



MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

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

SEPTEMBER, 2026

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Addendum 2: Appeal Submission Checklist	37
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ABBREVIATIONS

CAPA	Corrective and Preventive Action
CEO	Chief Executive Officer
COI	Conflict of Interest
HR	Human Resources
MoH	Ministry of Health
NMRA	National Medicines Regulatory Authority
PPB	Pharmacy and Poisons Board
PV	Pharmacovigilance
QMS	Quality Management Systems
TWG	Technical Working Group
WHO	World Health Organization

GLOSSARY

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

"Admissibility screening" means the preliminary review conducted by the Legal Services Department to confirm that an appeal is timely, complete, non-duplicative, within PPB's jurisdiction, and not frivolous or vexatious, before the appeal is referred to an Appeal Review Team.

"Appeal" is a formal written request for a review or reconsideration of a regulatory decision made by the Board and/or the outcome of an application. In this context, "appeal" and "review" are used interchangeably.

"Appeal Review Team" means an independent team of senior subject matter experts appointed, in relation to a specific appeal, by the Head(s) of Department(s) relevant to the subject matter of the appeal, none of whom was involved in making the initial regulatory decision under appeal, constituted to hear and determine appeals lodged against regulatory decisions of the Board.

"Board" means the Pharmacy and Poisons Board.

"CAPA" means Corrective and Preventive Action taken to eliminate the cause of a detected nonconformity or other undesirable situation and to prevent recurrence.

"Common Appeals Register" means a centralized official record maintained and domiciled in the Legal Services Department for documenting, tracking and monitoring all formal appeals submitted against regulatory decisions.

"Complaint" means an expression of dissatisfaction regarding the conduct, service delivery, or regulatory functions of the Board, or concerning 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 formal complaint with the Board.

"Complaints Register" means an official log maintained by the Board for the systematic recording and monitoring of all complaints received from stakeholders regarding regulated products, services, or personnel.

"Conflict of Interest" means any situation in which an officer's personal, professional or financial interest, or prior involvement in a matter, could improperly influence, or reasonably be perceived to influence, that officer's objectivity in handling a complaint or determining an appeal.

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

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

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

"Non-service-related complaints" are complaints relating to suspected defective Board-regulated products or regulatory infractions, including unregistered products; substandard or falsified products; expired products; and illegal importation, exportation, manufacturing, distribution, sale and use of Board-regulated products.

"Service-related complaints" are complaints relating to dissatisfaction with services provided by the Board, including mistakes that could result in

misunderstanding or omission; undue delays or inaction; Board officer conduct; poor or misleading information; and other service-related issues.

"Staff-conduct complaints" are complaints concerning the personal conduct, integrity or behaviour of a Board officer, which shall be routed to Human Resources and, where indicated, Legal Services or the Board's integrity function.

"Stay of a decision" means the suspension of the operation or enforcement of a regulatory decision pending determination of an appeal, granted only in the exceptional circumstances described in Section 9 of this Guideline.

Suspected or confirmed product defects and complaints are classified into three categories according to the risk posed to the public and/or consumers:

Critical: Potentially life-threatening or posing a serious risk to consumers, including patient or animal health.

Major: Could cause illness or mistreatment but is not critical.

Minor: Unlikely to pose a risk to consumers, including patient 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 mandates PPB to regulate medicines, medical devices, health technologies and the pharmacy profession.

In carrying out its regulatory mandate, complaints may arise concerning regulated products, services, regulatory processes or staff conduct. Persons affected by regulatory decisions may also seek review or reconsideration of such decisions.

This Guideline establishes a transparent, accessible, fair and risk-based framework for receiving, assessing, investigating and resolving complaints and appeals.

The Guideline distinguishes between complaints and appeals and establishes separate pathways to ensure that each matter is directed to the appropriate responsible office and handled within a timeframe proportionate to its risk and nature.

The Guideline provides information on the requirements for lodging complaints concerning medicines, medical devices and other regulated products, PPB services, regulatory processes and staff conduct. It also provides a mechanism for persons aggrieved by regulatory decisions of the Board to seek review or reconsideration.

Any person aggrieved by a regulatory decision of the Board has the right to appeal against that decision in accordance with this Guideline and applicable law.

The public and stakeholders are encouraged to provide feedback concerning PPB's regulatory functions and report suspected defects, unsafe or illegal activities involving regulated products.

1.1 Legal Framework

The Constitution of Kenya, under Article 47, provides for the right to administrative action that is expeditious, efficient, lawful, reasonable and procedurally fair.

Article 50 provides for fair and public hearing before an independent and impartial body in disputes capable of being resolved through application of law.

The Fair Administrative Action Act, 2015, gives effect to Article 47 and requires administrative bodies, including the PPB, to provide reasons for their decisions, accord affected persons a reasonable opportunity to be heard, and ensure that administrative action is not taken by a person with a personal interest in the matter.

The Board is empowered under the Pharmacy and Poisons Act to institute administrative proceedings.

Complaint and appeal processes shall therefore be conducted in a manner that is fair, expeditious, reasonable, lawful and procedurally sound.

This Guideline shall be implemented consistently with the Constitution, the Pharmacy and Poisons Act, the Fair Administrative Action Act, the Data Protection Act and other applicable laws.

1.2 Scope

This Guideline applies to:

- a) complaints concerning the quality, safety and/or efficacy/effectiveness of medicines, medical devices and other regulated products;
- b) complaints concerning advertising and other regulatory activities within PPB's mandate;
- c) complaints concerning PPB services and regulatory processes;
- d) complaints concerning staff conduct;
- e) complaints concerning regulatory irregularities; and
- f) appeals against PPB regulatory decisions.

Adverse drug reaction complaints arising from use of a medicine are excluded from the complaint pathway and shall be reported to the Pharmacovigilance Unit and managed in accordance with applicable pharmacovigilance procedures.

This Guideline establishes distinct pathways for receiving, triaging, investigating and resolving complaints and appeals.

1.3 Objective of the Guideline

The objectives of this Guideline are to:

- a) recognize and protect the right of a person to lodge a complaint within the limits of applicable law;
- b) publicize the existence of PPB complaint and appeal mechanisms;
- c) provide uniform, effective and risk-proportionate procedures for handling complaints and appeals;
- d) establish distinct pathways for product-quality and safety complaints, service complaints, staff-conduct complaints and appeals against regulatory decisions;
- e) ensure that appeals are reviewed independently and fairly;
- f) ensure that complainants and appellants are treated fairly and without discrimination or retaliation;
- g) ensure appropriate communication of decisions and outcomes; and
- h) support monitoring, trend analysis, CAPA and continuous improvement

1.4 Guiding Principles

The implementation of this Guideline shall be guided by:

- a) legality and adherence to due process;
- b) objectivity and impartiality;
- c) diversity, equity, non-discrimination and inclusivity;
- d) confidentiality and data protection;
- e) natural justice;
- f) independence and procedural fairness in appeal determination;
- g) risk-proportionate timeliness;
- h) fairness and accountability; and
- i) alignment with applicable regional and international obligations.

2.0 COMPLAINT AND APPEAL PATHWAYS

2.1 Complaints and appeals are distinct processes and shall not be handled through the same workflow. The following categories shall be routed as indicated below:

Category	Nature	Responsible office	Pathway
Product-quality/safety complaint	Concern's identity, quality, safety, efficacy/effectiveness, handling, storage, manufacture or illegal handling of regulated products	Post-Market Surveillance or relevant technical function	Section 3.0
Adverse reaction	Suspected adverse reaction arising from use of a medicine	Pharmacovigilance Unit	Applicable PV procedure
Service complaint	Dissatisfaction with service delivery, delays, officer behavior in a service context or misleading information	Responsible technical/administrative function, with QMS involvement where appropriate	Section 3.0
Staff-conduct complaint	Personal conduct, integrity or behavior of a Board officer	HR, with Legal Services or integrity function where appropriate	Section 3.0 and applicable HR procedures
Appeal	Formal request to review or reconsider a specific PPB regulatory decision	Appeals Review Team	Sections 4.0–7.0

2.1.1 Where a matter contains elements of more than one category, the receiving office shall:

- a) record the matter once;
- b) notify all relevant responsible offices;
- c) designate a lead office to coordinate the response; and
- d) ensure that actions are coordinated to prevent duplication or conflicting outcomes.

2.1.2 Where dissatisfaction with a complaint outcome concerns a regulatory decision, the person may pursue the matter through the appeal process under Section 4.0.

2.2 Regulatory Decisions Subject to Appeal

2.2.1 A person aggrieved by a specific regulatory decision made by the Pharmacy and Poisons Board may lodge an appeal in accordance with Section 4.0 of this Guideline and applicable law.

2.2.2 For purposes of this Guideline, regulatory decisions that may be subject to appeal include, as applicable and subject to the governing legislation and regulatory framework:

- a) decisions relating to the registration, licensing, authorization, renewal, variation, suspension, revocation or cancellation of regulated products, premises, persons or activities;
- b) decisions arising from inspection, audit or compliance assessment activities, including regulatory decisions made following inspection findings;
- c) decisions relating to Good Manufacturing Practice, Good Distribution Practice, Good Clinical Practice or other applicable regulatory compliance requirements;
- d) decisions relating to clinical trials and other regulated research activities;
- e) decisions relating to pharmacovigilance or other post-market regulatory measures, where the applicable legal framework provides for an appeal;

- f) decisions relating to advertising, promotion or other regulatory communications;
- g) decisions relating to importation, exportation, quarantine, market withdrawal, recall or other enforcement or public-health protective measures, where appealable under applicable law;
- h) decisions relating to applications submitted to the Board where the applicant is aggrieved by the regulatory outcome; and
- i) any other regulatory decision for which an internal appeal or review mechanism is provided under applicable law or PPB requirements.

2.2.3 The availability of an appeal shall be determined with reference to the applicable statutory and regulatory framework governing the decision. Where a specific statutory appeal or review mechanism applies, that mechanism shall take precedence.

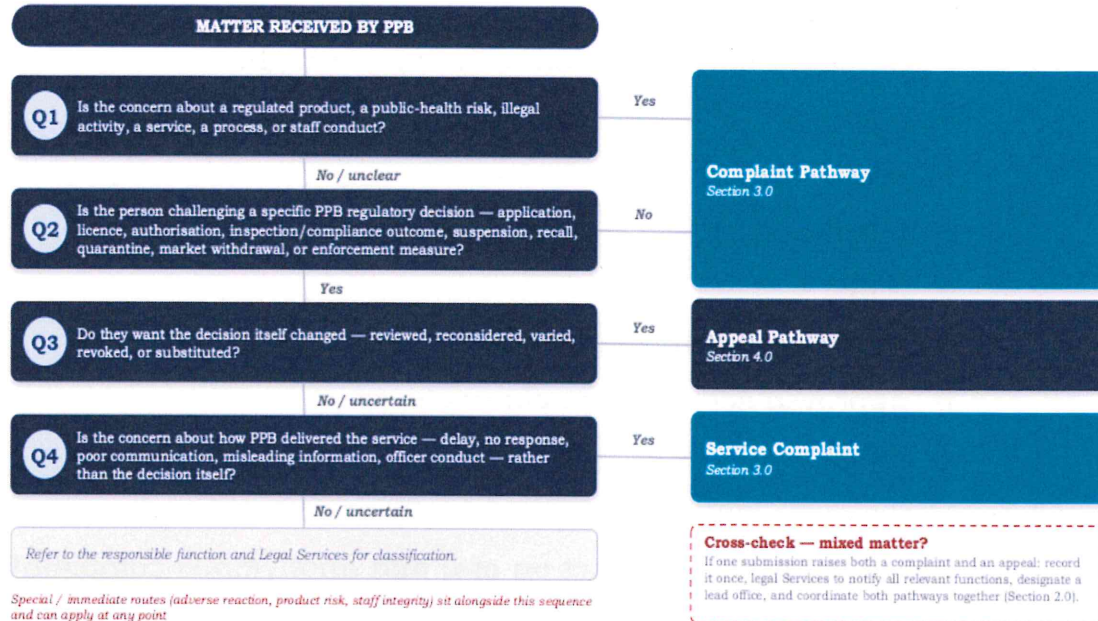
2.2.4 A complaint concerning the manner in which a regulatory service was provided shall not, by itself, constitute an appeal against the underlying regulatory decision. Where the substance of the matter challenges the legality, factual basis, procedural fairness, proportionality or other merits of a specific regulatory decision, the matter shall be directed to the appeal pathway.

2.2.5 Where a matter contains both a service complaint and a challenge to a regulatory decision, the matter shall be managed through coordinated complaint and appeal pathways in accordance with Section 2.0, without requiring the complainant or appellant to submit the same information repeatedly.

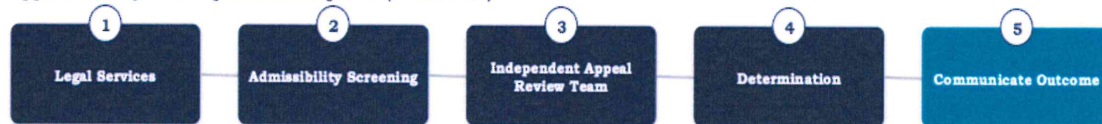
Decision Tree Regulatory Complaint and Appeal Routing Process

Complaint & Appeal Intake Classification Tree

Routes each matter to the correct process at first receipt. This tool classifies the matter — it is not a determination of the merits.



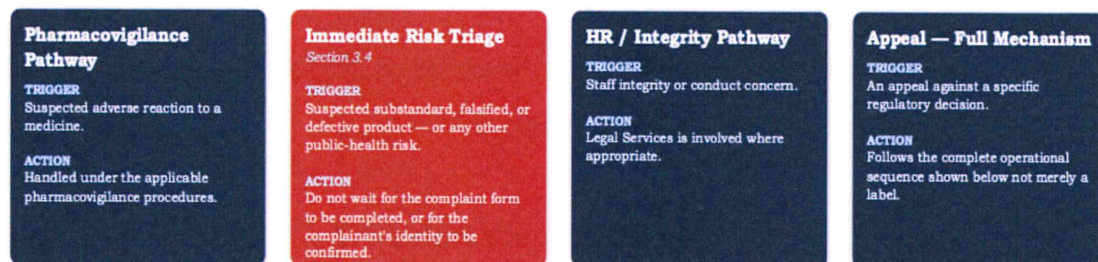
Appeal Pathway — full operational sequence (Section 4.0)



An appeal is not merely a label: it is this complete mechanism, from receipt through to communication of the outcome.

Special Routing & the Appeal Mechanism

These routes apply immediately, wherever public health or integrity is at stake.



Legend: ■ Navy — classification question / standard pathway ■ Teal — standard complaint-track outcome ■ Terracotta — urgent, act immediately

3.0 COMPLAINT MANAGEMENT

3.1 Submission Channels

3.1.1 A complaint may be lodged with PPB through:

- a) a letter;
- b) email;
- c) telephone;
- d) SMS;
- e) the Board's official online complaints platform;
- f) approved social media channels; or
- g) in person.

3.1.2 Complaints may be submitted orally or anonymously.

3.1.3 PPB shall accept and act on oral and anonymous complaints on the same basis as written and identified complaints, subject to limitations in obtaining additional information or communicating with an anonymous complainant.

3.2 Written Complaints

3.2.1 Where a complainant is able to provide a written complaint, the complainant should complete the prescribed complaint form to facilitate thorough investigation and record-keeping.

3.2.2 A completed complaint form shall, however, **not be a precondition for PPB to commence handling a complaint.**

3.2.3 Complaints may be submitted to:

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

OR

through the Board's approved online complaints platform:

<https://complaints.pharmacyboardkenya.org/home>

3.3 Receipt and Registration

3.3.1 Upon receipt of a complaint, the responsible complaints officer shall:

- a) record the date and mode of receipt;
- b) stamp the complaint form where a form is available;
- c) assign a unique sequential reference number;
- d) enter the complaint in the relevant Complaints Register;
- e) classify the complaint by category and severity;
- f) identify the responsible office; and
- g) initiate the applicable complaint-handling process.

3.3.2 The absence of a completed complaint form shall not prevent registration, triage or urgent action.

3.4 Oral, Anonymous or Incomplete Complaints

3.4.1 Where an oral, anonymous or incomplete complaint indicates a critical quality or safety defect or an urgent public health risk, PPB shall immediately triage the complaint.

3.4.2 Where warranted, PPB may take interim protective measures, including:

- a) public or stakeholder alerts;
- b) quarantine;
- c) inspection;
- d) product sampling or testing;
- e) market withdrawal or recall; or
- f) referral to another competent authority.

3.4.3 Such action shall not be delayed while awaiting completion of the complaint form or confirmation of the complainant's identity.

3.4.4 Where feasible, additional information shall be obtained in parallel for investigation and record-keeping.

3.5 Protection of Complainants

3.5.1 Complaint submission, investigation and resolution shall not result in discriminatory or retaliatory action against a complainant.

3.5.2 Complaints shall be handled fairly, including complaints submitted anonymously or in good faith.

3.6 **Complaint Assessment and Investigation**

3.6.1 The responsible function shall conduct an initial assessment of the substance and risk of the complaint.

3.6.2 The complaint shall first be classified according to severity and thereafter investigated in proportion to the identified risk.

3.6.3 The responsible function shall:

- a) assess the information and evidence available;
- b) determine the appropriate investigation;
- c) identify whether immediate regulatory or protective action is required;
- d) undertake the investigation;
- e) document findings;
- f) determine appropriate corrective, preventive or regulatory action; and
- g) provide feedback to the complainant where appropriate.

3.6.4 PPB shall maintain appropriate records of all actions taken.

3.7 **Risk Classification and Timelines**

3.7.1 Every complaint shall be classified as **critical, major or minor** using the definitions in the Glossary.

3.7.2 The classification shall determine the applicable response and investigation timeline.

Stage	Critical	Major	Minor
Triage / initial risk classification	Within 1 working day of receipt	Within 2 working days	Within 5 working days
Acknowledgement	Within 2 working days	Within 5 working days	Within 10 working days
Interim protective action, where warranted	Immediately upon identification of risk	As warranted without undue delay	Not ordinarily applicable
Escalation to Head of Department	Within 2 working days of triage	Within 5 working days of triage	Within 10 working days, where warranted
Investigation completed	Within 15 working days	Within 30 working days	Within 45 working days
Feedback to complainant	Within 5 working days of conclusion	Within 10 working days of conclusion	Within 15 working days of conclusion

Closure and register update	Within 5 working days of feedback	Within 10 working days	Within 15 working days
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3.7.3 The investigation period for complex critical complaints may be extended where justified.

3.7.4 Where a stage cannot be completed within the prescribed timeline, the responsible officer shall:

- a) document the reason for the delay;
- b) establish a revised target date;
- c) notify the Head of Department; and
- d) for critical complaints, notify the Head of QMS

3.8 **Investigation Outcome and Feedback**

3.8.1 Feedback on the outcome shall be based on the nature of the complaint, the information provided and the extent to which disclosure is appropriate.

3.8.2 Feedback shall include, where appropriate:

- a) a summary of the findings;
- b) actions taken or proposed;
- c) any relevant corrective or regulatory action; and
- d) information on available further avenues of redress.

3.8.3 Information shall not be disclosed where doing so would breach confidentiality, data protection, legal privilege or other applicable restrictions.

3.9 **Complaints Register**

3.9.1 PPB shall maintain Complaints Registers within relevant departments for recording, monitoring and tracking complaints relating to regulated products, services and staff conduct.

3.9.2 Each complaint shall have a unique reference number.

3.9.3 The Register shall include, as applicable:

- a) date of receipt;
- b) complaint category;
- c) severity classification;
- d) complainant details, where known;

- e) responsible department;
- f) actions taken;
- g) applicable timeline;
- h) outcome; and
- i) resolution/closure date.

3.9.4 Access to Complaints Registers shall be restricted to authorized officers and managed in accordance with applicable data protection and records management requirements.

4.0 APPEALS AGAINST REGULATORY DECISIONS

4.1 Right of Appeal and Timeframe

- 4.1.1 A person aggrieved by a regulatory decision of PPB may formally request, in writing, that the Board review or reconsider the decision, subject to applicable law.
- 4.1.2 An appeal may be lodged through any approved PPB appeal submission channel made in writing, and addressed to:

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

- 4.1.3 This may include:
- a) physical submission to the Board;
 - b) official PPB email or electronic submission platform; or
 - c) submission through an authorized representative.
- 4.1.4 The current approved appeal submission channels shall be published on the PPB official website and communicated in relevant regulatory decision notifications.
- 4.1.5 An appeal shall ordinarily be lodged within fourteen (14) calendar days from the date on which the appellant is notified of the regulatory decision.
- 4.1.6 The date of receipt of an appeal shall be determined by the date the appeal is received through an approved PPB submission channel. Where an appeal is submitted electronically, the date and time recorded by the PPB electronic system shall constitute the date and time of receipt, subject to verification where necessary.
- 4.1.7 The CEO may, on written request stating justified reasons, extend the period by up to thirty (30) additional calendar days.
- 4.1.8 Justified reasons may include:

- a) delayed or defective notification of the decision;
 - b) circumstances beyond the reasonable control of the appellant;
 - c) medical or other exceptional circumstances; or
 - d) other circumstances constituting good cause.
- 4.1.9 A request for extension should ordinarily be submitted before expiry of the initial fourteen (14) day period. A request submitted after expiry may be considered where the delay is satisfactorily explained.
- 4.1.10 The notification of a regulatory decision shall, where applicable, inform the affected person of:
- a) the decision made;
 - b) the principal reasons for the decision;
 - c) the right to appeal or seek review;
 - d) the applicable time limit;
 - e) the approved channel for lodging an appeal; and
 - f) the effect, if any, of lodging an appeal on the regulatory decision.
- 4.1.11 Legal Basis for Appeal
- a) Where a regulatory decision is subject to a specific statutory or regulatory appeal or review mechanism, the applicable statutory or regulatory provisions shall be identified in the decision notification and, where appropriate, in the appeal acknowledgment.
 - b) Where no specific statutory appeal mechanism is prescribed, an internal review or reconsideration may be undertaken in accordance with this Guideline to the extent permitted by applicable law.
 - c) Nothing in this Guideline shall be construed as limiting or replacing any right of appeal, review, complaint or other redress available to an affected person under the Constitution, written law or applicable regulatory framework.

4.2 **Grounds of Appeal**

4.2.1 An appeal may be based on one or more of the following grounds:

- a) factual error in the decision;
- b) error of law;
- c) procedural unfairness or breach of natural justice;
- d) failure to consider relevant evidence or reliance on irrelevant considerations;
- e) disproportionality of the decision or sanction relative to the conduct or risk;
- f) inconsistency with PPB decisions in comparable matters;
- g) new information or evidence that was not available when the original decision was made; or
- h) any other relevant ground raised by the appellant.

4.2.2 The availability of new information shall not be a precondition for lodging an appeal.

4.3 **Contents of an Appeal Submission**

4.3.1 An appeal submission shall include:

- a) a dated and signed appeal letter identifying the decision and stating the ground or grounds of appeal;
- b) a copy of the initial decision notification or other evidence of notification;
- c) information and documentation supporting the appeal, clearly linked to the relevant ground or grounds; and
- d) full disclosure of information and documents that the appellant intends to rely upon.

4.3.2 Additional information not disclosed at submission may be admitted where the Appeal Review Team considers that there is sufficient justification for doing so.

4.4 **Admissibility Screening**

4.4.1 Every appeal shall undergo admissibility screening before substantive review.

4.4.2 Legal Services shall, within at least five (5) working days of receipt, determine whether the appeal:

- a) was lodged within the prescribed 14-day period or an approved extension;
- b) contains the required information;
- c) is not a duplicate of a pending or previously determined appeal concerning the same decision;
- d) falls within PPB's jurisdiction; and
- e) is not frivolous, vexatious or manifestly unfounded on its face.

4.5 Defective or Inadmissible Appeals

- 4.5.1 Where an appeal has a curable defect, such as incomplete information, the appellant may be notified in writing, provided with reasons and given ten (10) working days to remedy the defect and resubmit.
- 4.5.2 Where an appeal is inadmissible on a non-curable ground, including being out of time without an approved extension or falling outside PPB jurisdiction, the appellant shall be notified in writing and provided with reasons.
- 4.5.3 The notification shall identify any further options for redress available under applicable law.

4.6 Referral for Review

- 4.6.1 An admissible appeal shall be referred to the responsible technical function for relevant technical input and acknowledgement, with Legal Services providing necessary legal support.
- 4.6.2 The appeal shall then proceed to the constitution of an Independent Appeal Review Team in accordance with Section 5.0.
- 4.6.3 The Appeal Review Team shall maintain appropriate communication with the appellant throughout the appeal process. The appellant shall be informed, as applicable, of:
 - a) receipt and registration of the appeal;
 - b) the admissibility outcome;
 - c) any curable deficiency requiring action by the appellant;

- d) constitution of the Appeal Review Team, subject to applicable confidentiality and conflict-of-interest requirements;
- e) any additional information or evidence required;
- f) the expected date of determination; and
- g) any material delay and the revised target date.

4.6.4 The appellant shall not be required to make repeated requests for information that PPB is required to communicate under this Guideline.

4.7 **Third-Party Appeals**

- 4.7.1 Where an appeal is lodged by a person who was not the direct recipient of the regulatory decision, PPB shall first determine whether the appellant has a sufficient legal or legitimate interest in the decision to warrant consideration of the appeal.
- 4.7.2 Where the appeal is accepted for consideration and another person or entity is directly affected by the decision, PPB shall, where appropriate and subject to applicable confidentiality and data protection requirements, notify the directly affected person or entity.
- 4.7.3 A directly affected person or entity shall be afforded a reasonable opportunity to make representations where the appeal may adversely affect its rights, interests or regulatory status.
- 4.7.4 Confidential, proprietary or commercially sensitive information shall be handled in accordance with applicable law and PPB confidentiality and data protection requirements.
- 4.7.5 The Appeal Review Team shall take appropriate measures to ensure that the determination is based only on information properly considered in accordance with applicable law and procedural fairness requirements.

5.0 INDEPENDENT APPEAL REVIEW TEAM

5.1 Constitution

5.1.1 Each admissible appeal shall be heard and determined by an Independent Appeal Review Team.

5.1.2 The Team shall be constituted specifically for the appeal and shall be independent of the function that made the original regulatory decision.

5.2 Appointment and Composition

5.2.1 The Appeal Review Team shall be appointed by the Head(s) of Department relevant to the subject matter of the appeal.

5.2.2 The Team shall comprise a minimum of three (3) senior subject-matter experts with necessary expertise to determine the appeal.

5.2.3 A chairperson shall be designated from among the appointed members.

5.3 Independence

5.3.1 A person shall not be appointed to or sit on the Appeal Review Team where the person:

- a) participated in making the original regulatory decision;
- b) recommended the original decision;
- c) reviewed or approved the original decision;
- d) has a conflict of interest in the matter; or
- e) is otherwise subject to a reporting or other relationship that compromises independence in relation to the matter under appeal.

5.3.2 The Team shall operate independently of the division or department whose decision is under appeal.

5.3.3 The Team shall not be subject to direction, control or influence from the original decision-maker in relation to its determination.

5.4 External Expertise

5.4.1 Where the responsible department lacks sufficient independent in-house expertise, the Head of Department may co-opt an

independent external subject-matter expert from another PPB Department.

- 5.4.2 An expert shall meet the applicable competence, independence and conflict-of-interest requirements in accordance with PPB requirements.

6.0 APPEAL REVIEW AND PROCEDURAL FAIRNESS

6.1 General Requirements

6.1.1 Appeal review shall comply with Articles 47 and 50 of the Constitution, the Fair Administrative Action Act and other applicable law.

6.1.2 The Appeal Review Team shall ensure that the appellant is afforded a fair opportunity to present and respond to the case.

6.2 Written and Oral Representations

6.2.1 The appellant shall be afforded a reasonable opportunity to make written representations.

6.2.2 Where requested by the appellant or considered necessary by the Appeal Review Team, the appellant may be given an oral hearing before determination.

6.2.3 Subject to legitimate confidentiality restrictions, including third-party commercial confidentiality and statutory restrictions on disclosure, the appellant shall be given access to material relevant to the decision under appeal and material the Appeal Review Team proposes to rely upon.

6.3 Response to Adverse Information

6.3.1 Where the Appeal Review Team intends to rely on information adverse to the appellant that was not previously provided to the appellant, the appellant shall be given:

- a) the information; and
- b) a reasonable opportunity to review and respond to it.

6.3.2 The appeal shall not be determined until the appellant has been given a reasonable opportunity to respond.

6.4 Impartiality

6.4.1 No member of the Appeal Review Team shall participate in determining a matter in which the member has an interest.

6.4.2 The principles of natural justice, including the rule that no person shall be a judge in their own cause, shall apply.

6.5 Effect of Lodging an Appeal

6.5.1 Lodging an appeal shall not, by itself, suspend, stay or otherwise affect the validity, force or enforceability of the regulatory decision under appeal.

6.5.2 This applies particularly to decisions involving:

- a) suspension;
- b) recall;
- c) quarantine;
- d) market withdrawal; or
- e) other measures intended to protect public health.

6.5.3 Such decisions shall ordinarily remain in force pending determination of the appeal.

6.6 Stay of a Regulatory Decision

6.6.1 The CEO may, upon the appellant's written request and on Legal Services' advice, grant a stay of the decision under appeal.

6.6.2 A stay shall only be granted in exceptional circumstances and where the CEO is satisfied that the stay will not compromise:

- a) public health;
- b) patient or consumer safety; or
- c) the integrity of the regulatory system.

6.6.3 A stay may be subject to conditions and may be revoked if those conditions are no longer met.

6.6.4 The notification of a regulatory decision and the acknowledgment of an appeal shall state that the decision remains in effect pending determination of the appeal unless a stay is granted.

6.7 Risk-Based Appeal Timelines

6.7.1 Appeals involving critical or public-health-sensitive decisions shall be expedited.

6.7.2 These may include appeals concerning:

- a) suspensions;
- b) recalls;
- c) quarantine orders; or
- d) matters presenting an immediate risk to patient or consumer safety.

6.7.3 All other appeals shall follow the standard timeline.

6.7.4 The timelines below shall run from the date PPB receives the appeal.

Stage	Critical / Public-Health-Sensitive	Standard
Admissibility screening	At least 2 working days	At least 5 working days
Decision communicated to appellant	Within 30 calendar days of receipt	Within 90 calendar days of receipt

6.7.5 Where any stage cannot be completed within the prescribed timeline, the chairperson shall document:

- a) the reason for the delay; and
- b) the revised target date.

6.7.6 The Appeals Review Team shall communicate the revised timeline to the appellant in writing.

7.0 APPEAL DETERMINATION AND COMMUNICATION OF DECISION

7.1 Appeal Determination

7.1.1 The Appeal Review Team shall consider the appeal, the representations made by the appellant, the evidence before it and the applicable legal and regulatory requirements and shall make a determination in accordance with this Guideline.

7.1.2 The determination shall be made independently and shall not be subject to direction or influence by the officer or function responsible for the original regulatory decision.

7.1.3 The Appeal Review Team may determine that the original regulatory decision should be:

- a) confirmed;
- b) revoked;
- c) varied; or
- d) substituted with another decision, where permitted by applicable law and within the regulatory authority of PPB.

7.1.4 Where the Appeal Review Team is authorized by law to make the final determination, its determination shall constitute the final internal PPB determination.

7.1.5 Where applicable law requires the determination to be made or formally approved by another statutory decision-maker, the Appeal Review Team shall submit its determination or recommendation to that decision-maker in accordance with the applicable legal framework.

7.1.6 No person who participated in making, recommending, reviewing or approving the original regulatory decision shall participate in the substantive determination of the appeal.

7.1.7 The final appeal decision shall be supported by documented reasons, including the material facts, evidence and legal or regulatory considerations relied upon.

7.2 Appeal Outcomes

- 7.2.1 Following review, the Appeal Review Team may recommend:
 - a) confirmation of the original regulatory decision;
 - b) revocation of the regulatory decision; or
 - c) variation or substitution of the regulatory decision.
- 7.2.2 Where the Appeal Review Team recommends that the regulatory decision be upheld, the original decision shall remain unchanged.
- 7.2.3 The Team may reach the same conclusion as the original decision for different reasons or based on additional evidence available during the appeal.
- 7.2.4 Where the Appeal Review Team recommends overturning the regulatory decision, the decision shall be revoked in accordance with the applicable legal and regulatory framework.
- 7.2.5 Where the Appeal Review Team recommends varying all or part of the regulatory decision, the decision may be replaced in whole or in part by a new decision. This may occur when the Team considers the original decision to have been partially or entirely incorrect, or when additional information received during review justifies a variation.

7.3 Communication of Decision

- 7.3.1 Following conclusion of the appeal review, PPB, through the CEO, shall communicate the decision in writing within the applicable timeline under Section 6.7.
- 7.3.2 The communication shall include:
 - a) the outcome of the appeal;
 - b) the reasons for the determination, including relevant findings and evidence; and
 - c) any consequential regulatory action.
- 7.3.3 Where the original decision was required to be published on the PPB website, and the appeal results in revocation, variation or substitution of that decision, the particulars of the current decision shall be published in accordance with applicable PPB requirements.

7.3.4 The written decision on the appeal shall state whether the internal appeal process is final. Where further redress is available, the communication shall identify applicable options, which may include:

- a) a sector tribunal established under applicable law;
- b) a complaint to the Commission on Administrative Justice;
and/or
- c) judicial review before the High Court.

7.3.5 The communication shall provide applicable timelines for pursuing further redress where known.

8.0 WITHDRAWING AN APPEAL APPLICATION

- 8.1 An appellant may withdraw an appeal at any time before the Appeal Review Team issues its determination.
- 8.2 Withdrawal shall be made in writing to the CEO.
- 8.3 Where withdrawal is received within ten (10) working days of submission and before constitution of the Appeal Review Team, Legal Services shall record the withdrawal and close the appeal file.
- 8.4 Where an appeal is withdrawn after constitution of the Appeal Review Team, Legal Services shall:
 - a) record the withdrawal;
 - b) notify the Team; and
 - c) close the appeal file without issuing a determination.
- 8.5 Withdrawal of an appeal shall not affect the validity or enforceability of the underlying regulatory decision.
- 8.6 The decision shall continue in force unless otherwise varied, suspended or revoked through an authorized process.
- 8.7 Legal Services shall retain records of all engagements relating to a withdrawn appeal in accordance with Section 11.0.

9.0 APPEALS REGISTER

- 9.1 PPB shall maintain an official **Common Appeals Register** as the central repository for recording, tracking and auditing all formal appeals received.
- 9.2 The Register shall be maintained by Legal Services
- 9.3 The Common Appeals Register shall contain, at minimum:
 - a) unique appeal reference number;
 - b) date of lodgment;
 - c) name of appellant;
 - d) subject matter;
 - e) department whose decision is under appeal;
 - f) members appointed to the Appeal Review Team;
 - g) regulatory decision under review;
 - h) outcome of the appeal; and
 - i) resolution/closure date.
- 9.4 Access to the Common Appeals Register shall be restricted to authorized officers.
- 9.5 Data security and confidentiality shall be maintained in accordance with applicable legal and PPB requirements.

10.0 MONITORING AND CONTINUOUS IMPROVEMENT

- 10.1 The Quality Management Systems (QMS) office shall analyze complaint and appeal data at least quarterly to identify:
- a) recurring issues;
 - b) common root causes;
 - c) trends by product, service, department or decision type;
 - d) timeliness and overdue matters; and
 - e) opportunities for improvement.
- 10.2 Recurring or significant root causes identified through complaints, appeals or trend analysis shall be addressed through CAPA.
- 10.3 CAPA shall be tracked to completion in accordance with the applicable PPB procedure.
- 10.4 Complaint and appeal performance shall be a standing agenda item at management review meetings at least twice annually.
- 10.5 Performance information shall include, where applicable:
- a) number and type of complaints and appeals;
 - b) timeliness;
 - c) overdue matters;
 - d) trends and root causes;
 - e) CAPA status; and
 - f) effectiveness of corrective actions.
- 10.6 PPB shall, at least annually, evaluate the effectiveness of its complaint and appeal processes.
- 10.7 Where feasible, feedback shall be obtained from complainants and appellants regarding their experience of the process.

11.0 RECORDS MANAGEMENT

11.1 Complaint and appeal records shall include, as applicable:

- a) complaints and appeal submissions;
- b) correspondence;
- c) evidence and supporting documentation;
- d) investigation records;
- e) Complaints Registers;
- f) Common Appeals Register entries;
- g) appointment letters;
- h) conflict-of-interest declarations;
- i) Appeal Review Team minutes; and
- j) final decisions and communications

11.2 Complaints and appeals records shall be retained for a minimum of seven (7) years from closure of the matter.

11.3 A longer retention period shall apply where required by:

- a) applicable law; or
- b) the PPB records retention schedule.

11.4 All entries and amendments to complaints and appeals registers, whether paper-based or electronic, shall be traceable to:

- a) the officer making the entry;
- b) date and time;
- c) nature of the entry or amendment; and
- d) original information where an amendment is made.

11.5 The record system shall preserve the integrity of the original entry.

11.6 Access to complaint and appeal records shall be restricted to authorized officers on a need-to-know basis.

11.7 Electronic systems shall use appropriate role-based access controls and physical files shall be securely maintained.

11.8 These shall form part of the appeal case file and shall be securely maintained

12.0 PUBLIC AVAILABILITY, IMPLEMENTATION AND REVIEW

- 12.1 The current approved version of this Guideline shall be published on the PPB official website, along with the approved complaint and appeal submission channels.
- 12.2 Evidence of publication shall be retained in accordance with PPB document-control requirements.
- 12.3 This Guideline shall be formally reviewed at least once every five (5) years from the date of authorization. In addition, a review shall be triggered, ahead of the scheduled cycle, by any of the following:
- a) a change in the Constitution, Pharmacy and Poisons Act, Fair Administrative Action Act, Data Protection Act or other applicable law;
 - b) a WHO or peer-NMRA benchmarking, assessment or audit finding indicating the need for revision;
 - c) significant nonconformities, recurring root causes or CAPA findings identified through monitoring;
 - d) significant changes to PPB's complaint or appeal processes; or
 - e) a directive from the CEO or Board
- 12.4 Legal Services, in collaboration with QMS, shall coordinate the review of this Guideline. The Head of QMS shall coordinate the review process.
- 12.5 The revised Guideline shall be approved by the CEO before implementation and publication.

13.0 CONFIDENTIALITY

- 13.1 All information relating to complaints and appeals shall be handled confidentially and used only for legitimate regulatory, administrative, quality or legal purposes.
- 13.2 Information shall be managed in accordance with the Data Protection Act and applicable ethical and PPB requirements.
- 13.3 Access to complaint and appeal information shall be limited to officers who require the information to perform their authorised duties.
- 13.4 Confidential information shall not be disclosed to unauthorised persons.
- 13.5 Disclosure may be made where:
 - a) authorized by the person entitled to the information;
 - b) required by law;
 - c) necessary for lawful regulatory action; or
 - d) otherwise permitted under applicable requirements.
- 13.6 Confidentiality requirements shall not prevent PPB from taking necessary public-health or regulatory action.

14.0 WHISTLEBLOWER PROTECTION

- 14.1 PPB shall protect persons who, in good faith, report:
- a) regulatory infractions;
 - b) public health or safety threats;
 - c) suspected illegal activities; or
 - d) other matters falling within PPB's regulatory mandate
- 14.2 A person who makes a complaint or report in good faith shall not be subjected to retaliation, discrimination or other adverse treatment because of the complaint or report.
- 14.3 The identity of a whistleblower shall be protected and disclosed only where:
- a) disclosure is authorised; or
 - b) disclosure is legally required.
- 14.4 The protection of identity shall be subject to the need to undertake an effective investigation and comply with applicable law

15.0 REVISION HISTORY

Revision No.	Date	Author	Section(s) Revised	Description of Change
1	31/07/2025	QAO	Glossary, 1.4, 4.0, 6.0, 7.0, 9.0, 10.0, Addenda 1–2	Added and updated definitions; strengthened complaint and appeal processes; introduced registers, confidentiality and whistleblower provisions; and updated related templates.
2	12/08/2026	QAO	Whole document, Addenda 2–3	Full revision: separated complaint and appeal pathways; clarified admissibility and grounds for appeal; introduced risk-based timelines and an Independent Appeal Review Team; strengthened procedural fairness, conflict-of-interest and recusal requirements; clarified the effect of appeals and stays; and strengthened further-redress, monitoring, CAPA, records management, public availability, implementation and review requirements.

16.0 ADDENDA

Addendum 1: Customer Complaints Handling Form

Pharmacy and Poisons Board	Customer Complaints Handling Form
Section I: To be filled by HQM	
Complaint Ref. No.	Date Received
Name of person making complaint:	Telephone number
Description of complaint:	
Nature of complaint: Product related..... Service related.....	
Has this matter been the subject of court proceedings?	
Is the matter in the public domain or of public interest?	
Classification of the complaint: Critical..... Major..... Minor.....	
Section 2: For minor complaints only	
Name of directorate/unit:	
Name of officer handling the complaint:	
Root cause determination:	

Description of actions taken:			
Feedback to complainant (Brief summary and date):			
Authorization of complaint resolution			
Name:	Title:	Signature:	Date:
Section 3: To be filled by the investigation team (major and critical)			
Names of Investigation Team			
Summary of Findings			
Recommendations			
Section 4: Complaint Resolution Committee			
Resolution by the complaints committee:			
Description of actions taken:			
Feedback to complainant (Brief summary and date)			
Attachments (if any)			

Authorization of complaint resolution			
Name:	Title:	Signature:	Date:

Addendum 2: Appeal Submission Checklist

To be completed by the Legal Services Department at admissibility screening.

Requirement	Yes / No	Comment
Appeal lodged within 14 days of notification, or within an approved extension		
Signed and dated appeal letter stating ground(s) of appeal		
Copy of initial decision notification or other evidence of notification		
Supporting information/documentation labelled to the ground(s) relied upon		
Full disclosure of information/documents to be relied upon		
Not a duplicate of a pending or determined appeal		
Within the Board's jurisdiction		
Not frivolous, vexatious or manifestly unfounded		
Third party notified, where applicable		
Admissibility Decision: ☐ Admissible ☐ Curable defect – appellant requested to remedy ☐ Inadmissible		
Reviewed by: Signature: _____ Date: _____		

ABBREVIATIONS	iv
GLOSSARY	v
ACKNOWLEDGEMENTS	viii
1.0 INTRODUCTION	1
1.1 Legal Framework	2
1.2 Scope	2
1.3 Objective of the Guideline	3
1.4 Guiding Principles	3
2.0 COMPLAINT AND APPEAL PATHWAYS.....	4
3.0 COMPLAINT MANAGEMENT.....	8
4.0 APPEALS AGAINST REGULATORY DECISIONS.....	13
5.0 INDEPENDENT APPEAL REVIEW TEAM	18
6.0 APPEAL REVIEW AND PROCEDURAL FAIRNESS.....	20
7.0 APPEAL DETERMINATION AND COMMUNICATION OF DECISION...	23
8.0 WITHDRAWING AN APPEAL APPLICATION	26
9.0 APPEALS REGISTER	27
10.0 MONITORING AND CONTINUOUS IMPROVEMENT.....	28
11.0 RECORDS MANAGEMENT.....	29
12.0 PUBLIC AVAILABILITY, IMPLEMENTATION AND REVIEW	30
13.0 CONFIDENTIALITY	31
14.0 WHISTLEBLOWER PROTECTION	32
15.0 REVISION HISTORY	33
16.0 ADDENDA.....	34
Addendum 1: Customer Complaints Report Form	34

Addendum 2: Appeal Submission Checklist	36
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ABBREVIATIONS

CAPA	Corrective and Preventive Action
CEO	Chief Executive Officer
COI	Conflict of Interest
HR	Human Resources
MoH	Ministry of Health
NMRA	National Medicines Regulatory Authority
PPB	Pharmacy and Poisons Board
PV	Pharmacovigilance
QMS	Quality Management Systems
TWG	Technical Working Group
WHO	World Health Organization

GLOSSARY

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

"Admissibility screening" means the preliminary review conducted by the Legal Services Department to confirm that an appeal is timely, complete, non-duplicative, within PPB's jurisdiction, and not frivolous or vexatious, before the appeal is referred to an Appeal Review Team.

"Appeal" is a formal written request for a review or reconsideration of a regulatory decision made by the Board and/or the outcome of an application. In this context, "appeal" and "review" are used interchangeably.

"Appeal Review Team" means an independent team of senior subject matter experts appointed, in relation to a specific appeal, by the Head(s) of Department(s) relevant to the subject matter of the appeal, none of whom was involved in making the initial regulatory decision under appeal, constituted to hear and determine appeals lodged against regulatory decisions of the Board.

"Board" means the Pharmacy and Poisons Board.

"CAPA" means Corrective and Preventive Action taken to eliminate the cause of a detected nonconformity or other undesirable situation and to prevent recurrence.

"Common Appeals Register" means a centralized official record maintained and domiciled in the Legal Services Department for documenting, tracking and monitoring all formal appeals submitted against regulatory decisions.

"Complaint" means an expression of dissatisfaction regarding the conduct, service delivery, or regulatory functions of the Board, or concerning 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 formal complaint with the Board.

"Complaints Register" means an official log maintained by the Board for the systematic recording and monitoring of all complaints received from stakeholders regarding regulated products, services, or personnel.

"Conflict of Interest" means any situation in which an officer's personal, professional or financial interest, or prior involvement in a matter, could improperly influence, or reasonably be perceived to influence, that officer's objectivity in handling a complaint or determining an appeal.

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

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

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

"Non-service-related complaints" are complaints relating to suspected defective Board-regulated products or regulatory infractions, including unregistered products; substandard or falsified products; expired products; and illegal importation, exportation, manufacturing, distribution, sale and use of Board-regulated products.

"Service-related complaints" are complaints relating to dissatisfaction with services provided by the Board, including mistakes that could result in

misunderstanding or omission; undue delays or inaction; Board officer conduct; poor or misleading information; and other service-related issues.

"Staff-conduct complaints" are complaints concerning the personal conduct, integrity or behaviour of a Board officer, which shall be routed to Human Resources and, where indicated, Legal Services or the Board's integrity function.

"Stay of a decision" means the suspension of the operation or enforcement of a regulatory decision pending determination of an appeal, granted only in the exceptional circumstances described in Section 9 of this Guideline.

Suspected or confirmed product defects and complaints are classified into three categories according to the risk posed to the public and/or consumers:

Critical: Potentially life-threatening or posing a serious risk to consumers, including patient or animal health.

Major: Could cause illness or mistreatment but is not critical.

Minor: Unlikely to pose a risk to consumers, including patient or animal health.

ACKNOWLEDGEMENTS

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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 mandates PPB to regulate medicines, medical devices, health technologies and the pharmacy profession.

In carrying out its regulatory mandate, complaints may arise concerning regulated products, services, regulatory processes or staff conduct. Persons affected by regulatory decisions may also seek review or reconsideration of such decisions.

This Guideline establishes a transparent, accessible, fair and risk-based framework for receiving, assessing, investigating and resolving complaints and appeals.

The Guideline distinguishes between complaints and appeals and establishes separate pathways to ensure that each matter is directed to the appropriate responsible office and handled within a timeframe proportionate to its risk and nature.

The Guideline provides information on the requirements for lodging complaints concerning medicines, medical devices and other regulated products, PPB services, regulatory processes and staff conduct. It also provides a mechanism for persons aggrieved by regulatory decisions of the Board to seek review or reconsideration.

Any person aggrieved by a regulatory decision of the Board has the right to appeal against that decision in accordance with this Guideline and applicable law.

The public and stakeholders are encouraged to provide feedback concerning PPB's regulatory functions and report suspected defects, unsafe or illegal activities involving regulated products.

1.1 Legal Framework

The Constitution of Kenya, under Article 47, provides for the right to administrative action that is expeditious, efficient, lawful, reasonable and procedurally fair.

Article 50 provides for fair and public hearing before an independent and impartial body in disputes capable of being resolved through application of law.

The Fair Administrative Action Act, 2015, gives effect to Article 47 and requires administrative bodies, including the PPB, to provide reasons for their decisions, accord affected persons a reasonable opportunity to be heard, and ensure that administrative action is not taken by a person with a personal interest in the matter.

The Board is empowered under the Pharmacy and Poisons Act to institute administrative proceedings.

Complaint and appeal processes shall therefore be conducted in a manner that is fair, expeditious, reasonable, lawful and procedurally sound.

This Guideline shall be implemented consistently with the Constitution, the Pharmacy and Poisons Act, the Fair Administrative Action Act, the Data Protection Act and other applicable laws.

1.2 Scope

This Guideline applies to:

- a) complaints concerning the quality, safety and/or efficacy/effectiveness of medicines, medical devices and other regulated products;

- b) complaints concerning advertising and other regulatory activities within PPB's mandate;
- c) complaints concerning PPB services and regulatory processes;
- d) complaints concerning staff conduct;
- e) complaints concerning regulatory irregularities; and
- f) appeals against PPB regulatory decisions.

Adverse drug reaction complaints arising from use of a medicine are excluded from the complaint pathway and shall be reported to the Pharmacovigilance Unit and managed in accordance with applicable pharmacovigilance procedures.

This Guideline establishes distinct pathways for receiving, triaging, investigating and resolving complaints and appeals.

1.3 Objective of the Guideline

The objectives of this Guideline are to:

- a) recognize and protect the right of a person to lodge a complaint within the limits of applicable law;
- b) publicize the existence of PPB complaint and appeal mechanisms;
- c) provide uniform, effective and risk-proportionate procedures for handling complaints and appeals;
- d) establish distinct pathways for product-quality and safety complaints, service complaints, staff-conduct complaints and appeals against regulatory decisions;
- e) ensure that appeals are reviewed independently and fairly;
- f) ensure that complainants and appellants are treated fairly and without discrimination or retaliation;
- g) ensure appropriate communication of decisions and outcomes; and
- h) support monitoring, trend analysis, CAPA and continuous improvement

1.4 Guiding Principles

The implementation of this Guideline shall be guided by:

- a) legality and adherence to due process;
- b) objectivity and impartiality;
- c) diversity, equity, non-discrimination and inclusivity;
- d) confidentiality and data protection;
- e) natural justice;
- f) independence and procedural fairness in appeal determination;
- g) risk-proportionate timeliness;
- h) fairness and accountability; and
- i) alignment with applicable regional and international obligations.

2.0 COMPLAINT AND APPEAL PATHWAYS

2.1 Complaints and appeals are distinct processes and shall not be handled through the same workflow. The following categories shall be routed as indicated below:

Category	Nature	Responsible office	Pathway
Product-quality/safety complaint	Concern's identity, quality, safety, efficacy/effectiveness, handling, storage, manufacture or illegal handling of regulated products	Post-Market Surveillance or relevant technical function	Section 3.0
Adverse reaction	Suspected adverse reaction arising from use of a medicine	Pharmacovigilance Unit	Applicable PV procedure
Service complaint	Dissatisfaction with service delivery, delays, officer behavior in a service context or misleading information	Responsible technical/administrative function, with QMS involvement where appropriate	Section 3.0
Staff-conduct complaint	Personal conduct, integrity or behavior of a Board officer	HR, with Legal Services or integrity function where appropriate	Section 3.0 and applicable HR procedures
Appeal	Formal request to review or reconsider a specific PPB regulatory decision	Appeals Review Team	Sections 4.0–7.0

2.1.1 Where a matter contains elements of more than one category, the receiving office shall:

- a) record the matter once;
- b) notify all relevant responsible offices;
- c) designate a lead office to coordinate the response; and
- d) ensure that actions are coordinated to prevent duplication or conflicting outcomes.

2.1.2 Where dissatisfaction with a complaint outcome concerns a regulatory decision, the person may pursue the matter through the appeal process under Section 4.0.

2.2 **Regulatory Decisions Subject to Appeal**

2.2.1 A person aggrieved by a specific regulatory decision made by the Pharmacy and Poisons Board may lodge an appeal in accordance with Section 4.0 of this Guideline and applicable law.

2.2.2 For purposes of this Guideline, regulatory decisions that may be subject to appeal include, as applicable and subject to the governing legislation and regulatory framework:

- a) decisions relating to the registration, licensing, authorization, renewal, variation, suspension, revocation or cancellation of regulated products, premises, persons or activities;
- b) decisions arising from inspection, audit or compliance assessment activities, including regulatory decisions made following inspection findings;
- c) decisions relating to Good Manufacturing Practice, Good Distribution Practice, Good Clinical Practice or other applicable regulatory compliance requirements;
- d) decisions relating to clinical trials and other regulated research activities;
- e) decisions relating to pharmacovigilance or other post-market regulatory measures, where the applicable legal framework provides for an appeal;
- f) decisions relating to advertising, promotion or other regulatory communications;

- g) decisions relating to importation, exportation, quarantine, market withdrawal, recall or other enforcement or public-health protective measures, where appealable under applicable law;
- h) decisions relating to applications submitted to the Board where the applicant is aggrieved by the regulatory outcome; and
- i) any other regulatory decision for which an internal appeal or review mechanism is provided under applicable law or PPB requirements.

2.2.3 The availability of an appeal shall be determined with reference to the applicable statutory and regulatory framework governing the decision. Where a specific statutory appeal or review mechanism applies, that mechanism shall take precedence.

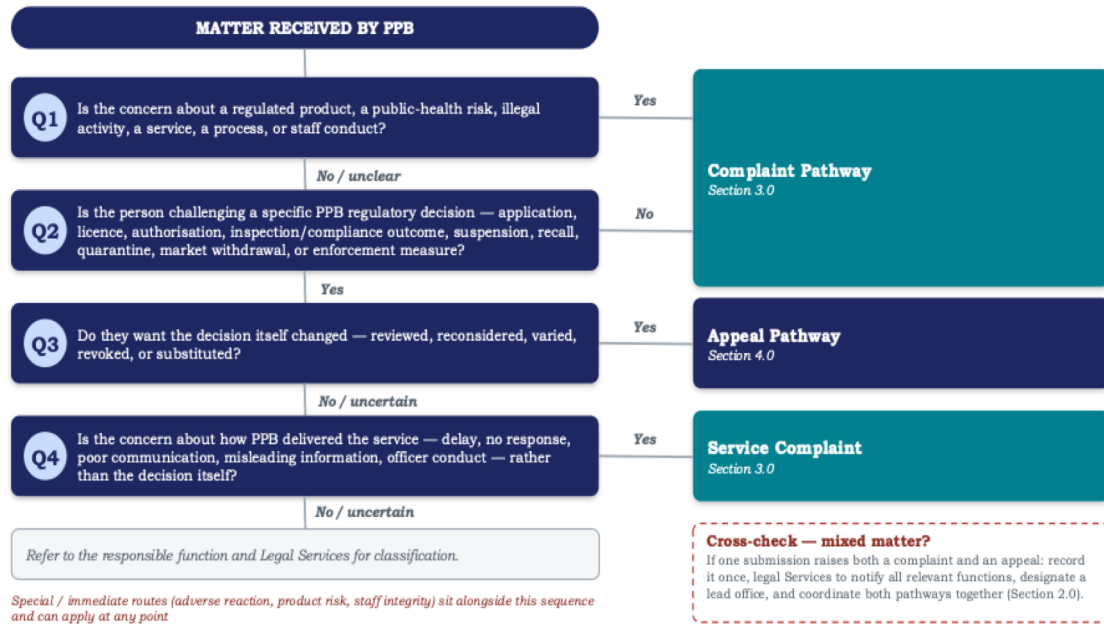
2.2.4 A complaint concerning the manner in which a regulatory service was provided shall not, by itself, constitute an appeal against the underlying regulatory decision. Where the substance of the matter challenges the legality, factual basis, procedural fairness, proportionality or other merits of a specific regulatory decision, the matter shall be directed to the appeal pathway.

2.2.5 Where a matter contains both a service complaint and a challenge to a regulatory decision, the matter shall be managed through coordinated complaint and appeal pathways in accordance with Section 2.0, without requiring the complainant or appellant to submit the same information repeatedly.

Decision Tree Regulatory Complaint and Appeal Routing Process

Complaint & Appeal Intake Classification Tree

Routes each matter to the correct process at first receipt. This tool classifies the matter — it is not a determination of the merits.



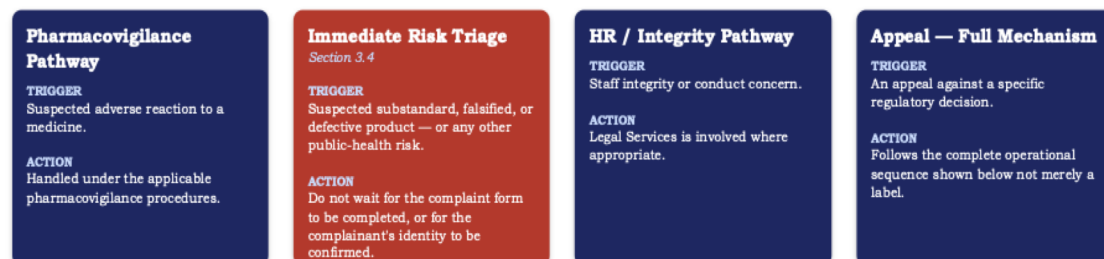
Appeal Pathway — full operational sequence (Section 4.0)



An appeal is not merely a label: it is this complete mechanism, from receipt through to communication of the outcome.

Special Routing & the Appeal Mechanism

These routes apply immediately, wherever public health or integrity is at stake.



Legend: ■ Navy — classification question / standard pathway ■ Teal — standard complaint-track outcome ■ Terracotta — urgent, act immediately

3.0 COMPLAINT MANAGEMENT

3.1 Submission Channels

3.1.1 A complaint may be lodged with PPB through:

- a) a letter;
- b) email;
- c) telephone;
- d) SMS;
- e) the Board's official online complaints platform;
- f) approved social media channels; or
- g) in person.

3.1.2 Complaints may be submitted orally or anonymously.

3.1.3 PPB shall accept and act on oral and anonymous complaints on the same basis as written and identified complaints, subject to limitations in obtaining additional information or communicating with an anonymous complainant.

3.2 Written Complaints

3.2.1 Where a complainant is able to provide a written complaint, the complainant should complete the prescribed complaint form to facilitate thorough investigation and record-keeping.

3.2.2 A completed complaint form shall, however, **not be a precondition for PPB to commence handling a complaint.**

3.2.3 Complaints may be submitted to:

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

OR

through the Board's approved online complaints platform:

<https://ppb.go.ke/complaint>

3.3 **Receipt and Registration**

3.3.1 Upon receipt of a complaint, the responsible complaints officer shall:

- a) record the date and mode of receipt;
- b) stamp the complaint form where a form is available;
- c) assign a unique sequential reference number;
- d) enter the complaint in the relevant Complaints Register;
- e) classify the complaint by category and severity;
- f) identify the responsible office; and
- g) initiate the applicable complaint-handling process.

3.3.2 The absence of a completed complaint form shall not prevent registration, triage or urgent action.

3.4 **Oral, Anonymous or Incomplete Complaints**

3.4.1 Where an oral, anonymous or incomplete complaint indicates a critical quality or safety defect or an urgent public health risk, PPB shall immediately triage the complaint.

3.4.2 Where warranted, PPB may take interim protective measures, including:

- a) public or stakeholder alerts;
- b) quarantine;
- c) inspection;
- d) product sampling or testing;
- e) market withdrawal or recall; or
- f) referral to another competent authority.

3.4.3 Such action shall not be delayed while awaiting completion of the complaint form or confirmation of the complainant's identity.

3.4.4 Where feasible, additional information shall be obtained in parallel for investigation and record-keeping.

3.5 **Protection of Complainants**

3.5.1 Complaint submission, investigation and resolution shall not result in discriminatory or retaliatory action against a complainant.

3.5.2 Complaints shall be handled fairly, including complaints submitted anonymously or in good faith.

3.6 **Complaint Assessment and Investigation**

3.6.1 The responsible function shall conduct an initial assessment of the substance and risk of the complaint.

3.6.2 The complaint shall first be classified according to severity and thereafter investigated in proportion to the identified risk.

3.6.3 The responsible function shall:

- a) assess the information and evidence available;
- b) determine the appropriate investigation;
- c) identify whether immediate regulatory or protective action is required;
- d) undertake the investigation;
- e) document findings;
- f) determine appropriate corrective, preventive or regulatory action; and
- g) provide feedback to the complainant where appropriate.

3.6.4 PPB shall maintain appropriate records of all actions taken.

3.7 **Risk Classification and Timelines**

3.7.1 Every complaint shall be classified as **critical, major or minor** using the definitions in the Glossary.

3.7.2 The classification shall determine the applicable response and investigation timeline.

Stage	Critical	Major	Minor
Triage / initial risk classification	Within 1 working day of receipt	Within 2 working days	Within 5 working days
Acknowledgement	Within 2 working days	Within 5 working days	Within 10 working days
Interim protective action, where warranted	Immediately upon identification of risk	As warranted without undue delay	Not ordinarily applicable
Escalation to Head of Department	Within 2 working days of triage	Within 5 working days of triage	Within 10 working days, where warranted
Investigation completed	Within 15 working days	Within 30 working days	Within 45 working days
Feedback to complainant	Within 5 working days of conclusion	Within 10 working days of conclusion	Within 15 working days of conclusion

Closure and register update	Within 5 working days of feedback	Within 10 working days	Within 15 working days
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3.7.3 The investigation period for complex critical complaints may be extended where justified.

3.7.4 Where a stage cannot be completed within the prescribed timeline, the responsible officer shall:

- a) document the reason for the delay;
- b) establish a revised target date;
- c) notify the Head of Department; and
- d) for critical complaints, notify the Head of QMS

3.8 **Investigation Outcome and Feedback**

3.8.1 Feedback on the outcome shall be based on the nature of the complaint, the information provided and the extent to which disclosure is appropriate.

3.8.2 Feedback shall include, where appropriate:

- a) a summary of the findings;
- b) actions taken or proposed;
- c) any relevant corrective or regulatory action; and
- d) information on available further avenues of redress.

3.8.3 Information shall not be disclosed where doing so would breach confidentiality, data protection, legal privilege or other applicable restrictions.

3.9 **Complaints Register**

3.9.1 PPB shall maintain Complaints Registers within relevant departments for recording, monitoring and tracking complaints relating to regulated products, services and staff conduct.

3.9.2 Each complaint shall have a unique reference number.

3.9.3 The Register shall include, as applicable:

- a) date of receipt;
- b) complaint category;
- c) severity classification;
- d) complainant details, where known;

- e) responsible department;
- f) actions taken;
- g) applicable timeline;
- h) outcome; and
- i) resolution/closure date.

3.9.4 Access to Complaints Registers shall be restricted to authorized officers and managed in accordance with applicable data protection and records management requirements.

4.0 APPEALS AGAINST REGULATORY DECISIONS

4.1 Right of Appeal and Timeframe

4.1.1 A person aggrieved by a regulatory decision of PPB may formally request, in writing, that the Board review or reconsider the decision, subject to applicable law.

4.1.2 An appeal may be lodged through any approved PPB appeal submission channel made in writing, and addressed to:

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

4.1.3 This may include:

- a) physical submission to the Board;
- b) official PPB email or electronic submission platform; or
- c) submission through an authorized representative.

4.1.4 The current approved appeal submission channels shall be published on the PPB official website and communicated in relevant regulatory decision notifications.

4.1.5 An appeal shall ordinarily be lodged within fourteen (14) calendar days from the date on which the appellant is notified of the regulatory decision.

4.1.6 The date of receipt of an appeal shall be determined by the date the appeal is received through an approved PPB submission channel. Where an appeal is submitted electronically, the date and time recorded by the PPB electronic system shall constitute the date and time of receipt, subject to verification where necessary.

4.1.7 The CEO may, on written request stating justified reasons, extend the period by up to thirty (30) additional calendar days.

4.1.8 Justified reasons may include:

- a) delayed or defective notification of the decision;
- b) circumstances beyond the reasonable control of the appellant;
- c) medical or other exceptional circumstances; or
- d) other circumstances constituting good cause.

4.1.9 A request for extension should ordinarily be submitted before expiry of the initial fourteen (14) day period. A request submitted after expiry may be considered where the delay is satisfactorily explained.

4.1.10 The notification of a regulatory decision shall, where applicable, inform the affected person of:

- a) the decision made;
- b) the principal reasons for the decision;
- c) the right to appeal or seek review;
- d) the applicable time limit;
- e) the approved channel for lodging an appeal; and
- f) the effect, if any, of lodging an appeal on the regulatory decision.

4.1.11 Legal Basis for Appeal

- a) Where a regulatory decision is subject to a specific statutory or regulatory appeal or review mechanism, the applicable statutory or regulatory provisions shall be identified in the decision notification and, where appropriate, in the appeal acknowledgment.
- b) Where no specific statutory appeal mechanism is prescribed, an internal review or reconsideration may be undertaken in accordance with this Guideline to the extent permitted by applicable law.
- c) Nothing in this Guideline shall be construed as limiting or replacing any right of appeal, review, complaint or other redress available to an affected person under the Constitution, written law or applicable regulatory framework.

4.2 **Grounds of Appeal**

4.2.1 An appeal may be based on one or more of the following grounds:

- a) factual error in the decision;
- b) error of law;
- c) procedural unfairness or breach of natural justice;
- d) failure to consider relevant evidence or reliance on irrelevant considerations;
- e) disproportionality of the decision or sanction relative to the conduct or risk;
- f) inconsistency with PPB decisions in comparable matters;
- g) new information or evidence that was not available when the original decision was made; or
- h) any other relevant ground raised by the appellant.

4.2.2 The availability of new information shall not be a precondition for lodging an appeal.

4.3 **Contents of an Appeal Submission**

4.3.1 An appeal submission shall include:

- a) a dated and signed appeal letter identifying the decision and stating the ground or grounds of appeal;
- b) a copy of the initial decision notification or other evidence of notification;
- c) information and documentation supporting the appeal, clearly linked to the relevant ground or grounds; and
- d) full disclosure of information and documents that the appellant intends to rely upon.

4.3.2 Additional information not disclosed at submission may be admitted where the Appeal Review Team considers that there is sufficient justification for doing so.

4.4 **Admissibility Screening**

4.4.1 Every appeal shall undergo admissibility screening before substantive review.

4.4.2 Legal Services shall, within at least five (5) working days of receipt, determine whether the appeal:

- a) was lodged within the prescribed 14-day period or an approved extension;
- b) contains the required information;
- c) is not a duplicate of a pending or previously determined appeal concerning the same decision;
- d) falls within PPB's jurisdiction; and
- e) is not frivolous, vexatious or manifestly unfounded on its face.

4.5 Defective or Inadmissible Appeals

- 4.5.1 Where an appeal has a curable defect, such as incomplete information, the appellant may be notified in writing, provided with reasons and given ten (10) working days to remedy the defect and resubmit.
- 4.5.2 Where an appeal is inadmissible on a non-curable ground, including being out of time without an approved extension or falling outside PPB jurisdiction, the appellant shall be notified in writing and provided with reasons.
- 4.5.3 The notification shall identify any further options for redress available under applicable law.

4.6 Referral for Review

- 4.6.1 An admissible appeal shall be referred to the responsible technical function for relevant technical input and acknowledgement, with Legal Services providing necessary legal support.
- 4.6.2 The appeal shall then proceed to the constitution of an Independent Appeal Review Team in accordance with Section 5.0.
- 4.6.3 The Appeal Review Team shall maintain appropriate communication with the appellant throughout the appeal process. The appellant shall be informed, as applicable, of:
 - a) receipt and registration of the appeal;
 - b) the admissibility outcome;
 - c) any curable deficiency requiring action by the appellant;

- d) constitution of the Appeal Review Team, subject to applicable confidentiality and conflict-of-interest requirements;
- e) any additional information or evidence required;
- f) the expected date of determination; and
- g) any material delay and the revised target date.

4.6.4 The appellant shall not be required to make repeated requests for information that PPB is required to communicate under this Guideline.

4.7 **Third-Party Appeals**

4.7.1 Where an appeal is lodged by a person who was not the direct recipient of the regulatory decision, PPB shall first determine whether the appellant has a sufficient legal or legitimate interest in the decision to warrant consideration of the appeal.

4.7.2 Where the appeal is accepted for consideration and another person or entity is directly affected by the decision, PPB shall, where appropriate and subject to applicable confidentiality and data protection requirements, notify the directly affected person or entity.

4.7.3 A directly affected person or entity shall be afforded a reasonable opportunity to make representations where the appeal may adversely affect its rights, interests or regulatory status.

4.7.4 Confidential, proprietary or commercially sensitive information shall be handled in accordance with applicable law and PPB confidentiality and data protection requirements.

4.7.5 The Appeal Review Team shall take appropriate measures to ensure that the determination is based only on information properly considered in accordance with applicable law and procedural fairness requirements.

5.0 INDEPENDENT APPEAL REVIEW TEAM

5.1 Constitution

5.1.1 Each admissible appeal shall be heard and determined by an Independent Appeal Review Team.

5.1.2 The Team shall be constituted specifically for the appeal and shall be independent of the function that made the original regulatory decision.

5.2 Appointment and Composition

5.2.1 The Appeal Review Team shall be appointed by the Head(s) of Department relevant to the subject matter of the appeal.

5.2.2 The Team shall comprise a minimum of three (3) senior subject-matter experts with necessary expertise to determine the appeal.

5.2.3 A chairperson shall be designated from among the appointed members.

5.3 Independence

5.3.1 A person shall not be appointed to or sit on the Appeal Review Team where the person:

- a) participated in making the original regulatory decision;
- b) recommended the original decision;
- c) reviewed or approved the original decision;
- d) has a conflict of interest in the matter; or
- e) is otherwise subject to a reporting or other relationship that compromises independence in relation to the matter under appeal.

5.3.2 The Team shall operate independently of the division or department whose decision is under appeal.

5.3.3 The Team shall not be subject to direction, control or influence from the original decision-maker in relation to its determination.

5.4 External Expertise

5.4.1 Where the responsible department lacks sufficient independent in-house expertise, the Head of Department may co-opt an

independent external subject-matter expert from another PPB Department.

- 5.4.2 An expert shall meet the applicable competence, independence and conflict-of-interest requirements in accordance with PPB requirements.

6.0 APPEAL REVIEW AND PROCEDURAL FAIRNESS

6.1 General Requirements

6.1.1 Appeal review shall comply with Articles 47 and 50 of the Constitution, the Fair Administrative Action Act and other applicable law.

6.1.2 The Appeal Review Team shall ensure that the appellant is afforded a fair opportunity to present and respond to the case.

6.2 Written and Oral Representations

6.2.1 The appellant shall be afforded a reasonable opportunity to make written representations.

6.2.2 Where requested by the appellant or considered necessary by the Appeal Review Team, the appellant may be given an oral hearing before determination.

6.2.3 Subject to legitimate confidentiality restrictions, including third-party commercial confidentiality and statutory restrictions on disclosure, the appellant shall be given access to material relevant to the decision under appeal and material the Appeal Review Team proposes to rely upon.

6.3 Response to Adverse Information

6.3.1 Where the Appeal Review Team intends to rely on information adverse to the appellant that was not previously provided to the appellant, the appellant shall be given:

- a) the information; and
- b) a reasonable opportunity to review and respond to it.

6.3.2 The appeal shall not be determined until the appellant has been given a reasonable opportunity to respond.

6.4 Impartiality

6.4.1 No member of the Appeal Review Team shall participate in determining a matter in which the member has an interest.

6.4.2 The principles of natural justice, including the rule that no person shall be a judge in their own cause, shall apply.

6.5 Effect of Lodging an Appeal

6.5.1 Lodging an appeal shall not, by itself, suspend, stay or otherwise affect the validity, force or enforceability of the regulatory decision under appeal.

6.5.2 This applies particularly to decisions involving:

- a) suspension;
- b) recall;
- c) quarantine;
- d) market withdrawal; or
- e) other measures intended to protect public health.

6.5.3 Such decisions shall ordinarily remain in force pending determination of the appeal.

6.6 Stay of a Regulatory Decision

6.6.1 The CEO may, upon the appellant's written request and on Legal Services' advice, grant a stay of the decision under appeal.

6.6.2 A stay shall only be granted in exceptional circumstances and where the CEO is satisfied that the stay will not compromise:

- a) public health;
- b) patient or consumer safety; or
- c) the integrity of the regulatory system.

6.6.3 A stay may be subject to conditions and may be revoked if those conditions are no longer met.

6.6.4 The notification of a regulatory decision and the acknowledgment of an appeal shall state that the decision remains in effect pending determination of the appeal unless a stay is granted.

6.7 Risk-Based Appeal Timelines

6.7.1 Appeals involving critical or public-health-sensitive decisions shall be expedited.

6.7.2 These may include appeals concerning:

- a) suspensions;
- b) recalls;
- c) quarantine orders; or
- d) matters presenting an immediate risk to patient or consumer safety.

6.7.3 All other appeals shall follow the standard timeline.

6.7.4 The timelines below shall run from the date PPB receives the appeal.

Stage	Critical / Public-Health-Sensitive	Standard
Admissibility screening	At least 2 working days	At least 5 working days
Decision communicated to appellant	Within 30 calendar days of receipt	Within 90 calendar days of receipt

6.7.5 Where any stage cannot be completed within the prescribed timeline, the chairperson shall document:

- a) the reason for the delay; and
- b) the revised target date.

6.7.6 The Appeals Review Team shall communicate the revised timeline to the appellant in writing.

7.0 APPEAL DETERMINATION AND COMMUNICATION OF DECISION

7.1 Appeal Determination

7.1.1 The Appeal Review Team shall consider the appeal, the representations made by the appellant, the evidence before it and the applicable legal and regulatory requirements and shall make a determination in accordance with this Guideline.

7.1.2 The determination shall be made independently and shall not be subject to direction or influence by the officer or function responsible for the original regulatory decision.

7.1.3 The Appeal Review Team may determine that the original regulatory decision should be:

- a) confirmed;
- b) revoked;
- c) varied; or
- d) substituted with another decision, where permitted by applicable law and within the regulatory authority of PPB.

7.1.4 Where the Appeal Review Team is authorized by law to make the final determination, its determination shall constitute the final internal PPB determination.

7.1.5 Where applicable law requires the determination to be made or formally approved by another statutory decision-maker, the Appeal Review Team shall submit its determination or recommendation to that decision-maker in accordance with the applicable legal framework.

7.1.6 No person who participated in making, recommending, reviewing or approving the original regulatory decision shall participate in the substantive determination of the appeal.

7.1.7 The final appeal decision shall be supported by documented reasons, including the material facts, evidence and legal or regulatory considerations relied upon.

7.2 Appeal Outcomes

7.2.1 Following review, the Appeal Review Team may recommend:

- a) confirmation of the original regulatory decision;
- b) revocation of the regulatory decision; or
- c) variation or substitution of the regulatory decision.

7.2.2 Where the Appeal Review Team recommends that the regulatory decision be upheld, the original decision shall remain unchanged.

7.2.3 The Team may reach the same conclusion as the original decision for different reasons or based on additional evidence available during the appeal.

7.2.4 Where the Appeal Review Team recommends overturning the regulatory decision, the decision shall be revoked in accordance with the applicable legal and regulatory framework.

7.2.5 Where the Appeal Review Team recommends varying all or part of the regulatory decision, the decision may be replaced in whole or in part by a new decision. This may occur when the Team considers the original decision to have been partially or entirely incorrect, or when additional information received during review justifies a variation.

7.3 **Communication of Decision**

7.3.1 Following conclusion of the appeal review, PPB, through the CEO, shall communicate the decision in writing within the applicable timeline under Section 6.7.

7.3.2 The communication shall include:

- a) the outcome of the appeal;
- b) the reasons for the determination, including relevant findings and evidence; and
- c) any consequential regulatory action.

7.3.3 Where the original decision was required to be published on the PPB website, and the appeal results in revocation, variation or substitution of that decision, the particulars of the current decision shall be published in accordance with applicable PPB requirements.

7.3.4 The written decision on the appeal shall state whether the internal appeal process is final. Where further redress is available, the communication shall identify applicable options, which may include:

- a) a sector tribunal established under applicable law;
- b) a complaint to the Commission on Administrative Justice;
and/or
- c) judicial review before the High Court.

7.3.5 The communication shall provide applicable timelines for pursuing further redress where known.

8.0 WITHDRAWING AN APPEAL APPLICATION

- 8.1 An appellant may withdraw an appeal at any time before the Appeal Review Team issues its determination.
- 8.2 Withdrawal shall be made in writing to the CEO.
- 8.3 Where withdrawal is received within ten (10) working days of submission and before constitution of the Appeal Review Team, Legal Services shall record the withdrawal and close the appeal file.
- 8.4 Where an appeal is withdrawn after constitution of the Appeal Review Team, Legal Services shall:
 - a) record the withdrawal;
 - b) notify the Team; and
 - c) close the appeal file without issuing a determination.
- 8.5 Withdrawal of an appeal shall not affect the validity or enforceability of the underlying regulatory decision.
- 8.6 The decision shall continue in force unless otherwise varied, suspended or revoked through an authorized process.
- 8.7 Legal Services shall retain records of all engagements relating to a withdrawn appeal in accordance with Section 11.0.

9.0 APPEALS REGISTER

- 9.1 PPB shall maintain an official **Common Appeals Register** as the central repository for recording, tracking and auditing all formal appeals received.
- 9.2 The Register shall be maintained by Legal Services
- 9.3 The Common Appeals Register shall contain, at minimum:
- a) unique appeal reference number;
 - b) date of lodgment;
 - c) name of appellant;
 - d) subject matter;
 - e) department whose decision is under appeal;
 - f) members appointed to the Appeal Review Team;
 - g) regulatory decision under review;
 - h) outcome of the appeal; and
 - i) resolution/closure date.
- 9.4 Access to the Common Appeals Register shall be restricted to authorized officers.
- 9.5 Data security and confidentiality shall be maintained in accordance with applicable legal and PPB requirements.

10.0 MONITORING AND CONTINUOUS IMPROVEMENT

- 10.1 The Quality Management Systems (QMS) office shall analyze complaint and appeal data at least quarterly to identify:
 - a) recurring issues;
 - b) common root causes;
 - c) trends by product, service, department or decision type;
 - d) timeliness and overdue matters; and
 - e) opportunities for improvement.
- 10.2 Recurring or significant root causes identified through complaints, appeals or trend analysis shall be addressed through CAPA.
- 10.3 CAPA shall be tracked to completion in accordance with the applicable PPB procedure.
- 10.4 Complaint and appeal performance shall be a standing agenda item at management review meetings at least twice annually.
- 10.5 Performance information shall include, where applicable:
 - a) number and type of complaints and appeals;
 - b) timeliness;
 - c) overdue matters;
 - d) trends and root causes;
 - e) CAPA status; and
 - f) effectiveness of corrective actions.
- 10.6 PPB shall, at least annually, evaluate the effectiveness of its complaint and appeal processes.
- 10.7 Where feasible, feedback shall be obtained from complainants and appellants regarding their experience of the process.

11.0 RECORDS MANAGEMENT

11.1 Complaint and appeal records shall include, as applicable:

- a) complaints and appeal submissions;
- b) correspondence;
- c) evidence and supporting documentation;
- d) investigation records;
- e) Complaints Registers;
- f) Common Appeals Register entries;
- g) appointment letters;
- h) conflict-of-interest declarations;
- i) Appeal Review Team minutes; and
- j) final decisions and communications

11.2 Complaints and appeals records shall be retained for a minimum of seven (7) years from closure of the matter.

11.3 A longer retention period shall apply where required by:

- a) applicable law; or
- b) the PPB records retention schedule.

11.4 All entries and amendments to complaints and appeals registers, whether paper-based or electronic, shall be traceable to:

- a) the officer making the entry;
- b) date and time;
- c) nature of the entry or amendment; and
- d) original information where an amendment is made.

11.5 The record system shall preserve the integrity of the original entry.

11.6 Access to complaint and appeal records shall be restricted to authorized officers on a need-to-know basis.

11.7 Electronic systems shall use appropriate role-based access controls and physical files shall be securely maintained.

11.8 These shall form part of the appeal case file and shall be securely maintained

12.0 PUBLIC AVAILABILITY, IMPLEMENTATION AND REVIEW

- 12.1 The current approved version of this Guideline shall be published on the PPB official website, along with the approved complaint and appeal submission channels.
- 12.2 Evidence of publication shall be retained in accordance with PPB document-control requirements.
- 12.3 This Guideline shall be formally reviewed at least once every five (5) years from the date of authorization. In addition, a review shall be triggered, ahead of the scheduled cycle, by any of the following:
 - a) a change in the Constitution, Pharmacy and Poisons Act, Fair Administrative Action Act, Data Protection Act or other applicable law;
 - b) a WHO or peer-NMRA benchmarking, assessment or audit finding indicating the need for revision;
 - c) significant nonconformities, recurring root causes or CAPA findings identified through monitoring;
 - d) significant changes to PPB's complaint or appeal processes; or
 - e) a directive from the CEO or Board
- 12.4 Legal Services, in collaboration with QMS, shall coordinate the review of this Guideline. The Head of QMS shall coordinate the review process.
- 12.5 The revised Guideline shall be approved by the CEO before implementation and publication.

13.0 CONFIDENTIALITY

- 13.1 All information relating to complaints and appeals shall be handled confidentially and used only for legitimate regulatory, administrative, quality or legal purposes.
- 13.2 Information shall be managed in accordance with the Data Protection Act and applicable ethical and PPB requirements.
- 13.3 Access to complaint and appeal information shall be limited to officers who require the information to perform their authorised duties.
- 13.4 Confidential information shall not be disclosed to unauthorised persons.
- 13.5 Disclosure may be made where:
 - a) authorized by the person entitled to the information;
 - b) required by law;
 - c) necessary for lawful regulatory action; or
 - d) otherwise permitted under applicable requirements.
- 13.6 Confidentiality requirements shall not prevent PPB from taking necessary public-health or regulatory action.

14.0 WHISTLEBLOWER PROTECTION

- 14.1 PPB shall protect persons who, in good faith, report:
- a) regulatory infractions;
 - b) public health or safety threats;
 - c) suspected illegal activities; or
 - d) other matters falling within PPB's regulatory mandate
- 14.2 A person who makes a complaint or report in good faith shall not be subjected to retaliation, discrimination or other adverse treatment because of the complaint or report.
- 14.3 The identity of a whistleblower shall be protected and disclosed only where:
- a) disclosure is authorised; or
 - b) disclosure is legally required.
- 14.4 The protection of identity shall be subject to the need to undertake an effective investigation and comply with applicable law

15.0 REVISION HISTORY

Revision No.	Date	Author	Section(s) Revised	Description of Change
1	31/07/2025	QAO	Glossary, 1.4, 4.0, 6.0, 7.0, 9.0, 10.0, Addenda 1–2	Added and updated definitions; strengthened complaint and appeal processes; introduced registers, confidentiality and whistleblower provisions; and updated related templates.
2	12/08/2026	QAO	Whole document, Addenda 2–3	Full revision: separated complaint and appeal pathways; clarified admissibility and grounds for appeal; introduced risk-based timelines and an Independent Appeal Review Team; strengthened procedural fairness, conflict-of-interest and recusal requirements; clarified the effect of appeals and stays; and strengthened further-redress, monitoring, CAPA, records management, public availability, implementation and review requirements.

Addendum 1: Customer Complaints Report Form

Pharmacy and Poisons Board	
Customer Complaints Report Form	
<i>The CEO/Registrar, Pharmacy and Poisons Board, P.O. Box 27663-00506, Email Address: complaints@ppb.go.ke, Tel. +254 709770100</i>	
A. COMPLAINANT DETAILS	
Title: ☐ Mr. ☐ Mrs. ☐ Ms. ☐ Dr. ☐ Other: _____	Full Name: _____
National ID No.* ☐ _____ Passport No.* ☐ _____	Telephone No.: _____ _____
Email Address: _____	
B. ADDRESS OF COMPLAINANT	
Address of complainant	
Physical Address	
House/Building: _____ Street/Road: _____	
Town: _____ County: _____	
Postal Address: _____	
C. DESCRIPTION OF COMPLAINT	
Description of Complaint*	
Supporting documents/evidence attached:	
☐ Yes ☐ No	
If Yes, specify: _____	
D. COURT PROCEEDINGS	
Has this matter been the subject of court proceedings?	
Yes ☐ No ☐	

If **Yes**, provide brief details:

Date: _____

Signature of Complainant: _____

Addendum 2: Appeal Submission Checklist

To be completed by the Legal Services Department at admissibility screening.

Requirement	Yes / No	Comment
Appeal lodged within 14 days of notification, or within an approved extension		
Signed and dated appeal letter stating ground(s) of appeal		
Copy of initial decision notification or other evidence of notification		
Supporting information/documentation labelled to the ground(s) relied upon		
Full disclosure of information/documents to be relied upon		
Not a duplicate of a pending or determined appeal		
Within the Board's jurisdiction		
Not frivolous, vexatious or manifestly unfounded		
Third party notified, where applicable		
Admissibility Decision: ☐ Admissible ☐ Curable defect – appellant requested to remedy ☐ Inadmissible		
Reviewed by: Signature: _____ Date: _____		

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