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Republic of Kenya

Ministry of Health

PHARMACY AND POISONS BOARD

**GUIDANCE DOCUMENT ON REGULATORY MEASURES ON GMP
CERTIFICATION DURING COVID-19 PANDEMIC.**

July 2020

**REGULATORY MEASURES ON GMP CERTIFICATION DURING COVID-19
PANDEMIC.**

The Pharmacy and Poisons Board, PPB, has taken appropriate measures to minimize risks of shortages while ensuring continued availability of high standards of quality, safety and efficacy of medicines to patients amidst COVID-19 pandemic restrictions impacting on some on-site Good Manufacturing Practices (GMP).

Due to travel restrictions attributed in part to COVID-19s' domestic and international safety measures and related travel embargo, it has become difficult to conduct on-site inspections related to good manufacturing (GMP). However, mitigation measures have been taken to ensure that there is continued availability of safe, quality and efficacious medicines to Kenyans.

To achieve this, PPB will carry out continued re-certification of manufacturing sites using internationally accepted off-site inspection criteria through risk based and balanced approaches and extension of cGMP certification validity to accommodate for adjustment of inspection procedures, verification of standards while making sure that good practice standards are being adhered to.

The validity of expiring GMP certificates will be extended for 12 months upon payment of applicable fees and as long as the manufacturing site meets the minimum requirements based on risk-based criteria defined by PPB and in line with international standards.

Some of the innovative and risk-based approaches that will be used include but not limited to; off-site inspection (desk-top review), cGMP recertification based on reliance on other MRA reports and/or certification, possibility of batch-to-batch PPB clearance based on specified documents and controls including: Batch Production Documents BMR/BPR accompanying each batch, Company Batch Analytical test reports and Sampling and testing in PPB Post registration Quality Assurance laboratory based on a justifiable sampling plan.