



MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

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When replying please quote our ref No:

PPB/HPT/LET/VOL.II/015/23

9th October, 2023

To: Marketing Authorisation Holders

Local Technical Representatives

RE: UPDATED REQUIREMENTS FOR SUMMARY OF PRODUCT CHARACTERISTICS (SmPCs) AND PATIENT INFORMATION LEAFLETS (PILs)

The Pharmacy and Poisons Board ("the Board") is mandated, under Section 3B(2)(q) of the Pharmacy and Poisons Act (Cap. 244), to disseminate information on medical products to health professionals and to the public in order to promote their rational use. In view of this, the Board has updated the requirements for Summary of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs) to enhance the clarity, comprehensibility, and accessibility of vital product information for all registered medicines and vaccines.

Consequently, in accordance with rule 8 of the Pharmacy and Poisons (Registration of Drugs) Rules, 2022, effective from **1st January, 2024**, all Marketing Authorisation Holders (MAHs) and/or their Local Technical Representatives (LTRs) are obligated to submit revised SmPCs and PILs for their registered medicines and vaccines during the annual retention process.

The Revised SmPCs and PILs are required to conform with the provisions of the revised Guideline on Summary of Product Characteristics, Patient Information Leaflet, and Labeling. The revised guideline is accessible on the Board's website via <https://web.pharmacyboardkenya.org/hpt-guidelines/>.

Do note that failure to comply with the requirements within the stipulated timeframe may result in regulatory action, including but not limited to suspension or withdrawal of marketing authorisation.

Should you need further information or clarification regarding the updated requirements, please do not hesitate to contact the Department of Product

Evaluation and Registration via email drug_reg@pharmacyboardkenya.org or Tel:
+254-70977010.

Your cooperation is greatly appreciated.

Yours sincerely,


Dr. F. M. Siyoi

CHIEF EXECUTIVE OFFICER