HPT/PER/POL/018

Revision No. 2

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

ROADMAP FOR THE IMPLEMENTATION OF BIOEQUIVALENCE REQUIREMENTS FOR MULTISOURCE DRUG PRODUCTS IN KENYA

MAY, 2025

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1.0 EXECUTIVE SUMMARY

This roadmap provides a structured plan for the phased implementation of bioequivalence (BE) requirements for generic medicines, with a final deadline of **31 December 2026.**

The Board has faced delays in enforcing Bioequivalence (BE) for multisource products since 2010. Earlier proposals of 10 years and 5 years tied to the ten proposed marketing authorization (MA) renewal "buckets" were rejected by WHO as excessively long. Following WHO recommendations, this roadmap provides for a 2-year implementation plan (Jan 2024 – Dec 2026), decoupled from renewal cycles.

Implementation of this roadmap is critical for safeguarding public health, ensuring therapeutic equivalence of generics, and enabling the Board to attain WHO Maturity Level 3 (ML.3).

2.0 BACKGROUND AND RATIONALE

BE requirements for generics were introduced in 2010 but repeatedly postponed at the request by/pushback from the industry and so as to allow the industry to grow.

In September 2023, The Board Issued circular No. PPB/HPT/LET/VOL.II/016/23 to all Marketing Authorization Holders notifying them of Commencement of Mandatory Therapeutic Equivalence Demonstration For Multisource (Generic) Medical Products In Kenya. As a result of this directive, effective 1st Janury 2024 all new applications for BE eligible products are screened for submission of Bio- Equivalence studies under Module 5.

For products already registered and available in Kenyan market, the board proposed a 10 year implementation period in the Roadmap For The Implementation of Bioequivalence Requirements For Multisource Drug

Products In Kenya, Effective September 2023. WHO rejected this Rodmap as being too long.

In 2024, The BE roadmap was revised, with a new reduced implementation period of 5 years in line with the renewal framework However, during the WHO virtual audit, 8th to 10th April 2025, the 5-year implementation period was rejected as delaying compliance and contrary to best practice.

WHO recommended a shorter 2–3 year transition, Independent of MA renewal cycles.

The current roadmap aligns with WHO guidance, ensuring full BE compliance by 31 December 2026 independent of the product renewal cycle. All MA will stand revoked after 31 Dec 2026 and communication to that effect made.

3.0 OBJECTIVES

3.1 Primary Objective

Ensure that all BE-eligible generic medicines demonstrate therapeutic equivalence to innovator products and achieve BE compliance by 31 Dec 2026.

3.2 Specific Objectives

Strengthen regulatory oversight in line with WHO GBT indicators.
Strengthen national regulatory systems to meet WHO Global Benchmarking Tool (GBT) sub-indicators related to efficacy, quality, and oversight and Support BOARD's progression to WHO Maturity Level 3.

Enhance public and stakeholder confidence in medicines marketted in Kenya.

4.0 GUIDING PRINCIPLES

4.1 MA04.04: The same criteria apply for assessing applications regardless of the origin of or destination for the medical products (e.g., domestic, foreign, public sector, or private sector).

4.2 Patient safety first – therapeutic equivalence ensures reliable treatment outcomes.

4.3 Transparency and fairness – all manufacturers subject to the same timelines.

4.4 Enforceability – compliance guaranteed through legally binding undertakings.

4.5 Stakeholder engagement – continuous communication with industry and partners.

5.0 IMPLEMENTATION PROVISIONS

5.1 **Category 1 – Products Due for Renewal (registered before 2020)**

5.1.1 Must demonstrate BE **before renewal** (Dec 2025) or by **31 Dec 2026**, whichever comes first.

5.1.2 Manufacturers must sign a **legally binding undertaking** by **31 Dec 2025 (Annex 1) .**

5.2 **Category 2 – Products with Valid MA (between Jan 2020 – Dec 2023)**

5.2.1 Manufacturers must sign a **legally binding undertaking** by **31 Dec 2025 (Annex 1) .**

5.2.2 Must demonstrate BE by **31 Dec 2026**.

5.3 **Category 3 – Products Registered from Jan 2024 Onward**

5.3.1 BE must be demonstrated at the time of registration**.**

6.0 DELIVERABLES

6.1 Product categorization list – products grouped by approval year.

6.2 Company list – manufacturers with BE-eligible products.

6.3 Undertaking/commitment templates – legally binding commitments signed by companies.

6.4 Communication package – official letters, website uploads, stakeholder meeting briefs.

6.5 Background narrative – evolution of timelines and rationale for current approach.

7.0 TIMELINE AND MILESTONES

SN	Activity	**Timeline**
1.	Roadmap approval by the Board	31st May 2025
2.	Notification to manufacturers & publication on PPB website	6th October 2025
3.	Category 1 undertakings signed	31st December 2025
4.	Category 2 undertakings signed	31st December 2025
5.	Submission of BE studies (category 1 & 2)	31st December 2026
6.	Enforcement actions for non-compliance	11th January 2027

8.0 COMMUNICATION STRATEGY

8.1 Circulate roadmap and requirements via official letters to all manufacturers.

8.2 Publish guidance and timelines on PPB website.

8.3 Conduct stakeholder forums to address queries and build consensus.

8.4 Provide quarterly progress updates to industry.

9.0 ENFORCEMENT AND LEGAL FRAMEWORK

9.1 Manufacturers must sign legally binding undertakings.

9.2 Failure to comply may result in:

9.2.1 Revocation or suspension of MA/license.

9.2.2 Public notice of the company's non-compliant products.

9.2.3 Refusal of new applications from non-compliant manufacturers.

9.2.4 Restriction on trade for the company's specific products

9.3 Provisions backed by the national Medicines and Pharmacy Law (Cap 244 and related regulations).

10.0 MONITORING AND REPORTING

10.1 Monthly updates using a CAPA-style compliance tracker maintained by the MA department.

10.2 Quarterly consolidated progress reports to the PPB Board.

10.3 Upload progress updates to WHO SharePoint as per reporting schedule.

10.4 Independent QMS-led audit by Sept 2026**.**

11.0 RISKS AND MITIGATION

Table 1: Risks Mitigation

	Risk	**Mitigation**
1.	Manufacturers delay BE studies	Binding undertakings, strict enforcement, early engagement.
2.	Lack of CRO capacity	Encourage manufacturers to utilize CROs outside Kenya Publish on PPB website CROs approved by host National Regulatory Authorities
3.	Industry resistance	Transparent communication, phased deadlines, stakeholder workshops.
4.	Legal challenges	Strong legal framework of engagement, Board-approved legally binding undertakings. Leverage powers of the Board to revoke product licenses.

12.0 EXPECTED OUTCOMES

12.1 Strengthened patient safety and product confidence.

12.2 By 31 Dec 2026, all BE-eligible generics will have demonstrated therapeutic equivalence.

12.3 Strengthened regulatory credibility and alignment with WHO standards.

12.4 PPB positioned for attainment of WHO Maturity Level 3.

12.5 Improved patient confidence medicines marketted in Kenya..

13.0 REVISION HISTORY

Revision No.	Date	Author/Reviewer	Section(s) Revised	Description of Change
1.0	15/12/2023	QAO	Section 1.14	Revised roadmap implementation period from 11 years to 5 years.
			Section 4.1	Revised time-bucket implementation period from 10 years to 5 years for products already issued with Marketing Authorization.
2.0	16/05/2025	QAO	Implementation Provisions	Revised implementation period from 5 years to 2 years for products already issued with Marketing Authorization.
			Section 6	Added Deliverables section.
			Section 7	Added Timeline and Milestones section.
			Section 8	Added Communication Strategy section.
			Section 9	Added Enforcement and Legal Framework section.
			Section 10	Added Monitoring and Reporting section.
			Section 11	Added Risks and Mitigation section.
			Section 12	Added Expected Outcomes section.
			Annex 1	Added template for legally binding undertaking to guide applicant commitments

				to regulatory requirements.
			Annex 2	Added template for manufacturer notification letter for standardized communication of regulatory requirements.
			Annex 3	Added product categorization list to support product classification and implementation prioritization.
			Annex 4	Added guidance to industry on conduct of bioequivalence (BE) studies using foreign CRO sites.
			Annex 5	Added bioequivalence study report submission checklist to ensure completeness and consistency of submissions.
			Annex 6	Added notice on commencement of mandatory therapeutic equivalence demonstration for multisource (generic) medical products in Kenya.

Annexes

Annex 1: Template legally binding undertaking.

Annex 2: Template manufacturer notification letter

Annex 3: Product categorization list

Annex 4: Guidance to Industry: Conduct of Bioequivalence (BE) Studies Using Foreign CRO Sites

Annex 5: Bioequivalence Study Report Submission Checklist

Annex 6: Notice On Commencement Of Mandatory Therapeutic Equivalence Demonstration For Multisource (Generic) Medical Products In Kenya

Annex 1: Template legally binding undertaking.

Template:

Legally Binding Undertaking on Bioequivalence (BE) Compliance

[Company Letterhead]

To:

The Chief Executive Officer

[Name of National Regulatory Authority]

[Address]

Date: [DD/MM/YYYY]

Subject: Undertaking on Bioequivalence (BE) Compliance for [Product Name(s)]

We, **[Company Name]**, duly incorporated under the laws of [Country], and holding a valid Manufacturing/Marketing Authorization (MA) for the product(s) listed below, hereby make this legally binding undertaking to the **[National Regulatory Authority] (BOARD)** with respect to compliance with bioequivalence (BE) requirements.

1. Product(s) Covered by this Undertaking

[List all product names, strengths, dosage forms, MA numbers, and dates of approval]

2. Commitment to BE Demonstration

In line with the BOARD's roadmap for implementation of BE requirements:

For products due for renewal before 31 December 2026: We commit to submit acceptable BE study reports before renewal or no later than 31 December 2026, whichever comes first.

For products with valid MA not yet due for renewal (approved Sept 2020 – Aug 2024): We commit to submit signed undertakings by 31 December 2025 and BE study reports by 31 December 2026.

For products registered from January 2024 onward: We acknowledge that BE demonstration is a prerequisite for registration, and no exemption will be claimed.

3. Regulatory Consequences

We acknowledge and accept that:

Failure to submit acceptable BE data within the specified timelines will constitute grounds for **revocation, suspension, or non-renewal of the MA/license** on efficacy grounds.

The Board reserves the right to publish a list of non-compliant products and manufacturers.

No compensation or damages shall be claimed against the BOARD for enforcement of these provisions.

4. Legal Effect

This undertaking is binding on the company, its successors, and assigns, and shall remain in force until full compliance is demonstrated or the MA is revoked by the Board.

Signatures

Signed on behalf of **[Company Name]**:

Name & Title of Authorized Person: _____

Signature & Company Seal: _____

Date: _____

Witnessed by (Board legal officer) :

Name & Title: _____

Signature: _____

Date: _____

Annex 2: Template manufacturer notification letter

PPB Letterhead]

Ref: [Insert Ref. Number]

Date: [Insert Date]

To:

Managing Director/Chief Executive Officer

[Manufacturer Name]

[Manufacturer Address]

Subject: Notification of Bioequivalence (BE) Implementation Roadmap Requirements

Dear Sir/Madam,

The [National Regulatory Authority – PPB] wishes to notify you of the mandatory requirements for the demonstration of bioequivalence (BE) for all BE-eligible generic medicines, as part of the PPB's roadmap to achieve WHO Maturity Level 3 (ML.3).

WHO has guided that BE implementation be completed within 2–3 years (January 2024 – December 2026). Accordingly, the PPB has adopted 31 December 2026 as the final deadline for full compliance.

1. Requirements

Products due for renewal before 31 December 2026

BE must be demonstrated before renewal or by 31 December 2026, whichever comes first.

Manufacturers must sign the attached legally binding undertaking by 31 December 2024.

Products with valid MA (approved Sept 2020 – Aug 2024, not yet due for renewal)

Manufacturers must sign the attached undertaking by 31 December 2025.

BE must be demonstrated by 31 December 2026.

Products registered from January 2024 onwards

BE demonstration is mandatory at the time of registration.

2. Regulatory Consequences

Failure to comply with the above requirements will result in regulatory actions including:

Revocation, suspension, or refusal of MA/renewal on efficacy grounds.

Public disclosure of non-compliant products and manufacturers.

Restriction of new applications from non-compliant companies.

3. Next Steps

You are required to:

Review the attached Roadmap for Implementation of BE Requirements.

Complete and return the attached Undertaking Form to the PPB no later than the applicable deadline.

Submit periodic updates on BE study progress, as requested by the PPB.

The PPB looks forward to your full cooperation in implementing these measures, which are critical for ensuring the quality, safety, and efficacy of medicines available to patients and for enabling the country to meet WHO ML.3 standards.

For clarification, please contact [Insert Department Contact Person, Title, Email, Phone].

Yours sincerely,

[Name]

Chief Executive Officer

[Pharmacy and Poisons Board]

Attachments:

Roadmap for Implementation of Bioequivalence (BE) Requirements (Jan 2024–Dec 2026)

Legally Binding Undertaking Form

Annex 3: Product categorization list

Category 1: BE Roadmap for Products Due for renewal (Products registered before 2020)

Products due for renewal (Products registered before 2020): Submissions of BE study data bioequivalence at renewal, or Signing of a legally binding undertaking by 31 December 2025, to submit BE data by 31 December 2026 confirming that the Board may revoke the license on efficacy grounds

	Action
BE Eligible	Submissions of BE study data at renewal, or Signing of a legally binding undertaking by 31 December 2025, to submit BE data by 31 December 2026 confirming that the Board may revoke the license on efficacy grounds
Additional Strength	Submissions of additional strength data at renewal, or Signing of a legally binding undertaking by 31 December 2025, to submit additional strength data by 31 December 2026 confirming that the Board may revoke the license on efficacy grounds

Category 2 : BE Roadmap for products not due for renewal (products registerd in the period 2020-2023)

Products not due for renewal(products registerd in the period 2020-2023): Signing of a legally binding undertaking by 31 December 2025, to submit BE data by 31 December 2026 confirming that the Board may revoke the license on efficacy grounds.

	Action
BE Eligible	Signing of a legally binding undertaking by 31 December 2025, to submit BE data by 31

	December 2026 confirming that the Board may revoke the license on efficacy grounds.
Additional Strength	Signing of a legally binding undertaking by 31 December 2025, to submit Additional strength data by 31 December 2026 confirming that the Board may revoke the license on efficacy grounds.
BE Submitted	No Action

Annex 4: Guidance to Industry: Conduct of Bioequivalence (BE) Studies Using Foreign CRO Sites

1. Purpose

This guidance provides clarity to pharmaceutical manufacturers and marketing authorization holders (MAHs) on the responsibilities and required steps when conducting bioequivalence (BE) studies for generic medicines at foreign Clinical Research Organization (CRO) sites.

This guidance ensures manufacturers understand that while CROs can execute studies, responsibility always lies with the sponsor and compliance with NRA/WHO requirements is mandatory.

2. General Principle

a) Who Develops the Protocol?

Primary Responsibility: Manufacturer (Sponsor)

The manufacturer (sponsor) is ultimately responsible for the design, conduct, and reporting of bioequivalence studies submitted to the NRA, regardless of whether the study is conducted internally or at a contracted foreign CRO.

The Marketing Authorization Holder (MAH) or manufacturer is responsible for developing the BE protocol because they are accountable for proving their generic product's equivalence to the innovator.

The sponsor may draft the protocol internally or contract the Clinical Research Organization (CRO) to develop it, but ultimate ownership and approval rests with the sponsor.

b) Role of the CRO

A qualified foreign CRO, if contracted, will provide scientific and operational input into the protocol, adapt it to ethics/regulatory requirements, and ensure feasibility of execution.

CROs typically draft operational sections (study design details, sample handling, statistical plan), but the sponsor must ensure alignment with regulatory requirements of the PPB (where marketing authorization is sought).

c) Sponsor Responsibilities

The sponsor is responsible for establishing, implementing and maintaining appropriate quality assurance and quality control processes and documented procedures to ensure that trials are conducted and data are generated, recorded and reported in compliance with the protocol, GCP and the applicable regulatory requirement(s).

Where the sponsor delegates duties to a CRO, the sponsor should ensure appropriate oversight of important trial -related activities that are transferred to service providers, including activities further subcontracted by the service provider

3. Protocol Development

a) The sponsor develops and owns the BE study protocol.

b) A foreign CRO may assist in drafting technical and operational aspects, but the sponsor must ensure the protocol complies with WHO guidelines, ICH Good Clinical Practice (E6), and PPB requirements**.**

c) The protocol must clearly identify the Test Product (generic) and Reference Product (innovator), study design, statistical methods, analytical procedures, and safety monitoring.

4. Steps to Be Followed

Step 1 – Pre-protocol Preparations

i. Identify the approved reference product recognized by the PPB.

ii. Validate analytical methods and confirm test and reference product suitability prior to study initiation.

Step 2 – Protocol Development

i. Draft the study protocol in line with ICH E6 (GCP), WHO BE guidance, NRA-specific BE guidelines. and obtain:

- Internal sponsor approval**.**
- Ethics Committee/IRB approval in the CRO's host country.
- Regulatory authority approval in the CRO's host country, where applicable.

ii. Protocol should cover:

- Study design (usually randomized, 2×2 crossover).
- Population (healthy volunteers, inclusion/exclusion).
- Qualification of investigators (current curriculum vitae)
- Analytical methods for drug concentration.
- Statistical methods (90% CI, log-transformed AUC and Cmax).
- Safety monitoring and ethical considerations.
- Final version of protocol including all approved protocol ammendmnets.

iii. Protocol review and approval

Sponsor signs off on the protocol and submits protocol for:

- Ethics Committee/IRB approval (in CRO's country).
- Regulatory approval if required by relevant regulatory authorities (some NRAs require pre-approval of BE protocols).

Step 3 – Study Conduct

i. The CRO recruits volunteers and conducts the trial in accordance with Good Clinical Practice (GCP) and Good Laboratory Practice (GLP).
ii. Volunteer recruitment, dosing, sample collection, and safety monitoring must follow the approved protocol.
iii. Safety oversight ensured by ethics committee, bioanalytical lab conducts validated assays and QA oversight with SOP adherence.

Step 4 – Data Analysis and Reporting

i. Bioanalytical assays must be validated.
ii. Statistical analysis of pharmacokinetic parameters (AUC, Cmax) must use appropriate methods with 90% confidence intervals.
iii. A full Clinical Study Report (CSR) must be prepared, signed by the CRO's Principal Investigator and the sponsor.

Step 5 – Submission to PPB

i. Review the report for accuracy consistency and completeness and liaise with the CRO in case any clarification or correction is required.
ii. Submit the complete BE package including:

- Approved protocol and amendments.

- Ethics and regulatory approvals.
- Study report (CSR).
- Certificates of Analysis for test and reference products.
- Method validation reports.
- Evidence of CRO GCP/GLP compliance (inspection certificates or recognition by a stringent authority/WHO).

5. NRA Review and Acceptance

The PPB will evaluate BE studies conducted at a CROs only when:

i. The CRO demonstrates compliance with GCP/GLP standards.
ii. Protocol and study design align with WHO and NRA requirements.
iii. Study data are complete, traceable, and verifiable.

Non-compliant studies may lead to rejection of applications, refusal of marketing authorization, or revocation of existing approvals**.**

6. Effective Enforcement

Manufacturers/MAHs must ensure strict adherence to this guidance. Any failure to follow these requirements may result in regulatory actions, including suspension or refusal of product registration.

Annex 5: Bioequivalence Study Report Submission Checklist

Bioequivalence Study Information

(Please fill in the following information)

1.	Study number/ study protocol number	
2.	Study title	
3.	Start and end dates for each period of the clinical study	
4.	Start and end date for bio-analytical study	
5.	Clinical Study facility (Name and full address of clinical study site)	
6.	Bio-analytical facility (Name and full address of bioanalytical study site)	
7.	Institutional Review Board/ Independent Ethical Committee	
8.	Relevant information on the test product used in the BE study	

Product name	
Strength *Please indicate whether the test product used has the same strength as product proposed for registration	
Dosage form	
Batch number	
Batch size	
Manufacture date	
Expiry date	
Name and full address of the drug substance manufacturing site	
Name and full address of the test product manufacturing site *Please indicate whether the test product used has the same qualitative and quantitative composition	

		as the product proposed for registration	
9.	Relevant information on the reference product used in the BE study	Product name	
		Strength	
		Dosage form	
		Batch number	
		Expiry date	
		Country where the product is sourced from	
		Name and full address of the reference product manufacturing site *Please indicate whether the reference product is the same as Malaysia Comparator Product (MCP). If NO, please provide document no. 7 & 9 under section B. Documents to be submitted.	

10. Summary results of the study

Parameter Logarithmic transformed data	Test (Geometric mean)	Reference (Geometric mean)	% Ratio of geometric means	90% Confidence interval	Intra-subject coefficient of variation, ISCV (%)
AUC0-t					
AUC0-∞					
Cmax					

Documents to be Submitted

	Document	**Name of Document and Location**
1.	Letter of approval of Institutional Review Board/ Independent Ethical Committee (IEC)	
2.	Study protocol approved by Independent Ethical Committee (IEC)	
3.	Informed consent form	
4.	Evidence of CRO's compliance with GCP/GLP (e.g., inspection certificates, WHO recognition, EMA/FDA/other NRA inspection reports).	

	Document	**Name of Document and Location**
5.	Formulation page and manufacturing process flow chart in the batch manufacturing record (BMR) of test product	
6.	Letter with a signed statement from the sponsor/manufacturer/product owner confirming that the **test product** is the same formulation, manufactured by the same process and using same equipment as the one that is submitted for marketing authorization	
7.	Certificate of analysis (COA) of BE test product	
8.	Certificate of analysis (COA) of reference product	
9.	Letter with a signed statement from the sponsor/manufacturer/product owner confirming that the **active substance** used in manufacturing of test product is the same as the one that is submitted for marketing authorization.	
10.	Outer packaging and/ or prescribing information sheet of BE reference product *The document should contain the information of the batch number, expiry date, name and address of manufacturer*	
11.	(i) Study report for comparative dissolution profile (CDP) conducted between test product and reference product in pH 1.2, 4.5, 6.8 and quality control media (if applicable) (ii) Dissolution study protocol (iii) *The dissolution study report should be dated and signed by analyst or relevant personnel.*	
12.	Clinical study report (i) Clinical Study Report (CSR) complete and signed by sponsor and PI. (ii) Deviations from protocol documented and justified. (iii) Raw data and individual subject data tables available. (iv) QA audit certificate of study included.	
13.	Pharmacokinetic and statistical analysis report (i) Correct statistical methods used (ANOVA, log-transformed AUC, Cmax). (ii) 90% confidence intervals reported. (iii) Results within accepted BE range (80–125%).	
14.	Bioanalytical method validation report and relevant addendum(s) (i) Summary Information (ICH M10, Sect. 8.1) (ii) Method Validation Report + Amendment(s), (if applicable) (iii) Detailed description of Method SOP(s) used	

	Document	**Name of Document and Location**
	(iv) Chromatograms (100%) of the Method Validation & Run Summary Tables	
15.	Bioanalytical study report (i) Summary Information (ICH M10, Sect. 8.1) (ii) List of SOP(s) used (iii) Bioanalytical Report + Amendment(s), (if applicable), (iv) Incurred Sample Reanalysis (ISR) (v) Chromatograms (100%) of the Study Analyses + Run Summary Tables	
16.	Quality assurance statement	
17.	Literature references (if applicable)	
Additional Strength Biowaiver Application		
18.	Application form for a biowaiver of additional strength (if applicable), together with justification and documents for biowaiver request (i) All strengths are manufactured by the same manufacturing process (ii) Qualitative and quantitative composition of the different strengths (all) (iii) Dissolution study report for comparative dissolution profile (CDP) conducted between test product and other proposed additional strengths in pH 1.2, 4.5, 6.8 and quality control media (if applicable) (iv) Dissolution study protocol *The dissolution study report should be dated and signed by analyst or relevant personnel.*	

Annex 6: Notice On Commencement of Mandatory Therapeutic Equivalence Demonstration For Multisource (Generic) Medical Products In Kenya

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

Telegram: "MINHEALTH" Nairobi
Telephone: 020-2716905/6, 020-3562107
Cellphone: 0733-884411/0720 608811
Fax: 2713409
Email: admin@pharmacyboardkenya.org
Website: www.pharmacyboardkenya.org

Pharmacy & Poisons Board Hse
Along Lenana Road
P. O. Box 27663-00506
NAIROBI

When replying please quote our ref No:

PPB/HPT/LET/VOL.II/016/23

15th September, 2023

To : All Marketing Authorization Holders,

RE: NOTICE ON COMMENCEMENT OF MANDATORY THERAPEUTIC EQUIVALENCE DEMONSTRATION FOR MULTISOURCE (GENERIC) MEDICAL PRODUCTS IN KENYA

Reference is made to the above and previous communications on the same.

The Pharmacy and Poisons Board (hereinafter referred to as "the Board"), is mandated, under Section 3B(2)(b) of the Pharmacy and Poisons Act (Cap. 244), to ensure that all medical products manufactured in, imported into, or exported from Kenya conform to prescribed standards of quality, safety, and efficacy.

In view of this, and in a bid to attain the World Health Organization (WHO) categorization of Maturity Level 3 (ML.3), the Board notifies all stakeholders that all generic products classified as Class II and IV under Biopharmaceutical Classification System (BCS), will be required to demonstrate therapeutic equivalence as a mandatory requirement. This directive aligns with the WHO Global Benchmarking Tool (WHO-GBT) requirement on application of the same criteria for assessing applications regardless of the origin of the medical products.

To enable a gradual and structured implementation of this requirement to demonstrate therapeutic equivalence, in accordance with the Guidelines on Bioequivalence Requirements in the Compendium of Guidelines of Medicines Evaluation and Registrations (HPT/PER/GUD/016 Rev No. 2), the Board has adopted a phased approach as follows:

1. Effective 1st January 2024, all new applications for eligible generic products manufactured locally shall be required to submit bioequivalence studies under Module 5;

2. All applications for eligible generic products that will not have been registered by 31st December 2023 will be subject to rescreening to ensure compliance with the mandatory bioequivalence requirement;
3. Effective 1st January 2025, all eligible generic products already registered and available in the Kenyan market, but have not previously submitted bioequivalence studies, will be required to provide bioequivalence information.

To enhance in-depth insights into regulatory requirements regarding implementation of the requirements contained in this circular, the Board will host a workshop for marketing authorization holders (MAH). This sensitization workshop is set to take place before the end of October 2023. It will provide MAH representatives with comprehensive information on the roadmap, guidelines, procedures and expectations.

For more details regarding the implementation of this mandatory bioequivalence requirement, please visit our official website accessible via ***web.pharmacyboardkenya.org*** or contact the Board through phone number **+254 709 770 100.**

The Board remains steadfast in its commitment to safeguarding the health of the public by ensuring the quality, safety, and efficacy of medical products and technologies in Kenya.

Yours sincerely,

Dr. F. M. Siyoi
CHIEF EXECUTIVE OFFICER

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