

KENYA MEDICAL SUPPLIES AUTHORITY

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All Correspondence should be addressed to Chief Executive Officer

When replying please quote our ref:

KEMSA/GF-PROC/TB - RSSH ONT 02/24-25

Date: 24th March, 2025

CLARIFICATION 3

ATTN.: ALL PROSPECTIVE BIDDERS

TENDER NO.: GF-ATM-TB-RSSH-C19RM- 2024/2025 - ONT 02 - SUPPLY OF COMMUNITY HEALTH PROMOTERS' KITS

In accordance with ITT Clause 7.1 (Clarification of Tendering Document) of the Open National Tender (ONT) issued under the above reference, we hereby respond to query raised by one prospective bidder:

Question 1

Clarification provided for First Aid Box stating – "First Aid Box requires KEBS Certification" in Clarification 1 with reference no: KEMSA/GF-PROC/TB - RSSH ONT 02/24-25 issued on 18th march 2025.

Request: Please clarify as valid registration or retention certificate with QR Code issued by the Kenya Pharmacy and Poisons Board (PPB) should be applicable to First Aid Box instead of KEBS registration since First Aid Box is registered at PPB.

Response

PPB or KEBS Registration for Non-Medical Supplies in the First Aid Box is acceptable

Question 2

Technical Evaluation (i) - Pharmaceutical Products, Point (d): This section requires "valid registration or retention certificate with QR Code issued by the Kenya Pharmacy and Poisons Board (PPB)."

Request: Please clarify whether KEBS registration is acceptable for item - Sanitizer 100ml (Liquid) 70% alcohol based, that fall under KEBS jurisdiction.

Response

PPB or KEBS Registration is acceptable

Question 3

Technical Evaluation (ii) - Non-Pharmaceutical/Laboratory Products, Point (b): This section requires a "current and valid manufacturing Certificate of Quality by an independent recognized body to the manufacturer of the product. The certificate must be item specific."

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Request: Please provide clarification regarding the requirement for **Certificate of Quality** for non-medical items included in the kits, such as the backpack bag, jacket, CHP badge holder with lanyard, flags, water bottle, medicine box, reusable waste bag, pocket sharp container, and first aid box. As these items do not typically require such **Certificate of Quality**, however they require Pharmacy and Poisons Board Listing.

Response

PPB Listing and certificate of quality are not Mandatory for Non-Medical Items Such as Back Pack Bag, Reflector Jacket, CHP Badge Holder with Lanyard, Flags, Water Bottle, Medicine Box, Reusable Waste Bag, Pocket Sharps Container in the Kit.

Question 4

The list of medicines for the Community Health Promoters Kit requires to provide Chlorine Clear Water Tablets, however the strength of the Tablet is not mentioned in the tender document.

Request: Please provide clarification regarding the strength of the Tablet required for Chlorine Clear Water Tablets.

Response

Strength for Chlorine Water Treatment Tablet is 67MG

Question 5

Clarification Regarding Technical Evaluation Requirements (B. Technical Evaluation (ii) - Non-Pharmaceutical/Laboratory Products):

We have carefully reviewed the requirements outlined in points (c) under "Non-Pharmaceutical/Laboratory Products" and wish to seek clarification on the following:

Point (c): This point mandates "Provide current and valid manufacturing Certificate of Quality (ISO 13485) by an independent recognized body to the manufacturer for *Digital Thermometer, Glucometer, BP machine and weighing scale*. The certificate must be item specific (MANDATORY)."

We recognize the necessity of *ISO 13485* certification for medical devices such as *digital thermometers, glucometers, and BP machines*. However, we respectfully point out that a *weighing Scale*, as commonly understood and used in this context, is not typically classified as a medical device. Therefore, an *ISO 13485* certification for a **weighing scale** is not applicable.

Request: We kindly request that the requirement for *ISO 13485* certification be specifically applied to the medical devices listed (*Digital Thermometer, Glucometer, and BP machine*) and that the *weighing scale* be excluded from this mandatory requirement.

Response

The Weighing Scale requires ISO 13485 or equivalent



Question 6

Clarification Regarding product parameter specifications for Glucometer –
It states “ Downloadable 360-value memory with 7-14 and 28 day averaging”.

Request: Please clarify if it is okay to provide Glucometer with - 360-value memory with 7-14 and 28 day averaging.

Response

The Glucometer should have downloadable 360-Value Memory With 7-14, 28-day averaging

Question 7

Clarification Regarding product parameter specifications for Blood Pressure (BP) Machine –
It states “” Power Source: “AAA” Batteries and USB charging”.

Request: Please clarify if it is AAA batteries or external power source.

Response

It has AAA batteries and external power source

With respect to arranging the documents and sample in line with tender requirement and clarification, we kindly request you to extend the Tender by 1 week.

Response

The request for extension of tender closing date is declined. The tender closing date remains 26th March 2025 at 10.00am.

Yours faithfully,



Moses Sudi
Procurement Director
FOR: CHIEF EXECUTIVE OFFICER