MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

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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