REPUBLIC OF KENYA
MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

SAFETY UPDATES AND RECOMMENDATIONS FOR HEALTHCARE PROFESSIONALS ON ANTI-TUBERCULOSIS MEDICATION (1 of 2022/2023)

The Pharmacy and Poisons Board (the Board) is mandated under the Pharmacy and Poisons Act (CAP 244) to disseminate information on health products and technologies to health professionals and the public to promote their rational use. The Board also has a mandate of ensuring patient safety. Through one of its committees, the Pharmacovigilance Experts Review and Advisory Committee (PERAC), the Pharmacovigilance division conducted a causality assessment of the serious cases suspected to have been caused by some anti-tuberculosis medicines received at the Board and wishes to make the following recommendations:

i. The committee noted with concern that a number of healthcare providers conducted rechallenges to confirm some of the reported events e.g., skin reactions and anaphylactic reactions. It is important to note that rechallenge is NOT recommended in such cases because anaphylactic shock could be fatal and some skin reactions can progress to serious reactions like Steven Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN) with fatal outcomes.

ii. Carry out baseline assessment for liver function in accordance with guidelines and policy issued by the National Leprosy, Tuberculosis and Lung Disease (NLTP) program for managing TB patients. This will allow for early detection of patients at risk for severe liver injury.

iii. Adhere to the guidelines issued by the National Leprosy, Tuberculosis and Lung Disease (NLTP) regarding the duration of treatment with Linezolid to minimize adverse reactions.

iv. Healthcare providers are also encouraged to capture in detail the medication and medical history of the patients on the adverse events being reported. This information is very important in conducting causality assessments. Additionally, detailed information on the management of the reported event should be documented by the HCPs.

The Board would like to thank the healthcare providers for their continued efforts to ensure the safety of the patients and encourage them to provide feedback by contacting the PPB Pharmacovigilance division at 0795 743 040 or emailing to pv@pharmacyboardkenya.org. Report any suspected adverse events or quality defects on health products and technologies at https://pv.pharmacyboardkenya.org or through the mobile App mPvERs platform on your phones.

CHIEF EXECUTIVE OFFICER

10TH JANUARY, 2023.