

Meeting:	KEMSA PRE-BID CONFERENCE																																					
Date Held:	13/10/2026																																					
Time:	10.15am – 11.50am																																					
Venue:	KEMSA, TENDER OPENING HALL																																					
Attendees:	As per attached registration list																																					
No.	Agenda																																					
	<u>Min 01/10/2026 – Prayers and Opening remarks</u> The Pre-bid meeting started at 10:15 a.m. with a word of prayer. <u>Min 02/10/2025 – Welcoming Remarks</u> The Procurement Director welcomed all prospective bidders present to the meeting. Further the bidders were informed that the pre-bid conference was important because it is the forum where tender requirements are clarified. <u>Min 03/10/2025 - PROCUREMENT PRESENTATION</u> The prospective bidders were taken through the procurement process as follows; ❖ Introduction ❖ Bid Submission ❖ Bid Evaluation ❖ Post Qualification ❖ Tender Notification ❖ Performance Security Submission and Contracting ❖ Delivery Tenders advertised <table><tr><th>No.</th><th>Tender No.</th><th>Tender Description</th><th>Tender Closing Date</th></tr><tr><td colspan="4">GLOBAL FUND- KEN-H-TNT</td></tr><tr><td>1</td><td>GF ATM HIV GC7/OIT 01/2026-2027</td><td>Supply of ARVs Pediatrics Medicines</td><td>27th October, 2026 at 10.00 am</td></tr><tr><td>2</td><td>GF ATM HIV GC7/OIT 02/2026-2027</td><td>Supply of ARVs Adult Medicines I</td><td>27th October, 2026 at 10.00 am</td></tr><tr><td>3</td><td>GF ATM HIV GC7/OIT 03/2026-2027</td><td>Supply of ARVs Adult Medicines II</td><td>27th October, 2026 at 10.00 am</td></tr><tr><td>4</td><td>GF ATM HIV GC7/OIT 04/2026-2027</td><td>Supply of Medicines for Opportunistic Infections (OIs)</td><td>29th October, 2026 at 10.00 am</td></tr><tr><td>5</td><td>GF ATM HIV GC7/OIT 05/2026-2027</td><td>Supply of Hepatitis B Surface & Cryptococcal Antigen Tests</td><td>29th October, 2026 at 10.00 am</td></tr><tr><td colspan="4">GOK HIV COUNTERPART FUNDING-KEN-H-TNT</td></tr><tr><td>1</td><td>KEMSA/GOK CPF HIV/OIT01/2026-2027</td><td>Supply of ARV Medicines</td><td>28th October, 2026 at 10.00am</td></tr></table>		No.	Tender No.	Tender Description	Tender Closing Date	GLOBAL FUND- KEN-H-TNT				1	GF ATM HIV GC7/OIT 01/2026-2027	Supply of ARVs Pediatrics Medicines	27 th October, 2026 at 10.00 am	2	GF ATM HIV GC7/OIT 02/2026-2027	Supply of ARVs Adult Medicines I	27 th October, 2026 at 10.00 am	3	GF ATM HIV GC7/OIT 03/2026-2027	Supply of ARVs Adult Medicines II	27 th October, 2026 at 10.00 am	4	GF ATM HIV GC7/OIT 04/2026-2027	Supply of Medicines for Opportunistic Infections (OIs)	29 th October, 2026 at 10.00 am	5	GF ATM HIV GC7/OIT 05/2026-2027	Supply of Hepatitis B Surface & Cryptococcal Antigen Tests	29 th October, 2026 at 10.00 am	GOK HIV COUNTERPART FUNDING-KEN-H-TNT				1	KEMSA/GOK CPF HIV/OIT01/2026-2027	Supply of ARV Medicines	28 th October, 2026 at 10.00am
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2.	KEMSA/GOK CPF HIV/OIT02/2026-2027	Supply of HIV Blood-based self-test kit	29 th October, 2026 at 10.00am
3.	KEMSA/GOK CPF HIV/OIT03/2026-2027	Supply of Hepatitis B Rapid Diagnostic Tests (RDTs)	29 th October, 2026 at 10.00 am
4.	KEMSA/GOK CPF HIV/OIT04/2026-2027	Supply of Male Condoms	3 rd November, 2026 at 10.00am
5.	KEMSA/GOK CPF HIV/OIT05/2026-2027	Supply of Medicines for Opportunistic Infections (OIs)	3 rd November, 2026 at 10.00 am
GOK MALARIA COUNTERPART FUNDING-KEN-M-TNT			
1.	KEMSA/GOK CPF MAL/OIT01/2026-2027	Supply of Anti-Malarial Medicines	28 th October, 2026 at 10.00 am
2.	KEMSA/GOK CPF MAL/OIT02/2026-2027	Supply of Malaria Rapid Diagnostic Tests (MRDT) Kit	28 th October, 2026 at 10.00 am

- ❖ The tender document has been published on Public Procurement Information Portal (PIIP) and KEMSA website.
- ❖ Bidders should complete the registration form provided in the tender document and email the form to the official email address provided.

BID SUBMISSION

- ❖ Bids shall be submitted manually.
- ❖ Completed serialized/paginated Bidding documents shall be submitted accompanied with a signed declaration of the number of pages.
- ❖ 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).
- ❖ The documents will be One 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 the amount specified in the SBD or equivalent in a freely convertible currency from Commercial Banks or Insurance Companies Approved by The Insurance Regulatory Authority (IRA) and listed by The Public Procurement Regulatory Authority.

BID EVALUATION

Bid evaluation will be undertaken in the following stages;

- ❖ Preliminary Examination
- ❖ Technical Evaluation (Documents and samples)
- ❖ Financial Evaluation
- ❖ Post Qualification

PRELIMINARY EXAMINATION (APPLICABLE TO ALL TENDERS)

- ❖ 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)**.
- ❖ Copy of Certificate of incorporation/Registration of business name **(MANDATORY)**
- ❖ Copy of current Tax Compliance Certificate **(MANDATORY FOR LOCAL BIDDERS)**
- ❖ Tender form (on a letterhead) 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)**
- ❖ Duly completed and signed self-Declaration that the person/ Tenderer is not debarred in the matter of the PPADA 2015 **(MANDATORY)**
- ❖ Duly completed and signed self-Declaration that the person/ Tenderer will not engage in any corrupt/fraudulent practice **(MANDATORY)**
- ❖ Duly completed and signed declaration and commitment to the code of ethics **(MANDATORY)**.
- ❖ **Original Bid Security** of an amount as indicated in the respective Tender Documents from Commercial Banks or Insurance Companies (Approved by the Insurance Regulatory Authority (IRA) and listed by Public Procurement Regulatory Authority) **valid for 240 days** from date of tender opening **(MANDATORY)**.

Note: Electronic tender securities with QR codes are acceptable and shall be authenticated through the use of the QR scanner (In Accordance to PPRA CIRCULAR NO. 01/2023). All tender securities submitted shall be subject to authentication by KEMSA

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

TECHNICAL EVALUATION DOCUMENTS TENDER: NO: GF ATM HIV GC7/OIT 01/2026-2027- SUPPLY OF ARVS PEDIATRICS MEDICINES, GF ATM HIV GC7/OIT 02/2026-2027- SUPPLY OF ARVS ADULT MEDICINES I, GF ATM HIV GC7/OIT 01/2026-2027- SUPPLY OF ARVS ADULTS MEDICINES II, KEMSA/GOK CPF HIV/OIT 01/2026-2027- SUPPLY OF ARVS MEDICINES&KEMSA/GOK CPF MAL/OIT 01/2026-2027- SUPPLY OF ANTI-MALARIAL MEDICINES

- ❖ 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)**.
- ❖ Product and Manufacturing Site must be WHO prequalified and or a WHO listed Authority (WLA). As per the Global Fund Quality Assurance Policy for pharmaceutical products.
Should be accompanied by the following in the technical tender: the WHO Prequalification Reference number and/ or proof of registration by an WLA and/ tentative approval reference number **(MANDATORY)**.
- ❖ Current and valid Good Manufacturing Practice (GMP) certificate issued by an independent regulatory authority. **(MANDATORY)**.
- ❖ For products registered within the year, provide Product Registration certificate issued by the Pharmacy and Poisons Board of Kenya. For products registered in prior years, provide valid Product Retention Certificate with QR codes issued by the Pharmacy and Poisons Board of Kenya **(MANDATORY)**.
- ❖ Current and valid Manufacturing License **(MANDATORY)**.
- ❖ Current and valid wholesale dealers license with QR codes issued by the Pharmacy and Poisons Board of Kenya- *Applicable to local bidders* **(MANDATORY)**.
- ❖ Current and valid Superintendent Pharmacist practicing license with QR codes issued by the Pharmacy and Poisons Board of Kenya - *Applicable to local bidders* **(MANDATORY)**.

TECHNICAL EVALUATION DOCUMENTS TENDER: NO:GF ATM HIV GC7/OIT04/2026-2027-SUPPLY OF MEDICINES FOR OPPORTUNISTIC INFECTIONS (OIs) & KEMSA/GOK CPF HIV/OIT 05/2026-2027- SUPPLY OF MEDICINES FOR OPPORTUNISTIC INFECTIONS (OIs)

- ❖ 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)**.
- ❖ Current and valid Good Manufacturing Practice (GMP) certificate issued by an independent regulatory authority. **(MANDATORY)**.
- ❖ For products registered within the year, provide Product Registration certificate issued by the Pharmacy and Poisons Board of Kenya. For products registered in prior years, provide valid Product Retention Certificate with QR codes issued by the Pharmacy and Poisons Board of Kenya **(MANDATORY)**.
- ❖ Current and valid Manufacturing License **(MANDATORY)**.

- ❖ Current and valid wholesale dealers license with QR codes issued by the Pharmacy and Poisons Board of Kenya- Applicable to local bidders **(MANDATORY)**.
- ❖ Current and valid Superintendent Pharmacist practicing license with QR codes issued by the Pharmacy and Poisons Board of Kenya - Applicable to local bidders **(MANDATORY)**.

TECHNICAL EVALUATION DOCUMENTS TENDER: NO:GF ATM HIV GC7/OIT05/2026-2027-SUPPLY OF HEPATITIS B SURFACE & CRYPTOCCOCAL ANTIGEN TESTS, KEMSA/GOK CPF HIV/OIT 02/2026-2027-SUPPLY OF HIV BLOOD-BASED SELF TEST KIT & KEMSA/GOK CPF HIV/OIT 03/2026-2027-SUPPLY OF HEPATITIS B RAPID DIAGNOSTICS TESTS (RDTs)

- ❖ 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)**.
- ❖ Current and valid ISO 13485 certificate issued by an independent regulatory authority. **(MANDATORY)**.
- ❖ Provide evidence that the product is WHO prequalified and or a WHO listed Authority (WLA). **(MANDATORY)**.
- ❖ For products registered within the year, provide Product Registration certificate issued by the Pharmacy and Poisons Board of Kenya. For products registered in prior years, provide valid Product Retention Certificate with QR codes issued by the Pharmacy and Poisons Board of Kenya **(MANDATORY)**.

TECHNICAL EVALUATION DOCUMENTS TENDER: KEMSA/GOK CPF MAL/OIT 02/2026-2027-SUPPLY OF MALARIA RAPID DIAGNOSTIC TESTS (MRDT KIT)

- ❖ 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)**.
- ❖ Product and Manufacturing Site must be WHO prequalified. **(MANDATORY)**.
- ❖ Current and valid manufacturing Certificate of Quality issued by an independent recognized body to the manufacturer of the product. The certificate must be item specific. **(MANDATORY)**.
- ❖ Must provide a valid registration with Pharmacy and Poisons Board (PPB) list of in vitro diagnostics. **(MANDATORY)**.

TECHNICAL EVALUATION DOCUMENTS TENDER: KEMSA/GOK CPF MAL/OIT 02/2026-2027-SUPPLY OF MALE CONDOMS

- ❖ 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)**.
- ❖ Must appear in the latest list of WHO/UNFPA Prequalification **(MANDATORY)**.

- ❖ Current and valid ISO 13485 certificate issued by an independent regulatory authority. (MANDATORY).
- ❖ Current and valid Good Manufacturing Practice (GMP) certificate issued by an independent regulatory authority. (MANDATORY).
- ❖ For products registered within the year, provide Product Registration certificate issued by the Pharmacy and Poisons Board of Kenya. For products registered in prior years, provide valid Product Retention Certificate with QR codes issued by the Pharmacy and Poisons Board of Kenya (MANDATORY).
- ❖ Current and valid Manufacturing License (MANDATORY).

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.
- ❖ **The prices quoted by the Tenderer Shall include all levies and taxes including Capacity Building levy as required by Legal Notice No. 206 on the Public Procurement Capacity Building Levy Order 2023. The Public Procurement Capacity Building Levy shall be at the rate of 0.03% of the value of the signed contract.**
- ❖ Procurements funded by Global Fund will be tax exempt.
- ❖ **Prices shall be quoted with a maximum of two decimal points.**
- ❖ Incoterm for Counterpart Funding tenders; DDP -KEMSA warehouse Nairobi.
- ❖ Incoterm for Global Fund tenders; DAP -KEMSA warehouse Nairobi

POST QUALIFICATION

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

- ❖ After determining the substantially responsive tender, which offers the lowest evaluated price, whether the tenderer is a manufacturer or a supplier: The Procuring Entity shall carry out a post-qualification
The bidder must provide evidence of maximum number of 3 (three) supply contracts for Health products and Technologies within the past 3 years equivalent to the contract sum. The value of one of the contracts must be at least 60 % of the tender sum. The Tenderer should provide documentary evidence in support of the experience of previous supply (Contracts, Purchase Orders, Reference letters and Contact details of previous supply contracts)
- ❖ The bidder must provide evidence of average annual turnover in the last three (3) years that is equivalent to the tender sum. (Provide certified financial statements for the past immediate three (3) years

- ❖ The bidder must provide statement of annual production capacity by a manufacturing firm (should be at least three times the quantities specified under the contract).

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. The performance measurement results shall be used as a basis for award of subsequent contracts.
- ❖ Performance indicators: Time, Quantity, Cost and Quality.
- ❖ Suppliers who will have had unsatisfactory past performance on contracted items of less than 71% shall not be recommended for award of similar items in subsequent tenders for a period of one (1) year.

NOTIFICATION

- ❖ The successful and unsuccessful bidders will be notified simultaneously in line with PPADA 2015 (revised) 2022
- ❖ The successful bidders will be required to accept the offer within 14 days from the date of notification.

PERFORMANCE SECURITY

- ❖ Performance Security should be 10% of the initial contract sum and valid for one year renewable.
- ❖ Performance security must be submitted not later than the 28th day from date of notification.

Failure to comply will lead to cancellation of award.

- ❖ The performance security must be issued by a local bank. If the supplier is foreign, the security must be issued by an authorised financial institution or by a corresponding bank in Kenya recognized by the Central Bank of Kenya.
- ❖ Performance securities from Insurance Companies are not acceptable.

CONTRACTING

- ❖ All successful bidders are enjoined to sign a contract with KEMSA within 28 days from date of notification.
- ❖ Prices should remain fixed over the contract period.
- ❖ The period of contract performance will start running immediately after signing the contract.
- ❖ The Purchase Order delivery dates will be pegged on the agreed delivery dates as per contract.

- ❖ Suppliers are expected to adhere to the delivery schedules agreed upon in the contracts.

TAX EXEMPTION & IMPORT PERMIT PROCESS

- ❖ Consignee must be KEMSA for documentation processing both Tax exemption & import permit
- ❖ Documents required for tax exemption application; Commercial invoice/ packing list, Airway Bill/ Bill of Lading -approval takes about 2 – 3 weeks
- ❖ Documents required for Import Permit application; Commercial invoice/ packing list, Import Declaration Form (IDF) & Product registration/retention certificate by PPB - approval takes about 3-5 days
- ❖ Non-Pharmaceuticals must be inspected prior to shipment by appointed KEBS agent at country of origin and accompanied by a Certificate of Conformity
- ❖ **All import consignments into Kenya must be accompanied by a valid Certificate of Origin (COO)**

CONSIGNMENT DELIVERY

- ❖ The primary, secondary and tertiary package should be labeled 'GOK not for sale' (not applicable to tender sample but to pre-delivery sample and full consignment for the successful Tenderer.
- ❖ Inspection and acceptance letter will be provided to facilitate delivery.

PAYMENT

- ❖ Payment will be done by the National Treasury upon completion of deliveries

04/10/2026 - QUALITY ASSURANCE PRESENTATION

GENERAL QUALITY PARAMETERS CHECKED

1. Name & Address of manufacturer clearly indicated.
2. Generic/chemical name and strength clearly indicated and matches specification.
3. Product Information on the product and insert is in English-
4. Batch No. Mfd and Exp Date clearly indicated in indelible ink
5. Proper labelling of products, no stickers (all packages)-original labelling from the manufacturer.

PRE-DELIVERY EVALUATION

- ❖ Pre-delivery samples must be submitted prior to delivery of the Full consignment and must be similar to the tender sample in all aspects.
- ❖ The pre-delivery must be a representative of the full consignment up to the tertiary level.
- ❖ The pre-delivery sample must be accompanied with the COA (for Health products) and CC (for Health technologies) for that particular batch

- ❖ Shelf life of above 75%
- ❖ An inspection and acceptance letter shall be sent to the bidders after the evaluation.

FULL CONSIGNMENT INSPECTION

- ❖ The remaining product Shelf life at delivery should be 75% and above. Manufacturer details must be as per awarded tender sample.
- ❖ Every batch shall be accompanied with the COA (for Health products) and CC (for Health Technologies) for that particular batch
- ❖ Products should have unique identifiers (batch number) that is not shared even for the same type of product that has different sizes.
- ❖ The Product shall be correctly packed as per the tender requirement.

PACKAGING AND LABELLING

- ❖ The Tertiary, secondary and primary pack (Where possible) shall conspicuously be printed 'KEMSA'
- ❖ Labeling should be in indelible ink (not stamped), clear, and tamper proof with same font size and font colour.
- ❖ Products shall be packed in Heavy Duty five-ply cartons and should be double strapped
- ❖ Implement the requirement GS1 bar coding
- ❖ Shrink Wrap Small Packs in 10s

PRODUCT COMPLAINTS/RECALLS

- ❖ CAPAs are expected on all complaints. Complaints should be resolved within 21days.
- ❖ Manufactures/Suppliers are expected to take full responsibility for medicines recalls, including follow-up checks to ensure that the recalls are successfully completed. Recalls should be concluded within 30days.

QUALITY PARAMETERS: SCORING CRITERIA

- ❖ Documentation-5%
- ❖ Packaging-5%
- ❖ Shelf Life-10%
- ❖ Labelling-5%
- ❖ Product Attributes-75%

Min 05/10/2026 Question and Answer Session

General Questions

1.Are tender Documents available on Kemsas website?

Answer: Kemsas website is inaccessible at the moment, bidders are required to access the documents in PPIP.

Question 2: SRA vs WHO Listed Authority Elaborate,

Answer: WLA is the new term.

Question 3: Clarify on how Counter Part Funding invoices should be prepared prior to submission for payments. In light of the email communications received on the pending payments at The National Treasury.

The implementation of eTIMS requires the PIN of the entity making the payment to be incorporated in the invoices. The invoicing process has been reviewed and revised to introduce a dual-invoicing mechanism.

The contracted suppliers will be required to:

1. Invoice KEMSA using the standard invoice, in fulfilment of their contractual obligations under the respective contracts, including requirements relating to customs clearance; and
2. Generate a separate eTIMS invoice addressed to the National Treasury for purposes of payment processing (*KRA PIN for TNT to be provided at the time of invoicing*).

Question 4: Clarify more on 60% and 3 contracts on post qualification;

Answer: The bidder must provide evidence of maximum number of 3 (three) supply contracts for Health products and Technologies within the past 3 years equivalent to the contract sum. The value of one of the contracts must be at least 60 % of the tender sum. The Tenderer should provide documentary evidence in support of the experience of previous supply (Contracts, Purchase Orders, Reference letters and Contact details of previous supply contracts)

Question 5: Clarify on the annual Product 3x the quote provided;

The annual production capacity by the manufacturing firm should be at least three times of the quantities specified.

NOTE: IMPLEMENTATION OF AUTHENTICATION AND TRACEABILITY SYSTEM - SERIALIZATION BY THE PHARMACY AND POISONS BOARD

Following the regulatory notice by the Pharmacy and Poisons Board (*copy attached*) on the go-live of the System on 3rd August 2026, a transition period applies until 31st December 2026, during which Authentication and Traceability for both locally manufactured and imported HPTs shall be implemented through Batch-Level Traceability using batch numbers declared to the Board.

	Effective 1st January 2027, all HPTs manufactured locally or imported into Kenya shall comply with the full national Authentication and Traceability requirements, including Batch-Level Traceability and Unit-Level Serialization compliant with GS1 Standards. For more information contact the Kenya Pharmacy and Poisons Board.
Signed by: Moses Sudi:	 13/1/26.



**MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD**

REGULATORY NOTICE

**IMPLEMENTATION OF AUTHENTICATION AND TRACEABILITY
REQUIREMENTS FOR HEALTH PRODUCTS AND TECHNOLOGIES AND
ONBOARDING ON PRACTICE 360 AND FACILITY 360**

The Pharmacy and Poisons Board ("the Board") is mandated under the Pharmacy and Poisons Act, CAP 244 Laws of Kenya to protect and promote public health by ensuring access to quality, safe, and efficacious Health Products and Technologies ("HPTs").

Implementation of Authentication and Traceability System

1. The Board wishes to notify all stakeholders that Section 17(h) of the Digital Health Act, 2023 establishes a Comprehensive Integrated Health Information System to support the authentication, tracking and tracing of HPTs throughout the supply chain.
2. Pursuant to this statutory requirement, the Board, in collaboration with the Digital Health Agency (DHA), has commenced implementation of the National Authentication and Traceability System for HPTs.
3. Additionally, the Board, in collaboration with DHA, has undertaken stakeholder engagement, sensitization and consultations on the implementation of the Authentication and Traceability System through national and sector-specific forums held between 7th and 13th July 2026.
4. In order to facilitate a phased implementation of the Authentication and Traceability System, the Board hereby notifies stakeholders as follows:
5. Following the go-live of the System on **3rd August 2026**, a transition period shall apply until 31st December 2026, during which Authentication and Traceability for both locally manufactured and imported HPTs shall be implemented through Batch-Level Traceability using batch numbers declared to the Board.
6. Effective **1st January 2027**, all HPTs manufactured locally or imported into Kenya shall comply with the full national Authentication and Traceability requirements, including Batch-Level Traceability and Unit-Level Serialization compliant with GS1 Standards.

7. Therefore, in preparation for piloting and go-live of the Authentication and Traceability System on 3rd August 2026, all Marketing Authorization Holders, manufacturers, importers and Local Technical Representatives shall be called upon by DHA to submit the required data in line with the requirements set out in paragraph 4 above.
8. All Marketing Authorization Holders, manufacturers, importers and Local Technical Representatives are required to complete the necessary system integration and implementation activities to ensure full compliance by 1st January 2027.
9. Wholesale dealers, distributors, retail pharmacies and other downstream supply chain actors shall be onboarded onto the Authentication and Traceability System in accordance with the same implementation timelines set out in paragraph 4 above. The Board, in collaboration with DHA, shall issue further guidance on the specific requirements applicable to these actors.
10. Detailed data specifications, submission templates and integration guidelines shall be communicated by DHA.

Onboarding on Practice 360 and Facility 360

1. Section 16(e) of the Digital Health Act, 2023 provides that the Comprehensive Integrated Health Information System shall comprise shared or common resources, including the facility registry and health worker registry.
2. In implementation of these statutory requirements, the Board, in collaboration with the DHA, has developed and is implementing Facility 360 and Practice 360 to operationalize the facility registry and health worker registry for the pharmacy profession.
3. To facilitate implementation, the Board in collaboration with the DHA conducted a national stakeholder sensitization on the digital platforms on 7th July 2026.
4. Accordingly, the Board, hereby requires all pharmaceutical premises, Pharmacists and Pharmaceutical Technologists to complete onboarding onto Facility 360 and Practice 360 not later than **31st October 2026**.
5. Completion of onboarding shall be a prerequisite for the processing of applications during the 2027 Annual Licensing Cycle.
6. Stakeholders are therefore encouraged to complete onboarding well in advance of the deadline to facilitate timely processing of annual practice and premise licences.

Stakeholder Support

1. The Board in collaboration with the DHA shall continue to provide technical support, stakeholder engagement and implementation guidance.
2. Additional implementation guidelines and technical specifications shall be communicated where necessary.

3. The Board appreciates the continued cooperation of all stakeholders in supporting the implementation of Kenya's integrated digital health ecosystem and strengthening the regulation, oversight and traceability of HPTs.

The Board remains committed to protecting and safeguarding public health, and will continue to provide the necessary technical guidance to support sustained regulatory compliance.

Dr. Ahmed I. Mohamed
CHIEF EXECUTIVE OFFICER
21st July 2026