REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINES FOR SUSPENSION, WITHDRAWAL, WITHHOLDING AND REVOCATION OF MARKETING AUTHORIZATION OF MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES IN KENYA

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Prepared by Deputy Director, Product Evaluation and Registration

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Date.....07/02/2022.....

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Authorized by Chief Executive Officer (CEO)

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Abbreviations and Acronyms

PPB-	Pharmacy and Poisons Board
GUD	Guidelines
GSP	Good Storage Practices
SOP	Standard Operating Procedure
QMS	Quality Management System
WHO	World Health Organization
GSP	Good Storage Practices.
MAH	Manufacturing Authorization Holder.
LTR	Local Technical Representative.
GMP	Good Manufacturing Practices
QP	Qualified Person
QPPV	Qualified Person for Pharmacovigilance
WHO	World Health Organization
EAC	East African Community
IGAD	Inter-governmental Authority for Development
PI	Product Information
NMRA	National Medicine Regulatory Authority

DEFINITION OF KEY TERMS

Withdrawal: Means voluntary withdrawal of a marketing authorization by the marketing authorization holder. A marketing authorisation holder may decide to have their marketing authorisation withdrawn for various reasons.

Withholding: Means withholding issuance of a marketing Authorization or withholding processing of a marketing authorization application until suspected risks on quality, safety and efficacy linked to the application or similar applications are resolved.

Revocation:

Cancellation:

Suspension: The suspension of a marketing authorization is a precautionary measure, during which time a medicinal product is not available. The lifting of the suspension is conditional on the marketing authorization holder resolving the issues identified by the NMRA

Marketing Authorization.

Standard operating procedure (SOP): An authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection).

Labelling: Process of identifying a pharmaceutical product including the following information, as appropriate: name of the product; active ingredient(s)

Preventive action: an action to eliminate the cause of a potential non-conformity or another undesirable potential situation.

Health Product:

Product recall: the removal of specific batch/batches of a pharmaceutical product from the market for reasons relating to deficiencies in quality, safety or efficacy

Quality system: An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality

Quarantine: The status of medical products and health technologies isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.

Repackaging & relabelling: Any operations in which the original labelling and or packaging materials more so, the primary and secondary packaging are subsequently changed or replaced, leading to loss of product traceability

Sampling: Operations designed to obtain a representative portion of a pharmaceutical product, based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments or batch release.

Shelf-life: The period of time during which a pharmaceutical product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product. The shelf-life is used to establish the expiry date of each batch.

Storage: The storing of medical products and health technologies up to the point of use.

Supplier: A person or entity engaged in the activity of providing products and/or services.

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FOREWARD

The Pharmacy and Poisons Board is established by law to protect and promote the health of the public by regulating the profession of pharmacy and ensuring access to quality, safe, efficacious and affordable health products and technologies (The Pharmacy and Poisons Act of 1957, Cap 244; and Health Act, 2017).

Marketing authorization also referred to as drug registration in Kenya started in 1982. Since the inception of marketing authorization, the board has made significant progress to secure the health of the public based on its mandate. It leverages on advanced science and technology and international best practices of marketing authorization that are intricately woven in robust strategies.

The guideline draws from lessons learnt as well as recent development in Kenya and globally to maintain a register of health products and technologies. Marketing authorization work has expanded remarkably and notable achievements include registration of medical devices, registration of blood products, issuance of conditional registration, growth of the workforce, automation and vigorous improvement of the quality management system.

This guideline reaffirms the Board's commitment to assuring the *highest attainable standard of health* for all Kenyans as a right enshrined The Constitution of Kenya 2010. This document shall enable the Board not only to ensure access to affordable products that are of good quality, safe and efficacious, but also to remove products from the market that may cause a threat to public health. Towards this end, the Board will rely on a participatory and inclusive approach to ensure that stakeholders including manufacturers, traders, and healthcare professionals are proactively engaged and involved.

With this guideline, I am confident that the Board has established a strong pillar for the management of registers of medical products or technologies by way of suspension or revocation of marketing authorization certificates.

Dr. F.M Siyoi
CHIEF EXECUTIVE OFFICER

1. INTRODUCTION

1.1 Background

This guideline aims to offer overarching principles and aspects towards marketing authorization of health product and technologies into the Kenyan territory. This guideline apply in all cases covering pre-marketing, marketing and post marketing authorization.

a. When applying for marketing authorisation, companies must provide documentation showing that the product is of suitable quality, safety and efficacy.
b. The manufacture or import of medicinal products itself is subject to authorisation
c. Safety and efficacy of medical products and health technologies continue to be monitored after marketing authorisation, through pharmacovigilance activities, or reviews of the benefit-risk balance.

If the qualitative and quantitative composition of a medicinal product does not meet these standards, the marketing authorisation will be refused, or if the product is already authorised suspended or withdrawn.

In such cases all appropriate steps will be taken to ensure that the supply is prohibited and the medicinal product withdrawn from the market.

1.2 Legal Framework

The Pharmacy and Poisons Act, Cap 244, mandates the Pharmacy and Poisons Board to, among others, set standards to ensure high levels of public health protection by ensuring access to quality, safe, efficacious and affordable health products and technologies. The Act promotes the functioning of the internal market with emphasis on marketing authorization as the main principle.
Sections 3A(c) and 3B(e)(f) of the Act provide for grant or revocation of marketing authorization and subsequent maintenance of registers of authorized medical products and health technologies. To facilitate the interpretation of the legislation and its uniform application, the Board has gazetted the Pharmacy and Poisons (Registration of Drugs) Rules and developed Guidelines on Medicines Evaluation and Registration (PPB/PER/MED/GUD/016), and Guidelines on Suspension and Revocation of Marketing Authorization of Medical Products and Health Technologies that are regulatory and scientific in nature.

1.3 **Scope**

This guideline serves to offer guidance on how to how to suspend, revoke, withdraw or cancel marketing authorization by Pharmacy and Poisons Board

2.1 GENERAL CONSIDERATIONS

2.1.1. Organization Structure And Management

The marketing authorization holder must be an entity that is appropriately authorized with ultimate responsibility for the performance of a medicinal product over its lifetime, its safety, quality and efficacy:

i. There should be an adequate organizational structure defined with the aid of an organizational chart. The responsibility, authority and interrelationships of all personnel should be clearly indicated. This must be duly dated, be current, valid and authorized.
ii. A designated qualified person (Pharmacist) to serve as a superintending Pharmacist that has the defined authority and responsibility for ensuring that a quality management system is implemented and maintained.
iii. Managerial and technical personnel must have the authority and resources needed to carry out their duties and to set up and maintain a quality management system, as well as to identify and correct deviations from the established quality management system.
iv. The responsibilities placed on any one individual should not be so extensive as to present any risks to the medical products and health technologies' quality or process. Individual responsibilities should be clearly defined and understood by the individuals concerned and recorded as written job descriptions. Certain activities may require special attention such as the supervision of performance of activities, in accordance with legislation.
v. Duties may be delegated or contracted out to suitably designated persons or entities as necessary and documented. There should, however, be no gaps or unexplained overlaps with regard to the application of Good Regulatory Practices. These activities should be documented in quality agreements or contracts. There should be periodic audits of such activities

2.1.2. Quality Management System

Every licensed MAH/LTR shall have a quality management system that assures quality of medicinal products and health technologies. Senior management should demonstrate its
commitment to the development and implementation of the Quality Management System (QMS) and continual improvement of its effectiveness and performance by:

i. Communicating the importance of adhering to customer, regulatory and legal requirements, including environmental, health and safety aspects;

ii. Establishing functional quality objectives;
iii. Ensuring regular reviews of quality management systems;
iv. Applying risk assessments;
v. Maintaining appropriate conditions throughout the organization for processes and systems
vi. Ensuring the availability of resources to support quality management system
vii. Ensuring the integration of quality management system into their operations and processes.
viii. Supporting other relevant management roles to demonstrate leadership as it applies to their areas of responsibilities.
ix. Ensuring that customer satisfaction is enhanced and maintained.
x. Establish a system for handling customer compliments and complaints

Every MAH/LTR shall establish and maintain documented information on:
i. Standard Operating Procedures (SOPs) for all activities affecting quality, safety and efficacy of medical products and health technologies;
ii. Work Instructions and Process Maps;
iii. Forms and Records.

Marketing authorization entities shall have in place effective measures for Risk Management to ensure risks are controlled to such an extent that unwanted outcome can be mitigated adequately.

Additionally, MAH/LTR should ensure that distributors and wholesalers should annually conduct risk assessments to assess potential risks to the quality and integrity of medical products and health technologies. The quality system should be developed and implemented to address any potential risks identified. The quality system should be reviewed and revised annually to address new risks identified during a risk assessment.

2.1.3 Responsibilities of MAH/LTR

The ultimate responsibility for the performance of a medicinal product over its lifetime in relation to its safety, quality and efficacy, lies with the Marketing Authorisation Holder (MAH). The MAH must have appropriate controls in place and operate a Quality Management System to support the activities related to these controls.
Specifically, the responsibilities are:

1. The MAH/LTR must ensure that clinical trials for the medical products or health technologies are designed and developed ethically and in accordance with the Pharmacy and Poisons Act and other relevant regulations;
2. The MAH must put in place necessary measures to ensure continued availability of safe and effective medicinal products for the patient. Controls must aim at ensuring the manufacture and distribution of medicinal products in accordance with GMP and GDP guidance and prevention of falsified medicines from entering the supply chain;
3. The MAH must identify a Qualified Person (QP) with responsibility for checking that each individual batch has been manufactured in line with the terms of the marketing authorisation (MA) and with Good Manufacturing Practice (GMP);
4. Presents information that is current and accurate on labelling of medical products or health technologies to ensure safe and effective use and prescribing;
5. Manages and guarantees a safe, controlled and compliant supply-chain from the raw material to the finished medicinal product reaching the customer;
6. In conjunction with the Board, coordinates the investigation of quality complaints and recall (where applicable) and any further action of medicinal products;
7. Operate a pharmacovigilance system to detect, assess and report adverse events associated with their medicinal products. The pharmacovigilance system should be regularly monitored, all adverse events reported in accordance with national and MAH is responsible to appoint and have at its disposal permanently and continuously, a qualified person for pharmacovigilance (QPPV) who is responsible for the maintenance of the MAH's pharmacovigilance system.
8. Timely and regular provision of new and revised medical information to medical information.

9. Undertakes promotional activities, including advertising, that comply with the provisions of the Pharmacy and Poisons Act, Cap 244;
10. It is the responsibility of the MAH to maintain a continuous supply of the medicinal product to ensure that patient needs are covered. The MAH must notify the Board of any medicinal product shortages or disruption of supply;
11. The MAH to maintain their marketing authorisations according to technical and scientific developments;
12. Liaison between MAH's and manufacturers in evaluating the results of Product Quality Review Reports, communicating regulatory changes to manufacturers, e.g. variation approvals, providing abbreviated versions of MA's to the QP certifying batches of medicinal products, regularly reviewing Technical Agreements with manufacturers to ensure their accuracy.

13. The MAH shall inform/notify the board on shortages or disruption of supplies via a letter through LTR. The board shall keep this record as per the board's preference.

2.2 MARKETING AUTHORIZATION

2.2.1 General Requirements

1. Marketing approval or authorization for medical products and health technologies is granted to a Marketing Authorisation Holder (MAH); a company, firm or non-profit organisation.
2. The marketing authorisation allows the holder to market a specific medicinal product.
3. Marketing Authorization Holder must be approved or licensed by The Pharmacy and Poisons Board, *the Board.*
4. A company that is not resident in Kenya shall appoint a Local Technical Representative (LTR) who must be a company incorporated in Kenya and authorized by *the Board* to deal in medical products and health technologies and must hold a wholesale dealers license. The appointment shall be notified to the Authority by submitting a letter of appointment supported by original copy of power of attorney duly notarised in country of origin, and registered with Chief Executive Officer (CEO) of Companies in Kenya.
5. *The Board* grants marketing authorization based on a system that subjects all pharmaceutical products and health technologies (under the scope of the PPB) to pre-marketing evaluation, marketing authorization (registration), and post-marketing review to ensure that they conform to required standards of quality, safety and efficacy.
6. Before granting marketing authorization, *the Board* may evaluate data on Discovery and Development, Pre-clinical Research, Clinical Research, Drug Manufacturing and Post Market Drug Safety Monitoring.

2.2.2 Procedures for Market Authorizations

The Board has adopted four ways of granting marketing authorisation in Kenya

1. For generic products with less complex molecules, the national full evaluation procedure for generic products applies. External experts are not involved,
2. In case of new products, national procedure including external scientific experts may be used,
3. The mutual recognition/reliance procedure that relies on the recognition by the Board of a first assessment performed through WHO Prequalification procedure or any other stringent regulatory authority as updated from time to

time applies incase of new products, vaccines, biotechnology products and medical products and technologies for emergence use.

4. EAC/IGAD Centralized procedure: Applications for certain products go through the EAC/IGAD procedure that is central and binding among partner states

2.2.3 TYPES OF MARKETING AUTHORIZATIONS

There are two types marketing authorizations

2. Conditional marketing authorization
3. Standard marketing authorization

2.2.3.1 Conditional Marketing Authorization

The Board, in the interest of public health, may grant a conditional marketing authorization for medical products and health technologies, based on less comprehensive clinical data than normally required.
This may include orphan medicine, public health emergence products, investigational products and donated products

2.2.3.2 Licensure Criteria for Conditional Marketing Authorization

a) the benefit-risk balance of the medicine is positive;
b) it is likely that the applicant will be able to provide comprehensive data post-authorisation;
c) the medicine fulfils an unmet medical need;
d) the benefit of the medicine's immediate availability to patients is greater than the risk inherent in the fact that additional data are still required.
e) Once a conditional marketing authorisation has been granted, the marketing authorisation holder must fulfil

specific obligations within defined timelines; and
f) To be renewed annually

2.2.3.3 Standard Marketing Authorization

a) An approval granted by the Board for marketing of medical product or health technology after positive pre-marketing evaluation, marketing authorization (registration), and post-marketing review.
b) This type of marketing authorization is granted for a medicinal product which meets statutory standards of safety, quality and efficacy

2.2.3.4 **Licensure Criteria for Standard Marketing Authorization**

a) The product(s) must conform with all the details provided in the application and as modified in subsequent correspondence,
b) No changes may be made to the product without prior approval, except for changes of the type listed in the Board's policy on "Changes to pharmaceutical aspects of registered products which may be made without prior approval,
c) The manufacturing sites for medical product or health technology must be approved by *the Board*
d) The approved shelf-life must be maintained
e) The only Product Information (PI) that may be supplied with or for the product must be the PI that is approved.
f) The Product information may not be altered without prior approval and any such safety-related changes must be notified to *the Board* and
g) To be renewed after 5 five years

3.0 Withholding of Marketing Authorization of Health Products and Technologies

3.1 Decision to withhold a marketed medicinal product:

If controls and examinations result in reasonable suspicions that a medicinal product does not meet the relevant requirements, the department of the Board dealing with Inspections may issue a notice to withhold the trade in certain lots of a medicinal product within the inspector's area of operations. The deputy director, Product Evaluation and Registration in conjunction with the Deputy director, Inspectorate and Enforcement may withhold the trade in certain lots of a medicinal product within the entire country; After the above decisions are issued, the trade in specified lots of a particular medicinal product are withheld at all wholesalers and pharmacies until laboratory test results that confirm or rule out the quality defect are obtained.

3.2 Notification for discontinued supply of Medical product of health technology

The marketing of a medicinal product is being discontinued or interrupted (including a possible shortage) due to justification such as:-

i. The marketing of a medicinal product is being discontinued or interrupted (including a possible shortage)
ii. A possible shortage because a medicinal product is being placed on the market in smaller quantities or to an insufficient degree
iii. A quality defect in relation to a medicinal product.
iv. A medicinal product is placed on the market for the first time, or again following an interruption

The MAH can revoke a previously made notification of a (possible) shortage because it will not occur through notification to the Board.

3.3 Suspension or Cancellation of Marketing Authorization of Health Products and Technologies

4.0 REASONS FOR SUSPENSION OR REVOCATION OF MARKETING AUTHORIZATION

4.1 There are several cases that may trigger suspension or cancellation of marketing authorizations for medical products and health technologies. These may include;

4.1.1 The product poses a threat to public health

4.1.2 The product fails to meet quality, safety and efficacy attributes

4.1.3 The products do not meet licensure conditions

4.1.4 Prolonged delays in releasing products to the market after grant of marketing authorization(3 years after granting MA)

4.1.5 Failure to meet manufacturing specifications

4.1.6 Voluntary withdrawal of marketing authorisation

4.1.7 Suspension or cancellation is occasioned where it is possible to take necessary action to ensure the medical product or health technology causes no harm.

4.1.8 Cancellation occurs where there is a potential risk of death, serious illness or serious injury if the medical product or health technology remains in circulation

4.1.9 Revocation or suspension may as well be initiated by the person or body corporate in whose name the products are registered

4.1.1 The Product poses a threat to Public Health

Threat to Public Health is the most critical scenario and leads to product withdrawal as one of the regulatory actions. The Board is not obliged to issue notice of intention to suspend or revoke marketing authorization.

1. There is a potential risk of death, serious illness or serious injury if the medical product or health technology remains in circulation hence marketing authorization must be revoked and be withdrawn from the Register urgently.
2. The second case is where it is likely that the MAH/LTR, within the period of the suspension, shall be able to take the action necessary to ensure that the medical product or health technology would not cause a potential risk of death, serious illness or serious injury if the medical product or health technology continue to be included in the Register.
3. In the two scenarios, withdrawal and or suspension, *the Board* may implement the actions without giving written notice and reasons for the proposed suspension or withdrawal.

4.1.2 Failure to Meet Quality, Safety and Efficacy Attributes

Medical products and health technologies must meet quality and safety standards and achieve desired clinical outcomes. Failure to meet these attributes may lead to suspension or revocation of the marketing authorizations.

1. The product has proved to be ineffective for the approved indication(s);
2. It is strongly suspected that the product is unsafe in the normal conditions of use;
3. The quantitative or qualitative composition is not as agreed in the marketing authorization;
4. The product found not to be in compliance with the conditions of marketing authorization;
5. For imported products, if marketing authorization is suspended or withdrawn in a country that supplied a WHO-type certificate, the marketing authorization holder should be asked to state (by a certain date) why the authorization should not be suspended. The company's statement should address the quality, safety and efficacy of the product and GMP certification of the sites(s) of manufacture.
6. In notifying the marketing authorization holder of any suspension or revocation of marketing authorization, the NMRA should state the reasons for the decision and the appeal mechanisms available.

4.1.3 Failure Tto Meet Licensure Conditions

It is required of the MAH/LTR to provide accurate and authentic data on preclinical studies, drug development, clinical studies and pharmacovigilance to facilitate appropriate regulation and control by the Board. Each marketing authorization has an addendum of conditions that must be made by the MAH/LTR. Presentation of data that is not accurate or failure to comply with licensure conditions may attract regulatory actions including suspension or revocation of marketing authorizations.

1. The product is found to have been promoted in an inappropriate or unethical manner whose impact is determined to be significant;
2. Appears to the Board that failure to cancel the registration or listing would create an imminent risk of death, serious illness or serious injury;
3. The medical product or health technology contains substances that are prohibited imports for the purposes of the Customs Act;
4. The MAH or LTR has refused or failed to comply with the conditions for grant of Conditional Marketing Authorization or any other conditions attached to the marketing authorization;
5. Data or certificates provided for registration was false or misleading;
6. The MAH/LTR contravenes a direction or a condition of licensure given in relation to the advertising and the Board is satisfied that the contravention is significant; and

7. The annual registration or listing charge is not paid within 28 days after it becomes payable

4.1.4 Cessation of the Marketing Authorisation if the Medicinal Product is Not Marketed

The purpose of granting marketing authorizations is to increase access, availability and affordability of medical products and health technologies to the public. This, therefore, addresses public health needs and improves health security. Prolonged delays in releasing products to the market after grant of marketing authorization may attract suspension or revocation of the licenses.

1. Any authorisation which within three years of its granting is not followed by the actual placing on the market of the authorised product in the Kenyan market will cease to be valid.
2. When an authorised product previously placed on the market in Kenya is no longer actually present on the market for a period of three consecutive years, the authorisation for that product will also cease to be valid.
3. The Board may, in exceptional circumstances and on public health grounds grant exemptions. Such exemptions must be duly justified.
4. The determination of the start of the three-year period from the granting of the marketing authorisation should be the date when the medicinal product can be marketed by the marketing authorisation holder, taking into account, e.g. the market protection and other protection rules which have to be respected.
5. The absence of the medicinal product from the market must be of three consecutive years, therefore in case the medicinal product would be put back on the market, the period of three years would restart. This situation may occur several times. However, each year draws a fine.
6. The marketing authorisation will remain valid if at least one presentation of the medicinal product is placed on the market and if at least one pack-size of the existing pack-sizes for that presentation is marketed. For the purposes of the application of these rules, a marketing authorisation comprises the initial authorisation and all variations and extensions granted to the marketing authorisation holder under the same name.
7. For the purposes of this guideline, a medicinal product is “placed on the market” at the date of release into the distribution chain. It is the date when the product comes out of the control of the marketing authorisation holder.
8. A medicinal product ceases to be placed on the market when the marketing authorisation holder ceases to release it in the distribution chain.
9. After a marketing authorisation has been granted, the holder of the authorisation must inform *the Board*, through the LTR*;* of the date of actual marketing of the

medicinal product in Kenya taking into account the various presentations authorised.

10. The holder must also notify *the Board*, through the LTR*;* if the product ceases to be placed on the market, either temporarily or permanently. Such notification must, otherwise than in exceptional circumstances, be made no less than 2 months before the interruption in the placing on the market of the product.
11. The marketing authorisation holder must inform *the Board* of the reasons for such action.
12. Upon request by *the Board*, particularly in the context of pharmacovigilance, the marketing authorisation holder must provide *the Board* with all data relating to the volume of sales of the medicinal product, and any data in his possession relating to the volume of prescriptions.

4.1.5 Failure to Meet Manufacturing Specifications

Products licensed by the Board should be manufactured only by licensed manufacturers regularly inspected by PPB authorized employees. This implies that requirements of the Marketing Authorisation, relating to the safety, quality and efficacy should be systematically incorporated into all the manufacturing, control and release of the finished medicinal products. Failure to meet these manufacturing requirements may lead to suspension or revocation of the marketing authorizations for products in question. More specifically;

1. Marketing authorization shall be revoked upon application of the manufacturer or MAH giving notice of intention to discontinue the manufacture of all products manufactured under such license OR based on any of the following:
2. Authorized employees of the Board after reasonable efforts have been unable to gain access to the manufacturing a location for the purpose of carrying out the Good Manufacturing Practice inspection,
3. Manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection or evaluation cannot be made,
4. The manufacturer has failed to report a change as required under Drug Registration Rules,
5. The Manufacturing Plant or any location thereof, or the product for which the license has been issued, fails to conform to the applicable standards established in the license to ensure the continued safety, purity, and potency of the manufactured product,
6. The Manufacturing Plant or the manufacturing methods have been so changed as to require a new showing that the establishment or product meets

the requirements established by the Board in order to protect the public health, or

7. The licensed product is not safe and effective for all of its intended uses or is misbranded with respect to any such use

4.1.6 Voluntary Withdrawal of Marketing Authorisation

1. A marketing authorisation holder must notify *the Board* of any action taken to suspend the marketing or to withdraw a medicinal product from the market, to request the withdrawal or to not request the renewal of a marketing authorisation together with the reasons for such action.
2. He must in particular declare if his action concerns the efficacy of the medicinal product or the protection of public health.

4.2 SUSPENSION OF MARKETING AUTHORIZATION

1. The Chief Executive Officer (CEO) may, by written notice given to the MAH or LTR suspend the registration or listing of the medical product or health technology if he is satisfied that there is a potential risk of death, serious illness or serious injury if the therapeutic goods continue to be included in the Register**; OR**

2. The Chief Executive Officer (CEO) may by written notice given to the MAH or LTR suspend the registration or listing of the medical product or health technology if he is satisfied that there is a potential risk it is likely that the person will, within the period of the suspension, be able to take the action necessary to ensure that the therapeutic goods would not cause a potential risk of death, serious illness or serious injury if the therapeutic goods were to continue to be included in the Register; **OR**

3. The Chief Executive Officer (CEO) is satisfied that it is likely that there are grounds for cancelling the registration or listing of the medical product or health technology due to any of the following:
    a) The product does not meet quality, safety and efficacy attributes
    b) The MAH/LTR does not to meet licensure conditions
    c) Failure by the MAH/LTR to put the medical product or health technology on the market within stipulated time(3 years)
    d) Product manufactured by a facility that does not meet manufacturing specifications

4. Before suspending the registration or listing of the medical product or health technology because of paragraph 3.2 (3) the Chief Executive Officer (CEO) must:

    a. inform the MAH/LTR by written notice that the Board proposes the suspension and set out the reasons for it; and

    b. give the MAH/LTR a reasonable opportunity to make submissions to the Board in relation to the proposed suspension.

5. The Chief Executive Officer (CEO) is not to make a decision relating to the proposed suspension until the Board has had regard to any submissions made by the MAH/LTR

5.0 WHEN SUSPENSION TAKES EFFECT

5.1 EFFECTIVE DATE

a) If the notice states that the suspension is necessary to prevent a potential risk of death, serious illness or serious injury (prevent threat to public health) it becomes effective on the day on which the notice is given; i.e., immediately;
b) In any other case—on the day specified for the purpose in the notice, being a day not earlier than 20 working days after the notice is given;

5.2 DURATION OF THE SUSPENSION

a) A notice of suspension of marketing authorization must specify the period of the suspension. The period must not exceed 6 months.
b) The suspension has effect until the Board revokes it under section 3.3; **OR**
c) The period specified in the notice of suspension **OR**
d) If the period is extended, the period is extended.
e) The Board may, by written notice given to the person, extend the period specified in the notice under subsection 3.2.2 (1) by a further specified period not exceeding 6 months
f) As soon as practicable after giving a notice under subsection 3.2.2 (1), *the Board* must cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the suspension or extension.

5.3 REVOCATION OF SUSPENSION

1. The Chief Executive Officer (CEO) must revoke a suspension under section 3.2, by written notice given to MAH/LTR for the medical product or health technology, if the Chief Executive Officer (CEO) is satisfied that:
   a. the ground on which the registration or listing of the medical product or health technology was suspended no longer applies; and
   b. there are no other grounds for suspending the registration or listing of the medical product or health technology
2. Chief Executive Officer (CEO)'s power to revoke the suspension may be exercised:
   a) if the MAH/LTR applies in writing to the Chief Executive Officer (CEO); or
   b) on the Chief Executive Officer (CEO)'s own initiative.
   c) As soon as practicable after giving a notice under subsection 3.4 (1) the Chief Executive Officer (CEO) must cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the revocation.
   d) If the Chief Executive Officer (CEO) decides, after an application is made under paragraph 3.4 (2)(a), not to revoke the suspension, the Chief Executive Officer (CEO) must:
      i. notify the applicant in writing of his or her decision; and
      ii. state in the notice the reasons for the decision.

5.4 EFFECT OF SUSPENSION

a) If the registration or listing of medical product or health technology is suspended the product is taken not to be included in the Register while the suspension has effect-i.e., not registered.

b) Dealing in un-registered medical products may be an offence.

c) While the suspension has effect, the Chief Executive Officer (CEO)s' power to cancel the registration or listing the therapeutic goods is not affected.

5.5 REVOCATION OF MARKETING AUTHORIZATION

5.5.1 REASONS FOR CANCELLATION OF MARKETING AUTHORIZATION

1. The Chief Executive Officer (CEO) may, by notice in writing given to MAH/LTR of registered

medical product or health technology, cancel the registration or listing of the products if:

a) it appears to the Chief Executive Officer (CEO) that failure to cancel the marketing authorization would create an imminent risk of death, serious illness or serious injury; or
b) the medical product or health technology become exempt goods; or
c) the MAH/LTR requests in writing the cancellation of the registration or listing; or
d) the HPT contain substances that are prohibited imports for the purposes of the *Customs Ac*; or
e) the MAH/LTR has refused or failed to comply with the condition to which the inclusion of the product in the register is subject to provision of specific information at a given time; or
f) in the case of a medicine, the data upon which registration was determined is incorrect and the manufacturing requirements are not fulfilled; or
g) In the case of a medicine registered, it appears to the Chief Executive Officer (CEO) that any of the certifications for quality, safety and efficacy or potency are incorrect or (if applicable) the manufacturing and laboratory requirements are not fulfilled.

2. Where the Chief Executive Officer (CEO) cancels the registration or listing of, under section 1. the products cease to be registered or listed on the day on which the notice of cancellation is given to the MAH/LTR

3. In the cases mentioned here below, where the Chief Executive Officer (CEO) cancels the registration or listing of, the products cease to be registered or listed on the day specified in the notice, which must be at least 20 working days after the notice is given to the person. The cases include:
4. The MAH/LTR contravenes a direction, or a condition of a direction, given in relation to the advertising of the products and the Chief Executive Officer (CEO) is satisfied that the contravention is significant; or
5. There is a breach of an applicable provision of the Pharmacy and Poisons Act Rules on advertisement, and the Chief Executive Officer (CEO) is satisfied that:
   (i) the breach is significant; and
   (ii) as a result of the breach, the presentation of the product is misleading to a significant extent; or

Note: Paragraph (above) does not apply to medicines that are manufactured in Kenya for export only, or are imported into Kenya for export only.

6. The Chief Executive Officer (CEO) is satisfied that a statement made in, or in connection with, the application for registration or listing of the medical product or health technology was false or misleading in a material particular; or
7. The annual registration or listing charge is not paid within 28 days after it becomes payable; or

8. The Chief Executive Officer (CEO) may, by notice in writing given to the MAH/LTR cancel the marketing authorization of the medicine if:
    (a) the medicine is not eligible for registration; or
    (b) the medicine is exempt from registration; or

9. The Chief Executive Officer (CEO) may, by notice in writing given to MAH/LTR cancel the registration of the medicine if:

    a. the Chief Executive Officer (CEO) gives the MAH/LTR a notice requiring the MAH/LTR to give to the Chief Executive Officer (CEO) information or documents relating to the medicine; and

    b. the notice is given for the purposes of ascertaining whether any of the certifications by the MAH/LTR in relation to the registration, manufacturing and testing of the medicine are incorrect; and

    c. the person fails to comply with the notice within 20 working days after the notice is given; or

10. The Chief Executive Officer (CEO) may, by notice in writing given to MAH/LTR, cancel

    the registration or listing of the medical product or health technology if:
    a) it appears to the Chief Executive Officer (CEO) that the quality, safety or efficacy of the product is unacceptable; or
    b) it appears to the Chief Executive Officer (CEO) that the presentation of the product in the case of registered product—is not acceptable; or
    c) the products have changed so that they have become separate and distinct from the product as so registered; or
    d) in the case of a medicine registered, it appears to the Chief Executive Officer (CEO) that any of the certifications provided for registration, manufacturing, testing are incorrect; or
    e) the MAH/LTR has refused or failed to comply with a condition to which the inclusion of the goods is subject; or

11. The Chief Executive Officer (CEO) gives the MAH/LTR a notice that requires MAH/LTR to give to the Chief Executive Officer (CEO) information, or to produce to the Chief Executive Officer (CEO) documents, relating to the

products; and the MAH/LTR fails to comply with that notice within a further 14 days after the end of the period specified in that notice; or

12. The MAH/LTR fails to notify adverse effects in relation to the products; or
13. The product become required to be included in the other part of the Register; or
14. the products do not conform to a standard applicable to the products; or
15. The MAH/LTR contravenes a direction, or a condition of a direction, given to the MAH/LTR in relation to the advertising of the product; or
16. Where the Chief Executive Officer (CEO) proposes to cancel the marketing authorization, the Chief Executive Officer (CEO) must: inform the MAH/LTR in writing that the Chief Executive Officer (CEO) proposes to cancel that registration or listing and set out the reasons for that proposed action; and give the MAH/LTR a reasonable opportunity to make submissions to the Chief Executive Officer (CEO) in relation to the proposed action.
17. Where the MAH/LTR makes submissions in accordance with paragraph (3)(b), the Chief Executive Officer (CEO) is not to make a decision relating to the cancellation until the Chief Executive Officer (CEO) has taken the submissions into account.
18. The Chief Executive Officer (CEO) must, by notice in writing given to MAH/LTR, cancel the registration of the products if the Chief Executive Officer (CEO) becomes aware that protected information was used when evaluating the goods for registration.

5.6 REVOCATION OF CANCELLATION OF MARKETING AUTHORIZATION

5.6.1 REVOCATION OF CANCELLATION OF MARKETING AUTHORIZATION UPON REQUEST

(1) If:

a) The Chief Executive Officer (CEO) cancels the marketing authorization of medical product or health technology because of the request of MAH/LTR 4.1 as per section (1)(c); and
b) Before the end of the period of 90 days beginning on the day the products ceased to be registered or listed, the MAH/LTR requests, in writing, the Chief Executive Officer (CEO) to revoke the cancellation; and
c) The request is accompanied by the prescribed application fee;
d) The Chief Executive Officer (CEO) may, by notice in writing given to the MAH/LTR, revoke the cancellation.

(2) If the cancellation is revoked, the cancellation is taken never to have occurred.

5.6.2 REVOCATION OF CANCELLATION OF MARKETING AUTHORISATION DUE TO NON-PAYMENT OF ANNUAL REGISTRATION OR LISTING CHARGE

(1) If:

a) the Chief Executive Officer (CEO) cancels the MA of medical products or health technology because the annual registration or listing charge was not paid within 28 days after it became payable (see paragraph 4.1(7); and
b) before the end of the period of 90 days beginning on the day the products ceased to be registered or listed, the MAH/LTR requests, in writing, the Chief Executive Officer (CEO) to revoke the cancellation; and
c) the annual registration or listing charge has been paid; and
d) the request is accompanied by the prescribed application fee;
e) the Chief Executive Officer (CEO) may, by notice in writing given to the MAH/LTR, revoke the cancellation.

(2) If the cancellation is revoked, the cancellation is taken never to have occurred.

5.6.3 PUBLICATION OF CANCELLATION OF MARKETING AUTHORIZATION

If the Chief Executive Officer (CEO) cancels the registration or listing of medical products or

health technology under section 4, the Chief Executive Officer (CEO) must, as soon as

practicable after the cancellation, cause to be published in the *Gazette*,

or on the Department's website, a notice setting out particulars of the

cancellation and maintain the records.

ANNEX 1

NOTIFICATION OF SUSPENSION OR REVOCATION OF A MARKET AUTHORIZATION/REGISTRATION BY THE APPLICANT(MAH)

The marketing authorization holder or registration holder or a company authorized by the holder should submit a written notification before the end of the authorization year if the authorization is to be cancelled and the annual fee left unpaid.

The Marketing Authorization is to be cancelled starting from the following date

Date	Month	Year

TYPE OF MEDICAL PRODUCT OR HEALTH TECHNOLOGY				
Human medicine	Veterinary medicine	Herbal product	Parallel product	Medical device

PRODUCT DETAILS	
Marketing authorization No.	
Name of product	
Strength	
Dosage/pharmaceutical form	
Marketing authorization holder	

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

ANNEX 2

NOTIFICATION OF SUSPENSION OR REVOCATION OF A MARKET AUTHORIZATION/REGISTRATION BY THE REGULATOR (PPB)

The Pharmacy and Poisons Board shall notify the MAH on intention to suspend or revoke product registration before the end of the authorization year and the annual fee left unpaid.

The Marketing Authorization is to be cancelled starting from the following date

Date	Month	Year

TYPE OF MEDICAL PRODUCT OR HEALTH TECHNOLOGY				
Human medicine	Veterinary medicine	Herbal product	Parallel product	Medical device

PRODUCT DETAILS	
Marketing authorization No.	
Name of product	
Strength	
Dosage/pharmaceutical form	
Marketing authorization holder	

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

REASON FOR SUSPENSION/REVOCATION

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

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