HPT/ISE/GMP/MAN/009
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MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINE FOR SUSPENSION AND REVOCATION OF GMP CERTIFICATION OF MANUFACTURERS

FEBRUARY, 2022

CITATION

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HPT/ISE/GMP/MAN/009	GUIDELINE FOR SUSPENSION AND REVOCATION OF GMP CERTIFICATION OF MANUFACTURERS	Revision No. 0	Effective Date: 1/02/2022 Review Date: 31/01/2027

Prepared by Deputy Director Inspectorate and Enforcement

Sign.....

Date.....19/1/2022.....

Reviewed by Director HPT

Sign.....

Date.....21/01/2022.....

Checked by HQM

Sign.....

Date.....24/1/22.....

Authorized by, CEO

Sign.....

Date.....24/1/22.....

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Abbreviations and Acronyms

HPT	Health Products and Technologies
GMP	Good Manufacturing Practices
GUD	Guideline
HQM	Head Quality Management
CEO	Chief Executive Officer
QC	Quality Control
PPB	Pharmacy and Poisons Board

Glossary of terms

Manufacture. All operations of purchase of materials and products, production, quality control (QC), release, storage and distribution of pharmaceutical products, and the related controls.

Manufacturer. A company that carries out operations such as production, packaging, repackaging, labelling and relabeling of pharmaceuticals.

Marketing authorization (product licence, registration certificate). A legal document issued by the competent medicines regulatory authority that establishes the detailed composition and formulation of the product and the Pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.

Master formula. A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.

Master record. A document or set of documents that serve as a basis for the batch documentation (blank batch record).

Packaging. All operations, including labelling and relabeling, that a bulk product has to undergo in order to become a finished product. Filling of a sterile product under aseptic conditions or a product intended to be terminally sterilized, would not normally be regarded as part of packaging.

Packaging material. Any material, including printed material, employed in the packaging of a pharmaceutical, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

Pharmaceutical product. Any material or product intended for human or veterinary use presented in its finished dosage form, or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state.

Production. All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabeling, to completion of the finished product.

Qualification. Action of proving that any premises, systems and items of equipment work correctly and actually lead to the expected results. The meaning of the word “validation” is sometimes extended to incorporate the concept of qualification.

Suspend/Revoke certificate. To annul certificate issued to manufacturer due to violation of conditions of issue.

Acknowledgements

The Pharmacy and Poisons Board wishes to express its appreciation to all whose efforts and valuable contributions in developing this guideline on suspension and or revocation of GMP compliance certificate.

1. General considerations

Licensed pharmaceutical products (marketing authorization) should be manufactured only by licensed manufacturers (holders of a manufacturing authorization) whose activities are regularly inspected by competent GMP inspectors with requisite education and appointed by the NMRA. GMP is used as a standard to justify GMP status, which constitutes one of the elements of the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce, through the assessment of applications for manufacturing authorizations and as a basis for the inspection of manufacturing facilities. The purpose of GMP inspection is to assess the GMP compliance status of a manufacturer. Upon compliance of a manufacturer to GMP standards GMP compliance certificate is issued. The compliance certification will remain in force for such a period as prescribed in the regulations. None the less if the conditions of issuance of the compliance certification changes then the issuing authority can suspend or revoke the compliance certificate. This guidance document spells out the procedure and conditions of suspension/revocation of GMP certificate. The guidance also provides for cancellation of suspension and revocation and provides steps taken to appeal the suspension/revocation.

2. CONDITIONS OF SUSPENSION/REVOCATION

1. If site is considered no longer compliance.
2. Dosage forms manufactured at the site have changed.
3. The categories of the dosage forms at the site have changed.
4. The manufacturing of the authorized products has changed.
5. Application by manufacturing license holder giving notice to discontinue manufacturing and reasons thereto.
6. Market complaints on products manufactured that the products are deleterious/fatal, do not meet the specifications on quality, safety and efficacy.
7. The GMP inspectors of the board are unable to gain access to the manufacturing site to conduct GMP inspection.

SUSPENSION OF GMP CERTIFICATE

The Chief Executive Officer (CEO) may, by written notice given to the manufacturer, suspend the GMP certificate if he is satisfied that:

1. The site considered is no longer GMP compliant.
2. Dosage forms manufactured at the site have changed.
3. Categories of the dosage forms manufactured have changed.
4. Manufacture of authorized products has been discontinued.
5. Application by manufacturer giving notice to discontinue manufacture and reasons thereto.
6. Market complaints on products manufactured at the site are deleterious/have fatal consequences, do not meet manufacturing specifications for quality, safety and efficacy.
7. The GMP inspectors of the board are unable to gain access to the manufacturing site to conduct GMP inspection.

WHEN SUSPENSION TAKES EFFECT

a) The notice of suspension may take effect immediately

b) The notice of suspension may take effect not earlier than 21 days after the notice was given.

DURATION OF SUSPENSION

1. A notice of suspension of GMP certificate must specify period of suspension. The suspension must not exceed 12 months.
2. The suspension has effect until the board revokes by written notice.
3. The period specified in the notice of suspension or until notice extended.
4. The CEO may by written notice extend the period of suspension stating in the notice period extended.

5. The CEO must cause to be published on the board website a notice setting out particulars of suspension or extension.

REVOCATION OF SUSPENSION

1. The CEO must revoke a suspension by written notice to the GMP certificate for HPT manufacturer if the CEO is satisfied that:
   a) The ground on which GMP certificate was suspended no longer applies.
   b) There are no other grounds for continued suspension of the GMP certificate of HPT manufacturer.
2. The CEO's power to revoke suspension may be exercised
   a) If the GMP of the site considered applies in writing to the CEO or
   b) On the CEO's own initiative.
3. As soon as practical, the CEO after giving notice of revocation of suspension must cause to be published in the board website a notice setting out particulars of revocation.
4. If the CEO decides after an application is made not to revoke the suspension, the CEO must:
   a) Notify the applicant in writing of his/her decision and
   b) State in the notice, the reasons for the decision.

EFFECT OF SUSPENSION

1. If the GMP certificate is suspended, the site is considered non-compliant while the suspension is in effect.
2. Manufacture of HPT in a non-compliant site is an offence.
3. While suspension is in effect, the CEO's power to cancel GMP certificate is not affected.

REVOCATION OF GMP CERTIFICATE

Reasons for revocation

1. The CEO may, by notice in writing given to the GMP compliant site revoke the GMP certificate if:
    a) It appears to the CEO that failure to revoke the GMP certificate would create an imminent risk of manufacture of HPT that are not in conformity with the specifications.
    b) The GMP certification may become exempt.
    c) The general manager of the site may request in writing the cancellation of the GMP certification.
    d) The manufacturing site has refused or failed to comply with the conditions to which the GMP certification was issued at the time of issue.
    e) The manufacturing conditions of HPT used during the certification are not maintained.
    f) It appears to the CEO that any of the manufacturing certifications and laboratory requirements are not fulfilled.
2. Where the CEO revokes the GMP certification of a manufacturer, the site ceases to be compliant on the day the notice of revocation was issued.
3. Where the CEO proposes to revoke the GMP certification the CEO must:
    a) Inform the general manager of the manufacturing site in writing that the CEO proposes to revoke the GMP certificate and set out the reasons for that action and give the site a

reasonable opportunity to make submissions to the CEO in relation to the proposed action.

b) Where the manufacturing site makes submissions to the CEO, the CEO shall not make decision relating to the revocation until the CEO has taken submission into account.

Revocation of cancellation of GMP certificate

1. Revocation of cancellation upon request:
    a) If the CEO cancels the GMP certification upon the request of the site.
    b) Request accompanied by requisite fee.
    c) The CEO may by notice in writing give to the manufacturing site, revoke the cancellation.
2. If the CEO revokes the GMP certificate of the site, the CEO must as soon as practicable after cancellation, cause to be published in the gazette, or on Pharmacy and Poisons Board's website, a notice setting out particulars of the cancellation and maintain the records.

References

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

Contributors/Reviewers

S.No.	NAME	POSITION
1.	Dr F.M Siyoi	CEO, PPB
2.	Dr Ahmed Mohamed	Director, Health Products and Technologies
3.	Dr Dominic Kariuki	Deputy Director, Inspectorate and Enforcement
4.	Dr Sichei Cheworei	Deputy Director, Quality Control
5.	Dr Shaban Sifuma	HEAD, GMP
6.	Dr Wanza Katatha	CEO assistant
7.	Dr Tom Kauki	Head, Central Region

ANNEXES

Form 1

NOTICE

NOTIFICATION OF SUSPENSION OR REVOCATION OF A GMP CERTIFICATION OF A MANUFACTURING SITE

The GMP compliance certificate holder or LTR or a company authorized by GMP compliance certificate holder should submit a written notification before the end of the certification period if the certification is to be cancelled and the GMP inspection fee left unpaid.

The GMP compliance certificate is to be cancelled starting from the following date

Date	Month	Year

TYPE OF DOSAGE FORMS MANUFACTURED AT THE SITE				
Oral solid dosage forms	Oral liquid dosage forms	Parenteral preparations	Beta lactam (Cephalosporin and Penicillin)	Other dosage forms (Steroids, Oncology, Herbal,Cosmetic etc)

GMP Compliance Certification Details	
GMP CERTIFICATE No.	
Name of site	

Manufacturing site address	
Dosage forms manufactured	
LTR	

DETAILS OF CONTACT PERSON/SENDER	
Name	
Address	
Telephone No.	
E-Mail Address	

REASON FOR SUSPENSION/REVOCATION

SIGNATURE		
Date	**Name**	**Signature**

The signed form shall be submitted without delay to the following address

The CEO, Pharmacy and Poisons Board

P.O. Box 27663 00506

Nairobi

Form 2

NOTICE

NOTIFICATION OF SUSPENSION OR REVOCATION OF A GMP COMPLIANCE CERTIFICAT BY THE REGULATOR (PPB)

The Pharmacy and Poisons Board shall notify the manufacturing site on intention to suspend or revoke GMP compliance certificate before the end of the certification period and the GMP inspection fee left unpaid.

The GMP compliance certificate is to be cancelled starting from the following date

Date	Month	Year

TYPE OF DOSAGE FORMS MANUFACTURED AT THE SITE				
Oral solid dosage forms	Oral liquid dosage forms	Parenteral preparations	Beta lactam (Cephalosporin and Penicillin)	Other dosage forms (Steroids, Oncology, Herbal, Cosmetic etc)

GMP Compliance Certification Details	
GMP CERTIFICATE No.	
Name of site	
Manufacturing site address	
Dosage forms manufactured	
LTR	

DETAILS OF CONTACT PERSON	
Name	
Address	
Telephone No.	
E-Mail Address	

REASON FOR SUSPENSION/REVOCATION

SIGNATURE		
Date	**Name**	**Signature**