REPUBLIC OF KENYA

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

PUBLIC NOTICE

IMPLEMENTATION OF RISK-BASED INSPECTIONS OF PHARMACEUTICAL PREMISES

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").

Legal and Regulatory Basis

1. Section 45 of CAP 244 empowers authorized officers of the Board to enter and inspect pharmaceutical premises where activities relating to medical products are conducted, in order to verify compliance with the provisions of the law and applicable regulatory requirements.
2. Section 47 of CAP 244 also requires that licenses, records, and other regulatory documentation maintained by pharmaceutical establishments be made available for inspection by authorized officers of the Board at all reasonable times.
3. Any person who obstructs or hinders an authorized officer in the lawful exercise of these regulatory functions commits an offence under the Act.
4. Accordingly, inspections of pharmaceutical premises will be conducted within the framework of:
    a. The Pharmacy and Poisons Act, Cap 244 and its subsidiary legislation
    b. Applicable rules, regulations, and national guidelines issued by the Board
    c. The World Health Organization (WHO) Technical Report Series (TRS) 1025 Annex 7: Good Storage and Distribution Practices for Medical Products

Inspection Approach

1. During the 2026 licensing cycle, pharmaceutical premises including wholesalers and retail pharmacies will be inspected on a risk-based basis to determine compliance with Good Storage and Distribution Practices and applicable regulatory requirements.
2. Compliance will be determined based on the number and classification of deficiencies identified during inspection, as follows:
    a. Where critical deficiencies and/or more than 7 major deficiencies are identified, the premises shall be deemed non-compliant.

b. In such cases, the establishment will be required to implement corrective actions and request a follow-up inspection, which will be conducted once the establishment indicates readiness for re-inspection.

c. Where one (1) to six (6) major deficiencies are identified, the establishment will be required to submit a Corrective and Preventive Action plan for evaluation by the Board within 30 days before confirmation of compliance.

d. Where only minor deficiencies are identified, the establishment will be required to implement appropriate Corrective and Preventive Actions, which will be verified during subsequent routine inspections.

Stakeholder Responsibilities

1. All entities are therefore required to:
    a. Review their premises, storage facilities, distribution systems, and documentation practices
    b. Ensure alignment with Good Storage and Distribution Practices as provided under WHO TRS 1025 Annex 7
    c. Maintain appropriate quality management systems and regulatory records to support compliance.
2. The guideline may be accessed here: https://www.who.int/publications/m/item/trs-1025-annex-7

The Board remains committed to strengthening regulatory oversight of the pharmaceutical sector and ensuring that all health products and technologies circulating in Kenya meet the required standards throughout the supply chain.

Dr. Ahmed I. Mohamed
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30th October 2025