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MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

GUIDELINE FOR LODGING COMPLAINTS AND APPEALS AT THE PHARMACY AND POISONS BOARD

JANUARY 2022

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ABBREVIATIONS

MoH	Ministry of Health
NMRAs	National Medicine Regulatory Authorities
PPB	Pharmacy and Poisons Board
TWG	Technical Working Group
WHO	World Health Organization

GLOSSARY

"Act" means the Pharmacy and Poisons Act Cap 244 Laws of Kenya

"Appeal" is a formal request for a review of a regulatory decision and/or an outcome of an application. Appeal and review are used interchangeably in this document

"Board" Means the Pharmacy and Poisons Board

"Complaint" This is defined as an expression of dissatisfaction about a service provided by the Board or the identity, quality, safety, efficacy/effectiveness, handling/storage, manufacturing etc. of a Board regulated product or illegal activities concerning the Board's regulated products.

"Complainant" means any person who has lodged a complaint with the Board

"Customer" Internal or external recipient of a product or service anywhere along the product's life cycle.

"Decision" means any administrative or decision made, proposed to be made, or required to be made, as the case may be;

"evidence" The means by which facts are either proved or disproved to the satisfaction of persons inquiring into them

"Non-service related complaints" These are complaints relating to suspected defective Board regulated products or regulatory infractions such as:

a) Unregistered products
b) Substandard or falsified products
c) Expired products
d) Illegal importation, exportation, manufacturing, distribution, sale and use of Board regulated products

"Service-related complaints" These are complaints relating to dissatisfied services provided by the Board such as

a) Mistakes that could result in misunderstanding or omission
b) Undue delays
c) Board officer behavior

d) Poor or misleading information

e) Other service related issues.

Suspected or confirmed defects may be classified into three categories, according to the risk posed to the general public and/or consumers.

Critical quality defects are potentially life threatening or could pose a serious risk to consumers, including patient or animal health.

Major quality defects are those which could cause illness or mistreatment but are not critical

Minor quality defects are those which are unlikely to pose a risk to consumers, including patients and or animal health.

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1.0 INTRODUCTION

The Pharmacy and Poisons Board (PPB) is the national regulatory authority established under the Pharmacy and Poisons Act, Cap 244 Laws of Kenya ("the Act"). The Act mandates the PPB to regulate medical products, health technologies and the profession of Pharmacy. In its day to day execution of her mandate complaints are inevitable.

In the performance of its functions, complaints arising from regulatory decisions or processes and appeals are inevitable. This guideline outlines the information required when lodging a complaint on a medicine and medical devices, and it also facilitates the investigation process.

This document has been established to provide the public and stakeholders with guidance on complaint management process regarding the quality of services provided as well as the quality, safety, efficacy/effectiveness, handling/storage, manufacture etc of the Board's-regulated products. It also provides guidance to applicants who are aggrieved by any regulatory decision of the PPB with regards to the services provided.

If any person is aggrieved by a regulatory decision of the Board, it is the person's right to appeal against the decision in line with the provisions of and this guideline.

The general public is encouraged to give feedback on the various regulatory functions relating to the services provided by the Board and product defects identified on the market.

1.1 Legal Framework

The Constitution of Kenya, under Article 47, grants every person the right to administrative action that is expeditious, efficient, lawful, reasonable and procedurally fair. Further, Article 50 of the Constitution grants every person the right to have any dispute that can be resolved by the application of law decided in a fair and public hearing before an independent and impartial body.

The Board under Section 3A(j) of the Act is empowered to institute administrative proceedings. Therefore, the handling of complaints administratively by the Board shall be fair, expeditious and reasonable.

1.2 Scope

This guideline covers all types of complaints on medicines, medical devices quality, safety and / or efficacy, and advertising of medicines including regulatory irregularities relating to the services/activities of the Board, but excludes adverse reaction complaints resulting from the use of a medicine, which should be reported to the Pharmacovigilance Unit at the Board.

This Guideline sets out the steps to be taken by clients and the Board with respect to making, receiving and resolving of health products and technologies regulatory related requests for appeal.

1.3 Objective of the Guideline

The Objectives of this guideline are to:

a. Recognize and protect the consumers rights to complain within the constraints of the Act and the rules

b. Publicize the existence of the Board's complaints procedures on health products and technologies regulation

c. Provide uniform and effective complaints handling procedures on regulation of health products and technologies in accordance with the requirements of the Act.

1.4 Guiding **Principles**

The following values and principles inform this guideline;

i. The diversity of the people
ii. Impartiality and gender equity
iii. All treaties ratified by Kenya regionally and internationally
iv. All commitments ratified by Kenya internationally and regionally
v. The rules of natural justice
vi. Fairness; and
vii. Accountability

2.0 GENERAL REQUIREMENT

A. COMPLAINTS

2.1 Complaints may be lodged at the Board through letters, e-mail, telephone, social media (Facebook & twitter), SMS or in person.

2.2 A duly filed complaint form shall be lodged with the Board in writing, and addressed to:

THE CHIEF EXECUTIVE OFFICER
PHARMACY AND POISONS BOARD
LENANA ROAD, OPPOSITE DOD
P.O BOX 27663-00506

NAIROBI.

2.3 Complaint submission, investigation and response shall not result in any discriminatory actions against the complainant. All complaints will be treated fairly including those submitted anonymously.

B. APPEALS

2.4 Person who is aggrieved by a regulatory decision made by the Board may formally request in writing for the Board to reconsider/review the initial decision within 30 days after the date of notification of the decision. All appeal requests shall be made in writing, and addressed to:

THE CHIEF EXECUTIVE OFFICER
PHARMACY AND POISONS BOARD
LENANA ROAD, OPPOSITE DOD
P.O BOX 27663-00506
NAIROBI.

2.5 An aggrieved customer shall ensure that the representation includes the following:

a) the appeal letter, dated and signed by the aggrieved person requesting for the review
b) a copy of the initial decision notification letter (or other evidence of notification) stating clearly the regulatory decision for which the appeal is requested
c) any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why review is requested
d) any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why review is requested

2.6 The aggrieved shall ensure that all information and documents that are intended to be relied upon are availed to the Board for a proper determination of the appeal.

2.7 In the event that the aggrieved person whose interests are affected is a third party (i.e. the applicant was not the person to whom the regulatory decision was issued by the Board), the Board shall also notify in writing, the person to whom the regulatory decision was issued (e.g. the Market Authorization Holder (MAH) of the product, Sponsor of a Clinical Trial, etc) advising that a request for review has been received by the Board.

2.8 All appeals received by the Board shall be acknowledged and adequately investigated by the responsible Division/Department with inputs from the Legal Service Department where applicable.

2.9 The Head of the responsible Division/Department shall make representation to an Administrative Appeal Committee that shall be established to hear and determine appeals lodged by persons aggrieved by the decisions of the Authority. The committee shall consider new information submitted with the appeal application.

3.0 MANAGEMENT OF COMPLAINTS

3.1 Upon lodging with the Board, the complaints officer shall;

a) Stamp the complaint form with a "Received date" stamp
b) Allocate a unique sequential number to each complaint and enter it on the Customer Complaint Register
c) Send email response to the complainant acknowledging receipt of the complaint, within ten (10) working days after receipt of the complaint.

3.2 The complaints handling process will only commence once the Board receives a duly completed complaint form.

3.3 After receipt of the complaint the Board will carry out a process of initial assessment and investigations on the substance of the complaint. The Board will first consider the severity of the complaint using the severity classification criteria and thereafter undertake the necessary investigatory action.

3.4 Feedback to the outcome of the investigation will be based on the mode of submission or the complaint, information provided during submission or as appropriate.

3.5 The general public is assured that the Board has defined routes and procedures to:

- Formally receive compliant through proper documentation and completion of the appropriate completion form;
- Process compliant in a uniform and timely manner;
- Evaluate the content/nature of the compliant and accompanying documentation and generate an outcome to provide guidance for redress;
- Effect regulatory action, and
- Provide feedback to the complainant with a summary of the actions taken.

3.6 Confidentiality

All Complaints information will be handled sensitively and will follow relevant data protection requirements.

3.7 In the case that a complainant is not satisfied with the outcome of the complaint, the complainant may appeal against the decision as per the guide below.

4.0 REVIEWING AN APPEAL APPLICATION

4.1 Upon review of the appeal application, the Board shall give a response in writing of the outcome of the appeal application, which shall include a statement of reasons (i.e. findings, references to evidence and reasons for the decision). The response shall be addressed to the aggrieved person within 90 days after submitting an appeal application.

4.2 If the initial decision is one of which is required to be published on the Board's website (such as a decision to register a product or revoke/cancel/suspend a product registration, facility license, etc.), and the Board upon revision of the regulatory decision decides to 'revoke and substitute' the regulatory decision, the particulars of the current decision shall be published on the Board's website.

4.3 An appeal of a regulatory decision will result in one of the under listed outcomes:

a. Endorse the regulatory decision
b. Revoke the regulatory decision
c. Revoke and substitute the regulatory decision with a new decision

Endorsing the regulatory decision

Where upon review the Board decides to uphold the regulatory decision, the regulatory decision shall remain unchanged.

It is however possible that upon review, the Board may have come to the same conclusion as the regulatory decision but for different reasons. The committee may assess evidence in support of the regulatory decision differently or come to another conclusion on the basis of available evidence (which might be additional to what was available when making the regulatory decision).

Revoking the regulatory decision

Where upon review the Board decides to overturn a regulatory decision, the regulatory decision would be reversed as though the regulatory decision was never made.

Revoking and substituting the regulatory decision with a new decision

Where upon review the Board decides to vary all or part of the regulatory decision, the regulatory decision would be partially or entirely replaced (substituted) by a new decision.

Upon review of the initial decision, the Board may decide that a variation (to one or more specific aspects) of the initial decision is, under certain circumstances, the correct outcome. The Board may assess the initial decision as being partially or entirely incorrect at the time it was made or as being partially or entirely incorrect in light of additional information made available to the Board upon review of the initial decision.

5.0 WITHDRAWING AN APPEAL APPLICATION

5.1 An aggrieved person may withdraw their request at any time before the Board convenes a committee to review the regulatory decision.

5.2 Withdrawal of an appeal application should be notified in writing to the Board within ten (10) working days of the initial appeal submission.

5.3 Notification of the withdrawal of an appeal application should be addressed to the Chief Executive Officer (CEO).

5.4 Nonetheless, the committee shall work independently of the office associated with the appeal and the Chair of the committee shall document and maintain records of all engagements related to the appeal process.

5.5 The Board shall suspend all routine evaluation activities related to the appeal pending the completion of the appeal review process and pending confirmation that the client wishes to proceed with the regulation.

6.0 FUTURE REVIEW OF APPEALS HANDLING PROCEDURE

The Appeals handling procedure is subject to interpretation in light of the changing circumstances, and in some matters, it may be necessary, from time to time, to introduce new requirements.

7.0 CONFIDENTIALITY

All Appeals information will be handled sensitively and will follow relevant data protection requirements.

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