

# NATIONAL PHARMACY COUNCIL DISCIPLINARY MEASURES

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#### FOREWORD

The Rwanda National Pharmacy Council (NPC) is a statutory authority accountable for regulation of pharmacy profession and it plays an advisory role to the Ministry of Health and the pharmacy training institutions on all matters related to the pharmacy profession. It was established by law no 45/2012 of 14/01/2013 relating to its organization, functioning, and competence. The Council is governed by the National Council Board as a supreme organ.

The Council is responsible for ensuring that the rules, honor, and dignity of the pharmacy profession are complied with and ensure the protection of public health. It ensures compliance with the principles of morality, integrity, and dedication essential to the practice of the pharmacy profession and ensures that all its members comply with their professional obligations and the laws and regulations governing the pharmacy profession.

In line with our mandate, we developed comprehensive guidelines that outline the procedures for investigating and addressing instances of pharmacy professional malpractice. These guidelines are designed to ensure the highest levels of morality, integrity, and dedication in the practice of pharmacy profession in Rwanda, ultimately serving the best interests of public health.

It is essential that all pharmacy professionals in Rwanda familiarize themselves with these guidelines and strictly adhere to them. They not only serve as a framework for maintaining professional ethics but also outline the disciplinary and administrative measures that may be taken in cases of non-compliance with the laws and regulations governing the pharmacy profession in Rwanda.

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# **CHAPTER I: GENERAL PROVISIONS**

#### Article 1: Purpose of these disciplinary measures guidelines

The purpose of these guidelines is to:

- 1. **Maintain Professional Standards**: These guidelines aim to uphold and enforce the highest professional standards within the pharmacy profession. By setting clear disciplinary measures, the National Pharmacy Council ensures that all members adhere to the prescribed code of conduct, ethics, and professional requirements.
- 2. **Protect Public Health and Safety:** These guidelines serve the purpose of safeguarding public health and safety. By having disciplinary measures in place, the National Pharmacy Council addresses any misconduct, negligence, or unethical behaviour of registered pharmacy professionals that may potentially harm the public. This helps to maintain public trust in the pharmacy profession and ensures pharmaceutical services are delivered with professionalism.
- 3. **Ensure Compliance with Laws and Regulations**: The purpose of these disciplinary measures guidelines is to ensure that all registered pharmacy professionals of the National Pharmacy Council comply with the laws, regulations, and standards governing the practice of the pharmacy profession. The compliance deters pharmacy professionals from engaging in behaviors that are considered harmful, unlawful, or contrary to societal norms while upholding the rule of law.
- 4. **Uphold Professional Integrity and Ethics:** These guidelines aim to promote and maintain professional integrity and ethics within the pharmacy profession. By having these disciplinary measures guidelines in place, the National Pharmacy Council ensures that the rules, honor and dignity of the pharmacy profession are complied with and ensure the protection of public health.
- 5. **Promote accountability of pharmacy professionals:** this refers to the responsibility that the professionals have to uphold the highest professional standards, protect public health and safety, comply with laws and regulations, and uphold professional integrity and ethics. It helps to protect the public, maintain the integrity of the profession, and ensure that pharmacy professionals are held responsible for their actions.



# Article 2: Definitions and meaning of relevant terms

In these guidelines, the following terms shall have the following meanings:

**Council:** The Council of Pharmacists that is established by Law  $n^{\circ}$  45/2012 of 14/01/2013 relating to its Organization, functioning, and Competence. It is referred to as the Rwanda National Pharmacy Council as determined by the internal rules and regulations.

**Pharmacist:** a person holding a bachelor of Pharmacy, Doctor of Pharmacy (PharmD), and registered with the National Pharmacy Council.

**Pharmacy Technician**: a person holding an advanced diploma in pharmacy/pharmaceutical sciences and registered with the National Pharmacy Council.

**Pharmacy professionals**: any Pharmacist and Pharmacy technician registered as such in the Register of the Council.

**Register**: means the Register kept by the Council as per the provisions of the internal rules and regulations.

**Supervisor:** means a pharmacy professional approved by the Council to supervise the internship of a pharmacy graduate or the in-service training of pharmacy professionals.

**Internship**: practical and/or a mentorship training undertaken by a pharmacist, a pharmacy graduate, or a pharmacy technician in terms of a contract of a limited period under the direct supervision of a registered pharmacist in a pharmaceutical establishment or any other relevant institution, recognized by the Council for purpose of such training or at an institution registered as a provider of qualification in pharmacy education, training or internship.

**Additional training:** Additional training, refers to a requirement imposed on a pharmacy professional as part of a disciplinary action or sanction. The pharmacy professional undergoing the training holds the primary responsibility for covering all financial obligations associated with the training. Before the initiation of training the designated training provider will present a comprehensive breakdown of all costs to the pharmacy professional.

The training may cover various topics such as ethics, professionalism, specific areas of practice, legal requirements, or any other relevant subjects that aim to improve the professional's competence and ethical conduct.

It aims at promoting professional development, rehabilitation, and the prevention of future **Page** | 2



ethical violations or misconduct. It provides an opportunity for the professionals to learn from their misconduct, gain a deeper understanding of professional standards, and adopt corrective measures to ensure they practice ethically.

**The Committee**: refers to a commission in charge of Ethics and discipline of pharmacy professionals established by internal rules and regulations of the Council.

**Complaint:** means an expression of dissatisfaction made in writing to the NPC by an interested person or party according to the provisions of these guidelines.

**Charge:** a charge refers to an allegation or accusation made against a pharmacy professional regarding a professional misconduct. It is a formal or informal accusation that someone has acted or omitted in a way that goes against professional codes of conduct.

**A Professional misconduct/ fault**: refers to an act or omission by a professional that deviates from the established standards, ethics and code of conducts of Pharmacy profession resulting in a failure to meet the expected level of ethical conduct. It is a breach of the pharmacy professional's duty to exercise competence and diligence in their work, leading to harm, loss, or negative consequences for clients, patients, profession or the public in general.

Any other misconduct /fault committed outside the course of professional practice that is likely to undermine the honor and dignity of the pharmacy profession shall constitute the professional misconduct and be sanctioned by these guidelines through the principle of equity.

**Ethical values and standards for the pharmacy profession**: values and standards determined by the ministerial order no 20/37 of 30/10/2015 determining the code of ethics for the pharmacy profession.

**Warning Letter:** A warning letter is a formal document issued by the National Pharmacy Council to a pharmacy professional to address and document his/her misconduct or violation of policies or codes of conduct. A warning letter is an approach to list issues and address them, and provide the recipient with an opportunity to make adjustments before more serious punishments are applied.

**Reprimand Letter:** A reprimand letter is a formal document issued by the National Pharmacy Council to a pharmacy professional to express strong disapproval for his/her misconduct, violation of policies, or failure to meet expected standards of ethics. It is a more severe form of disciplinary action (sanction) than a warning letter.



**Temporary Suspension**: a Pharmacy professional suspended is not allowed to practice the pharmacy profession both in public and private sector or to be involved in all health-related activities as a job or as a volunteer during the period of suspension.

**Removal from the Register:** is also deregistering a pharmacy professional due to the following cause but not limited to:

- i. Incapacity approved by a qualified medical practitioner;
- ii. Death;
- iii. Sanction as a disciplinary measure
- iv. Temporal suspension for a Pharmacy professional who is convicted by a court of an offense (petty offense, misdemeanor or felony) with an impact on the health profession. The professional can request for reinstatement after serving the sentence.
- v. He / She has been definitively sentenced to life imprisonment
- vi. Misrepresentation of qualifications: providing false or misleading information regarding qualifications, credentials, or other required documents to obtain or maintain registration as a pharmacy professional.

**Incapacity:** This refers to a legal status where a pharmacy professional is deemed unable to make decisions or take actions on their own behalf due to a lack of mental capacity. It recognizes that a pharmacy professional may be unable to understand the nature and consequences of his/her actions, comprehend relevant information, or communicate his/her decisions effectively.

**Calendar day**: A calendar day is a period of 24 hours from midnight to midnight. It includes all days of the week, including weekends and holidays. In the context of these guidelines, calendar days are numbered consecutively throughout the year, starting with January 1 and ending with December 31, with February 29 being added in leap years.



**Abuse of the pharmacy profession:** this refers to the unethical, negligent, or wrongful conduct of pharmacy professionals that deviates from the accepted standards and principles of the pharmacy profession.

It involves actions or omissions that result in harm, injury, or negative consequences to patients, the public, or the integrity of the profession itself. Professional malpractice or abuse is split into two classes : Class I relating to the general professional malpractice and Class II relating to the abuse of trust by Pharmacy professionals.

#### **Class I: General Professional malpractice**

This includes but not limited to:

- i. **Dispensing Errors:** This involves mistakes in dispensing medications, such as providing the wrong medication, incorrect dosage, or incorrect instructions, dispensing expired medicines which can lead to patient's harm or adverse reactions.
- ii. **Medication Mismanagement:** This includes issues like improper storage of medications, failure to properly handle or administer medications, or inadequate monitoring of patient response to medications.
- iii. **Unlawful dispensing**: dispensing prescription medications without a valid prescription for medicines requiring the medical prescription or in violation of legal requirements.
- iv. **Unprofessional Conduct**: This encompasses behaviours that violate /undermines trust, professionalism, and the reputation of the pharmacy profession such as conflict of interest, or inappropriate relationship with patients/ public only to name a few.
- v. **Negligence**: This involves cases where a pharmacy professional fails to exercise reasonable care or provide an appropriate standard of care, resulting in harm to patients. Examples may include failure to identify potential drug interactions, failure to properly counsel patients on medication use, or failure to detect and report medication errors.



#### Class II: Abuse of trust by pharmacy professionals

This refers to situations where pharmacy professionals who exercise their authority and knowledge to take advantage of employers, patients, public, colleagues, or the healthcare system for personal gain or unethical purposes.

Abuse of trust also encompasses any pharmacy professional who is given or entrusted with an item and is obliged to return it or use it as instructed but misappropriates, embezzles, scatters, or gives it to another person.

This includes but is not limited to:

- i. **Diversion of medication**: Pharmacy professionals who divert prescription drugs or other medical supplies intended for patients for their own personal use or for illegal distribution.
- ii. **Prescription fraud**: This involves forging or altering prescriptions or engaging in other fraudulent practices to obtain medications for personal use or unauthorized distribution.
- iii. **Unauthorized access to patient information**: Pharmacy professionals abusing their access to patient records or confidential information to obtain personal information or misuse it for personal gain, such as identity theft or fraudulent activities.
- iv. **Theft or misappropriation of funds:** This can include but is not limited to embezzlement or stealing money from the institution's accounts, insurance claims fraud, or manipulating financial transactions for personal benefit or unlawful enrichment from unethical behavior.
- v. **Substance Abuse:** This pertains to cases where pharmacy professionals misuse or abuse drugs or alcohol, potentially impairing their professional judgment and posing risks to patient safety.
- vi. **Dispensing counterfeit or substandard medications:** Pharmacy professionals may knowingly or unknowingly dispense counterfeit or substandard medications, compromising patient safety and health.



- vii. **Unethical business practices**: This can involve bribes, or conflicts of interest where pharmacy professionals engage in unethical relationships with the public, pharmaceutical companies, healthcare providers, or suppliers that compromise public health.
- viii. **Unauthorized practice or provision of services**: Pharmacy professionals who engage in the unauthorized practice of pharmacy profession or provide services outside their scope of practice, risking patient safety and violating professional regulations.
  - ix. **Fraudulent billing practices:** This refers to cases where pharmacy professionals intentionally overcharge patients or insurance providers, submit false claims, or engage in fraudulent billing practices resulting in financial loss to patients or healthcare systems.
  - x. **Dishonesty of a pharmacy professional**: which refers to cases where a pharmacy professional engages in other deceptive or fraudulent practices that violate the principles of honesty, integrity, and professional ethics;
  - xi. **The exploitation of vulnerable patients:** refers to taking advantage of vulnerable patients, such as elderly or mentally impaired individuals, by overcharging for medications, providing unnecessary or excessive medications, or manipulating billing practices.

# Article 3: Principles governing the disciplinary measures

Investigation of professional fault and imposing related sanction must be in respect of the following principles:

- 1. A pharmacy professional alleged to have committed a professional fault shall continue being respected for his /her inalienable rights as a human being;
- 2. No professional sanction shall be imposed without prior consideration of the means of defense of the pharmacy professional.
- 3. The sanction for a professional fault shall be based on its category/gravity / class;
- 4. Determining the sanction for a professional fault shall base on the gravity i.e., severity or class of the fault;
- 5. A professional fault and the disciplinary sanction shall be independent from the criminal or civil liabilities and related proceedings;
- 6. A professional disciplinary action is independent of judicial prosecution due to fault or offenses committed



- 7. The liability of a professional fault shall be personal; the disciplinary proceeding shall be conducted in a clear way, reasonable manner with due transparency, impartiality and professionalism.
- 8. The principle of equity denotes the judicious application of fairness and justice, especially when clear guidelines are absent or ambiguous.

It mandates the committee or the National Council Board that when a strict adherence to guidelines might result in undue consequences, discretion is employed to achieve a balanced outcome. This entails recognizing unique circumstances not clearly addressed by the guidelines and using equitable judgment to ensure that disciplinary actions are fair, proportionate, and consistent with the overarching principles of justice and fairness.

# CHAPTER II. PROFESSIONAL MISCONDUCTS/MALPRACTICE AND THEIR SANCTIONS

#### Article 4: Description of professional misconducts/malpractice and their sanction

#### Minor misconduct/fault:

This is the **category I** of professional misconduct and malpractice. A minor misconduct/fault refers to a relatively less serious or less severe violation of the law or regulation governing the pharmacy profession as determined by the National Pharmacy Council. It typically involves conduct that is considered less harmful or carries a lower penalty compared to more serious misconduct/faults.

Upon conviction, the pharmacy professional shall be sanctioned with a warning letter, unless the severity of the malpractice warrants a reprimand or suspension. A suspension may last up to three months, during which time the pharmacy professional will lose the right to vote and be elected in the organs of the Council. If the pharmacy professional has already been elected, s/he will be automatically removed from office.

# Moderate misconduct/fault:

This is **category II** of professional misconduct and malpractice. A moderate misconduct/fault refers to a violation of the law or regulation governing the pharmacy profession that is of intermediate severitUpon conviction, the pharmacy professional is temporarily suspended for three to six (3- 6) months with the loss of the rights to vote and to be elected in the organs of the Council for a period of three (3) years, and with automatic removal from office if the pharmacy professional has been already elected.



The case shall be submitted to the competent authority for prosecution as determined by the law establishing the offenses and penalties in general.

In addition to the sanction, the National Pharmacy Council may recommend additional training before re-licensure, at its discretion and depending on the degree or severity of the misconduct.

# Severe misconduct/fault:

This is **category III** of professional misconduct and malpractice that has a **very serious** negative impact or consequence to the public or pharmacy profession honor and dignity. The sanction of the misconduct/fault shall be temporal removal from the register of the pharmacy professional until the end of the sentence with the loss of rights to vote and to be elected in the organs of the Council, and with automatic removal from office if the pharmacy professional has been already elected. In addition to the sanction, the National Pharmacy Council may recommend additional training before re-licensure, at its discretion and depending on the degree or severity of the misconduct.

# Article 5: Temporary suspension of a pharmacy professional by the Bureau of the National Council Board

Awaiting the decision of the National Council Board which must be taken within thirty calendar days (30 days), the Bureau of the National Council Board may temporarily suspend a pharmacy professional suspected of having committed a serious misconduct punishable by temporary suspension or removal from the Register of the members of the Council.

Without prejudice to the provisions of the Paragraph One of this article, a pharmacy professional who is subject to removal from the Register of members of the Council for gross misconduct may apply for re-registration on the register after three (3) years.

The National Council Board which had taken such a measure shall reconsider it to make a final decision.



# **CHAPTER III: DISCIPLINARY PROCEDURES**

# Article 6: Application of the Code of Ethics

Without prejudice to other legal and professional provisions, the Council shall, in all cases, apply the principles and provisions of the Code of Ethics of the Pharmacy profession during:

- 1. Investigations,
- 2. Sanctioning,
- 3. Ethical review of the pharmacy profession.

# Article 7: Disciplinary action(s)

The Council shall institute disciplinary action(s) against a pharmacy professional on its own initiative or upon the request by any other interested person.

# **Article 8: Disciplinary Measures**

Disciplinary measures that may be taken by the Council against a pharmacy professional in contravention of laws regulating the pharmacy profession are:

- 1. Warning;
- 2. Reprimand;
- 3. Temporary suspension to practice for a period not exceeding twelve (12) months;
- 4. Removal from the register.

# Article 9: Responsibilities of the Committee

The Committee is responsible for examining all complaints against pharmacy professionals and recommending the decisions to the Bureau for review and enforcement.



# **Article 10: Functions of the Committee During Disciplinary Proceedings**

The committee shall have the following functions:

- 1. To ensure that the rights and obligations of the pharmacy professional subject to the disciplinary proceedings are made known to him before the hearing;
- 2. To hear and decide upon charges presented to the Committee by the provisions of laws, internal rules, and regulations governing the pharmacy profession and of these guidelines;
- 3. To ensure that disciplinary hearings are carried out in a fair and orderly manner by giving adequate opportunity to both the plaintiff and suspected pharmacy professional accused of malpractice or misconduct, to present their evidence and witnesses and to support their cause and make cross-examination.

# Article 11: Introduction of a complaint

Any complaint or request brought to the attention of the Council is addressed in writing to the Chairperson of the Council.

# Article 12: Reception of the Complaint

The Bureau through the Permanent secretariat receives the complaint and transmits it to the Committee to analyze the nature of the complaint and recommends resolutions thereof.

# Article 13: Investigation of the case

When a case is presented to the Council, and transmitted to the committee, it must be thoroughly investigated taking into consideration the following aspects:

- 1. The prospect of the case leading to the finding of actual misconduct;
- 2. The need to ensure the proper interpretation of the code of ethics and the need to keep this updated with current realities;
- 3. The need to protect the public health against malpractice and misconduct on both a professional and ethical basis;
- 4. The need for ensuring that the rules, honor and dignity of the pharmacy profession are complied with and ensure the protection of public health.
- 5. And any other matter deemed necessary or relevant to the complaint in question



After the investigation, on the basis of sufficient and relevant facts, the Committee can decide to:

- 1. Recommend for alternative dispute resolutions between parties (negotiation, mediation, conciliation, arbitration);
- 2. Consider the case closed and take no further action;
- 3. Suspend the case until further notice for valid grounds;
- 4. Take further action against the pharmacy professional;
- 5. Recommend the case to be handled by Competent courts of law

# Article 14: Summoning a pharmacy Professional

A pharmacy professional suspected to be involved in disciplinary misconduct/fault is summoned to appear before the Committee. The summon letter shall outline the fault. The summon letter is submitted to the official email of the addressee, administrative authorities, relative, employee, or employer.

The summon letter is issued at least five (5) to fifteen (15) calendar days before his/her appearance before the Committee and summoned pharmacy professional must react in writing with the facts to the alleged misconduct/fault before appearance to the committee. In case of emergency due to the serious impact of the misconduct/fault to the profession and /or public health, the summon period may range from two (2) to five calendar days (5).

The summon letter is signed by the Chairperson of the Council, Deputy Chairperson, Registrar or any delegate assigned the power by the Chairperson of the Council. The summoned pharmacy professional has the right to be assisted by one or more witnesses.

# Article 15: Appearance before the Committee

During his/ her appearance before the Committee, the claimant must prove a claim, failing which the respondent wins the case.

Likewise, a party who alleges that he/she has been discharged from an obligation established by evidence must justify the cause as a result of which the obligation has extinguished. Failure to do so, the other party wins the case.



# Article 16: Postponement or Adjournment of the Proceedings

Where before the date of the hearing of an inquiry or at any stage of the hearing either the plaintiff or the defendant/suspect brings to the attention of the Committee that there is a justified cause for the postponement or adjournment of the hearing; the Committee shall discuss the merits of this reason and decide accordingly to adjourn or proceed with the hearing of the case.

# Article 17: The Hearing of the Case

The summoned pharmacy professional is heard in a free and fair hearing. After hearing the summoned pharmacy professional, the Committee hears the witness (es) of both parties where applicable.

The statements are recorded in writing by the rapporteur of the Committee and signed by the witness(es), the Chairperson of the Committee, the pharmacy professional, the rapporteur as well as the committee members.

However, the non-signature of the summoned pharmacy professional/ alleged person (plaintiff or defendant) does not impact the enforcement of the decision taken.

The Hearing shall be conducted physically in person, unless otherwise provided by the National Council Board.

The report of hearing is recorded as minutes.

# Article 18: Conduct of the Hearing of other Professional Faults not provided for by these Guidelines

The disciplinary hearings of the Pharmacy professional must adhere to the following substantial principles:

1° being fair and impartial;

2° Respect the right to defense;

- 3° Transparency and principles of laws;
- 4° Based on evidence lawfully produced



The disciplinary procedure is carried out and completed in accordance with the laws governing the pharmacy profession in Rwanda, the internal rules and regulations of the Council, and any other approved document of the National Pharmacy Council relevant to the case. In case of absence of legal document, the committee shall use the equity in conducting and deciding on the case.

If a pharmacy professional commits an act/omission or behaves in a way that violates his/her professional obligations, and such conduct is not specifically listed as a professional fault in these disciplinary guidelines, the National Council Board, upon the recommendation of the ethics and disciplinary committee, shall determine the severity of the act(s), omission(s), or behavior as a professional fault and impose the appropriate sanction from among those provided for in these guidelines, following the established procedure.

# Article 19: Procedure for Conducting the Hearing

The Chairperson of the Committee or his/ her representative is responsible for conducting and closing the hearing. The hearing is conducted in the following order:

1° the Council states the date, time, and place of the hearing;

2° The Chairperson of the Committee announces the commencement of the hearing;

3° the rapporteur of the Committee calls upon the parties and reads out the initial charges;

4° the Chairperson examines whether the identities of the parties are complete and agrees with the parties on their particulars;

5° the Chairperson examines the identities of the witnesses, if present, and asks the parties if there are witnesses that are not accepted and confirm those who will be heard, puts them in private and separates them;

6° the Chairperson of Committee asks the parties to indicate the facts of the case and evidence;

7° if the Pharmacy professional admits the charge; the Committee shall investigate the relevance and proceeds with hearing;

8° in case the Pharmacy professional refutes the charge, the Chairperson of the Committee asks the plaintiff to justify his claim(s), and if necessary, he calls upon the witnesses to testify;



9° on the other hand, the Chairperson of the Committee asks the defendant pharmacy professional to present his/her defense, and where necessary, the defense witnesses are given the opportunity as well;

 $10^{\circ}$  parties can cross-examine witnesses of the other party where necessary

11° the Chairperson and the other members of the Committee can, at any time, during the presentation of evidence and examination of witnesses ask questions that can assist the Committee to understand the submissions of parties and to examine whether the evidence and their relevancy as presented by parties regarding each point in the case are understood clearly and similarly, whether on the side of the Committee as well as on the side of the parties;

12° parties are allowed to respond to the testimony, and where necessary, to cross-examine each other or between them and witnesses;

13° After hearing all parties on all points of the case, the Committee Chairperson closes the hearing and informs the parties that the Council will announce its decision on a given date;

14° After the hearing, the chairperson, rapporteur, committee members, parties, and witnesses sign the hearing minutes. The lack of a signature from a party or witness does not affect the validity of the resolutions;

15° The decision is delivered by the channels used in article 14

# Article 20: Procedure for deliberation of a case

After the closure of the hearing, the Committee shall deliberate on the facts, evidence, and arguments presented by both parties to determine, whether the misconduct/fault has been fully proven, partially proven, or not proven.

When the misconduct/fault has not been adequately proven, the Committee shall clear the suspect pharmacy professional of the charge(s) brought against him or her.

When the Committee determines that the misconduct/fault has been fully or partially proven, the misconduct/fault shall consequently classify itself as minor, moderate, or severe and then determine the appropriate disciplinary sanction to be applied in such a case as annexed in the appendices.



The sanction to be applied shall reflect, but not exclusively, the principles of:

- a) Proportionality to the breach in the Code of ethics;
- b) Proportionality to the negative impact on the honor and dignity of the pharmacy profession or its practice;
- c) Proportionality to the negative effects, both material and non-material, to the aggrieved person or entity and on the public health in general.
- d) Fair justice in compliance with the laws applicable in Rwanda, regulations and guidelines regulating the pharmacy profession and pharmacy professionals.

# Article 21: Confidentiality of the Deliberations

All pharmacy professionals, members of the Council's organs, and participants in the Council's functioning are bound by professional secrecy for any information they gain or acquire in the course of their duties, even after they cease to perform those duties. This applies to both parties in a hearing.

A breach of confidentiality is punishable in accordance with Rwandan law and these disciplinary guidelines. However, final cases handled by the ethics and disciplinary committee may be used as precedents, and this is not considered a breach of confidentiality.

# Article 22: Sanction

After hearing the parties, the Committee shall recommend the decision to be taken by the Bureau of the National Council Board and/ or the National Council Board following the report of its findings.

The sanction for misconduct/fault classified by the Committee as minor, moderate, or severe shall be as specified in Chapter II of these guidelines

In any case, recidivism imposes the aggravation and the severity for the disciplinary measures to be pronounced.

# Article 23: Notification of the sanction

The decision of the bureau and the National Council Board shall be notified to the concerned person by means of a registered mail or hand-delivered to him/her or through any other means of communication against acknowledgment of receipt within thirty (30) calendar days from the date the decision was taken.



Any decision made by the Council in disciplinary matters shall be duly validated, both in law and in act. It shall be notified to the person concerned and the pharmacy professional.

A decision to sanction a pharmacy professional with a suspension or removal from the register shall take effect within thirty (30) calendar days after notification to the concerned practitioner.

However, if the facts stated in defense of the pharmacy professional pose a severe danger to public health or honor and dignity of the pharmacy profession, the Bureau and /or Board shall declare the suspension or removal immediately enforceable.

The Council has the right to notify all stakeholders that may facilitate the enforcement of a measure against a pharmacy professional, including but not limited to the Ministry of Health, Rwanda FDA, Rwanda Investigation Bureau, the National Public Prosecution, local government, private sector, general public, and other government or private agencies. The pharmacy professional's failure to acknowledge receipt of the sanction does not affect the measure taken against them.

# Article 24: Notification to the Minister

The National Council Board shall notify the Minister of Health of any disciplinary decision within 30 calendar days of making the decision.



# **CHAPTER IV: REMEDIES**

# Article 25: Notice of right of appeal and opposition

When notifying a person or institution of any decision made by the Council as the outcome of the hearing of a pharmacy professional, the Council shall, at the same time, inform such a person or institution of his/her right to oppose or appeal against the decision of the Council.

# Article 26: Opposition

A pharmacy professional against whom a measure was taken in absentia may file an opposition to such action within fifteen (15) calendar days of notification.

When the person who has filed an opposition fails to appear once again without acceptable reasons he/she can no longer file a new opposition.

# Article 27: Lodging an opposition

The opposition is filed by registered mail or by any other means with the guarantee for reception, addressed to the Chairperson of the National Pharmacy Council within fifteen (15) calendar days from the notification of the decision taken in absentia. The submissions for opposition must contain proof justifying reasons for failure to appear in the hearing of the case to be reviewed in opposition.

# Article 28: Admissibility of opposition

Opposition is accepted only when the pharmacy professional who failed to appear in the first hearing presents an exceptional and serious reason for his/her absence backed by evidence otherwise, it is rejected. In any case, no one may apply for new opposition.

# Article 29: Effect of an opposition application

The opposition formed timely and following the procedures described in these guidelines suspends the execution of the disciplinary measures taken against the Pharmacy professional unless the bureau/Board has declared an immediately enforceable decision as stipulated in article 23.



# Article 30: Procedure for opposition hearing

When the opposition is accepted, the hearing procedure is the same as provided in article 19. The decision that is subject to the opposition is quashed only by the resulting new decision.

# Article 31: Right of appeal

The appeal shall be made in writing. An official letter shall be addressed to the Chairperson and shall be sent to the official address of the Council. Such an appeal may be made within thirty (30) calendar days from the date of its notification either by the concerned pharmacy professional or by the Minister in charge of health or any other interested person.

The notification is as for article 23.

The appeal against a measure shall lead to the suspension of its enforcement.

# Article 32: Lodging an appeal

Within the period specified in Article 31, any person or institution affected by a decision of the Council (hereinafter referred to as the plaintiff) may file a notice of appeal with valid grounds for appeal.

# Article 33: Notification of an appeal

The notice of appeal shall be made in writing and addressed to the Chairperson of the Council containing the following information:

- 1. The Council decision against which the appeal is lodged,
- 2. The ground for appeal against the Council decision,
- 3. The relief that the plaintiff is seeking.
- 4. Evidences to support the appeal.

# Article 34: Procedure for the Appeal hearing

The National Council Board is the appeal organ of the Council.

However, the National Council Board may delegate power to some of its members as an appeal committee for purposes of hearing the appeal.



No member of the appeal committee may be a member of the Disciplinary Committee, from which the original decision emanated, or may have been involved in the process leading to the decision.

After the receipt of the notice of the appeal, the Chairperson of the Council shall determine a date, place, and time for the hearing.

The chairperson of the Council shall inform the appellant of place and time of the appeal hearing at least fifteen (15) calendar days before the appeal is heard.

The procedure for hearing applicable in article 19 shall govern the hearing procedures during the appeal.

The parties may address the appeal committee on the merits at the hearing, and thereafter the appeal shall deliberate in privacy on the matter. The sanctions in annex shall be applied in a fair justice.

# Article 35: Findings of the appeal organ

The appeal organ shall:

- 1) Confirm the decision of the disciplinary committee;
- 2) Reduce the sanction imposed by the disciplinary committee;
- 3) Increase the sanction imposed by the disciplinary committee;
- 4) Issue a declaration that the decision of the disciplinary committee is invalid or unenforceable;
- 5) Order the disciplinary committee to conduct further investigations;
- 6) Repeal the decision of the disciplinary committee;
- 7) Dismiss the appeal.

The decision of the National Council Board must be put in writing and communication to the plaintiff and pharmacy professional within thirty (30) calendar days.

The decision of the Council shall be in force and effect from the date determined by the Bureau or the National Council Board and is communicated to the Minister having health in his or her attributions as provided in the articles 23 and 24.



The Disciplinary proceedings against a pharmacy professional shall not prevent:

- 1) legal proceedings in criminal courts;
- 2) legal proceedings before civil courts;
- 3) Administrative proceedings
- 4) Suspension of the pharmacist's license
- 5) Revocation of the pharmacist's license
- 6) Other means of disputes resolutions such as mediation, conciliation, negotiation, arbitration
- 7) disciplinary proceedings before other government or non-government agencies.

# Article 36: Records

Through the Council secretariat, the Council shall keep, in printed or electronic form, records of the charge, the decision of the Committee, and of the disciplinary measure taken.

All documentation, evidence, and transcripts of the procedures shall be duly filed and kept in the Council secretariat for five (5) years.

The Secretariat shall file and store the records in a manner that ensures their preservation, access, and reference by the Council, the Committee, and the general public.

# Article 37: Repealing provision

All prior provisions contrary to these guidelines are repealed, and these guidelines shall not retrospectively applicable.

# Article 38: Commencement

These guidelines are considered and adopted on July 14, 2023, and become enforceable immediately.



# ANNEX: COMMON PROFESSIONAL FAULTS/ MALPRACTICE AND THEIR SANCTIONS

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SN.	MALPRACTICE/FAULT	CITATION OF THE LAW	CATEGORY OF THE MALPRACTICE/ MISCONDUCT	MEASURES TO BE TAKEN
1	General professional Malpractice (Abuse of the Pharmacy profession class I as defined in article 2)	Ministerial order No 20/37 of 30/10/2015 determining the code of ethics for the pharmacy profession. Article.5. Law No 45/2012 of 14/01/2013 on organization, functioning and competence of the Council of Pharmacists. Art. 3,4,17,27,28 & 29	Minor	Upon conviction, the pharmacy professional shall be sanctioned with a warning letter, unless the severity of the malpractice warrants a reprimand or suspension. A suspension may last up to three months, during which time the pharmacy professional will lose the right to vote and be elected in the organs of the Council. If the pharmacy professional has already been elected, s/he will be automatically removed from office.
2	Failure to exercise professional judgment and act in the interest of the public due to personal interest or any other reason behind it.	Ministerial order No 20/37 of 30/10/2015 determining the code of ethics for the pharmacy profession.Art.6&9 Law No 45/2012 of 14/01/2013 on organization, functioning and competence of the Council of Pharmacists. Art. 3,4,17,27,28 &29	Minor	Upon conviction, the pharmacy professional shall be sanctioned with a warning letter, unless the severity of the malpractice warrants a reprimand or suspension. A suspension may last up to three months, during which time the pharmacy professional will lose the right to vote and be elected in the organs of the Council. If the pharmacy professional has already been elected, s/he will be automatically removed from office.



3	Failure to protect the professional secrecy/confidentiality of patients/clients aside from the cases provided by the laws.	Constitution of the republic of Rwanda, art ,23 Law No 45/2012 of 14/01/2013 on organization, functioning and competence of the Council of Pharmacists. Art. 3,4,17,27,28, 29 &31. Ministerial order No 20/37 of 30/10/2015 determining the code of ethics for the pharmacy profession. Art.4	Moderate	Upon conviction, the pharmacy professional is temporarily suspended for three to six (3- 6) months with the loss of the rights to vote and to be elected in the organs of the Council for a period of three (3) years, and with automatic removal from office if the pharmacy professional has been already elected. The case shall be submitted to the competent authority for prosecution as determined by the law establishing the offenses and penalties in general. In addition to the sanction, the National Pharmacy Council may recommend additional training before re-licensure, at its discretion and depending on the degree or severity of the misconduct.
4	Abuse of the trust by Pharmacy professional (Abuse of the Pharmacy profession class II defined in article 2)	Law No 45/2012 of 14/01/2013 on organization, functioning and competence of the Council of Pharmacists. Art. 3,4,17,27,28,29 &31.	Moderate	Upon conviction, the pharmacy professional is temporarily suspended for three to six (3- 6) months with the loss of the rights to vote and to be elected in the organs of the Council for a period of three (3) years, and with automatic removal from office if the pharmacy professional has been already elected.

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5	A Pharmacy professional is convicted by a court of an offense (petty offense, misdemeanor) with an impact on the pharmacy profession.	Law No 45/2012 of 14/01/2013 on organization, functioning and competence of the Council of Pharmacists. Art. Art. 3,4,17,27,28, 29& 35, alinea2. Ministerial order No 20/37 of 30/10/2015 determining the code of Ethics for the pharmacy profession.Art.5	Severe	The case shall be submitted to the competent authority for prosecution as determined by the law establishing the offenses and penalties in general. In addition to the sanction, the National Pharmacy Council may recommend additional training before re-licensure, at its discretion and depending on the degree or severity of the misconduct. Temporal removal from the register of the pharmacy professional until the end of the sentence with the loss of rights to vote and to be elected in the organs of the Council, and with automatic removal from office if the pharmacy professional has been already elected. In addition to the sanction, the National Pharmacy Council may recommend additional training before re-licensure, at its discretion and depending on the degree or severity of the misconduct.
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6	Pharmacy professionals who illegally (not in conformity with the requirements of the laws) manufacture, import, prepare, package, label, store, keep, exhibit, register, market, advertise, publicize, distribute, cause to distribute, sell, donate pharmaceutical products, foods, medical devices, and cosmetics	Law No 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products Art. 5,6, 7, 8, 9,10, 11, 12, 13,14,15, 16,17,18,19,20,21,22,23,24,25,26,27,2 8,33,34,35,37,38, 40,43. Ministerial order No 20/37 of 30/10/2015 determining the code of Ethics for the pharmacy profession. Law No 45/2012 of 14/01/2013 on organization, functioning and competence of the Council of Pharmacists. Art. Art. 3,4,17,27,28 &29	Severe	Suspension of the convicted pharmacy professional from six months up to twelve months (6-12 months), with the loss of the rights to be elected in the organs of the Council, and with an automatic removal from office if the pharmacy professional has been already elected. The Pharmacy professional will also lose the rights to vote for a period of three (3) years. The case shall be submitted to the competent authority for investigation and prosecution. In addition to the sanction, the National Pharmacy Council may recommend additional training before re-licensure, at its discretion and depending on the degree or severity of the misconduct.

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7	Pharmacy professionals actively involved in illegal distribution to the public of prohibited or controlled narcotic drugs and other pharmaceutical products.	Law 03/2012 of 15/02/2012 governing narcotic drugs, psychotropic substances precursors in Rwanda, Art. 7, 10, and 27. Law No47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products Art. 41. Law No 45/2012 of 14/01/2013 on organization, functioning and competence of the Council of Pharmacists. Art. 3,4,17,27,28 & 29	Severe	Suspension of the convicted pharmacy professional from six months up to twelve months (6-12 months), with the loss of his/her rights to be elected in the organs of the Council, and with an automatic removal from office if the professional has been already elected. The Pharmacy professional will also lose the rights to vote for a period of three (3) years. The case shall be submitted to the competent authority for investigation and prosecution. In addition to the sanction, the National Pharmacy Council may recommend additional training before re-licensure, at its discretion and depending on the degree or severity of the misconduct.
8	A Registered pharmacy professional in the practice of pharmacy profession without a valid license to practice	Law No 45/2012 of 14/01/2013 on organization, functioning, and competence of the Council of Pharmacists. Art. 3,4,17,27,28 &29 & 32.	Severe	Suspension of the convicted pharmacy professional from six months up to twelve (6-12) months, with the loss of the rights to be elected in the organs of the Council, and with an automatic removal from office if the pharmacy professional has been already elected. The Pharmacy professional will also lose his/her rights to vote for a period of three (3) years.



				The case shall be submitted to the competent authority for investigation prosecution of the pharmacy professional and his/her employer. In addition to the sanction, the National Pharmacy Council may recommend additional training before re-licensure, at its discretion and depending on the degree or severity of the misconduct.
9	A non-registered pharmacy graduate in the practice of pharmacy profession	Law No 45/2012 of 14/01/2013 on organization, functioning, and competence of the Council of Pharmacists. Art. 3,4,17,27,28, 29 & 32	Severe	The case shall be submitted to the competent authority for investigation and prosecution of the pharmacy graduate and his/her employer and the professional shall be denied for the registration permanently as a pharmacy professional
10	Misrepresentation of qualifications: providing false or misleading information regarding qualifications,	Law No 45/2012 of 14/01/2013 on organization, functioning and competence of the Council of Pharmacists. Art. 3,4,17,27,28 &29	Severe	Removal from the register, with the loss of the right to vote and be elected in the organs of the Council, and with automatic removal from office if the pharmacy professional has already been elected. If the misrepresentation was provided to obtain registration with the Council, the applicant shall be

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	credentials, or other required documents to obtain or maintain registration as a pharmacy professional (Forgery, falsification and use of forged documents)	Law Nº68/2018 of 30/08/2018 determining offences and penalties in general. Article 243 & 276		denied permanent registration. The case shall be submitted to the competent authority for investigation and prosecution of the pharmacy professional.
11	A Pharmacy professional is convicted by a court of an offense of felony with an impact on the health profession.	Law No 45/2012 of 14/01/2013 on organization, functioning and competence of the Council of Pharmacists. Art. 3,4,17,27,28,29& 35, alinea2.	Severe	Temporally removal of the pharmacy professional from the register with the loss of the rights to vote and to be elected in the organs of the Council, and with automatic removal from office if he /she has been already elected. In addition to the sanction, the National Pharmacy Council may recommend additional training before re-licensure, at its discretion and depending on the degree or severity of the misconduct.

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#### **LEGAL REFERENCES**

- 1. Constitution of the Republic of Rwanda
- 2. Law Nº 027/2019 of 19/09/2019 relating to the criminal procedure
- 3. Law Nº68/2018 of 30/08/2018 determining offenses and penalties in general.
- 4. Law nº 22/2018 of 29/04/2018 relating to the civil, commercial, labor and administrative procedure
- 5. Law No 45/2012 of 14/01/2013 on organization, functioning, and competence of the Council of Pharmacists.
- 6. Law No 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products
- 7. Law 03/2012 of 15/02/2012 governing narcotic drugs, psychotropic substances precursors in Rwanda.
- 8. Ministerial order No 20/37 of 30/10/2015 determining the code of ethics for the pharmacy profession.
- 9. Internal rules and regulations of the Rwanda National Pharmacy Council