequently confirmed through issuance of LPOs.

8.6 MEDS decision shall be final.

9. PURCHASE ORDERS

The following shall apply:

9.1 Purchase Orders issued by MEDS will indicate the quantity to be supplied, the required delivery schedule, the unit price of each item and the total order value.

9.2 The manufacturer's name and country of origin may be indicated where necessary.

9.3 Purchase Orders will bear at least two signatories which may include Officer, Procurement, Procurement Coordinator , Manager, Procurement, Director Supply Chain & Logistics and the Chief Executive Officer (CEO) based on applicable authorization levels.

9.4 Orders values of 2 million Kenya Shillings and above will bear third and fourth signatories from MEDS' Secretariats i.e. Kenya Conference of Catholic Bishops (KCCB) and Christian Health Association of Kenya (CHAK).

10. DELIVERY

10.1 General

10.1.1 The supplier has full responsibility for the entire transportation process and its associated risks.

10.1.1 MEDS will not be liable at all for any demurrage or any costs or damages, whatsoever, related to deliveries.

10.1.2 Not more than **Three** batches shall be supplied for a single product in any one consignment. Requests for the supply of more than three batches shall only be considered under exceptional circumstances and for large consignments.
Note: More than three batches may be accepted on SKUs whose consumption exceeds the batch size provided upon approval by MEDS.

10.1.3 An invoice must be included with each delivery.

10.1.4 A separate invoice must be submitted for each purchase order and must quote the number of the Purchase Order issued by MEDS.

10.1.5 Invoices must accurately show Batch Number(s) and quantities being delivered for each batch.

10.1.6 Goods shall be delivered to MEDS Centre located along Mombasa Road unless specified otherwise in writing.

10.2 Delivery Schedule

10.2.1 Goods shall be delivered in the manner specified under Terms and Conditions of the tender.

10.2.2 The Supplier should share a delivery planner at least 24 hours prior to delivery. The planner should indicate SKUs intended for delivery and their respective quantities.

10.2.3 Deliveries should be made on working days between **7.30am** to **5:00pm** and be received and stamped at MEDS receiving bay.

10.2.4 Deliveries due in a given month should be completed by the last working day in the month.

10.2.5 The quantity to be delivered in a month should be divided into equal weekly deliveries unless advised otherwise.

10.2.6 Suppliers must inform MEDS of any anticipated delay or inability to deliver, at least two weeks before the required delivery date.

10.2.7 MEDS reserves the right to cancel an order if the supplier fails to adhere to the required delivery schedule

10.3 **Overseas Supplies**

The supplier shall:

10.3.1 Ensure that ALL Goods are inspected prior to shipment. Any charges incurred as a result of failure to comply with this requirement shall be borne by the supplier.

Notify MEDS when each item on a purchase order is ready for delivery so that MEDS can give shipping instructions.

10.3.2 Address ALL relevant documents for Goods that are to be directly consigned to MEDS by Air or Sea e.g. Airway Bill, Bill of Lading, Letter of Donation, Packing Lists, Clean Report of findings, etc. to the consignee as follows:

Mission for Essential Drugs and Supplies (MEDS)
P.O Box 78040, VIWANDANI 00507
Nairobi, Kenya
Attention: Procurement Manager

10.3.3 Such documents, in addition to certificates of analysis (where applicable) for batches to be supplied must be sent to MEDS **prior** to shipment.

10.3.4 The cost of Goods should not be indicated on packing lists.

11 INSPECTION

The following shall apply:

11.1 MEDS accepts Goods for receipt subject to rigorous checks on quality and quantity.

11.2 Invoices and delivery notes shall be stamped **"Stock Received BUT Not Inspected"** at the time of delivery.

11.3 MEDS will check deliveries as quickly as possible, not more than Seven (7) from date of receipt; and notify the supplier of any defective Goods or of short/excess deliveries.

11.4 Defective Goods will be rejected.

12 REJECTS AND RETURNS

12.1 **Rejects**

12.1.1 Defective Goods will be rejected and collected by the supplier. This includes Goods returned to MEDS by clients due unacceptable quality or as a result of recall.

12.1.2 An RTS note will accompany all Goods rejected by MEDS.

12.1.3 The RTS note will indicate if MEDS requires the goods to be replaced or if a Credit Note should be issued

12.1.4 Replacements or Credit Notes should be issued within 7 days. MEDS shall withhold payment of the affected invoice if the supplier has replacements/credit notes outstanding beyond 7 days.

12.1.5 Where the supplier is replacing returned Goods or making good short deliveries, the supplier should not issue a new invoice but should deliver the goods with a delivery note clearly marked **"Replacement Goods"** quoting purchase order, RTS number(s) and the supplier's original invoice number.

12.1.6 Goods shall be replaced at awarded Contract prices.

12.1.7 Where the supplier cannot replace rejected Goods or make good short deliveries within 7 days, the supplier must issue a credit note.

13 TRADE TERMS

The following shall apply:

13.1 Trade terms shall be "DDP"

13.2 The term "DDP" shall have the respective meaning ascribed thereto in the latest

available version of the Incoterms.

14 INDEMNITY

14.1 The supplier shall indemnify MEDS against all claims and shall bear the cost of defending such claims that are related to quality, patent rights, trademarks, designs and royalties.

15 PAYMENT

The following shall apply:

15.1 Payment shall be made by Cheque and/or Electronic Fund Transfer (EFT) in accordance with terms agreed with the supplier from date of statement.

15.2 All shipments will be inspected by MEDS quality assurance team and payment made subject to a clean report of findings.

15.3 The supplier shall raise a written complaint to MEDS Chief Executive Officer in the event of dissatisfaction with handling of payment or any other issue related to the Contract.

16 PERFORMANCE BOND

The following shall apply:

16.1 A successful bidder will be called upon to deposit with MEDS a performance bond of 3% for LPO values of Ksh 1 million and above.

16.2 The performance bond must be submitted at the point of LPO collection.

16.3 The amount covered by the performance bond will be claimed by MEDS if the contract is not completed within the time limit and to the satisfaction of MEDS.

17 PENALTY FOR DEFAULT

The following shall apply:

17.1 The supplier will be considered to have defaulted if there is failure to:

a) Deliver the supplies by the due date provided in the delivery schedule contained in the Tender Requirements Document.
b) Replace any rejected supplies within seven (7) days.
c) Comply with each and every other condition of the contract.

17.2 A supplier who fails to supply a product as stipulated in the Tender Documents and/or the purchase order shall be held liable for the losses incurred by MEDS thereafter as a result of stock outage or purchase of products at higher prices from other sources.

17.3 MEDS may do any one or combination of the following:

a) Caution the supplier
b) Following a notice to the supplier, cancel purchase order for affected Goods and obtain needed supplies from other suitable sources.
c) Recover from the supplier any losses sustained resulting from the supplier's failures either by recovering from the supplier as a debt or deducting from outstanding payment owed to the supplier
d) Claim the performance bond deposited with MEDS
e) Blacklist the supplier

17.4 MEDS shall periodically prepare reports indicating losses incurred and seek compensation of the same from the defaulting supplier.

17.5 The supplier shall make good such loss within 30 days from date of the performance report.

17.6 Previous Contract performance of the supplier will be considered before levying this penalty.

18 ETHICAL CONSIDERATIONS

Suppliers shall observe and uphold the following:

18.1 Avoid use of child labour

The Supplier commits to not engage child to perform any of the service and activities related to this contract. All the work's employee assigned to this agreement shall be in compliance with Kenya labor laws and related to the minimum of age authorized to work. Non-respect of this clause will force the MEDS to terminate the contract.

18.2 Respect basic social rights of their employees

18.3 Provide appropriate working conditions for employees in line with local and International labour standards.

18.4 MEDS shall not deal with suppliers engaged in any of the following activities:

a) Environmental degradation or unethical exploitation of natural resources
b) Supporting armed conflicts
c) Involvement in the supply or trading of illicit arms and/or land-mines

18.5 Suppliers shall not offer gifts, entertainment, favours, or services to any **individual** MEDS employee. Any such offers may be regarded as an intention to exert undue influence, and may result in termination of contract.
(Refer to Annex 1: Supplier's Code of Conduct)

19 DISPUTE RESOLUTION

19.1 The parties shall endeavour to settle amicably any dispute arising from the Contract by direct negotiation. Any dispute which cannot be amicably settled between the parties shall be referred by either party to the arbitration and final decision of a person to be agreed between the parties. Failing agreement to concur in the appointment of an Arbitrator, the Arbitrator shall be appointed by the chairman of the chartered Institute of Arbitrators, Kenya Branch, on the request of the applying branch. The decision of the Arbitrator shall be final.

20 LAW

The Contract shall be governed by the Laws of Kenya

21 FORCE MAJEURE

The following shall apply:

21.1 For the purpose of this Contract, a "Force Majeure" event means an event beyond the control of either party, which by its nature could not have been foreseen by such party, or if it could have been foreseen, was unavoidable and includes without limitation, an act of God, storms, floods, earthquakes, strikes, lockouts or any other industrial action, civil commotion or civil unrest, sabotage, riot, acts of war (declared and undeclared), fires, explosions, epidemic outbreak or other natural physical disaster

21.2 The supplier shall not be liable for failure to perform the Contract to the extent that such failure is as a direct result of a Force Majeure situation provided the supplier notifies MEDS in writing within five (5) days of such event or situation arising specifying the nature and extent of the event or situation and the cause thereof

21.3 In case of dispute as to whether or not a Force Majeure situation has arisen, MEDS' opinion shall be final

I confirm that I am in agreement with the terms and conditions stated above.

Supplier:…….

Name…… Position……

Signature…….. Date……

Stamp: