

Dear Healthcare Professional (Pharmacist, Pharm Tech, Doctor, Nurse, CHO)

REPORTING INCIDENTS OF THERAPEUTIC INEFFECTIVENESS/FAILURE AS ADVERSE EVENTS

An efficacious drug can for several reasons be ineffective in a given patient for several reasons such as: *pharmaceutical defects, drug interactions, inappropriate use (under dose or overdose), resistance, tolerance and tachyphylaxis.*

Therapeutic failure or ineffectiveness may be due to wrong diagnosis, selection of an inappropriate drug or dosage, use of Spurious, Substandard, Falsified, Falsely-Labeled Counterfeit medicinal product (SSFFC), the patient's non-adherence, a drug's poor bioavailability, medication error, or product quality defects. The potential causes of therapeutic failure depend on a complex interplay of social and medical factors. Failures can occur at every step of the life cycle of medicines. These include development, regulation (including registration), marketing, distribution, prescription, dispensing, and use of the drug.

The National Pharmacovigilance Centre of the Pharmacy Board of Sierra Leone has received reports of therapeutic ineffectiveness. However, anecdotal reports have indicated that there are similar cases that are not reported by healthcare professionals to the PBSL. Some of these products:

1. *Contain impurities at levels higher than Pharmacopoeia standards,*
2. *Contain no Active Pharmaceutical Ingredient (API) or lower levels of API than the Pharmacopoeia standards and*
3. *Are not registered by PBSL.*

The Pharmacy Board of Sierra Leone hereby encourages all health care professionals to closely monitor patients under their care and report any suspected therapeutic failure using the Adverse Reaction Reporting Form at your facility.

All Adverse reactions to medicines, vaccines, food supplements, herbal and traditional medicines and medical devices should be reported to the National Pharmacovigilance Centre, Pharmacy Board of Sierra Leone, Central Medical Stores Compound, New England Ville Freetown. You can download the adverse drug reaction form from our website www.pharmacyboard.gov.sl

The National Pharmacovigilance Centre can be contacted on mobile: **025282886** or e-mail: info@pharmacyboard.gov.sl

Yours faithfully,

Wiltshire C.N. Johnson
REGISTRAR