



MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

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When replying please quote our ref No:

PPB/PDS/VMS/LET/189/24

1st April 2025

Dear Stakeholders,

**RE: SUBMISSION OF AGGREGATE REPORTS (PBRERS/PSURS) AND
INDIVIDUAL CASE SAFETY REPORTS (E2B FORMAT) VIA THE
PHARMACOVIGILANCE ELECTRONIC REPORTING SYSTEM (PvERS)**

Reference is made to the above subject matter.

The Pharmacy and Poisons Board ("the Board") is the National Regulatory Authority (NRA) of Kenya, established under the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya. The Board is mandated to protect and promote public health by regulating the pharmacy profession and ensuring access to quality, safe, and effective health products and technologies (HPTs).

As part of our continuous efforts to enhance the safety surveillance of HPTs in Kenya, the Board requires all entities who have received marketing authorization for their products to ensure timely and accurate submission of safety reports as prescribed in the **Guidelines on the safety and vigilance of health products and technologies**.

To enhance pharmacovigilance reporting and support effective regulatory oversight, we are pleased to inform you that, starting **April 15, 2025**, all aggregate reports (PBRERs/PSURs) and ICSRs in E2B format will need to be submitted through the Pharmacovigilance Electronic Reporting System (PvERS).

The Pharmacovigilance department will announce the sensitization date for April regarding the use of the PvERS platform for submission of safety reports.

For further assistance or clarification, please contact Dr. Pamela Nambwa at pnambwa@ppb.go.ke (0722454600) or Dr. Martha Mandale at mandale@ppb.go.ke and the PV department at pv@ppb.go.ke (0795743040).

Thank you for your continued cooperation in ensuring the safety of health products in Kenya.

Yours sincerely,


Dr. F. M. Siyoi
CHIEF EXECUTIVE OFFICER

PN/mm