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MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

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

JULY, 2026

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1.0 EXECUTIVE SUMMARY

This Roadmap establishes the regulatory framework for the phased implementation of mandatory bioequivalence (BE) requirements for BE-eligible multisource (generic) medicinal products in Kenya. It provides a structured, risk-based and enforceable approach for achieving full compliance with national bioequivalence requirements while safeguarding public health and strengthening confidence in the quality, safety and efficacy of multisource medicinal products.

The Roadmap applies to all BE-eligible products already authorized for marketing, products undergoing evaluation, and new applications submitted to the Pharmacy and Poisons Board (PPB). It defines the regulatory requirements applicable to different categories of products, establishes implementation timelines, and introduces mechanisms for regulatory monitoring, compliance management and enforcement.

To facilitate implementation, every Marketing Authorisation Holder (MAH) with affected products shall submit a legally binding Product-specific Bioequivalence Submission Plan (BESP) identifying the activities, milestones, timelines and documentary evidence that will lead to submission of acceptable BE data. The Board shall review, approve and monitor implementation of each BESP through a structured compliance monitoring system.

Implementation of this Roadmap will enable the Board to systematically monitor progress towards full bioequivalence compliance, apply consistent regulatory oversight, and implement proportionate regulatory actions where agreed implementation milestones are not achieved. The Roadmap also supports implementation of WHO Global Benchmarking Tool (GBT) requirements relating to marketing authorisation, regulatory consistency and lifecycle oversight and contributes towards attainment and maintenance of WHO Maturity Level 3 (ML.3).

2.0 BACKGROUND AND RATIONALE

2.1 Bioequivalence (BE) is internationally recognized as the scientific standard for demonstrating the therapeutic equivalence of multisource (generic) medicinal products to their corresponding reference products. Demonstration of bioequivalence provides assurance that approved generic medicines are expected to have the same safety, efficacy and therapeutic performance as the reference product when used under the conditions specified in the approved product information.

2.2 The Pharmacy and Poisons Board (PPB) introduced bioequivalence requirements for eligible multisource medicinal products in 2010. However, implementation for locally manufactured products already authorized for marketing was progressively deferred following stakeholder consultations and concerns regarding industry preparedness, availability of bioequivalence study facilities and the potential impact on the availability of essential medicines.

2.3 Recognising the need to strengthen regulatory oversight of therapeutic equivalence, the Board issued Circular No. **(PPB/HPT/LET/VOL.II/016/23)** in September 2023, notifying Marketing Authorization Holders (MAHs) of the commencement of mandatory demonstration of therapeutic equivalence for BE-eligible multisource medicinal products. Effective 1 January 2024, all new applications for BE-eligible products have been required to include acceptable bioequivalence data, or other evidence acceptable to the Board (in support of the Biowaiver Application) in accordance with applicable regulatory requirements, as part of the marketing authorization application.

2.4 To facilitate implementation for products already authorized before the mandatory BE requirement came into effect, the Board initially adopted a phased transition period linked to marketing authorization renewal cycles. During the WHO Global Benchmarking Tool (GBT) assessments and subsequent follow-up reviews, the World Health Organization

determined that the proposed transition periods did not provide adequate assurance of timely implementation and recommended a shorter implementation period that was independent of renewal cycles. The Board therefore revised its implementation approach to require completion of bioequivalence implementation within a defined transition period ending on 31 December 2026.

2.5 While establishment of a final implementation deadline is necessary, effective regulatory oversight requires continuous monitoring of implementation progress rather than verification only at the end of the transition period. Accordingly, this Roadmap establishes a structured compliance management framework requiring each Marketing Authorization Holder with affected products to submit a Product-specific Bioequivalence Submission Plan (BESP). The BESP shall identify the implementation activities, measurable milestones, target completion dates and documentary evidence required to demonstrate progress towards submission of acceptable bioequivalence data.

2.6 The Board shall review and approve each BESP, monitor implementation against agreed milestones through an internal Bioequivalence Compliance Tracking System, and implement appropriate regulatory interventions where implementation progress is unsatisfactory or agreed milestones are not achieved. This approach enables early identification of implementation challenges, facilitates regulatory engagement with MAHs, and supports consistent, transparent and risk-based regulatory decision-making.

2.7 Implementation of this Roadmap is intended to strengthen the regulation of multisource medicinal products throughout their lifecycle, improve assurance of therapeutic equivalence, promote consistency in regulatory decision-making, and demonstrate compliance with the WHO Global Benchmarking Tool (GBT) requirements relating to marketing authorisation, regulatory oversight and lifecycle management.

3.0 OBJECTIVES

3.1 Primary Objective

To establish and implement a transparent and enforceable risk-based regulatory mechanism for the implementation of mandatory bioequivalence (BE) requirements for all BE-eligible multisource medicinal products, ensuring that therapeutic equivalence is demonstrated within the prescribed implementation period and maintained throughout the product lifecycle.

3.2 Specific Objectives

This Roadmap seeks to:

1. Ensure that all BE-eligible marketed products for which BE data was not formally submitted including products with Valid MA and Products pending renewal of MA demonstrate therapeutic equivalence through submission of acceptable bioequivalence data by 31st December 2026.
2. Establish a standardized regulatory framework for implementation of bioequivalence requirements applicable to all Marketing Authorisation Holders (MAHs), irrespective of the origin of manufacture, regulatory pathway or ownership of the product.
3. Require every MAH with affected products to develop and implement Product-specific Bioequivalence Submission Plans (BESPs) identifying implementation activities, measurable milestones, target completion dates and documentary evidence
4. Establish a structured regulatory mechanism for reviewing, approving and monitoring Product-specific Bioequivalence Submission Plans and for assessing implementation progress against approved milestones.
5. Strengthen regulatory oversight through implementation of a Bioequivalence Compliance Tracking System that enables continuous monitoring of implementation progress, identification of

implementation risks and timely regulatory intervention where necessary.

6. Promote consistency, transparency and predictability in regulatory decision-making by applying standardized implementation requirements, monitoring criteria and enforcement actions to all affected products.
7. Strengthen communication and engagement with Marketing Authorisation Holders by providing clear implementation requirements, monitoring expectations, reporting obligations and regulatory consequences for non-compliance.
8. Facilitate timely identification and resolution of implementation challenges through periodic progress reviews, risk assessment and corrective regulatory actions.
9. Strengthen lifecycle regulatory oversight by ensuring that implementation of bioequivalence requirements is monitored from initiation of the implementation plan through submission and regulatory assessment of acceptable bioequivalence data.
10. Support implementation of the WHO Global Benchmarking Tool (GBT) sub-indicators relating to marketing authorisation, regulatory oversight, consistency of regulatory decision-making and lifecycle management, thereby contributing to attainment and maintenance of WHO Maturity Level 3 (ML.3).

4.0 GUIDING PRINCIPLES

Implementation of this Roadmap shall be guided by the following regulatory principles:

1. **Protection of Public Health;** The implementation of bioequivalence requirements shall be undertaken to protect and promote public health by ensuring that all BE-eligible multisource medicinal products marketed in Kenya are therapeutically equivalent to their respective reference products and are expected to provide comparable safety, efficacy and quality throughout their lifecycle.
2. **Risk-based Regulatory Oversight;** The Board shall apply a risk-based approach to the implementation, monitoring and enforcement of this Roadmap. Regulatory oversight shall be proportionate to the level of public health risk, the implementation status of each product and the extent of compliance demonstrated by the Marketing Authorisation Holder (MAH).
3. **Equal Application of Regulatory Requirements;** Bioequivalence requirements shall be applied consistently to all BE-eligible products irrespective of the country of manufacture, ownership, applicant type, regulatory pathway or source of supply, in accordance with the principle that equivalent regulatory requirements apply to all products seeking or holding marketing authorisation.
4. **Accountability of Marketing Authorisation Holders;** Marketing Authorisation Holders shall bear primary responsibility for demonstrating therapeutic equivalence of their products, implementing approved Product-specific Bioequivalence Submission Plans (BESPs), maintaining compliance with approved implementation milestones and submitting complete and accurate information to the Board within the prescribed timelines.
5. **Transparency and Predictability;** Implementation requirements, regulatory expectations, monitoring procedures, implementation milestones, reporting obligations and regulatory consequences shall be communicated clearly to all stakeholders to promote

transparency, consistency and predictability in regulatory decision-making.

6. **Evidence-based Regulatory Decision-making;** All regulatory decisions relating to implementation of this Roadmap shall be based on objective scientific evidence, documented implementation progress, compliance with approved BESPs and applicable legal and regulatory requirements.
7. **Lifecycle Regulatory Oversight;** Implementation of bioequivalence requirements shall be monitored throughout the product lifecycle, from commencement of implementation planning to submission, assessment and acceptance of bioequivalence data, ensuring continuous regulatory oversight rather than assessment only at the final implementation deadline.
8. **Continuous Monitoring and Improvement;** The Board shall establish mechanisms for continuous monitoring of implementation progress, periodic review of compliance, identification of implementation risks and timely corrective regulatory interventions to ensure achievement of the objectives of this Roadmap.
9. **Regulatory Consistency;** The Board shall implement standardized procedures, monitoring criteria and decision-making processes to ensure consistent review of Product-specific Bioequivalence Submission Plans, objective monitoring of implementation milestones and equitable application of regulatory actions across all affected products.
10. **Proportionate Compliance Management and Enforcement;** The Board shall encourage voluntary compliance through stakeholder engagement, guidance and routine monitoring. Where non-compliance is identified, regulatory actions shall be proportionate to the nature, extent and public health significance of the deficiency and shall be applied in accordance with applicable legislation and documented regulatory procedures.
11. **Collaboration and Stakeholder Engagement;** The Board shall maintain continuous engagement with Marketing Authorisation

Holders, manufacturers, contract research organisations, development partners and other relevant stakeholders to facilitate implementation of bioequivalence requirements, address emerging challenges and promote timely achievement of implementation milestones.

5.0 IMPLEMENTATION FRAMEWORK

5.1 Scope of Implementation

This Roadmap applies to all bioequivalence (BE)-eligible multisource medicinal products that require demonstration of therapeutic equivalence in accordance with the applicable laws, regulations, guidelines and policies of the Pharmacy and Poisons Board (PPB).

The roadmap shall apply to:

a) All BE-eligible marketed products for which BE data was not formally submitted including products with Valid MA and Products pending renewal of MA
b) Marketing Authorisation Applications Under Review and New Applications
c) Additional strengths requiring demonstration of therapeutic equivalence or eligibility for a biowaiver in accordance with applicable regulatory requirements.

5.2 Product Classification

For implementation purposes, products shall be classified into the following categories.

a) BE-eligible products currently holding a valid Marketing Authorisation (MA) and those due for renewal;

   This category comprises BE-eligible products that were registered before implementation of mandatory bioequivalence requirements. These products shall:

   - Submit acceptable bioequivalence data before renewal or no later than 31 December 2026, whichever occurs first;
   - Submit a legally binding undertaking (annex 1)
   - submit a Product-specific Bioequivalence Submission Plan (BESP) (annex 2)
   - comply with all approved implementation milestones;
   - submit periodic implementation progress reports

b) Marketing Authorisation Applications Under Review and New Applications;

No application requiring bioequivalence data shall be approved unless acceptable evidence of therapeutic equivalence has been demonstrated to the Board.

5.3 **Product-specific Bioequivalence Submission Plans (BESPs)**

Every Marketing Authorisation Holder (MAH) with one or more affected products shall submit a separate Product-specific Bioequivalence Submission Plan (BESP) for each product requiring demonstration of bioequivalence.

The BESP shall be submitted within timelines prescribed by the Board following notification of the implementation requirements. Each BESP shall include:

- Product Name;
- Registration Number
- BCS Classification
- CRO Contracting date
- Study Initiation date
- Study Completion Date
- BE Study Report status
- Date of Submission of BE Report to PPB

The BESP shall be signed by an authorized representatives of the MAH listed and the legally binding undertaking which shall constitute a regulatory commitment to implement the approved activities within the agreed timelines.

5.4 **Review and Approval of BESPs**

The Board shall review every submitted BESP to determine whether:

- Timelines are realistic;
- Documentary evidence is adequate;

- Implementation is capable of achieving submission of acceptable bioequivalence data within the prescribed implementation period.

Where necessary, the Board may require revision of the BESP before approval.

Implementation shall commence only after acceptance of the BESP by the Board.

5.5 **Implementation of Approved BESPs**

Marketing Authorisation Holders shall implement approved BESPs in accordance with the agreed implementation milestones and timelines.

Where circumstances arise that may significantly affect implementation, the MAH shall promptly notify the Board, provide justification for the delay and submit a revised implementation plan for consideration.

Any revision to an approved BESP shall require prior review and acceptance by the Board and shall not extend beyond the implementation deadline of 31st December 2026.

5.6 **Progress Reporting to PPB**

Marketing Authorisation Holders shall submit implementation progress reports at intervals determined in the approved BESP document.

Progress reports shall include documentary evidence demonstrating completion of the relevant milestone and shall identify any actual or anticipated implementation delays.

The Board may request additional information or documentary evidence where necessary to verify implementation progress.

5.7 **Regulatory Oversight**

The Board shall establish and maintain an internal Bioequivalence Compliance Tracking System to monitor implementation of approved BESPs.

Implementation progress shall be reviewed periodically to ensure that all affected products remain on course to achieve compliance within the implementation period established under this Roadmap.

6.0 REGULATORY DELIVERABLES

The implementation of this Roadmap shall result in the development, maintenance and continual updating of regulatory tools and records necessary to support implementation, monitoring, regulatory oversight and enforcement of bioequivalence requirements.

6.1 Product Categorisation Register

The Board shall establish and maintain a comprehensive register of all BE-eligible medicinal products classified according to their implementation category under this Roadmap;

The register shall include, at a minimum:

- Product name
- Active pharmaceutical ingredient
- Strength
- Dosage form
- Marketing Authorisation Number
- Marketing Authorisation Holder
- Year of registration
- Therapeutic class

6.2 Product-specific Bioequivalence Submission Plans (BESPs)

Each Marketing Authorisation Holder with one or more affected products shall submit a Product-specific Bioequivalence Submission Plan for every product requiring demonstration of bioequivalence.

The BESP shall:

- Product Name;
- Registration Number
- BCS Classification
- Therapeutic Classification
- CRO Contracting date
- Study Initiation date

- Study Completion Date
- BE Study Report status
- BE Report Submission date

The approved BESP shall constitute the operational implementation plan for monitoring regulatory compliance.

6.3 Legally Binding Undertakings (annex 1)

Every Marketing Authorisation Holder with affected products shall execute and submit a legally binding undertaking committing to:

- comply with this Roadmap;
- implement approved Product-specific BESPs;
- submit acceptable bioequivalence data within the prescribed timelines;
- cooperate with regulatory monitoring;
- acknowledge the regulatory consequences arising from failure to comply.

The legally binding undertaking shall complement, but not replace, the Product-specific BESP.

6.4 Bioequivalence Compliance Register

The Board shall establish and maintain an internal Bioequivalence Compliance Register for monitoring implementation of this Roadmap.

The register shall include, as appropriate:

- Product identification
- Marketing Authorisation Holder
- Product category
- Date of notification
- Date legally binding undertaking received
- Date Product-specific Bioequivalence Submission Plan (BESP) received
- Current implementation milestone

- Planned milestone completion date
- Actual completion date
- Current compliance status
- Regulatory action taken

The Compliance Register shall constitute the primary regulatory tool for monitoring implementation progress.

6.5 Standard Regulatory Templates

The Board shall develop and maintain standardized templates to facilitate consistent implementation of this Roadmap.

These shall include:

- Legally binding undertaking template (annex 1);
- Product-specific BESP template (annex 2);
- Compliance assessment SOP.

6.6 Communication Materials

The Board shall prepare and periodically update communication materials necessary to facilitate implementation of this Roadmap, including:

- Notification letters;
- Guidance documents;
- Frequently asked questions;
- Website publications;
- Implementation circulars.

6.7 Monitoring Dashboards

The Board shall establish electronic dashboards for monitoring implementation progress.

The dashboards shall present, at a minimum:

- Products requiring BE;
- Products with approved BESPs;

- Products meeting implementation milestones;
- Overdue milestones;
- Products that have submitted BE data;
- Products achieving compliance;
- Products requiring regulatory intervention.

The dashboards shall support routine management review and regulatory decision-making.

6.8 **Implementation Reports**

The Board shall prepare periodic implementation reports summarising:

- implementation progress;
- milestone achievement;
- compliance trends;
- implementation risks;
- corrective actions;
- regulatory interventions;
- overall progress towards completion of the Roadmap.

Implementation reports shall be submitted to Management and the Board at intervals determined by the Board.

7.0 IMPLEMENTATION MATRIX

Implementation of this Roadmap shall be undertaken through clearly defined implementation activities, regulatory milestones and monitoring points. The implementation schedule shall facilitate the timely submission of bioequivalence data while enabling the Board to monitor progress, identify implementation risks and institute appropriate regulatory interventions where necessary.

The implementation activities and corresponding milestones are set out in Table 1.

Table 1. Implementation Timeline and Regulatory Milestones

Phase	Activity	Responsible Party	Timeline	Evidence of Completion
1.	Stakeholder consulation with Marketing Authorisation Holders	PPB	Within 3 days of approval	Circulars, notification letters
2.	Publication of the Roadmap	PPB	Within 3 days of approval	website publication
3.	Identification and categorisation of all affected BE-eligible products	PPB	Within 3 days of publication	Updated Product Categorisation Register
4.	Submission of legally binding undertakings	MAHs	By 17 July	Signed undertaking
5.	Submission of Product-specific Bioequivalence Submission Plans (BESPs)	MAHs	By 17 July	Accepted BESP
6.	Review and acceptance of BESPs	PPB	Within 3 days of receipt	Accepted BESP and review report
7.	Submission of implementation progress reports	MAHs	As per accepted BESP timeline	Progress reports with supporting evidence
8.	Verification of implementation milestones	PPB	As per accepted BESP timeline	Updated Compliance Register
9.	Review of implementation progress	PPB	Monthly	Compliance review report
10.	Follow-up of compliance with the accepted BESP	PPB	Two (2) days after lapse accepted BESP timeline	Follow-up communication

11.	Submission of acceptable BE study reports	MAHs	Not later than 31 December 2026	Complete BE submission
12.	Scientific assessment of submitted BE data	PPB	In accordance with internal timelines	Assessment report
13.	Completion of implementation and verification of compliance	PPB	By 31 December 2026	Final compliance report
14.	Regulatory action for products remaining non-compliant	PPB	From 1 January 2027	Regulatory decision

7.1 Product-specific Bioequivalence Submission Plans

Each Marketing Authorisation Holder shall submit a Product-specific Bioequivalence Submission Plan (BESP) for every BE-eligible product requiring demonstration of bioequivalence.

The BESP shall provide a realistic implementation pathway from the current stage of product development to submission of acceptable bioequivalence data and shall include measurable implementation milestones that enable routine regulatory monitoring by the Board

7.2 Mandatory Implementation Milestones

Each BESP shall include, where applicable, the following implementation milestones:

- Appointment of the Contract Research Organisation (CRO) or confirmation of the study site.
- Commencement of the bioequivalence study.
- Finalisation of the Clinical Study Report.
- Submission of the complete bioequivalence dossier to the Board.

Where a milestone is not applicable to a particular product, the MAH shall provide a documented justification acceptable to the Board.

7.3 Documentary Evidence for Milestone Verification

Completion of each implementation milestone shall be supported by objective documentary evidence acceptable to the Board.

Such evidence may include, as appropriate:

Milestone	**Documentary Evidence**
Appointment of the Contract Research Organisation (CRO) or confirmation of the study site.	Executed contracts or agreements with CROs (may be redacted as appropriate)
Commencement of the bioequivalence study.	Study confirmation letter by the CRO.
Finalisation of the Clinical Study Report.	Any of the following; i. Progress reports from the CRO ii. Study completion notifications; iii. BE study Report
Submission of the complete bioequivalence dossier to the Board.	Complete BTIF & bioequivalence study reports, and acknowledgement of receipt.

The Board may request additional supporting documentation where necessary to verify implementation progress.

7.4 **Review of Implementation Progress**

The Board shall review implementation progress as described in Implementation Timeline and Regulatory Milestones.

Implementation reviews shall evaluate:

- achievement of planned milestones;
- compliance with approved implementation timelines;
- adequacy of documentary evidence;
- corrective actions proposed by the MAH;
- revised implementation schedules where justified.

Following each review, the Board shall determine whether:

- implementation is progressing satisfactorily;
- additional information is required;
- implementation timelines require revision;
- regulatory intervention is necessary.

7.5 **Management of Delays**

Where a Marketing Authorisation Holder anticipates that an approved implementation milestone cannot be achieved within the agreed timeline, the MAH shall notify the Board in writing before the milestone becomes overdue.

The notification shall include:

- the reason for the delay;
- an assessment of the impact on the overall implementation schedule;
- corrective actions undertaken;
- proposed revised milestone dates; and
- supporting documentary evidence.

The Board shall evaluate the justification and determine whether revision of the approved BESP is warranted. Approval of revised implementation milestones shall not extend the final implementation deadline of 31st December 2026.

8.0 COMMUNICATION STRATEGY AND STAKEHOLDER ENGAGEMENT

The successful implementation of this Roadmap depends upon effective communication and continuous engagement between the Pharmacy and Poisons Board (PPB), Marketing Authorisation Holders (MAHs), manufacturers, Contract Research Organisations (CROs), industry associations and other relevant stakeholders. The Board shall implement a structured communication strategy to ensure that regulatory requirements are clearly communicated, implementation expectations are understood, and stakeholders receive timely guidance throughout the implementation period.

Communication activities shall promote transparency, consistency, accountability and timely compliance with the requirements of this Roadmap.

8.1 Communication of Regulatory Requirements

The Board shall formally communicate the requirements of this Roadmap to all affected Marketing Authorisation Holders and other relevant stakeholders.

Communication shall include, as appropriate:

- publication of the approved Roadmap;
- regulatory circulars and official notification letters;
- publication on the PPB website;
- guidance documents and frequently asked questions;
- implementation timelines and regulatory milestones;
- Product-specific Bioequivalence Submission Plan (BESP) requirements;
- reporting obligations;
- regulatory consequences of non-compliance.

8.2 Notification of Marketing Authorisation Holders

Each affected Marketing Authorisation Holder shall receive formal written notification of the applicable regulatory requirements.

The notification shall specify, as applicable:

- products affected;
- product implementation category;
- requirement to submit a legally binding undertaking;
- requirement to submit Product-specific BESPs;
- applicable implementation timelines;
- reporting requirements;
- documentary evidence required for milestone verification;
- applicable regulatory consequences for non-compliance.

8.3 Stakeholder Engagement

The Board shall conduct stakeholder engagement activities throughout implementation to facilitate understanding of regulatory requirements and promote timely compliance.

Such activities may include:

- stakeholder consultative meetings;
- industry workshops;
- technical webinars;
- scientific advisory meetings;
- bilateral meetings with MAHs where necessary;
- publication of implementation guidance.

Stakeholder engagement shall not modify the regulatory requirements established under this Roadmap unless formally approved by the Board.

8.4 **Regulatory Guidance**

The Board shall provide guidance to facilitate consistent implementation of bioequivalence requirements.

Guidance may include:

- preparation of Product-specific BESPs;
- acceptable implementation milestones;
- documentary evidence requirements;
- conduct of bioequivalence studies;
- selection of Contract Research Organisations;
- preparation of bioequivalence dossiers;
- submission procedures;
- reporting of implementation progress.

Where regulatory requirements are amended during implementation, revised guidance shall be issued promptly.

8.5 **Communication During Implementation**

Communication between the Board and Marketing Authorisation Holders shall continue throughout implementation.

The Board shall communicate, where applicable:

- acknowledgement of submitted BESPs;
- requests for additional information;
- approval or rejection of BESPs;
- comments arising from implementation reviews;
- reminders of upcoming milestones;
- notification of overdue implementation activities;
- regulatory decisions;

Marketing Authorisation Holders shall promptly notify the Board of:

- Completion of implementation milestones;
- Anticipated implementation delays including their justifications;

- Changes affecting implementation;
- Requests for revision of approved BESPs;
- Submission of bioequivalence data.

9.0 COMPLIANCE MANAGEMENT AND REGULATORY ACTIONS

The Pharmacy and Poisons Board (PPB) shall implement a structured compliance management system to monitor implementation of this Roadmap, promote voluntary compliance, identify implementation risks at an early stage and apply proportionate regulatory actions where non-compliance is identified.

The objective of the compliance management system is to facilitate timely implementation of approved Product-specific Bioequivalence Submission Plans (BESPs), ensure consistent regulatory oversight and safeguard public health.

9.1 Compliance Management Framework

Compliance with this Roadmap shall be monitored throughout the implementation period using:

- approved Product-specific Bioequivalence Submission Plans (BESPs);
- legally binding undertakings;
- implementation progress reports;
- milestone verification;
- periodic regulatory reviews;
- The Bioequivalence Compliance Tracking System.

Compliance shall be assessed against approved implementation milestones rather than only against the final submission deadline.

9.2 Responsibilities of Marketing Authorisation Holders

Every Marketing Authorisation Holder shall:

1. Implement the approved Product-specific BESP;
2. Comply with approved implementation milestones;
3. Submit implementation progress reports within prescribed timelines;
4. Provide documentary evidence demonstrating completion of implementation milestones;
5. notify the Board promptly of actual or anticipated implementation delays;

6. implement corrective actions where deficiencies are identified;
7. Submit acceptable bioequivalence data within the implementation period established under this Roadmap.

Failure to comply with these obligations shall constitute non-compliance with this Roadmap.

9.3 **Responsibilities of the Board**

The Board shall:

1. review and approve BESPs;
2. monitor implementation progress;
3. verify completion of implementation milestones;
4. maintain the Bioequivalence Compliance Register;
5. identify implementation risks;
6. communicate implementation deficiencies;
7. review proposed corrective actions;
8. determine appropriate regulatory interventions;
9. Maintain complete records of regulatory decisions.

9.4 **Identification of Non-compliance**

Non-compliance may include, but shall not be limited to:

1. failure to submit a legally binding undertaking;
2. Failure to submit a Product-specific BESP;
3. failure to implement an approved BESP;
4. failure to submit required implementation progress reports;
5. failure to achieve approved milestones without acceptable justification;
6. submission of incomplete or misleading implementation information;
7. failure to provide documentary evidence supporting implementation progress;
8. Failure to submit acceptable BE data within the prescribed implementation period.

9.5 **Compliance Review**

Implementation progress shall be reviewed periodically using documented compliance review procedures.

Each compliance review shall evaluate:

1. implementation progress;
2. milestone achievement;
3. adequacy of supporting evidence;
4. implementation delays;
5. implementation risks;
6. corrective actions implemented;
7. likelihood of achieving the final implementation deadline.

The outcome of every compliance review shall be documented.

9.6 **Management of Implementation Delays**

Where implementation delays are identified, the Board shall evaluate:

1. significance of the delay;
2. public health impact;
3. reasons for delay;
4. adequacy of corrective actions;
5. revised implementation schedule;
6. previous compliance history.

Where justified, the Board may approve revised implementation milestones provided that such revisions do not compromise the objectives of this Roadmap or extend the final implementation deadline unless exceptional circumstances exist.

9.7 **Regulatory Action and Escalation Framework for Non- Compliance**

The Board shall apply a graduated approach to compliance management.

9.7.1 Level 1 — Routine Monitoring

Implementation progressing according to approved milestones.

Regulatory action:

- routine monitoring;
- periodic review.

9.7.2 Level 2 — Early Intervention

Minor implementation delays.

Regulatory action:

- written reminder;
- request for clarification;
- review meeting.

9.7.3 Level 3 — Corrective Action

Repeated delays or failure to achieve agreed milestones.

Regulatory action:

- formal warning;
- submission of Corrective and Preventive Action (CAPA) plan;
- intensified monitoring;
- management meeting.

9.7.4 Level 4 — Significant Non-compliance

Persistent failure to implement the approved BESP.

Regulatory action:

- regulatory hearing;
- restriction of regulatory privileges where permitted by law;
- consideration of renewal restrictions;
- increased regulatory oversight.

9.7.5 Level 5 — Regulatory Enforcement

i. Failure to submit BESP by 17th July 2026

ii. Failure to submit acceptable bioequivalence data within the implementation period or persistent non-compliance despite previous regulatory interventions.

The Board may, in accordance with the applicable legislation:

- refuse renewal of the Marketing Authorisation;
- suspend the Marketing Authorisation;
- restrict manufacturing
- revoke the Marketing Authorisation;
- withdrawal/recall of the product of the market

- refuse approval of related applications where permitted under applicable legislation;
- publish regulatory actions where necessary for protection of public health.

9.8 **Corrective and Preventive Actions (CAPAs)**

Where implementation deficiencies are identified, the Board may require the Marketing Authorisation Holder to submit a CAPA.

The CAPA shall include:

- root cause analysis;
- corrective actions;
- preventive actions;
- implementation timelines;
- responsible persons;
- effectiveness indicators.

The Board shall verify the implementation and effectiveness of CAPAs.

9.9 **Regulatory Decision-making**

All regulatory decisions arising from the implementation of this Roadmap shall be based on the principles of Good Regulatory & Review Practices as established by WHO.

Records of regulatory decisions shall be maintained as part of the implementation record.

9.10 **Legal Authority**

The implementation of this Roadmap shall be supported by the Pharmacy and Poisons Act (Cap. 244), applicable subsidiary legislation, marketing authorisation regulations, and other relevant legal and regulatory instruments governing the regulation of medicinal products in Kenya.

The Board may exercise all powers conferred upon it under the applicable legislation to ensure implementation of this Roadmap and protection of public health.

10.0 MONITORING, PERFORMANCE INDICATORS AND REPORTING

10.1 Purpose

The Pharmacy and Poisons Board (PPB) shall establish and maintain a structured monitoring, performance measurement and reporting system to evaluate implementation of this Roadmap, verify compliance with approved Product-specific Bioequivalence Submission Plans (BESPs), identify implementation risks and support timely regulatory decision-making.

Monitoring shall be undertaken throughout the implementation period to ensure that implementation remains on course for the achievement of full bioequivalence compliance within the timelines established under this Roadmap.

10.2 Bioequivalence Compliance Tracking System

The Board shall establish and maintain an electronic Bioequivalence Compliance Tracking System as the primary tool for monitoring implementation of this Roadmap.

The system shall capture, at a minimum:

- Product name;
- Marketing Authorisation Number;
- Marketing Authorisation Holder;
- Product category;
- Date of notification;
- Date legally binding undertaking received;
- Date Product-specific BESP received;
- Current implementation stage;
- Current implementation milestone;
- Planned milestone completion date;
- Actual milestone completion date;
- Documentary evidence received;

- Current compliance status;
- Regulatory interventions undertaken;
- Final implementation outcome.

The system shall be maintained by the Marketing Authorisation Department and shall be accessible to relevant regulatory functions involved in implementation and oversight.

10.3 **Key Performance Indicators**

Implementation performance shall be monitored using measurable Key Performance Indicators (KPIs).

The indicators shall include, but not be limited to:

a) Regulatory Implementation Indicators

- Percentage of affected products identified and categorised.
- Percentage of MAHs notified.
- Percentage of legally binding undertakings received.
- Percentage of Product-specific BESPs submitted.
- Percentage of BESPs reviewed within target timelines.
- Percentage of BESPs approved

b) Implementation Progress Indicators

- Percentage of products progressing according to approved milestones.
- Percentage of milestones completed on schedule.
- Percentage of overdue milestones.
- Number of revised BESPs approved.
- Number of products requiring regulatory intervention.

c) Bioequivalence Compliance Indicators

- Percentage of products that have completed BE studies.
- Percentage of products that have submitted acceptable BE data.
- Percentage of BE submissions accepted for scientific review.
- Percentage of products achieving full compliance.
- Percentage of products remaining non-compliant.

d) Regulatory Performance Indicators

- Average time for review of BESPs.
- Average time for review of progress reports.
- Percentage of regulatory reviews completed within target timelines.
- Number of compliance reviews conducted.
- Number of CAPAs implemented and verified.

10.4 **Monitoring Activities**

The Board shall conduct routine monitoring activities including:

- review of implementation progress reports;
- verification of milestone completion;
- review of documentary evidence;
- updating of the Bioequivalence Compliance Register;
- trend analysis;
- identification of implementation risks;
- review of overdue milestones;
- verification of implementation of CAPAs.

Monitoring activities shall be documented.

10.5 **Compliance Dashboard**

The Board shall maintain a Bioequivalence Compliance Dashboard to provide real-time oversight of implementation progress.

The dashboard shall include, as appropriate:

- total BE-eligible products;
- products requiring implementation;
- products with approved BESPs;
- products on schedule;
- products at risk of delay;
- overdue milestones;
- products with completed BE studies;
- products with submitted BE data;
- products achieving compliance;

- products requiring regulatory intervention.

Dashboard information shall support routine management review and regulatory decision-making.

10.6 **Reporting**

Marketing Authorisation Holders shall submit implementation progress reports in accordance with timelines prescribed by the Board.

The Board shall prepare:

a) Monthly Reports

Including:

- implementation progress;
- milestone achievement;
- overdue milestones;
- implementation risks;
- regulatory interventions.

b) Quarterly Reports

Including:

- implementation trends;
- KPI performance;
- compliance statistics;
- CAPA implementation;
- management recommendations.

c) Annual Reports

Summarising:

- overall implementation performance;
- achievement of roadmap objectives;
- regulatory outcomes;
- lessons learnt;
- recommendations for continuous improvement.

10.7 **Management Review**

Implementation performance shall be reviewed periodically by Management.

Management reviews shall evaluate:

- achievement of implementation milestones;
- KPI performance;
- implementation risks;
- effectiveness of regulatory interventions;
- adequacy of resources;
- implementation challenges;
- effectiveness of stakeholder engagement;
- recommendations for improvement.

Management review decisions shall be documented and monitored to completion

10.8 **Data Quality and Integrity**

Information generated during implementation of this Roadmap shall be complete, accurate, contemporaneous, attributable, legible and readily retrievable.

The Board shall implement appropriate controls to ensure the integrity of implementation records, monitoring data and regulatory decisions.

Where electronic systems are used, appropriate measures shall be implemented to ensure data security, traceability and controlled acces

10.9 **Continuous Improvement**

The Board shall periodically review implementation performance to identify opportunities for improving the effectiveness of this Roadmap.

Continuous improvement activities may include:

- revision of implementation procedures;
- refinement of monitoring indicators;
- enhancement of stakeholder guidance;
- improvement of internal workflows;

- strengthening of electronic monitoring systems;
- review of regulatory policies.

Lessons learnt during implementation shall be incorporated into future revisions of this Roadmap.

10.10 **WHO Global Benchmarking Reporting**

The Board shall maintain documentary evidence demonstrating implementation of this Roadmap for purposes of regulatory oversight, management review and verification during WHO Global Benchmarking Tool (GBT) assessments.

Evidence may include:

- implementation registers;
- approved BESPs;
- compliance dashboards;
- KPI reports;
- management review minutes;
- CAPA records;
- regulatory decisions;
- implementation reports.

11.0 RISK MANAGEMENT

11.1 Purpose

The Pharmacy and Poisons Board (PPB) shall implement a structured risk management process to identify, assess, monitor and mitigate risks that may affect successful implementation of this Roadmap.

Risk management shall be undertaken throughout the implementation period to facilitate timely regulatory intervention, minimise implementation delays and ensure achievement of the objectives of this Roadmap.

11.2 Risk Management Principles

Implementation risks shall be managed in accordance with the following principles:

- proactive identification of implementation risks;
- risk-based prioritisation of regulatory activities;
- timely implementation of mitigation measures;
- continuous monitoring of residual risks;
- periodic review of risk effectiveness;
- documentation of risk management decisions;
- continuous improvement of mitigation strategies

11.3 Risk Identification

Implementation risks shall be identified through:

- review of Product-specific Bioequivalence Submission Plans (BESPs);
- implementation progress reports;
- compliance reviews;
- monitoring dashboards;
- stakeholder engagement activities;
- management reviews;
- regulatory inspections;
- scientific assessment activities.

Newly identified risks shall be documented and incorporated into the implementation risk register.

11.4 Risk Assessment

Each identified risk shall be assessed considering:

- likelihood of occurrence;
- potential impact on implementation timelines;
- impact on public health;
- number of products affected;
- ability of the Marketing Authorisation Holder to implement corrective actions;
- potential impact on the achievement of the Roadmap objectives.

The Board may prioritise regulatory interventions based on the assessed level of risk.

11.5 Risk Register

The Board shall establish and maintain an Implementation Risk Register throughout the implementation period.

The Risk Register shall include:

- description of the risk;
- source of the risk;
- products affected;
- current risk rating;
- mitigation measures;
- responsible regulatory officer;
- implementation status;
- review date;
- residual risk assessment.

The Risk Register shall be reviewed periodically and updated whenever new implementation risks are identified.

11.6 **Implementation Risks and Mitigation Measures**

Table 2. Implementation Risks and Mitigation Measures

Risk	Potential Impact	Mitigation Measures	Monitoring Indicator
Delayed submission of Product-specific BESPs	Delay in commencement of implementation	Early notification, reminders, stakeholder engagement, compliance monitoring	% BESPs submitted on time
Delayed commencement or completion of BE studies	Failure to achieve implementation milestones	Routine progress reviews, regulatory meetings, CAPAs, intensified monitoring	% milestones achieved on schedule
Limited capacity of Contract Research Organisations	Delay in conducting BE studies	Early planning, recognition of acceptable foreign CROs, publication of guidance	Number of studies initiated
Poor quality or incomplete BE submissions	Delays in regulatory assessment	Guidance documents, submission checklist, scientific advice meetings	% acceptable first submissions
Delays in applicant responses to regulatory requests	Extended implementation timelines	Routine follow-up, defined response timelines, escalation procedures	Average response time
Industry resistance to implementation	Reduced compliance	Continuous stakeholder engagement, publication of regulatory expectations, transparent communication	Number of stakeholder engagements
Legal challenges	Delay in implementation	Clear legal framework, documented regulatory decisions, legally binding undertakings	Number of legal disputes
Internal resource constraints	Reduced monitoring effectiveness	Resource planning, workload prioritisation, management review	Completion of monitoring activities

11.7 **Risk Monitoring**

The Board shall monitor implementation risks throughout the implementation period.

Monitoring shall include:

- review of emerging risks;
- reassessment of existing risks;
- evaluation of mitigation effectiveness;
- identification of residual risks;

- implementation of additional mitigation measures where necessary.

Risk monitoring outcomes shall be documented.

11.8 **Escalation of High-risk Issues**

Where implementation risks are assessed as having the potential to significantly affect achievement of the objectives of this Roadmap, the matter shall be escalated to Management for consideration.

Management may determine appropriate regulatory or administrative actions including:

- intensified monitoring;
- allocation of additional resources;
- revision of implementation priorities;
- stakeholder consultation;
- regulatory intervention.

11.9 **Review of Risk Management Effectiveness**

The effectiveness of risk management activities shall be reviewed periodically.

The review shall consider:

- implementation of mitigation measures;
- reduction in risk ratings;
- achievement of implementation milestones;
- adequacy of regulatory interventions;
- lessons learned;
- opportunities for improvement.

Where necessary, the Risk Register and mitigation strategies shall be revised.

11.10 **Continuous Improvement**

Lessons learned during implementation shall be incorporated into future revisions of this Roadmap, supporting continual improvement of

regulatory oversight, compliance management and implementation planning.

12.0 EXPECTED REGULATORY OUTCOMES

Successful implementation of this Roadmap shall establish a sustainable regulatory framework for the implementation, monitoring and enforcement of bioequivalence (BE) requirements for multisource medicinal products in Kenya. The Roadmap is expected to strengthen regulatory oversight, improve assurance of therapeutic equivalence and enhance confidence in regulatory decision-making while contributing to protection of public health.

By completion of the implementation period, the Pharmacy and Poisons Board (PPB) shall have achieved the following regulatory outcomes.

12.1 Full Implementation of Bioequivalence Requirements

All BE-eligible marketed medicinal products and all eligible marketing authorization applications submitted before mandatory implementation of bioequivalence requirements shall have:

- demonstrated therapeutic equivalence through submission of acceptable bioequivalence data; or
- been subject to appropriate regulatory action in accordance with applicable legislation where compliance has not been achieved.

Implementation shall be completed within the timelines established under this Roadmap.

12.2 Strengthened Regulatory Oversight

The Board shall have established and implemented a structured regulatory oversight system for monitoring implementation of bioequivalence requirements, including:

- Product-specific Bioequivalence Submission Plans (BESPs);
- Bioequivalence Compliance Tracking System;
- Bioequivalence Compliance Register;
- implementation monitoring dashboards;
- documented compliance review procedures;
- routine management review.

12.3 **Improved Compliance by Marketing Authorisation Holders**

Marketing Authorization Holders shall demonstrate improved regulatory compliance through:

- timely submission of Product-specific BESPs;
- achievement of approved implementation milestones;
- submission of implementation progress reports;
- timely submission of acceptable bioequivalence data;
- prompt implementation of corrective actions where required.

12.4 **Consistent and Transparent Regulatory Decision-making**

Implementation of this Roadmap shall promote consistent, evidence-based and transparent regulatory decision-making through:

- standardized implementation requirements;
- standardized monitoring procedures;
- documented regulatory decisions;
- objective milestone verification;
- consistent application of regulatory actions.

12.5 **Enhanced Quality Management**

The Board shall establish a quality management system supporting implementation of this Roadmap through:

- documented implementation procedures;
- measurable performance indicators;
- implementation dashboards;
- risk management processes;
- management review;
- continuous improvement activities.

12.6 **Strengthened Public Health Protection**

Implementation of mandatory bioequivalence requirements shall strengthen assurance that multisource medicinal products available on the Kenyan market are therapeutically equivalent to their respective

reference products and are expected to provide comparable quality, safety and efficacy throughout their lifecycle.

12.7 **Increased Stakeholder Confidence**

Implementation of this Roadmap shall improve confidence among patients, healthcare professionals, manufacturers, development partners and other stakeholders by demonstrating that regulatory decisions relating to therapeutic equivalence are:

- scientifically justified;
- transparent;
- predictable;
- consistently implemented;
- supported by effective regulatory oversight.

12.8 **Sustainable Regulatory System**

The Board shall establish a sustainable regulatory system capable of supporting continued implementation of bioequivalence requirements beyond completion of this Roadmap.

The system shall include:

- standardized regulatory procedures;
- trained regulatory personnel;
- electronic monitoring systems;
- documented implementation records;
- established performance indicators;
- periodic management review;
- continual improvement mechanisms.

12.9 **Alignment with International Best Practices**

Implementation of this Roadmap shall strengthen alignment of the Kenyan regulatory system with internationally accepted principles for regulation of multisource medicinal products, including WHO guidance

on therapeutic equivalence, lifecycle regulatory oversight, Good Regulatory Practices and risk-based regulatory decision-making.

12.10 **Contribution to WHO Global Benchmarking Tool (GBT) Maturity**

Implementation of this Roadmap shall contribute to continued implementation of the WHO Global Benchmarking Tool by demonstrating:

- effective lifecycle oversight of marketing authorisations;
- consistent implementation of bioequivalence requirements;
- risk-based regulatory monitoring;
- documented compliance management;
- transparent regulatory decision-making;
- effective quality management;
- continuous improvement of regulatory processes.

These outcomes shall support the Board's progression towards, and maintenance of, WHO Maturity Level 3 (ML.3).

13.0 REVISION HISTORY

Revision No.	Date	Author/Reviewer	Section(s) Revised	Description of Change
1.0	15/12/2023	QAO	Section 1.14	Revision of the roadmap implementation period from 11 years to 5 years.
			Section 4.1	Revision of time buckets implementation period from 10 years to 5 years for products already issued with Marketing Authorization.
2.0	31/05/2025	QAO	Implementation Provisions	Revision of implementation period from 5 years to 2 years for products already issued with Marketing Authorization.
			Section 6	Addition of Deliverables section.
			Section 7	Addition of Timeline and Milestones section.
			Section 8	Addition of Communication Strategy section.
			Section 9	Addition of Enforcement and Legal Framework section.
			Section 10	Addition of Monitoring and Reporting section.
			Section 11	Addition of Risks and Mitigation section.
			Section 12	Addition of Expected Outcomes section.
			Annexes	**Addition of:** • 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.
3.0	18/06/2026	QAO	Section 4	Inclusion of Guiding Principles.
			Section 5	Inclusion of BESP Implementation Framework.
			Section 6	Regulatory Deliverables updated.
			Section 7	Provision of BESP Implementation Matrix.
			Section 8	Inclusion of Communication Strategy and Stakeholder Engagement.

			Section 9	Compliance Management and Regulatory Actions.
			Section 10	Inclusion of Monitoring, Performance Indicators and Reporting.
			Section 11	Update of Risk Management.
			Section 12	Provision for Expected Regulatory Outcomes.
			Annexes	**Deletion of:** • 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. **Inclusion of:** • Annex 2: Product-specific Bioequivalence Submission Plan (BESP).

Annexes

Annex 1: Template legally binding undertaking.

Annex 2: Product-specific Bioequivalence Submission Plan (BESP)

Annex 3: Notice On Commencement of Mandatory Therapeutic Equivalence Demonstration For Multisource (Generic) Medical Products In Kenya

Annex 1: Template Legally Binding Undertaking on Bioequivalence (BE) Compliance

[MAH Letterhead]

To:
The Chief Executive Officer
Pharmacy and Poisons Board
P.O. Box 27663 – 00506,
Nairobi. Lenana Road Opp. DOD

Date: [DD/MM/YYYY]

Subject: Undertaking on Bioequivalence (BE) Compliance for Marketed Products

We, **[MAH Name]**, a company duly incorporated under the laws of **[Country]** and the Marketing Authorization Holder of the products marketed in Kenya and/or currently undergoing renewal evaluation, as listed below, hereby provide this legally binding undertaking to the Pharmacy and Poisons Board [the Board] with respect to the demonstration of therapeutic equivalence for the said products.

1. Product(s) Covered by this Undertaking
[List all product names, strengths, dosage forms, MA numbers, and dates of approval]

2. Commitment to Demonstration of Bioequivalence
In accordance with the Board's roadmap for the implementation of Bioequivalence (BE) requirements, we hereby undertake to

a) submit acceptable BE study reports to the Board prior to renewal of the respective Marketing Authorization or no later than 31 December 2026, whichever occurs first.
b) Submit a complete Product-specific Bioequivalence Submission Plan (BESP) for each affected product by 17th July 2026.
c) Implement each approved Product-specific Bioequivalence Submission Plan in accordance with the activities, milestones and timelines approved by the Board.
d) Ensure that adequate financial, technical and human resources are allocated to enable timely implementation of each approved BESP.
e) Submit periodic implementation progress reports together with documentary evidence demonstrating achievement of the approved implementation milestones.

f) Submit acceptable bioequivalence study reports for each affected product within the timelines established under the Bioequivalence Implementation Roadmap.
g) Provide & maintain complete, accurate, truthful information and records in all submissions made to the Board relating to implementation of the Roadmap and the approved BESPs.
h) Cooperate fully with the Board during monitoring, review and verification of implementation activities and provide any additional information or documentary evidence reasonably required by the Board.

3. Acknowledgement of regulatory action

We acknowledge that failure to comply with this Undertaking, failure to submit or implement an approved Product-specific Bioequivalence Submission Plan, failure to submit required progress reports, or failure to achieve approved implementation milestones without acceptable justification shall constitute non-compliance.

We further acknowledge that the Board may take regulatory action in accordance with the Pharmacy and Poisons Act, the applicable Regulations and the Bioequivalence Implementation Roadmap, including but not limited to:

- issuance of written reminders or warning letters;
- requests for corrective and preventive actions (CAPAs);
- enhanced regulatory monitoring;
- regulatory compliance meetings;
- refusal to renew a Marketing Authorisation where the applicable requirements have not been met;
- suspension or revocation of a Marketing Authorisation; or
- any other regulatory action authorised under the applicable legislation.

4. Duration of the undertaking

This Undertaking shall take effect on the date of signature and shall remain in force until all obligations under the Bioequivalence Implementation Roadmap have been fulfilled for each affected products.

5. Declaration

I hereby certify that:

- I am duly authorised to execute this Undertaking on behalf of the Marketing Authorisation Holder;
- the information contained in this Undertaking is true and correct;
- I understand the obligations arising from this Undertaking; and

- I accept this Undertaking on behalf of the Marketing Authorisation Holder.

6. Execution and signature page

This undertaking is executed on behalf of **[MAH Name]** and becomes legally binding upon signature by the authorized representatives below, who certify that they are duly authorized to execute this undertaking and that the information provided herein is true, complete, and accurate.

Signatory	Name	Signature	Date
Director *(as appearing in the CR12)*			
Director *(as appearing in the CR12)*			
Finance Director / Chief Finance Officer			
Superintendent Pharmacist / Company Pharmacist			

Official Company Seal/Stamp:

FOR OFFICIAL USE ONLY
Received by:

Signatory	Name	Signature	Date
Corporation Secretary Pharmacy and Poisons Board			

Annex 2: Product-specific Bioequivalence Submission Plan (BESP)

Field	
Retention ID	
Product ID	
CTD No.	
Trade Name	
INN/API	
Strength	
Dosage Form	
MAH	
Therapeutic Category	
Manufacturer Site	
Manufacturer Site Address	
BCS Classification	
Name and Address of CRO Contracted	
CRO Contracting Date	
BE Study Initiation Date	
BE Study Completion Date	
BE Report Status	
BE Report Submission Status	
BE Report Submission Date	
Additional Remarks	
Declaration Confirmed	
Declared By	
Designation	
Organization	
Declaration Date	
Declaration I do hereby solemnly and sincerely declare that the above information is a true and accurate account of all Products eligible for Bioequivalence currently held within the supply chain in Kenya. I further declare that: I understand this declaration is subject to verification by the Board.	

Knowingly providing false or misleading information is an offense under the Pharmacy and Poisons Act and may result in immediate legal action and suspension of our license.
Authourized person Signature;.....

Annex 3: Notice On Commencement of Mandatory Therapeutic Equivalence Demonstration For Multisource (Generic) Medical Products In Kenya

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

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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