

## MINISTRY OF HEALTH

## PHARMACY AND POISONS BOARD

# CODE OF CONDUCT AND ETHICS FOR INSPECTORS OF HEALTH PRODUCTS AND TECHNOLOGIES

November 2023

Citation of this Document

The author of this document is the Pharmacy and Poisons Board, a State

Corporation under the Ministry of Health, Republic of Kenya. It may be

reproduced or adopted on condition that the recommended citation below is

made

**Recommended Citation:** Republic of Kenya, Ministry of Health, Pharmacy

and Poisons Board, Code of Conduct and Ethics for Inspectors of Health

Products and Technologies, Version 2, 2023.

All rights reserved:

©Pharmacy and Poisons Board, 2023

For clarifications, comments, or suggestions, please contact:

The Chief Executive Officer

Pharmacy and Poisons Board

P.O. Box 27663 - 00506, Nairobi

Telephone: 0709770100

Email: info@pharmacyboardkenya.org

Website: www.pharmacyboardkenya.org

PT/ISE/MAN/023	Code of Conduct and Ethics for Inspectors of Health Products and Technologies	Revision No. 2	Effective Date: 10/11/20  Review Date: 09/11/2028
	Deputy Director Inspectors	ate and Enforcem	ent
Name	min C Karınlı		ALLOWATE TO ASSESSED.
Sign	All		e actropost coalast '
Date2	11/2023.		
	, Director Health Products a	and Technologies	oTester A.I.
NameAt	tmes 1. Mottam	ED)	
Sign	65-5		de East C E.C ·
Date	3/11/2023		Ta karye 7.2
Checked by,			
Name	talst pro TH	W.	2.7,6 Invest 2. Greenway, C.
Sign			rational Section 5.0
Date		nythana ah wa	cettofind v.c
Authorized by	y, Chief Executive Officer		
Name. Fa	ED MOIN SIYO		

Date....7/11/2023

	E OF CONTENTS viations and Acronyms	iv
Gloss	ary of Terms	V
Ackno	owledgements	vii
Prefac	ce-Executive Summary	viii
1.0	INTRODUCTION	1
1.1	Legal framework	1
1.2	Scope	2
1.4	Vision	2
1.5	Mission	2
1.6	Core values	3
2.0	OVERVIEW OF DRUG INSPECTION	3
2.1	What is Drug inspection?	3
2.2	Overall objective of Drug inspection	3
2.3	What needs to be inspected?	3
2.4	Types of inspections	4
2.	4.1 Routine inspection	4
2.	4.2 Follow-up inspection	4
2.	4.3 Pre-registration inspection	
2.	4.4 Investigative inspection	5
3.0	GENERAL CONDUCT FOR PPB INSPECTORS OF DRUGS	5
3.1	Do's & don'ts for PPB inspectors	6
3.2	What is expected of an Inspectors of Drugs?	6
3.3	Inspector of drugs core values	7
3.4	Guidelines for the security and safety of inspectors	7
3.5	Inspection rationale	9
3.6	PPB Inspectors of drugs general rules and responsibilities	9
3.7	Responsibilities of PPB inspectors	10
3.8	Quality assurance of the inspectorate and inspection process	11
4.0	CODE OF CONDUCT AND REQUIREMENTS	
4.1	Introduction	12
4.2	Office Hours	13
4.3	Official Office Attire	
4.4	Core Values, Guiding Values, Principles & Requirements	
4.5	Rule of Law	
46	Conflict of Interest	1/1

4.7	Improper Enrichment or Receiving of Gifts	15
4.8	Harambees	16
4.9	Declaration of Income, Assets & Liabilities	16
4.1	0 Undue influence	17
4.1	1 Professionalism and Integrity	17
4.1	2 Confidentiality and the Official Secrets Act, Cap 187	17
4.1	3 Official Documents and Legal Proceedings:	18
4.1	4 Rule of Law	18
4.1	5 Respect and Courtesy	18
4.1	6 Discrimination	18
4.1	7 Confidentiality and Trust	18
4.1	8 Care of Assets	18
4.1	9 Media Interviews & Interactions with the Media	18
4.2	Private Agencies	19
4.2	Political Views	19
4.2	Trading	20
4.2	Borrowing and Lending Money	20
4.2	4 Harassment	21
4.2	Nepotism	21
4.2	Acting through others	21
4.2	7 Absence from Duty	22
4.2	Newspapers and Publications	22
4.2	Pecuniary Embarrassment	23
4.3	Security Measures	23
4.3	Whistle Blowing	24
4.3	Defense of Officers in Criminal and Civil Suits	24
4.3	Civil Proceedings by Officers for Defamation	24
4.3	Enforcement of the code	25
5.0	REFERENCES	25
6.0	Revision History	26
7.0	CONTRIBUTORS/REVIEWERS	27

## **Abbreviations and Acronyms**

GDP: Good Distribution Practices

HPT: Health Products and Technologies

PPB: Pharmacy and Poisons Board

POE: Ports of Entry

#### **Glossary of Terms**

"advertisement" includes a notice, circular, label wrapper or other document, and any announcement made orally or by means of producing or transmitting light or sound;

**"authorized officer"** means the registrar, pharmaceutical analyst, pharmaceutical inspector, a medical officer, an inspector of drugs, an administrative officer or a police officer not below the rank of Superintendent;

"authorized seller of poisons" means any person such as is referred to in section 24;

**"Board"** means the Pharmacy and Poisons Board appointed under the provisions of section 3;

"clinical trial" means any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, identify any adverse reaction to investigational products, to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety;

"dispense", in relation to a medicine or poison means to supply a medicine or poison on and in accordance with a prescription duly given by a duly qualified medical practitioner, dentist or veterinary surgeon;

"drug" includes any medicine, medicinal preparation or therapeutic substance;

"duly qualified", in relation to a medical practitioner, dentist or veterinary surgeon, means permitted by law to practice his profession as such in Kenya;

"enrolled pharmaceutical technologist" means a holder of a diploma in pharmacy from a training institution recognized by the Board and whose name appears on the Roll;

"Good Manufacturing Practice", also referred to as "GMP", "cGMP" or "current Good Manufacturing Practice" is the part of quality management which ensures that products are consistently produced and controlled

according to their intended use as required by the marketing authorization, clinical trial authorization or product specification;

**"health facility"** has the meaning assigned to it in the Health Act, (No. 21 of 2017);

"health product" includes human and veterinary medicines, medical products, medicinal substances, vaccines, diagnostics, medical devices, blood products, traditional and alternative medicine, therapeutic feeds and nutritional formulations, cosmetics and related products;

"health technology" means the application of organized knowledge and skills in the form of devices, medicine, vaccines, procedures and systems developed to solve a health problem and improve the quality of life;

"**inspector of drugs**" means a person who is competitively recruited by the Board as a pharmaceutical inspector and who holds a minimum of a diploma in pharmacy;

## **Acknowledgements**

The preparation of this manual has been made possible by technical and financial support from the Pharmacy and Poisons Board. The Inspectorate would like to express profound gratitude to the Chief Executive Officer, Dr. Fred Siyoi, Director HPT, Dr. Mohammed Ahmed and to the Deputy Director, Inspectorate and Enforcement Dr. Dominic Kariuki and all the inspectors for supporting the department's efforts to come up with this manual.

**Preface-Executive Summary** 

Drug inspectors serve as face of the National Drug Regulatory authority in

Kenya and are on the front lines in ensuring that the safety, quality and

efficacy of drugs manufactured and marketed in the country is maintained.

In this respect, drug inspectors have an important role in protecting

consumers. Importantly, the inspector's job is law enforcement. A drug

inspector is empowered by the law, at all reasonable times, to enter any

premises that is on the register or any premises in which he/she has

reasonable cause to suspect that the law has been or is about to be

contravened. The powers of drug inspectors are well stipulated in cap 244

laws of Kenya.

The Board is dependent on the experience, expertise and integrity of the

Inspectors of Drugs and welcomes suggestions from them for improvements

in its inspection processes. The Department of Inspectorate and Enforcement

monitors the Current Good Distribution Practices for pharmaceutical

products, Border patrols at the gazetted Ports of Entry/Exit, Good

manufacturing practices and the Office of Drug crime investigation. To

conceive this task, the Board has deployed a pool of highly specialized

technical human resource capacity to perform the duties of inspectors of

Drugs.

Dr. F.M Siyoi

**CHIEF EXECUTIVE OFFICER** 

viii

#### 1.0 INTRODUCTION

The Board aims to implement the appropriate regulatory measures to achieve the highest standards of safety, efficacy and quality for all drugs, chemical substances and medical devices, locally manufactured, imported, exported, distributed, sold, or used, to ensure the protection of the consumer as envisaged by the laws regulating drugs in force in Kenya. The code of conduct and ethics for PPB Inspectors places a personal obligation to inspectors of drugs to act with integrity in public interest, and to exercise all reasonable professional skill and care. They should endeavour to uphold the PPB core values as they carry out their duties.

Officers are required to adhere to their respective professional codes of conduct. It is imperative that an officer adheres to these rules of conduct, and such other rules which may be introduced from time to time.

All employees shall be required to sign the code of code of conduct upon employment and they will be bound by any amendments to the code of conduct.

## 1.1 Legal framework

The Pharmacy and Poisons Board is the National Drug Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulates the Practice of Pharmacy and the Manufacture and Trade in drugs and poisons.

person has the right to the highest attainable standard of health. Highest standards of health are only attainable if the quality of health products and technologies in the market are of the right quality.

As defined by the Leadership and Integrity Act, 2012; A State officer shall respect and abide by the Constitution and the law. (2) A State officer shall carry out the duties of the office in accordance with the law. In addition, an officer is required to comply with the provisions of Chapter Six of the Constitution on Leadership and Integrity and Articles 10 and 232 of the Constitution; Public Officer Ethics Act, 2003; Anticorruption and Economic Crimes Act, 2003; Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya, Labour Relations Act, 2007 and the Employment Act, 2007.

Article 43 (1) (a) of the constitution of Kenya 2010 provides that every

#### 1.2 Scope

The code of conduct and ethics for PPB Inspectors applies to Inspectors of Drugs to act with integrity in public interest, and to exercise all reasonable professional skill and care. They should endeavour to uphold the PPB core values as they carry out their duties. Officers are required to adhere to their respective professional codes of conduct

#### 1.4 Vision

To be a global leader in promoting and protecting public health.

#### 1.5 Mission

To protect and promote the health of the public by regulating the profession of pharmacy and ensuring access to quality, safe, efficacious and affordable health products and technologies

#### 1.6 Core values

- a) Commitment to public health
- b) Professionalism
- c) Accountability and Transparency
- d) Integrity and Respect
- e) Quality
- f) Diversity and inclusion

#### 2.0 OVERVIEW OF DRUG INSPECTION

#### 2.1 What is Drug inspection?

It is the systematic process of identification and verification of premises, personnel, processes, documents and Health Products and Technologies to confirm compliance with set guidelines, regulations and laws.

## 2.2 Overall objective of Drug inspection

To ensure that HPTs, either locally manufactured or imported, meet set standards of quality, safety and efficacy and are distributed in authorized premises by qualified pharmaceutical personnel.

The safety of patients and the public is assured by enforcing drug laws and regulations governing manufacturing, compounding, distribution, importation, exportation, storage, and use of drugs.

#### 2.3 What needs to be inspected?

To ensure the quality of drugs entering or circulating in the Kenyan market, the following establishments associated with drug supply and the distribution chain should be inspected regularly:

- a) Imports and Exports of HPTs at the Ports of entry (POEs)
- b) Premises: Pharmacies, (both established and new ones, before they are licensed), Pharmaceutical Wholesalers (both established and

new ones before they are licensed), Manufacturing facilities (both established and new ones before they are licensed)

- c) All other drug distribution outlets.
- d) Pharmaceutical personnel

## 2.4 Types of inspections

There are four types of inspections:

- Routine
- ❖ Follow-up
- Investigative
- ❖ Pre-registration.

## 2.4.1 Routine inspection

Routine inspections are generally for establishments that have previously been inspected. These inspections are done with a view to assessing standards of good pharmacy practice, and the outcome helps in the proper assessment of the establishment. Routine inspections can be announced or unannounced.

#### 2.4.2 Follow-up inspection

Follow-up inspections are normally carried out to ensure that corrective measures have been undertaken following advice and notice given during a previous inspection. If a time limit was given for applying the corrective measures, the inspection should be unannounced. Follow-up inspection also applies to assessment of ongoing cases in court and giving evidence in court as witnesses.

#### 2.4.3 Pre-registration inspection

Pre-registration inspections are generally intended for a new establishment or for an establishment that has applied for a permit to operate, extend its scope of operations, made important changes in its key personnel, moved to a new premise, or has not been inspected in a long time. The inspection should be announced except when an inspection has not been conducted in a long time.

## 2.4.4 Investigative inspection

Investigative inspections are undertaken to deal with specific complaints received about lapses or noncompliance with standards of professional practice. The inspection should be unannounced.

#### 3.0 GENERAL CONDUCT FOR PPB INSPECTORS OF DRUGS

- 1) The PPB inspector shall strive to achieve the highest ethical standards for conduct that he/she is capable of.
- 2) The PPB inspector shall uphold the honor and dignity of his/her profession and avoid association with any enterprise of questionable character or apparent conflict of interest.
- 3) The PPB inspector shall protect and promote the interests of the client to the best of his/her ability and knowledge, recognizing that the client has placed their trust and confidence in PPB.
- 4) The PPB inspector shall always endeavor to maintain and increase his/her level of knowledge regarding new developments in the field.
- 5) The PPB inspector shall conduct his/her business in a manner that will ensure that he/she is independent from outside influence and interest, which would compromise his/her ability to render a fair and impartial opinion regarding any activity conducted.
- 6) The PPB inspector shall promptly disclose to the client any interest in any other business that may affect the client or the quality or result of his/her work.
- 7) The PPB inspector shall not knowingly use his/her position to obtain work in another field.
- 8) The PPB inspector shall make every effort to uphold, maintain, and improve the professional practice, integrity, and reputation of PPB technical experts and the institution as a whole.

## 3.1 Do's & don'ts for PPB inspectors

- 1) Exercise confidentiality.
- 2) Make accurate reports of the facts observed.
- 3) Be courteous and demonstrate poise and competence in your work.
- 4) Refrain from expressing personal views; such remarks or opinions may be interpreted as official.
- 5) Do not lose your temper when abused or accused. Always stay calm.
- 6) Be careful not to overlook any correspondence, record, accounts book, chit, rough book, or other relevant papers that may prove to be material evidence in determining the conduct, transactions, circumstances, and so on of the establishment being inspected.
- 7) Do not fail to record all items seized. Full details and descriptions of the incriminating articles or circumstances for which a charge will be opened (in case of intention to institute legal charges) should be recorded with witnesses' present, and signatures of responsible persons should be obtained on the seizure document.

## 3.2 What is expected of an Inspectors of Drugs?

- 1) Contact the person in charge of the establishment by approaching him or her in a dignified, authoritative, and cordial manner. Avoid being arrogant.
- 2) Present credentials (e.g., your identity card) and explain the purpose of your visit.
- 3) Use diplomacy, tact, and persuasiveness to acquire the necessary information and all necessary inspection details. To achieve this, use the appropriate standard operating procedures (SOPs) for the particular type of inspection and fill in the respective inspection form.
- 4) In case of refusal to undergo inspection, explain that obstruction is a criminal offence and courteously discuss the matter with the owner or responsible person on the premises.

- 5) Make suggestions for minor corrections to be made as you perform the inspection. Upon completion of inspection, discuss the findings with the owner or person in charge.
- 6) Adopt a courteous attitude in calling attention to the practices or conditions observed at the time of inspection.
- 7) If any samples have been taken for testing, furnish a documentation for these samples to the person from whom samples are taken.
- 8) The results of the samples shall be shared with the person from whom the samples were taken.

## 3.3 Inspector of drugs core values.

- 1) Commitment to public health
- 2) Professionalism
- 3) Accountability and Transparency
- 4) Integrity and Respect
- 5) Quality
- 6) Diversity and inclusion

#### 3.4 Guidelines for the security and safety of inspectors

- 1) Law enforcement is the mainstay of the work of a PPB inspector of drugs
- 2) The inspector has the duty to protect public health by ensuring that all regulated products, including medicinal products, in the market comply with the required standards.
- 3) This compliance is achieved by ensuring that all products circulating in the market have market authorization and that the premises where these medicines are dispensed are operated according to the prescribed rules and regulations.
- 4) An inspector, in addition to being a guardian of public health in issues related to medicines, is expected to discharge his/her duties diligently and professionally.

- 5) The role of the inspector is to help ensure the integrity of the market and create a fair business environment where conscientious players can compete. It should be noted that the marketplace generally falls to the lowest level of competition; unless law enforcement keeps the market fair and competitive, anarchy will rule the market and consumers will suffer. The work of inspectors of drugs as law enforcers is certainly associated with risks to their safety.
- 6) This risk is understandable because in the process of discharging their duties, inspectors frequently interfere with illegal and unscrupulous commercia interests. In many instances, the inspection activities cause financial losses to proprietors. In some cases, the inspector may encounter unscrupulous individuals whose business may have thrived in the unregulated environment and who may resort to any means to maintain their illegal business dealings.
- 7) Problems of security for inspectors of drugs cannot be entirely eliminated, but the risks to the inspector can be reduced if inspectors adhere to the following guidelines:
- 8) Upon a new appointment or transfer to a new station, the supervisor shall make sure that the officers are introduced and that they have an introductory letter from the PPB.
- 9) The inspector shall introduce and present their credentials and letter to the regional authorities, including the Regional Commissioner, Regional/County Police Commander, and other key government officers. Explain to them what your duties and responsibilities as a drug inspector are. By doing so, you create a politically and technically conducive work environment for executing your duties with support from other state entities and stakeholders.
- 10) Whenever you have inspection work to do, it is good practice and safer not to do it alone. (It is easier to threaten an individual than a group of officials.)

- 11) Always perform inspections in a courteous but firm manner. Follow the SOPs. Inform the other members of the inspection team and the owner of what is expected and of any deficiencies identified during the inspection.
- 12) Whenever there is a threat to your life (communicate verbally, in writing, or through a third person), inform the police immediately. The PPB should be apprised of this situation on telephone and in writing immediately.
- 13) If a threat has been issued, be careful with whatever you do, especially after office hours. Avoid situations that would put your life in jeopardy. Don't let people know about your travel plans. If possible, do not drive your car alone and be careful where you take your meals. The risk of intentional food or drink poisoning cannot be overlooked when threats have been made against you.
- 14) If you uncover any criminal violations in the course of your work, immediately involve the police in the matter, as they are trained and equipped to deal with criminal investigations.

#### 3.5 Inspection rationale

PPB's fundamental purpose is to provide globally respected and rigorous inspection-based approaches to enhance the standards and quality of pharma regulation in Kenya. As indicated in the PPB mission statement, 'To protect and promote the health of the public by regulating the profession of pharmacy and ensuring access to quality, safe, efficacious and affordable health products and technologies' one of the principal ways that PPB fulfils this aim is through the inspection and inspection report writing processes, which are carried out by PPB inspectorate.

#### 3.6 PPB Inspectors of drugs general rules and responsibilities

1) PPB inspectors are contracted to undertake specific tasks on permanent employment basis. Inspectors are issued with certificates of employment/identification badges.

- 2) It is essential that inspectors familiarise themselves with the procedures and requirements set out in this handbook, and the code of ethics for drug inspectors and ask for clarification where required.
- 3) Inspectors are also required to keep up to date with changes to legislation and changes made to the requirements imposed by regulatory bodies

## 3.7 Responsibilities of PPB inspectors

- 1) Inspectors should treat documentation and other information supplied by PPB, as well as the outcome of the inspection, with confidentiality.
- 2) Inspectors should familiarize themselves fully on the operations of the inspected institution before the inspection and on PPB's procedures and criteria as set out in the SOPs and guidelines.
- 3) Inspectors are required to complete an annual **Declaration of conflict of Interest** stating any institutions with which they
  have connections with. In accepting PPB's invitation to
  participate in a particular inspection, inspectors are declaring
  that they are not involving themselves or PPB in any possible
  conflict of interest. They are also asked to state specifically
  that they have no conflict of interest in regard to each
  inspection in which they are deployed.
- 4) Inspectors are to sign a code of conduct annually, which sets out the high standards of behavior that are expected from them when accepting an inspection assignment and throughout the inspection process. This code of conduct is supported by PPB's anti-corruption policy. Inspectors are expected to familiarize themselves with the content of these documents and ensure that they abide by their terms and conditions at all times.

- 5) Inspectors are expected to treat staff in the inspected institutions with decorum.
- 6) Inspectors are expected to present themselves in a manner which engenders professional respect and avoids negative comment, whether in terms of dressing, personal hygiene or behavior. They should wear PPB branded jackets and their identity badges at all times during the inspection and be courteous especially if their legitimate enquiries appear to be being deliberately frustrated.
- 7) Inspectors should pay particular attention to the avoidance of any behavior or comment that could be construed to be unlawfully discriminatory or against the legitimate interests of the inspected premises. Inspectors are given general protection under PPB's professional indemnity insurance when giving professional advice.
- 8) During and after an inspection, drug inspectors should carry out the duties reasonably assigned to them by the HOR including, within an agreed time period, the production of a short-written report on the areas assigned to them.
- 9) Any difficulties arising out of an inspection or in connection with the execution of an inspector's duties should be reported to the Board without delay. The LI should ensure that all the members of the inspection team have his/her contact telephone number in case they have any last-minute problems.

#### 3.8 Quality assurance of the inspectorate and inspection process

PPB demonstrates its commitment to the quality assurance of its processes through the following;

- 1) Regular training
- 2) Briefing of inspectors of drugs

- 3) Independent audit committee
- 4) Supervisory visits to inspection teams by the Head GDP, Head POE, Deputy director Inspectorate and Enforcement, manager regional offices and Director, Health Products and Technologies.

## 4.0 CODE OF CONDUCT AND REQUIREMENTS

#### 4.1 Introduction

This Section contains general rules of conduct to be observed by officers so as to maintain integrity and uphold the dignity of the public office to which he has been appointed.

Every officer occupies a special position in the Board and should ensure that his conduct both in public and in private life does not bring the Board into disrepute.

Regulations governing discipline in the Board and the procedure to be followed in cases of breach of discipline are contained in this manual.

#### 4.2 Office Hours

The official hours are as follows:

- a) Nairobi and all other Regions Monday to Friday: 8.00 a. m. to 1.00 p. m 2.00 p. m. to 5.00 p. m
- b) Mombasa & Northern Kenya Monday to Friday: 7.45 a. m. to 12.30 p. m 2.00 p. m. to 4.30 p. m
- c) PPB allows staff to enjoy flexible work arrangements. However, staff must work for the required work period. Flex-time is a flexible hour's schedule that allows workers to alter workday start and finish times.
- d) Though the general office hours will be as stated herein, HoDs will not be restricted to utilize employees outside these hours, when there is any cause requiring their services either earlier or later, as long as the employees put up a maximum of 40 hours per week.
- e) For the effective running of the Board, the employees should observe punctuality and regular work attendance. In case an employee is not in a position to report to work in the morning or is delayed, the head of the respective department should be notified before, as close to the regular starting time as possible. This should not be later than 12.00pm after which the employee will be considered absent.

#### 4.3 Official Office Attire

- a) The employees of the Board are expected to dress in formal and acceptable office attire between Mondays and Thursdays.
- b) Dress-down policy: staff members are free to dress down on Fridays and days preceding public holidays. It should, however, be noted that the free manner of dressing should also be acceptable and decent.
- c) Employees may put on branded corporate attires on specific functions of the Board.

#### 4.4 Core Values, Guiding Values, Principles & Requirements

- a) The employees of the Board shall be guided by the national values and principles of governance in Article 10 of the Constitution; provisions of Chapter 6 of the Constitution on Leadership and Integrity; Part II of the Leadership and Integrity Act, 2012 as well as the Public officers Ethics Act, 2003 revised in 2009.
- b) The employees of the Board shall aspire to uphold the national values and principles of governance being;
- c) Patriotism, national unity, the rule of law, democracy and participation of the people;
- d) Human dignity, equity, social justice, inclusiveness, equality, human rights, non-discrimination and protection of the marginalized;
- e) Good governance, integrity, transparency and accountability; and
- f) Sustainable development.

#### 4.5 Rule of Law

All employees shall carry out their duties in accordance with the law. In carrying out his duties, a public employee shall not violate the rights and freedoms of any person under Part V of the Constitution.

#### 4.6 Conflict of Interest

- a) An employee shall declare to the CEO his personal interest (including the interest of a spouse, relative or business associate); where such interests are likely to interfere with official duties or affect personal judgment on official matters. According to the provisions of the Public Officer Ethics Act, 2003, an officer shall:
- b) Use his best efforts to avoid being in a position in which his personal interests conflict with his official duties
- c) Not hold shares; corporate, partnership or of another body or through another person that would result to conflict of interest
- d) Declare personal interests to the CEO/Committee and comply with any directions to avoid the conflict and also refrain from

- participating in any deliberations where such interest would conflict official duties
- e) Not award a contract or influence the award of such a contract to himself, spouse, close relative, business associate, or a corporation, partnership or other body in which the employee has an interest.
- f) Not use his office to improperly enrich himself or another person
- g) Not use or allow use of information acquired through his public office that is not public, for his own or other peoples' benefit.
- h) Any employee whose personal interests are potentially or actually in conflict with those of his duties shall declare the personal interests to his superior/Committee Chair or the CEO in writing.
- i) Other situations which constitute a conflict of interest: -
- j) Soliciting for any help, funds, favours, gifts and sponsorship from persons or institutions associated with the Board or using the name of the Board without the knowledge and approval of the Board.

#### 4.7 Improper Enrichment or Receiving of Gifts

- a) Board employees shall not accept gifts, benefits or favors from a client where these may influence or may be seen to influence his decisions. Gifts exceeding a threshold of Kshs. 20,000.00 should not be accepted. Gifts in cash should not be accepted under any circumstance.
- b) A Board employee (s) shall not use their office to improperly enrich themselves or others. In this regard, a Board employee shall not accept or request gifts or favours from a person who:

has an interest that may be affected by the carrying out, or not carrying out, of the public officer's duties;

Carries on regulated activities with respect to which the Board has a role; or

has a contractual or similar relationship with the Board;

Improperly uses their office to acquire properties for themselves or another person, whether or not the properties are paid for; or For their personal benefit or another, use or allow the use of information that is acquired in connection with the public employee's duties and that is not public.

c) Employees are prohibited from receiving valuable presents (other than gifts from personal friends and relatives) and/or other benefits and from giving such presents. This applies for example to Christmas presents or such kind of gifts.

This section applies not only to the employee himself, but also to his family. It is not intended to apply to cases of remuneration for special services rendered and paid for with the consent of the Board.

Presents from public personages which cannot be refused without being offensive will be handed over to the Board unless prior permission has been obtained from the CEO for the employee to retain the present.

When presents are exchanged between employees acting on behalf of the CEO in ceremonial occasions with other organizations or their representatives, the presents received will be handed over to the Board and any present in return will be given at the Board 's expense.

#### 4.8 Harambees

A Board employee shall not preside over a Harambee, play a central role in its organization or play the role of "guest of honour"; nor participate in a Harambee in such a way as to reflect adversely on their integrity or impartiality or to interfere with the performance of their official duties.

## 4.9 Declaration of Income, Assets & Liabilities

Every employee shall on first appointment and after every two years thereafter submit a declaration of income, assets and liabilities of himself, spouse(s) and dependent children less than eighteen (18) years to the Public Service Commission in accordance with the Public Officer Ethics Act, 2003. The appropriate form will be supplied annually as required.

#### 4.10Undue influence

Employees are warned that the practice of seeking the influence of Politicians or other persons in order to be considered for promotion or other favours is viewed with disapproval. Any such attempt to obtain such favours is considered irregular and will not be of advantage to the employee and on the other hand, may actually be detrimental to the employee's interests.

## 4.11Professionalism and Integrity

All employees shall: -

- a) Carry out their duties in a manner that treats the public and the fellow employees with courtesy and respect;
- b) Seek to improve the standards of performance and level of professionalism in the Board;
- c) Observe the ethical and professional requirements of a professional body of which they are members;
- d) Maintain an appropriate standard of dress and personal hygiene; and
- e) Avoid practices that could lead an individual vulnerable to financial embarrassment.

## 4.12Confidentiality and the Official Secrets Act, Cap 187

Disclosure of Information: An employee must not disclose any information concerning the affairs of the Board or its employees, or show or release any official document to any person not connected with the Board, or even insiders, unless he is required to do so in the course of his duties, or such disclosure as is authorized by the CEO. Individual invitations to give technical advice or present papers should be channeled through the CEO.

#### 4.13Official Documents and Legal Proceedings:

An employee must not without permission make use of any official document which comes into his possession by virtue of his employment the subject of legal proceedings.

#### 4.14Rule of Law

Employees shall carry out their duties in accordance with the law. In carrying out one's duty, an employee shall not violate the rights and freedoms of any person as provided for in the Constitution.

## 4.15Respect and Courtesy

All employees will be expected to portray utmost respect for one another, irrespective of seniority or personal status.

#### 4.16Discrimination

The Board is opposed to all forms of discrimination. Discrimination of any sort will be reported to the CEO so that the matter can be investigated and appropriate action taken. Any reported incidences of alleged discrimination will be treated in utmost confidence.

## 4.17Confidentiality and Trust

While in the course of their duties, employees will be exposed to confidential information. In such cases, they will be expected to uphold strict standards in regard to confidentiality of information.

Disciplinary action will be taken against any employee proven to have divulged confidential information without the permission of the Board.

#### 4.18Care of Assets

Employees are expected to ensure that assets entrusted to them are adequately protected and not misused or misappropriated.

## 4.19Media Interviews & Interactions with the Media

a) An employee shall not, under any circumstances, communicate with the media either in writing or otherwise, or make statements

- on 80 matters affecting the Board's programs or policies without specific authority from the CEO.
- b) An employee, whether on duty or on leave, shall not do the following without the permission of the CEO:
- c) Act as the editor of any newspaper or take part directly or indirectly in the management thereof; nor
- d) Publish in any manner anything which may be reasonably regarded as of a political or administrative nature, whether under his own name, under a pseudonym or anonymously.
- e) Allow himself to be interviewed on questions of public policy or on matters affecting the Board without the permission of the CEO.
- f) While it is not desired to interfere with the liberty of free speech, any lack of discretion on the part of an employee in expressing an opinion that may embarrass the Board, may result in disciplinary action being taken against him
- g) An employee may however, publish matters relating to other subjects.

## 4.20Private Agencies

No employee may undertake any private commission in any matter connected with the exercise of his public duties. No employee shall in any manner that may be detrimental to the security interests of the Board and Kenya at large, be an agent for or further the interests of a foreign Government, organization or individual.

#### 4.21 Political Views

a) Though an employee as a Kenyan is entitled to his own political views on political matters, he shall ensure that his utterances do not implicate or compromise the Board and the government at large.

- b) An employee shall not, in connection with the performance of his duties, do the following:
- c) Act as an agent for a political party or so as to further the interest of the party; or
- d) Indicate support for or opposition to any political party or candidate in an election; or
- e) Engage in political activity that may compromise or be seen to compromise the political neutrality of his office; or
- f) Use his political stand to intimidate others perceived to be of a different view.

## 4.22Trading

- a) Trading on official premises is strictly forbidden except where official permission has been received.
- b) Away from official premises no employee may act as an agent for the sale of any articles or merchandise whilst on duty or in uniform.

## 4.23Borrowing and Lending Money

An employee is strictly forbidden:

- a) To become an agent for a moneylender.
- b) To borrow money from the Board's stakeholders or members of staff of any Company doing business with the Board, with whom his official duties bring him into contact.
- c) To accept premiums from other staff of the Board as consideration for instructing them on how to perform their duties.

#### 4.24Harassment

- a) Harassment is generalized as insulting and degrading behavior or statements, which could be verbal, physical, deliberate, unsolicited and unwelcome.
- b) Harassment in any form is prohibited. Examples of harassment include: -
- c) Verbal harassment in the form of derogatory comments or slurs.
- d) Unwelcome sexual advances, requests for sexual favours and other verbal or physical conduct of a sexual nature.
- e) Physical harassment in the form of assault, impeding or blocking movement, any physical interference with normal work or movement.
- f) Visual harassment through derogatory posters or drawings.
- g) If an employee encounters such behaviour from anyone, including supervisors, fellow employees or other external parties, he should report the incident immediately to the supervisor or to the Manager, Human Resource Management and Development.
- h) If the harassment is from the Manager, HRM&D or from the CEO, an employee will be at liberty to report the incident directly to a member of the Board or to the Chairperson.

#### 4.25Nepotism

An officer shall not practice undue favoritism to their relations and close relatives at the expense of the service.

#### 4.26Acting through others

a) An officer contravenes the code if he causes anything to be done through another person that would constitute a contravention of the code if done by the officer, or allows or directs a person under their supervision or control to do anything that is in contravention of the code.

- b) Contravention shall not apply where anything is done without the officer's knowledge or consent or if the officer has taken reasonable steps to prevent it.
- c) An officer who acts under unlawful direction shall be responsible for his action.

## 4.27Absence from Duty

- a) An employee shall not absent himself from duty during working hours, leave his appointed place of work or proceed to a place other than which he is usually employed, without due permission of his immediate supervisor.
- b) An employee who absents himself from duty due to ill health shall be required to produce within forty-eight (48) hours a medical certificate signed by a certified Medical Officer. If such a certificate is not forthcoming, the employee will be regarded as having been absent from duty without leave and may be liable to disciplinary action, which may include summary dismissal, with loss of all benefits.
- c) Where an officer is absent from duty without leave or reasonable or lawful cause for a period exceeding Forty-Eight (48) hours, and is not traced within a period of seven (7) days from the commencement of such absence, the officer's salary shall be stopped and action to dismiss the officer initiated.
- d) An employee who, without leave or reasonable cause, absents himself from duty for more than seven (7) days shall be regarded as having vacated his office and is liable to summary dismissal.

#### 4.28 Newspapers and Publications

a) An employee must not, except with the express written permission of the Board, act as an editor of any newspaper, or take part directly or indirectly in the management thereof, nor publish in any manner anything which may reasonably be regarded as being of a political or administrative nature, whether under his own name, under a pseudonym or anonymously.

- b) An employee may, however, publish in his own name, matters relating to subjects of professional or general interests not involving public matters, politics, the Board or Government affairs.
- c) An employee who wishes to publish an article or deliver a speech, the substance of which may subsequently be published, or the substance of which may reasonably be regarded as being of political or administrative nature, shall seek permission to do so from the CEO and a draft of the proposed article or speech submitted for approval.

## 4.29 Pecuniary Embarrassment

- a) Pecuniary embarrassment from whatever cause will be regarded as impairing the efficiency of the employee and may render him liable to disciplinary action.
- b) Employees who may be in financial difficulty will be given assistance to extricate themselves from their problems. However, there is a limit beyond which an employee may be assisted and it may be necessary to terminate the services of anyone who is persistently in financial difficulties to the extent that he either becomes a risk to the Board or is unable to carry out his duties effectively.

## 4.30Security Measures

- a) Employees shall be required to safeguard sensitive documents from unauthorized persons by ensuring that documents are not carelessly left on their tables in their absence. Such records shall at all times be kept under lock and key.
- b) Entry of all visitors into the premises shall be regulated.
- c) Articles brought in and out of the Board's premises shall be limited and the employee in charge of security shall be obliged to check on such articles or luggage as he may deem appropriate

#### 4.31Whistle Blowing

Any employee or stakeholder having well founded suspicion of proven fraud, corruption, misuse of funds and assets, or any irregularities under this Code or governing laws of the Board is encouraged to report such irregularities.

#### 4.32Defense of Officers in Criminal and Civil Suits

- a) When criminal or civil proceedings are instituted against an officer as a result of an act of omission by him in the course of his official duties, he may apply to the CEO for assistance in his defense. If the latter is satisfied that the officer acted in good faith in the execution of his official duties and that it is in the public interest that the officer should be defended, the CEO shall immediately report the matter to the Attorney General, who will decide whether or not the officer should be defended.
- b) Unless the proper procedure is followed, the Attorney General may decline to provide support to the officer. It is further emphasized that speed is of essence in reporting such cases to the Attorney General.

#### 4.33Civil Proceedings by Officers for Defamation

- a) Where an officer has been defamed in respect of matters arising out of his official position, e.g. in the press or at a political meeting, it may be that the Government Authority is also defamed by implication, and may, therefore, agree to give legal aid to the officer. Where such a case occurs, the officer may apply for legal aid through the CEO to the Attorney General. Legal aid will not be granted unless:
- b) The Government has a substantial interest in seeing that the defamatory statement is repudiated; b.) There is, in the opinion of the Attorney General, a good prospect of success in the action; and

c) The consent of the Attorney General shall be obtained before proceedings are commenced.

#### 4.34Enforcement of the code

The code of conduct and ethics for PPB Inspectors places a personal obligation to inspectors of drugs to act with integrity in public interest, and to exercise all reasonable professional skill and care. They should endeavour to uphold the PPB core values as they carry out their duties. It should be noted that failure to comply with the established rules, regulations, and standard operating procedures is an offence that shall warrant disciplinary action.

#### 5.0 REFERENCES

- 1. Constitution of Kenya 2010
- 2. Pharmacy and Poisons Act, Cap 244 laws of Kenya
- 3. Guidelines for good Distribution Practices
- 4. PPB 2020-2025 Strategic plan
- 5. Code of ethics for PPB Inspectors
- 6. Handbook for PPB Inspectors of Drugs
- 7. Leadership and Integrity Act, 2012;
- 8. Public Officer Ethics Act, 2003;
- 9. Anti-corruption and Economic Crimes Act, 2003;
- 10. Labour Relations Act, 2007

# 6.0 Revision History

Revision	Date	Author	Section (s) revised	Description
No				of change
Revision No.1	12/07/2022	Mr. Julius Kaluai	Document numbering	To align with Organogram
Revision No.2	01/11/2023	Mr. John Muinami	Page 1. Change of court of arms	To conform with the current Court of Arms.
	01/11/2023	Mr. John Muinami	Deletion of the Preamble	To align with the Guideline for Development, Review and Approval of Regulatory Instruments
	01/11/2023	Mr. John Muinami	Addition of the Legal framework	To align with the Guideline for Development, Review and Approval of Regulatory Instruments
	01/11/2023	Mr. John Muinami	Revision of the introduction section	To align with the Guideline for Development, Review and Approval of Regulatory Instruments
	01/11/2023	Mr. John Muinami	Addition of scope	To align with the Guideline for Development, Review and Approval of Regulatory Instruments
	01/11/2023	Mr. John Muinami	Replacement of Foreword title with Preface-Executive summary	To align with the Guideline for Development, Review and Approval of Regulatory Instruments
	01/11/2023	Mr. John Muinami	Contributers/Reviewers	Addition of Mr.John Muinami

# 7.0 CONTRIBUTORS/REVIEWERS

S.No	NAME	POSITION
1.	Dr F.M Siyoi	CEO, PPB
2.	Dr. Ahmed Mohamed	Director, Health Products and Technologies, PPB
3.	Dr Dominic Kariuki	Deputy Director, Inspectorate and Enforcement, PPB
4.	Dr Tom Kauki	Regional Head, Central Region, PPB
5.	Julius Kaluai	Regional Head, Nairobi Region, PPB
6.	Dr Paddy Agoro	Regional Head, Coast Region, PPB
7.	Dr Kibet Chebeo	Regional Head, North Rift Region PPB
8.	Dr Sibalile Simiyu	Regional Head, South Rift Region PPB
9.	Dr Onesmus Kilonzo	Regional Head, Western Region PPB
10.	Dr Washington Oyoo	Regional Head, Nyanza Region PPB
11.	Dr James Gathogo	Regional Head, Upper Eastern Region PPB
12.	Dr Benson Kanji	Regional Head, Lower Eastern Region PPB
13.	Mr. Omar Sheikh	Regional Head, North Eastern Region PPB
14.	Mr. Peter Kiptoo	Head POE, PPB
15.	Mr. Denis Otieno	Head DCI, PPB
16	Mr. John Muinami	Senior Regulatory Officer, Nairobi Region

## **End of Document**

Pharmacy and Poisons Board 2023.

All rights reserved. This is a controlled document.

It must not be copied without authorization from the Pharmacy and Poisons Board•