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MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

GUIDELINES FOR REGISTRATION AND LICENSING OF PREMISES

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ABBREVIATIONS

CPD	Continuing Professional Development
FIP	International Pharmaceutical Federation
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
GPP	Good Pharmacy Practice
KMPDC	Kenya Medical Practitioners and Dentist Council
KPA	Kenya Pharmaceutical Association
MoH	Ministry of Health
PPB	Pharmacy and Poisons Board
PSK	Pharmaceutical Society of Kenya
WHO	World Health Organization

GLOSSARY

The definitions given below apply to the terms as used in this document. They may have different meanings in other contexts.

"**Registered pharmacist**" means a person whose name is entered in the register of pharmacists in Kenya.

"Enrolled pharmaceutical technologist" means a pharmaceutical technologist whose name appears on the roll of pharmaceutical technologists in Kenya.

"Superintendent" means any person who is a manager and controls the business and is overall in charge of ensuring compliance.

"Premises" means the fixed portion of any building, structure or vessel leased, used, or controlled by the licensee in the conduct of the pharmacy business registered by the Board at the address for which the registration was issued under section 23 of the Pharmacy and Poisons Act and includes all those areas where medicinal products are, or are intended to be, sold or supplied, prepared, dispensed, compounded or stored.

"Registered premises" means premises registered in accordance with section 23 of the Pharmacy and Poisons Act, and where a valid certificate for registration is available.

"registered pharmacy" means any retail pharmacy premises and shall include, in cases where e-pharmacy or an online pharmacy practice has been licensed, the premises where the practice is domiciled.

A **"pharmacy"** is the premises upon which a pharmacy business is conducted and it includes:

(a) the portion of the premises where goods of any kind are for sale; and
(b) a professional service room.

The definition of a pharmacy does not include premises located in a public hospital controlled by a public health organization.

"Pharmacy Business" is where the dispensing and compounding of prescriptions for any substance specified as a Part 1 poison in the Poisons List proclaimed under the Pharmacy and Poisons Act occurs.

A **"new pharmacy"** is one in which the site has not been occupied by a pharmacy or a site which was previously occupied by a previous pharmacy business which has been closed. A 'new pharmacy' is not an existing pharmacy business which is notifying a change of partnership, trading name or trading address, or a change in part of the members of the board of directors or ownership.

"Professional services" means pharmaceutical services provided in accordance with approved professional qualifications and as licensed by the Board. A separate room within registered premises may be considered and approved for such services.

"Medical Product" means medicines, vaccines, blood and blood products and medical devices, including in-vitro diagnostics, food supplements, cosmetics, radiopharmaceuticals, cells, tissues and organs, complementary and alternative medicines and borderline products.

"Manufacture" means any process carried out in the course of making a product or medicinal substance and includes packaging, blending, mixing, assembling, distillation, processing, changing of form or application of any chemical or physical process in the preparation of a medicinal substance or product; but does not include dissolving or dispensing the product by diluting or mixing it with some other substances used as a vehicle for administration.

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The PPB gratefully acknowledges the contributions of the following persons who contributed to the guidelines:

1. Dr. Fred Siyoi CEO, Pharmacy and Poisons Board
2. Dr. Wilfred O. Oguta Director, Pharmacy Practice & Training, PPB
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7. Mr. George Muthuri Registration & Enrolment, PPB

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PREFACE

The Pharmacy and Poisons Board is the National Medicines' Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board is mandated to regulate the profession of Pharmacy, the manufacture and trade in medical products and health technologies. The overall goal is to maintain the required level of oversight while facilitating innovation and access to safe, effective and good quality medical products and professionals that are fit to practice.

Pursuant to the Pharmacy and Poisons Act, a person cannot carry on a pharmacy business in Kenya unless the premises have a current approval and all the holders of the financial interest in the pharmacy business are registered as pharmacists or enrolled as pharmaceutical technologists.

These Guidelines are intended to provide guidance to dealers in pharmaceuticals and the public on registration of premises and licensing of pharmaceutical business for purposes of manufacturing, storage and sale of medical products and pharmacy practice. It aims to highlight the minimum requirements for licensing and also guide through the licensure and registration process, how to apply for a pharmacy registration, and the types of licenses.

The guidelines are also intended to address challenges in the current practice environment, enhance implementation of current legislation, align licensing requirements with other PPB guidelines and respond to changes in technology.

These guidelines do not overrule the Law or the Regulations, and will be revised from time to time as policies are developed or amended to incorporate up-to-date practices.

Dr. F.M. Siyoi
CHIEF EXECUTIVE OFFICE

1. INTRODUCTION

The mission of the Board is to ensure that pharmaceutical services available in Kenya satisfy the needs of all for the prevention, diagnosis and treatment of diseases using safe, efficacious, high quality and cost-effective pharmaceutical products. This is also in line with Article 43(1)(a) of the Constitution of Kenya which provides that every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care.

The Pharmacy and Poisons Board (PPB) is the national regulatory authority established under the Pharmacy and Poisons Act, Cap 244 Laws of Kenya ("the Act"). The Act mandates the PPB to regulate medical products, health technologies and the profession of Pharmacy. Sec 3B (2)(j) of the law provides for the Board to carry out the function of inspecting and licensing all manufacturing premises, importing and exporting agents, wholesalers, distributors, pharmacies, including those in hospitals and clinics, and other retail outlets.

To enable performance of its regulatory functions, Section 3A of the Act empowers the Board to formulate guidelines and levy fees for services provided.

Pharmacy businesses can only operate on registered premises. Registered premises details are entered onto the Register on confirmation of satisfactory inspection of premises. Approval is subject to meeting the requirements provided in Guidelines for Good Distribution Practices for medical products and health technologies in Kenya, hereinafter referred to as "GDP guidelines". Every part of the pharmacy's operations must be on approved premises, following a satisfactory inspection by a Board. Proprietors cannot operate any part of its business, be it a pop-up stall, stand or mobile unit, that is outside the pharmacy's approved premises boundary.

Every registered premise will be under supervision of a registered pharmacist or enrolled pharmaceutical technologist (hereinafter called the superintendent) with a valid practice license. The superintendent will be

directly responsible for regulatory compliance. In the absence of the superintendent another duly licensed person may be engaged to offer services and oversee operations when the business is open. One person shall only be eligible to superintend over one registered premise at a time.

The Board has automated processes for registration and licensing for ease of doing business. All applications are made through the online licensing portal and the licenses or registration certificates issued are downloadable directly from the portal https://practice.pharmacyboardkenya.org/

Premises are issued with unique registration numbers and premise codes (health safety codes) which are verifiable through mobile phone short codes. The real-time license status is also verifiable through the Board's website. https://practice.pharmacyboardkenya.org/LicenseStatus

2. SCOPE

2.1. These guidelines apply to all premises that are subject to mandatory registration and licensure by law. All premises where medical products are manufactured, prepared, packaged, stored, supplied or dispensed. It also includes professional services rooms where pharmaceutical services and consultancies are offered. The main categories of premises are as follows:

2.1.1. Premises for Wholesale (for carrying on the business of a pharmacist)

2.1.2. Retail pharmacies

a) Premises for a pharmacist (for carrying on the business of a pharmacist) or

b) Premises for a pharmaceutical technologist (for carrying on the business of a pharmaceutical technologist)

2.1.3. Hospital pharmacies

2.1.4. Telehealth, telemedicine and Online/internet pharmacy services

2.1.5. Warehouses where medical products are stored

2.1.6. Manufacturing premises

2.1.7. Establishments for Medical Devices

2.1.8. Scientific Offices

2.2. In addition to premise license, these guidelines will also cover the annual licensing of:

2.2.1. Pharmacists

2.2.2. pharmaceutical technologists

2.2.3. pharmaceutical representatives

2.3. The scope of practice or the services or acts which can lawfully be performed carried on in the different types of premises and the conditions under which those services may be provided or the acts may be performed shall be as prescribed by the Board in regulations and guidelines.

3. GENERAL REQUIREMENTS FOR PREMISES

3.1. The minimum requirements for premises and standards of practice are contained in the Pharmacy and Poisons Board guidelines for Good Distribution Practices (GDP) for Pharmaceuticals (see separate document).

3.2. In addition, and in order to enhance service delivery to customers, licensed establishments shall be required to comply with Good Pharmacy Practice (GPP) standards as prescribed by the Board.

3.3. All licensed facilities will be inspected regularly to verify compliance with the Pharmacy and Poisons Act, other applicable laws and regulations as well as guidelines and standards prescribed by the Board.

4. LOCATION AND DESIGN

4.1. The premises shall be durable, safe and made of permanent building materials so as to protect pharmaceuticals from potential harmful influences and minimize the risk of unauthorized access to the premises and scheduled medicines in the premises.

4.2. The premises should be of a reasonable size

4.3. The Board shall consider the needs and population size of an area during evaluation of applications for registration of new premises. A reasonable distance (at least 200 meters) shall be maintained between any two registered premises to discourage unfair competitive trade practices.

4.4. Retail premise design may include a professional services room where licensed/approved professional services or consultation may be offered.

4.5. The premises shall be located away from sites or activities that emit obnoxious materials like fumes and contaminants, open sewerage, offensive trade etc.

4.6. Premises located within or near petrol stations shall be furnished in such a way that the activities including fuel fumes does not affect in any way the quality of medicines and dispensation process in the pharmacy. The premises shall be required to address among other issues, the fire prevention facilities.

4.7. Premises located within shopping centers, e.g. shopping malls, supermarkets etc., shall be confined and restricted from other activities conducted thereat.

4.8. Pharmacies located within hospitals or medical facilities will be licensed on condition that the medical facility is also duly licensed by the KMPDC.

4.9. In the case of pharmacies that operate within close proximity to, or within a medical center or a hospital, the pharmacy premises must be separate or distinct from the rest of the medical center and the premises must be approved by the Board.

5. OWNERSHIP AND BENEFICIAL INTERESTS

5.1. The ownership of pharmacies may be:

5.1.1. A sole proprietor, or;

5.1.2. A partnership, or;

5.1.3. A limited company/body corporate, or;

5.1.4. Other structures of companies established in the Companies Act 2015.

5.2. Applicants shall provide documents to demonstrate the interests held by all parties in the respective type of business

5.3. Ownership by non-pharmacy professionals is not allowed. Exemptions may be given to pharmacies within medical centers or hospitals, pharmacies owned by not for profit organizations and faith-based organizations

5.4. In addition to the information and documentation provided by the applicant, the Board may conduct a search of the records kept by the Registrar of Companies to verify the registered owners of any establishment making an application for registration of premises or Wholesale Dealer's License.

6. PERSONNEL

6.1. Manufacturing facilities shall be under the control of one or more authorized and qualified persons to be responsible for compliance.

6.2. In addition to the authorized and qualified person(s), local manufacturing facilities, wholesale dealers who are local technical representatives of foreign MAH and parallel importers shall have a Qualified Person for Pharmacovigilance.

6.3. Premises where sale, supply, stocking, dispensing and compounding of any pharmaceutical product on retail or wholesale basis shall not be registered/licensed or renewed unless there is a superintendent who is a registered pharmacist or enrolled pharmaceutical technologist in direct control of distribution of medical products.

6.4. The superintendent shall not act in a similar capacity for any other premise or be someone engaged in a full-time job in other establishments.

6.5. If the owner is not a superintendent, he shall be made to sign a contract agreement with the superintendent of which among other things shall address the terms of terminations. A copy of the contract agreement shall be presented to the Board at the time of submitting the application for registration of premises

6.6. The superintendent shall be available to oversee the distribution of medical products at the facility.

6.7. The superintendent may be assisted by one or more duly qualified and licensed pharmacists or pharmaceutical technologists depending on the workload. This should be subject to audit from time to time to assess workload versus licensed personnel

6.8. If the owner is not a superintendent, he shall be made to sign a contract agreement with the superintendent of which among other things shall address the terms of terminations.

6.9. The owner and superintendent shall individually and jointly ensure that unqualified personnel who do not possess the prerequisite knowledge or license do not have access to handling or dispensing of pharmaceuticals.

6.10. Registered pharmacists and enrolled pharmaceutical technologists are expected to participate in adequate continuing professional development (CPD) activities every year.

6.11. Only persons who are duly licensed are allowed to offer professional services in licensed establishments. An exception to this will be

pharmacy students on attachment and interns working under supervision of an approved preceptor.

7. PRACTICE LICENSES

7.1. All registered pharmacists and enrolled pharmaceutical technologists shall be required to obtain annual practice licenses in the manner prescribed by the Board irrespective of whether they superintend over an establishment.

7.2. A person who is not a superintendent but is domiciled in a specific establishment must obtain a license under that establishment or premise

7.3. A person who is not domiciled in any establishment or premise may obtain a license as a locum but shall, if the status changes so that the person is engaged full time by a specific establishment or premise, apply for variation of licence to be domiciled in the new place.

7.4. Variation of a licence may be made by any licensed person only once in a year.

7.5. A person who meets the requirements for a specialist or consultant license may apply for such a license and will be eligible to offer consultancy services in approved premises or professional services rooms.

7.6. A person who meets the requirements for a pharmaceutical representative and intends to work as such shall apply for a permit annually.

8. ELIGIBILITY TO SUPERINTEND

8.1. A Pharmacist shall only be eligible to superintend over registered premises if he/ or she holds a valid practice licence.

8.2. A pharmaceutical technologist shall only be eligible to superintend over premises registered for a pharmaceutical technologist and only if he/ or she:

8.2.1. holds a valid license to practice as a pharmaceutical technologist and

8.2.2. has worked under supervision of another qualified superintendent (pharmacist or pharmaceutical technologist) for a period of not less than three (3) years from the time of enrolment as a pharmaceutical technologist.

8.3. In addition to the above, the Board may prescribe additional requirements and/or assessments for fitness to practice as may be necessary

9. BUSINESS NAMES

9.1. The Board shall consider the names of all pharmacies for suitability and approve or decline.

9.2. Pharmacy names that are false, misleading, deceptive, or imply an unjustified expectation of beneficial treatment or promote unnecessary or inappropriate use of pharmacy services will not be approved.

9.3. Names which suggest or imply an activity or a location which cannot be supported may also be rejected by the Board.

9.4. Pharmacy business names are required to be registered by the Registrar of Companies as per the Companies Act, 2015.

9.5. It is in the pharmacy proprietors' best interests to make their own enquiries about company registration before proceeding.

9.6. If the applicant has any doubts about a pharmacy business name, they should seek the advice of the Board in the first instance.

9.7. The Board will require that a business name, as approved by the Board and registered as a business name, be used without abbreviation wherever it is used. This particularly includes:

9.7.1. all signage inside or outside of the pharmacy

9.7.2. advertisements, including telephone directories

9.7.3. business cards, labels, stationery, prescription stamps, envelopes and computer-generated documents including repeat authorizations.

10. EQUIPMENT AND STORAGE FACILITIES

10.1. The basic equipment that must be available in the premises are prescribed in the GDP guidelines.

10.2. There should be adequate storage space. The premises are to be laid out and equipped so that:

10.2.1. any medical product stored in the premises can be stored in accordance with the relevant medical product's storage conditions, and

10.2.2. all the medical products being prepared, packaged or stored in the premises, for supply to a particular patient or to a health care facility for supply to a particular patient or resident of that facility, can be stored together, and

10.2.3. any documentation physically stored in the premises relating to that patient or resident can be stored with those medical products.

10.3. The requirements for manufacturing license are prescribed as per Good Manufacturing Practices guidelines and are specific to the categories of medical products manufactured in the facility.

11. RESOURCES FOR PHARMACY PREMISES

11.1. Before starting the business, approved applicants will be required to procure pharmacy reference materials related to the type of business.

11.2. There should be adequate access to electronic publications of reference materials.

12. PREMISES REGISTRATION NUMBERS, LICENSE NUMBERS AND CODES

12.1. Every registered premises shall be issued with a unique registration number and codes (Health Safety Code).

12.2. Licenses renewed annually will also bear a unique number for each license.

12.3. The Health Safety codes (numbers) issued by the Pharmacy and Poisons Board have a prefix of "P" for pharmacists' and "PT" for pharmaceutical technologists' premises respectively.

12.4. The licenses and codes are supposed to be displayed conspicuously to enable interested parties to verify the license status of the premises.

13. DISPLAY OF LICENSES AND NAMES

13.1. The name and certificate of registration of the person having control of the business are to be conspicuously exhibited in the premises in which the business is carried on as provided in section 20 of the Pharmacy and Poisons Act.

13.2. Wherever the display of a pharmacist or pharmaceutical technologist's name is made, the name must be consistent with the name recorded on the Register of Premises held by the Board, and the Register of Pharmacists or Roll of Pharmaceutical Technologists held by the Board. Nicknames, abbreviations or other versions of a pharmacist or pharmaceutical technologist's name cannot be used unless it is registered with the Board, as applicable.

13.3. The law demands the presence of a registered pharmacist or enrolled pharmaceutical technologist with a valid practice license in the premises where such business is being carried out at all times when the pharmacy business is open.

13.4. The licenses issued by the Board bear the photo of the superintendent. In addition, there is a QR code that can be scanned by any smart device to confirm validity of the license and the name and registration/enrolment number of the superintendent.

14. RETAIL PREMISES FOR PHARMACISTS

14.1. The minimum requirements and standards for premises for pharmacists are prescribed in the GDP guidelines.

14.2. Premises for a pharmacist shall be registered as either retail or wholesale business but NOT as both. Where a person wishes to carry out retail and

wholesale business then the person shall lodge an application for registration of different sets of premises and each set must have a designated superintendent.

14.3. Where a person wishes to carry out more than one business of a pharmacist, then the person shall lodge an application for registration of different sets of premises and each set must have a designated superintendent.

15. RETAIL PREMISES FOR PHARMACEUTICAL TECHNOLOGISTS

15.1. The minimum requirements and standards retail premises for pharmaceutical technologists are prescribed in the GDP guidelines

15.2. Premises for a pharmaceutical technologist shall be registered as retail or hospital pharmacies.

15.3. Where a person wishes to carry out more than one business of a pharmaceutical technologist, then the person shall lodge an application for registration of different sets of premises and each set must have a designated superintendent.

16. ONLINE/INTERNET PHARMACIES

16.1. An online pharmacy can be established only in connection with an existing pharmacy operating on approved physical premises.

16.2. The online operations are considered to form part of the pharmacy business's operations and it is therefore regarded as an online presence for an existing pharmacy, not a pharmacy business in its own right.

16.3. The minimum requirements and standards of online pharmacies are prescribed in regulations and Guidelines for Internet Pharmacy Services in Kenya.

16.4. The Guidelines for Internet Pharmacy Services in Kenya shall also apply to telehealth or telemedicine establishments.

16.5. Hospitals or companies offering telehealth or telemedicine services and wish to supply their patients with medication shall be required to operate

from registered premises under a superintendent pharmacist or pharmaceutical technologist.

17. WHOLESALE PREMISES

17.1. The minimum requirements and standards of wholesale premises are prescribed in the GDP guidelines

17.2. Notwithstanding the requirement for registration of premises, a person intending to carry out the business as a wholesale dealer in pharmaceuticals is further required to apply for and obtain a valid Wholesale Dealers' License. Premises registered for wholesale shall be used solely for that purpose.

17.3. A pharmaceutical technologist is not eligible for a Wholesale Dealers' License.

17.4. The Wholesale Dealers License automatically expires on the 31st day of December in the year it is issued.

18. SCIENTIFIC OFFICES

18.1. Scientific offices that intend to store or handle Part I poisons for promotion activities shall require to be registered as premises for the business of a pharmacist.

18.2. In making the application, the applicant will be required to specify the licensed wholesale dealer who will be in charge of the importation and distribution of products in Kenya.

18.3. All pharmaceutical representatives working under the scientific office must meet the minimum requirements and be licensed annually.

18.4. For purposes of samples, the premises shall be equipped and designed to allow handling of the samples stored and handled from the premises.

19. MEDICAL DEVICES ESTABLISHMENTS

19.1. Premises established for purposes of manufacture, wholesale dealing, importation or exportation of medical devices shall be registered and licensed annually.

19.2. The requirements for licensing are contained in Guidelines for Registration of Medical Devices Establishments in Kenya.

20. WAREHOUSES

20.1. A warehouse must meet the standards for premises prescribed in the GDP guidelines.

20.2. Warehouses shall be designed and constructed to ensure good storage conditions, sufficient lighting and ventilation.

20.3. Warehouses shall have sufficient capacity to allow storage of various categories of pharmaceutical products.

20.4. The floor shall be durable to withstand heavy traffic and loads; the premises shall be provided with well-fitted shelves or pallets.

20.5. The premises shall be equipped with temperature and humidity control facilities/monitors and fire extinguishers.

20.6. A residential home shall not be used as a warehouse.

20.7. A warehouse shall only be used for storage purposes and no retail sales shall be allowed.

21. MANUFACTURING FACILITIES

21.1. Facilities used for manufacture of medical products and health technologies shall be required to obtain manufacturing licenses.

21.2. The minimum requirements and standards manufacturing premises are prescribed in the GMP guidelines.

21.3. The authorized person/company pharmacist in charge of a manufacturing facility will apply for the license through the online licensing portal. The issuance of the license will be subject to compliance with the prescribed Good Manufacturing Practices and the evidence should be attached to the application for evaluation.

21.4. The applicant is also required to submit the list of approved products to be manufactured at the site.

22. APPLICATION FOR NEW PREMISES

22.1. Any person(s) who wants to apply for registration of premises shall do so through the "New Facility" tab in the online licensing portal.

22.2. The applicant is expected to declare the ownership details, the size of the premises and the distance to the nearest pharmacy and attach the documents prescribed in these guidelines or as may be prescribed by the Board.

22.3. The supporting documents that are applicable include copies of the following:

22.3.1. The Certificate of Incorporation or the Business Name Registration (BN3)

22.3.2. The CR12 or a search showing the directors or shareholders of the company

22.3.3. The personal PIN of the superintendent pharmacist or pharmaceutical technologist making the application

22.3.4. The national Identity Card of the applicant

22.3.5. The PIN of the company

22.3.6. Current license from Kenya Medical Practitioners and Dentists Council (KMPDC) for hospital pharmacies

22.3.7. Current Certificate of Good Manufacturing Practices for manufacturing premises

22.3.8. Any partnership agreement for the business

22.3.9. Any agreement under which any other person has a financial interest in the business

22.3.10. Any agreement between persons having financial interests in the pharmacy business, which regulates their rights e.g. a shareholders' agreement

22.3.11. If the owner is not a superintendent, a contract agreement with the superintendent of which among other things addresses the terms of terminations

22.3.12. A sketch plan setting out all those areas where medicinal products are, or intended to be, sold or supplied, prepared, dispensed, compounded or stored at the licensed premises. The sketch plan need not be a detailed plan, but should include the overall measurements of the pharmacy premises and/or professional service room. Specifically highlighted must be:

a) The location and overall floor area of the dispensary;
b) The bench area including sink, refrigerator, barcode scanner(s) and work areas;
c) Direct public access (for pharmacy premises only).

22.4. Documents which are submitted to the Board must be complete (not draft) copies, which are appropriately signed, witnessed and where appropriate, stamped and/or registered.

22.5. The document to be submitted will vary depending on the nature of business and the ownership structure.

22.6. Failure to supply the information/documents or knowingly furnishing false information/documents is an offense.

23. EVALUATION PROCESS FOR NEW PREMISES

23.1. The processing timelines are specified in the Board's Customer Service Charter. Applicants for new facilities are encouraged to apply before they start fitting the premises and stocking medical products. This would enable adequate time to process the application before commencing business and also avoid inconveniences in case of situations where the application is declined totally.

23.2. The pre-registration application is reviewed and if it meets the threshold then a pre-registration approval is made.

23.3. The pre-registration approval will trigger the applicant to proceed to the next stage where further documents are attached and the prescribed fees paid. An application is only complete after the fees have been paid. The recommended method for payment is by Mobile money (Mpesa). A downloadable receipt is available upon successful submission of payment. Only paid up applications are available for review.

23.4. After review of the application, if approved, the applicant will receive a text message notifying of the approval and to liaise with the nearest Board office for inspection of the premises. The head of the Board's regional office will also receive communication of the approval.

23.5. The declarations on premise size, ownership and distance from the nearest pharmacy will be verified during the inspection stage. Applicants are required to make accurate and true declarations when applying for new premises.

23.6. After inspection, the inspection report, including photos of the premises, is loaded online. The report is reviewed by a second reviewer and if satisfactory then the final approval is made and the applicant notified by text message and mail. The license issued is an electronic document which is downloadable directly from the applicant's portal.

23.7. Having considered all factors and matters relating to the application the Board will either:

23.7.1. Issue a certificate of registration of premises under part II of the Pharmacy and Poisons Act, Cap 244 Laws of Kenya; or

23.7.2. Advise the applicant in writing, in case of an unsuccessful application, and clearly state the reason the application was unsuccessful.

23.8. Any notification by text message or email sent to an applicant on the registered mobile number or email address shall be considered as sufficient communication.

23.9. At every stage of the application, applicants can view the evaluation status in the portal as "PENDING" before review, 'REJECTED" or "APPROVED". When an application is declined, the reason is usually stated and the applicant notified by text message and email.

23.10. In the case of an unsuccessful application, the applicant will be given further opportunity to respond to the requirements or queries raised by the reviewer. Where the applicant is able to revise the application and comply with the requirements, a license will be issued.

23.11. During the processing period, the premises shall remain unregistered and the file will be closed after about 6 months from the date of initial application.

23.12. The registration of premises is subject to compliance with the provisions of the Pharmacy and Poisons Act and regulations.

23.13. Nothing in these guidelines shall make it lawful to carry out the business in premises which are not registered even when an application is under processing but the license has not yet been issued.

24. RENEWAL OF LICENSES

24.1. All licenses issued by the Board expire on the 31st day of December of the year they are issued and are renewable annually.

24.2. Application for renewal of licenses shall be made to the Board through the online licensing portal using the "Renewal" tab.

24.3. The portal will be open for renewals from November and applicants are expected to apply for renewal before 31st December every year in order to facilitate timely processing of the licenses.

24.4. An application is only complete after the fees have been paid. The recommended method for payment is by Mobile money (Mpesa). A downloadable receipt is available upon successful submission of payment. Only paid up applications shall be reviewed.

24.5. Notwithstanding licenses having been issued the previous year, the application for renewal shall be evaluated every time and the Board shall not be obliged to renew the licenses except for applications which, as per the prevailing conditions at the time of application, still meet the requirements.

24.6. The applications go through two levels of review and the applicant is notified of the decision by text message and email. At every stage of the application, the status can be "PENDING" before review, "REJECTED" or "APPROVED". When an application is declined, the reason is usually stated and the applicant notified by text message and email. A rejected application can be resubmitted after the applicant has complied with the requirements or responded to the queries raised by the reviewer.

24.7. Renewal of licenses is subject to compliance with the Continuing Professional Development (CPD) guidelines. Only applicants who have attained the minimum CPD points for the year will be eligible for licensing.

24.8. Premises which, after re-assessment, are deemed to have become unsuitable for carrying on the business will not have their registration renewed and the previous one would automatically become void.

24.9. **Penalty for late renewal:**

Any application for renewal of licenses that is lodged later than 31st December will attract a penalty for late application and this will be in the form of a percentage of the standard application fees as may be prescribed by the Board. The penalty is 10% levied on a monthly incremental basis from the end of January onwards.

25. NOTIFIABLE CHANGES

25.1. The Board shall be notified in writing (complete with all details) at least 30 days prior to changing any part of existing registration details are implemented.

25.2. The changes may lead to variation of license or issuance of fresh registration of premises.

25.3. Changes may be classified as minor or major.

25.3.1. Minor changes are changes that may lead to variation of existing registration details without requiring re-inspection of the premises. These may include change of:

a) Business name
b) Postal address and/or email address
c) Change of ownership - including the acquisition or disposal of a financial interest in a pharmacy business, change in share distribution, change of directors, partners/owners/members
d) Superintendent/ responsible pharmacist/ pharmaceutical technologist

25.3.2. Major changes are those which significantly modify the conditions under which the business is carried out and may require re-inspection or fresh registration or licensing. These may include change of:

a) Registered premises i.e. change in location, plot number, building, floor in the same building etc.
b) Nature of business- wholesale/ retail.
c) Change from the business of a pharmacist to the business of a pharmaceutical technologist and vice versa.
d) Altering (including expansion or reduction in size) and renovating substantially without relocating the pharmacy business and without changing the ownership or address. Registration will not be affected but the changed or renovated premises must be inspected and approved before trading can commence.
e) Deceased licensed person in the context of section 10(3) and 26(1)(g) of the Pharmacy and Poisons Act.
f) Any other significant changes.

25.3.3. In the case of change in premises, the new premises will be subjected to registration just like any other new facility.

26. RELOCATION OR CHANGE OF ADDRESS

26.1. A relocated pharmacy is classified as an existing pharmacy business which has simply relocated from one address to another without changing ownership.

26.2. The premises of relocated pharmacies must be approved and inspected by the Board prior to commencing business.

26.3. No retail trade of any sort, including the sale of non-pharmaceutical items, can occur until confirmation is given by the Board that the new premises are approved.

27. VARIATION OF LICENSES

27.1. A duly registered or licensed premise can apply for variation of the license during the license validity period using the "Variation" tab. Applications for variation shall be accompanied by supporting documents or variation evidence and may be subject to variation fees depending on the nature of variation.

28. ACCESS TO INFORMATION BY THE PUBLIC

28.1. Any member of the public will have access to data on licensed premises and persons. The license status can be verified through the Board's website by searching directly.

28.2. A Health Safety Code will also be given to each licensed establishment and any interested party can verify the real-time status through mobile SMS by sending the code to a short code provided.

28.3. A person applying for a copy of the Register of Premises must state the purpose(s) for which it will be used.

29. APPLICATION FEES STRUCTURE

29.1. The following fees structure is applicable as at the time of approval of these guidelines but may change if and when need arises:

29.1.1. Retail pharmacy and hospital pharmacies (applies to both premises for a pharmacist and premises for a pharmaceutical technologist)

a) Annual practice license Kshs.5,000
b) Premises registration fee Kshs.10,000

29.1.2. Wholesale Pharmacy premises

a) Annual practice license Kshs.5,000
b) Premises registration fee Kshs.10,000
c) Wholesale dealer's license Kshs.30,000

29.1.3. Manufacturing premises

a) Annual practice license Kshs.5,000
b) Premises registration fee Kshs.10,000
c) Wholesale dealer's license Kshs.30,000
d) Manufacturing License Kshs.50,000

29.2. Exemptions on fees:

29.2.1. Facilities in Special Economic Zones, Export Processing Zones (EPZ) may be exempt from premises fees, Wholesale fees and manufacturing license fees. However, the applicant is expected to be duly licensed having paid the annual practice license fees.

29.2.2. Other exemptions may be for government facilities and people living with disabilities as part of disability mainstreaming. The pharmacists and pharmaceutical technologists are however expected to be licensed having paid the annual practice license fees and complied with other licensing requirements.

30. INSPECTIONS

30.1. Authorized Persons appointed under the Pharmacy and Poisons Act, shall carry out pre-registration and routine inspections of all pharmacies in Kenya.

30.2. The powers of the Board to inspect and license are detailed in section 3B(2)(j) of the Pharmacy and Poisons Act and, while the inspectors will make every reasonable attempt to co-operate, pharmacists should remember that the inspectors are empowered to enter pharmacy premises at any reasonable time. It is an offense under section 48 for a person to prevent, hinder or obstruct an inspector, or other authorized persons, in the carrying out of their duties.

30.3. Inspections for manufacturing premises shall be carried out as per the Guidelines for GMP Inspections and related Standard Operating Procedures.

30.4. A pharmacy, and any associated professional services room, must be inspected prior to the opening of any new business, and immediately on completion of any substantial renovations to an existing pharmacy or professional services room.

30.5. It is the responsibility of the owner of the pharmacy business to contact a Board Inspector to arrange a mutually convenient time to inspect the premises. This should be done immediately on receipt of advice of the approval of the application for a new pharmacy, relocation or renovation of a pharmacy, or a new professional services room. The inspection must occur within three months of receipt of the application.

30.6. Pharmacy premises should be near completion and ready for commencement of operation by the inspection date.

30.7. There is no fee associated with this inspection of retail, hospital and wholesale premises.

30.8. Routine inspections of licensed establishments will be carried out with a primary objective of assisting pharmacists or pharmaceutical technologists to understand, and comply with, the provisions of the Law, Regulations, guidelines and directives of the Board.

31. CONTRAVENTIONS AND OFFENSES

31.1. The proprietors of a pharmacy are responsible for ensuring the ownership and operation of a pharmacy does not contravene the laws and regulations, and that an offense is not committed. Where a contravention or offense is detected, all proprietors and the pharmacist or pharmaceutical technologist in charge, if it was not a proprietor, are held responsible.

31.2. A contravention of the law or regulation may form grounds for a complaint of unsatisfactory professional conduct, and in the case of a statutory offense, the proprietor(s) and/or pharmacist in charge will be prosecuted in court. Most offenses carry a monetary penalty and may result in a criminal conviction, if proven.

32. VALIDITY OF LICENSES

32.1. The Certificate for Registration of Premises (Form 33) expires on the 31st day of December of the year it is issued.

32.2. The Wholesale Dealer's License (Form 7) expires on the 31st day of December of the year it is issued

32.3. The Certificate for Registration of Premises for a Pharmaceutical Technologist's Practice (Form 31) expires on the 31st day of December of the year it is issued.

32.4. Manufacturing license expires on the 31st day of December of the year it is issued.

32.5. The above expiry dates will apply irrespective of the actual date of issue of the license in question.

32.6. Licensees are encouraged to apply for renewal of licenses on time to avoid inconveniences.

33. CLOSURE OF BUSINESS

33.1. The Board must be notified when a licensed establishment is to cease operations and close

33.2. Where a pharmacy is closed for any reason for a period longer than three months, the Board must be notified

33.3. The closure of a pharmacy and ceasing to have a financial interest in the pharmacy business should be notified in writing to the Board, within 14 days of closure.

33.4. Closure may be permanent or temporary

33.4.1. Where temporary, and for a **period of more than three months** the Board will require complete re-registration of the business and a new inspection and approval of the premises.

33.4.2. Where closure is temporary, and for a **period of less than three months**, the Board is to be notified in writing. The pharmacy registration will continue for the period of closure and, unless changes to the registration or the approved premises occurred in that time, registration will be automatically restored upon notification of reopening. In the event of closure for renovations, an inspection and new approval will be required.

34. SUSPENSION OR REVOCATION OF LICENCE

34.1. The Board has the power to suspend or revoke the licence of a pharmacy premises if:

34.1.1. It is closed or no longer being used to conduct a pharmacy business.

34.1.2. the conditions under which the business was licensed are no longer being met.

34.2. The Board shall suspend or revoke Manufacturing licenses of manufactures who fail to meet GMP requirements or when their GMP license is suspended or revoked as per Guidance on suspension of revocation of GMP certification **(HPT/ISE/GMP/MAN/009)**

34.3. Suspension or revocation of licenses or permits for Medical devices premises will be handled in accordance with Guidelines for Registration of Medical Devices Establishments.

35. REFERENCES

35.1. The Constitution of Kenya, 2010

35.2. Pharmacy and Poisons Act Chapter 244 Laws of Kenya Revised Edition 2019

35.3. Guidelines for Good Distribution Practices (GDP) for Pharmaceuticals

35.4. Pharmacy and Poisons Board Customer Service Charter.

35.5. Joint FIP/WHO Guidelines on Good Pharmacy Practice Available online at: http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf

35.6. Guidelines for Suspension and Revocation of Marketing Authorization of Health Products and Health Technologies in Kenya.

35.7. Guidelines for Registration of Medical Devices Establishments.

35.8. Guidelines for Implementation of Continuing Professional Development in Kenya.

35.9. Guidelines for Internet Pharmacy Services in Kenya

ANNEXES

Annex 1: Specimen Health Safety Code -Annex 1


LICENSED PHARMACY
HEALTH SAFETY CODE:
P0001
TO VERIFY:
SEND CODE TO 21031
PHARMACY AND
POISONS BOARD
www.pharmacyboardkenya.org

Annex 2: Specimen Certificate for Registration of Premises (Form 33)

SR No. 021566/21

FORM 33

MINISTRY OF HEALTH

THE PHARMACY AND POISONS ACT
(*Cap.244, Sub. Leg.*)
(*The Pharmacy and Poisons Rules*)

CERTIFICATE FOR REGISTRATION OF PREMISES

Messrs. PPB SAMPLE LTD

of P.O. BOX 00000-00100, NAIROBI

Plot No. Plot No. LR/002/6554 is registered to carry on business of a pharmacist as provided for by section 23.

Registered No. of premises PPB/PP/999

18-11-2021
Date

Note. (i) This Registration expires on 31st December 2022

(ii) No change of premises is permitted without authority of the board.

(iii)This registration shall become void upon expiration of 30 days from any change of ownership of the business.

Fee: KShs. 10000 **Licence No. BU202299999**

Annex 3: Specimen Wholesale Dealer's License (Form 7)

SAMPLE

SR No. 021566/21

FORM 7

MINISTRY OF HEALTH

THE PHARMACY AND POISONS ACT
(*Cap.244, Sub. Leg.*)
(*The Pharmacy and Poisons Rules*)

WHOLESALE DEALER'S LICENCE

Messrs. PPB SAMPLE LTD of P.O. BOX 00000-00100, NAIROBI

carrying on business at LENANA ROAD, are hereby authorized to sell poisons by way of wholesale dealing.

18-11-2021
Date

Note. (i) This licence expires on 31st day of December 2022

Fee: KShs. 30000 Licence No. BU202200227

Annex 4: Specimen Certificate for Registration of Premises for a Pharmaceutical Technologist's Practice (Form 31)

SR No. 000907/22
FORM 31

SAMPLE

MINISTRY OF HEALTH

THE PHARMACY AND POISONS ACT
(*Cap.244, Sub. Leg.*)
(*The Pharmacy and Poisons Rules*)

PREMISES REGISTRATION CERTIFICATE FOR PHARMACEUTICAL TECHNOLOGIST'S PRACTICE

Name of Premises..... SAMPLE LTD .....

Registration No of Premises..... PPB/PP/103 .....

Location of Premises..... NAIROBI .....

Town..... NAIROBI ..... Street..... 2ND AVENUE,5TH STREET .....

Plot No..... Plot No. 36/1/103 .....

Name of pharmaceutical technologist..... JANE DOE .....

ID No..... 000000 ..... Enrollment No. 1126 .....

Has met the necessary conditions for the business of a pharmaceutical technologist to be carried therein

..... 10-01-2022 .....
Date

Note. (i) This Registration expires on 31st December ..... 2022 .....

(ii) No change of premises is permitted without authority of the Board.

(iii)This registration shall become void upon expiration of 30 days from any change of ownership of the business.

KShs. 15000 Licence No. BU202299999

Annex 5: Specimen Manufacturing License

SAMPLE

SR No. 021566/21
Form 22

MINISTRY OF HEALTH

THE PHARMACY AND POISONS ACT
(*Cap.244, Sub. Leg.*)
(*The Pharmacy and Poisons Rules*)

LICENCE TO MANUFACTURE DRUGS FOR SALE

PPB SAMPLE LTD of P.O. BOX 00000-00100, NAIROBI

and having premises situated at :LENANA ROAD

is hereby licensed to manufacture for sale the following drug(s)/medicine(s)

AS PER ATTACHED LIST

under the direct personal supervision of Dr. JOHN DOE

at Plot No. LR/209/6554, LENANA ROAD, NAIROBI

Note. (i) This licence expires on 31st day of December 2022

Registration No. PPB/PP/150

Date 18-11-2021

Any change of the person under whose direct personal supervision the manufacture is carried on, whether temporary or permanent, must be notified to the Registrar immediately.

Fee: KShs. 50000 **Licence No. BU202299999**

Annex 6: Specimen Annual Practice License for a Pharmacist

SR No. 021999/21

MINISTRY OF HEALTH

THE PHARMACY AND POISONS ACT
(*Cap.244, Sub. Leg.*)
(*The Pharmacy and Poisons Rules*)

2022 ANNUAL PRACTICE LICENCE FOR PHARMACIST

Name: Dr. JOHN DOE

ID No: 999999

Registration No: 9900

Premise: PPB SAMPLE LTD

Plot No. LR/99/LP

P.O. BOX 00000-00100, NAIROBI

Town: NAIROBI

The above named person is hereby licensed to practise as a Pharmacist in accordance with the Pharmacy and Poisons Act.

This Licence is valid upto 2022-12-31, subject to compliance of the provisions of the Act.

Fee: KShs. 5000

Licence No. P2022D99999

Annex 7: Specimen Annual Practice License for a Pharmaceutical Technologist

SR No. 000906/22

MINISTRY OF HEALTH

THE PHARMACY AND POISONS ACT
(*Cap.244, Sub. Leg.*)
(*The Pharmacy and Poisons Rules*)

2022 ANNUAL PRACTICE LICENCE FOR PHARMACEUTICAL TECHNOLOGIST

Name: JANE DOE

ID No: 9999941

Enrollment No: 0122

Premise: PPB SAMPLE LTD

Plot No. 36/1/103

PO BOX 0000-00100 NAIROBI

Town: Street

The above named person is hereby licensed to practise as a Pharmaceutical Technologist in accordance with the Pharmacy and Poisons Act.

This Licence is valid upto 2022-12-31, subject to compliance of the provisions of the Act.

Fee: KShs. 5000

Licence No. PT2022D99999

Annex 8: Screenshot of home page of online licensing portal