KENYA MEDICAL SUPPLIES AUTHORITY YOUR PARTNER IN HEALTHCARE

Open International Tender (OIT)

Tender Document

For the

Supply of Nutrition Supplements

Invitation for Tender (IFT) Number: KEMSA/GOK-MOH/OIT006/2022-2024

Tender Closing date: 21st October 2022
Time: -10.00 a.m. Local time

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INVITATION TO TENDER

PROCURING ENTITY: Kenya Medical Supplies Authority, 13 Commercial Street, Industrial Area, P.O Box 47715-00100, Nairobi. Tel No: +254 719033000/ +254 726618520/1 Email: procure@kemsa.co.ke

Tender Number and Description: KEMSA/GOK-MOH/OIT006/2022-2024- Supply of Nutrition Supplements

1. The Ministry of Health has set aside funds for use in the procurement of HIV Commodities under GOK funding. It is intended that part of the proceeds of the funds will be used to cover eligible payments under the contract for the Supply of Nutrition Supplements.

2. KEMSA now invites sealed bids from eligible Suppliers for the Supply of Nutrition Supplements.

3. Bidding will be conducted through the procedures specified in the Public Procurement and Asset Disposal Act (PPADA) 2015 and is open to all.

4. Interested eligible Bidders may obtain further information from Procurement office situated at:

   Kenya Medical Supplies Authority,
   13 Commercial Street, Industrial Area
   P.O Box 47715-00100, Nairobi
   Tel No: +254 719033000/ +254 726618520/1
   Email: procure@kemsa.co.ke

   On normal working days on Monday to Friday between 0900hrs and 1600hrs except on Public Holidays.

   Interested eligible bidders may download a complete set of tender documents from the KEMSA Website www.kemsa.co.ke and/ or PPIP Portal: **https://tenders.go.ke.**

   Documents downloaded are free of charge and bidders are advised to register at the Procurement Office or via email at procure@kemsa.co.ke. (Refer to registration form in the tender document)

5. Completed serialized/paginated bidding documents shall be submitted accompanied with a signed declaration of the number of pages. The documents will be an original and a copy in plain sealed envelopes clearly marked on top with the Tender Number and description and accompanied by a Bid security of an amount of **KES 200,000.00** or equivalent in a freely convertible currency from Commercial Banks or Insurance Companies (Approved by Public Procurement Regulatory Authority) and should be addressed to:

   The Chief Executive Officer
   Kenya Medical Supplies Authority
   13 Commercial Street, Industrial Area
   P.O Box 47715-00100
   Nairobi

And **MUST BE DEPOSITED** in the Tender Box No. 1 marked GOK/ World Bank at the Reception on the Ground Floor KEMSA's Commercial Street Office in Nairobi on or before local **10.00am** local time on **21st October 2022.**

6. Bidders **MUST** submit their **TENDER SAMPLE (S)** at Procurement Offices, Commercial Street on or before tender closing date and time.

7. Tenders will be opened promptly in public on **21st October 2022** in the presence of Bidders' and/ or representatives who choose to attend the opening at KEMSA tender opening Hall at 10.00am local time.

8. Late bids, portion of bids, electronic bids, bids not received, bids not opened and not readout in public at bid opening ceremony shall not be accepted for evaluation irrespective of circumstances.

Kenya Medical Supplies Authority reserves the right to accept or reject any or all bids without incurring liability to the affected tenderers.

REGISTRATION FORM

Tender No. **KEMSA/GOK-MOH/OIT006/2022-2024** for **Supply of Nutrition Supplements**

NOTE: Bidders are required to provide their contact details as shown below.

Name of the firm:……..

Postal Address:……..

Telephone Contacts:……...……

Company email address:……..

Contact Person:……

Once completed please submit this form to the email address below;

procure@kemsa.co.ke

PART 1 - TENDERING PROCEDURES

SECTION I - INSTRUCTIONS TO TENDERERS

A General

1. Scope of Tender

1.1 In connection with this Invitation to Tenderer (ITT), the Procuring Entity issues this tendering document for the Supply of Health Products as specified in Section V, Schedule of Requirements. The name, identification and number of items or lots (contracts) of this ITT are specified **in the TDS.**

2. Definitions

Throughout this tendering document:

a) The term "in writing" means communicated in written form (e.g. by mail, e-mail, including if specified **in the TDS**, distributed or received through the electronic-procurement system used by the Procuring Entity) with proof of receipt;

b) If the context so requires, "singular" means "plural" and vice versa; and "Day" mean scale day, unless otherwise specified as "Business Day." A Business Day is any day that is an official working day of the Procuring Entity. It excludes the Procuring Entity's official public holidays.

3. Fraud and Corruption

3.1 The Procuring Entity requires compliance with the provisions of the Public Procurement and Asset Disposal Act, 2015, Section 62 "Declaration not to engage in corruption". The tender submitted by a person shall include a declaration that the person shall not engage in any corrupt or fraudulent practice and a declaration that the person or his or her sub-contractors are not debarred from participating in public procurement proceedings.

3.2 The Procuring Entity requires compliance with the provisions of the Competition Act 2010, regarding collusive practices in contracting. Any tenderer found to have engaged in collusive conduct shall be disqualified and criminal and/or civil sanctions may be imposed to this effect, Tenderer's shall be required to complete and sign the "Certificate of Independent Tender Determination" annexed to the Form of Tender.

3.3 Unfair Competitive Advantage-Fairness and transparency in the tender process require that the firms or their Affiliates competing for a specific assignment do not derive a competitive advantage from having provided consulting services related to the assignment in question. To that end, the Procuring Entity shall indicate in the **Data Sheet** and make available to all the firms together with this tender document all information that would in that respect give such firm any unfair competitive advantage over competing firms.

3.4 Tenderers shall permit and shall cause their agents (where declared or not), subcontractors, sub-consultants, service providers, suppliers, and their personnel, to permit the Procuring Entity to inspect all accounts, records and other documents relating to any initial selection process, prequalification process, tender submission, proposal submission, and contract

performance (in the case of award), and to have them audited by auditors appointed by the Procuring Entity.

4 Eligible Tenderers

4.1 A Tenderer may be a firm that is a private entity, a state-owned enterprise or institution subject to ITT4.6 or any combination of such entities in the form of a joint venture (JV) under an existing agreement or with the intent to enter in to such an agreement supported by a Form of intent. In the case of a joint venture, all members shall be jointly and severally liable for the execution of the entire Contract in accordance with the Contract terms. The JV shall nominate a Representative who shall have the authority to conduct all business for and on behalf of any and all the members of the JV during the Tendering process and, in the event the JV is awarded the Contract, during contract execution. Members of a joint venture may not also make an individual tender, be a subcontractor in a separate tender or be part of another joint venture for the purposes of the same Tender. The maximum number of JV members shall be specified in the **TDS.**

4.2 Public Officers of the Procuring Entity, their spouse, child, parent, brother, sister, child, parent or brother, sister of a spouse their business associates or agents and firms/organizations in which they have a substantial or controlling interest shall not be eligible to tender or be awarded a contract. Public Officers are also not allowed to participate in any procurement proceedings.

4.3 A Tenderer shall not have a conflict of interest. Any Tenderer found to have a conflict of interest shall be disqualified. A Tenderer may be considered to have a conflict of interest for the purpose of this Tendering process, if the Tenderer:

a Directly or indirectly controls, is controlled by or is under common control with another Tenderer; or

b Receives or has received any direct or indirect subsidy from another Tenderer; or

c has the same legal representative as another Tenderer; or

d has a relationship with another Tenderer, directly or through common third parties, that puts it in a position to influence the Tender of another Tenderer, or influence the decisions of the Procuring Entity regarding this Tendering process; or

e or any of its affiliates participated as a consultant in the preparation of the design or technical specifications of the goods that are the subject of the Tender; or

f or any of its affiliates has been hired (or is proposed to be hired) by the Procuring Entity or Procuring Entity for the Contract implementation; or

g would be providing goods, works, or non-consulting services resulting from or directly related to consulting services for the preparation or implementation of the project specified in the TDS ITT 2.1 that it provided or were provided by any affiliate that directly or indirectly controls, is controlled by, or is under common control with that firm; or

h has a close business or family relationship with a professional staff of the Procuring Entity who: (i) are directly or indirectly involved in the preparation of the tendering document or specifications of the Contract, and/or the Tender evaluation process of such Contract; or (ii) would be involved in the implementation or supervision of such contract unless the conflict stemming from such relationship has been resolved in a manner acceptable to the Procuring Entity throughout the Tendering process and

execution of the Contract.

A firm that is a Tenderer (either individually or as a JV member) shall not participate in more than one Tender, except for permitted alternative Tenders. This includes participation as a subcontractor. Such participation shall result in the disqualification of all Tenders in which the firm is involved. A firm that is not a Tenderer or a JV member may participate as a subcontractor in more than one Tender.

4.4 A Tenderer may have the nationality of any country, subject to the restrictions pursuant to ITT4.9. A Tenderer shall be deemed to have the nationality of a country if the Tenderer is constituted, incorporated or registered in and operates in conformity with the provisions of the laws of that country, as evidenced by its articles of incorporation (or equivalent documents of constitution or association) and its registration documents, as the case may be. This criterion also shall apply to the determination of the nationality of proposed subcontractors or sub-consultants for any part of the Contract including related Services.

4.5 A tenderer that has been debarred from participating in public procurement shall be ineligible to be prequalified for, initially selected for, tender for, propose for, or be awarded a contract during such period of time as the PPRA shall have determined. The list of debarred firms and individuals is available at **PPRA's website** info@ppra.go.ke or complaints@ppra.go.ke.

4.6 Tenderers that are state-owned enterprises or institutions in Kenya may be eligible to compete and be awarded a Contract(s) only if they can establish, in a manner acceptable to the Procuring Entity, that they (i) are legally and financially autonomous (ii) operate under commercial law, and (iii) are not under supervision of the Procuring Entity.

4.7 A tenderer shall not be under suspension from tendering by the Procuring Entity as the result of the operation of a Tender–Securing Declaration or Proposal-Securing Declaration.

4.8 Firms and individuals may be ineligible if (a) as a matter of law or official regulations, Kenya prohibits commercial relations with that country, or (b) by an act of compliance with a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations, Kenya prohibits any import of goods or contracting of works or services from that country, or any payments to any country, person, or entity in that country.

4.9 Foreign tenderers are required to source at least forty (40%) percent of their contract inputs (in supplies, subcontracts and labor) from national suppliers and contractors. To this end, a foreign tenderer shall provide in its tender documentary evidence that this requirement is met. Foreign tenderers not meeting this criterion will be automatically disqualified. Information required to enable the Procuring Entity determine if this condition is met shall be provided in for this purpose is be provided in *"SECTION III - EVALUATION AND QUALIFICATION CRITERIA, item 9"*.

4.10 Pursuant to the eligibility requirements of ITT 4.10, a tender is considered a foreign tenderer, if the tenderer is not registered in Kenya or if the tenderer is registered in Kenya and has less than 51 percent ownership by Kenyan citizens. JVs are considered as foreign tenderers if the individual member firms are not registered in Kenya or if are registered in Kenya and have less than 51 percent ownership by Kenyan citizens. The JV shall not subcontract to foreign firms more than 10 percent of the contract price, excluding provisional sums.

4.11 The Competition Act of Kenya requires that firms wishing to tender as Joint Venture

undertakings which may prevent, distort or lessen competition in provision of services are prohibited unless they are exempt in accordance with the provisions of Section 25 of the Competition Act, 2010. JVs will be required to seek for exemption from the Competition Authority. Exemption shall not be a condition for tender, but it shall be a condition of contract award and signature. A JV tenderer shall be given opportunity to seek such exemption as a condition of award and signature of contract. Application for exemption from the Competition Authority of Kenya may be accessed from the website www.cak.go.ke.

4.12 A Kenyan tenderer shall provide evidence of having fulfilled his/her tax obligations by producing a valid tax compliance clearance certificate or tax exemption certificate issued by the Kenya Revenue Authority.

5. Eligible Goods and Related Services

5.1 All the Goods and Related Services to be supplied under the Contract may have their origin in any eligible country.

5.2 For purposes of this ITT, the term "goods" includes any goods that are the subject of this Invitation to Tender, and "Related Services" includes services such as transportation, insurance, commissioning and training.

5.3 The term "origin" means the country where the goods have been mined, grown, cultivated, produced, manufactured or processed; or, through manufacture, processing, or assembly, another commercially recognized article results that differs substantially in its basic characteristics from its components.

5.4 Any goods, works and production processes with characteristic that have been declared by the relevant national environmental protection agency or by other competent authority as harmful to human beings and to the environment shall not be eligible for procurement.

B. Contents of Tendering Document

6. Sections of Tendering Document

The tendering document consists of Parts1,2, and 3, which includes all the sections indicated below, and should be read in conjunction with any Addenda issued in accordance with ITT 8.

PART 1 - Tendering Procedures
Section I - Instructions to Tenderers (ITT)
Section II - Tendering Data Sheet (TDS)
Section III - Evaluation and Qualification Criteria
Section IV - Tendering Forms

PART 2 - Supply Requirements
Section V - Schedule of Requirements

PART 3 - Contract
Section VI - General Conditions of Contract
Section VII - Special Conditions of Contract
Section VIII - Contract Forms

The Specific Procurement Notice-Invitation to Tender (ITT) notice issued by the Procuring

Entity is not part of this tendering document.

Unless obtained directly from the Procuring Entity, the Procuring Entity is not responsible for the completeness of the document, responses to requests for clarification, or Addenda to the tendering document in accordance withITT10.Incaseofanycontradiction, documents obtained directly from the Procuring Entity shall prevail.

The Tenderer is expected to examine all instructions, forms, terms, and specifications in the tendering document and to furnish with its Tender all information or documentation as is required by the tendering document.

7. Clarification of Tendering Document

7.1 A Tenderer requiring any clarification of the tendering document shall contact the Procuring Entity in writing at the Procuring Entity's address specified **in the TDS**. The Procuring Entity will respond in writing to any Invitation to clarification, provided that such request is received prior to the deadline for submission of Tenders within a period specified **in the TDS.** The Procuring Entity shall forward copies of its response to all Tenderers who have acquired the tendering document in accordance with ITT 6, including a description of the inquiry but without identifying its source. If so specified **in the TDS**, the Procuring Entity shall also promptly publish its response at the web page identified **in the TDS**. Should the clarification result in changes to the essential elements of the tendering document, the Procuring Entity shall amend the tendering document following the procedure under ITT 8 and ITT 22.2.

8. Amendment of Tendering Document

At any time prior to the deadline for submission of Tenders, the Procuring Entity may amend the tendering document by issuing addenda.

Any addendum issued shall be part of the tendering document and shall be communicated in writing to all who have obtained the tendering document from the Procuring Entity in accordance with ITT 6. The Procuring Entity shall also promptly publish the addendum on the Procuring Entity's web page in accordance with ITT 7.1.

To give prospective Tenderers reasonable time in which to take an addendum into account in preparing their Tenders, the Procuring Entity may, at its discretion, extend the deadline for the submission of Tenders, pursuant to ITT 22.2.

C. Preparation of Tenders

9. Cost of Tendering

9.1 The Tenderer shall bear all costs associated with the preparation and submission of its Tender, and the Procuring Entity shall not be responsible or liable for those costs, regardless s of the conduct or outcome of the Tendering process.

10. Language of Tender

10.1 The Tender, as well as all correspondence and documents relating to the Tender exchanged by the Tenderer and the Procuring Entity, shall be written in the English Language**.** Supporting documents and printed literature that are part of the Tender may be in another language provided they are accompanied by an accurate translation of the relevant

passages into the English Language**,** in which case, for purposes of interpretation of the Tender, such translation shall govern.

11. Documents Comprising the Tender

The Tender shall comprise the following:

a) **Form of Tender** prepared in accordance with ITT 12;
b) **Price Schedules**: completed in accordance with ITT 12 and ITT 14;
c) **Tender Security** or **Tender-Securing Declaration**, in accordance with ITT 19.1;
d) **Alternative Tender**, if permissible, in accordance with ITT 13;
e) **Authorization**: written confirmation authorizing the signatory of the Tender to commit the Tenderer, in accordance with ITT20.3;
f) **Tenderer's Qualifications**: documentary evidence in accordance with ITT 17 establishing the Tenderer's qualifications to perform the Contract if its Tender is accepted;
g) **Tenderer's Eligibility**: documentary evidence in accordance with ITT 17 establishing the Tenderer's eligibility to Tender;
h) **Eligibility of Goods and Related Services**: documentary evidence in accordance with ITT 16, establishing the eligibility of the Goods and Related Services to be supplied by the Tenderer;
i) **Conformity**: documentary evidence in accordance with ITT 16, that the Goods and Related Services conform to the tendering document; and
j) Any other document required **in the TDS.**

In addition to the requirements under ITT 11.1, Tenders submitted by a JV shall include a copy of the Joint Venture Agreement entered into by all members. Alternatively, a Form of intent to execute a Joint Venture Agreement in the event of a successful Tender shall be signed by all members and submitted with the tender, together with a copy of the proposed Agreement. The Tenderer shall chronologically serialize pages of all tender documents submitted.

The Tenderer shall furnish in the Form of Tender information on commissions and gratuities, if any, paid or to be paid to agents or any other party relating to this Tender.

12. Form of Tender and Price Schedules

12.1 The Form of Tender and Price Schedules shall be prepared using the relevant forms furnished in Section IV, Tendering Forms. The forms must be completed without any alterations to the text, and no substitutes shall be accepted except as provided under ITT 20.3. All blank spaces shall be filled in with the information requested.

13 Alternative Tenders

13.1 Unless otherwise specified **in the TDS,** alternative Tenders shall not be considered.

14. Tender Prices and Discounts

The prices and discounts quoted by the Tenderer in the Form of Tender and in the Price Schedules shall conform to the requirements specified below.

All lots (contracts) and items must be listed and priced separately in the Price Schedules.

The price to be quoted in the Form of Tender in accordance with ITT 11.1 shall be the total

price of the Tender, including any discounts offered.

The Tenderer shall quote any discounts and indicate the methodology for their application in the Form of Tender.

Prices quoted by the Tenderer shall be fixed during the Tenderer's performance of the Contract and not subject to variation on any account, unless otherwise specified **in the TDS.** A Tender submitted with an adjustable price quotation shall be treated as non-responsive and shall be rejected, pursuant to ITT 29. However, if in accordance with the TDS, prices quoted by the Tenderer shall be subject to adjustment during the performance of the Contract, a Tender submitted with a fixed price quotation shall not be rejected, but the price adjustment shall be treated as zero.

If so specified in ITT 1.1, Tenders are being invited for individual lots (contracts) or any combination of lots (packages). Unless otherwise specified **in the TDS,** prices quoted shall correspond to 100 % of the items specified for each lot and to 100% of the quantities specified for each item of a lot. Tenderers wishing to offer discounts for the award of more than one Contract shall specify in their Tender the price reductions applicable to each package, or alternatively, to individual Contracts within the package. Discounts shall be submitted in accordance with ITT 14 provided the Tenders for all lots (contracts) are opened at the same time.

The terms EXW, CIP, and other similar terms shall be governed by the rules prescribed in the current edition of Incoterms, published by The International Chamber of Commerce, as specified **in the TDS.**

Prices shall be quoted as specified in each Price Schedule included in Section IV, Tendering Forms. The dis- aggregation of price components is required solely for the purpose of facilitating the comparison of Tenders by the Procuring Entity. This shall not in any way limit the Procuring Entity's right to contract on any of the terms offered. In quoting prices, the Tenderer shall be free to use transportation through carriers registered in any eligible country, in accordance with Section V, Eligible Countries. Similarly, the Tenderer may obtain insurance services from any eligible country in accordance with Section V, Eligible Countries. Prices shall be entered in the following manner:

a) For Goods manufactured in Kenya:
   i) the price of the Goods quoted EXW (ex-works, ex-factory, ex warehouse, ex showroom, or off-the- shelf, as applicable), including all customs duties and sales and other taxes already paid or payable on the components and raw material used in the manufacture or assembly of the Goods;
   ii) any Kenya sales tax and other taxes which will be payable on the Goods if the Contract is awarded to the Tenderer; and
   iii) the price for inland transportation, insurance, and other local services required to convey the Goods to their final destination (Project Site) **specified in the TDS**;
b) for Goods manufactured outside Kenya, to be imported:
   i) the price of the Goods, quoted CIP named place of destination, in Kenya, as **specified in the TDS**; and
   ii) the price for inland transportation, insurance, local taxes payable on the goods and other local services required to convey the Goods from the named place of destination to their final destination (Project Site) **specified in the TDS**;

c) for Goods manufactured outside Kenya, already imported:
   i) the price of the Goods, including the original import value of the Goods; plus, any mark-up (or rebate); plus, any other related local cost, and custom duties and other import taxes already paid or to be paid on the Goods already imported;
   ii) the custom duties and other import taxes already paid (need to be supported with documentary evidence) or to be paid on the Goods already imported;
   iii) the price of the Goods, obtained as the difference between (i) and (ii) above;
   iv) any Kenya sales and other taxes which will be payable on the Goods if the Contract is awarded to the Tenderer; and
   v) the price for inland transportation, insurance, and other local services required to convey the Goods from the named place of destination to their final destination (Project Site) specified **in the TDS.**

d) for Related Services, other than inland transportation and other services required to convey the Goods to their final destination, whenever such Related Services are specified in the Schedule of Requirements:
   i) the price of each item comprising the Related Services (inclusive of any applicable taxes).

15. Currencies of Tender and Payment

The currency(ies) of the Tender and the currency(ies) of payments shall be the same. The Tenderer shall quote in the currency of Kenya the portion of the Tender price that corresponds to expenditures incurred in Kenya Shillings, unless otherwise specified **in the TDS.**

The Tenderer may express the Tender price in any currency. If the Tenderer wishes to be paid in a combination of amounts in different currencies; it may quote its price accordingly but shall use no more **than two foreign currencies in** addition to the currency of Kenya.

The rates of exchange to be used by the Tenderer shall be the selling exchange rate provided by the Central Bank of Kenya on the tender closing date.

16. Documents Establishing the Eligibility and Conformity of the Goods and Related Services

16.1 To establish the eligibility of the Goods and Related Services in accordance with ITT 5, Tenderers shall complete the country-of-origin declarations in the Price Schedule Forms, included in Section IV, Tendering Forms.

16.2 To establish the conformity of the Health Sector Goods and Related Services to the tendering document, the Tenderer shall furnish as part of its Tender the documentary evidence that the Goods conform to the technical specifications and standards specified in Section VII, Schedule of Requirements.

16.3 The documentary evidence may be in the form of literature, drawings or data, and shall consist of:

a) an item-by-item commentary on the provisions of Section VII, Schedule of Requirements demonstrating substantial responsiveness of the Goods and Services to the specifications, or a statement of deviations and exceptions to the provisions of the specifications; and

b) any other procurement-specific documentation requirement as stated **in the TDS.**

16.4 Unless the **TDS** stipulates otherwise, the Goods to be supplied under the Contract shall be registered with the relevant authority in Kenya. A Tenderer who has already registered its Goods by the time of Tendering should submit a copy of the Registration Certificate with its Tender. Otherwise, the successful Tenderer, by the time of Contract signing, shall submit to the Procuring Entity either:

a) A copy of the Registration Certificate of the Goods for use in Kenya; or

b) If such Registration Certificate has not yet been obtained, evidence establishing to the Procuring Entity's satisfaction that the Tenderer has complied with all the documentary requirements for registration as specified **in the TDS**

16.5The Procuring Entity shall at all times cooperate with the successful Tenderer to facilitate the registration process within Kenya. The agency and contact person able to provide additional information about registration are identified **in the TDS.**

If the Goods of the successful Tenderer have not been registered in Kenya at the time of Contract signing, then the Contract shall become effective upon such date as the Certificate of Registration is obtained.

16.6 Standards for workmanship, process, material, and equipment, as well as references to brand names or catalogue numbers specified by the Procuring Entity in the Schedule of Requirements, are intended to be descriptive only and not restrictive. The Tenderer may offer other standards of quality, brand names, and/or catalogue numbers, provided that it demonstrates, to the Procuring Entity's satisfaction, that the substitutions ensure substantial equivalence or are superior to those specified in the Section VII, Schedule of Requirements.

17. Documents Establishing the Eligibility and Qualifications of the Tenderer

17.1 To establish Tenderer's eligibility in accordance with ITT 4, Tenderers shall complete the Form of Tender, included in Section IV, Tendering Forms.

17.2 The documentary evidence of the Tenderer's qualifications to perform the Contract if its Tender is accepted shall establish to the Procuring Entity's satisfaction:

a) that a Tenderer that does not manufacture or produce the Health Sector Goods it offers to supply shall submit the Manufacturer's Authorization using the form included in Section IV, Tendering Forms to demonstrate that it has been duly authorized by the manufacturer or producer of the Goods to supply these Goods in Kenya;

b) that in case of a Tenderer not doing business within Kenya (or for other reasons will not itself carry out service obligations), the Tenderer is or will be (if awarded the Contract) represented by a local service provider in Kenya equipped and able to carry out the Tenderer's warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications; and

c) that the Tenderer meets each of the qualification criterion specified in Section III, Evaluation and Qualification Criteria (see additional ITT for Health Products and vaccines).

17.3 Tenderers shall be asked to provide, as part of the data for qualification, such information, including details of ownership, as shall be required to determine whether, according to the classification established by the Procuring Entity a supplier or group of suppliers' qualifies for a margin of preference. Further the information will enable the Procuring Entity identify any actual or potential conflict of interest in relation to the procurement and/or contract management processes, or a possibility of collusion between tenderers, and thereby help to

prevent any corrupt influence in relation to the procurement process or contract management.

17.4 The purpose of the information described **in ITT 17.2** above overrides any claims to confidentiality which a tenderer may have. There can be no circumstances in which it would be justified for a tenderer to keep information relating to its ownership and control confidential where it is tendering to undertake public sector work and receive public sector funds. Thus, confidentiality will not be accepted by the Procuring Entity as a justification for a Tenderer's failure to disclose, or failure to provide required information on its ownership and control.

17.5 The Tenderer shall provide further documentary proof, information or authorizations that the Procuring Entity may request in relation to ownership and control which information on any changes to the information which was provided by the tenderer under ITT17.3.The obligations to require this information shall continue for the duration of the procurement process and contract performance and after completion of the contract, if any change to the information previously provided may reveal a conflict of interest in relation to the award or management of the contract.

17.6 All information provided by the tenderer pursuant to these requirements must be complete, current and accurate as at the date of provision to the Procuring Entity. In submitting the information required pursuant to these requirements, the Tenderer shall warrant that the information submitted is complete, current and accurate as at the date of submission to the Procuring Entity.

17.7 If a tenderer fails to submit the information required by these requirements, its tenderer will be rejected. Similarly, if the Procuring Entity is unable, after taking reasonable steps, to verify to a reasonable degree the information submitted by a tenderer pursuant to these requirements, then the tender will be rejected.

17.8 If information submitted by a tenderer pursuant to these requirements, or obtained by the Procuring Entity (whether through its own enquiries, through notification by the public or otherwise), shows any conflict of interest which could materially and improperly benefit the tenderer in relation to the procurement or contract management process, then:

i) If the procurement process is still ongoing, the tenderer will be disqualified from the procurement process,

ii) If the contract has been awarded to that tenderer, the contract award will be set aside,

iii) the tenderer will be referred to the relevant law enforcement authorities for investigation of whether the tenderer or any other persons have committed any criminal offence.

17.9 If a tenderer submits information pursuant to these requirements that is in complete, in accurate or out-of-date, or attempts to obstruct the verification process, then the consequences ITT 17.7 will ensue unless the tenderer can show to the reasonable satisfaction of the Procuring Entity that any such act was not material, or was due to genuine error which was not attributable to the intentional act, negligence or recklessness of the tenderer.

18. Period of Validity of Tenders

18.1 Tenders shall remain valid for the Tender Validity period specified **in the TDS**. The Tender Validity period starts from the date fixed for the Tender submission deadline (as prescribed

by the Procuring Entity in accordance with ITT22.1). A Tender valid for a shorter period shall be rejected by the Procuring Entity as non-responsive.

18.2 In exceptional circumstances, prior to the expiration of the Tender validity period, the Procuring Entity may request Tenderers to extend the period of validity of their Tenders. The request and the responses shall be made in writing. If a Tender Security is requested in accordance with ITT 19, it shall also be extended for a corresponding period. A Tenderer may refuse the request without forfeiting its Tender Security. A Tenderer granting the request shall not be required or permitted to modify its Tender.

19. Tender Security

19.1 The Tenderer shall furnish as part of its Tender, either a Tender-Securing Declaration or a Tender Security, as specified **in the TDS,** in original form and, in the case of a Tender Security, in the amount and currency specified **in the TDS.**

19.2 A Tender-Securing Declaration shall use the form included in Section IV, Tendering Forms.

If a Tender is specified pursuant to ITT 19.1, the Tender Security shall be a:

i) cash;

ii) a bank guarantee;

iii) a guarantee by an insurance company registered and licensed by the Insurance Regulatory Authority listed by the Authority; or

iv) a guarantee issued by a financial institution approved and licensed by the Central Bank of Kenya.

v) Any other Form specified in the **TDS**.

19.3 If a Tender Security is specified pursuant to ITT 19.1, any Tender not accompanied by a substantially responsive Tender Security shall be rejected by the Procuring Entity as non-responsive.

19.4 If a Tender Security is specified pursuant to ITT 19.1, the Tender Security of unsuccessful Tenderers shall be returned as promptly as possible upon the successful Tenderer's signing the Contract and furnishing the Performance Security pursuant to ITT 45. The Procuring Entity shall also promptly return the tender security to the tenderers where the procurement proceedings are terminated, all tenders were determined non-responsive or abider declines to extend tender validity period.

19.5 The Tender Security of the successful Tenderer shall be returned as promptly as possible once the successful Tenderer has signed the Contract and furnished the required Performance Security.

19.6 The Tender Security may be forfeited or the Tender-Securing Declaration executed:

a) if a Tenderer withdraws its Tender during the period of Tender validity specified by the Tenderer on the Form of Tender, or any extension thereto provided by the Tenderer; or

b) if the successful Tenderer fails to:

i) sign the Contract in accordance with ITT 44; or

ii) furnish a Performance Security in accordance with ITT 45.

19.7 Where tender securing declaration is executed, the Procuring Entity shall recommend to the

PPRA that PPRA debars the Tenderer from participating in public procurement as provided in the law.

19.8 The Tender Security or Tender- Securing Declaration of a JV must be in the name of the JV that submits the Tender. If the JV has not been legally constituted into a legally enforceable JV at the time of Tendering, the Tender Security or Tender-Securing Declaration shall be in the names of all future members as named in the Form of intent referred to in ITT 4.1and ITT 11.2.

20. Format and Signing of Tender

20.1 The Tenderer shall prepare one original of the documents comprising the Tender as described in ITT 11 and clearly mark it "ORIGINAL." Alternative Tenders, if permitted in accordance with ITT 13, shall be clearly marked "ALTERNATIVE" In addition, the Tenderer shall submit copies of the Tender, in the number specified **in the TDS** and clearly mark them "COPY." In the event of any discrepancy between the original and the copies, the original shall prevail.

20.2 Tenderers shall mark as "CONFIDENTIAL" information in their Tenders which is confidential to their business. This may include proprietary information, trade secrets or commercial or financially sensitive information.

20.3 The original and all copies of the Tender shall be typed or written in indelible ink and shall be signed by a person duly authorized to sign on behalf of the Tenderer. This authorization shall consist of a written confirmation as specified **in the TD S**and shall be attached to the Tender. The name and position held by each person signing the authorization must be typed or printed below the signature. All pages of the Tender where entries or amendments have been made shall be signed or initialed by the person signing the Tender.

20.4 In case the Tenderer is a JV, the Tender shall be signed by an authorized representative of the JV on behalf of the JV, and so as to be legally binding on all the members as evidenced by a power of attorney signed by their legally authorized representatives.

20.5 Any inter-lineation, erasures, or overwriting shall be valid only if they are signed or initialed by the person signing the Tender.

D. Submission and Opening of Tenders

21. Sealing and Marking of Tenders

21.1 The Tenderer shall deliver the Tender in a single, sealed envelope (one-envelope Tendering process). Within the single envelope the Tenderer shall place the following separate, sealed envelopes:

a) In an envelope marked "ORIGINAL", all documents comprising the Tender, as described in ITB11; and

b) in an envelope marked "COPIES", all required copies of the Tender; and

c) if alternative Tenders are permitted in accordance with ITB13, and if relevant:

i) in an envelope marked "ORIGINAL-ALTERNATIVE", the alternative Tender; hand

ii) in the envelope marked "COPIES-ALTERNATIVE TENDER" all required copies of the alternative Tender.

21.2 The outer envelopes, shall:

d) Be addressed to the Procuring Entity in accordance with ITT 22.1;

e) Bear the specific identification of this Tendering process indicated in ITT 1.1; and

f) bear a warning not to open before the time and date for Tender opening.

The inner envelopes shall bear the name and address (include email and telephone number) of the Tenderer and all the information above ITT21.2 (a) to (c).

21.3 If all envelopes are not sealed and marked as required, the Procuring Entity will assume no responsibility for the misplacement or premature opening of the Tender. Tenders that are misplaced or opened prematurely will not be accepted.

22. Deadline for Submission of Tenders

22.1 Tenders must be submitted bidding documents to Kenya Medical Supplies Authority not later than tender closing/opening date and time.

22.2 The Procuring Entity may, at its discretion, extend the deadline for the submission of Tenders by amending the tendering document in accordance with ITT8, in which case all rights and obligations of the Procuring Entity and Tenderers previously subject to the deadline shall thereafter be subject to the deadline as extended.

23. Late Tenders

24. Withdrawal, Substitution, and Modification of Tenders

24.1 A Tenderer may withdraw, substitute, or modify its Tender after it has been submitted by sending a written notice, duly signed by an authorized representative, and shall include a copy of the authorization (the power of attorney) in accordance with ITT 20.3, (except that withdrawal notices do not require copies). The corresponding substitution or modification of the Tender must accompany the respective written notice. All notices must be:

a) prepared and submitted in accordance with ITT 20 and 21 (except that withdrawal notices do not require copies), and in addition, the respective envelopes shall be clearly marked "WITHDRAWAL," "SUBSTITUTION," or "MODIFICATION;" and

b) received by the Procuring Entity prior to the dead line prescribed for submission of Tenders, in accordance with ITT 22.1.

24.2 Tenders requested to be withdrawn in accordance with ITT24 shall be returned unopened to the Tenderers.

24.3 No Tender may be withdrawn, substituted, or modified in the interval between the deadline for submission of Tenders and the expiration of the period of Tender validity specified by the Tenderer on the Form of Tender or any extension thereof.

25. Tender Opening

25.1 Except as in the cases specified in ITT23 and ITT24.2, the Procuring Entity shall publicly open and read out in accordance with this ITT all Tenders received by the deadline at the date, time and place specified **in the TDS** in the presence of Tenderers' designated representatives and anyone who choose to attend. All Tenderers, or their representatives and any interested party may attend a public opening. Any specific electronic Tender

opening procedures required if electronic Tendering is permitted in accordance with ITT22. 1, shall be as specified **in the TDS.**

25.2 First, envelopes marked "WITHDRAWAL" shall be opened and read out and the envelope with the corresponding Tender shall not be opened, but returned to the Tenderer. If the withdrawal envelope does not contain a copy of the "power of attorney" confirming the signature as a person duly authorized to sign on behalf of the Tenderer, the corresponding Tender will be opened. No Tender withdrawal shall be permitted unless the corresponding withdrawal notice contains a valid authorization to request the withdrawal and is read out at Tender opening.

25.3 Next, envelopes marked "SUBSTITUTION" shall be opened and read out and exchanged with the corresponding Tender being substituted, and the substituted Tender shall not be opened, but returned to the Tenderer.NoTendersubstitutionshallbepermittedunlessthecorrespondingsubstitutionnotice containsavalid authorizationtorequestthesubstitutionandisreadoutatTenderopening.

25.4 Next, envelopes marked "MODIFICATION" shall be opened and read out with the corresponding Tender. No Tender modification shall be permitted unless the corresponding modification notice contains a valid authorization to request the modification and is read out at Tender opening.

25.5 Next, all remaining envelopes shall be opened one at a time, reading out: the name of the Tenderer and whether there is a modification; the total Tender Prices, per item or lot (contract) if applicable, including any discounts and alternative Tenders; the presence or absence of a Tender Security, if required; and any other details as the Procuring Entity may consider appropriate.

25.6 Only Tenders, alternative Tenders and discounts that are opened and read out at Tender opening shall be considered further for evaluation. The Form of Tender and the Price Schedules are to be initialed by representatives of the Procuring Entity attending Tender opening in the manner specified **in the TDS.**

25.7 The Procuring Entity shall neither discuss the merits of any Tender nor reject any Tender (except for late Tenders, in accordance with ITT 23.1).

25.8 The Procuring Entity shall prepare a record of the Tender opening that shall include, as a minimum:

a) The name of the Tenderer and whether there is a withdrawal, substitution, or modification;
b) The Tender Price, per lot(contract)if applicable, including any discounts;
c) any alternative Tenders; and
d) the presence or absence of a Tender Security or Tender Securing Declaration, if one was required.
e) Number of pages of each tender document submitted

25.9 The Tenderers' representatives who are present shall be requested to sign the record. The omission of a Tenderer's signature on the record shall not invalidate the contents and effect of the record. A copy of the tender opening register shall be issued to a tenderer upon request.

E. Evaluation and Comparison of Tenders

26. Confidentiality

26.1 Information relating to the evaluation of Tenders and recommendation of contract award, shall not be disclosed to Tenderers or any other persons not officially concerned with the Tendering process until the Notification of Intention to Award the Contract is transmitted to all Tenderers in accordance with ITT 40.

26.2 Any effort by a Tenderer to influence the Procuring Entity in the evaluation or contract award decisions may result in the rejection of its Tender.

26.3 Notwithstanding ITT 26.2, from the time of Tender opening to the time of Contract Award, if any Tenderer wishes to contact the Procuring Entity on any matter related to the Tendering process, it should do so in writing.

27. Clarification of Tenders

27.1 To assist in the examination, evaluation, comparison of the Tenders, and qualification of the Tenderers, the Procuring Entity may, at its discretion, ask any Tenderer for a clarification of its Tender. Any clarification submitted by a Tenderer in respect to its Tender and that is not in response to a request by the Procuring Entity shall not be considered. The Procuring Entity's Invitation to clarification and the response shall be in writing. No change, including any voluntary increase or decrease, in the prices or substance of the Tender shall be sought, offered, or permitted, except to confirm the correction of arithmetic errors discovered by the Procuring Entity in the Evaluation of the Tenders, in accordance with ITT 31.

27.2 If a Tenderer does not provide clarifications of its Tender by the date and time set in the Procuring Entity's Invitation to clarification, its Tender may be rejected.

28. Deviations, Reservations, and Omissions

28.1 During the evaluation of Tenders, the following definitions apply:

a) "Deviation" is a departure from the requirements specified in the tendering document;

b) "Reservation" is the setting of limiting conditions or withholding from complete acceptance of the requirements specified in the tendering document; and

c) "Omission" is the failure to submit part or all of the information or documentation required in the tendering document.

29. Determination of Responsiveness

29.1 The Procuring Entity's determination of a Tender's responsiveness is to be based on the contents of the Tender itself, as defined in ITT 11.

29.2 A substantially responsive Tender is one that meets the requirements of the tendering document without material deviation, reservation, or omission. A material deviation, reservation, or omission is one that:

a) If accepted, would:

i) affect in any substantial way the scope, quality, or performance of the Goods and Related Services specified in the Contract; or

ii) limit in any substantial way, inconsistent with the tendering document, the

Procuring Entity's rights or the Tenderer's obligations under the Contract; or

b) if rectified, would unfairly affect the competitive position of other Tenderers presenting substantially responsive Tenders.

29.3 The Procuring Entity shall examine the technical aspects of the Tender submitted in accordance with ITT 16 and ITT 17, in particular, to confirm that all requirements of Section VII, Schedule of requirements have been met without any material deviation or reservation, or omission.

29.4 If a Tender is not substantially responsive other requirements of tendering document, it shall be rejected by the Procuring Entity and may not subsequently be made responsive by correction of the material deviation, reservation, or omission.

30. Non-conformities, Error sand Omissions

30.1 Provided that a Tender is substantially responsive, the Procuring Entity may waive any non-conformity in the Tender.

30.2 Provided that a Tender is substantially responsive, the Procuring Entity may request that the Tenderer submit the necessary information or documentation, within a reasonable period of time, to rectify nonmaterial non- conformities or omissions in the Tender related to documentation requirements. Such omission shall not be related to any aspect of the price of the Tender. Failure of the Tenderer to comply with the request may result in the rejection of its Tender.

30.3 Provided that a Tender is substantially responsive, the Procuring Entity shall rectify quantifiable nonmaterial non-conformities related to the Tender Price. To this effect, the Tender Price shall be adjusted, for comparison purposes only, to reflect the price of a missing or n on-conforming item or component in the manner specified **in the TDS**.

31. Arithmetical Errors

31.1 The tenders submitted and read out during the tender opening shall be absolute and final and shall not be the subject of correction, adjustment or amendment in any way by any person or entity.

31.2 Provided that the Tender is substantially responsive, the Procuring Entity shall handle errors on the following basis:

a) Any error detected if considered a major deviation that affects the substance of the tender, shall lead to disqualification of the tender as non-responsive.

b) Any errors in the submitted tender arising from a miscalculation of unit price, quantity, and subtotal and total bid price shall be considered as a major deviation that affects the substance of the tender and shall lead to disqualification of the tender as non-responsive. and

c) If there is a discrepancy between words and figures, the amount in words shall prevail

31.3 Tenderers shall be notified of any error detected in their bid during the notification of award.

32. Conversion to Single Currency

32.1 For evaluation and comparison purposes, the currency(ies) of the Tender shall be converted

in a single currency as specified **in the TDS.**

33. Margin of Preference and Reservations

33.1 A margin of preference may be allowed on locally manufactured Health goods only when the contract is open to international tendering, where the tender is likely to attract foreign goods and where the contract exceeds the threshold specified in the Regulations. A margin of preference shall not be allowed unless it is specified so in the **TDS**.

33.2 Contracts procured on basis of international competitive tendering shall not be subject to reservations to specific groups as provided in ITT 33.3.

33.3 Where it is intended to reserve a contract to a specific group of businesses (these groups are Small and Medium Enterprises, Women Enterprises, Youth Enterprises and Enterprises of persons living with disability, as the case maybe), and who are appropriately registered as such by a competent authority, a procuring entity shall ensure that the invitation to tender specifically indicates that only businesses or firms belonging to the group are eligible to tender. No tender shall be reserved to more than one group. If not so stated in the Tender documents, the invitation to tender will be open to all interested tenderers.

34. Evaluation of Tenders

34.1 The Procuring Entity shall use the criteria and methodologies listed in this ITT and Section III, Evaluation and Qualification criteria. No other evaluation criteria or methodologies shall be permitted. By applying the criteria and methodologies, the Procuring Entity shall determine the Lowest Evaluated Tender. This is the Tender of the Tenderer that meets the qualification criteria and whose Tender has been determined to be:

a) Substantially responsive to the tendering document; and

b) The lowest evaluated cost.

34.2 To evaluate a Tender, the Procuring Entity shall consider the following:

c) Price adjustment due to discounts offered in accordance with ITT 14.

d) Price adjustment due to quantifiable non material non-conformities in accordance with ITT 30.3; and

e) converting the amount resulting from applying (a) and (b) above, if relevant, to a single currency in accordance with ITT 32;

f) any additional evaluation factors specified in Section III, Evaluation and Qualification Criteria.

34.3 The estimated effect of the price adjustment provisions of the Conditions of Contract, applied over the period of execution of the Contract, shall not be taken in to account in Tender evaluation.

34.4 In the case of multiple contracts or lots, Tenderers are allowed to tender for one or more lots and the methodology to determine the lowest evaluated cost of the lot (contract) and for combinations, including any discounts offered in the Form of Tender, is specified in Section III, Evaluation and Qualification Criteria.

34.5 The Procuring Entity's evaluation of a Tender will exclude and not taken to account:

g) in the case of Goods manufactured in Kenya, sales and other similar taxes, which will

be payable on the goods if a contract is awarded to the Tenderer;

h) in the case of Goods manufactured outside Kenya, already imported or to be imported, customs duties and other import taxes levied on the imported Good, sales and other similar taxes, which will be payable on the Goods if the contract is awarded to the Tenderer;

i) any allowance for price adjustment during the period of execution of the contract, if provided in the Tender.

34.6 The Procuring Entity's evaluation of a Tender may require the consideration of other factors, in addition to the Tender Price quoted in accordance with ITT 14. These factors may be related to the characteristics, performance, and terms and conditions of purchase of the Goods and Related Services. The effect of the factors selected, if any, shall be expressed in monetary terms to facilitate comparison of Tenders, unless otherwise specified **in the TDS** from amongst those set out in Section III, Evaluation and Qualification Criteria. The criteria and methodologies to be used shall be as specified in ITT 34.2

35. Comparison of Tenders

35.1 The Procuring Entity shall compare the evaluated costs of all substantially responsive Tenders established in accordance with ITT 34.2 to determine the Tender that has the lowest evaluated cost. The comparison shall be on the basis of CIP (place of final destination) prices for imported goods and EXW prices, plus cost of inland transportation and insurance to place of destination, for goods manufactured within Kenya, together with prices for any required installation, training, commissioning and other services. The evaluation of prices shall not take into account custom duties and other taxes levied on imported goods quoted CIP and sales and similar taxes levied in connection with the sale or delivery of goods.

36. Abnormally Low Tenders and Abnormally High Tenders

Abnormally Low Tenders

36.1 An Abnormally Low Tender is one where the Tender price in combination with other constituent elements of the Tender, appears unreasonably low to the extent that the Tender price raises material concerns with the Procuring Entity as to the capability of the Tenderer to perform the Contract for the offered Tender price.

37.2 In the event of identification of a potentially Abnormally Low Tender by the evaluation committee, the Procuring Entity shall seek written clarification from the Tenderer, including a detailed price analyses of its Tender price in relation to the subject matter of the contract, scope, delivery schedule, allocation of risks and responsibilities and any other requirements of the tendering document.

37.3 After evaluation of the price analyses, in the event that the Procuring Entity determines that the Tenderer has failed to demonstrate its capability to perform the contract for the offered Tender price, the Procuring Entity shall reject the Tender.

Abnormally High Tenders

37.4 An abnormally high tender price is one where the tender price, in combination with other constituent elements of the Tender, appears unreasonably too high to the extent that the Procuring Entity is concerned that it (the Procuring Entity) may not be getting value for

money or it may be paying too high a price for the contract compared with market prices or that genuine competition between Tenderers is compromised.

37.5 In case of an abnormally high price, the Procuring Entity shall make a survey of the market prices, check if the estimated cost of the contract is correct and review the Tender Documents to check if the specifications, scope of work and conditions of contract are contributory to the abnormally high tenders. The Procuring Entity may also seek written clarification from the tenderer on the reason for the high tender price. The Procuring Entity shall proceed as follows:

(i) If the tender price is abnormally high based on wrong estimated cost of the contract, the Procuring Entity may accept or not accept the tender depending on the Procuring Entity's budget considerations.

(ii) If specifications, scope of work and/or conditions of contract are contributory to the abnormally high tender prices, scope of work and conditions of contract, as the case may be.

37.6 If the Procuring Entity determines that the Tender Price is abnormally too high because genuine competition between tenderers is compromised (*often due to collusion, corruption or other manipulations*), the Procuring Entity shall reject all Tenders and shall institute or cause competent Government Agencies to institute an investigation on the cause of the compromise, before retendering.

37. Qualification of the Tenderer

37.1 The Procuring Entity shall determine to its satisfaction whether the Tenderer that is selected a shaving submitted the lowest evaluated cost and substantially responsive Tender is eligible and meets the qualifying criteria specified in ITT 11.1 as applicable, and Section III, Evaluation and Qualification Criteria.

37.2 The determination shall be based upon an examination of the documentary evidence of the Tenderer's qualifications submitted by the Tenderer, pursuant to ITT 17. The determination shall not take into consideration the qualifications of other firms such as the Tenderer's subsidiaries, parent entities, affiliates, sub-contractors or any other firm (s) different from the Tenderer.

37.3 An affirmative determination shall be a prerequisite for award of the Contract to the Tenderer. A negative determination shall result in disqualification of the Tender, in which event the Procuring Entity shall proceed to the Tenderer who offers a substantially responsive Tender with the next lowest evaluated cost to make a similar determination of that Tenderer's qualification stopper form satisfactorily.

38. Procuring Entity's Right to Accept Any Tender, and to Reject Any or All Tenders

38.1 The Procuring Entity reserves the right to accept or reject any tender, and to annul the Tendering process and reject all Tenders at any time prior to Contract Award, without thereby incurring any liability to Tenderers. In case of annulment, all Tenderers shall be notified with reasons and all Tenders submitted and specifically, tender securities, shall be promptly returned to the Tenderers.

F. Award of Contract

39. Award Criteria

39.1 The Procuring Entity shall award the Contract to the successful tenderer whose tender has been determined to be the Lowest Evaluated Tender.

40. Notice of Intention to enter into a Contract

40.1 Upon award of the contract and prior to the expiry of the Tender Validity Period the Procuring Entity shall issue a Notification of Intention to Enter in to a Contract/Notification of award to all tenderers which shall contain, at a minimum, the following information:

a) The name and address of the Tenderer submitting the successful tender;

b) The Contract price of the successful tender;

c) a statement of the reason(s) the tender of the unsuccessful tenderer to whom the letter is addressed was unsuccessful, unless the price information in (c) above already reveals the reason;

d) the expiry date of the Stands till Period; and

e) instructions on how to request a de briefing and/or submit a complaint during the stand still period;

41. Standstill Period

41.1 The Contract shall not be signed earlier than the expiry of a Standstill Period of 14 days to allow any dissatisfied tender to launch a complaint. Where only one Tender is submitted, the Standstill Period shall not apply.

41.2 Where a Standstill Period applies, it shall commence when the Procuring Entity has transmitted to each Tenderer the Notification of Intention to enter in to a Contract with the successful Tenderer.

42. Debriefing by the Procuring Entity

42.1 On receipt of the Procuring Entity's Notification of Intention to Enter into a Contract referred to in ITT 40, an unsuccessful tenderer may make a written request to the Procuring Entity for a debriefing on specific issues or concerns regarding their tender. The Procuring Entity shall provide the debriefing within five days of receipt of the request. Debriefings of unsuccessful full Tenderers may be done in writing or verbally. The Tenderer shall bear its own costs of attending such a debriefing meeting.

43. Letter of Award

46.1 Prior to the expiry of the Tender Validity Period and upon expiry of the Standstill Period specified in ITT 41.1, upon addressing a complaint that has been filed within the Standstill Period; the Procuring Entity shall transmit the Letter of Award to the successful Tenderer. The letter of award shall request the successful tenderer to furnish the Performance Security within 21days of the date of the letter.

44. Signing of Contract

44.1 Upon the expiry of the fourteen days of the Notification of Intention to enter in to contract

and upon the parties meeting their respective statutory requirements, the Procuring Entity shall send the successful Tenderer the Contract Agreement.

44.2 Within fourteen (14) days of receipt of the Contract Agreement, the successful Tenderer shall sign, date, and return it to the Procuring Entity.

44.3 The written contract shall be entered into within the period specified in the notification of award and before expiry of the tender validity period

45. Performance Security

45.1 Within Twenty-Eight (28) days of the receipt of the Letter of Award from the Procuring Entity, the successful Tenderer shall furnish the Performance Security and, any other documents required in the **TDS**, in accordance with the General Conditions of Contract, using the Performance Security and other Forms included in Section X, Contract Forms, or another form acceptable to the Procuring Entity. A foreign institution providing a bank guarantee shall have a correspondent financial institution located in Kenya, unless the Procuring Entity has agreed in writing that a correspondent bank is not required.

45.2 Failure of the successful Tenderer to submit the above-mentioned Performance Security and other documents required in the **TDS** or sign the Contract shall constitute sufficient grounds for the annulment of the award and forfeiture of the Tender Security. In that event the Procuring Entity may award the Contract to the Tenderer offering the next Best Evaluated Tender.

45.3 Performance security shall not be required for contracts estimated to cost less than the amount specified in the Regulations.

46 **Publication of Procurement Contract**

46.1 Within fourteen days after signing the contract, the Procuring Entity shall publish the awarded contract at its noticeboards and websites; and on the Website of the Authority. At the minimum, the notice shall contain the following information:

a) Name and address of the Procuring Entity;

b) Name and reference number of the contract being awarded, a summary of its scope and the selection method used;

c) the name of the successful Tenderer, the final total contract price, the contract duration.

d) Dates of signature, commencement and completion of contract;

e) names of all Tenderers that submitted Tenders, and their Tender prices as read out at Tender opening.

47. Procurement Related Complaint

47.1 The procedures for making a Procurement-related Complaint are as specified in the **TDS.**

SECTION II - TENDER DATA SHEET (TDS)

The following specific data for the Maintenance Services to be procured shall complement, supplement, or amend the provisions in the Instructions to Tenderers (ITT). Whenever there is a conflict, the provisions here in shall prevail over those in ITT.

[Where an e-procurement system issued, modify the relevant parts of the TDS accordingly to reflect thee-procurement process].

[Instructions for completing the Tender Data Sheet are provided, as needed, in the notes in italics mentioned for the relevant ITT].

ITT Reference	**A. General**
ITT 1.1	The reference number of the Invitation to Tenders (ITT) is: ***[KEMSA/GOK-MOH/OIT006/2022-2024]***
	The Procuring Entity is: ***Kenya Medical Supplies Authority (KEMSA)***
	The name of the ITT is: **Supply of Nutrition Supplements** The number and identification of lots (contracts)comprising this ITT is: *5 item(s)*
ITT 1.2(a)	*Not Applicable*
ITT 4.1	Maximum number of members in the Joint Venture (JV) shall be: *1*
B. Contents of Tendering Document	

ITT 7.1	Purchaser's address: Kenya Medical Supplies Authority (KEMSA) Office address: The Chief Executive Officer Kenya Medical Supplies Authority (KEMSA) Commercial Street, Industrial Area Nairobi/Kenya Postal address: P.O. Box: 47715 00100 Nairobi Kenya Tel No: +254 719033000/ +254 726618520/1 E- mail procure@kemsa.co.ke For clarifications on the Tender document please contact: The Chief Executive Officer P. O. Box 47715 00100 Nairobi/Kenya Tel: +254 719033000/ +254 726618520/1 E- mail: procure@kemsa.co.ke Requests for clarification should be received by the Procuring Entity no later than: 18th July 2021 (*a third of number of days before deadline for tender submission*). The Procuring Entity shall publish its response at the website: *http://www.kemsa.co.ke /tenders/ and* www.tenders.go.ke
C. Preparation of Tenders	
ITT 11.1 (j)	The Tenderer shall submit the following additional documents in its Tender: *As detailed under section III*
ITT 13.1	Alternative Tenders *shall not be considered.*
ITT 14.5	The prices quoted by the Tenderer *shall not* be subject to adjustment during the performance of the Contract.
ITT 14.6	Prices quoted for each lot (contract) shall correspond at least to *[insert figure]* percent of the items specified for each lot (contract): ***Not Applicable.*** Prices quoted for each item of a lot shall correspond at least to *[insert figure]percent* of the quantities specified for this item of a lot: ***Not Applicable.***
ITT 14.7	The Incoterms edition is: ***incoterms 2020*** edition.
ITT 14.8 (a) iii, (b) (i) and (c) (v)	Place of destination: *Delivered Duty Paid (DDP)* KEMSA Warehouse – Nairobi - Kenya

ITT 14.8 (a) (iii), (b) (ii) and c (v)	Final Destination (Project Site): *Delivered Duty Paid (DDP)* KEMSA Warehouse – Nairobi – Kenya
ITT 15.1	The Tenderer may express the Tender price in any currency. If the Tenderer wishes to be paid in a combination of amounts in different currencies; it may quote its price accordingly but shall use no more than **two foreign currencies** in addition to the currency of Kenya. The date of exchange rate determination is the selling rate on the tender closing date
ITT 16.3(b)	Other procurement-specific documentation requirements are: Documentation and sample requirements for eligibility of the offered Goods. In addition to the documents stated in Clause 16.3 (a) the following shall be included with the Tender: For each Health product offered, documentary evidence demonstrating that such product has been manufactured in accordance with the latest publicly available monographs and that the finished product meets the standards as described in any of the following pharmacopoeia: I. International Pharmacopoeia II. British Pharmacopoeia III. United States Pharmacopeia IV. European Pharmacopoeia V. Manufacturers Specifications VI. Any other Pharmacopoeia recognized by the PPB **and** documentary evidence demonstrating that such product meets one of the above standards must be provided. (a) The Tenderer is requested to provide, in support of their technical offer, a sample for tests for each of the items offered under separate cover at or before the tender closing date and time. The sample is to be clearly labeled with the tenderer's name, tender reference and identification of the product. The sample requested is to be submitted as per technical specification offered by the Tenderer and shall represent exactly the Health product that is intended to be supplied in case of contract award. (b) If, for reasons other than the tender specific labeling requirements, the sample is not consistent with the required technical specifications then the offer for the particular item shall be rejected. (c) For quality assurance reasons, for each sample provided a protocol (**certificate of analysis**) of a product test conducted by the laboratory of the manufacturer has to be provided from the same production batch in case of award of contract
ITT 16.4	Goods to be supplied under the Contract shall be registered with the Pharmacy & Poisons Board in Kenya.
ITT 16.5	The contact person in the Procuring Entity able to provide additional information about registration is*: The Chief Executive Officer*
ITT 18.1	The Tender validity period shall be 120 days.
ITT 18.3 (a)	Not Applicable

ITT 19.3 (v)	*Not Applicable*
ITT 19.6	If the Tenderer performs any of the actions prescribed in subparagraphs ITT 19.6 (a) or (b) of this provision, the Procuring Entity will declare the Tenderer ineligible to be awarded a contract by the Procuring Entity for a period not less than 3 years.
ITT 20.1	Tenderer must submit Complete serialized/paginated bidding documents **one original and a copy** in plain sealed envelopes clearly marked on top with the tender Number and description.
ITT 20.3	The written confirmation of authorization to sign on behalf of the Tenderer shall consist of: *A written Power of Attorney*
ITT 21.1	Applicable to submission of tender security.
ITT 19.1	A *Tender Security shall be* required. The amount and currency of the Tender security shall be KES 297,000 or equivalent in freely convertible currency.

D. Submission and Opening of Tenders	
ITT 22.1	For Tender submission purposes only, the Procuring Entity's address is: *Kenya Medical Supplies Authority* The Chief Executive Officer Kenya Medical Supplies Authority (KEMSA) Commercial Street, Industrial Area Nairobi/Kenya Postal address: P.O. Box: 47715 00100 Nairobi Kenya Tel No: +254 719033000/ +254 726618520/1 E- mail: procure@kemsa.co.ke The deadline for Tender submission is: 21st October 2022 Time: ***10:00 a.m***
ITT 25.1	Tender opening shall take place at: The Tender Opening Hall Kenya Medical Supplies Authority (KEMSA) Commercial Street, Industrial Area Nairobi/Kenya Postal address: P.O. Box: 47715-00100 Nairobi, Kenya 1. Date: 21st October 2022 Time: ***10.00 a.m.***
ITT 25.1	*Applicable to tender security*
ITT 25.6	Not applicable
E. Evaluation and Comparison of Tenders	
ITT **30.3**	Not Applicable
ITT 32.1	The currency that shall be used for Tender evaluation and comparison purposes to convert at the selling exchange rate all Tender prices expressed in various currencies into a single currency is: *[Kenya Shillings]* The source of exchange rate shall be: *Central Bank in Kenya* The date for the exchange rate shall be: Date of tender closing.
ITT 33.1	A margin of domestic preference *shall* apply.

ITT 33.3	The specific group of businesses is (*not applicable)*

ITT 34.6	***Not Applicable***

F. Award of Contract	
ITT 47.1	The procedures for making a Procurement-related Complaint are detailed in the "Notice of Intention to Award the Contract" herein and are also available from the PPRA website www.ppra.go.ke. If a Tenderer wishes to make a Procurement-related Complaint, the Tenderer should submit its complaint following these procedures, in writing (by the quickest means available, that is by email), to: The Chief Executive Officer Kenya Medical Supplies Authority (KEMSA) Commercial Street, Industrial Area Nairobi/Kenya E- mail: procure@kemsa.co.ke In summary, a Procurement-related Complaint may challenge any of the following: 1. the terms of the Tendering Documents; and. 2. the procuring Entity's decision to award the contract.

SECTION III - EVALUATION AND QUALIFICATION CRITERIA

General Provision1.This section contains the criteria that the Procuring Entity shall use to evaluate tender and qualify tenderers. No other factors, methods or criteria shall be used other than specified in this tender document. The Tenderer shall provide all the information requested in the forms included in Section IV, Tendering Forms. The Procuring Entity should use **the Standard Tender Evaluation Report for Health products for** evaluating Tenders.

2. Evaluation and contract award Criteria

2.1 The Procuring Entity shall use the criteria and methodologies listed in this Section to evaluate tenders and arrive at the Lowest Evaluated Tender. The tender that (i) meets the qualification criteria, (ii) has been determined to be substantially responsive to the Tender Documents, and (iii) is determined to have the Lowest Evaluated Tender price shall be selected for award of contract.

3. Preliminary examination for Determination of Responsiveness

3.1 The Procuring Entity will start by examining all tenders to ensure they meet in all respects the eligibility criteria and other mandatory requirements in the ITT, and that the tender is complete in all aspects in meeting the requirements provided for in the preliminary evaluation criteria outlined below. The Standard Tender Evaluation Report Document for Goods and Works for evaluating Tenders provides very clear guide on how to deal with review of these requirements. Tenders that do not pass the Preliminary Examination will be considered non-responsive and will not be considered further.

[The Procuring Entity will provide the preliminary evaluation criteria. To facilitate, a template may be attached or clearly described all information and list of documentation to be submitted by Tenderers to enable preliminary evaluation of the Tender]

4. Tender Evaluation (ITT 34)

a) In addition to the criteria listed in ITT 34.2(a)–(c) the additional evaluation factors as per ITT 34.2 (d) is specified as follows:

_____

_____

4.1 To evaluate Items or Lots that include at least the percentages of items per lot and quantity per item as specified in ITT 14.6, if applicable. Tender evaluation of such tenders will be carried out as per the following procedures. The average price (or highest price as specified in TDS 30.3) of an item quoted by substantially responsive Tenders will be added to the Tender price of those who did not quote for that item and the equivalent total cost of the tender so determined will be used for Tender comparison, evaluation, and award.

b) **Delivery schedule.** (As specified in the TDS)

The Goods specified in the List of Goods are required to be delivered within the acceptable time range (1-14 weeks) specified in Section VII, Schedule of Requirements.

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b) **Delivery schedule.** (As specified in the TDS)

The Goods specified in the List of Goods are required to be delivered within the acceptable time range (1-14 weeks) specified in Section VII, Schedule of Requirements.

c) **Deviation in payment schedule**. *[insert tone of the following]*

i) Tenderers shall state their Tender price for the payment schedule outlined in the SCC. Tenders shall be evaluated on the basis of this base price. tenderers are, however, permitted to state an alternative payment schedule and indicate the reduction in Tender price they wish to offer for such alternative payment schedule. The Procuring Entity may consider the alternative payment schedule and the reduced Tender price offered by the tenderer selected on the basis of the base price for the payment schedule out lined in the SCC.

Or

i) *The SCC stipulates the payment schedule specified by the Procuring Entity. If a Tender deviate from the schedule and if such deviation is considered acceptable to the Procuring Entity ,the Tender will be evaluated by calculating interest earned for any earlier payments involved in the terms outlined in the Tender as compared with those stipulated in the SCC, at the rate per annum [insert adjustment rate].*

d) Specific additional criteria

[Other specific additional criteria to be considered in the evaluation, and the evaluation method shall be detailed in TDS34.6][If specific ***sustainable procurement technical requirements*** *have been specified in Section VII- Specification,* ***either*** *state that (i) those requirements will be evaluated on a pass/fail (compliance basis)* ***or*** *otherwise (ii)in addition to evaluating those requirements on a pass s/fail (compliance basis), if applicable, specify the monetary adjustments to be applied to Tender Prices for comparison purposes on account of Tenders that exceed the specified minimum sustainable procurement technical requirements.]not applicable*

5. Multiple Contracts (ITT 34.4)

5.1 Multiple contracts will be permitted in accordance with ITT 34.4. Tenderers are evaluated on basis of individual items and the lowest evaluated tenderer identified for each item.

i) If a tenderer wins only one item, the tenderer will be awarded a contract for that item, provided the tenderer meets the Eligibility and Qualification Criteria for that item.

ii) If a tenderer wins more than one item, the tender will be awarded contracts for all won items, provided the tenderer meets the aggregate Eligibility and Qualification Criteria for all the items.

6. Alternative Tenders (ITT13.1)

6.1 An alternative if permitted under ITT 13, will be evaluated as follows: The Procuring Entity shall consider Tenders offered for alternatives as specified in Part II Section II, Schedule of Requirements. Only the technical alternatives, if any, of the Tenderer with the Lowest Evaluated Tender conforming to the basic technical shall be considered by the Procuring Entity. *Not applicable*

7. Margin of Preference

7.1 If the TDS so specifies, the Procuring Entity will grant a margin of preference of 15% (fifteen percent) to Tenderers offering goods manufactured, mined, extracted, grown, assembled or semi-processed in Kenya.

7.2 The margin of preference will be applied in accordance with, and subject to, the following provisions:

a) Tenderers applying for such preference on goods offered shall be asked to provide, as

part of the data for qualification, such information, including details of the goods produced in Kenya, so as to determine whether, according to the classification established by the Procuring Entity, a particular category of goods or group of goods qualifies for a margin of preference.

b) After Tenders have been received and reviewed by the Procuring Entity, goods offered in the responsive Tenders shall be assessed to ascertain they are manufactured, mined, extracted, grown, assembled or semi- processed in Kenya. Responsive tenders shall be classified into the following groups:

i) **Group A:** Tenders offering goods manufactured in Kenya, for which (a) labor, raw materials, and components from within Kenya account for more than forty (40) percent of the Ex-Works price; and (b) the production facility in which they will be manufactured or assembled has been engaged in manufacturing or assembling such goods at least since the date of Tender submission date;

ii) **Group B:** All other Tenders offering Goods manufactured in Kenya;

iii) **Group C:** Tenders offering Goods manufactured outside Kenya that have been already imported or that will be imported.

a) To facilitate this classification by the Procuring Entity, the tenderer shall complete whichever version of the Price Schedule furnished in the Tendering document is appropriate, provided however, that the completion of an incorrect version of the Price Schedule by the Tenderer shall not result in rejection of its Tender, but merely in the Procuring Entity's reclassification of the Tender in to its appropriate Tender group.

b) The Tenders in each group will then be compared to determine the Tender with the lowest evaluated cost in that group. The lowest evaluated cost Tender from each group shall then be compared with each other and if as a result of this comparison a Tender from Group A or Group B is the lowest, it shall be selected for the award.

c) If as a result of the preceding comparison, a Tender from Group C is the lowest evaluated cost, an amount equal to or 15% of the respective tender price, including unconditional discounts and excluding provisional sums, if any, shall be added to the evaluated price offered in each tender from Group C. If the tender from Group C is still the lowest tender, it shall be selected for award. If not, the lowest evaluated tender from Group A or B based on the first evaluation price shall be selected.

8. Post qualification and Contract award (ITT37), more specifically,

8.1 After determining the substantially responsive tender which offers the lowest-evaluated price, whether the tenderer is a manufacturer or just a supplier: The Procuring Entity shall carry out the post-qualification, if no prequalification was done using the following criteria:

a) In case the tender <u>was subject to post-qualification</u>, the contract shall be awarded to the lowest evaluated tenderer, subject to confirmation of prequalification data, if so required.

b) In case the tender <u>was not subject to post-qualification</u>, the tender that has been determined to be the lowest evaluated tenderer shall be considered for contract award, subject to meeting each of the following conditions.

i) The Tenderer shall demonstrate that it has access to, or has available, liquid assets, unencumbered real assets, lines of credit, and other financial means sufficient to meet the cash flow of Kenya Shillings_____.

ii) Minimum <u>average</u> annual turnover of Kenya Shillings_____*[insert*

amount], equivalent calculated as total certified payments received for contracts in progress and/or completed within the last_____*[insert of year]* years.

iii) At least_____(*insert number)* of contract(s) of a similar nature executed within Kenya, or the East African Community or abroad, that have been satisfactorily and substantially completed as a prime contractor, or joint venture member or sub-contractor each of minimum value Kenya shillings_____equivalent.

iv) Other conditions depending on their seriousness.

a) **History of non-performing contracts**:

Tenderer and each member of JV in case the Tenderer is a JV, shall demonstrate that Non-performance of a contract did not occur because of the default of the Tenderer, or the member of a JV in the last_____(*specify years*). The required information shall be furnished in the appropriate form.

b) Pending Litigation

Financial position and prospective long-term profitability of the Single Tenderer, and in the case the Tenderer is a JV, of each member of the JV, shall remain sound according to criteria established with respect to Financial Capability under Paragraph (i) above if all pending litigation will be resolved against the Tenderer. Tenderer shall provide information on pending litigations in the appropriate form.

c) Litigation History

There shall be no consistent history of court/arbitral award decisions against the Tenderer, in the last _____(*specify years*). All parties to the contract shall furnish the information in the appropriate form about any litigation or arbitration resulting from contracts completed or ongoing under its execution over the years specified. A consistent history of awards against the Tenderer or any member of a JV may result in.

Specific Experience Requirements

The Specific Experience Requirements under 4.2 (b) (from the table above) are as follows:

4.2(b)(i) Documentary evidence in accordance with TDS ITT 11.1 4.2(b)

(ii) Technical and Production Capability.

The Tenderer shall provide evidence that it has the technical, and production capability necessary to perform the Contract:

(i) That it has successfully completed or substantially completed at least [*3*] similar contracts for supply of the goods and within the last three years.[*The number of similar contracts required should be not less than three and not more than five (normally four), depending on the size and complexity of the subject contract].*]Similar contracts are those of approximately the same size and that includes comparable products, e.g., capsules, tablets, vaccines.

The goods may have been supplied by the Tenderer as a manufacturer or by its agent, with references being submitted to confirm satisfactory performance.

(ii) That it has achieved an annual average production rate of_*[The annual production rate required should be at least three times the quantities specified under the contract*] during the last three years.

4.2 (b) (iii) Experience on Packaging, Distribution and Transportation

The Tenderer should provide proof of experience with and knowledge of modes of packing, distribution, and transportation of **Health Products** similar to those subject to Tendering under logistical and climatic conditions similar to the ones in Kenya. It should provide names of countries to which the Tenderer has supplied (including packaged, distributed, and transported) products worth at least the amount [*insert the amount*] within the past three years.

*[*Note to the Procuring Entity: *If Tenders for individual lots are permitted; the qualification criteria for each lot should be given separately].*

SPECIFIC EVALUATION CRITERIA

A) PRELIMINARY EXAMINATION

Requirements

1. Tender documents must be paginated/serialized. All bidders are required to submit their documents paginated in a continuous ascending order from the first page to the last in this format; (i.e. 1, 2, 3…….. n where n is the last page) **(MANDATORY).**
2. Provide a copy of Certificate of Incorporation/Registration **(MANDATORY).**
3. Provide a copy of valid and current Tax Compliance Certificate **(MANDATORY FOR LOCAL BIDDERS).**
4. Tender form (on a letterhead showing the tenderers complete name and business address) duly **completed and signed.** ***The Form of Tender shall include the following Forms duly completed and signed by the Tenderer or authorized representative (attach power of attorney where applicable)*** **(MANDATORY).**
    i. ***Tenderer's Eligibility-Confidential Business Questionnaire*** **(MANDATORY).**
    ii. ***Certificate of Independent Tender Determination*** **(MANDATORY).**
    iii. ***Self-Declaration of the Tenderer*** **(MANDATORY).**
        a) Duly completed and signed self-Declaration that the person/ Tenderer is not debarred in the matter of the PPADA 2015 **(MANDATORY).**
        b) Duly completed and signed self-Declaration that the person/ Tenderer will not engage in any corrupt/fraudulent practice **(MANDATORY).**
        c) Duly completed and signed declaration and commitment to the code of ethics **(MANDATORY).**
5. Provide Original Bid Security valid for 150 days from date of tender opening. Value of Bid Security should be **KES 200,000.00 (Kenya Shillings, One Hundred and Fifty-Five Thousand Only** or equivalent in a freely convertible currency. **(MANDATORY).**

NOTE: Failure to comply with Mandatory requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation.

B) TECHNICAL EVALUATION

Bidders are required to submit the following documents:

a) Manufacturers Authorization which must be on a manufacturer's letterhead and addressed to KEMSA that is both tender and item specific and signed by an authorized signatory (Applicable to bidders who are not manufacturers) **(MANDATORY)**

b) Current quality certificate as specified in the technical specifications **(MANDATORY).**

c) Current and valid Product listing with QR codes from the Kenya Pharmacy and Poisons Board or Approved as safe for human consumption by Kenya Bureau of Standards (**MANDATORY).**

NOTE: Failure to comply with Mandatory requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation.

C) PRODUCT EVALUATION

The product evaluation will be done on the sample submitted by the Bidders and will involve the following:

1) Evaluation of the Physical Properties and presentation of the products - The evaluation will be based on product type, product form i.e., the physical configuration and shape, product ingredients i.e., content, components and composition, measurements i.e., dimension and weight, elasticity where applicable, absorbency where applicable, texture where applicable

2) Evaluation of the product packaging based on Good Manufacturing and pharmaceutics practices of the particular dosage form and specifications in this Tender document.

3) Evaluation of the product labeling criteria based on technical specifications spelt out in this tender document.

The evaluation will be on a "Yes/No" basis;

NOTE: Only bidders who are successful at this stage will proceed to the next stage of evaluation.

D) FINANCIAL EVALUATION

Bidders who are successful at preceding stages of evaluation will have their prices compared and award recommended to the lowest evaluated responsive bid.

Appendix 1: Domestic Preferences

PREFERENCE AND RESERVATIONS

For purposes of section 157(8)(b) of the Act, the margin of preference of international tendering and competition pursuant to section 89 of the Act shall be:

1. Twenty percent (20%) margin of preference of the evaluated price of the tender given to candidates offering goods manufactured, mined, extracted, grown, assembled or semi-processed in Kenya and the percentage of shareholding of Kenyan citizens is more than fifty percent (50%)

2. Fifteen percent (15%) margin of preference of the evaluated price of the tender given to candidates offering goods manufactured, mined, extracted, grown, assembled or semi-processed in Kenya.

3. Ten percent (10%) margin of preference of the evaluated price of the tender, where the percentage of shareholding of Kenyan citizens is more than fifty percent (50%).

4. Eight percent (8%) margin of preference of the evaluated price of the tender, where the percentage of shareholding of Kenyan citizens is less than fifty percent (50%) but above twenty (20%); and

5. Six percent (6%) margin of preference of the evaluated price of the tender, where the percentage of shareholding of Kenyan citizens is five percent (5%) but less than twenty percent (20%).

6. Where citizen contractors have entered into contractual arrangements with foreign contractors, a ten percent (10%) margin of preference in the evaluated price of the tender shall be applied.

NOTE: Bidders who wish to be considered for Reservations and Preferences should provide CR 12 showing shareholding and nationality of shareholders issued by the Registrar of Companies. CR12 should have been issued within the last twelve months.
For sole proprietorship and partnerships, provide a copy/copies of National Identification Card/Passport.

E) SUPPLIER PERFORMANCE MEASUREMENT TOOL REPORT

PAST PERFORMANCE

A supplier performance measurement tool with detailed performance indicators has been developed and will be used to measure the performance of contracted suppliers. Suppliers who will have had unsatisfactory past performance on specific items of less than 71% shall not be recommended for award of similar items in subsequent tenders.

PERFORMANCE INDICATORS

The performance of suppliers, contractors, service providers and consultants are monitored at contract level to ensure the terms and conditions of the contract are met. The extent of performance monitoring applied shall be determined by the level of risk and the nature of the items. Good monitoring of suppliers anticipates, identifies and facilitates correction of shortcomings before the relationship with the supplier is adversely affected and before compromising value for money.

1.Time

The time indicator measures the duration in days for the supplier to deliver or complete the task as specified in the contract. The required data to be captured from the source documents into the performance tool shall include: Item code, item description, contract number, purchase order number, supplier name, contract signing date, contract effective date, contractual delivery date, earliest delivery date, extended delivery date, actual delivery date, supplier offered delivery date, and latest delivery date. For each item, the earliest delivery date and the latest delivery date are derived from the issued tender document. The supplier offered delivery date is derived from the bid.

Contract Delivery Period: The number of calendar days from the date of signing the contract to the date the delivery is required per the contract. If a contract is extended, the additional days are confirmed through addendum (letter) to the contract and the duration added to the Contract Delivery Period. In call-off orders under framework contracts, Contract Delivery Period is the number of calendar days from the date of call-off order to the required delivery date.

Actual Delivery Period: The number of calendar days from the contract effective date to the actual delivery date. Where call off orders apply, the Actual Delivery Period is the number of calendar days from the date of call-off order to actual delivery date. For staggered deliveries under definite quantity contracts, actual delivery period is the number of calendar days from date of notification of the required quantity.

Delivery on Time: Delivery of goods on or within the Contract Delivery Period yields a Delivery on Time indicator score of 100%. Delivery within 2 weeks after Contract Delivery Period still yields a Time indicator score of 100%. Delivery made thereafter yields a time Indicator score of zero (0).
Failure to fully deliver within 8 weeks from lapse of Contract Delivery Period will result in contract termination.

2. Quantity

The supplier is required to deliver the ordered quantity of the product in full. Contractors should deliver the product per the required specifications.

Sometimes, due to practical reasons, a supplier may be requested in writing to deliver a portion of the order. In that event, the measurement will be done after substantial completion of contracted quantity. The quantity indicator measures Delivery in Full, which is the difference between the quantity of the product in the purchase order or contract and the quantity that is certified received.

Delivery in Full: The indicator is measured by the percentage of the ordered quantity which is actually certified received. *Example*: If the purchase order quantity was 200,000 units. Of this, the quantity received was 190,000 units. The indicator of Delivery in Full is computed as (190,000/200,000) *100=95%. The target performance score for Delivery in Full indicator is 100%.
The required data are order quantity, delivered quantity, and deferred quantity.

3. Cost

The historical unit prices for each item are captured in the ERP system. The Award Price arise from recommendations for award and signed supplier contract. The Final Price is the award price plus the price variation that is approved at contract implementation; excluding those from the application of a price adjustment formula if provided for in the signed contract.

The Price Ratio is defined as [Award Price x 100/Final Price]; which should be 100% where the Final Price is equal to the Award Price. Where the Final Price is higher than the Award Price, the performance score is prorated. *Example*: if the Final Price is KES2,700, Award Price is KES2,400, then the Price Ratio is [2,400*100/2700 = 89%]. The data to be captured in the ERP system include the following: Item Code, Item Description, Contract Number, Order Number, Supplier Name, Plan Price, Award Price, Price Variation, Final Price.

4. Quality

The contract provides the technical specifications. At the delivery point, the products are inspected and tested to ensure they comply with the quality specifications. Products that do not comply with Quality Specifications will be rejected. However, an assessment shall be made to check if there is suitable product packaging. Percentage of damaged cartons acceptable is 0.5%. Above this %, the damaged cartons will be rejected.

5. Ratings and Scores

The supplier contract performance scores provide a structured way of rating suppliers with an aim of identifying areas of improvement and a basis for future engagement depending on historical performance. The scorecard will be used to measure, rate and rank suppliers with the aim of ensuring suppliers consistently meet and surpass their contractual obligations. Table 3 summarizes the ratings and scores.

Table 1. Ratings and scores measurement system

Rating	Range	Performance Description
1	0-30	**Falls far below expectations**: Performance jeopardized the achievement of contract requirements, despite contract administrative interventions.
2	31-50	**Missed expectations**: There are a number of performance issues that required KEMSA to provide additional contract administrative interventions to ensure that contract requirements are met.
3	51-70	**Does not fully meet expectations**: There are performance issues but supplier has somehow met contract requirements.

4	71-80	**Mostly meets expectations**: There are minor performance issues but the supplier has largely met the contract requirements
5	81-100	**Exceeds Expectations**: Supplier has demonstrated a performance level in measurable within contract requirements

6. Performance Index

The Performance Index combines the indices for (1) time, (2) quantity, (3) cost and (4) quality. Each of the four performance indicators is scored out of 100%. The parameters are then weighted using a predefined matrix and the overall Supplier Performance Index is the sum of the weighted scores.

Table 2. Supplier Performance Index (Example)

#	Indicator	Score (%)	Weight	Weighted Score
1	Time	100	0.5	50.00
2	Quantity	95	0.3	28.50
3	Cost	89	0.1	8.90
4	Quality	83	0.1	8.30
	Supplier Performance Index			95.70

7. Performance Decision

A supplier with a **Performance Index Score** of less than **71%** shall not be eligible for award of contracts by KEMSA for a period of ONE YEAR from the date of notification of the performance score.
This information shall form part of the Post Contract Qualification Criteria in the subsequent tender document and evaluation stated as follows:

"Non-performance of a contract did not occur as a result of supplier default since 1 January [*insert year*] or the bidder has a Performance Score of less than 71% as measured using the KEMSA Supplier Performance Measurement Tool as notified to the supplier or service provider in writing prior to this tender notice."

The Procurement Directorate shall debrief the supplier and prepare minutes to record the debriefing, which shall form part of the permanent records.

SECTION IV - TENDERING FORMS

FORM OF TENDER

INSTRUCTIONS TO TENDERERS

i) The Tenderer must prepare this Form of Tender on stationery with its letterhead clearly showing the Tenderer's complete name and business address.

ii) All italicized text is to help Tenderer in preparing this form.

iii) Tenderer must complete and sign TENDERER'S ELIGIBILITY - CONFIDENTIAL BUSINESS QUESTIONNAIRE, *CERTIFICATE OF INDEPENDENT TENDER DETERMINATION and the SELF DECLARATION OF THE TENDERER,* all *attached to this Form of Tender.*

iv) The Form of Tender shall include the following Forms duly completed and signed by the Tenderer.

- *Tenderer's Eligibility-Confidential Business Questionnaire*
- *Certificate of Independent Tender Determination*
- *Self-Declaration of the Tenderer*

Date of this Tender submission: 21st October 2022

Invitation to Tender No.: [*KEMSA/GOK-MOH/OIT006/2022-2024*] **Alternative No.**: [*N/A*] To: *Kenya Medical Supplies Authority*

a) **No reservation:** We have examined and have no reservations to the tendering document, including Add and issued in accordance with Instructions to Tenderers (ITT 8);

b) **Eligibility:** We meet the eligibility requirements and have no conflict of interest in accordance with ITT 4;

c) We have not been suspended nor declared in eligible by the Procuring Entity based on execution of a Tender- Securing Declaration or Proposal-Securing Declaration in Kenya in accordance with ITT 4.8;

d) **Conformity:** We offer to supply in conformity with the tendering document and in accordance with the Delivery Schedules specified in the Schedule of Requirements the following Goods: *[Supply of Health Products]*;

e) **Tender Price:** The total price of our Tender, is: *[[insert the total price of the Tender in words and figures ……)*

f) **Tender Validity Period**: Our Tender shall be valid for the period specified in TDS 18.1 (as amended if applicable) from the date fixed or the Tender submission deadline specified in TDS 22.1 (as amended if applicable), and it shall remain binding upon us and may be accepted at any time before the expiration of that period;

g) **Performance Security**: If our Tender is accepted, we commit to obtain a Performance Security in accordance with the tendering document;

h) **One Tender per Tenderer**: We are not submitting any other Tender(s) as an individual Tenderer, and we are not participating in any other Tender(s) as a Joint Venture partner or as a sub-contractor, and meet the requirements of ITT 4.4, other than alternative Tenders submitted in accordance with ITT 13;

i) **Suspension and Debarment:** We, along with any of our sub-contractors, suppliers, consultants, manufacturers, or service providers for any part of the contract, are not subject to, and not controlled by any entity or individual that is subject to, a temporary suspension or a debarment imposed by the PPRA. Further, we are not ineligible under Kenya laws or official regulations or pursuant to a decision of the United Nations Security Council;

j) **State-owned enterprise or institution:** *[select the appropriate option and delete the other] [We are not a state-owned enterprise or institution]/ [We are a state-owned enterprise or institution but meet the requirements of ITT 4.7];*

k) **Commissions, gratuities, fees:** We have paid, or will pay the following commissions, gratuities, or fees with respect to the Tendering process or execution of the Contract:*[insert complete name of each Recipient, its full address, the reason for which each commission or gratuity was paid and the amount and currency of each such commission or gratuity]*

Name of Recipient	Address	Reason	Amount

(If none has been paid or is to be paid, indicate "none.")

l) **Binding Contract:** We understand that this Tender, together with your written acceptance thereof included in your notification of award, shall constitute a binding contract between us, until a formal contract is prepared and executed;

m) **Procuring Entity Not Bound to Accept:** We understand and that you are not bound to accept the lowest evaluated cost Tender, the Lowest Evaluated Tender or any other Tender that you may receive; and

n) **Fraud and Corruption:** We here by certify that we have taken steps to ensure that no person acting for us or on our behalf engages in any type of Fraud and Corruption.

o) **Collusive practices**: We hereby certify and confirm that the tender is genuine, non-collusive and made with the intention of accepting the contract if awarded. To this effect we have signed the "Certificate of Independent tender Determination" attached below.

p) **Code of Ethical Conduct**: We undertake to adhere by the Code of Ethics for Persons Participating in Public Procurement and Asset Disposal, copy available from____(*specify website*) during the procurement process and the execution of any resulting contract.

q) **Beneficial Ownership Information:** We commit to provide to the procuring entity the Beneficial Ownership Information in conformity with the Beneficial Ownership Disclosure Form upon receipt of notification of intention to enter into a contract in the event we are the successful tenderer in this subject procurement proceeding.

r) We, the Tenderer, have completed fully and signed the following Forms as part of our Tender:

a) Tenderer's Eligibility; Confidential Business Questionnaire – to establish we are not in any conflict to interest.

b) Certificate of Independent Tender Determination - to declare that we completed the tender without colluding with other tenderers.

c) Self-Declaration of the Tenderer–to declare that we will, if awarded a contract, not engage in any form of fraud and corruption.

d) Declaration and commitment to the Code of Ethics for Persons Participating in Public Procurement and Asset Disposal.

Further, we confirm that we have read and understood the full content and scope of fraud and corruption as in formed in **"Appendix 1-Fraud and Corruption**" attached to the Form of Tender.
Name of the Tenderer:**[insert complete name of the Tenderer]*
Name of the person duly authorized to sign the Tender on behalf of the Tenderer: ***[insert complete name of person duly authorized to sign the Tender]*

Title of the person signing the Tender: *[insert complete title of the person signing the Tender]*

Signature of the person named above: *[insert signature of person whose name and capacity are*

shown above] **Date signed** *[insert date of signing]* **day of** *[insert month],[insert year]*

*: In the case of the Tender submitted by a Joint Venture specify the name of the Joint Venture as Tenderer.

**: Person signing the Tender shall have the power of attorney given by the Tenderer. The power of attorney shall be attached with the Tender Schedules.

TENDERER'S ELIGIBILITY- CONFIDENTIAL BUSINESS QUESTIONNAIRE

Instruction to Tenderer

Tender is instructed to complete the particulars required in this Form, *one form for each entity if Tender is a JV*. Tenderer is further reminded that it is an offence to give false information on this Form.

a) Tenderer's details

	ITEM	DESCRIPTION
1	Name of the Procuring Entity	
2	Reference Number of the Tender	
3	Date and Time of Tender Opening	
4	Name of the Tenderer	
5	Full Address and Contact Details of the Tenderer.	1.Country 2. City 3.Location 4. Building 5.Floor 6. Postal Address 7. Name and email of contact person.
6	Current Trade License Registration Number and Expiring date	
7	Name, country and full address (*postal and physical addresses, email, and telephone number*) of Registering Body/Agency	
8	Description of Nature of Business	
9	Maximum value of business which the Tenderer handles.	
10	State if Tenders Company is listed in stock exchange, give name and full address (*postal and physical addresses, email, and telephone number*) of state which stock exchange	

General and Specific Details

b) Sole Proprietor, provide the following details.

Name in full_____Age_____ Nationality_____

_____Country of Origin__ Citizenship_____

_____

c) **Partnership,** provide the following details.

	Names of Partners	Nationality	Citizenship	% Shares owned
1				
2				
3				

d) **Registered Company,** provide the following details.

i) Private or public Company __

ii) State the nominal and issued capital of the Company:-

Nominal Kenya Shillings (Equivalent) .....

Issued Kenya Shillings (Equivalent) .....

iii) Give details of Directors as follows.

	Names of Director	Nationality	Citizenship	% Shares owned
1				
2				
3				

e) **DISCLOSURE OF INTEREST -Interest of the Firm in the Procuring Entity.**

i) Are there any person/persons in.....(*Name of Procuring Entity)*
who has/ have an interest or relationship in this firm?Yes/No..... If yes, provide details as follows.

	Names of Person	Designation in the Procuring Entity	Interest or Relationship with Tenderer
1			
2			
3			

ii) **Conflict of interest disclosure**

	Type of Conflict	Disclosure YES OR NO	If YES provide details of the relationship with Tenderer
1	Tenderer is directly or indirectly controls, is controlled by or is under common control with another tenderer.		
2	Tenderer receives or has received any direct or indirect subsidy from another tenderer.		
3	Tenderer has the same legal representative as another tenderer		
4	Tender has a relationship with another tenderer, directly or through common third parties, that puts it in a position to influence the tender of another tenderer, or influence the decisions of the Procuring Entity regarding this tendering process.		
5	Any of the Tenderer's affiliates participated as a consultant in the preparation of the design or technical specifications of the works that are the subject of the tender.		
6	Tenderer would be providing goods, works, non-consulting services or consulting services during implementation of the contract specifiedin this Tender Document.		
7	Tenderer has a close business or family relationship with a professional staff of the Procuring Entity who are directly or indirectly involved in the preparation of the Tender document or specifications of the Contract, and/or the Tender evaluation process of such contract.		
8	Tenderer has a close business or family relationship with a professional staff of the Procuring Entity who would be involved in the implementation or supervision of the such Contract.		
9	Has the conflict stemming from such relationship stated in item 7 and 8 above been resolved in a manner acceptable to the Procuring Entity throughout the tendering process and execution of the Contract.		

f) Certification

On behalf of the Tenderer, I certify that the information given above is complete, current and accurate as at the date of submission.

Full Name_____ Title or Designation_____

_____ _____

(Signature) *(Date)*

CERTIFICATE OF INDEPENDENT TENDER DETERMINATION

I, the undersigned, in submitting the accompanying Letter of Tender to the_____*[Name of Procuring Entity]* for:_____*[Name and number of tender]* in response to the request for tenders made by:_____*[Name of Tenderer]* do hereby make the following statements that I certify to be true and complete in every respect:

I certify, on behalf of_____*[Name of Tenderer]* that:

1. I have read and I understand the contents of this Certificate;

2. I understand that the Tender will be disqualified if this Certificate is found not to be true and complete in every respect;

3. I am the authorized representative of the Tenderer with authority to sign this Certificate, and to submit the Tender on behalf of the Tenderer;

4. For the purposes of this Certificate and the Tender, I understand that the word "competitor" shall include any individual or organization, other than the Tenderer, whether or not affiliated with the Tenderer, who:
   a) Has been requested to submit a Tender in response to this request for tenders;
   b) could potentially submit a tender in response to this request for tenders, based on their qualifications, abilities or experience;

5. The Tenderer discloses that [check one of the following, as applicable]:
   a) The Tenderer has arrived at the Tender independently from, and without consultation, communication, agreement or arrangement with, any competitor;
   b) the Tenderer has entered into consultations, communications, agreements or arrangements with one or more competitors regarding this request for tenders, and the Tenderer discloses, in the attached document(s), complete details thereof, including the names of the competitors and the nature of, and reasons for, such consultations, communications, agreements or arrangements;

6. In particular, without limiting the generality of paragraphs (5) (a) or (5) (b) above, there has been no consultation, communication, agreement or arrangement with any competitor regarding:
   a) prices;
   b) methods, factors or formulas used to calculate prices;
   c) the intention or decision to submit, or not to submit, a tender; or
   d) the submission of a tender which does not meet the specifications of the request for Tenders; except as specifically disclosed pursuant to paragraph (5)(b) above;

7. In addition, there has been no consultation, communication, agreement or arrangement with any competitor regarding the quality, quantity, specifications or delivery particulars of the works or services to which this request for tenders relates, except as specifically authorized by the procuring authority or as specifically disclosed pursuant to paragraph(5)(b) above;

8. The terms of the Tender have not been, and will not be, knowingly disclosed by the Tenderer, directly or indirectly, to any competitor, prior to the date and time of the official tender opening, or of the awarding of the Contract, whichever comes first, unless otherwise required by law or as specifically disclosed pursuant to paragraph (5)(b) above.

Name_____ Title_____

Date_____

[Name, title and signature of authorized agent of Tenderer and Date]

SELF- DECLARATION FORMS

FORM SD1

SELF DECLARATION THAT THE PERSON / TENDERER IS NOT DEBARRED IN THE MATTER OF THE PUBLIC PROCUREMENT AND ASSET DISPOSAL ACT 2015

I, ……., of Post Office Box …….……. being a resident of
…….. in the Republic of ……. do hereby make a statement as follows:-

1. THAT I am the Company Secretary/ Chief Executive/Managing Director/Principal Officer/ Director of
……...…….. *(insert name of the Company)* who is a Bidder in respect of **Tender No.……..**for…….. *(insert tender title / description)* for……. (*insert name of the Procuring entity)* and duly authorized and competent to make this statement.

2. THAT the aforesaid Bidder, its Directors and subcontractors have not been debarred from participating in procurement proceeding under Part IV of the Act.

3. THAT what is deponed to here in above is true to the best of my knowledge, information and belief.

…….	…….	……
(Title)	(Signature)	(Date)

Bidder Official Stamp

FORM SD2

SELF DECLARATION THAT THE PERSON/TENDERER WILL NOT ENGAGE IN ANY CORRUPT OR FRAUDULENT PRACTICE

I,.....of P.O. Box.....being a resident of
…….. in the Republic of.....do hereby make a statement as follows:-

1. THAT I am the Chief Executive / Managing Director /Principal Officer/Director of…….....…..…….....*(insert name of the Company)* who is a Bidder in respect of **Tender No.**……..for……..……..*(insert tender title /description)* for……*(insert name of the Procuring entity)* and duly authorized and competent to make this statement.

2. THAT the aforesaid Bidder, it's servants and/or agents/sub-contractors will not engage in any corrupt or fraudulent practice and has not been requested to pay any inducement to any member of the Board, Management, Staff and/or employees and/or agents of ……..*(insert name of the Procuring entity)* which is the procuring entity.

3. THAT the aforesaid Bidder, its servants and/or agents /subcontractors have not offered any inducement to any member of the Board, Management, Staff and/or employees and/or agents of……..*(name of the procuring entity).*

4. THAT the aforesaid Bidder will not engage /has not engaged in any corrosive practice with other bidders participating in the subject tender

5. THAT what is deponed to herein above is true to the best of my knowledge information and belief.

…… …… ……..…….....…….....…… ……..…….....……
(Title) (Signature) (Date)

Bidder's Official Stamp

DECLARATION AND COMMITMENT TO THE CODE OF ETHICS

I, (person) on behalf of (***Name of the Business/Company / Firm***) .... declare that I have read and fully understood the contents of the Public Procurement & Asset Disposal Act, 2015, Regulations and the Code of Ethics for persons participating in Public Procurement and Asset Disposal and my responsibilities under the Code.

I do here by commit to abide by the provisions of the Code of Ethics for persons participating in Public Procurement and Asset Disposal.

Name of Authorized signatory.....

Sign…….....

Position.....

Office address…….

Telephone.....Email….....

Name of the Firm/Company…….....

Date…….....

(Company Seal/ Rubber Stamp where applicable)

Witness Name

…….....……

Sign…….....

Date…….....

APPENDIX 1- FRAUD AND CORRUPTION

(Appendix 1 shall not be modified)

1. Purpose

1.1 The Government of Kenya's Anti-Corruption and Economic Crime laws and their sanction's policies and procedures, Public Procurement and Asset Disposal Act *(no. 33 of 2015)* and its Regulation, and any other Kenya's Acts or Regulations related to Fraud and Corruption, and similar offences, shall apply with respect to Public Procurement Processes and Contracts that are governed by the laws of Kenya.

2. Requirements

2.1 The Government of Kenya requires that all parties including Procuring Entities, Tenderers, (applicants/proposers), Consultants, Contractors and Suppliers; any Sub-contractors, Sub-consultants, Service providers or Suppliers; any Agents (whether declared or not); and any of their Personnel, involved and engaged in procurement under Kenya's Laws and Regulation, observe the highest standard of ethics during the procurement process, selection and contract execution of all contracts, and refrain from Fraud and Corruption and fully comply with Kenya's laws and Regulations as per paragraphs 1.1 above.

2.2 Kenya's public procurement and asset disposal act *(no. 33 of 2015)* under Section 66 describes rules to be followed and actions to be taken in dealing with Corrupt, Coercive, Obstructive, Collusive or Fraudulent practices, and Conflicts of Interest in procurement including consequences for offences committed. A few of the provisions noted below high light Kenya's policy of no tolerance for such practices and behavior:

1) A person to whom this Act applies shall not be involved in any corrupt, coercive, obstructive, collusive or fraudulent practice; or conflicts of interest in any procurement or asset disposal proceeding;

2) A person referred to under subsection (1) who contravenes the provisions of that sub-section commits an offence;

3) Without limiting the generality of the subsection (1) and (2), the person shall be—

a) disqualified from entering into a contract for a procure mentor asset disposal proceeding; or

b) if a contract has already been entered into with the person, the contract shall be voidable;

4) The voiding of a contract by the procuring entity under subsection (7) does not limit any legal remedy the procuring entity may have;

5) An employee or agent of the procuring entity or a member of the Board or committee of the procuring entity who has a conflict of interest with respect to a procurement: -

a) Shall not take part in the procurement proceedings;
b) shall not, after a procurement contract has been entered into, take part in any decision relating to the procurement or contract; and

c) shall not be a subcontractor for the tenderer to whom was awarded contract, or a

member of the group of tenderers to whom the contract was awarded, but the subcontractor appointed shall meet all the requirements of this Act.

6) An employee, agent or member described in subsection (1) who refrains from doing anything prohibited under that subsection, but for that subsection, would have been within his or her duties shall disclose the conflict of interest to the procuring entity;

7) If a person contravenes subsection (1) with respect to a conflict of interest described in sub section (5)(a) and the contract is awarded to the person or his relative or to another person in whom one of them had a direct or indirect pecuniary interest, the contract shall be terminated and all costs incurred by the public entity shall be made good by the awarding officer. Etc.

In compliance with Kenya's laws, regulations and policies mentioned above, the Procuring Entity:

a) Defines broadly, for the purposes of the above provisions ,the terms set forth below as follows:

i) "corrupt practice" is the offering, giving, receiving, or soliciting, directly or indirectly, anything of value to influence improperly the actions of another party;

ii) "fraudulent practice" is any act or omission, including misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain financial or other benefit or to avoid an obligation;

iii) "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;

iv) "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

v) "obstructive practice" is:

- Deliberately destroying, falsifying, altering, or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede investigation by Public Procurement Regulatory Authority (PPRA) or any other appropriate authority appointed by Government of Kenya in to allegations of a corrupt, fraudulent, coercive, or collusive practice; and/or threatening, harassing, or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or
- Acts intended to materially impede the exercise of the PPRA's or the appointed authority's inspection and audit rights provided for under paragraph 2.3 e. below.

b) Defines more specifically, in accordance with the above procurement Act provisions set forth for fraudulent and collusive practices as follows:

"fraudulent practice" includes a misrepresentation of fact in order to influence a procurement or disposal process or the exercise of a contract to the detriment of the procuring entity or the tenderer or the contractor, and includes collusive practices amongst tenderers prior to or after tender submission designed to establish tender prices at artificial non-competitive levels and to deprive the procuring entity of the benefits of free and open competition.

c) Rejects a proposal for award[1]of a contract if PPRA determines that the firm or individual recommended for award, any of its personnel, or its agents, or its sub-

consultants, sub-contractors, service providers, suppliers and/ or their employees, has, directly or indirectly, engaged in corrupt, fraudulent, collusive, coercive, or obstructive practices in competing for the contract in question;

d) Pursuant to the Kenya's above stated Acts and Regulations, may sanction or recommend to appropriate authority(ies) for sanctioning and debarment of a firm or individual, as applicable under the Acts and Regulations;

e) Requires that a clause be included in Tender documents and Request for Proposal documents requiring (i) Tenderers(applicants/proposers),Consultants, Contractors, and Suppliers, and their Sub-contractors, Sub- consultants, Service providers, Suppliers, Agents personnel, permit the PPRA or any other appropriate authority appointed by Government of Kenya to inspect[2] all accounts, records and other documents relating to the procurement process, selection and/or contract execution, and to have them audited by auditors appointed by the PPRA or any other appropriate authority appointed by Government of Kenya; and

f) Pursuant to Section 62 of the above Act, requires Applicants/Tenderers to submit along with their Applications/Tenders/Proposals a "Self-Declaration Form" as included in the procurement document declaring that they and all parties involved in the procurement process and contract execution have not engaged/will not engage in any corrupt or fraudulent practices.

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[1] *For the a voidance of doubt, a party's ineligibility to be awarded a contract shall include, without limitation,(i) applying for pre-qualification expressing interest in A consultancy, and tendering, either directly or as a nominated sub-contractor, nominated consultant, nominated manufacturer or supplier, or nominated service provider, in respect of such contract, and (ii) entering into an addendum or amendment introducing a material modification to any existing contract.*

[2] *Inspections in this context usually are investigative (i.e., forensic) in nature. They involve fact-finding activities undertaken by the Investigating Authority or persons appointed by the Procuring Entity to address specific matters related to investigations/audits, such as evaluating the veracity of an allegation of possible Fraud and Corruption, through the appropriate mechanisms. Such activity includes but is not limited to: accessing and examining a firm's or individual's financial records and information, and making copies thereof as relevant; accessing and examining any other documents, data and information (whether in hard copy or electronic format) deemed relevant for the investigation/audit, and making copies there of as relevant; interviewing staff and other relevant individuals; performing physical inspections and site visits; and obtaining third party verification of information.*

TENDERER INFORMATION FORM

[The Tenderer shall fill in this Form in accordance with the instructions indicated below. No alterations to its format shall be permitted and no substitutions shall be accepted.]

Date:.....*[insert date(as day ,month and year)of Tender*

submission] ITT No.:.....*[insert number of tendering process]*

Alternative No.:..... *[insert identification No. if this is a Tender for an alternative]*

Page_____of_____pages

1.Tenderer's Name*[insert Tenderer's legal name]*
2.IncaseofJV,legalnameofeachmember:*[insert legal name of each member in JV]*
3.Tenderer'sactualorintendedcountryofregistration:*[insertactualorintendedcountryofregistration]*
4.Tenderer'syearofregistration:*[insertTenderer'syearofregistration]*
5.Tenderer's Addressincountryofregistration:*[insertTenderer'slegaladdressincountryofregistration]*
6.Tenderer'sAuthorizedRepresentativeInformation Name:*[insert Authorized Representative's name]* Address:*[insert Authorized Representative's Address]* Telephone/Fax numbers: *[insert Authorized Representative's telephone/ fax numbers]* Email Address: *[insert Authorized Representative's email address]*
• 7. Attached are copies of original documents of *[check the box(es) of the attached original documents]* • ☐ Articles of Incorporation (or equivalent documents of constitution or association), and/ or documents of registration of the legal entity named above, in accordance with ITT 4.4. ☐ Incase of JV, Form of intent to form JV or JV agreement, in accordance with ITT 4.1. ☐ Incaseofstate-ownedenterpriseorinstitution,inaccordancewithITT4.7documentsestablishing: 2. Included are the organizational chart, a list of Board of Directors, and the beneficial ownership.

FORM ELI - 1.1 (continued)

Tenderer Information Form

Date: *[insert day, month, year]*

ITT No. and title: *[insert ITT number and title]*

Page *[insert page number]* of *[insert total number]* pages

1.Tenderer's name			
2.2. Street Address:	Postal Code:	City:	Country:
3.			
P.O. Box and Mailing Address: 4.			
Telephone Number: 5.			
Fax Number: 6.			
E-mail Address: 7.			
Web Site: 8.			
Contact Name: 9.			
Contact Title: 10.			
Type of Business: 11.			
If Other, specify: 12.			
Nature of Business: 13.			
Year Established: 14.			
Dates, Numbers, and Expiration Dates of Current Licenses and Permits: 15.			
Current health authority registration information: 16.			
Proof of product and facility registrations with Kenya regulatory authority and international agencies (e.g.,WHO Certification Scheme, GMP) 17.			
Name of government agency(ies) responsible for inspecting and licensing of facilities in the country of origin of the raw material and or processing of the goods:			
Date of last inspection: 18.			
Quality Assurance Certification (Please include a copy of your latest certificate): 19.			
Production capacity: *[insert peak and average production capacity over the last three years in units/day or units/month, etc.]*			

TENDERER'S JV MEMBERS INFORMATION FORM

[The Tenderer shall fill in this Form in accordance with the instructions indicated below. The following table shall be filled in for the Tenderer and for each member of a Joint Venture]].

Date:..... *[insert date (as day, month and year) of Tender submission*]

ITT No.: .....*[insert number of tendering process]*

AlternativeNo.:.....*[insertidentificationNoifthisisaTenderforanalterna*

tive] Page__of_____pages

Tenderer's Name:*[insert Tenderer's legal name]*

1. Tenderer's JV Member's name: *[insert JV's Member legal name]*
2. Tenderer's JV Member's country of registration: *[insert JV's Member country of registration]*
3. Tenderer's JV Member's year of registration: *[insert JV's Member year of registration]*
4. Tenderer's JV Member's legal address in country of registration: *[insert JV's Member legal address in country of registration]*
5. Tenderer's JV Member's authorized representative information
6. Name:*[insert name of JV's Member authorized representative]* Address:*[insert address of JV's Member authorized representative]* Telephone/Fax numbers: *[insert telephone/ fax numbers of JV's Member authorized representative]* Email Address: *[insert email address of JV's Member authorized representative]*
Attached are copies of original documents of *[check the box(es)of the attached original documents]*
☑ Articles of Incorporation (or equivalent documents of constitution or association), and/or registration documents of the legal entity named above ,in accordance with ITT 4.4 ☐ Tax Obligations for Kenyan Tenderers, attach copy of current tax clearance certificate or tax exemption certificate issued by the Kenya Revenue Authority in accordance with ITT 4.13. ☐ Incase of a state-owned enterprise or institution, documents establishing legal and financial autonomy, operation in accordance with commercial law, and not under the supervision of the Procuring Entity, in accordance with ITT 4.7. 2. Included are the organizational chart, a list of Board of Directors, and the beneficial ownership.

FORM FIN – 3.1

FINANCIAL SITUATION AND PERFORMANCE

[The following table shall be filled in for the Tenderer and for each member of a Joint Venture]

Tenderer's Name: *[insert full name]*

Date: *[insert day, month, year]*

Joint Venture Member Name: *[insert full name]* ITT No. and title: *[insert ITT number and title]*

Page *[insert page number]* of *[insert total number]* pages

Type of Financial information in (currency)	**Historic information for previous** _ *[insert number] years, [insert in words]* **(amount in currency, currency, exchange rate, USD equivalent)**				
	Year 1	Year 2	Year 3		
Statement of Financial Position (Information from Balance Sheet)					
Total Assets (TA)					
Total Liabilities (TL)					
Total Equity/Net Worth (NW)					
Current Assets (CA)					
Current Liabilities (CL)					
Working Capital (WC)					
Information from Income Statement					
Total Revenue (TR)					
Profits Before Taxes (PBT)					
Cash Flow Information					
Cash Flow from Operating Activities					

3. FINANCIAL DOCUMENTS

The Tenderer and its parties shall provide copies of financial statements for the last *[3]* years pursuant Section III, Qualifications Criteria and Requirements, Sub-factor 3.1. The financial statements shall:

a) reflect the financial situation of the Tenderer or in case of JV member, and not an affiliated entity(such as parent company or group member).

b) Be independently audited or certified in accordance with local legislation.

c) Be complete, including all notes to the financial statements.

d) Correspond to accounting periods already completed and audited.

☐ Attached are copies of financial statements for the last *[3]* years required above; and complying with the requirements

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[4] *If the most recent set of financial statements is for a period earlier than 12 months from the date of tendering, the reason for this should be justified.*

FORM FIN - 3.2

AVERAGE ANNUAL TURNOVER (ANNUAL SALES VALUE)

[The following table shall be filled in for the Tenderer and for each member of a Joint Venture]

Tenderer's Name: *[insert full name]*

Date: *[insert day, month, year]*

Joint Venture Member Name: *[insert full name]* ITT No. and title: *[insert ITT number and title]*

Page *[insert page number]* of *[insert total number]* pages

Annual turn over data			
Year	**Amount** **Currency**	**Exchange rate**	**USD equivalent**
[indicate calendar year]	*[insert amount and indicate currency]*		
		Average Annual Turnover *	

* Total USD equivalent for all years divided by the total number of years.

FORM CON-1
CURRENT CONTRACT COMMITMENTS / CONTRACTS IN PROGRESS FORM

1. Name of Contract(s)
2. Procuring Entity Contact Information *[insert address, telephone, fax, e-mail address]*
3. Value of outstanding contracts *[current US$ equivalent]*
4. Estimated delivery date
5. Average monthly invoices over the last six months (US$/mon.)

FORM - EXP - 1 - EXPERIENCE

Contracts over…… *[insert amount]* during the last three years:				
Procuring Entity	**Value**	**Year**	**Goods/Services Supplied**	**Country of Destination**

FORM - PER 1

HISTORICAL CONTRACT NON-PERFORMANCE, AND PENDING LITIGATION AND LITIGATION HISTORY

[The following table shall be filled in for the Tenderer and for each member of a Joint Venture]

Tenderer's Name:.....*[insert full name]*

Date:.....*[insert day, month, year]*

Joint Venture Member Name:..... *[insert full name]* ITT No. and title:.....*[insert ITT number and title]*

Page..... *[insert page number]* of .....*[insert total number]* pages.

Non-Performed Contracts in accordance with Section III, Qualification Criteria and Requirements			
Contract non-performance did not occur since 1st January *[insert year]* specified in Section III, Qualification Criteria and Requirements, Sub-Factor 2.1. Contract(s) not performed since 1st January *[insert year]* specified in Section III, Qualification Criteria and Requirements, requirement 2.1			
Year	**Non-performed portion of contract**	**Contract Identification**	**Total Contract Amount (current value, currency, exchange rate and US$ equivalent)**
[insert year]	*[insert amount and percentage]*	Contract Identification: *[indicate complete contract name/ number, and any other identification]* Name of Procuring Entity: *[insert full name]* Address of Procuring Entity: *[insert street/city/country]* Reason(s) for nonperformance: *[indicate main reason(s)]*	*[insert amount]*
Pending Litigation, in accordance with Section III, Qualification Criteria and Requirements			
No pending litigation in accordance with Section III, Qualification Criteria and Requirements, Sub-Factor 2.3 Pending litigation in accordance with Section III, Qualification Criteria and Requirements, Sub-Factor 2.3 as indicated below.			
Year of dispute	**Amount in dispute (currency)**	**Contract Identification**	**Total Contract Amount (currency), USD Equivalent (exchange rate)**
[insert year]	*[insert amount]*	Contract Identification: [indicate complete contract name, number, and any other identification] Name of Procuring Entity: *[insert full name]* Address of Procuring Entity: *[insert street/city/country]* Matter in dispute: *[indicate main issues in dispute]* Party who initiated the dispute: *[indicate "Procuring Entity" or "Supplier"]*	*[insert amount]*

		Status of dispute: *[Indicate if it is being treated by the Adjudicator, under Arbitration or being dealt with by the Judiciary]*	

☐ No consistent history of court/arbitral award decisions in accordance with Section III, Qualification Criteria and Requirements, Sub-Factor 2.4.

☐ Consistent history of court/arbitral award decisions in accordance with Section III, Qualification Criteria and Requirements, Sub-Factor 2.4 as indicated below.

Year of award	**Outcome as percentage of Net Worth**	**Contract Identification**	**Total Contract Amount (currency), USD Equivalent (exchange rate)**
[insert year]	*[insert percentage]*	Contract Identification: [indicate complete contract name, number, and any other identification] Name of Procuring Entity: *[insert full name]* Address of Procuring Entity: *[insert street/city/country]* Matter in dispute: *[indicate main issues in dispute]* Party who initiated the dispute: *[indicate "Procuring Entity" or "Supplier"]* Court/ arbitral award decision: *[Indicate if the award decision was against the Tenderer or any member of a*	*[insert amount]*

Price Schedule Form

			Supply of Nutrition Supplements							
			Tender Registration No. KEMSA/GOK-MOH/OIT006/2022-2024							P. O. BOX 47715, 00100, NAIROBI
			Date of Tender Notice:			**3rd September, 2021**				TEL: +254 719033000/ +254 726618520/1
			Closing date:			**28th September, 2021**				**E-MAIL:** procure@kemsa.co.ke
			Time:			10.00 am				
Name of Firm Bidding:										
Address:										
Phone, fax, e-mail:										
No	**Item Description**	**Pack Size**	**Initial Quantity**	**Special Note**	**Unit Price**	**Total Price**	**Brand**	**Manufacturer**	**Country of Origin**	**Delivery period**
1	F75 Therapeutic Milk, 400g Tin	Tin	12,144	Packed in a carton of 24 tins						
2	F100 Therapeutic Milk, 400g Tin	Tin	10,488	Packed in a carton of 24 tins						
3	Rehydration Solution for Malnutrition (ReSoMal), 42g	Sachet	12,100	Packed in carton of 100 sachet						
4	Fortified Blended Flour (FBF)	Packet of 1.5 kg	38,400	Packed in bag of 24kg						
5	Ready to Use Therapeutic Food (RUTF), 92gm – 6 months and above	Sachet	690,000	Packed in a carton of 150s						
NAME (in the capacity of):								**Company Seal**		
Signature:										
Date:										
Total Value Tendered (*in figures and words*): **Currency:……**			**Amount in figure**:…….**Amount in word**:…….. ……							

NOTE:

1. **Prices shall remain fixed over the contract period.**
2. **The contract will a two (2) years framework contract**
3. **Delivery Schedule shall be between 1-14 weeks** from effective date of contract.
4. **Delivery Terms: DDP KEMSA Warehouse – Nairobi - Kenya**
5. **Submit samples for evaluation as follows.**

No	Item Description	Pack Size	Sample Quantity
1	F75 Therapeutic Milk, 400g Tin	Tin	2 Tins
2	F100 Therapeutic Milk, 400g Tin	Tin	2 Tins
3	Rehydration Solution for Malnutrition (ReSoMal), 42g	Sachet	5 Sachets
4	Fortified Blended Flour (FBF)	Packet of 1.5 kg	2 Packets
5	Ready to Use Therapeutic Food (RUTF), 92gm – 6 months and above	Sachet	5 Sachets

TECHNICAL SPECIFICATION FOR SUPPLEMENTARY NUTRITION SUPPLIES

Item 1: F75 Therapeutic Milk, 400g Tin

a) General Description

F-75 is therapeutic milk diet with added vegetable fat, carbohydrates, vitamins and minerals; it comes as powder packed in a canister to prepare a liquid diet with an energy density of approximately 75kcal/100 ml.

b) Intended Use

- The F-75 liquid therapeutic diet is intended for starting phase of treatment of children diagnosed with Severe Acute Malnutrition (SAM). It is intended to stabilize the child's metabolism and support rehydration.
- The specified quantity of powdered therapeutic milk is mixed with the specified quantity of water boiled and cooled down to not below 70˚C to obtain a defined quantity of liquid therapeutic diet with an energy density of approximately 75 kcal/100ml.
- F 75 must be used under medical supervision. A cautious approach is required because of child's fragile physiological state and reduced homeostatic capacity, hence F-75 is not designed for weight gain. (WHO. Guideline: Updates on the management of severe acute malnutrition in infants and children. Geneva: World Health Organization; 2013:4)

c) Target Population

Children aged 6 months and over diagnosed with SAM, in phase 1 or stabilization phase of their treatment.

d) Technical Specifications:

General Quality

Milk based white or pale yellowish fine powder; free from impurities, coloured particles, caking or lumps.

Ingredients: milk powder, refined vegetable oil, sugar, maltodextrin, milk derivate, emulsifier (lecithin) vitamin and mineral (optionally premix can be used).

e) Nutritional Composition

Macronutrients per 100grams	Macronutrients per 100ml
Energy: 445kcal (425- 465) kcal Protein: 5 (4-7) % of total energy 6.2 (5-8.5) g Lipids: 32 (25-35) % of total energy 14.6 (12-18) g Lipids: 2.5 (2.0-3.0) g n-6 fatty acid: 6.5 (3 -10) % of total energy n-3 fatty acid: 1.5 (0.3- 2.5) % of total energy Carbohydrate: 64 (57-69) % of total energy 66.6 (59.2-73.9) g Lactose: 3.6 - 7.5g Ash: max 4.0% Moisture: max 4% Solubility max: 0.5ml max (ISO 8156:2005) Burnt particules: 15 maximum (disc B) Osmolarity of prepared liquid: 240-320 mMol /L	Energy: 75 (70-80) kcal Protein: 1 (0.75-1.5) g Lipids: 2.5 (2.0-3.0) g Carbohydrate: 12 (10.5-14) g

All therapeutic foods approved for the initial feeding or starting phase of treatment of children with severe acute malnutrition must provide at least 50% of protein in the form of dairy protein. For the purposes of conversion from unit weight to unit energy, protein and carbohydrate are assumed to contribute 4 kcal/g and lipids 9 kcal/g.

Minerals		Vitamins	
Minerals per 100g:	**Minerals per 100ml**	**Vitamins per 100g:**	**Vitamins per 100ml**
Sodium: 100 mg maximum	17mg maximum	Vitamin A: 0.8-1.7 mg	0.1-0.3 mg
Potassium: 735-940 mg	122-156 mg	Vitamin D3: 15-30 mcg	2.5-5.0 mcg
Calcium: 300-600 mg	50-100 mg	Vitamin E: 20-40 mg	3.3-6.5 mg
Phosphorus: 300-600 mg	50-100 mg	Vitamin K: 15 mcg minimum	2.5mcg minimum
Magnesium: 48-64 mg	8.5-11 mg	Ascorbic acid: 50 mg minimum	10 mg minimum
Iron: 0.3mg maximum	0.05 mg maximum	Thiamine: 0.5 mg minimum	0.08 mg minimum
Zinc: 11-18 mg	1.8-3.0 mg	Riboflavine: 1.6 mg minimum	0.3 mg minimum
Copper: 1.4-1.8 mg	0.2-0.3 mg	Niacin: 5 mg minimum	0.8 mg minimum
Selenium: 20-40 mcg	3.5-7.0 mcg	Pantothenic acid: 3 mg minimum	0.5 mg minimum
Iodine: 70-140 mcg	12.3-24.5 mcg	Vitamin B6: 0.6 mg minimum	0.1 mg minimum
		Folic acid: 200 mcg minimum	35 mg minimum
		Vitamin B12: 1.6 mcg minimum	0.3mcg minimum
		Biotin: 60 mcg minimum	10mcg minimum

f) Formulation and Starting Materials

F75 shall be manufactured referencing the formula described in the WHO document: Management of severe malnutrition: a manual for physicians and other senior health workers World health organization, 1999 (refer to Table 7, Table 8 and Appendix 4).
http://www.who.int/nutrition/publications/severemalnutrition/9241545119/en/

The product must provide at least 50% of protein in the form of dairy protein. After reconstitution according to the manufacturer´s preparation instruction the product shall be a homogenous liquid that does not separate into oil/liquid phases or leave a solid sediment upon standing in a refrigerator with occasional gentle stirring. Frothing of the therapeutic milk after preparation should be minimal to enable accurate dosage measurements of the milk to each individual recipient. The product should have a characteristic milk taste and smell. It shall be white as cream, shall not have rancid, pungent or unpleasant taste or smell.

All ingredients, including optional ingredients, shall be clean, of good quality, safe and with minimal fibre removed when necessary. All ingredients and food additives shall be gluten free.
Applicable codex references for ingredients can be found in this link: http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/

Milk

• Full cream milk powder • Skimmed milk powder and/or • Whey powder (NB: may produce bitter taste)	**Applicable standards reference:** • Codex STAN 207-1999 Codex Standard for Milk Powders and Cream Powder. • Codex STAN 289-1995: Codex Standard for Whey Powders

Carbohydrates

• Carbohydrates used shall be gluten free and readily soluble in water. • Lactose shall not be added. • Glucose polymers to be used.	**Applicable standards reference:** Codex STAN 212 – 1999: Codex Standard for Sugars

Oil

Edible refined vegetable oil. The manufacturer shall choose judiciously the type of oil and establish specifications for oil to ensure that the specifications in finished product are met (with particular attention to requirements for omega 3 and omega 6 fatty acids. **Hydrogenated vegetable oils are not to be used.**	**Applicable standards reference:** Codex STAN 210 -1999: Codex Standard for Named Vegetable Oils.

Vitamins and Minerals
The used nutrient compounds shall comply with the criteria established in CAG/GL 10 – 1979 (Rev. 2008 last amendment 2015) Advisory lists of Nutrient Compounds for use in foods for Special Dietary uses for Infants and Young Children. http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/ . Another list of acceptable vitamin compounds can be found in Annex 3 of the COMMISSION DIRECTIVE 2006/141/EC of 22 December 2006 on infant formulae, follow-on formulae and amending Directive 1999/21/EC. http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006L0141

If the manufacturer uses a mineral and vitamin premix (es), they must source it from specialized premix manufacturers.

Vitamins and minerals shall be in such forms that they are easily absorbed by patients with SAM who are often achlorhydric. The added minerals shall be water-soluble and shall not form insoluble components when mixed together. **Iron salts are not to be added.**

The liquid therapeutic diet prepared from the product according to the manufacturer´s instruction for use shall have a mineral composition that will not alter the acid-base metabolism of patients with SAM. In particular, it shall have a moderate positive non-metabolisable base sufficient to eliminate the risk of metabolic acidosis. The non-metabolisable base can be estimated using the formula:
Estimated absorbed millimoles (sodium+ potasium+ calcium+magnesium) minus (phosphates + chlorides)
See: http://www.who.int/maternal_child_adolescent/documents/a91065/en/

Added minerals shall be in the form of water soluble salts. Minerals used shall be in forms that are known to be bioavailable, **nitrite and nitrate salts shall not be used**. Recommended forms of minerals can be found in Appendix 4, Management of Severe Malnutrition a manual for senior health workers.
http://www.who.int/nutrition/publications/severemalnutrition/9241545119/en/
http://apps.who.int/iris/bitstream/10665/44295/1/9789280641479_eng.pdf?ua=1

Flavouring
The use of artificial flavourings is not permitted, only natural flavourings may be used. Natural flavourings are defined in CAC/GL 29-1987 General Requirements for Natural Flavourings and in Regulation of the European parliament and of the Council (EC) N° 1334/2008. https://www.fsai.ie/uploadedFiles/Reg%201334_2008.pdf

Antioxidants
The use of artificial antioxidants is not permitted, only natural antioxidants such as ascorbyl palmitate or mixed tocopherols may be used.

Other Additives
Essential L-amino acids, choline, taurine, carnitine, inositol, carotene and other semi-essential or biologically valuable nutrients may be added to meet the specification at levels considered to be safe for children with severe malnutrition.

Shelf-life
The product shall retain the above-mentioned specifications for at least 18-24 months from date of manufacture when stored in dry conditions at a temperature of 30°C, supported by real time shelf life data. Shelf life studies shall be conducted in accordance with the UNICEF/MSF Requirements for stability study for Therapeutic Food.

Packaging
Primary Packaging (Canister)
All packaging material being in contact with food or intended to come in contact with food, including inks and glue shall be of food-contact grade. Product shall be packed in airtight canisters. Packaging under inert gas (nitrogen or carbon dioxide) prolongs products shelf-life and is recommended.

Packaging must be free of damage such as, but not limited to: tears, cuts, holes, and abrasions through one or more layers, leakage of any seal. The closure seal must be free of wrinkles and occluded maters.

Canister
Canisters should be hermetically sealed and resistant to humid and hot climates. Seal and canister integrity shall be adequate to withstand pressure changes associated with international distribution channels such as air transport. The canister shall be capped with a reusable lid to adequately close the canister and protect its content from external contamination and humidity during storage. The period when opened canister can be used shall be minimum 4 weeks.

Primary Label (Canister)
Labels must have adequate information to permit identification, safe transport, storage and use of the product throughout its shelf life. The canister label is to be white with black printing. Labels must be self-adhesive and made from paper, e.g. pharmaceutical defiberised paper (80gsm), that is film or UV coated for protection against humidity and firmly affixed to be tamper proof and to prevent detachment in tropical climates. Type preferably by lithography directly on container/packaging.

Ink/colour: The writing on primary and secondary packs must be in indelible ink, in black on white. The labelling shall be in English which may be replaced by a local language as requested by Ministry of Health.

The label shall contain the following information:
- Generic name: F-75 Therapeutic Milk
- Clear statement: For the initial phase (or Phase 1) of treatment of Children > 6 months with Severe Acute Malnutrition, not suitable for long term feeding of well-nourished children. Use under medical supervision.
- Applicable warnings (such as handling product leftovers, how long reconstituted diet can be kept at room temperature and in the refrigerator, use by date after opening, scoop hygiene. etc.)
- Breastfeeding logo and a message: Breastfeeding is recommended for at least the first 24 months and exclusively until 6 months
- List of ingredients (starting materials used) in descending order quantity
- Nutritional composition per 100g of powder and 100ml of reconstituted diet.
  Name and address of the manufacturer and packer, or distributor, or importer, or exporter, or vendor and country of origin
- Net weight
- Batch number clearly identified and visible
- Date of manufacture
- Best before date clearly identified and visible
- Storage conditions
- Pre-delivery sample and final product delivered should have a label "**GOK - Not for Sale**" clearly labelled in a place where it is visible.

Additionally, to this information, the canister label shall also contain:
- Clearly Visible instructions for preparation of reconstituted diet, e. g.
  - Levelled scoop added to 50 ml water = XX ml milk
  - Levelled scoops added to 100 ml water = XX ml milk
  - The entire content of the packaging e.g. 400g (estimate); added to 2200 ml water = XX ml milk
  - Instruction for hygienic use of the scoop.
  - Instruction to 'Discard any feed that has not been consumed within two hours.

Model instruction for preparation
A pictogram schema for preparation instructions shall be included on the canister label OR as a package leaflet. The preparation instructions shall be based on the World Health Organization 2007. How to Prepare Powdered Infant Formula in Care Settings.
http://www.who.int/foodsafety/publications/micro/PIF_Care_en.pdf

Scoop (canister)
A scoop must be included in each F-75 canister. Scoops should be made of a food contact material and a design that is easily kept clean, white in colour and marked with the product name "F-75" in addition to the manufacturer's name. Size of a scoop must allow the reconstitution at the following proportion: 2 levelled scoops: 50 ml water to produce approximately 37.5-40 kcal/50ml. (The exact powder weight per scoop should be specified by the supplier.)

Secondary Packaging
Canisters shall be placed in strong, carton boxes. Carton boxes shall be shock and puncture resistant. Cartons shall be of a sturdy quality and provide protection of the goods for carriage by air, sea and/or road to final destination including remote locations under adverse climatic and storage conditions, and high humidity - for example an ECT (Edge Crush test*) > 11kN/m with minimum 60% remaining with 90% humidity at the highest recommended storage temperature.

Additional References:
1. Recommended guideline for food hygiene in rooms where the Therapeutic Milk is prepared and stored ISO/TS 22002-1:2013 – Prerequisite programs for food safety. Part 3. – Catering 2. World Health Organization 2007 Safe preparation, storage and handling of powdered infant formula: guidelines. "World Health Organization in collaboration with Food and Agriculture Organization of the United Nations."

Secondary Packaging Label
Carton label shall contain these information:

- Generic name: F-75 Therapeutic Milk (or Therapeutic Formula F-75)
- A clear statement: For initial phase (or Phase 1) of treatment of Children with Severe Acute Malnutrition
- Any applicable warnings
- Name and address of the manufacturer and packer, or distributor, or importer, or exporter, or vendor and country of origin
- Gross weight
- Number of canisters per carton
- Batch number clearly identified and printed
- Date of manufacture
- Use by date clearly identified and printed
- Storage conditions and maximum stacking height (e.g. 2 meters maximum)
- An image indicating that boxes should not be stood on
- Pre-delivery sample and final product delivered should have a label "**GOK - Not for Sale**" clearly labelled in a place where it is visible.

Palletization
Cartons shall be securely closed, stacked (cross stacked if possible, to maximize stacking strength) on one-way pallets and wrapped with stretch/shrink.

Processing Requirements

General
All processing and drying shall be carried out in a manner that minimizes loss of nutritive value, particularly protein quality and vitamin content.
Products must be manufactured in accordance with the CAC/RCP 66 – 2008: Code of Hygienic Practice for Powdered Formulae for Infants and Young Children. http://www.fao.org/fao-who- codexalimentarius /standards/list-of-standards/en/. and CAC/RCP 1-1969, Rev. 4-2003: Recommended International Code of Practice. General Principles of Food Hygiene. http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/., and other applicable codex references and GMPs (Good manufacturing practices). The producer must have a food safety policy in place and an effective food safety management system based on a Hazard Analysis and Critical Control Points (HACCP) approach. Prerequisite programs including environmental monitoring programs must be implemented.

Other Applicable Standards reference:
ISO 22000:2005 - Food Safety Management Systems – Requirements for any Organization in the Food Chain.

The manufacturer must elaborate and implement an analytical plan of the finished product, starting materials and the processing environment. All analytical test procedures must be described in sufficient details, e.g. the sampling plan, acceptance/release criteria, analytical methods. ISO 17025 certified laboratories shall preferably be used. Refer to section 9 for the minimum analyses to be performed for each batch.

Process Validation
The coefficient of variation, shall be as low as possible, and always <5%. For calculator refer to WFP method: http://foodqualityandsafety.wfp.org/coefficient-of-variation-calculator

Traceability
A complete traceability system must be in place. For every batch number, the manufacturer must be able to identify full history of the finished products (composition, sources and batches of starting materials used, processing parameters, analytical results, quantity produced and dispatched, customers and sites where delivered).

Batch Size
The batch size shall be defined as one bulk mix.

Product Safety
Therapeutic milk shall be free from objectionable matter. It shall not contain any toxic substances originating from microorganisms or any other poisonous or deleterious substances, including anti-nutritional factors, heavy metals or pesticide residues in amounts that may represent a hazard to health. It shall not contain detectable levels of residues of antibiotics or other veterinary drugs used in animal husbandry.

Microbiological Criteria
Manufacturers are responsible for ensuring the compliance of finished products with the microbiological criteria as specified. In regard to limitations of the end-product testing the compliance shall be ensured through the design of an appropriate food safety control system and verification of the effectiveness of the applied control measures through appropriate auditing methods, including review of monitoring records, deviations and assuring that critical control points (CCPs) are kept under control and good hygienic practices (GHPs) are adhered to. These activities can be supplemented, as necessary, by appropriately documented microbiological sampling and analysis plans. The microbiological testing shall include, as appropriate, analysis of samples taken from starting materials, environment, production line and finished product. Environmental samples shall be taken from both: the points considered as most likely to cause product contamination and being most contaminated.

Where results of monitoring the control measures and surveillance or verification indicate that the product batch, lot or consignment, or its part is unsafe (not in compliance with the set microbiological criteria), it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

Food Safety Criteria
The criteria set out in Annex 1 Code of Hygienic Practice for powdered formulae for Infants and Young Children CAC/RCP 66-20083 using ISO 6579 and ISO 22964 or other validated methods applied to the finished product (powder form) after primary packing completed or anytime thereafter up to the point when the primary packaging is opened. The batch shall not be released if there is a failure to meet these criteria.

1) NOTE: No composite sample. Maximum pooling authorized is 4 pooled samples of 375g (25g from 15 units), only if the laboratory method has been validated and accredited for that method.

2) NOTE: No composite sample. One pooled sample of 300g (10g from 30 units) authorized, only if the laboratory method has been validated and accredited for that method.

Food Hygiene Criteria
The safe production of these products is dependent on maintaining a high level of hygiene control. The criteria

for process hygiene as set out in Code of Hygienic Practice for powdered formulae for Infants and Young Children CAC/RCP 66-20083 are intended to be used by the manufacturer as a means of ongoing assessment of its hygiene programs. As such these tests are not intended to be used for assessing the safety of a specific batch of product, but instead are intended to be used for verification of the hygiene programs.

3) NOTE: No composite sample. No pooled samples.

4) NOTE: For ISO 21528-1: One pooled sample of 300g (10g from 30 units) authorized, only if the laboratory method has been validated and accredited. In case of positive result, another test using the ISO 21528-2 is mandatory (no composite sample, no pooled samples authorized for ISO 21528-2.

Chemical and Other Safety

Contaminants

Nitrates < 200mg NO3/kg Nitrites < 2mg NO2/kg Aluminium < 0.6mg/kg Melamine < 1mg/kg	Mycotoxins (as per Codex standard when applicable for the starting materials used) Ochratoxin A <0.5ppb Aflatoxin B1 <0.1ppb Aflatoxin M1 <0.025ppb Palutin <10ppb Deoxynivalenol <200ppb Zearalenone <20ppb Fumonisins <200ppb

Applicable Standards reference:
CAC/RCP 49-2001 Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals.
CODEX STAN 228-2001: General Methods of Analysis for Contaminants.
CODEX STAN 193-1995: Codex General Standard for Contaminants and Toxins in Food.

Pesticides
In general, pesticide levels must be below 10 ppb. Verifying pesticide levels are below accepted limits is the responsibility of the manufacturer.

Carbamates <10 ppb Organochlorines<10 ppb Organophosphates<10 ppb Pyrethroids <10 ppb	**The maximum residue levels of specific pesticides or their metabolites in therapeutic milk powder set in below shall not be exceed:** Substance and Maximum residue level (mg/kg) Cadusafos: 0.006 Demeton-S-methyl/demeton-S.methyl sulfone/ oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl) 0.006 Ethoprophos 0.008 Fipronil (sum of fipronil and fipronil-deslfinyl, expressed as finpronil) 0.004 Propineb/propylenethiourea (sum of propined and propylenethiourea) 0.006

The following pesticides shall not be used in the agricultural production intended for the production of therapeutic formulae:

- Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone, expressed as disulfoton)
- Fensulfotion (sum of fensulfothion, its oxygen analogue and their sulfone, expressed as fensulfothion)
- Fentin, expressed as triphenyltin cation
- Haloxfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)
- Hexachlorobenzene
- Nitrofen
- Ometholate
- Terbufos (sum of terbufos, ist sulfoxide and sulfone, expressed as terbufos)

- Aldrin and dieldrin, expressed as dieldrin, Endrin

Applicable standards reference: CODEX STAN 229-1993, REV.1-2003: Analysis of Pesticide Residues: Recommended Methods

Heavy Metals*
Verifying that heavy metal levels are below accepted limits is the responsibility of the manufacturer. Examples of heavy metals that must be controlled include, but are not limited to:

- Arsenic <0.052mg/kg
- Cadmium <0.112mg/kg
- Lead <0.2mg/kg
- Mercury<0.037mg/kg
- Tin <105mg/kg

*Based on 5 kg child with SAM and PTWI, CODEX STAN 193- 1995 General Standard for Contaminants and Toxins in Food and feed.

Hydrocarbons
Benzo[a]pyrene <1ppb

Radioactivity
Radioactive contamination can occur when using milk powder derived from cows that have eaten contaminated feed. This risk is managed by using certified radioactivity free milk products. The nuclear radiation level shall meet the values valid in the area of consumption. If limits are not defined, the value must not exceed 370Bq/kg (Cs 134 & Cs136).
The product and its components shall not be treated by ionizing radiation.

GMO (Genetically Modified Organisms)
Information regarding the presence/absence of GMO to be declared.

Other Contaminants
The product shall meet the codex CODEX STAN 72 – 1981 requirements for other contaminants (residues of hormones, antibiotics and pharmacologically active substances.)

Minimum requirement for release of F75 Powder
Certificate of Analysis (CoA) is required for every batch supplied. It shall be forwarded prior to its shipment. The manufacturer is expected to perform the necessary finish product analysis in order to prove that the batch complies with the specification. In case vitamin and mineral premix is used it may be adequate to test for tracers as indicated above. In case single addition of vitamins and minerals are used, then individual analysis of each component is expected.
A Certificate of Analysis must be provided for each batch.
The principal tests listed below must be performed in order to check if the quality of F-75 meets above requirements. Additional analyses shall be defined in case of further quality assessment.
List of the minimum tests results for Certificate of Analysis and reference data are listed below:

Microbiological food safety criteria set in 7.1.2 and food hygiene criteria set in 7.1.3.

Nutrient values per 100g		
Energy: 425-465kcal Protein: 4.0-7.0% total energy Lipids: 25-35% total energy Lactose: 6-7.5g Ash 4.0g max Moisture 4% max	Vitamin C >50mg minimum Vitamin A 0.8-1.7 mg RE Potassium 735-940mg Sodium <100mg maximum Iron <0.3mg Osmolarity (of prepared liquid): 240-320 mOsMol/L (freezing point depression)	Actual value of the powder´s bulk density in ml/100g Burnt particles: 15mg maximum (disc B minimum) Solubility index: 0.5 ml maximum (ISO 8156:2005)

The manufacturer shall conduct at least one complete finished product analysis annually in order to verify that the finished product is manufactured according to this specification.

Items to be supplied with:
- Supplier shall provide one white scoop inside each canister
- Supplier should indicate items required, but not supplied: thermometer, measuring jug, feeding cup, feeding spoon in their leaflet or label

Shelf life
- Unopened canister should have minimum 18-24 months shelf life from the date of manufacture.
- Supplier should indicate shelf life of opened canister e.g. Use within 4 weeks after opening, keep in original container, do not store above 30°C; protect from direct sunlight, protect from moisture.
- Supplier should indicate shelf life of opened canister e.g. Use within 4 weeks after opening, keep in original container.
- Supplier should indicate instruction for use for reconstituted milk: Use within 2hrs if at room temperature or 24 hours if stored in the refrigerator

Storage and Transport Information:
- Supplier must indicate storage and transport temperature conditions. Do not store above 30 °C is preferred.
- Supplier shall provide Weight of carton, around: 13.7-14kg/ carton
- Supplier shall provide gross volume of carton, around: 0.03476 m3 / carton
- Supplier must include other important instructions e.g Protect from direct sunlight

Material safety data sheet information (MSDS): N/A
Packaging and labeling: preparation instructions included on the label or in a leaflet

Item 2: F100 Therapeutic Milk, 400g Tin

1) General Description
F-100 therapeutic milk diet with added vegetable fat, carbohydrates, vitamins and minerals. It comes as powder packed in a can to prepare a liquid therapeutic diet with an energy density of approximately 100 kcal/100ml.

2) Intended use
- The F-100 liquid therapeutic diet is intended for the rehabilitation phase of treatment of children with Severe Acute Malnutrition (SAM), it is intended to achieve rapid weight gain.
- The specified quantity of powdered therapeutic milk is mixed with the specified quantity of water boiled and cooled down to not below 70˚C to obtain a defined quantity of liquid therapeutic diet with an energy density of approximately 100 kcal/ 100ml.
- F100 must be administered under medical supervision.
- (WHO. Guideline: Updates on the management of severe acute malnutrition in infants and children. Geneva: World Health Organization; 2013:4)

3) Target population
Children aged 6 months and over diagnosed with SAM, in phase 2, or nutritional rehabilitation phase of their treatment.

4) Technical specifications

a) General Quality
Milk based white or pale yellowish fine powder; free from impurities, coloured particles, caking or lumps.

b) Ingredients
The main components of the therapeutic milk are: milk powder, refined vegetable oil, sugar, maltodextrin, milk derivate, emulsifier (eg lecithin), vitamin and minerals (optionally a premix can be used). For flavorings, antioxidants and other additive requirements see section 4.5.5 to 4.5.6

Nutritional composition per 100 g:

Micronutrients per 100g

Energy	530 (520-550) kcal.
Protein	11 (10-12) % of total energy 14 (12-16) g
Lipids	53 (45-60) % of total energy 30.5(25.8-36.3) g
n-6 fatty acid	6.5 (3-10) % of total energy
n-3 fatty acid	1.5 (0.3-2.5)% of total energy
Carbohydrate	36 (28-45) % of total energy 46 (35-65) g
Lactose	22 (21-23) g
Moisture content (of powder):	2.5% maximum
Ash	4.0% maximum
Solubility index	1ml maximum
Burnt particles	15 maximum (disc B min)
Osmolarity (of prepared liquid):	260-320 mOsmol/L (freezing point depression)

Macronutrients per 100 ml	
Energy	100 (95-105) kcal
Protein	3 (2.3-3.1) g
Lipids	5.8 (4.9-6.9) g
Carbohydrate	9 (7 - 12) g

Minerals

Minerals	**per 100g**	**per 100ml**
Sodium	290 mg max	55 mg
Potassium	1100-1400 mg	
Calcium	300-600 mg	55-115 mg
Phosphorus* *(excluding phytate)	300-600 mg	55-115 mg
Magnesium	80-140 mg	15-25 mg
Iron	0.3 mg maximum	0.05 mg maximum
Zinc	11-14 mg	2.0-3.0 mg
Copper	1.4-1.8 mg	0.25-0.35 mg
Selenium:	20-40 mcg	3.5-7.7 mcg
Iodine:	70-140 mcg	13-27 mcg

Vitamins

Vitamins	**per 100g**	**per 100ml**
Vitamin A	0.8-1.7 mg	0.15-0.32mcg
Vitamin D3	15-30 mcg	3.0-5.3mcg
Vitamin E	20-40 mg	4.0-6.5mg
Vitamin K	15 mcg minimum	3.0 mcg minimum
Thiamine	0.5 mg minimum	0.1 mg minimum
Riboflavine	6 mg minimum	1. 0.3 mg minimum
Ascorbic acid	50 mg minimum	9.6 mg minimum
Vitamin B6	0.6 mg minimum	0.1mg minimum
Vitamin B12	1.6 mcg minimum	0.3 mg minimum
Folic acid	200 mcg minimum	38 mg minimum
Niacin	5 mg minimum	1.0 mg minimum
Pantothenic acid	3 mg minimum	0.6 mg minimum
Biotin	60 mcg minimum	11 mg minimum

Lactose	4.2 (4.0-4.4) g maximum		

All therapeutic foods approved for use in the rehabilitation of individuals with severe acute malnutrition must provide at least 50% of protein in the form of dairy protein. For the purposes of conversion from unit weight to unit energy, protein and carbohydrate are assumed to contribute 4 kcal/g and lipids 9 kcal/g.

Formulation and Starting materials

All ingredients, including optional ingredients, shall be clean, of good quality, safe and with minimal fibre removed when necessary. All ingredients and food additives shall be gluten free.

After reconstitution according to the manufacturer´s preparation instruction the product shall be a homogenous liquid that does not separate into oil/liquid phases or leave a solid sediment upon standing in a refrigerator with occasional gentle stirring. Frothing of the therapeutic milk after preparation should be minimal to enable accurate dosage measurements of the milk to each individual recipient. The product should have characteristic milk taste and smell. It shall be white as cream, shall not have rancid, pungent or unpleasant taste or smell.

The product must provide at least 50% of protein in the form of dairy protein.

All ingredients, including optional ingredients, shall be clean, of good quality, safe and with minimal fibre removed when necessary. All ingredients and food additives shall be gluten free.

Applicable reference link for raw materials codex standards: http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/

Milk

• Full cream milk powder • Skimmed milk powder and/or • Whey powder (NB: may produce a bitter taste)	**Applicable standards reference:** • Codex STAN 207-1999 Codex Standard for Milk Powders and Cream Powder. • Codex STAN 289-1995: Codex Standard for Whey Powders

Carbohydrates

• Carbohydrates used shall be gluten free and readily soluble in water. • Glucose and lactose polymers to be used.	**Applicable standards reference:** Codex STAN 212 – 1999: Codex Standard for Sugars

Oil

Edible refined vegetable oil. The manufacturer shall choose judiciously the type of oil and establish specifications for oil to ensure that the specifications in finished product are met (with particular attention to requirements for omega 3 and omega 6 fatty acid content). Hydrogenated vegetable oils are not to be used.	**Applicable standards reference:** Codex STAN 210 -1999: Codex Standard for Named Vegetable Oils.

Vitamins and minerals

The used nutrient compounds shall comply with the criteria established in CAG/GL 10 – 1979 (Rev. 2008 last amendment 2015) Advisory lists of Nutrient Compounds for use in foods for Special Dietary uses for Infants and Young Children http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/. Another list of acceptable vitamin compounds can be found in Annex 3 of the COMMISSION DIRECTIVE 2006/141/EC of 22 December 2006 on infant formulae, follow-on formulae and amending Directive 1999/21/EC. http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006L0141

If the manufacturer uses a mineral and vitamin premix(es), they must source it from specialized premix

manufacturers.
Vitamins and minerals shall be in such forms that they are easily absorbed by patients with SAM, who are often achlorhydric. The added minerals shall be water-soluble and shall not form insoluble components when mixed together. Iron salts are not to be added.

The liquid therapeutic diet prepared from the product according to the manufacturer´s instruction for use shall have a mineral composition that will not alter the acid-base metabolism of patients with SAM. In particular, it shall have a moderate positive non-metabolisable base sufficient to eliminate the risk of metabolic acidosis. The non-metabolisable base can be estimated using the formula:
Estimated absorbed millimoles (sodium+ potasium+calcium+magnesium) minus (phosphates + chlorides) See : http://www.who.int/maternal_child_adolescent/documents/a91065/en/
Added minerals shall be in the form of water soluble salts. Minerals used shall be in forms that are known to be bioavailable, nitrite and nitrate salts shall not be used. Recommended forms of minerals can be found in Appendix 4, Management of Severe Malnutrition a manual for senior health workers.
http://www.who.int/nutrition/publications/severemalnutrition/9241545119/en/
http://apps.who.int/iris/bitstream/10665/44295/1/9789280641479_eng.pdf?ua=1

Flavoring
The use of artificial flavorings is not permitted, only natural flavorings may be used. Natural flavorings are defined in CAC/GL 29-1987 General Requirements for Natural Flavorings and in Regulation of the European parliament and of the Council (EC) N° 1334/2008.

Antioxidants
The use of artificial antioxidants is not permitted, only natural antioxidants such as ascorbyl palmitate or mixed tocopherols may be used.
Other additives
Essential L-amino acids, choline, taurine, carnitine, inositol carotene and other semi-essential or biologically valuable nutrients may be added to meet the specification at levels considered to be safe for children with severe malnutrition.

Shelf life
The product shall retain the above mentioned specifications for at least 18-24 months from date of manufacture when stored in dry conditions at a temperature of 30°C, supported by real time shelf life data. Shelf life studies shall be conducted in accordance with the UNICEF/MSF Requirements for stability study for Therapeutic Food.

Packaging
Primary packaging (Canister)
All packaging material being in contact with food or intended to come in contact with food, including inks and glue shall be of food-contact grade. Product shall be packed in airtight canisters. Packaging under inert gas (nitrogen or carbon dioxide) prolongs products shelf-life and is recommended.
Packaging must be free of damage such as, but not limited to: tears, cuts, holes, and abrasions through one or more layers, leakage of any seal. The closure seal must be free of wrinkles and occluded maters.

Canister
Canisters should be hermetically sealed and resistant to humid and hot climates. Seal and canister integrity shall be adequate to withstand pressure changes associated with international distribution channels such as air transport. The canister shall be capped with a reusable lid to adequately close the canister and protect its content form external contamination and humidity during storage. The period when opened canister can be used shall be minimum 4 weeks.

Primary label (Canister)
Labels must have adequate information to permit identification, safe transport, storage and use of the product throughout its shelf life. The canister label is to be white with blue printing. Labels must be self-adhesive and made from paper, e.g. pharmaceutical defiberised paper (80gsm), that is film or UV coated for protection against humidity and firmly affixed to be tamper proof and to prevent detachment in tropical climates. Type

preferably by lithography directly on container/packaging.
Ink/colour: The writing on primary and secondary packs must be in indelible ink, in blue on white. The labeling shall be in English, Arabic and French, one of these languages may be replaced by a local language as requested by UNICEF/Ministry of Health

The label shall contain the following information:

- Generic name: F-100 Therapeutic Milk
- Clear statement: For the rehabilitation phase (or Phase 2) of treatment of Children > 6 months with Severe Acute Malnutrition, not suitable for long term feeding of well-nourished children. Use under medical supervision.
- Applicable warnings (such as handling product leftovers, how long reconstituted diet can be kept at room temperature and in the refrigerator, use by date after opening, scoop hygiene. When to dispose the opened canister, etc.)
  - Breastfeeding logo and a message: Breastfeeding is recommended for at least the first 24 months and exclusively until 6 months
  - List of ingredients (starting materials used) in descending order quantity
  - Nutritional composition per 100 g of powder and 100 ml of reconstituted diet.
  - Name and address of the manufacturer and packer, or distributor, or importer, or exporter, or vendor and country of origin
  - Net weight
  - Batch number clearly identified and visible
  - Date of manufacture
  - Best before date clearly identified and visible
  - Storage conditions
  - Pre-delivery sample and final product delivered should have a label "**GOK - Not for Sale**" clearly labelled in a place where it is visible.

Additionally, to this information, the canister label shall also contain:

- Clearly Visible Instructions for preparation of reconstituted diet, e. g.
  - levelled scoop added to 50 ml water = XX milk (approx.)
  - levelled scoops added to 100 ml water = XX milk
- The entire content of the packaging e.g. 400 g (estimate); added to 1850 ml water = XX ml milk
- Instruction for hygienic use of the scoop.
- Instruction to 'Discard any feed that has not been consumed within two hours'.

Model instruction for preparation
A pictogram schema for preparation instructions shall be included on the canister label OR as a package leaflet. The preparation instructions shall be based on the World Health Organization 2007. How to Prepare Powdered Infant Formula in Care Settings.
http://www.who.int/foodsafety/publications/micro/PIF_Care_en.pdf

Scoop (canister)
A scoop must be included in each F-75 canister. Scoops should be made of a food contact material and a design that is easily kept clean, blue in colour and market with the product name 'F-100' in addition to the manufacturers name. Size of a scoop must allow the reconstitution at the following proportion: 2 levelled scoops: 50 ml water, approximately 47.5-52.5 kcal/50ml). The scoops should be placed inside the canister. Scoops shall be coloured blue and marked with the product name "F-100" in addition to the manufacturer's name. (The exact powder weight in each of the vendor's scoop for the vendor's product shall be specified by the supplier).

Secondary packaging
Canisters shall be placed in strong, carton boxes. Carton boxes shall be shock and puncture resistant. Cartons shall be of a sturdy quality and provide protection of the goods for carriage by air, sea and/or road to final destination worldwide, including remote locations under adverse climatic and storage conditions, and high humidity - for example an ECT (Edge Crush test*) > 11kN/m with minimum 60% remaining with 90%

humidity at the highest recommended storage temperature.

Additional references:

1. Recommended guideline for food hygiene in rooms where the therapeutic milk is prepared and stored ISO/TS 22002-1:2013 – Prerequisite programs for food safety. Part 3. – Catering
2. World Health Organization 2007 Safe preparation, storage and handling of powdered infant formula: guidelines. "World Health Organization in collaboration with Food and Agriculture Organization of the United Nations."

Secondary packaging Label

Carton label shall contain this information:

- Generic name: F-100 Therapeutic Milk (or Therapeutic Formula F-100)
- A clear statement: For rehabilitation phase (or Phase 2) of treatment of Children with Severe Acute Malnutrition
- Any applicable warnings
- Name and address of the manufacturer or packer, or distributor, or importer, or exporter, or vendor and country of origin
- Gross weight
- Number of canisters per carton
- Batch number clearly identified and printed out
- Date of manufacture
- Use by date clearly identified and printed out
- Storage conditions and maximum stacking height (e.g. 2 meters maximum)
- An image indicating that boxes should not be stood on:
- Pre-delivery sample and final product delivered should have a label "**GOK - Not for Sale**" clearly labelled in a place where it is visible.

Palletization

Cartons shall be securely closed, stacked (cross stacked if possible, to maximize stacking strength) on one-way pallets and wrapped with stretch/shrink. Please see UNICEF supply division Packing Specifications (non-CPH destinations)

https://www.unicef.org/supply/files/Non_CPH_WH_packing_specifications_April_2017.pdf

Processing requirements

General

All processing and drying shall be carried out in a manner that minimizes loss of nutritive value, particularly protein quality and vitamin content.

Products must be manufactured in accordance with the CAC/RCP 66 – 2008: Code of Hygienic Practice for Powdered Formulae for Infants and Young Children. http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/. and CAC/RCP 1-1969, Rev. 4-2003: Recommended International Code of Practice. General Principles of Food Hygiene.

http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/. other applicable codex references and GMPs (Good manufacturing practices). The producer must have a food safety policy in place and an effective food safety management system based on a Hazard Analysis and Critical Control Points (HACCP) approach. Prerequisite programs including environmental monitoring programs must be implemented.

Other Applicable standards reference:

ISO 22000:2005 - Food Safety Management Systems – Requirements for any Organization in the Food Chain.
ISO/TS 22002-1:2009 – Prerequisite Programs for Food Safety. Part 1. – Food Manufacture.

The manufacturer must elaborate and implement an analytical test plan of the finished product, starting materials and the processing environment. All analytical test procedures must be described in sufficient

details, e.g. the sampling plan, acceptance/release criteria, analytical methods. ISO 17025 certified laboratories shall preferably be used. Refer to section 9 for the minimum analyses to be performed for each batch.

Process validation
The coefficient of variation, shall be as low as possible, and always <5%. For calculator refer to WFP method: http://foodqualityandsafety.wfp.org/coefficient-of-variation-calculator

Traceability
A complete traceability system must be in place. For every batch number, the manufacturer must be able to identify full history of the finished products (composition, sources and batches of starting materials used, processing parameters, analytical results, quantity produced and dispatched, customers and sites where delivered).

Batch Size
The batch size shall be defined as one bulk mix.

Product Safety
Therapeutic milk shall be free from objectionable matter. It shall not contain any toxic substances originating from microorganisms or any other poisonous or deleterious substances, including anti-nutritional factors, heavy metals or pesticide residues in amounts that may represent a hazard to health. It shall not contain detectable levels of residues of antibiotics or other veterinary drugs used in animal husbandry.

Microbiological criteria
Manufacturers are responsible for ensuring the compliance of finished products with the microbiological criteria as specified. In regards to limitations of the end-product testing the compliance shall be ensured through the design of an appropriate food safety control system and verification of the effectiveness of the applied control measures through appropriate auditing methods, including review of monitoring records, deviations and assuring that critical control points (CCPs) are kept under control and good hygienic practices (GHPs) are adhered to. These activities can be supplemented, as necessary, by appropriately documented microbiological sampling and analysis plans. The microbiological testing shall include, as appropriate, analysis of samples taken from raw materials, environment, production line and finished product. Environmental samples shall be taken from both: the points considered as most likely to cause product contamination and being most contaminated.

Where results of monitoring the control measures and surveillance or verification indicate that the product batch, lot or consignment, or its part is unsafe (not in compliance with the set microbiological criteria), it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

Food Safety Criteria
The criteria set out in Annex 1 Code of Hygienic Practice for powdered formulae for Infants and Young Children CAC/RCP 66-20083 using ISO 6579 and ISO 22964 or other validated methods applied to the finished product (powder form) after primary packing completed or anytime thereafter up to the point when the primary packaging is opened. The batch shall not be released if there is a failure to meet these criteria.
Note:

1. No composite sample. Maximum pooling authorized is 4 pooled samples of 375g (25g from 15 units), only if the laboratory method has been validated and accredited for that method.
2. No composite sample. One pooled sample of 300g (10g from 30 units) authorized, only if the laboratory method has been validated and accredited for that method.

Food hygiene criteria
The safe production of these products is dependent on maintaining a high level of hygiene control. The criteria for process hygiene as set out in Code of Hygienic Practice for powdered formulae for Infants and Young Children CAC/RCP 66-20083 are intended to be used by the manufacturer as a means of ongoing assessment of its hygiene programs. As such these tests are not intended to be used for assessing the safety of a specific batch of product, but instead are intended to be used for verification of the hygiene programs.

Note:

1. No composite sample. No pooled samples.
2. For ISO 21528-1: One pooled sample of 300g (10g from 30 units) authorized, only if the laboratory method has been validated and accredited. In case of positive result, another test using the ISO 21528-2 is mandatory (no composite sample, no pooled samples authorized for ISO 21528-2.

Chemical and other Safety
Contaminants

- Nitrates < 200mg NO3/kg
- Nitrites < 2mg NO2/kg
- Aluminium < 0.6mg/kg
- Melamine < 1mg/kg

Mycotoxins (as per CODEX standard when applicable for the starting materials used)

- Ochratoxin A <0.5ppb
- Aflatoxin B1 <0.1ppb
- Aflatoxin M1 <0.025ppb
- Palutin <10ppb
- Deoxynivalenol <200ppb
- Zearalenone <20ppb
- Fumonisins <200ppb

Applicable standards reference:
CAC/RCP 49-2001 Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals.
CODEX STAN 228-2001: General Methods of Analysis for Contaminants.
CODEX STAN 193-1995: Codex General Standard for Contaminants and Toxins in Food.

Pesticides
In general, pesticide levels must be below 10 ppb. Verifying pesticide levels are below accepted limits is the responsibility of the manufacturer.

- Carbamates <10 ppb
- Organochlorines<10 ppb
- Organophosphates <10 ppb
- Pyrethroids <10 ppb

The maximum residue levels of specific pesticides or their metabolites in therapeutic milk powder set in below shall not be exceed:

Substance and Maximum residue level (mg/kg)

- Cadusafos: 0.006
- Demeton-S-methyl/demeton-S.methyl sulfone/
- oxydemeton- methyl (individually or combined, expressed as demeton-S-methyl) 0.006
- Ethoprophos 0.008
- Fipronil (sum of fipronil and fipronil-deslfinyl, expressed as finpronil) 0.004
- Propineb/propylenethiourea (sum of propined and propylenethiourea) 0.006

The following pesticides shall not be used in the agricultural production intended for the production of therapeutic formulae:

- Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone, expressed as disulfoton)
- Fensulfotion (sum o fensulfothion, its oxygen analogue and their sulfone, expressed as fensulfothion)
- Fentin, expressed as triphenyltin cation
- Haloxfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)
- Hexachlorobenzene
- Nitrofen

- Ometholate
- Terbufos (sum of terbufos, ist sulfoxide and sulfone, expressed as terbufos)
- Aldrin and dieldrin, expressed as dieldrin, Endrin

Applicable standards reference: CODEX STAN 229-1993, REV.1-2003: Analysis of Pesticide Residues: Recommended Methods

Heavy Metals*
Verifying that heavy metal levels are below accepted limits is the responsibility of the manufacturer. Examples of heavy metals that must be controlled include, but are not limited to:

- Arsenic <0.052mg/kg
- Cadmium <0.112mg/kg
- Lead <0.2mg/kg
- Mercury<0.037mg/kg
- Tin <105mg/kg

*Based on 5 kg child with SAM and PTWI, CODEXSTAN 193- 1995 General Standard for Contaminants and Toxins in Food and feed.

Hydrocarbons
Benzo[a]pyrene <1ppb

Radioactivity
Radioactive contamination can occur when using milk powder derived from cows that have eaten contaminated feed. This risk is managed by using certified radioactivity free milk products. The nuclear radiation level shall meet the values valid in the area of consumption. If limits are not defined, the value must not exceed 370Bq/kg (Cs 134 & Cs136).
The product and its components shall not be treated by ionizing radiation.

GMO (Genetically Modified Organisms)
Information regarding the presence/absence of GMO to be declared.

Other contaminants
The product shall meet the codex CODEX STAN 72 – 1981 requirements for other contaminants (residues of hormones, antibiotics and pharmacologically active substances.)

Minimum requirement for release of F100 Powder
Certificate of Analysis (CoA) is required for every batch supplied against MOH/UNICEF Purchase Orders. It shall be forwarded prior to its shipment. The manufacturer is expected to perform the necessary finish product analysis in order to prove that the batch complies with the specification. In case vitamin and mineral premix is used it may be adequate to test for tracers as indicated above. In case single addition of vitamins and minerals are used, then individual analysis of each component is expected.
A Certificate of Analysis must be provided for each batch.
The principal tests listed below must be performed in order to check if the quality of F-100 meets above requirements. Additional analyses shall be defined in case of further quality assessment.

List of the minimum tests results for Certificate of Analysis and reference data are listed below:

Microbiological food safety criteria set in 7.1.2 and food hygiene criteria set in 7.1.3.

Nutrient Value per 100g

Energy: 520-550 kcal	Vitamin C: 50mg minimum
Protein: 10-12 % total energy	Vitamin A: 0.8-1.7 mg RE
Lipids: 45-60 % total energy	Potassium: 1100-1400 mg
Ash: 4.0 % maximum	Sodium: <290mg maximum
Moisture: 2.5 % maximum	Iron: <0.3mg

Actual value of powders bulk density in ml/100g
Burnt particules: 15mg maximum (disc B minimum)
Solubility index. 1 ml maximum (ISO 8156:2005)
Osmolarity (of prepared liquid): 260-320 mOsmol/L (freezing point depression)

The manufacturer shall conduct at least one complete finished product analysis annually in order to verify that the finished product is manufactured according to this specification.

Items to be supplied with:
Supplier shall provide one blue scoop inside each canister
Supplier should indicate items required, but not supplied: thermometer, measuring jug, feeding cup, feeding spoon in their leaflet or label

Shelf life:
- Unopened canister should have minimum 18-24 months shelf life from the date of manufacture. Supplier must indicate storage and transport temperature conditions. Do not store above 30 °C is preferred.
- Supplier should indicate shelf life of opened canister e.g Use within 4 weeks after opening, keep in original container, do not store above 30°C; protect from direct sunlight, protect from moisture.
- Supplier should indicate shelf life of opened canister e.g Use within 4 weeks after opening, keep in original container
- Supplier should indicate instruction for use for reconstituted milk: Use within 2hrs if at room temperature or 24 hours if stored in the refrigerator
- Supplier must include other important instructions e.g Protect from direct sunlight

Storage and Transport conditions:
Supplier should indicate storage and transport instructions: Do not store above 30°C; protect from direct sunlight, protect from moisture.

Material safety data sheet information (MSDS): N/A
Packaging and labelling: preparation instructions included on the label or in a leaflet
Supplier shall provide Weight of carton, around: 11-14kg/ carton
Supplier shall provide gross volume of carton, around: 0.03476-0.04640 m3 / carton

Item 3: Technical Specifications for ReSoMal

General Description:
ReSoMal (ORS for severely malnourished children), 42g sachet to be diluted in 1 litre of purified/boiled and cooled water, carton of 100 sachets.

Technical Specifications: (Contents per sachet of 42 grams)

Sucrose: 25 g	Tripotassium Citrate: 0.65 g
Glucose Anhydrous: 10 g	Magnesium Chloride Anhydrous: 0.61 g
Sodium Chloride: 1.75 g	Zinc Acetate: 0.0656 g
Trisodium Citrate, dihydrate:1.45 g	Copper Sulphate Anhydrous: 0.0112 g
Potassium Chloride: 2.54 g	Osmolarity: 300 mmol/L

All the ingredients must comply with one of the pharmacopeia:
BP, Ph.Eur, Ph.Int, USP.
Finished product must comply with the requirements stated under Oral Rehydration Salts Ph. Int. Oral Rehydration Salts BP or Oral Rehydration Salts USP.

What ReSoMal is and what it is used for
ReSoMal is a powder for preparation of oral rehydration solution (ORS) for treatment of dehydration in children with Severe Acute Malnutrition (SAM.)
ReSoMal must be used only after dehydration in SAM children is carefully assessed, based on medical history

and clinical signs and ONLY in Inpatient facilities under medical supervision with strict monitoring.

ReSoMal should be stopped if:

- The respiratory and pulse rates increase;
- The jugular veins become engorged; or
- There is an increasing oedema (e.g. puffy eyelids).

The assessment of need for rehydration with ReSoMaL and monitoring during treatment, as well as dosage should be done strictly according to national guidelines for the management of severe acute malnutrition or: WHO 2014 Management of Severe Malnutrition: a manual for physicians and other senior health workers. ReSoMaL should not and never be freely available for caretakers to give to their children whenever they have a loose stool as this practice is dangerous and may seriously worsen child's medical condition.

Instructions for use
One sachet of 42 grams is to be diluted in 1 litre of purified/boiled and cooled water which will give 1 litre of liquid ReSoMal.

The reconstituted solution has to be consumed immediately or used within 24 hours if stored in a refrigerator.

Shelf life:

- ✓ 36 months

Storage conditions: as defined by the manufacturer
Dosage: Quantity to be determined based on child's weight and health status in line with national guidelines/WHO 2014 Management of Severe Malnutrition: a manual for physicians and other senior health workers.

Target population (beneficiaries: type and number of persons concerned): Children 6-59m old suffering from Dehydration and Severe Acute Malnutrition.
Note: Should not be used for cholera patients.

NOTE: Why have improvements been made to packaging of F75 and F100

1. Minimizing Contamination Risk and Incorrect Reconstitution during preparation of feeds
2. Adherence to WHO's 2007 guideline "Safe preparation, storage and handling of powdered infant formula and Codex Code of Hygienic practice for Infant Formula, CAC/RCP 66-2008 to minimize contamination risks

<u>Primary and Secondary Labelling</u>

- Generic name: ReSoMal
- A clear statement: For Rehydration of Patients with Severe Acute Malnutrition
- Any applicable warnings
- Name and address of the manufacturer or packer, or distributor, or importer, or exporter, or vendor and country of origin
- Gross weight
- Number of Sachet per carton
- Batch number clearly identified and printed out
- Date of manufacture
- Use by date clearly identified and printed out
- Storage conditions and maximum stacking height (e.g. 2 meters maximum)
- An image indicating that boxes should not be stood on:
- Pre-delivery sample and final product delivered should have a label "**GOK - Not for Sale**" clearly labelled in a place where it is visible.

Item 4: Fortified Blended Flour (FBF)

1. FBF (CSB) for children (above 5yrs, pregnant and lactating women

1.1 Product purpose

SUPER CEREAL- Corn Soya Blend (hereafter called the product) is intended for children older than 5 years of age and adults.

1.2 Product type

The product is prepared from heat treated maize and whole soya beans, vitamins and minerals. The product is consumed as a porridge or gruel, it should be prepared by mixing an appropriate proportion of flour and clean water (i.e. 40g of the product with 250g of water) followed by a boiling time at simmering point from five to ten minutes. The product shall not be consumed in dry powder form, without preparation and cooking.

1.3 Standards and recommendations

The manufacturer shall be registered under national food law as a manufacturer of supplementary foods for special dietary needs, or manufacturer of baby foods, or equivalent for either, as per country regulation. The product shall comply, in terms of raw materials, composition or manufacture, except when specified otherwise in this contract, with the following guidelines or standards of Codex Alimentarius.

- Guidelines on Formulated Supplementary Foods for Older Infants and Young Children, CAC/GL 08-1991 of the Codex Alimentarius.
- Codex standard for processed cereal-based foods for infants and young children. CODEX STAN 074-1981, Rev. 1-2006, of the Codex Alimentarius.
- Code of Hygienic Practice for Foods for Infants and Children CAC/RCP 66 - 2008 of the Codex Alimentarius.
- Recommended International Code of Practice: General Principles of Food Hygiene; CAC/RCP 1-1969 Rev 4 - 2003 including Annex "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its application".
- General principles for addition of essential nutrients to foods: CAC/GL 09-1987 (amended 1989, 1991), of the Codex Alimentarius.
- General standard for contaminants and toxins in food and feed: CODEX STAN 193- 1995.

2. Raw Materials

2.1 Main ingredients

The product shall be manufactured from maize and soybeans of good quality and shall comply with all relevant national food laws and standards. Requirements for the raw materials are:

Maize

- Conform to Codex STAN 153-1985.
- Be tested for aflatoxins (total, B1, Fumonisins)
- Be tested for Deoxynivalenol (DON)
- Be obtained from non-genetically modified varieties (*if required by the contract*).

Soya beans

- Conform to Codex STAN 171-1989 (Rev.1-1995).
- Be obtained from non-genetically modified varieties (*if required by the contract*).

Note: Maize and soya beans shall be free from the following toxic or noxious seeds and their metabolites in amounts which may represent a hazard to human health.

– Crotolaria (Crotalaria spp.), Corn cockle (Agrostemma githago L.), Castor bean (Ricinus communis L.), Jimson weed (Datura spp.), and other seeds that are commonly recognized as harmful to health.

Maize and soya beans shall be stored under dry, ventilated and hygienic conditions. Only safe insecticides (i.e. phosphine) may be used for fumigation control. Where needed, fumigation shall be performed by certified operators. It shall be done as specified in the GAFTA Standard for Fumigation[1].

2.2 Vitamins and minerals

Micronutrient premixes are used at the following rate per metric ton of finished product:

- 2.0 kg of vitamin premix (**FBF-V-13**).
- 12.3 kg of Dicalcium Phosphate Anhydrous.

- And 2.7 kg of Potassium chloride.

Requirements Potassium chloride and Dicalcium Phosphate Anhydrous are:

- Shall meet at least food chemical codex.
- Particle size for Potassium chloride min 100% < 600 µm (microns).
- Dicalcium Phosphate Anhydrous, compliant with food chemical codex, min 95%<250 micron, total aerobic viable count <1000 CFU/g, yeast<10 CFU/g, mould <100 CFU/g, and enterobacteria negative/g.

The composition of micronutrient premixes is presented in table 2.

2.3 Homogeneity of micronutrients

Theoretical calculations indicate that a mixing system with a Coefficient of Variation of 10% using iron as the indicator element, will enable product to meet the above variation target on 95%, provided that all conditions of mixing are rigorously applied. The guidelines for this calculation is shown at http://foodqualityandsafety.wfp.org/coefficient-of-variation-calculator

3. Processing

3.1 Formula

The product is manufactured according to the following formula:

Table 1: **SUPER CEREAL- Corn Soya Blend** *formula*

Nº	**Ingredients**	**Percentage (by weight)**
1	Maize	78.30
2	Whole soya beans	20
3	Vitamin/Mineral **FBF-V-13**	0.20
4	Dicalcium Phosphate anhydrous	1.23
5	Potassium chloride	0.27

Premix is mixed with extruded product, not directly with maize and soybeans. Soybeans have varying levels of protein and fat depending on origin. To ensure that the nutritional targets of finished product are fully met, the processor should check the quality of incoming materials i.e. fat and protein contents of soya and if necessary, adjust the ratio of maize to soya in the formulation. All formulation adjustments shall be documented and reported.

3.2 Method of processing

The product shall be processed as a partially pre-cooked food under conditions which permit improvements in the pre-gelatinization of starches, digestibility of proteins and in particular the de-activation of trypsin inhibitors in soya as indicated by the urease test. Preferred heat treatments include wet extrusion, dry extrusion and drum drying.

Note: Roasting is not acceptable.

3.3 Food safety and risk assessment at manufacturing premises

For compliance with Codex standards the processor shall be able to demonstrate by principle and practice the adoption, implementation and recording of:

- Good Manufacturing Practice
- Hazard Analysis Critical Control Point program

In this context an appointed Inspector / Quality Surveyor is entitled to visit the factory without prior notice during any period when the product is being manufactured to check that the production is done as per contract specification. The Inspector / Quality Surveyor may request to see:

- **Records** (i.e. names of people in charge of the process and quality control, temperatures of the process, mixing times / net contents, cleaning schedules, CCP monitoring, traceability etc.).
- **Procedures** (e.g. cleaning, personnel hygiene, risk assessment and HACCP, environmental monitoring programme, sampling & analysis, product release and control of non-conformance etc.).
- **Instructions** (e.g. process instructions, cleaning instructions, zoning instructions etc.).
- The **quality manual** for the process or factory.

- Conditions in the factory (process rooms, warehouses, laboratories, cloakrooms, factory grounds, utility rooms, etc.)

4. Product Specifications

4.1 General requirements

The product shall be suitable for young children and adults after a boiling at simmering point for a minimum of five minutes and a maximum of ten minutes.

Finished product shall have a pleasant smell and palatable taste. It shall have a uniform fine texture with the following particle distribution:

- 95% shall pass through a 600 microns sieve.
- 100% shall pass through a 1,000 microns sieve.
  - Energy requirement of finished product should be minimum 380 kcal/100g flour.

4.2 Additional requirements

4.2.1 Consistency

Flow rate (Bostwick test) of 15% dry matter porridge should be minimum 55 mm per 30 sec at 45^{o}C and at the proposed preparation dosage (i.e. 40g of product plus 250g water after a boiling at simmering point for five minutes).

4.2.2 Depressiveness

It shall be free from lumping or balling when mixed with water of ambient temperature.

4.3 Specific requirements

The product shall be fortified to provide the following net micro nutrient **supplement** per 100g of finished product specified in table 2.

It shall also comply with other requirements specified in table 5.

4.4 Contaminants

4.4.1 Toxic or noxious seeds and their metabolites

The product shall be free from the following toxic or noxious seeds, toxic plants or their metabolites in amount which may represent a hazard to human health.

– *Crotolaria (Crotalaria spp.), Corn cockle (Agrostemma githago L.), Castor bean (Ricinus communis L.), Jimson weed (Datura spp.), Mexican Prickly Poppy (Argemone mexicana)* and other seeds that are commonly recognized as harmful to health.

4.4.2 Heavy metals

The product shall be free from heavy metals in amounts which may represent a hazard to health.

4.4.3 Pesticide residues

The product shall comply with those maximum residue limits established by the Codex Alimentarius Commission for this commodity.

4.4.4 Mycotoxins

The product shall comply with those maximum mycotoxin limits established by the Codex Alimentarius Commission for this commodity.

Maximum level of Deoxynivalenol (DON) is 1.0 mg/kg (on dry matter basis).

4.4.5 Other contaminants

The product shall be free from other contaminants in amounts which may represent a hazard to health

Table 2: Micronutrient rate and chemical form

	Target/100g flour	**Form**
Vitamin/Mineral premix FBF-V-13		
Vitamin A	3460 IU	Dry Vitamin A Palmitate 250 Cold Water Dispersible Stabilized
Vitamin D3	441.6 IU	Dry Vitamin D3 100 Water Dispersible Stabilized
Vitamin E TE	8.3 mg	Dry Vitamin E Acetate 50% Water Dispersible
Vitamin K1	30 µg	Dry Vitamin K1 5% Water Dispersible
Vitamin B1	0.2 mg	Thiamine mononitrate
Vitamin B2	1.4 mg	Vitamin B2 fine powder
Vitamin B6	1 mg	Pyridoxine hydrochloride
Vitamin C	90 mg	Ascorbic acid
Pantothenic acid	1.6 mg	Calcium D Panthotenate

Folate, (DFE)	110 µg	Folic acid*
Niacin	8 mg	Niacinamide
Vitamin B12	2 µg	Vitamin B12 0.1% or 1% Spray Dried
Biotin	8.2 µg	Biotin 1%
Iodine	40 µg	Potassium Iodide*
Iron (a)	4 mg	Ferrous fumarate fine powder
Iron (b)	2.5 mg	Iron-sodium EDTA
Zinc	5 mg	Zinc Sulphate Monohydrate
Carrier		Corn maltodextrin
		* Adequate dilution shall be used in order to guarantee premix homogeneity
Other minerals		
Potassium	140 mg	Potassium Chloride with 0.5% silicon dioxide as anticaking agent, compliant with food chemical codex, min 100% <600 micron
Calcium	362 mg	Dicalcium Phosphate Anhydrous, compliant with food chemical codex, min 95%<250 micron, total aerobic viable count <1000 CFU/g, yeast<10 CFU/g, mould <100 CFU/g, and enterobacteria negative in 1 g.
Phosphorous	280 mg	

Note: Variable levels of micronutrients (i.e. iron, zinc, etc.) naturally present in maize and soya may lead to variable amount of micronutrients in finished product.

4.5 Hygiene

It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969), and other Codes of Practice recommended by the Codex Alimentarius Commission which are relevant to these products.

When tested by appropriate methods of sampling and examination, the products:

- shall be free from any foreign matter/bodies, control through appropriate measures like sieves, metal detector/X-ray detector on final product;
- shall be free from micro-organisms in amounts which may represent a hazard to health;
- shall be free from insects, its parts or its wiggler, parasites and rodents' excreta which may represent a hazard to health; and
- shall not contain any substance originating from micro-organisms or any other poisonous or deleterious substance such as anti-nutritional factors, heavy metals or pesticide residues, in amounts which may represent a hazard to health.
- Air meeting product after extrusion needs to be filtered, preferably using HEPA Filtration. Filtration effectiveness should be validated for microbiological clearance. High risk areas need to have positive air flow and dust filtration is mandatory.

4.6 Shelf life

The product covered by the provision of this specification shall retain above qualities for at least 18 months from date of manufacture when stored dry at ambient temperatures prevalent in the country of destination. The supplier should conduct their own shelf life studies to confirm shelf-life claims for the labelling. Any major change in production processes, suppliers, ingredients should be addressed in the change management protocol and a clear definition of triggers new shelf-life study should be included.

4.7 Fit for human consumption guarantee

Suppliers shall have to check the quality of their products and guarantee that the product is '**fit for human consumption'**.

5. Packaging

5.1 General requirements

The product covered by the provision of this specification shall be packed in appropriate packaging which safeguard the hygienic, nutritional, technological, and organoleptic qualities of the product. The packaging shall be made of substances which are safe and suitable for their intended use.

5.2 Product net weight

- 1.5 kg Net weight and follow contract requirement for specified net weight,
- Weight and quantity tolerance shall meet The International Organization of Legal Metrology International Recommendation OIML R 87 (OIML R 78 Quantity of commodity in pre-packages https://www.oiml.org/en/files/pdf_r/r087-e04.pdf, latest edition to be followed).

5.3 Primary packaging

Sachets shall be:

- Food grade materials compliant with the last amendments of national regulations in the country of production (if not existing: compliance with EU or FDA legislations requested).
- Optimized shape to avoid space loss in the sachets and in the cartons
- Properly sealed with no leakages (test example: ASTM F2338 – 09, ASTM D3078 – 02 or equivalent)
- The sachets shall be placed in an appropriate way in the carton box during the packing process to avoid packaging damage
- The laminate shall include a barrier layer to highly reduce permeability of oxygen and water vapour. The minimum requirements are:
  - WVTR < 1.5 g/m².day (38°C/90% RH) (ASTM F1249-06 or equivalent)
  - OTR < 5 cc/m².day (23°C/0% RH) (ASTM D-3985 or equivalent)
- Reverse printing is highly recommended

Typically, a laminate composed of "(polyolefin or polyester) * + metallized (polyolefin or polyester) *"

- typical thickness: 70-90 microns - or equivalent can be used. *e.g.
PE, PET, PP
- Nitrogen flushing should be applied during the filling of the powder in sachets. The residual limit of oxygen (O2) should be maximum 2%.

5.4 Secondary packaging

The product shall be packed in cartons suitable for the humanitarian supply chain.
It is under supplier responsibility to select a packaging material that will resist to multiple handling and up to 2 meters stacking.
Cartons shall be:

- New, manufactured from well-constructed double walled corrugated board
- With an edge crush resistance of 60ECT = 60 lbs/in eq 11 kN/m (ISO 3037) and a specific weight of 700 to 1000 grams per square meter
- fully filled for maximum strength and dimensions adjusted to the load
- The fluting shall be vertical, supporting the load
- The carton should be plain brown
- No stapling will be accepted
- firmly closed (top and bottom)

Unless otherwise specified in the contract, two percent (2%) empty, marked cartons (included in the price) shall be sent with the lot.

5.5 Stuffing in Containers and other transport vehicles

Use of desiccant is mandatory in each container to absorb moisture and condensation during shipment to preserve the commodity and packaging performance.
The following table provides a guideline on the quantity to be used;
Table 3: Guideline on the quantity to be used for calcium chloride-based desiccants:

Estimated days in container	20 ft container	40 ft container
15-59 days	9.00 kg	17.50 kg
60-89 days	11.25 kg	22.50 kg
90-120 days	13.50 kg	25.00 kg

- Empty containers/vehicles shall be clean, pest free and free of damage, odors and previous cargo remains. Ventilation holes shall remain clear and unsealed.

If pallets are used inside containers: it is highly recommended to have 3 first bottom layers placed as column stacking, the rest can be interlocked (cross-stacking) for load stability. Pallet shall be wrapped in a suitable manner (locked to the pallet, enough containment force) and the cartons should be banded when necessary. The cartons shall be secured to pallets in order to prevent any damage to the contents or packaging during

shipment. Pallet used should be strong enough to support the charge during transportation. Pallets shall be stackable (minimum double stock) without damage to the cartons during shipment. Also, kraft paper shall be adhered to all internal sides, door, and floor of container. Kraft paper also need to be placed on the top of packaging.

If no pallets are used inside container: dunnage (of strong sheets such as carton, plywood…) should be placed inside each container at every three layers of cartons to provide the required stacking strength. In addition, protecting material like air bag, carton, polystyrene, can be used. Also, kraft paper shall be adhered to all internal sides, door, and floor of container. Kraft paper also need to be placed on the top of packaging.

MARKING

The labelling of the product covered by the provision of this specification shall comply with CODEX STAN

1-1985 The following information should be available on bags and carton:

Table 4: Generic marking requirements

Description	Bags	Cartons
Product name	**SUPER CEREAL - Corn Soya Blend**	
Net weight	1.5 kg to 2.0 kg or *as per contract*	*as per contract*
Ingredient list*	XX[1]; (including allergens[2])	--
Production date (dd/mm/yyyy)	XX	
Best Before End (mm/yyyy)	XX	
Batch/lot number**	XX	
Manufactured by: Name & address	XX	
Supplied by: Name and address***	XX	
Country of Origin	Product of XX	
Storage instruction	"Store under dry, ventilated and hygienic conditions and away from direct sunlight"	Keep dry; Keep away from heat; Stack limitation; Side up Picto
Other requirements	Not for Sale	
Preparation instructions	[pictorial of opening the bag] [pictorial of blending with water] [pictorial of cooking] [pictorial of feeding to adult] [pictorial of closing the bag]	--

*=*Maize, Whole Soya Beans, Minerals and Vitamins*

= *supplier need to clearly describe the batch/lot size for the traceability of the product *=if different from the manufacturer*

[1]All XX shall be provided by the manufacturer.

[2]Allergen labelling guidelines: All ingredients considered allergens as per EU Regulation1169/2011 – Annex II -shall be labelled in bold letters in the ingredient list. The supplier is responsible for creating and maintaining an updated list of allergens present in the manufacturing facility. All products manufactured in that facility shall be labelled with the entire list of allergens identified in that facility, either as ingredients or as cross-contamination.

Templates for artwork available on: https://foodqualityandsafety.wfp.org/specifications

7. Storing

The product shall be stored under dry, ventilated and hygienic conditions.

8. Analytical Requirements

Additional tests may be defined in case further quality assessment is required. The following analytical plans are currently utilized and shared only for suppliers' information. Suppliers should follow its own food safety and quality management plan.

Table 5: List of compulsory tests and reference methods

No	Tests	Requirements	**Reference method***(or equivalent validated methods)*
1	Moisture	Max. 7.0%	ISO 712: 2009

2	Protein	Min. 14.0 g/100g flour (N x 6.25)	ISO 20483 AOAC 992.23 EN ISO 16634-2:2016
3	Fat	Min. 6.0 g/100g flour	ISO 11085
4	Crude fibre	Max. 4.0 g/100g flour	ISO 5498 AOAC 962.09
5	Total ash	Max. 4.1 g/100g flour	ISO 2171 / AOAC 923.03
6	Peroxide value	Max. 10.0 meq/kg fat	AOAC 965.33
7	Urease index	Max. 0.20 pH units	AOCS Ba 9-58 (1997)
8	Particle size	- 95% shall pass through a 600 microns sieve. - 100% shall pass through a 1,000 microns sieve	
9	Organoleptic (smell, taste, color)	Pleasant smell and palatable taste, typical color	Sensorial inspection
10	Consistency (Bostwick flow rate)	Min. 55mm /30s for 15% dry matter porridge	WFP's SOP http://foodqualityandsafety.wfp.org
11	Vitamin A	2770-4160 IU/100g flour	AOAC 992.04
12	Iron	9.4-14.1 mg/100g flour	AOAC 944.02
13	Calcium	340-510 mg/100g flour	AOAC 984.27
14	Potassium	580-870 mg/100g flour	AOAC 984.27
15	Aflatoxin (total)	Max. 10 ppb (total of B1, B2, G1, G2)	ISO 16050 / EN 12955
16	Deoxynivalenol (DON)	Max. 1.0 mg/kg (on dry matter basis)	EN 15891:2010
17	Mesophyllic aerobic bacteria	< 100,000 cfu/g flour	ISO 4833-1:2013 ICC No 125 AACC 42-11.01
18	Coliforms	< 100 cfu/g flour	ISO 4832:2006 AOAC 2005.03 AACC 45-15.02
19	Salmonella	0 cfu/25g flour	ISO6579-1:2017 AACC 42-25.03
20	Escherichia Coli	< 10 cfu/g flour	AOAC 991.14 ISO 16649-2:2001
21	Staphylococcus aureus	< 10 cfu/g flour	EN ISO 6888-2:2004 AACC 42-30.04
22	Bacillus cereus	< 50 cfu/g flour	AOAC 980.31 ISO 7932:2004
23	Yeasts and moulds	< 1,000 cfu/g flour	ISO 21527-2:2008 ICC No 146 AACC 42-50.02
24	GMO *(only if required)*	Negative (< 0.9% of GMO material)	ISO 21569 ISO 24276

9 Manufacturer's Product Assurance

- The manufacturer shall certify that the product provided, meets the requirements of this technical specifications.
- The purchaser or procuring entity shall require proof of conformance

10 Regulatory Requirements

The delivered product shall comply with all applicable Government, County, and local by-laws and regulations relating to the manufacturing, storage, and distribution of packaged foods for human consumption, including all applicable provisions of Food, Drugs and Chemical Substances Act Chapter 254 (2012), Public Health Act Cap 242 (2012) and regulations promulgated thereunder.

All certificates of analysis for both raw materials and delivered product will be from a Kenya National Accreditation Services (KENAS) accredited laboratories or from labs with valid ISO 17025:2005 certification

11 Quality Assurance Provisions

The product manufacturer shall be required to provide evidence, by certificate, that the manufacturing plant has undertaken one of the following quality assurance measures within 12 months prior to providing a bid, or no later than 10 business days from the date of awarding of the contract. Failure to provide this documentation within the proper time frame may result in the contract being terminated for cause.

11.1 ISO 22000 Assessment

A supplier quality assessment (SQA) verifies the manufacturer's capability to produce products in a clean sanitary environment in accordance with ISO 22002-1:2009 – *Prerequisite programmes on food safety part 1: Food Manufacturing* and verifies that the manufacturer has in place an internal quality assurance and food safety program

- A supplier quality audit (SQA) based on ISO 22000:2005 by a third party auditing service is required within 12 months prior to the date of the awarding of the contract.
- The food manufacturer must have attained an SQA score of 75% or above
- The food manufacturer must be ISO 22000 certified.
- The relevant certificate/letter bearing the name of any of the above bodies must be submitted for scrutiny.

11.2 Kenya Bureau of Standards (KEBS) certification

KEBS is the standards authority in Kenya and therefore all food must be approved as safe for human consumption. The locally produced product must have the Standardization mark as this is a mandatory product certification scheme for locally manufactured.

12.0 Packaging and Labelling specifications

All labelling, package inserts and specifications shall be in English.

i. Primary package label:

- ✓ Product Name (both International Non-proprietary Name and Brand)
- ✓ Nutritional information inscribed on the sachet
- ✓ Composition / ingredients
- ✓ Batch number
- ✓ Manufacturing date
- ✓ Best before date
- ✓ Directions for use: Should have pictorials on how the sachet is administered.
- ✓ **Pre-delivery sample and final product delivered** should have a label "*GOK - Not for sale*" clearly labelled in a place where it is visible.

ii. Secondary package label: -

Each Secondary package should have a Product information insert in English containing:

- ✓ Product Name (both International Non-proprietary Name and Brand)
- ✓ Quantity:

The secondary package Carton should contain 16 packets of 1.5kg

- ✓ Batch number
- ✓ Manufacturing date
- ✓ Best before date
- ✓ Storage instructions
- ✓ Contraindications
- ✓ Precautions/Allergies
- ✓ Adverse effects
- ✓ Dosage based on class of body weight as per national guidelines
- ✓ Manufacturers contact information and physical address

- ✓ **Pre-delivery sample and final product delivered** should have a label "*GOK - Not for sale*" clearly labelled in a place where it is visible.

iii. Additional packaging specifications: -

- ✓ Each primary package (sachet/packet) shall contain only one product and one batch.
- ✓ The packaging material should be food grade.
- ✓ All primary packaging must be air tight and UV resistant.
- ✓ Unitary packaging: pallets (as required for sea or for air transport).

Shelf life

Upon the date of receipt to the warehouse, the products should have a minimum of 80% remaining shelf-life. Regardless of whether the deliveries are staggered, the 80% rule will apply.

Item 5: Technical Specifications for Ready to Use Therapeutic Foods (RUTF)

Formulation: Ready-to-use paste

Target population

- ✓ Individuals with severe acute malnutrition
- ✓ Age: **From age 6 months and above**

Ingredients

i. Milk:

>50% proteins from milk/dairy products

Acceptable sources of dairy protein:

- ✓ Skimmed milk powder / Full cream milk powder
- ✓ Whey protein powder

Codex STAN 207-1999: Codex Standard for Milk Powders and Cream Powder

Codex STAN 289-1995: Codex Standard for Whey Powders

ii. Peanut or peanut paste

Codex STAN 200–1995: Codex Standard for Peanuts

CAC/RCP 55-2004: Code of Practice for the Prevention and Reduction of Aflatoxin contamination in Peanuts.

iii. Oil: edible refined vegetable oil

- ✓ Type of oil judiciously chosen

Codex STAN 210-1999: Codex Standard for Named Vegetable Oils

iv. Carbohydrates (sweetener): Lactose & glucose polymers

- ✓ Lactose
- ✓ Sucrose
- ✓ Maltodextrine
- ✓ Fructose
- ✓ Precooked and/or gelatinised starches
- ✓ No honey (risk of Clostridium botulinum toxicity)

=> Properly ground (to avoid granulation, oil separation and leakage)

Codex STAN 212-1999: Codex Standard for Sugars

v. Complex of minerals and vitamins (premix)

- ✓ Shall provide from the list of sources of premix authorized by WFP (DSM Nutritional products / Fortitech, Nicholas Piramal Healthcare Ltd, Hexagon Nutrition, BASF (SternVitamin), GAIN premix facility)
- ✓ CoA provided to the manufacturer for each batch delivered

- ✓ Soluble and easily absorbed by patients with SAM.
- ✓ Added minerals water-soluble and shall not form insoluble components when mixed together.
- ✓ Mineral composition shall not alter the acid-base metabolism of patients with Severe Acute Malnutrition (SAM): moderate positive non-metabolisable base sufficient to eliminate the risk of metabolic acidosis:

vi. Emulsifying agents

Lecithin max 0.5g / 100 grams
Mono and diglycerides max 2g/100g
Level between 1.5 and 2.0 g/100g can be accepted because there is no adverse effect - all triglyceride oil is decomposed to monoglycerides in the digestion system prior to absorption).

vii. Flavoring

Artificial flavorings not allowed, only natural flavors

viii. Antioxidants

Only natural antioxidants
- ✓ Ascorbyl palmitate
- ✓ Mixed tocopherols

BHA and BHT not added as antioxidant

A. Nutritional Composition: the nutritional composition of RUTF should be as indicated below per 100g:

Moisture content	2.5% maximum	Vitamin A	800-1200 µg
Water activity	0.6 maximum	Vitamin D	15-20 µg
Energy	520-550 Kcal	Vitamin E	20 mg minimum
Protein	10-12% of total energy	Vitamin K	15-30 µg
Lipids	45-60% of total energy	Vitamin B1	0.5 mg minimum
ω-6 Fatty acids	3-10% of total energy	Vitamin B2	1.6 mg minimum
ω-3 fatty acids	0.3-2.5% of total energy	Vitamin C	50 mg minimum
Sodium	290 mg Maximum	Vitamin B6	0.6 mg minimum
Potassium	1100-1400mg	Vitamin B12	1.6 µg minimum
Calcium	300-600 mg	Folic Acid	200 µg minimum
Phosphorus	300-600 mg	Niacin	5mg minimum
Magnesium	80-140 mg	Pantothenic Acid	3 mg minimum
Zinc	11-14 mg	Biotin	60 µg minimum
Cooper	1.4-1.8 mg		
Iron	10-14 mg		
Iodine	70-140 µg		
Selenium	20-40 µg		

Product Stability: Should be stable at tropical temperatures and humidity.

Registration

- ✓ Certifications: ALL laboratory analysis certificates MUST be from Kenya Accreditation Services (KENAS) accredited laboratories and/or have ISO 17025:2005 certification.
  - The certificates of analysis must indicate the following parameters:

i. Microbiology

The manufacturer must establish microbiological criteria
Salmonella = highest priority

- ✓ CAC/GL 21, 1997, the Principles for the Establishment and Application of Microbiological Criteria for Foods (revision scheduled for 2013).
- ✓ CAC/GL 63-2007: Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)

Other indicators: **Enterobacteriacea (EB)**

Other criteria: particular attention to:

- ✓ Listeria monocytogenes,
- ✓ Clostridium botulinum and
- ✓ mesophilic aerobic bacteria

ii. List of compulsory tests

S/NO	Parameters	Limit	Method of analysis (or alternative validated method)
1	Protein	10-12% of total energy	AOAC 991.20*
2	Lipid	45-60% of total energy	ISO 17189*
3	Vitamin C	50 mg minimum	EN 14130:2003*, AOAC 2012.21* AOAC 985.33*
4	Iron (Fe)	10-14 mg	AOAC 990.05* ISO 8294*
5	Total Aflatoxin	Max 5 ppb	ISO 16050*
6	Salmonella	As per table below	ISO 6579**
7	Enterobacteriaceae	As per table below	ISO 21528-2***

* Minimum 12 individual sachets from 12 randomly chosen cartons to be mixed into 1 (one) composite test sample by the laboratory

** 25 g analytical unit, samples may be pooled dry, by the laboratory, if lab method has been validated. The total analytical unit should be 625g

*** 10 g analytical unit, no pooling

Microorganisms	n	c	m	M	p-class
Salmonella	25	0	Absent in 25 g	n/a	2
Enterobacteriaceae	10	2	≤10 cfu/g	≤100 cfu/g	3

Where

n: number of sample units;

c: the maximum allowable number of defective sample units in a 2-class plan or marginally acceptable sample units in a 3-class plan;

m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality or, in a 3-class plan, separates good quality from marginally acceptable quality;

M: a microbiological limit which, in a 3-class plan, separates marginally acceptable quality from defective quality;

p: 2 or 3 class plan

- ✓ The food manufacturer must be ISO 22000 certified or have a supplier quality audit certificate (SQA) of above 90% rating (world class standards)
  - The relevant certificate/letter bearing the name of any of the above bodies must be submitted for scrutiny.
- ✓ Approved as safe for human consumption by Kenya Bureau of Standards

iii. Chemical safety

- **Pesticides and Heavy Metals**

Pesticides	ppb	Heavy metals	Mg/kg
Carbamates	<10ppb	Arsenic	<0.06mg/kg
Organochlorine	<10ppb	Cardmium	<0.03mg/kg
Organophosphorus	<10ppb	Lead	<0.1mg/kg
Pyrethroid	<10ppb	Mercury	<0.02mg/kg

- **Melamine:** max 1mg/kg
- **Radioactivity:** <370bq/kg (Cs 134 & Cs 137)

Packaging and Labelling specifications

All labelling, package inserts and specifications shall be in English.

i. **Primary package label:**
- ✓ Product Name (both International Non-proprietary Name and Brand)
- ✓ Nutritional information inscribed on the sachet
- ✓ Composition / ingredients
- ✓ Batch number
- ✓ Manufacturing date
- ✓ Best before date
- ✓ Directions for use: Should have pictorials on how the sachet is administered.
- ✓ **Pre-delivery sample and final product delivered** should have a label "*GOK - Not for sale*" clearly labelled in a place where it is visible.

ii. **Secondary package label: -**
- ✓ Each Secondary package should have a Product information insert in English containing:
- ✓ Product Name (both International Non-proprietary Name and Brand)
- ✓ Quantity:

The secondary package Carton should contain 150 sachets of 92g
- ✓ Batch number
- ✓ Manufacturing date
- ✓ Best before date
- ✓ Storage instructions
- ✓ Contraindications
- ✓ Precautions/Allergies
- ✓ Adverse effects
- ✓ Dosage based on class of body weight as per national guidelines
- ✓ Manufacturers contact information and physical address
- ✓ **Pre-delivery sample and final product delivered** should have a label "*GOK - Not for sale*" clearly labelled in a place where it is visible.
- ✓ The carton should be 5 ply.

iii. **Additional packaging specifications: -**

- ✓ Each primary package (sachet) shall contain only one product and one batch.
- ✓ The packaging material should be food grade.
- ✓ All primary packaging must be air tight and UV resistant.
- ✓ Unitary packaging: pallets (as required for sea or for air transport).

Shelf life

Upon the date of receipt to the warehouse, the products should have a minimum of 80% remaining shelf-life. Regardless of whether the deliveries are staggered, the 80% rule will apply.

Batch Size:

The Ministry of Health (MoH) does not wish to receive batches that exceed 250MT or one (1) week of production. In terms of call down, MoH will not accept products with the same shelf life.

FORM OF TENDER SECURITY - (BANK GUARANTEE)

[The bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.] [Guarantor letterhead or SWIFT identifier code] Beneficiary: *[Procuring Entity to insert its name and address]* ITT No.: *[Procuring Entity to insert reference number for the Invitation to Tender]* Alternative No.: *[Insert identification No if this is a Tender for an alternative]* Date: *[Insert date of issue]*

TENDER GUARANTEE No.: *[Insert guarantee reference number]*

Guarantor: *[Insert name and address of place of issue, unless indicated in the letterhead]*
We have been informed that_[insert name of the Tenderer, which in the case of a joint venture shall be the name of the joint venture (whether legally constituted or prospective) or the names of all members there of] (herein after called" the Applicant") has submitted or will submit to the Beneficiary its Tender (hereinafter called" the Tender") for the execution of_____under Invitation to Tender No._____("the ITT").

Furthermore, we understand that, according to the Beneficiary's conditions, Tenders must be supported by a Tender guarantee.

At the request of the Applicant, we, as Guarantor, hereby irrevocably undertake to pay the Beneficiary any sum or sums not exceeding in total an amount of__(_____) upon receipt by us of the Beneficiary's complying demand, supported by the Beneficiary's statement, whether in the demand itself or a separate signed document accompanying or identifying the demand, stating that either the Applicant:

(a) Has withdrawn its Tender during the period of Tender validity set forth in the Applicant's Form of Tender ("the Tender Validity Period"), or any extension there to provide by the Applicant; or

(b) Having been notified of the acceptance of its Tender by the Beneficiary during the Tender Validity Period or any extension there to provide by the Applicant, (I) has failed to execute the contract agreement, or (ii) has failed to furnish the Performance Security, in accordance with the Instructions to Tenderers ("ITT") of the Beneficiary's tendering document.

This guarantee will expire: (a) if the Applicant is the successful Tenderer, upon our receipt of copies of the contract agreement signed by the Applicant and the Performance Security issued to the Beneficiary in relation to such contract agreement; or (b) if the Applicant is not the successful Tenderer, upon the earlier of (I) our receipt of a copy of the Beneficiary's notification to the Applicant of the results of the Tendering process; or (ii) twenty-eight days after the end of the Tender Validity Period.

Consequently, any demand for payment under this guarantee must be received by us at the office indicated above on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees (URDG) 2010 Revision, ICC Publication No. 758.

_____

[Signature(s)]
;Note: All italicized text is for use in preparing this form and shall be deleted from the final product.

FORM OF TENDER SECURITY (TENDER BOND)

[The Surety shall fill in this Tender Bond Form in accordance with the instructions indicated.]

BOND NO._____

BY THIS BOND *[name of Tenderer]* as Principal (here in after called "the Principal"), and *[name, legal title, and addressofsurety]*,authorizedtotransactbusinessinKenya,asSurety(hereinaftercalled"theSurety"),are held and firmly bound unto *[name of Procuring Entity]* as Oblige (here in after called" the Procuring Entity") in the sum of *[amount of Bond]*[5] *[amount in words]*, for the payment of which sum, well and truly to be made, we, the said Principal and Surety, bind ourselves, our successors and as signs, jointly and severally, firmly by these presents.

WHEREAS the Principal has submitted or will submit a written Tender to the Procuring Entity dated the_____ day of__,20_____, for the supply of [name of Contract](herein after called the "Tender").

NOW, THEREFORE, THE CONDITION OF THIS OBLIGATION is such that if the Principal:

a) has withdrawn its Tender during the period of Tender validity set forth in the Principal's Form of Tender ("the Tender Validity Period"), or any extension there to be provided by the Principal; or

b) having been notified of the acceptance of its Tender by the Procuring Entity during the Tender Validity Period or any extension thereto provided by the Principal; (i) failed to execute the contract agreement; or (ii) has failed to furnish the Performance Security, in accordance with the Instructions to Tenderers("ITT") of the Procuring Entity's tendering document.

Then the Surety under takes to immediately pay to the Procuring Entity up to the above amount upon receipt of the Procuring Entity's first written demand, without the Procuring Entity having to substantiate its demand, provided that in its demand the Procuring Entity shall state that the demand arises from the occurrence of any of the above vents, specifying which event(s) has occurred.

The Surety hereby agrees that its obligation will remain in full force and effect up to and including the date 30 days after the date of expiration of the Tender Validity Period set forth in the Principal's Form of Tender or any extension thereto provided by the Principal.

IN TESTIMONY WHERE OF, the Principal and the Surety have caused these presents to be executed in the irrespective names this_day of_____20_____.

Principal:_____ Surety:_____

Corporate Seal (where appropriate)

_____ _____

(Signature) (Signature)

(Printed name and title) (Printed name and title)

[5]*The amount of the Bond shall be denominated in the currency of Kenya or the equivalent amount in a freely convertible currency.*

TENDER - SECURING DECLARATION FORM

[TheBiddershallcompletethisForminaccordancewiththeinstructionsindicated]

Date: .....*[insert date (as day, month and year) of Tender Submission]*

Tender No.: .....*[insert number of tendering process]*

To: .....*[insert complete name of Purchaser]*

I/We, the undersigned, declare that:

1. I / We understand that, according to your conditions, bids must be supported by a Tender-Securing Declaration.

2. I/We accept that I/ we will automatically be suspended from being eligible for tendering in any contract with the Purchaser for the period of time of [insert number of months or years]starting on [insert date], if we are in breach of our obligation(s) under the bid conditions, because we–(a) have withdrawn our tender during the period of tender validity specified by us in the Tendering Data Sheet; or(b) having been notified of the acceptance of our Bid by the Purchaser during the period of bid validity,(i)fail or refuse to execute the Contract, if required, or(ii) fail or refuse to furnish the Performance Security, in accordance with the instructions to tenders.

3. I / We understand that this Tender Securing Declaration shall expire if we are not the successful Tenderer(s),upon the earlier of:
   a) ourreceiptofacopyofyournotificationofthenameofthesuccessfulTenderer;or
   b) thirty days after the expiration of our Tender.

4. I / We understand that if I am/we are/in a Joint Venture, the Tender Securing Declaration must be in the name of the Joint Venture that submits the bid, and the Joint Venture has not been legally constitute d at the time of bidding, the Tender Securing Declaration shall be in the names of all future partners as named in the letter of intent.

Signed:……..…….....

Capacity / title (director or partner or sole proprietor, etc.)

Name:…….....

Duly authorized to sign the bid for and on behalf of: *[insert complete name of Tenderer]*

Dated on…….....…. day of…….....…. *[Insert date of signing]*

Seal or stamp

MANUFACTURER'S AUTHORIZATION

[The Tenderer shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This Form of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the Manufacturer. The Tenderer shall include it in its Tender, if so indicated in the TDS.]

Date: .....*[insert date (as day, month and year) of Tender submission]*

ITT No.: .....*[insert number of tendering process]*

Alternative No.: .....*[insert identification No if this is a Tender for an alternative]*

To: .....*[insert complete name of Procuring Entity]*
WHEREAS

We *[insert complete name of Manufacturer]*, who are official manufacturers of *[insert type of goods manufactured]*, having factories at *[insert full address of Manufacturer's factories*], do hereby authorize *[insert complete name of Tenderer]* to submit a Tender the purpose of which is to provide the following Goods, manufactured by us*[insert name and or brief description of the Goods]*,and to subsequently negotiate and sign the Contract.

We here by extend our full guarantee and warranty in accordance with Clause 28 of the General Conditions of Contract, with respect to the Goods offered by the above firm.

Signed: .....*[insert signature(s)of authorized representative(s) of the*

Manufacturer] Name: .....*[insert complete name(s)of authorized*

representative(s)of the Manufacturer] Title: .....*[insert title]*

Dated on_____day of_____, _____*[insert date of signing]*

SPECIMEN CERTIFICATE OF A HEALTH PRODUCT

Certificate of a Health Product 1

This certificate conforms to the format recommended by the World Health Organization (general instructions and explanatory notes attached).

No. of certificate:.....

Exporting (certifying) country:.....

Importing (requesting) country: .....

1. Name and dosage form of product:

.....

Active ingredients 1 and amount(s) per unit dose 3

.....

.....

.....

For complete qualitative composition including excipients, see attached 4

Is this product licensed to be placed on the market for use in the exporting country 5 yes/no (key in as appropriate)?

Is this product actually on the market in the exporting country? yes/no/unknown (key in as appropriate) If the answer to 1.2 is yes, continue with section 2A and omit section 2B. If the answer to 1.2 is no, omit section 2A and continue with section 2B 6

2A.1 Number of product license[7] and date of issue:

.....

2A.2 Product-license holder *(name and address)*:

.....

.....

.....

2A.3 Status of product-license holder 8 a/b/c (key in appropriate category as defined in note 8)

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage for are: 9

2A.4 Is Summary Basis of Approval appended 10 yes/no (key in as appropriate)

2A.5 Is the attached, officially approved product information complete and consonant

with the license 11 yes/no/not provided (key in as appropriate)

2A.6 Applicant for certificate, if different from license holder (name and address): 12

2B.1 Applicant for certificate (name and address):

2B.2 Status of applicant: a/b/c (key in appropriate category as defined in note 8

2B.2.1 For categories band c the name and address of the manufacturer producing the dosage for mare: 9

.....

.....

.....

2B.3 Why is marketing authorization lacking?

Not required/not requested/under consideration/ refused (key in as appropriate)

2B.4 Remarks: 13

3. Does the certifying authority arrange for period inspection of the manufacturing plant in which the dosage form is produced?

Yes /no/ not applicable 14 (key in as appropriate) If no or not applicable proceed to question 4. Periodicity of routine inspections(years): Has the manufacture of this type of dosage form been inspected? yes/no(key in as appropriate) Do the facilities and operations conform to GMP as recommended by the World Health Organization[15]yes/no/notapplicable16(key in as appropriate)

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? 11

yes/no (key in as appropriate) If no, explain:

.....

.....

.....

Address of certifying authority:

Telephone number:.....Fax number:.....

Name of authorized person:

.....

Signature:

.....

Stamp and date:

.....

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

1 This certificate, which is in the format recommended by WHO, establishes the status of the Health product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

2Use whenever possible international nonproprietary names (INNs) or national nonproprietary names

.3The formula (complete composition) of the dosage form should be given on the certificate or be appended

.4Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-license holder

.5When applicable, append details of any restriction applied to the sale, distribution, or administration of the product that is specified in the product license. 6Sections 2A and 2B are mutually exclusive.

7Indicate, when applicable, if the license is provisional or if the product has not yet been approved.

8Specify whether the person responsible for placing the product on the market:

a) *Manufactures the dosage form;*
b) *Packages and/or labels a dosage form manufactured by an independent company; or*
c) *Is involved in none of the above.*

9This information can be provided only with the consent of the product-license holder or, in the case of non-registered products, the applicant. Non completion of this Section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license must be updated or it will cease to be valid.

10This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed. 11This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).

12In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission must be provided to the authority by the applicant.

13Please indicate the reason that the applicant has provided for not requesting registration:

a) *The product has been developed exclusively for the treatment of conditions-particularly tropical diseases-not endemic in the country of export.*
b) *The product has been reformulated with a view to improving its stability under tropical conditions.*
c) *The product has been reformulated to exclude excipients not approved for use in* **Health** *products in the country of import.*
d) *Theproducthasbeenreformulatedtomeetadifferentmaximumdosagelimitforanactiveingredient.*
e) *Any other reason, please specify.*

[14]*Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.*

[15]*The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for* ***Health Products*** *Preparations (WHO Technical Report Series, No.823,1992, Annex1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No.822,1992, Annex1).*

[16]*This section is to be completed when the product-license holder or applicant conforms to status(b) or(c) as described in note7above. It is of particular importance*
when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

PART 2 – SUPPLY REQUIREMENTS

SECTION VII - SCHEDULE OF REQUIREMENTS

CONTENTS

NOTES FOR PREPARING THE SCHEDULE OF REQUIREMENTS

The Schedule of Requirements shall be included in the tendering document by the Procuring Entity, and shall cover, at a minimum, a description of the goods and services to be supplied and the delivery schedule.

The objective of the Schedule of Requirements is to provide sufficient information to enable Tenderers to prepare their Tenders efficiently and accurately, in particular, the Price Schedule, for which a form is provided in Section IV. In addition, the Schedule of Requirements, together with the Price Schedule, should serve as a basis in the event of quantity variation at the time of award of contract pursuant to ITT 42.1.

The date or period for delivery should be carefully specified, taking into account (a)the implications of delivery terms stipulated in the Instructions to Tenderers pursuant to the *Incoterms* rules (i.e., EXW, or CIP, FOB, FCA terms-that "delivery" takes place when goods are delivered **to the carriers**), and (b) the date prescribed here in from which the Procuring Entity's delivery obligations start (i.e., notice of award, contract signature, opening or confirmation of the Form of credit).

1. LIST OF GOODS AND DELIVERY SCHEDULE

[The Procuring Entity shall fill in this table, with the exception of the column "Tenderer's offered Delivery date "to be filled by the Tenderer]

Line Item N°	**Description of Goods**	**Quantity**	Unit Of Measure	Place of Delivery	**Delivery (as per Incoterms) Date**		
					Earliest Delivery Date	**Latest Delivery Date**	**Tenderer's offered Delivery date [*to be provided by the Tenderer*]**
[insert item No]	*[insert description of Goods]*	*[insert quantity of item to be supplied]*	*[insert physical unit for the quantity]*	KEMSA (Embakasi Warehouse-Nairobi)	One Week	Fourteen Weeks	*[insert the number of days following the date of effectiveness the Contract]*

2. TECHNICAL SPECIFICATIONS

The purpose of the Technical Specifications (TS), is to define the technical characteristics of the Goods and Related Services required by the Procuring Entity. The Procuring Entity shall prepare the detailed TS take into account that:

- The TS constitute the benchmarks against which the Procuring Entity will verify the technical responsiveness of Tenders and subsequently evaluate the Tenders. Therefore, well-defined TS will facilitate preparation of responsive Tenders by Tenderers, as well as examination, evaluation, and comparison of the Tenders by the Procuring Entity.
- Technical Specifications shall be fully descriptive of the requirements in respect of, but not limited to, the following:
    a) Standards of materials and workmanship required for the production and manufacturing of the Goods.
    b) Detailed tests required (type and number).
    c) Other Related Services required to achieve full delivery/completion.
    d) Detailed activities to be performed by the Supplier, and participation of the Procuring Entity there on.
    e) List of detailed functional guarantees covered by the Warranty and the specification of the liquidated damages to be applied in the event that such guarantees are not met.

A set of precise and clear specifications is a prerequisite for Tenderers to respond realistically and competitively to the requirements of the Procuring Entity without qualifying their Tenders. The sample text provided in this section should serve as guidance only. This text is not intended to be used verbatim since technical specifications specific to each procurement should be drafted by the Procuring Entity for inclusion in the tendering document. In the context of international competitive procurement process among qualified firms, the specifications must be drafted to permit the widest possible The technical specifications establish the requirements for good manufacturing practices (GMPs), pharmacopeial standards, nomenclature, and description required for each product, shelf life and package expiration date parameters, labeling instructions, packaging instructions, GMP and quality assurance certificates required, and other evidence of product quality to be submitted with the Tender and with each shipment. Only if this is done will the objectives of economy, efficiency, and fairness in procurement be realized, responsiveness of Tenders be ensured, and the subsequent task of Tender evaluation facilitated.

Specific pharmacopeia standards should be listed for each product; if any of a range of standards is adequate (British Pharmacopoeia, United States Pharmacopoeia, European Pharmacopoeia, or International Pharmacopoeia), this should be noted. If special packaging or labeling is required for a subset of products, this should be indicated on the schedule of requirements (see above), but a generic statement of packaging and labeling applied to all products should be included in the general technical specifications. Instructions about labeling (contents and language)and package inserts can be included in the technical specifications, unless there are specific requirements for each batch or schedule of requirement.

TECHNICAL SPECIFICATIONS: **HEALTH PRODUCTS,** CONDOMS, VACCINES

SAMPLE TECHNICAL SPECIFICATIONS HEALTH PRODUCTS

1. Product and Package Specifications

1.1.1The Goods to be purchased by the Procuring Entity under this Invitation to Tender are included in the current Kenya Essential Medicines List (KEML)or national formulary. The required packing standards and labeling must meet the latest requirements of the World Health Organization (WHO) good manufacturing practices (GMP) standards in all respects. (These standards are contained in "Good Practices in the Manufacture and Quality Control of Drugs.")

1.1.2Product specifications indicate dosage form (e.g., *tablet, capsules, dry syrup, liquid, ointment, injectable, emulsion, suspension,* etc.) and the drug content (exact number of mg *or international units*[iu] or %v/v, *w/w or w/v or/and an* acceptable range). The Goods should conform to standards specified in the following compendia: The *British Pharmacopoeia,* the *United States Pharmacopeia,* the *International Pharmacopoeia*, or the *European Pharmacopoeia, The standards will be the latest edition unless otherwise stated by the Procuring Entity or other if applicable.* In case the health product is not included in the specified compendium, *but included in the KEML, the Procuring Entity shall clearly indicate and* the Supplier upon award of the Contract, must provide the reference standards and testing protocols to allow for quality control testing.

1.1.3Not only the **Health Products** item, but also the packaging and labeling components (e.g., bottles, closures, and labeling) should also meet specifications suitable for distribution, storage, and use in a climatic zones assigned to Kenya. All packaging must be properly sealed and tamper-proof, and packaging components must meet the latest compendium standards and be approved for **Health Products** packaging by the manufacturer's national regulatory authority(RA). The Procuring Entity should specify any additional special requirements.

1.1.4 All labeling and packaging inserts shall be in English.

1.1.5 Goods requiring refrigeration or freezing *or those that should not fall below a certain minimum temperature* or stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry.

1.2 General

1.2.1 Not only the **Health Products** or Vaccine item, but also the packaging components (e.g., bottles and closures) should meet specifications suitable for use in a climatic zone assigned to Kenya. All packaging must be properly sealed and tamper-proof.

1.2.2 The successful bidder shall provide such packing of the Health Products 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 Health Products' final destination and the absence of heavy handling facilities at all points in transit.

1.2.3 Whenever plastics are used as packing for I.V. Fluids, the type of plastics used should

be clearly indicated in the offer and specification relating to their properties.

1.2.4 Certificate of quality control for sterility, Pyrogenicity, Acute toxicity and physicochemical test.

1.2.5 Method of analysis of the same accompanied with the samples, if different method of analysis is used than indicates in USP or BP, should be submitted along with the offer

1.2.6 Light-sensitive **Health Products** must be packed in containers that allow maximum protection from light. Labels on the containers should bear " Protect from Light"

1.2.7 Packing should be suitable to resist heat & humidity at the port of embarkation for:-

- Humidity up to 12-100%
- Temperature up to 50^{o} C
- All plastic and glass containers should be of **Health Products** Grade and should meet the parameters in BP or USP for containers.

1.3 Specific

The following are some of the packing conditions for the tender:-

1.3.1 Infusions

For all plastic containers a study at least covering sterility, pyrogenicity, acute toxicity, and physicochemical test should accompany the offer during the supply of the products. The concentration of electrolytes shall be stated on the label in milli equivalents (meq). The label of the product shall also indicate the quantity of ingredients in terms of weight or percentage concentration.

1.3.2 Ampoules and Vials

Ampoules must be packed in rigid paperboard boxes, strong enough to resist crushing during transportation in units of 5, 10 or similar multiples.
Vials must be packed in rigid paperboard boxes, strong enough to resist crushing during transportation in units of 5, 10 or similar multiples but should not exceed 50. The vials must be separated using separators,
.

1.3.4 Topical Preparations

Content with less than 50gm in leak-proof collapsible metallic or plastic tube, for volumes above 50gm in aluminum foil or plastic jars with close fitting caps or slip on lids

1.3.5 Elixir Oral Suspension & Syrup

Oral suspension should be packed in Pilfer proof cap plastic or glass bottles. Light sensitive products shall be packed in Pilfer proof cap amber colored glass or non-transparent plastic bottles with measuring accessories co-packed. This should be packed in well-padded strong carton. Bottles of powder for oral suspension should have a clear marking to show the required volume. The cap and wad on every bottle should be watertight and leak proof.

1.3.6 Tablets, Capsules

Tablets should be packed in suitable polythene bags or blister pack laminated aluminum strips, packed in well closed and light resistant containers of appropriate size. The containers should be tamper-proof and sealed.

1.4 Packaging of Products

Items should be packaged as follows:

(i) 100 ml bottles, not more than 100 per carton
(ii) 200 ml bottles, not more than 50 per carton
(iii) 500 ml bottles, not more than 24 per carton
(iv) 1.0 litre bottles, not more than 12 per carton
(v) 2.5 litre bottles, not more than 6 per carton
(vi) 5.0 litre bottles, not more than 4 per carton
(vii) For ear- and eye drops a maximum of 24 should be packed in each carton and the box must be partitioned if the contents are more than 6.

Specifications for plastic containers used shall be as follows:

- 5 Litre Jerry can- High Density
- 2 Litre Jerry can– High Density
- 1 Litre jerry can- High Density

1.5 Tertiary Packing (Not applicable to tender sample but at pre-delivery and full consignment for the successful tenderer, however bidders are advised to verify the nature of packaging material before bidding.)

1.5.1 Tertiary packing shall be undertaken in Heavy Duty five-ply non-recycled cartons **(175K/B/175K/C/175K)** duly labeled, marked and double strapped. The shapes of the cartons must be consistent and complementary to allow stacking. Sample available at KEMSA Procurement Offices for viewing.

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

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

1.5.4 All carton flaps must be properly secured and sealed with special repackers gum paper tapes and double strapped..

1.5.5 To facilitate manual loading and off-loading, the dimensions of each carton should not exceed 610mm x 460mm x 355 mm. The Gross weight of each parked carton should not exceed 30kg

2. Labeling Instructions

2.1 The label of the primary container for each **Health Products** and vaccine product shall meet the W210 GMP standard and include:

a) The international nonproprietary name (INN) or generic name prominently displayed.,

where a brand name has been given it must be in addition to the INN.

b) Dosage form, e.g., tablet, ampoule, syrup, etc.;
c) The active ingredient" per unit, dose, tablet or capsule, etc.";
d) The applicable pharmacopoeia standard;
e) the procuring entity unique marking (to be checked at predelivery);
f) Content per pack;
g) Instructions for use;
h) Storage requirements;
i) Batch/ lot number;
j) Date of manufacture and date of expiry (in clear English language, not code);
k) Name and address of manufacture;
l) Any additional cautionary statement.

All labeling and packaging inserts shall be in English.

THE SAMPLE INCLUDING LITERATURE (INSERTS) SHOULD BE SUBMITTED.

All outer cartons should be labeled as follows:

KEMSA
TENDER NO. KEMSA/GOK-MOH/OIT006/2022-2024
KENYA MEDICAL SUPPLIES AUTHORITY
COMMERCIAL STREET
P. O. BOX 47715-00100, NAIROBI

2.2 The outer case or carton should also display the above information.

3. Cartons/ Case Identification

3.1 All cases/cartons should prominently indicate the following:

a) Procuring entity's Name and Address
b) The generic name of the product;
c) The dosage form(tablet, ampoule, syrup);
d) Date of manufacture and expiry (in clear English language not code);
e) Batch number;
f) Quantity per case;
g) instructions for storage
h) The phrase " Keep out of the reach of children"
i) Name and address of both the manufacturer and manufacturing site.
j) All labeling shall be original and imprinted (by use of indelible ink) on the product package
k) Any additional cautionary statements.

3.2 No case/carton should contain **Health Products** from more than one batch.

4. Unique Identifiers

4.1 The word "**KEMSA**" shall be extensively and conspicuously imprinted (by use of indelible ink) on the primary, secondary and tertiary packaging of products to be supplied to the

procuring entity. (Not applicable to tender sample but at pre-delivery and full consignment for the successful tenderer.)

Bar coding Requirements for All KEMSA Medical Supplies
(Application of International Barcoding Standards)

Bar code Requirements

Product, primary and secondary packaging

These barcode requirements must be provided together with any other requirements in this document.

The barcode should be an internationally recognised barcode.

Product barcode: The product barcode should be provided on the product and the primary product packaging. The barcode should be an internationally recognised barcode. The product barcode should be clearly printed on the product in both barcode format and human readable format.

In addition, the following should be provided in barcode format and human readable format.

1. Manufacture date (barcode format and human readable format)
2. Expiry date (barcode format and human readable format)
3. Batch No. (barcode format and human readable format)

All other human readable Information on product packaging shall be as required under Existing Regulatory labeling & marking requirements

5. Standards of Quality Control for Supply

5.1 The successful bidder will be required to furnish to the Procuring Entity:

a) With a certificate of analysis for each batch containing the requisite test parameters as per the compendia or in house test methods

b) Assay methodology of any or all tests if requested.

c) Evidence of bio-availability and/or bio-equivalence for certain critical Goods upon request. *This information would be supplied on a strictly confidential basis only.*

d) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.

5.2 The Supplier will also be required to provide the Procuring Entity with access to its manufacturing facilities to inspect the compliance with the GMP requirements and quality control mechanisms.

6. Tender Sample

6.1 A properly labeled sample of each item quoted must be delivered to Kenya Medical Supplies Authority on or before closing of the tender at 10.00 a.m. on **Tuesday, 21st October 2022.** The sample must be of the required pack size as indicated in the schedule of requirements.

6.2 The sample including literature **(inserts)** should be submitted in their normal or usual commercial packing as registered by the Kenya Pharmacy and Poison's Board, and should be labeled in English. The sample must be a true representative of the product tendered for and remaining shelf life of at least 120 days from date of submission.

SAMPLE TECHNICAL SPECIFICATION

VACCINES

1. Product Specifications

2.1 Dosage form (e.g.: oral or injectable; liquid or freeze dried with sterile diluent packed separately, etc.).

2.2 Type (e.g.: "live attenuated," "manufactured from purified inactivated (...) obtained from human plasma or manufactured using recombinant DNA technology," etc.).

2.3 Administration (e.g.: "intended for intramuscular injection," etc.).

2.4 Description of intended use (e.g.: "immunization of new born infants," etc.).

2.5 Dosage size (if not restrictive), or expected immune genic reaction (e.g.: each dose shall contain that amount of Hbs ag-protein with micrograms/ml specified by the manufacturer for new born dosage, that when given as part of a primary immunization series[3doses] is capable of producing specific humoral anti-body [anti-HBs] at a level of at least10milliinternationalunitsin>-90 percent of recipients," etc.).

2.6 Dose package (e.g.: "5 infant dose sterile glass vials," etc.).

2.7 Filling volume (e.g.: "final product should contain 15% overfill," etc.).

2.8 Closures (e.g.: "vaccine vials shall befitted with closures that conform to ISO standard 8362-2").

2.9 Storage temperature (e.g.: "2–8 degrees C. Do not freeze," or as appropriate, etc.).

2.10 The product should remain stable up to the indicated test expiry date if kept according to the required storage temperature.

2.11 Standards (e.g.: "The vaccine should conform to standards established by Kenya or, where no standard has been adopted, meet current requirements published by the WHO Expert Committee on Biological Standardization, or requirements of an established body of equivalent stature such as the *U.S. Pharmacopoeia, the British Pharmacopoeia, the French Pharmacopoeia, or the International Pharmacopoeia*").

2. Labeling Requirements

3.1 Each vial or ampoule shall carry the manufacturer's standard label in the language of Kenya, if available at no extra charge; otherwise, the label shall be in English.

3.2 Each vial or ampoule label shall state the following:

a) Name of the vaccine;

b) Name of the manufacturer;

c) Place of manufacture;

d) Lot number;

e) composition;

f) concentration;

g) dose mode for administration;

h) expiration date;

i) Special instructions for storage (Should state the actual temperatures);

j) any other information that is appropriate.

3.3 All labeling shall with stand immersion in water and remain intact.

3. Packing Requirements

4.1 Inner boxes: Inner Boxes shall contain no more than (*number*) individual vials/ampoules and shall be constructed of sturdy white cardboard outfitted with individual segments for protecting and separating each vial/ampoules.

4.2 Printed materials: Each inner box shall contain at least (*number*) manufacturer's standard package inserts in the language of Kenya if available at no extra charge; otherwise, package insert shall be in English.

4.3 Over packing: Inner boxes shall be over packed so that the vaccine remains refrigerated as designated in Clause 2.9. The over packing must be suitable for export handling and be in accordance with WHO Expanded Program of Immunization (EPI) Guidelines on International Packaging and Shipping of Vaccines including all measures needed to maintain required temperatures for seventy-two (72) hours. It must have adequate insulation and sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above that designated in Sub-Clause 2.9 when exposed to continuous outside temperature of +43 degrees C, nor fall below that specified of-20 degrees C during transit and for a period of at least twenty-four (24) hours after arrival at the airport destination. Additional cushioning shall be provided sufficient to protect the vials/ampoules from breakage during transit and handling.

4.4 Exterior shipping cartons: Product and printed materials, packaged as described above, shall be packed in weather-resistant, triple-wall corrugated fiberboard cartons with a bursting test strength of not less than 1,900k Pa. The overall dimensions of the exterior shipping cartons should be such that the product does not become damaged during transportation and storage.

No shipping carton should contain vaccine from more than one lot.

4.5 Cold chain monitor cards: Each insulated shipping container must include appropriate temperature-monitoring devices designated by the Procuring Entity.

a) At least two suitable cold chain monitor cards, as approved by the Procuring Entity, shall be packed in each transport case of vaccine.

b) Freeze watch indicators shall be included in each transport case at the direction of Procuring Entity.

4.6 The bidder is required at the time of delivery to use a cold chain vehicle whose temperatures meet the storage requirements of the awarded product. However, bidders should communicate to KEMSA before delivery of the product.

4. Marking Requirements

5.1 All containers and invoices must bear the following information:

a) The name of the vaccine;

b) Expiration date of the vaccine;

c) Appropriate storage temperature.

5.2 Inner boxes: The inner boxes containing vaccine vials or ampoules shall be marked with the following information in a clearly legible manner that is acceptable to the Procuring Entity:

d) Generic name and trade name of the vaccine;

e) Manufacturer's name and trade registered address;
f) Manufacturer's national registration number;
g) Lot or batch number;
h) Composition and concentration;
i) Number of vials contained in box;
j) Manufacturing date (month and year in clear English language, not code);
k) Expiration date (month and year in clear English language, not code);
l) Instructions for storage and handling;
m) Site of manufacture (Made in_).

5.3 Exterior Shipping Cartons: The following information shall be stenciled or labeled on the exterior shipping cartons on two opposing sides in bold letters at least 30 mm high with waterproof ink in a clearly legible manner that is acceptable to the Procuring Entity.

n) Generic name and trade name of the vaccine;
o) Lot or batch number;
p) Manufacturing date (month and year in clear English language, not code);
q) Expiration date (month and year in clear English language, not code);
r) Manufacturer's name and registered address;
s) Manufacturer's national registration number;
t) Destination airport and routing;
u) Consignee's name and address in full;
v) Consignee contact name and telephone number;
w) Number of vials or ampoules contained in the carton;
x) Gross weight of each carton (in kg);
y) Carton#___of_____;
z) Instructions for storage and handling;
aa) Contract number;
bb) Site of manufacture (Made in_).

5. Quality Control for Supply

6.1 All goods must:

a) Meet the requirements of manufacturing legislation and regulation of vaccines in the country of origin;
b) Meet internationally recognized standards for safety, efficacy ,and quality;
c) conform to all the specifications and related documents contained herein;
d) be fit for the purposes expressly made known to the Supplier by the Procuring Entity;
e) be free from defects in workmanship and materials; and
f) be certified by competent authority in the manufacturer's country according to resolution WHA28-65(2), of the WHO release certificate.

6.2 The Supplier will be required to furnish to the Procuring Entity with each consignment;

a) A certificate of quality control and test results in conformity with the WHO release certificate.

b) Assay methodology of any or all tests if required.

c) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.

6.3 Pre-shipment inspection and testing: The Supplier will be required to provide the Procuring Entity or their representative with access to the product as packed for shipment at the sellers' factory and/or warehouse at a mutually agreeable time prior to shipment of the product.

a) The Procuring Entity may inspect and sample, or cause to be sampled, such product.

b) The Procuring Entity may cause independent laboratory testing to be performed as deemed necessary to ensure that the Goods conform to prescribed requirements.

The testing laboratory shall be of the Procuring Entity's choice and suitably equipped and qualified to conduct quality control test on biological products.

SAMPLE TECHNICAL SPECIFICATIONS

CONDOMS

1. Product and Package Specifications

1.1 The Goods must conform to the manufacturer's current standards for condoms and specified in line with the ISO 4074 Standard for Latex Rubber Condoms.

1.2 Biocompatibility assessments shall be conducted in accordance with ***ISO 10993–1.*** Specifically, tests shall be conducted for cytotoxicity according to *ISO 10993–5* and for irritation and sensitization according to ***ISO 10993–10.*** Manufacturers should choose accredited laboratories for these tests, and the results should be interpreted by an accredited toxicologist or other suitably qualified expert. Expert reports should be available for review. *Manufacturers and/or the purchasers are advised to confirm local requirements for safety testing with appropriate regulatory authorities in the countries in which the condoms are to be distributed.* In accordance with *ISO 10993–1,* manufacturers may provide data on equivalent products.

1.3 The specifications for the Goods shall indicate critical factors, i.e., bursting volume and pressure, freedom from holes, width and length, thickness, lubricant quality, and viscosity.

1.4 The Goods and packaging and labeling components shall meet the standards specified in the latest WHO specification, including batch-by-batch independent quality control laboratory tests.

1.5 Condoms should be shipped in special containers to ensure stability in transit from point of shipment to port/air port of entry and point of destination for CIP deliveries. Any special temperature requirements must be designed to meet the climatic conditions prevailing in Kenya, and the Procuring Entity should advise the Supplier of any particular requirements.

2. Labeling

2.1 The primary pack should be labeled in accordance with the latest WHO specifications and include:

a) Manufacturer's name and registered address;

b) Batch/ Lot number (printed at the time of packaging);

c) Month and year of manufacture and Expiry (Year should be written as four- digit number and month as a two-digit number)

d) Nominal width of condom expressed in millimeters

e) Number of condoms in the box

f) Instructions for storage

2.2 The secondary packing, i.e., the inner box, should be labeled in accordance with the latest WHO specifications and include:

g) Batch/Lot number ;

h) Month and year of manufacture and Expiry (Year should be written as four- digit number and month as a two-digit number) (including the words: Date of Manufacture/month/year);

i) Manufacturer's name and registered address;

j) Nominal width expressed in millimeters;

k) Number of condoms in box/carton;

l) Instructions for storage;

m) Shipping carton clearly labelled "**KEMSA"**

3. Packaging Specification

3.1 All exterior shipping cartons and packaging must comply with the latest WHO specification for packaging of condoms.

4. Case Identification

4.1 All cases should predominantly indicate the following:

a) Batch/Lot number;

b) Month and year of manufacture (including the words: Date of Manufacture/month/year);

c) Name and address of supplier;

d) Nominal width expressed in millimeters;

e) Number contained in the carton;

f) Instructions for storage and handling; and

g) Month and year of expiry.

5. Lot Traceability

5.1 All exterior shipping cartons for each batch should be assembled and shipped together to facilitate the monitoring of batch quality during shipping and storage.

5.2 Both codes should be used on exterior shipping cartons, color coded for ease of identification if requested by the Procuring Entity.

6. Unique Identifiers

6.1 The Procuring Entity will have the right to request the Supplier to imprint, provided the quantity justifies it, a logo on the packaging of the condoms. The design and details will be clearly indicated at the time of Tendering and shall be provided to the Supplier at the time of contract award.

7. Standards of Quality Control for Supply

7.1 The Supplier will be required to provide the Procuring Entity with access to its manufacturing facilities to inspect compliance with the GMP requirements and quality control mechanisms.

8. Quality Control Testing

8.1 a) The Supplier shall be required to carry out testing of a proposed shipment in line with the WHO specification, and the size of sample will be calculated by reference to ISO2859-1.

b) With each consignment the Supplier must provide a certificate of quality control test results in conformity with the WHO specifications and in accordance with the general sampling levels appropriate to each feature as necessary.

3. INSPECTIONS AND TESTS

The following inspections and tests shall be performed: *[insert list of inspections and tests].*

1.0 In-house Examination by KEMSA
2.0 Test conducted by the NQCL
3.0 Tests conducted by Kenya Bureau of Standards (KEBS)

PART 3 - CONTRACT

SECTION VIII - GENERAL CONDITIONS OF CONTRACT

1. Definitions

1.1 The following words and expressions shall have the meanings here by assigned to them:

"Completion" means the fulfillment of the Related Services by the Supplier in accordance with the terms and conditions set forth in the Contract.

"Contract Documents" means the documents listed in the Contract Agreement, including any amendments thereto.

"Contract Price" means the price payable to the Supplier as specified in the Contract Agreement, subject to such additions and adjustments thereto or deductions therefrom, as may be made pursuant to the Contract.

"Contract" means the Contract Agreement entered into between the Procuring Entity and the Supplier, together with the Contract Documents referred to therein, including all attachments, appendices, and all documents incorporated by reference therein.

"Day" means calendar day. "GCC "means the General Conditions of Contract.

"Goods" means all of the **Health Products** including nutritional supplement and oral and injectable forms of contraception, vaccines, and condoms Supplier is required to supply to the Procuring Entity under the Contract.

"Laws" means all national legislation, statutes, ordinances, and regulations and by-laws of any legally constituted public authority.

"Letter of Acceptance" means the letter of formal acceptance, signed by the contractor. Procuring Entity, including any annexed memoranda comprising agreements between and signed by both Parties.

"Procuring Entity" means the Entity named in the Special Conditions of Contract.

"Procuring Entity" means the entity purchasing the Goods and Related Services, as

specified **in the SCC.**

"Public Procurement Regulatory Authority (PPRA)"shall mean the agency responsible in Kenya for regulating and monitoring the public procurement function

"Registration Certificate" means the certificate of registration or other documents in lieu thereof establishing that the Goods supplied under the Contract are registered for use in Kenya in accordance with the Applicable Law.

"Related Services" means the services incidental to the supply of the goods, such as insurance, installation, training and initial maintenance and other such obligations of the Supplier under the Contract.

"Supplier" means the person, private or government entity, or a combination of the above, who's Tender to perform the Contract has been accepted by the Procuring Entity and is named as such in the Contract Agreement.

"The Project Site," where applicable, means the place named **in the SCC.**

SCC" means the Special Conditions of Contract.

2. Contract Documents

Subject to the order of precedence set forth in the Contract Agreement, all documents forming the Contract (and all parts thereof) are intended to be correlative, complementary, and mutually explanatory. The Contract Agreement shall be read as a whole. The documents forming the Contract shall be interpreted in the following order of priority:

a) The Contract Agreement,
b) The Letter of Acceptance,
c) The Special Conditions– Part A,
d) The Special Conditions–Part B
e) The General Conditions of Contract
f) The Form of Tender,
g) The Specifications and Schedules of the Drawings(if any),and
h) The Schedules of Requirements and any other documents forming part of the Contract.

3. Fraud and Corruption

3.1 The Procuring Entity requires compliance with anti-corruption laws and guidelines and its prevailing sanctions policies and procedures as set forth in Laws of Kenya.

3.2 The Procuring Entity requires the Supplier to disclose any commissions or fees that may have been paid or are to be paid to agents or any other party with respect to the Tendering process or execution of the Contract. The information disclosed must include at least the name and address of the agent or other party, the amount and currency, and the purpose of the commission, gratuity or fee.

4. Interpretation

4.1 If the context so requires it, singular means plural and vice versa.

4.2 Incoterms

a) Unless inconsistent with any provision of the Contract**,** the meaning of any trade term and the rights and obligations of parties there under shall be as prescribed by Incoterms specified **in the SCC**.

b) The terms EXW, CIP, FCA, CFR and other similar terms, when used, shall be governed by the rules prescribed in the current edition of Incoterms specified **in the SCC** and published by the International Chamber of Commerce in Paris, France.

4.3 Entire Agreement

The Contract constitutes the entire agreement between the Procuring Entity and the Supplier and supersedes all communications, negotiations and agreements (whether written or oral) of the parties with respect there to made prior to the date of Contract.

4.4 Amendment

No amend mentor other variation of the Contract shall be valid unless it is in writing, is dated, expressly refers to the Contract, and is signed by a duly authorized representative of each party thereto.

4.5 Non waiver

a. Subject to GCC Sub-Clause4.5 (b)below, no relaxation, forbearance, delay, or indulgence by either party in enforcing any of the terms and conditions of the Contractor the

granting of time by either party to the other shall prejudice, affect, or restrict the rights of that party under the Contract, neither shall any waiver by either party of any breach of Contract operate as waiver of any subsequent or continuing breach of Contract.

b. Any waiver of a party's rights, powers, or remedies under the Contract must be in writing, dated, and signed by an authorized representative of the party granting such waiver, and must specify the right and the extent to which it is being waived.

4.6 Severability

If any provision or condition of the Contract is prohibited or rendered invalid or unenforceable, such prohibition, invalidity or unenforceability shall not affect the validity or enforceability of any other provisions and conditions of the Contract.

5. Language

5.1 The Contract as well as all correspondence and documents relating to the Contract exchanged by the Supplier and the Procuring Entity, shall be written in the English language**.** Supporting documents and printed literature that are part of the Contract may be in another language provided they are accompanied by an accurate translation of the relevant passages in the English language**,** in which case, for purposes of interpretation of the Contract, this translation shall govern.

5.2 The Supplier shall bear all costs of translation to the governing language and all risks of the accuracy of such translation, for documents provided by the Supplier.

6. Joint Venture, Consortium or Association

6.1 If the Supplier is a joint venture, consortium, or association, all of the parties shall be jointly and severally liable to the Procuring Entity for the fulfillment of the provisions of the Contract and shall designate one party to act as a leader with authority to bind the joint venture, consortium, or association. The composition or the constitution of the joint venture, consortium, or association shall not be altered without the prior consent of the Procuring Entity.

7. Eligibility

7.1 The Supplier and its Subcontractors shall have the nationality of an eligible country. A Supplier or Subcontract shall be deemed to have the nationality of a country if it is a citizen or constituted, incorporated, or registered, and operates in conformity with the provisions of the laws of that country.

7.2 All Goods and Related Services to be supplied under the Contract shall have their origin in Eligible Countries. For the purpose of this Clause, origin means the country where the goods have been grown, mined, cultivated, produced, manufactured, or processed; or through manufacture, processing, or assembly, another commercially recognized article results that differs substantially in its basic characteristics from its components.

8. Notices

8.1 Any notice given by one party to the other pursuant to the Contract shall be in writing to the address specified **in the SCC.** The term "in writing" means communicated in written form with proof of receipt.

8.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

9. Governing Law

9.1 The Contract shall be governed by and interpreted in accordance with the laws of Kenya**.**

9.2 Throughout the execution of the Contract, the Supplier shall comply with the import of goods and services prohibitions in Kenya when

a) As a matter of law or official regulations, Kenya prohibits commercial relations with that country; or

b) by an act of compliance with a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations, Kenya prohibits any import of goods from that country or any payments to any country, person, or entity in that country.

10. Settlement of Disputes

10.1 The Procuring Entity and the Supplier shall make every effort to resolve amicably by direct negotiation any disagreement or dispute arising between them under or in connection with the Contract.

10.1.1If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the Procuring Entity or the Supplier may give notice to the other party of its intention to commence arbitration, as herein after provided, as to the matter in dispute, and no arbitration in respect of this matter may be commenced unless such notice is given. Any dispute or difference in respect of which a notice of intention to commence arbitration has been given in accordance with this Clause shall be finally settled by arbitration. Arbitration may be commenced prior to or after delivery of the Goods under the Contract.

10.2 Arbitration proceedings shall be conducted as explained in SCC

10.2.1 Any claim or dispute between the Parties arising out of or in connection with the Contract not settled amicably in accordance with Sub-Clause10.1shall be finally settled by arbitration.

10.2.2 No arbitration proceedings shall be commenced on any claim or dispute where notice of a claim or dispute has not been given by the applying party within thirty days of the occurrence or discovery of the matter or issue giving rise to the dispute.

10.2.3 Notwithstanding the issue of a notice as stated above, the arbitration of such a claim or dispute shall not commence unless an attempt has in the first instance been made by the parties to settle such claim or dispute amicably with or without the assistance of third parties. Proof of such attempt shall be required.

10.2.4 The Arbitrator shall, without prejudice to the generality of his powers, have powers to direct such measurements, computations, or valuations as may in his opinion be desirable in order to determine the rights of the parties and assess and award any sums which ought to have been the subject of or included in any due payments.

10.2.5 Neither Party shall be limited in the proceedings before the arbitrators to the evidence, or to the reasons for the dispute given in its notice of a claim or dispute.

10.2.6 Arbitration may be commenced prior to or after delivery of the goods. The obligations of the Parties shall not be altered by reason of any arbitration being conducted during the progress of the delivery of goods.

10.2.7 The terms of the remuneration of each or all the members of Arbitration shall be mutually agreed upon by the Parties when agreeing the terms of appointment. Each Party shall be responsible for paying one-half of this remuneration.

10.3 Arbitration Proceedings

10.3.1 Arbitration proceedings with both national suppliers will be conducted in accordance with

the Arbitration Laws of Kenya. In case of any claim or dispute, such claim or dispute shall be notified in writing by either party to the other with a quest to submit it to arbitration and to concur in the appointment of an Arbitrator within thirty days of the notice. The dispute shall be referred to the arbitration and final decision of a person or persons to be agreed between the parties. Failing agreement to concur in the appointment of an Arbitrator, the Arbitrator shall be appointed, on the request of the applying party, by the Chairman or Vice Chairman of any of the following professional institutions;

i) Kenya National Chamber of Commerce

ii) Chartered Institute of Arbitrators (Kenya Branch)

iii) The Law Society of Kenya

10.3.2 The institution written to first by the aggrieved party shall take precedence overall other institutions.

10.4 Arbitration with Foreign Suppliers

10.4.1 Arbitration with foreign suppliers shall be conducted in accordance with the arbitration rules of the United Nations Commission on International Trade Law (UNCITRAL); or with proceedings administered by the International Chamber of Commerce (ICC) and conducted under the ICC Rules of Arbitration; by one or more arbitrators appointed in accordance with said arbitration rules.

10.4.2 The place of arbitration shall be a location specified in the **SCC;** and the arbitration shall be conducted in the language for communications defined in Sub-Clause1.4 [Law and Language].

10.5 Alternative Arbitration Proceedings

10.5.1 Alternatively, the Parties may refer the matter to the Nairobi Centre for International Arbitration (NCIA) which offers a neutral venue for the conduct of national and international arbitration with commitment to providing institutional support to the arbitral process.

11. Inspections and Audit by the PPRA

11.1 The Supplier shall keep, and shall make all reasonable efforts to cause its Subcontractors and sub-consultants to keep accurate and systematic accounts and records in respect of the Goods in such form and details as will clearly identify relevant time changes and costs.

11.2 Pursuant to paragraph 2.2e. of Appendix to the General Conditions the Supplier shall permit and shall cause its subcontractors and sub-consultants to permit, PPRA and/or persons appointed by the PPRA to inspect the Site and/or the accounts and records relating to the procurement process, selection and/ or contract execution, and to have such accounts and records audited by auditors appointed by the PPRA. The Supplier's and its Subcontractors' and sub-consultants' attention is drawn to Sub-Clause 3.1 which provides, inter alia, that acts intended to materially impede the exercise of the PPRA's inspection and audit rights constitute a prohibited practice subject to contract termination.

12. Scope of Supply

12.1 The Goods and Related Services to be supplied shall be as specified in the Schedule of Requirements.

13. Delivery and Documents

13.1 Subject to GCC Sub-Clause 33.1, the Delivery of the Goods and Completion of the Related Services shall be in accordance with the Delivery and Completion Schedule specified in the Schedule of Requirements. The details of shipping and other documents to be furnished by

the Supplier are specified **in the SCC.**

14. Supplier's Responsibilities

14.1 The Supplier shall supply all the Goods and Related Services included in the Scope of Supply in accordance withGCCClause12, and the Delivery and Completion Schedule, as per GCCClause13.

15 Contract Price

15.1 Prices charged by the Supplier for the Goods supplied and the Related Services performed under the Contract shall not vary from the prices quoted by the Supplier in its Tender, with the exception of any price adjustments authorized **in the SCC.**

16. Terms of Payment

16.1 The Contract Price, including any Advance Payments, if applicable, shall be paid as specified **in the SCC.**

16.2 The Supplier's Invitation to payment shall be made to the Procuring Entity in writing, accompanied by invoices describing, as appropriate, the Goods delivered and Related Services performed, and by the documents submitted pursuant to GCCClause13 and upon fulfillment of all other obligations stipulated in the Contract.

16.3 Payments shall be made promptly by the Procuring Entity, but in no case later than sixty (60) days after submission of an invoice or Invitation to payment by the Supplier, and after the Procuring Entity has accepted it.

16.4 The currencies in which payments shall be made to the Supplier under this Contract shall be those in which the Tender price is expressed.

16.5 In the event that the Procuring Entity fails to pay the Supplier any payment by its due date or within the period set forth **in the SCC,** the Procuring Entity shall pay to the Supplier interest on the amount of such delayed payment at the rate shown **in the SCC,** for the period of delay until payment has been made in full, whether before or after judgment or arbitrage award.

17. Taxes and Duties

17.1 For goods manufactured outside Kenya, the Supplier shall be entirely responsible for all taxes, stamp duties, license fees, and other such levies imposed outside Kenya.

17.2 For goods Manufactured within Kenya, the Supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted Goods to the Procuring Entity.

17.3 If any tax exemptions, reductions, allowances or privileges may be available to the Supplier in Kenya, the Procuring Entity shall use its Lowest efforts to enable the Supplier to benefit from any such tax savings to the maximum allowable extent.

18. Performance Security

18.1 If required as specified in the SCC, the Supplier shall, within twenty-eight (28) days of the notification of contract award, provide a Performance Security for the performance of the Contract in the amount specified **in the SCC.**

18.2 The proceeds of the Performance Security shall be payable to the Procuring Entity as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.

18.3 As specified in the SCC, the Performance Security, if required, shall be denominated in the currency (ies) of the Contract, or in a freely convertible currency acceptable to the Procuring Entity; and shall be in one of the format stipulated by the Procuring Entity **in the SCC,** or in another form at acceptable to the Procuring Entity.

18.4 The Performance Security shall be discharged by the Procuring Entity and returned to the Supplier not later than twenty-eight (28) days following the date of Completion of the Supplier's performance obligations under the Contract, including any warranty obligations, unless specified otherwise **in the SCC.**

19. Certification of Goods in Accordance with Laws of Kenya

19.1 If required under the Applicable Law, Goods supplied under the Contract shall be registered for use in Kenya. The Procuring Entity undertakes to cooperate with the Supplier to facilitate registration of the Goods for use in Kenya as specified **in the SCC**.

19.2 Unless otherwise specified **in the SCC,** the Contract shall become effective on the date("the Effective Date") that the Supplier receives written notification from the relevant authority in Kenya that the Goods have been registered for use in Kenya.

19.3 If thirty (30) days, or such longer period specified **in the SCC,** elapse from the date of Contract signing and the Contract has not become effective pursuant to Sub-Clause 19.2 above, then either party may, by not less than seven (7) days' written notice to the other party, declare this Contract null and void. In such event, the Supplier's Performance Security shall be promptly returned.

20. Confidential Information

20.1 The Procuring Entity and the Supplier shall keep confidential and shall not, without the written consent of the other party hereto, divulge to any third party any documents, data, or other information furnished directly or indirectly by the other party hereto in connection with the Contract, whether such information has been furnished prior to, during or following completion or termination of the Contract. Notwithstanding the above, the Supplier may furnish to its Subcontractor such documents, data, and other information it receives from the Procuring Entity to the extent required for the Subcontractor to perform its work under the Contract, in which event the Supplier shall obtain from such Subcontractor an undertaking of confidentiality similar to that imposed on the Supplier under GCC Clause 20.

20.2 The Procuring Entity shall not use such documents, data, and other information received from the Supplier for any purposes unrelated to the contract. Similarly, the Supplier shall not use such documents, data, and other information received from the Procuring Entity for any purpose other than the performance of the Contract.

20.3 The obligation of a party under GCC Sub-Clauses20.1 and 20.2 above, however, shall not apply to information that:

a) the Procuring Entity or Supplier need to share with the PPRA or other institutions participating in the financing of the Contract;
b) now or here after enters the public domain through no fault of that party;
c) can be proven to have been possessed by that party at the time of disclosure and which was not previously obtained, directly or indirectly, from the other party; or
d) otherwise lawfully becomes available to that party from a third party that has no obligation of confidentiality.

20.4 The above provisions of GCC Clause 20 shall not in any way modify any undertaking of confidentiality given by either of the parties hereto prior to the date of the Contract in respect of the Supply or any part thereof.

20.5 The provisions of GCC Clause 20 shall survive completion or termination, for whatever reason,

of the Contract.

21. Subcontracting

21.1 The Supplier shall notify the Procuring Entity in writing of all subcontracts awarded under the Contract if not already specified in the Tender. Such notification, in the original Tender or later shall not relieve the Supplier from any of its obligations, duties, responsibilities, or liability under the Contract.

21.2 Subcontractors shall comply with the provisions of GCC Clauses 3 and 7.

22. Specifications and Standards

22.1 The Goods supplied under this Contract shall conform to technical specifications and standards mentioned in Section VII, Schedule of Requirements and, when no applicable standard is mentioned, to the authoritative standards appropriate to the Goods' country of origin. Such standards shall be the latest issued by the concerned institution.

23. Packing and Documents

23.1 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. During transit, the packing shall be sufficient to withstand, without limitation, rough handling and exposure to extreme temperatures, salt and precipitation, 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.

23.2 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 the SCC,** and in any other instructions ordered by the Procuring Entity.

24. Insurance

24.1 Unless otherwise specified **in the SCC, the** Goods supplied under the Contract shall be fully insured-in a freely convertible currency from an eligible country—against loss or damage incidental to manufacture or acquisition, transportation, storage, and delivery, in accordance with the applicable Incoterms or in the manner specified in the **SCC.**

25. Transportation and Incidental Services

25.1 Unless otherwise specified **in the SCC,** responsibility for arranging transportation of the Goods shall be in accordance with the specified Incoterms.

25.2 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 start-up 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 Procuring Entity's personnel, at the Supplier's plant and/or on-site, in assembly, start-up, operation, maintenance, and/or repair of the supplied Goods.

25.3 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

26. Inspections and Tests

26.1 The Supplier shall at its own expense and at no cost to the Procuring Entity carry out all such tests and/or inspections of the Goods and Related Services as are specified **in the SCC.**

26.2 The inspections and tests may be conducted on the premises of the Supplier or the manufacturer, at point of delivery, and /or at the Goods' final destination, or in another place in Kenya as specified **in the SCC.** Subject to GCCSub-Clause26.3, if conducted on the premises of the Supplier or the manufacturer, all reasonable facilities and assistance, including access to production data, shall be furnished to the inspectors at no charge to the Procuring Entity.

26.3 The Procuring Entity or its designated representative shall be entitled to attend the tests and/or inspections referred to in GCC Sub-Clause 26.2, provided that the Procuring Entity bear all of its own costs and expenses incurred in connection with such attendance including, but not limited to, all traveling and board and lodging expenses.

26.4 Whenever the Supplier is ready to carry out any such test and inspection, it shall give a reasonable advance notice, including the place and time, to the Procuring Entity. The Supplier shall obtain from any relevant third party or manufacturer any necessary permission or consent to enable the Procuring Entity or its designated representative to attend the test and/or inspection.

a) Said inspection and testing is for the Procuring Entity's account. In the event that inspection and testing is required prior to dispatch, the Goods shall not be shipped unless a satisfactory inspection and quality control report has been issued in respect of those Goods.

b) The Supplier may have an independent quality test conducted on a batch ready for shipment. The cost of such tests will be borne by the Supplier.

c) Upon receipt of the Goods at place of final destination, the Procuring Entity's representative shall inspect the Goods or part of the Goods to ensure that they conform to the condition of the Contract and advise the Procuring Entity that the Goods were received in apparent good order. The Procuring Entity will issue an Acceptance Certificate to the Supplier in respect of such Goods (or part of Goods). The Acceptance Certificate shall be issued within ten (10) days of receipt of the Goods or part of Goods at place of final destination.

26.5 Where the Supplier contests the validity of the rejection by the Procuring Entity or his representative, of any inspection as required by 26.4 above conducted before shipment or at ultimate destination, whether based on product or packing grounds, a sample drawn jointly by the Supplier and Procuring Entity or his or her representative and authenticated by both, will be forwarded for umpire analysis within four weeks of the time the Supplier contests to an independent agency mutually agreed by the Procuring Entity and Supplier. The umpire's finding, which will be promptly obtained, will be final and binding on both parties. The cost of umpire analysis will be borne by the losing party;

26.6 The Procuring Entity may require the Supplier to carry out any test and/or inspection not required by the Contract but deemed necessary to verify that the characteristics and performance of the Goods comply with the technical specifications codes and standards under the Contract, provided that the Supplier's reasonable costs and expenses incurred in the carrying out of such test and/or inspection shall be added to the Contract Price. Further, if such test and/or inspection impedes the progress of manufacturing and/or the Supplier's performance of its other obligations under the Contract, due allowance will be made in respect of the Delivery Dates and Completion Dates and the other obligations so affected.

26.7 The Supplier shall provide the Procuring Entity with a report of the results of any such test and/or inspection.

26.8 The Procuring Entity may reject any Goods or any part there of that fail to pass any test and/or inspection or do not conform to the specifications. The Supplier shall either rectify or replace such rejected Goods or parts thereof or make alterations necessary to meet the specifications at no cost to the Procuring Entity, and shall repeat the test and/or inspection, at no cost to the Procuring Entity, upon giving a notice pursuant to GCC Sub- Clause26.4.

26.9 The Supplier agrees that neither the execution of attest and/or inspection of the Goods or any part thereof, nor the attendance by the Procuring Entity or its representative, nor the issue of any report pursuant to GCC Sub-Clause 26.7, shall release the Supplier from any warranties or other obligations under the Contract.

27. Liquidated Damages

27.1 Except as provided under GCC Clause 32, if the Supplier fails to deliver any or all of the Goods by the Date (s) of delivery or perform the Related Services within the period specified in the Contract, the Procuring Entity may without prejudice to all its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage specified **in the SCC** of the delivered price of the delayed Goods or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage specified **in the SCC.** Once the maximum is reached, the Procuring Entity may terminate the Contract pursuant to GCCClause35.

28. Warranty

28.1 All goods must be of fresh manufacture and must bear the dates of manufacture and expiry.

The Supplier further warrants that all Goods supplied under the Contract will have remaining a minimum of five-sixths (5/6) of the specified shelf life upon delivery at port/ airport of entry for goods with a shelf life of more than two years and three-fourths (3/4) for goods with shelf life of two years or less, unless otherwise specified **in the SCC;** have "overages" within the ranges set forth in the Technical Specifications, where applicable; are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect willfully comply in all respects with the Technical Specifications and with the conditions laid down in the Contract.

28.2 The Procuring Entity shall have the right to make claims under the above warranty for three months after the Goods have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the Procuring Entity, the Supplier shall, with all reasonable speed, replace the defective Goods without cost to the Procuring Entity. The Supplier will be entitled to remove, at his own risk and cost, the defective Goods once the replacement Goods have been delivered.

28.3 In the event of a dispute by the Procuring Entity, a counter-analysis will be carried out on the manufacturer's retained samples by an independent neutral laboratory agreed by both the Procuring Entity and the Supplier. If the counter-analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective goods. In the event of the independent analysis confirming the quality of the product, the Procuring Entity will meet all costs for such analysis.

28.4 If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 28.2 above, the Supplier fails to replace the defective Goods within the period specified **in the SCC** the Procuring Entity may proceed to take such remedial action as may be necessary, including removal and disposal, at the Supplier's risk and expense and without prejudice to any other rights that the Procuring Entity may have against the Supplier under the Contract. The Procuring Entity will also be entitled to claim for storage in respect of the defective Goods for the period following notification and deduct the sum from payments due to the Supplier under this Contract. *Recalls.* In the event any of the Goods are recalled,

the Supplier shall notify the Procuring Entity within fourteen (14) Days, providing full details of the reason for the recall and promptly replace, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfill its recall obligation promptly, the Procuring Entity will, at the Supplier's expense, carry out the recall.

29. Patent Indemnity

29.1 The Supplier shall, subject to the Procuring Entity's compliance with GCC Sub-Clause 29.2, indemnify and hold harmless the Procuring Entity and its employees and officers from and against any and all suits, actions or administrative proceedings, claims, demands, losses, damages, costs, and expenses of any nature, including attorney's fees and expenses, which the Procuring Entity may suffer as a result of any infringement or alleged infringement of any patent, utility model, registered design ,trade mark, copyright, or other intellectual property right registered or otherwise existing at the date of the Contract by reason of:

a) The installation of the Goods by the Supplier or the use of the Goods in the country where the Site is located; and

b) the sale in any country of the products produced by the Goods. Such indemnity shall not cover any use of the Goods or any part thereof other than for the purpose indicated by or to be reasonably inferred from the Contract, neither any infringement resulting from the use of the Goods or any part thereof, or any products produced there by in association or combination with any other equipment, plant, or materials not supplied by the Supplier, pursuant to the Contract.

29.2 If any proceedings are brought or any claim is made against the Procuring Entity arising out of the matters referred to in GCC Sub-Clause 29.1, the Procuring Entity shall promptly give the Supplier a notice thereof, and the Supplier may at its own expense and in the Procuring Entity's name conduct such proceedings or claim and any negotiations for the settlement of any such proceedings or claim.

29.3 If the Supplier fails to notify the Procuring Entity within twenty-eight (28) days after receipt of such notice that it intends to conduct any such proceedings or claim, then the Procuring Entity shall be free to conduct the same on its own behalf.

29.4 The Procuring Entity shall, at the Supplier's request, afford all available assistance to the Supplier in conducting such proceedings or claim, and shall be reimbursed by the Supplier for all reasonable expenses incurred in so doing.

29.5 The Procuring Entity shall indemnify and hold harmless the Supplier and its employees, officers, and Subcontractors from and against any and all suits, actions or administrative proceedings, claims, demands, losses, damages, costs, and expenses of any nature, including attorney's fees and expenses, which the Supplier may suffer as a result of any infringement or alleged infringement of any patent, utility model, registered design, trademark, copyright, or other intellectual property right registered or otherwise existing at the date of the Contract arising out of or in connection with any design, data, drawing, specification, or other documents or materials provided or designed by or on behalf of the Procuring Entity.

30 Limitation of Liability

31.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 29,

a) the Supplier shall not be liable to the Procuring Entity, 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 liquidated damages to the Procuring Entity and

b) the aggregate liability of the Supplier to the Procuring Entity, 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, or to any obligation of the supplier to indemnify the Procuring Entity with respect to patent infringement.

31. Change in Laws and Regulations

31.1 Unless otherwise specified in the Contract, if after the date of 30 days prior to date of Tender submission, any law, regulation, ordinance, order or bylaw having the force of law is enacted, promulgated, abrogated, or changed in the place of Kenya where the Site is located (which shall be deemed to include any change in interpretation or application by the competent authorities) that subsequently affects the Delivery Date and/or the Contract Price, then such Delivery Date and/or Contract Price shall be correspondingly increased or decreased, to the extent that the Supplier has thereby been affected in the performance of any of its obligations under the Contract. Notwithstanding the foregoing, such additional or reduced cost shall not be separately paid or credited if the same has already been accounted for in the price adjustment provisions where applicable, in accordance with GCCClause15.

32. Force Majeure

32.1 The Supplier shall not be liable for forfeiture of its Performance Security, liquidated damages, or termination for default if and to the extent that it's delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.

32.2 For purposes of this Clause, "Force Majeure" means an event or situation beyond the control of the Supplier that is not foreseeable, is unavoidable, and its origin is not due to negligence or lack of care on the part of the Supplier. Such events may include, but not be limited to, acts of the Procuring Entity in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes.

32.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Procuring Entity in writing of such condition and the cause there of. Unless otherwise directed by the Procuring Entity 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.

33. Change Orders and Contract Amendments

33.1 The Procuring Entity may at any time order the Supplier through notice in accordance GCC Clause 8, to make changes within the general scope of the Contract in any one or more of the following:

a) drawings, designs, or specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Procuring Entity;
b) the method of shipment or packing;
c) the place of delivery; and
d) the Related Services to be provided by the Supplier.

33.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or in the Delivery/Completion Schedule, or both, and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this Clause must be asserted within twenty-eight (28) days from the date of the Supplier's

receipt of the Procuring Entity's change order.

33.3 Prices to be charged by the Supplier for any Related Services that might be needed but which were not included in the Contract 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.

33.4 Subject to the above, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties. This includes, if specified **in the SCC**, any variation to the contract resulting from a value engineering proposal agreed between the parties.

34. Extensions of Time

34.1 If at any time during performance of the Contract, the Supplier or its sub-contractors should encounter conditions impeding timely delivery of the Goods or completion of Related Services pursuant to GCC Clause 13, the Supplier shall promptly notify the Procuring Entity in writing of the delay, its likely duration, and its cause. As soon as practicable after receipt of the Supplier's notice, the Procuring Entity shall evaluate the situation and may at its discretion extend the Supplier's time for performance, in which case the extension shall be ratified by the parties by amendment of the Contract.

34.2 Except in case of Force Majeure, as provided under GCCClause32, a delay by the Supplier in the performance of its Delivery and Completion obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 27, unless an extension of time is agreed upon, pursuant to GCC Sub-Clause 34.1.

35. Termination

35.1 Termination for Default

a) The Procuring Entity, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate the Contract in whole or in part:
   i) if the Supplier fails to deliver any or all of the Goods within the period specified in the Contract, or within any extension thereof granted by the Procuring Entity pursuant to GCCClause34;
   ii) if the Supplier fails to perform any other obligation under the Contract; or
   iii) if the Supplier, in the judgment of the Procuring Entity has engaged in Fraud and Corruption, as defined in paragraph 2.2a of the Appendix to the GCC, in competing for or in executing the Contract.

b) In the event the Procuring Entity terminates the Contract in whole or in part, pursuant to GCC Clause 35.1(a), the Procuring Entity may procure, upon such terms and in such manner as it deems appropriate, Goods or Related Services similar to those undelivered or not performed, and the Supplier shall be liable to the Procuring Entity for any additional costs for such similar Goods or Related Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.

35.2 Termination for Insolvency.

c) The Procuring Entity may at any time terminate the Contract by giving notice to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. In such event, termination will be without compensation to the supplier, provided that such termination will not prejudice or affect any right of action or remedy that has accrued or will accrue thereafter to the Procuring Entity.

35.3 Termination for Convenience.

d) The Procuring Entity, by notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify

that termination is for the Procuring Entity's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.

e) The Goods that are complete and ready for shipment within twenty-eight (28) days after the Supplier's receipt of notice of termination shall be accepted by the Procuring Entity at the Contract terms and prices. For the remaining Goods, the Procuring Entity may elect:

   i) To have any portion completed and delivered at the Contract terms and prices; and/or

   ii) to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Related Services and for materials and parts previously procured by the Supplier.

36. Assignment

36.1 Neither the Procuring Entity nor the Supplier shall assign, in whole or in part, their obligations under this Contract, except with prior written consent of the other party.

37. Export Restriction

Notwithstanding any obligation under the Contract to complete all export formalities, any export restrictions attributable to the Procuring Entity, to Kenya or to the use of the products/goods, systems or services to be supplied, which arise from trade regulations from a country supplying those products/goods, systems or services, and which substantially impede the Supplier from meeting its obligations under the Contract, shall release the Supplier from the obligation to provide deliveries or services, always provided, however, that the Supplier can demonstrate to the satisfaction of the Procuring Entity that it has completed all formalities in a timely manner, including applying for permits, authorizations and licenses necessary for the export of the products/goods, systems or services under the terms of the Contract. Termination of the Contract on this basis shall be for the Procuring Entity's convenience pursuant to Sub-Clause 35.3.

APPENDIX TO GENERAL CONDITIONS

Section IX-Special Conditions of Contract The following Special Conditions of Contract (SCC) shall supplement and/ or amend the General Conditions of Contract (GCC). Whenever there is a conflict, the provisions here in shall prevail over those in the GCC.

[The Procuring Entity shall select insert the appropriate wording using the samples below or other acceptable wording, and delete the text in italics]

Special Conditions of Contract

GCC 1.1 (j)	The Procuring Entity is: Kenya Medical Supplies Authority (KEMSA)
GCC 1.1 (o)	The project site/ final destination is: KEMSA Embakasi Supply Chain Centre
GCC 4.2 (a)	Incoterms 2020
GCC 4.2 (b)	DDP Incoterms 2020
GCC 5.1	The Language shall be English
GCC 8.1	For **notices** the procuring entity's address shall be: Kenya Medical Supplies Authority (KEMSA) Commercial Street, Industrial Area Nairobi/Kenya Postal address: P.O. Box: 47715 00100 Nairobi Kenya Tel No: +254 719033000/ +254 726618520/1 E- mail procure@kemsa.co.ke
GCC 10.2.4	The place of arbitration shall be: Nairobi, Kenya-the venue shall be as agreed by the parties
GCC 10.2	Clause 10.2 (a) shall be retained in the case of a Contract with a foreign Supplier and Clause 10.2 (b) shall be retained in the case of a Contract with a national of the Purchaser's country. The dispute resolution mechanism to be applied pursuant to GCC Sub-Clause 10.2 shall be as follows: *(i)* ***Contracts with foreign Supplier:*** GCC 10.2 (a) –All disputes arising in connection with the present Contract shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with said rules. (ii) ***Contracts with Supplier national of the Purchaser's country:*** In the case of a dispute between the Purchaser and a Supplier who is a national of the Purchaser's country, the dispute shall be referred to adjudication or arbitration in accordance with the laws of the Purchaser's country.
GCC 13.1	**For goods supplied from abroad under Incoterms DDP, KEMSA** Upon shipment, the Supplier shall notify the Purchaser and the insurance company in writing the full details of the shipment including Contract number, description of the Goods, quantity, date and place of shipment, mode of transportation, and estimated date of arrival at place of destination. In the event of Goods sent by airfreight, the Supplier shall notify the Purchaser a minimum of forty-eight (48) hours ahead of dispatch, the name of the carrier, the flight number, the expected time of arrival, and the waybill number. Under all transport modes, the Supplier shall send the following documents to the Purchaser, with a copy to the

insurance company:

(i) Three originals and two copies of the Supplier's invoice, showing Purchaser as Consignee; the Contract number, grant no., goods description, quantity, unit price, and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/seal;

(ii) one original and two copies of the negotiable, clean, on-board through MT Document marked "freight prepaid" and showing Purchaser as Consignee and Notify Party as stated in the Contract, with delivery through to final destination as per the Schedule of Requirements and two copies of non-negotiable bill of lading, or three copies of railway consignment note, road consignment note, truck or air waybill, or multi-modal transport document, marked "freight prepaid" and showing delivery through to final destination as per the Schedule of Requirements;

(iii) copy of the packing list identifying contents of each package;

(iv) copy of the Insurance Certificate, showing the Purchaser as the Beneficiary;

(v) one original of the manufacturer's or supplier's Warranty Certificate covering all items supplied;

(vi) one original of the Supplier's Certificate of Origin covering all items supplied;

(vii) each batch to be accompanied by Certificate of Analysis (CoA) stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods origin;

(viii) any other procurement-specific documents required for delivery/payment purposes;

(ix) one original of the Certificate of Pharmaceutical Product as per the WHO's recommended template for each of the items supplied;

(x) one original and one copy of a protocol (certificate of analysis) of a product test per batch conducted by the laboratory of the manufacturer .

At arrival of the goods at port of clearance, the Supplier or its Shipping agent shall provide the Purchaser with:

1) Arrival notice

and

2) Delivery note.

	The above documents 1) and 2) shall be received by the Purchaser immediately after arrival of the Goods at port of clearance and, if not received, the Supplier will be responsible for any consequent expenses. **Note:** In the event that the documents presented by the Supplier are not in accordance with the Contract, payment will be made against issue of the Acceptance Certificate, to be issued in accordance with **SCC** 9 (GCC 9) above.
	For goods supplied from within the Purchaser's country under Incoterms EXW, delivered to named place of destination: The Supplier shall notify the Purchaser at least forty-eight (48) hours ahead of delivery of the goods in writing and deliver the following documents to the Purchaser: (i) two originals and two copies of the Supplier's invoice, showing Purchaser, the Contract number, grant number, goods description, quantity, unit price, and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/seal; (ii) two copies of delivery note, railway consignment note, road consignment note, truck or air waybill, or multimodal transport document showing Purchaser as consignee and delivery through to final destination as stated in the Contract; (iii) copy of the Insurance Certificate, showing the Purchaser as the Beneficiary; (iv) four copies of the packing list identifying contents of each package; (v) one original of the manufacturer's or Supplier's Warranty certificate covering all items supplied; (vi) one original of the Supplier's Certificate of Origin covering all items supplied; (vii) each batch to be accompanied by Certificate of Analysis (CoA) stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods (viii) other procurement-specific documents required for delivery/payment purposes (ix)
GCC 15.1	The prices charged for the goods supplied and the related services performed *shall not* be adjustable
GCC 16.1	Payment shall be made in supplier's currency.
GCC 16.5	Not Applicable
GCC 18.1	A performance Security shall be required for awards above Kenya Shillings Five Million. Performance Security shall not exceed 10% of the contract value.
GCC 18.3	The Performance Security shall be in the form of a Bank Guarantee

	The Performance Security shall be denominated in a freely convertible currency.
GCC 18.4	Discharge of Performance Security shall be done twenty- Eight (28) days following the date of Completion of the Supplier's performance obligations under the Contract.
GCC 19.1	The registration and other certification necessary to prove registration in Kenya shall be: Product registration and retention with Pharmacy and Poisons Board of Kenya (PPB).
GCC 19.2	Not Applicable
GCC 19.3	Not used
GCC 23.2	Additional requirements for packing and transport are indicated in Technical Specifications
GCC 24.1	The insurance coverage shall be as specified in the incoterms
GCC 25.1	Responsibility for transportation shall be as specified in the incoterms
GCC 25.2	Incidental services to be provided: The Supplier shall provide all necessary licenses and permissions for use of the Goods in the Purchaser's country that may be required for the Goods. The cost shall be deemed included in the Contract Price.
GCC 26.1	The Supplier shall demonstrate conformity to Kenya Standards or approved equivalents by evidence of Test report or Certificate from ISO/IEC 17025 accredited laboratory, recognized by the International Laboratory Accreditation Co-operation (ILAC) or preferable from any conformity body recognized by the International Federation of Inspection Agencies (IFIA) prior to shipment. Cost shall be borne by the supplier.
GCC 26.2	The tests and inspection can be conducted at an ISO/IEC 17025 accredited laboratory, recognized by the International Laboratory Accreditation Co-operation (ILAC) or preferable from any conformity body recognized by the International Federation of Inspection Agencies (IFIA)
GCC 27.1	The applicable rate is one-half (0.5) percent per week, the maximum rate is ten (10) percent of the Contract Price and this shall be deducted from the payment due to the supplier.
GCC 28.1	All Goods supplied under the Contract will have a remaining minimum of seventy-five percent (75%) of the shelf life but for commodities that have a shelf life of less than one year, a remaining shelf life of 50% shall be acceptable.
GCC 28.4	The Supplier shall remove, at his own risk and cost, the defective Goods Within fourteen (14) Days of the advice by the Procuring Entity.
GCC 33.4	Not Applicable

HEALTH PRODUCTS

(Additional Clauses)

The below data should be included in the Special Conditions of Contract used in tendering document for the procurement of **Health Products**.

GCC 13.1	1.
	2. A copy if the retention certificate from Pharmacy and Poisons Board of Kenya.
	3. A record of cold chain transportation conditions for goods on transit.

Special Conditions of Contract

VACCINES

Additional Clauses under SCC for Vaccines

GCC 13.1	1.
	2. A copy if the retention certificate from Pharmacy and Poisons Board of Kenya.
	3. A record of cold chain transportation conditions for goods on transit.
	4. one copy of the Lot Release Certificate issued by the NCA of the country of manufacture for each lot shipped.
GCC 28.1	The Procuring Entity reserves the right to request evidence of bio-availability and/orbio-equivalence data and/or evidence of the basis for expiration dating and other stability data concerning the Goods to verify shelf life claimed for the Goods. If an adverse event following immunization (AEFI) occurs in Kenya and the cause of such event cannot be immediately established, the Procuring Entity will, with allurgency and in accordance with the procedures laid down by the NCA of Kenya, take steps to advise the Supplier in order that an investigation may be launched immediately. If the vaccine has been supplied through an agency of the United Nations, the most current procedures laid down by the WHO for such situations will be used.

Special Conditions of Contract

CONDOMS

GCC13.1	*The Supplier shall test batches of Goods ready for shipment in accordance with the WHO specification. The size of the sample for testing will be calculated by reference to ISO2859-1. With each consignment, the Supplier must provide a certificate of quality control test results in conformity with the standards laid down in ISO 2859-1 and in accordance with the general sampling levels appropriate to each feature as necessary. The Supplier will bear the cost of such tests.* (x) original copy of the certificate of inspection furnished to Supplier by nominated inspection agency and six copies *[where separate inspection is required].*
	For Goods from within Kenya: (ix) certificate of in-house analysis.

SECTION X - CONTRACT FORMS

This Section contains forms which, once completed, will form part of the Contract. The forms for Performance Security and Advance Payment Security, when required, shall only be completed by the successful Tenderer after Contract award.

Table of Forms

NOTIFICATION OF INTENTION TO AWARD

[This Notification of Intention to Award shall be sent to each Tenderer that submitted a Tender.]

[*Send this Notification to the Tenderer's Authorized Representative named in the Tenderer Information Form*] For the attention of Tenderer's Authorized Representative Name: .....*[insert Authorized Representative's name]*

Address:.....*[insert Authorized Representative's Address]* Telephone/Fax numbers:.....*[insert Authorized Representative's telephone/fax numbers]*

Email Address:.....*[insert Authorized Representative's email address]*

[IMPORTANT: insert the date that this Notification is transmitted to Tenderers. The Notification must be sent to all Tenderers simultaneously. This means on the same date and as close to the same time as possible.]

DATE OF TRANSMISSION: This Notification is sent by:.....*[email/fax]* on *[date]* (local time)

Notification of Intention to Award Procuring Entity: .*Kenya Medical Supplies Authority*

Contract title:.....*[insert the name of the contract]*

ITT No:.....*[insert ITT reference number from Procurement Plan]*

This Notification of Intention to Award (Notification) notifies you of our decision to award the above contract. The transmission of this Notification begins the Standstill Period. During the Standstill Period you may:

a) Request a debriefing in relation to the evaluation of your Tender, and/or

b) Submit a Procurement-related Complaint in relation to the decision to award the contract.

1. The successful Tenderer

Name:	*[insert name of successful Tenderer]*
Address:	*[insert address of the successful Tenderer]*
Contract price:	*[insert contract price of the successful Tender]*

2. **Other Tenderers** ***[INSTRUCTIONS:*** *insert names of all Tenderers that submitted a Tender. If the Tender's price was evaluated include the evaluated price as well as the Tender price as readout.]*

Name of Tenderer	Tender price	Evaluated Tender price (if applicable)
[*insert name*]	[*insert Tender price*]	[*insert evaluated price*]
[*insert name*]	[*insert Tender price*]	[*insert evaluated price*]
[*insert name*]	[*insert Tender price*]	[*insert evaluated price*]
[*insert name*]	[*insert Tender price*]	[*insert evaluated price*]
[*insert name*]	[*insert Tender price*]	[*insert evaluated price*]

3. **Reason/s why your Tender was unsuccessful**

[INSTRUCTIONS: *State the reason/s why this Tenderer's Tender was unsuccessful. Do NOT include:(a) a point by point comparison with another Tenderer's Tender or (b) information that is marked confidential by the Tenderer in its Tender.]*

5. How to request a debriefing

DEADLINE: The deadline to request a debriefing expires at midnight on [*the 3rd day after date of notification*] (local time).

You may request a debriefing in relation to the results of the evaluation of your Tender. If you decide to request a debriefing your written request must be made within three (3) Business Days of receipt of this Notification of Intention to Award.

Provide the contract name, reference number, name of the Tenderer, contact details; and address the Invitation to debriefing as follows:

Attention:
The Chief Executive Officer
Kenya Medical Supplies Authority (KEMSA)
Commercial Street, Industrial Area
Nairobi/Kenya

Postal address:
P.O. Box: 47715
00100 Nairobi
Kenya
Tel No: +254 719033000/ +254 726618520/1

E- mail: procure@kemsa.co.ke

If your Invitation to a debriefing is received within the 3 Business Days deadline, we will provide the debriefing within five (5) Business Days of receipt of your request.

The debriefing will be in writing,..

If the deadline to request a debriefing has expired, you may still request a debriefing. In this case, we will provide the debriefing as soon as practicable, and normally no later than fifteen (15) Business Days from the date of publication of the Contract Award Notice.

5. How to make a complaint

Period: Procurement-related Complaint challenging the decision to award shall be submitted by midnight,
***[of the 14th day after date of notification]* (local time).**

Provide the contract name, reference number, name of the Tenderer, contact details; and address the Procurement- related Complaint as follows:
The Chief Executive Officer
Kenya Medical Supplies Authority (KEMSA)
Commercial Street, Industrial Area
Nairobi/Kenya

Postal address:
P.O. Box: 47715
00100 Nairobi
Kenya
Tel No: +254 719033000/ +254 726618520/1

E- mail: procure@kemsa.co.ke.At this point in the procurement process, you may submit a Procurement-related Complaint challenging the decision to award the contract. You do not need to have requested, or received, a debriefing before making this complaint. Your complaint must be submitted within the Standstill Period and received by us before the Standstill Period ends.

Further information:
Further information: For more information refer to the Public Procurement and Disposals Act 2015 and its Regulations available from the Website info@ppra.go.keor complaints@ppra.go.ke provides a useful explanation of the process, as well as a sample Form of complaint.

In summary, there are four essential requirements:

1. You must be an 'interested party'. In this case, that means a Tenderer who submitted a Tender in this tendering process, and is the recipient of a Notification of Intention to Award.
2. The complaint can only challenge the decision to award the contract.
3. You must submit the complaint with in the period stated above.
4. You must include, in your complaint, all of the information required by the Procurement Regulations

6. Standstill Period

DEADLINE: The Standstill Period is due to end *on the 14th day after date of notification]* at midnight on *[insert date]* (local time).

The Stand still Period lasts fourteen (14) Days after the date of transmission of this Notification of Intention to Award. The Standstill Period may be extended as stated in Section 4 above.

If you have any questions regarding this Notification please do not hesitate to

contact us. On behalf of the Procuring Entity:

Signature:_____ **Name:**_____

Title/position:_____ **Telephone:**_____

Email:_____

NOTIFICATION OF AWARD-FORM OF ACCEPTANCE

[letterhead paper of the Procuring Entity] [date] To:*[name and address of the Supplier]*

Subject: ***Notification of Award Contract No.***.....

This is to notify you that your Tender dated.....***[insert date]***.....for execution of the..... ***[insert name of the contract and identification number, as given in the SCC]***.....for the Accepted Contract Amount of..... ***[insert amount in numbers and words and name of currency]***, as corrected and modified in accordance with the Instructions to Tenderers is here by accepted by our Agency.

You are requested to furnish the Performance Security within 30days in accordance with the Conditions of Contract, using for that purpose the of the Performance Security Form included in Section X, Contract Forms, of the tendering document.

Authorized Signature: …….

Name and Title of Signatory: ……..

Name of Agency: ……..

Attachment: Contract Agreement

CONTRACT AGREEMENT

[The successful Tenderer shall fill in this form in accordance with the instructions indicated]

THIS AGREEMENT made the *[insert: **number**]* day of [*insert: **month***], *[insert:*

year]. BETWEEN

1) *[insert complete name of Procuring Entity]*, a *[insert description of type of legal entity, for example, an agency of the Ministry of.... of the Government of Kenya, or corporation in Kenya* and having its principal place of business at *[insert address of Procuring Entity**]*** (hereinafter called "the Procuring Entity"), of the one part, and

2) *[insert name of Supplier]*, a corporation incorporated under the laws of *[insert: country of Supplier]* and having its principal place of business at *[insert: address of Supplier]* (herein after called "the Supplier"), of the other part:

   WHEREAS the Procuring Entity invited Tenders for certain Goods and ancillary services, viz., *[insert brief description of Goods and Services]*and has accepted a Tender by the Supplier for the supply of those Goods and Services.

The Procuring Entity and the Supplier agree as follows:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Contract documents referred to.

2. The following documents shall be deemed to form and be read and construed as part of this Agreement. This Agreement shall prevail overall other contract documents.
   a) The Form of Tender
   b) the Addenda Nos. (if any)
   c) Special Conditions of Contract
   d) General Conditions of Contract
   e) The Specification (including Schedule of Requirements and Technical Specifications)
   f) the completed Schedules (including Price Schedules)
   g) The Purchaser's Notification of Award
   h) Acceptance by the tenderer
   i) Performance Bond (where applicable)
   j) Bidders' current CR12 (should have been issued within the last 12 months)

3. In consideration of the payments to be made by the Procuring Entity to the Supplier as specified in this Agreement, the Supplier hereby covenants with the Procuring Entity to provide the Goods and Services and to remedy defects therein conformity in all respects with the provisions of the Contract.

4. The Procuring Entity here by covenants to pay the Supplier in consideration of the provision of the Goods and Services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

IN WITNESS where of the parties here to have caused this Agreement to be executed in accordance with the laws of
Kenya on the day, month and year indicated above. For and on behalf of the Procuring Entity

Signed:_____ *[insert signature]* in the capacity of *[insert title or other appropriate designation]* in the presence of *[insert identification of official witness]* For and on behalf of the Supplier

Signed:*[insert signature of authorized representative(s) of the Supplier]* in the capacity of *[insert title or other appropriate designation]* in the presence of*[insert identification of official witness]*

PERFORMANCE SECURITY

Bank Guarantee *[The bank, as requested by the successful Tenderer, shall fill in this form in accordance with the instructions indicated] [Guarantor letterhead or SWIFT identifier code]* Beneficiary: ..... *[insert name and Address of Procuring Entity]*

Date:.....*[Insert date of issue]*

PERFORMANCE GUARANTEE No.:.....*[Insert guarantee reference number]*

Guarantor:.....*[Insert name and address of place of issue, unless indicated in the letterhead]*

We have been informed that.....*[insert name of Supplier, which in the case of a joint venture shall be the name of the joint venture]* (hereinafter called "the Applicant") has entered into Contract No. [insert reference number of the contract] dated [insert date] with the Beneficiary, for the supply of.....*[insert name of contract and brief description of Health Goods and related Services]* (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, a performance guarantee is required.

At the request of the Applicant, we as Guarantor, hereby irrevocably undertake to pay the Beneficiary any sum or sums not exceeding in total amount of.....*[insert amount in figures]* (.....) *[insert amount in words]*,[1] such sum being payable in the types and proportions of currencies in which the Contract Price is payable, upon receipt by us of the Beneficiary's complying demand supported by the Beneficiary's statement, whether in the demand itself or in a separate signed document accompanying or identifying the demand, stating that the Applicant is in breach of its obligation (s)under the Contract, without the Beneficiary needing to prove or to show grounds for your demand or the sum specified therein.

This guarantee shall expire, no later than the.....Day of.....,2.....[2], and any demand for payment under it must be received by us at this office indicated above on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees (URDG) 2010 Revision, ICC Publication No.758, except that the supporting statement under Article 15(a) is here by excluded.

_____

[Signature]

Note: All italicized text (including foot notes) is for use in preparing this form and shall be deleted from the final product.

[1] *The Guarantor shall insert an amount representing the percentage of the Accepted Contract Amount specified in the Form of Acceptance,and denominated either in the currency(ies) of the Contract or a freely convertible currency acceptable to the Beneficiary.*

[2] *Insert the date twenty-eight days after the expected completion date as described in GC Clause 18.4. The Procuring Entity should note that in the event of an extension of this date for completion of the Contract, the ProcuringEntitywouldneedtorequestanextensionofthisguaranteefromtheGuarantor.Suchrequest must be in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee, the Procuring Entity might consider adding the following text to the form, at the end of the penultimate paragraph:"The Guarantor agrees to a one-time extension of this guarantee for a period not toexceed ……..[six months][one year],in response to the Beneficiary's written Invitation to such extension ,such request to be presented to the Guarantor before the expiry of the guarantee."*

ADVANCE PAYMENT SECURITY

[Guarantor letter head or SWIFT identifier code]

Beneficiary:.....*[Insert name and Address of Procuring Entity]*

Date:.....*[Insert date of issue]*

ADVANCE PAYMENT GUARANTEE No.:.....*[Insert guarantee reference number]*

Guarantor:.....*[Insert name and address of place of issue, unless indicated in the letter head]*

We have been informed that.....*[insert name of Supplier, which in the case of a joint venture shall be the name of the joint venture]* (here in after called "the Applicant") has entered into Contract No. .....*[insert reference number of the contract]* dated.....*[insert date]* with the Beneficiary, for the execution of.....*[insert name of contract and brief description of Health Goods and related Services]* (herein after called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, an advance payment in the sum [insert amount in figures] () *[insert amount in words]* is to be made against an advance payment guarantee.

At the request of the Applicant, we as Guarantor, here by irrevocably undertake to pay the Beneficiary any sum or sums not exceeding in total an amount of.....*[insert amount in figures]* (.....) *[insert amount in words]*[1] upon receipt by us of the Beneficiary's complying demand supported by the Beneficiary's statement, whether in the demand itself or in a separate signed document accompanying or identifying the demand, stating either that the Applicant:

a) Has used the advance payment for purposes other than toward delivery of Goods; or

b) has failed to repay the advance payment in accordance with the Contract conditions, specifying the amount which the Applicant has failed to repay.

A demand under this guarantee may be presented as from the presentation to the Guarantor of a certificate from the Beneficiary's bank stating that the advance payment referred to above has been credited to the Applicant on its account number.....*[insert number]*at.....*[insert name and address of Applicant's bank]*.

The maximum amount of this guarantee shall be progressively reduced by the amount of the advance payment repaid by the Applicant as specified in copies of interim statements or payment certificates which shall be presented to us. This guarantee shall expire, at the latest, upon our receipt of a copy of the interim payment certificate indicating that ninety (90) percent of the Accepted Contract Amount, has been certified for payment, or on the.....*[insert day]* day of..... *[insert month]*, 2 *[insert year]*, whichever is earlier. Consequently, any demand for payment under this guarantee must be received by us at this office on or before that date.

_____

[Signature]

Note: *All italicized text (including foot notes)is for use in preparing this form and shall be deleted from the final product.*

_____

[1]*The Guarantor shall insert an amount representing the amount of the advance payment and denominated either in the currency (ies) of the advance payment as specified in the Contract, or in a freely convertible currency acceptable to the Procuring Entity.*

BENEFICIAL OWNERSHIP DISCLOSURE FORM

(Amended and issued pursuant to PPRA CIRCULAR No. 02/2022)

> ***INSTRUCTIONS TO TENDERERS: DELETE THIS BOX ONCE YOU HAVE COMPLETED THE FORM***
>
> *This Beneficial Ownership Disclosure Form ("Form") is to be completed by the successful tenderer pursuant to Regulation 13 (2A) and 13 (6) of the Companies (Beneficial Ownership Information) Regulations, 2020. In case of joint venture, the tenderer must submit a separate Form for each member. The beneficial ownership information to be submitted in this Form shall be current as of the date of its submission.*
>
> *For the purposes of this Form, a Beneficial Owner of a Tenderer is any natural person who ultimately owns or controls the legal person (tenderer) or arrangements or a natural person on whose behalf a transaction is conducted, and includes those persons who exercise ultimate effective control over a legal person (Tenderer) or arrangement.*

Tender Reference No.:_______________________________________[*insert identification no*] Name of the Tender Title/Description:_______________________[*insert name of the assignment]* to:_________________[*insert complete name of Procuring Entity]*

In response to the requirement in your notification of award dated*[insert date of notification of award]* to furnish additional information on beneficial ownership:_____*[select one option as applicable and delete the options that are not applicable]*

I) We here by provide the following beneficial ownership information.

Details of beneficial ownership

	Details of all Beneficial Owners		**% of shares a person holds in the company Directly or indirectly**	**% of voting rights a person holds in the company**	**Whether a person directly or indirectly holds a right to appoint or remove a member of the board of directors of the company or an equivalent governing body of the Tenderer** (Yes / No)	**Whether a person directly or indirectly exercises significant influence or control over the Company (tenderer) (Yes / No)**
1.	Full Name		Directly----------- % of shares Indirectly---------- % of shares	Directly……….……% of voting rights Indirectly----------% of voting rights	1. Having the right to appoint a majority of the board of the directors or an equivalent governing body of the Tenderer: Yes -----No---- 2. Is this right held directly or indirectly?: Direct………… ………	1. Exercises significant influence or control over the Company body of the Company (tenderer**)** Yes -----No---- 2. Is this influence or control exercised directly or indirectly? Direct…………..
	National identity card number or Passport number					
	Personal Identification Number (where applicable)					
	Nationality					
	Date of birth *[dd/mm/yyyy]*					
	Postal address					

	Details of all Beneficial Owners		**% of shares a person holds in the company Directly or indirectly**	**% of voting rights a person holds in the company**	**Whether a person directly or indirectly holds a right to appoint or remove a member of the board of directors of the company or an equivalent governing body of the Tenderer** (Yes / No)	**Whether a person directly or indirectly exercises significant influence or control over the Company (tenderer) (Yes / No)**
	Residential address				Indirect…… ……...	Indirect……
	Telephone number					
	Email address					
	Occupation or profession					
2.	Full Name		Directly---------- % of shares Indirectly---------- % of shares	Directly…… …….% of voting rights Indirectly---------- % of voting rights	1. Having the right to appoint a majority of the board of the directors or an equivalent governing body of the Tenderer: Yes -----No---- 2. Is this right held directly or indirectly?: Direct…… …… Indirect…… ……...	1. Exercises significant influence or control over the Company body of the Company (tenderer**)** Yes -----No---- 2. Is this influence or control exercised directly or indirectly? Direct…….. Indirect……
	National identity card number or Passport number					
	Personal Identification Number (where applicable)					
	Nationality(ies)					
	Date of birth *[dd/mm/yyyy]*					
	Postal address					
	Residential address					
	Telephone number					
	Email address					
	Occupation or profession					
3.						
e.t.c						

II) Am fully aware that beneficial ownership information above shall be reported to the Public Procurement Regulatory Authority together with other details in relation to contract awards and shall be maintained in the Government Portal, published and made publicly available pursuant to Regulation 13(5) of the Companies (Beneficial Ownership Information) Regulations, 2020.(Notwithstanding this paragraph Personally Identifiable Information in line with the Data Protection Act shall not be published or made public). *Note that Personally Identifiable Information (PII) is defined as any information that can be used to distinguish one person from another and can be used to deanonymize previously anonymous data. This information includes National identity card number or Passport number, Personal Identification Number, Date of birth, Residential address, email address and Telephone number.*

III) In determining who meets the threshold of who a beneficial owner is, the Tenderer must consider a natural person who in relation to the company:

(a) holds at least ten percent of the issued shares in the company either directly or indirectly;

(b) exercises at least ten percent of the voting rights in the company either directly or indirectly;

(c) holds a right, directly or indirectly, to appoint or remove a director of the company; or

(d) exercises significant influence or control, directly or indirectly, over the company.

IV) What is stated to herein above is true to the best of my knowledge, information and belief.

Name of the Tenderer: .....[insert complete name of the Tenderer]*_____

*Name of the person duly authorized to sign the Tender on behalf of the Tenderer: ** [insert complete name of person duly authorized to sign the Tender]*

Designation of the person signing the Tender: ..... [insert complete title of the person signing the Tender]

Signature of the person named above: ..... [insert signature of person whose name and capacity are shown above]

Date this ..... [insert date of signing] day of..... [Insert month], [insert year]

Bidder Official Stamp