DOCUMENT TITLE: IMPLEMENTATION OF BIOEQUIVALENCE (BE)		
DOC. REF. NO.:	**EFFECTIVE DATE:**	**REVIEW DUE DATE:**
NAFDAC-BEP-001-00	**10-04-2025**	**09-04-2030**

Strategic Plan for Managing the Implementation of Bioequivalence (BE) Regulatory Requirements

The National Agency for Food and Drug Administration and Control (NAFDAC) is committed to ensuring the safety, efficacy, and quality of medicines available in Nigeria. A key part of this is making sure that generic medicines are bioequivalent to their reference products. The development of a strategic plan for the assessment of bioequivalence (BE) study reports is critical for NAFDAC's mission to ensure the safety, efficacy, and quality of pharmaceuticals in Nigeria. Also, having a strategic plan for assessment for BE study reports is important in ensuring compliance with international standard and global best Practices (ICH M13, WHO TRS No.937 2006, WHO TRS No. 992, 2015, WHO Expert Committee on Specifications for Pharmaceutical Preparations, 2011 etc) which helps promote global regulatory harmonization.

Goals:

1. To establish a robust legal framework for the implementation and enforcement of BE requirements.
2. To ensure the effective implementation of BE regulatory requirements for both locally produced and imported medicines in Nigeria.

Objectives:

1. Develop and implement clear legal regulations and guidelines for BE studies.
2. Establish a robust framework for the assessment of BE study reports.
3. Ensure compliance with international standards and global best practices.
4. Enhance the quality and reliability of BE studies conducted by Contract Research Organizations (CROs).
5. Strengthen public health and encourage the local pharmaceutical industry.

Current Status/Progress Made:

1. **Drafting of Bioequivalence Regulation:** A comprehensive regulation outlining the legal framework for implementing BE requirements has been drafted and is at an advanced stage of being gazetted. The draft regulation has been presented to and approved by the NAFDAC Governing Council and is now with the Ministry of Health/Ministry of Justice for review and gazetting.

2. **Communication with Stakeholders:**
   a. A meeting with the Federation of Nigerian Pharmaceutical Industry Associations (FeNPIA) was convened to share updates on mandatory regulatory requirements for market authorization. The meeting took place on December 12th, 2024.
   b. A letter (reference number: NAFDAC/DG/12/MSBSD.09.12), dated December 14th,

2024, was issued to the Pharmaceutical Manufacturing Group of the Manufacturers Association of Nigeria, regarding the mandatory submission of biowaiver study data.

c. A letter (reference number: NAFDAC/DG/12/NP.IDMA/FU.MSBSD/GFDA/16.12), dated December 31st, 2024, was also issued to the Indian Drug Manufacturers Association (IDMA), as a follow-up on the mandatory submission of bioequivalence study data.

3. **Training:**
   a. Training on "Introduction to Bioequivalence and Documentation in the Common Technical Document" was held from January 8-10, 2025, with 280 participants.
   b. Training on "ICH M13A – Bioequivalence" was conducted from April 9th to April 11th, 2025. Approximately 249 participants attended (120 in-person), including 48 newly drafted NAFDAC BE regulatory officers/assessors trainees.
4. **Bioequivalence Studies Submissions and Ongoing Review:** NAFDAC has been receiving a growing number of Bioequivalence Study reports. As of December, last year, 25 reports had been submitted. In January 2025, an additional 65 reports were received, bringing the total to 81 as of April 2025. The review of these reports is currently ongoing.
5. **BE Studies submissions segregated according to therapeutic index class and pharmacological class:** NAFDAC has also categorized BE studies submissions according to therapeutic index class and pharmacological class.
6. **External Review and Capacity Building:** NAFDAC is utilizing external reviewers to support the assessment of BE studies while simultaneously developing the capacity of its own staff.
7. **Website Announcement:** NAFDAC published a notice on its website (Note to Industry on Requirement for Bioequivalence Study) outlining the bioequivalence (BE) study requirements for the registration of new and existing products.
8. **CRO Qualification Criteria:** NAFDAC established stringent requirements for potential Contract Research Organizations (CROs) conducting BE studies.

Implementation Strategies:

Phase 1: Awareness and Capacity Building (Timeline: [Started 2023 and ongoing])

- Announce NAFDAC's BE study requirements for registration and existing products on the website and through various communication channels.
- Develop and disseminate clear guidelines, templates, and FAQs to stakeholders.
- Organize stakeholder meetings with the Nigerian pharmaceutical industry to provide guidance on BE and Biowaiver (BW) qualifications.
- Conduct virtual meetings with Indian manufacturing sectors to ensure understanding of NAFDAC's BE requirements.
- Source external reviewers to ensure high-quality assessments of BE studies while building internal capacity through training and mentorship.

- Conduct training workshops on BE study assessment in collaboration with international regulatory bodies.

Phase 2: Implementation and Monitoring (Timeline: [Started January 2025 and ongoing])

- Implement mandatory BE study requirements for new registrations and renewals in a phased manner, starting with specific drug classes.
- Establish clear and stringent requirements for CROs to ensure compliance with NAFDAC standards.
- Conduct pre-qualification assessments and periodic audits of CROs to ensure adherence to standards.
- Establish a centralized monitoring framework to track compliance and address any challenges.
- Provide regular updates and guidance to stakeholders on BE requirements and implementation progress.

Phase 3: Evaluation and Improvement (Timeline: [Ongoing])

- Regularly evaluate the effectiveness of the implemented strategies and make necessary adjustments.
- Continuously monitor the quality and safety of generic medicines in the market.
- Conduct post-marketing surveillance to assess the long-term impact of BE requirements on public health.

Risk Assessment and Mitigation:

Potential Risks	Mitigation Strategies
Low stakeholder awareness	Use multiple communication channels to amplify reach.
Website accessibility issues	Develop a user-friendly website design and optimize for mobile devices.
High volume of inquiries	Set up a dedicated helpdesk or email support and automate responses for common queries.
Misinterpretation of information	Provide clear, concise content with practical examples in the FAQs
Non-compliance with standards by CROs	Offer comprehensive training programs, guidance documents, and pre-assessment consultations.

Insufficient oversight of CROs	Establish a centralized monitoring framework with real-time reporting and dedicated oversight teams.
Non-response or delayed response from Indian manufacturers	Send follow-up reminders and include clear guidelines in formal letters.
Difficulty in identifying qualified external reviewers	Leverage professional networks and partner with international agencies for recommendations.
Over-reliance on external reviewers	Integrate a phased plan to gradually reduce reliance while building internal capabilities.

Success Indicators:

- Increased awareness and understanding of BE requirements among stakeholders.
- Improved quality and reliability of BE studies conducted in Nigeria.
- Enhanced compliance with international standards and global best practices.
- Strengthened public confidence in the safety and efficacy of generic medicines.
- Increased access to affordable and quality-assured generic medicines for the Nigerian population.

Conclusion:

This strategic plan provides a roadmap for the effective management and implementation of BE regulatory requirements in Nigeria. By proactively addressing potential challenges and engaging with stakeholders, NAFDAC can ensure the successful implementation of these requirements, ultimately contributing to the improved health and well-being of the Nigerian people.