REPUBLIC OF KENYA

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

REGULATORY NOTICE

INTRODUCTION OF A CONCURRENT SUBMISSION PILOT FRAMEWORK FOR CLINICAL TRIAL APPLICATIONS

The Pharmacy and Poisons Board ("the Board"), established under the Pharmacy and Poisons Act, Cap 244, Laws of Kenya (The Act), is mandated to protect and promote public health by ensuring access to quality, safe, and efficacious Health Products and Technologies ("HPTs") including the conduct of clinical trials, to ensure that such products meet the requisite standards of quality, safety and efficacy.

Legal and Regulatory Requirements

1. Section 25A of the Pharmacy and Poisons Act, Cap 244 Laws of Kenya as read together with Rule 4(1) of the Pharmacy and Poisons (*Conduct of Clinical Trials*) Rules, 2022, provides that a person shall not conduct a clinical trial of any health product unless written authorization has first been obtained from the Board.

2. Rule 4(4)(n) of the Pharmacy and Poisons (*Conduct of Clinical Trials*) Rules, 2022, requires an application for authorization to conduct a clinical trial to be accompanied by a recommendation from the relevant Ethics Committee.

3. Accordingly, all clinical trials involving health rpoducts conducted within the jusrisdiction of Kenya are subject to both regulatory and ethical oversight.

4. Regulatory authorisation by the Board and the rquisite approval of the relevant Ethics Committee are mandatory prequisites to the commencement of a Clinical Trial.

Concurrent Submission Pilot Framework

5. Following stakeholder engagements and as part of ongoing measures to strengthen the efficiency, coordination and predictability of clinical trial review processes in Kenya, the Board is introducing a Concurrent Submission Pilot Framework for Clinical Trial Applications.

6. The Framework will enable applicants to submit the same clinical trial application concurrently to the Board and a participating Institutional Review Board (IRB)/Ethics Committee, thereby allowing the regulatory and ethical review processes to proceed in parallel.

7. The pilot is being implemented by the Board, with support from the Garnet Partners Limited project, in collaboration with Kenya Medical Research Institute – Scientific and Ethics Review Unit; and Moi Teaching and Referral Hospital/Moi University Institutional Research and Ethics Committee.

8. The pilot shall commence on 17th August 2026 and shall run for a period of twelve (12) months.

9. The Concurrent Submission Pilot Framework is intended to improve coordination between regulatory and ethical review processes, reduce delays associated with sequential reviews, enhance the efficiency, transparency and predictability of clinical trial review, and generate evidence to inform broader implementation of concurrent submission.

Concurrent Submission Requirements

10. For purposes of this pilot, concurrent submission means submission of the same clinical trial application dossier to the Board and one of the participating IRBs/Ethics Committees within five (5) working days of each other. Applicants participating in the pilot shall:

    a. Submit the complete clinical trial application to either of the participating IRBs/Ethics Committees and obtain evidence of submission;

    b. Submit the same clinical trial application to the Board within five (5) working days and provide evidence of submission to the participating IRB/Ethics Committee;

    c. Respond to queries or requests for additional information raised during the respective regulatory and ethical reviews;

    d. Ensure that any documents amended during either review process are appropriately submitted to both the Board and the relevant IRB/Ethics Committee, where applicable; and

    e. Submit the final ethics decision/recommendation to the Board upon completion of the ethical review process

11. The Board and the participating IRB/Ethics Committee shall undertake their respective reviews concurrently and independently, in accordance with the applicable legal, regulatory and ethical requirements.

12. For avoidance of doubt, concurrent submission does not dispense with or modify the statutory requirement for ethics approval. The Board shall only issue final authorization to conduct the clinical trial upon receipt of the requisite approval/recommendation from the relevant ethics committee and satisfactory completion of the regulatory review.

Stakeholder Support

13. The Board, together with the participating institutions, shall continue to provide appropriate guidance and support during implementation of the pilot.

14. Applicants submitting clinical trial applications through the participating IRBs/ethics committees during the pilot period are encouraged to utilize the concurrent submission pathway and comply with the requirements outlined in Clause 10.

15. For further information, stakeholders may contact:

    a. Pharmacy and Poisons Board
    Clinical Trials Division
    Telephone: +254 709 770 100
    Website: https://web.pharmacyboardkenya.org/clinical-trials
    Clinical Trials Portal: https://ctr.pharmacyboardkenya.org

    b. Kenya Medical Research Institute
    Scientific and Ethics Review Unit
    Telephone: 0722 205 901 / 0733 400 003
    Direct Mobile: +254 717 719 477
    Email: seru@kemri.go.ke

    c. MTRH/Moi University Institutional Research and Ethics Committee
    Telephone: +254 787 723 677
    Email: irecoffice@gmail.com / irec@mtrh.go.ke

16. The Board appreciates the continued cooperation and collaboration of all stakeholders in strengthening Kenya's clinical trial oversight framework.

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
14th August 2026