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Ministry of Health

PHARMACY AND POISONS BOARD

GUIDANCE DOCUMENT ON REGULATORY MEASURES ON GMP, GCP AND GDP CERTIFICATION DURING EMERGENCIES

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Abreviations/Acronyms

API	-	Active Pharmaceutical Ingredient
BMR	-	Batch Manufacturing Record
EAC	-	East African Community
EAC-NMRA Authority	-	East African Community National Medicines Regulatory
EMA	-	European Pharmaceutical products Agency
EU	-	European Union
FPP	-	Finished Pharmaceutical Product
GCP	-	Good Clinical Practice
GDP	-	Good Distribution Practices
GLP	-	Good Laboratory Practice
GMP	-	Good Manufacturing Practice
ICH	-	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
MA	-	Marketing Authorization
NMRA	-	National Medicines Regulatory Authority
PIC/S	-	Pharmaceutical Inspection Convention Scheme
PPB	-	Pharmacy and Poisons Board
TWG	-	Technical Working Group
WHO	-	World Health Organization
QA	-	Quality Assurance
HVAC	-	Heating Ventilation and Air Conditioning
QC	-	Quality Control
QRM	-	Quality Risk Management
SOP	-	Standard Operating Procedure

REGULATORY MEASURES ON GMP, GCP AND GDP CERTIFICATION DURING EMERGENCIES.

The Pharmacy and Poisons Board 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 emergencies restrictions impacting on some on-site Good Manufacturing Practices (GMP), Good Clinical Practices (GCP) and Good Distribution Practices (GDP) inspections.

Due to travel restrictions attributed in part to emergencies like pandemics, domestic and international safety measures and related travel embargo it can become difficult to conduct on-site inspections related to GMP, GCP and GDP. However, mitigation measures can be 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 and Contract Research Organizations using internationally accepted off-site inspection criteria through risk based and balanced approaches and extension of cGMP and GCP certification validity to accommodate for adjustment of inspection procedures, verification of standards while making sure that good practice standards are being adhered to.

REGULATORY MEASURES ON GMP CERTIFICATION DURING EMERGENCIES

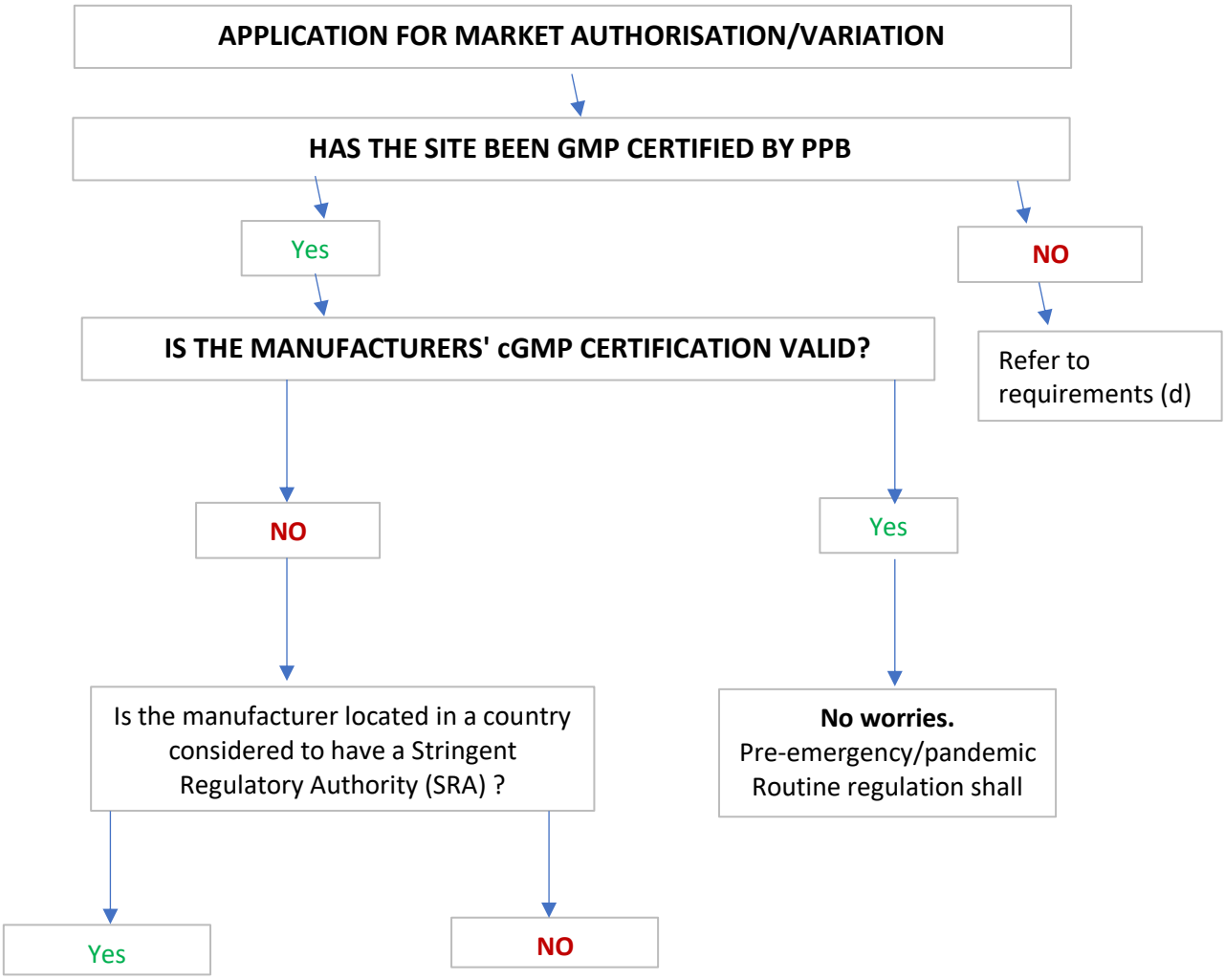
The validity of expiring GMP certificates will be extended for 12 months upon payment of applicable fees and as long as the criteria outlined below is achieved.

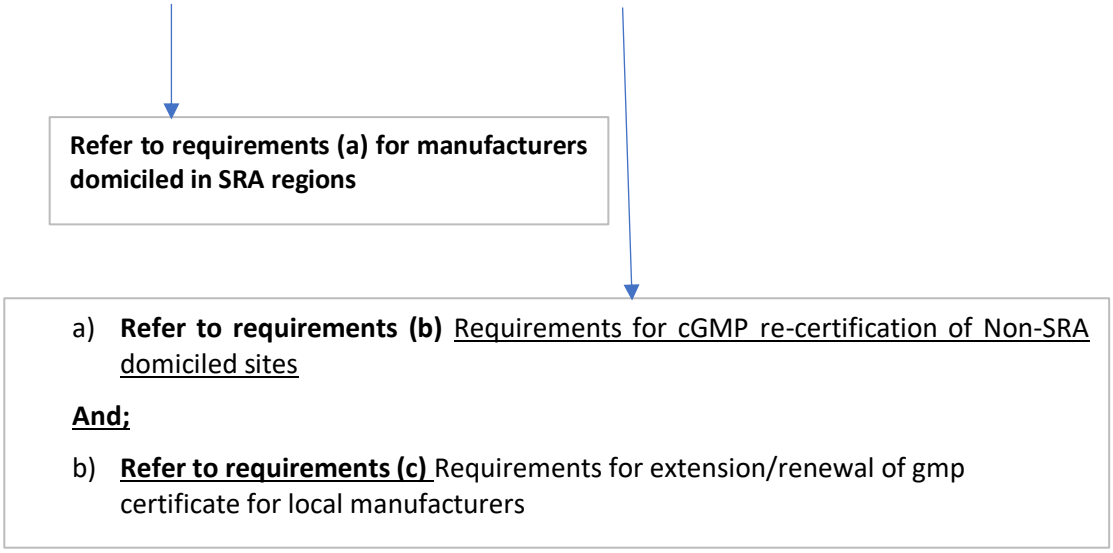
Some of the innovative and risk-based approaches that will be used include but not limited to; off-site inspection (desk review), cGMP recertification based on reliance on other MRA reports and/or certification, possibility of batch-to-

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 lab (aka PPB QC lab) of all/some of batches based on a justifiable sampling plan

The route to be followed for GMP re-certification of a manufacturer of medicines is outlined in the decision tree below.

Decision Tree





a) **Requirements for manufacturers domiciled in SRA regions**

All companies will under-go desk-top review.

b) **Requirements for cGMP re-certification of Non-SRA domiciled sites**

Site type	Conditions	Actions
Site with previous PPB cGMP certification but with no issues	No adverse reports from post market surveillance	• Requisite fees payment. • Extend PPB cGMP by 12 months. • GMP inspection upon end of emergency/pandemic
Site with previous PPB GMP certification but with issues	The required documents will depend on the adverse reports from post market surveillance etc.	• Requisite fees payment. • Batch-to-batch PPB clearance • Company Batch Analytical test reports • Select Batch Production Documents (BMR & BPR) • PQR for select products, particularly for products with critically insoluble APIs • Reports on closing of any outstanding CAPAs • GMP inspection upon end of emergency/pandemic

c) **Requirements for extension/renewal of GMP certification for local manufacturers**

1. Updated site master file
2. Updated CAPA from previous inspections
3. Annual product quality review
4. Batch manufacturing records
5. Qualification records
6. Process validation data
7. Continuous review of GMP elements

d) **Requirements for sites that have not been previously inspected by PPB**

Site with No previous PPB cGMP: a) High priority medicines (oncology and Orphan medicines) where there is only the innovator product b) Therapeutics, vaccines, Medical devices or IVDs undergoing Emergency use/ compassionate use Authorisation (EUCUA)	Required documents will be evaluated on a case to case basis or as stated in other guidelines eg Guidelines for compassionate use or fast track	• Requisite fees payment. • Batch-to-batch PPB clearance • All Batch Production Documents (BMRs & BPRs) • Company Batch Analytical test reports • PQR for select products (particularly for 6(a) sites). • Pre-approval analysis in PPB recognised laboratory. • Sampling and testing in PPB Post registration Quality Assurance lab (PPB QC lab) of some of the batches based on a justifiable sampling plan • GMP inspection upon end of emergency for 6(a) sites. GMP inspection for 6(b) sites upon end of emergency/pandemic provided the products would be moving to registration.

e) **Requirements for importation of medicines to Kenya during the period of emergency:**

1. Pro-forma invoice/Commercial invoice used for applying import permits should include Batch numbers.
2. An applicant of parallel imported products shall have declared the batch numbers of all products batches previously imported under these conditions
3. The products shall be manufactured by firms determined to be GMP compliant following onsite inspection (or by alternative means) and published in a current list of GMP certified companies.
4. The products shall have current retention certificates and contained in a current published list of retained products.

f) **Requirements for companies that fail GMP inspection**

Companies that fail GMP inspection and wish to be considered re-inspection shall apply to the CEO requesting for the same. Such companies shall be required to re-apply for inspection and pay the requisite fees. These companies MUST be done on-site inspection.

REGULATORY MEASURES ON GCP CERTIFICATION DURING EMERGENCIES.

PPB will carry out continued re-certification of Contract Research Organizations using internationally accepted off-site inspection criteria

through risk based and balanced approaches and extension of GCP 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 GCP certificates will be extended for 12 months upon payment of applicable fees.

Some of the innovative and risk-based approaches that will be used include but not limited to; off-site inspection (desk review) and GCP recertification based on reliance on other MRA reports and/or certification.

REGULATORY MEASURES ON GDP CERTIFICATION DURING EMERGENCIES.

The validity of expiring GDP certificates will be extended for 12 months upon payment of applicable fees.

REFERENCES

1. WHO Technical Report Series 986, Annex 2
2. EAC Compendium for Good Manufacturing Practices.

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