

KENYA MEDICAL SUPPLIES AUTHORITY

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All Correspondence should be addressed to Chief Executive Officer

When replying please quote our ref:

KEMSA/PROC/OIT 01/2026-2027

Date: 9th October 2026

To all Bidders,

ADDENDUM NO. 1

Dear Sir/Madam,

RE: TENDER NO. KEMSA/GOK CPF MAL/OIT 01/2026-2027 – SUPPLY OF
ANTIMALARIAL MEDICINES

We refer to the above tender and advise that the specifications for Artesunate Injection 60mg have been amended as attached.

Yours faithfully,

Moses Sudi
Procurement Director
For: Chief Executive Officer

Technical Specifications for Artesunate Injection

Pre-qualification & quality standard

General specifications

Prequalification and quality standard

- The product must be prequalified by the WHO Prequalification Programme and /or authorized by a WHO Listed Authorities (WLA) as per the Global Fund QA Policy for Pharmaceutical products. Those prequalified for use by the WHO Prequalification Team should be listed in the current WHO List of prequalified malaria medicines.
- The product must be accompanied by the following in the technical tender: the WHO Prequalification Reference number and/ or proof of registration by an WLA and/or the United States Food and Drug Administration (USFDA) approval/ tentative approval reference number
- Should meet the requirements of the pharmaceutical legislation and regulation of the country of origin for manufacturing and distribution of medicines. "Country of origin" here means the country where the finished product is manufactured.
- The manufacturer should adhere to Good Manufacturing Practices (GMP) standards set out by the WHO and PPB in all respects for manufacturing, packaging, and labelling of products. Manufacturer to show proof of adherence to GMP standards and provide GMP license from PPB.
- Should also be compliant with monographs set by WHO International Pharmacopeia (Int. Ph.) or the United States Pharmacopoeia (USP) or British Pharmacopeia (BP) or European Pharmacopeia or validated in-house specifications.
- The supplier or manufacturer must provide stability data supporting the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) zone IVb climatic conditions to ensure the formulation maintains quality, safety, and efficacy throughout its shelf life in Kenya's climate.
- The supplier or manufacturer must provide a certificate of analysis for each batch/lot of the product being supplied.
- The bidder is expected to submit the required number of samples, each equivalent to one (1) pack per product, as described, for tender evaluation.

PRE-PROCUREMENT TESTING

Supplier shall submit a certificate of analysis from an independent quality control laboratory for the brand to be prequalified

POST PROCUREMENT TESTING

The MoH/NMCP/Procuring Agencies will take samples of the procured medicines so as to undertake post-shipment batch testing, through the relevant WHO certified laboratories.

Local and registration requirements

The medicine product must be registered and retained with the local pharmaceutical regulatory authority of Kenya, i.e., Pharmacy and Poisons Board (PPB). Bidders should provide registration, re-registration, and/or retention certificates from PPB.



Packing marking and labelling specifications

- The product's primary, secondary and tertiary packages shall have the same batch number.

PRIMARY PACKAGING:

Primary package should be clearly labelled with indelible ink indicating the following, as a minimum:

- International Nonproprietary Name (INN) / generic name of the medicine
- Strength of the active pharmaceutical ingredient(s) (i.e., quantity of active ingredient) per unit dosage form
- List of excipients that are known to be a patient safety concern
- Dosage form / formulation (e.g., injection)
- Total contents (number of dosage units) of container / pack size
- Date of manufacture
- Expiry date
- Batch number
- Storage and handling instructions, including any specific storage conditions such as not to store above temperature of 30°C; to protect from light; not to refrigerate or freeze.
- Name and location of manufacturer (physical address, with country of origin. The "country of origin" is defined as the country where the finished product is manufactured.)
- All labelling and package inserts must be legible and comprehensible, in indelible ink and in English and/or Kiswahili
- Labels should not contain material or graphics that target to directly promote the product's use by infants and children; however, pictograms that clarify usage information may be included in the product package
- Special markings: for products procured through GoK and GFATM support, there should be special markings on packaging as follows: "GoK - Not for sale", and "To be used for treatment of severe malaria"
- All primary packaging must be sealed, tamper-proof and air-tight
- Light sensitive medication must be packaged in USP approved packaging
- Note: as per the PPB guidelines to submission for drug registration, date of manufacture, manufacturer address, storage conditions may be omitted on primary package if it is a blister or strip pack of vial/ampoule of volume less than 10mL. Manufacturer name may be substituted with a trademark or other symbol. Primary packaging of blisters and strips should have the following minimum labelling: Name, strength, and pharmaceutical form of the finished pharmaceutical products; manufacturer name; batch number; and dates of manufacture and expiry in uncoded form.

SECONDARY PACKAGING:

Labelling on outer packaging (or where there is no outer packaging - on the immediate packaging), should include:

- Name of the finished pharmaceutical product (FPP)
- List of active pharmaceutical ingredients (using International Nonproprietary Name (INN) or generic name, if applicable)
- Pharmaceutical dosage form / formulation (e.g., injection)
- Strength of the active pharmaceutical ingredient(s) per unit dosage form
- Total contents (number of dosage units) of container / pack size

- List of excipients that are known to be a patient safety concern
- Indication(s) and recommended dosage, where practicable
- Batch number
- Date of manufacture and expiry in uncoded form
- Storage and handling instructions, including any specific storage conditions
- Directions for use, and any necessary warnings or precautions
- Manufacturer name and address
- Name and address of the company / organization responsible for placing the product on the Kenyan market (if different from manufacturer)
- Kenya marketing authorization number
- Legal category, i.e., if prescription only medicine (POM) or over the counter medicine (OTC)

TERTIARY PACKAGING:

Individual unit containers shall be packed in carton boxes made of strong corrugated cardboard that are:

- Strong enough to withstand rough handling & exposure to extreme tropical temperatures & moisture

The label for the tertiary or outer carton shall be in indelible ink and shall include:

- Shipping marks
- International Nonproprietary Name (INN) or generic name - prominently displayed
- Pharmaceutical dosage form / formulation
- Strength/concentration of the product
- Date of manufacture and date of expiry (in clear language, no code)
- Batch number
- Quantity per carton
- Special instructions for storage and handling
- Manufacturer name and address
- Carton numbering specifying the number of the carton out of the total number in the shipment, e.g., carton 1/40
- Special marking "GOK - Not for Sale" on 3 adjacent sides of the tertiary packaging
- Any additional cautionary statements

Shelf life

Artesunate is manufactured with a shelf life of between 24 and 36 months. The guaranteed minimum remaining shelf life upon delivery is negotiated as part of the bidding process, but shall be at least 75% at time of delivery to the procuring agent.

Specifically, shelf life must be the following minimum:

- 24 months - products must have a minimum of 18 months of usable shelf life remaining at time of delivery to the procuring entity
- 36 months - products must have a minimum of 27 months of usable shelf life remaining at time of delivery to the procurement entity

Product-specific specifications

Table 1: Specifications for Inj Artesunate

#	Product (Active ingredient) name/ International Non-Proprietary name (INN)	Formulation	Strength	Pack size	Additional requirements
1	Artesunate	Injection [Intravenous (IV) / Intramuscular (IM)]	60mg	1 Vial (made of USP Type I glass)	Co-packed with both solvent and diluent for solution for injection or single sodium bicarbonate and arginine-based formulation Diluent *See section Complementary items that are packed with the product below

Complementary items that are packed with the product

Each vial of Inj Artesunate is co-packed with two diluents, one ampoule of sodium bicarbonate 5%w/v (50mg/ml) and one ampoule of sodium chloride 0.9% (9mg/ml), or single sodium bicarbonate (8.4 mg/ml) and arginine (20mg/ml) based formulation Diluent as follows:

Table 2: Specifications for co-pack

Strength of Artesunate	Sodium bicarbonate co-pack	Sodium chloride co-pack	Sodium bicarbonate and Arginine (Single Diluent)
30mg	0.5ml	2.5ml	1.5 ml
60mg	1ml	5ml	3ml
120mg	2ml	10ml	6ml
180 mg	-	-	9 ml

Other requirements

The MoH/NMCP will take samples of the procured medicines so as to undertake post-shipment batch testing, through the relevant WHO certified laboratories.