PRA/LPP/GPP/GUD/060

Revision No. 04

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINES FOR REGISTRATION AND LICENSING OF PREMISES

OCTOBER 2024

Citation and Address

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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 of Terms

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

Authorized Person	An "authorized person" in the context of a manufacturing facility means the person responsible for certification that each production batch has been produced and controlled in accordance with the requirements of the marketing authorization and any other regulations relevant to the production, control and release of the pharmaceutical products.
Enrolled pharmaceutical technologist	A pharmaceutical technologist whose name appears on the roll of pharmaceutical technologists in Kenya
Health Products and Technologies	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.
Key Personnel	Key personnel in a manufacturing facility means the key personnel specified in the Guidelines for Good Manufacturing Practices and include the heads of production, the head(s) of quality unit(s) and the authorized person. The quality unit(s) typically comprise the quality assurance and quality control functions.
Manufacture	Any process carried out in the course of making a product or medicinal substance including 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.

New Pharmacy	One in which the site has not been occupied by a pharmacy or a site which was previously occupied by a 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.
Parallel Importation	The importation into Kenya, by a licensed importer of medicinal substance other than the marketing authorization holder or his or her technical representative of the following medicinal substances which require marketing authorization in Kenya (a) patented medicinal substances under section 58(2) of the Industrial Property Act, 2001; (b) non-patented medicinal substances; or (c) branded generic medicinal substances;
Pharmacy	The premises upon which a pharmacy business is conducted, and includes: (a) the portion of the premises where health products and technologies are for sale, dispensing; and (b) a professional service rooms.
Premises	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, manufactured, or stored.
Consultation services	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.

Registered pharmacist	A person whose name is entered in the register of pharmacists in Kenya.
Registered Pharmacy	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.
Registered premises	Premises registered in accordance with section 23 of the Pharmacy and Poisons Act, and where a valid certificate for registration is available.
Superintendent	The person who is overall in charge of ensuring regulatory compliance.

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1.0 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 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 guide 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 the 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 OFFICER

2.0 Introduction

2.1 Background

The mission of the Board is to protect and promote the health of the public by regulating the profession of pharmacy and ensuring access to quality, safe, efficacious, and affordable health products, and technologies.

The Board ensures 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 purpose of this document is to guide on the process and requirements of registration and licensing of premises.

2.2 Legal Framework

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".

2.3 **Scope**

These guidelines apply to all premises that are subject to mandatory registration and licensure by law. All premises where health 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:

a) Premises for Wholesale (for carrying on the business of a pharmacist)
b) Retail pharmacies
    - Premises for a pharmacist (for carrying on the business of a pharmacist) or
    - Premises for a pharmaceutical technologist (for carrying on the business of a pharmaceutical technologist)
c) Hospital pharmacies
d) Telehealth, telemedicine, and online/internet pharmacy services
e) Warehouses where medical products are stored
f) Manufacturing premises
g) Establishments for Medical Devices
h) Scientific Offices
i) In addition to the premise license, these guidelines will also cover the annual practice licensing of:
j) Pharmacists
k) Pharmaceutical technologists
l) Pharmaceutical representatives

The scope of practice or the services or acts which can lawfully be performed in the different types of premises and the conditions under which those services may be provided or the acts may be

performed will be as prescribed by the Board in regulations and guidelines.

3.0 General Requirements for Premises

3.1 The minimum requirements for premises and standards of practice are contained in the Pharmacy and Poisons Board Guidelines on Good Distribution Practices for Medical Products and Health Technologies in Kenya (HPT/ISE/EFS/GUD/019).

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 Every registered premise will be under the 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.

3.4 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/

3.5 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

3.6 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.

4.0 Location and Design

4.1 The premises' location and design shall be in compliance with the Board's GMP and GDP guidelines.

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

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

4.4 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 their business, be it a pop-up stall, stand or mobile unit, that is outside the pharmacy's approved premises boundary.

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

4.6 Premises located within or near petrol stations shall be furnished in such a way that the activities including fuel fumes do 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 Kenya Medical Practitioners and Dentists Council (KMPDC). All pharmacies located within the hospital / medical facility shall be registered individually by the Board.

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.

4.10 For manufacturing premises, refer to Guidance Notes for Establishing Medical Products and Health Technologies Manufacturing Facilities in Kenya (HPT/ISE/GMP/MAN/006)

5.0 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.

6.0 Personnel

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

6.2 In addition to the authorized and key personnel, local manufacturing facilities, wholesale dealers who are local technical representatives of foreign marketing authorization holders (MAH) and parallel importers shall have a Qualified Person for

Pharmacovigilance (QPPV).Refer to Annex 11:Parallel Import Certificate

6.3 Premises where sale, supply, stocking, dispensing, and compounding of any pharmaceutical product on retail or wholesale, 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/she shall be made to sign a contract agreement with the superintendent 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 applying for registration of premises

6.6 The superintendent shall be available to oversee the handling 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 The owner and superintendent shall individually and jointly ensure that only qualified personnel have access to handling or dispensing of pharmaceuticals.

6.9 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 the supervision of an approved preceptor.

6.10 The key personnel working in a manufacturing facility shall comply with the criteria set in Qualification and Experience Requirements and Responsibilities for Key Personnel of Licensed Manufacturers of

Medical Products and Health Technologies Kenya (HPT/ISE/GMP/MAN/009)

7.0 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 or not.

7.2 Registered pharmacists and enrolled pharmaceutical technologists are expected to participate in adequate continuing professional development (CPD) activities every year and obtain the minimum CPD points as per CPD Guidelines.

7.3 Variation of a license may be made by any licensed person during the license year and the application shall be accompanied by adequate justification/ variation evidence

7.4 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.

7.5 All Practice Licenses shall be valid for one year with an expiry date of 31st December. All pharmacists and pharmaceutical technologists shall be required to apply for renewal of their practice licenses, at least 30 days before the expiry of the current practice license.

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

8.0 Eligibility to Superintend

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

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 the supervision of another qualified and experienced 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

9.0 Business Names

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

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 and to avoid any names or symbols that may bring the profession into disrepute

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.

10.0 Equipment and Storage Facilities

10.1 The basic equipment that must be available in the premises is prescribed in the Guidelines on Good Distribution Practices for Medical Products and Health Technologies in Kenya (HPT/ISE/EFS/GUD/019) and in the GMP 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 should be stored per the manufacturer's and the Board's recommended storage conditions,

10.2.2 The safety and well-being of the personnel is adequately addressed

10.2.3 There is adequate space for quarantined health products and technologies

11.0 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 that they will be undertaking.

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

12.0 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 shall have a prefix of "P" for pharmacists' and "PT" for pharmaceutical technologists' premises respectively.

12.4 The licenses and codes shall be displayed conspicuously to enable the public to verify the license status of the premises.

13.0 Display of Licenses and Certificate of Registration of a Premise

13.1 The license and certificate of registration of the person having control of the business shall be conspicuously displayed on the premises in which the business is carried on as provided in section 20 of the Pharmacy and Poisons Act.

13.2 The displayed superintendent's 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 shall bear the photo of the superintendent. In addition, there is a QR code that can be scanned by any smart device to confirm the validity of the license and the name and registration/enrollment number of the superintendent.

14.0 Premises for Pharmacists

14.1 The minimum requirements and standards for premises for pharmacists are prescribed in the GDP guidelines. (Guidelines on Good Distribution Practices for Medical Products and Health Technologies in Kenya (HPT/ISE/EFS/GUD/019)

14.2 Premises for a pharmacist shall be registered as either retail, hospital pharmacies or wholesale business.

14.3 A wholesale business shall not retail on the same premise

14.4 A hospital pharmacy shall not do wholesale business.

14.5 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.

15.0 Premises for Pharmaceutical Technologists

15.1 The minimum requirements and standards for retail premises for pharmaceutical technologists are prescribed in the GDP guidelines. (Guidelines on Good Distribution Practices for Medical Products and Health Technologies in Kenya (HPT/ISE/EFS/GUD/019)

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.

16.0 Online/Internet Pharmacies

16.1 An online pharmacy can be established only in connection with an existing retail 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 the regulations and Guidelines for Internet Pharmacy Services in Kenya (PRA/LPP/GUD/033).

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 wishing to supply their patients with medication shall be required to operate from registered premises under a superintendent pharmacist or pharmaceutical technologist.

17.0 Wholesale Premises

17.1 The minimum requirements and standards of wholesale premises are prescribed in the GDP guidelines. (Guidelines on Good Distribution Practices for Medical Products and Health Technologies in Kenya (HPT/ISE/EFS/GUD/019)

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 Dealer's 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.

18.0 Certificate of Parallel Importation

18.1 A person lawfully carrying on business as a wholesale dealer may, in addition, apply for a certificate of parallel importation.

18.2 The application will be accompanied with documentation specified in Rule 6 of the Pharmacy and Poisons (Parallel Importation) Rules

19.0 Scientific Offices

19.1 Scientific offices that intend to store or handle Part I poisons shall be required to be registered as premises for the business of a pharmacist.

19.2 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.

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

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

20.0 Medical Devices Establishments

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

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

21.0 Warehouses

21.1 A warehouse must meet the standards for premises prescribed in the GDP guidelines. (Guidelines on Good Distribution Practices for Medical Products and Health Technologies in Kenya (HPT/ISE/EFS/GUD/019)

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

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

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

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

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

22.0 Manufacturing Facilities

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

22.2 The minimum requirements and standards of manufacturing premises are prescribed in the Guidance notes for establishing medical products and health technologies manufacturing facilities in Kenya (HPT/ISE/GMP/MAN/006).

22.3 The 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.

22.4 The applicant is required to provide names of key personnel in accordance with Qualification and Experience Requirements and Responsibilities for Key Personnel of Licensed Manufacturers of Medical Products and Health Technologies Kenya, document number HPT/ISE/GMP/MAN/009

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

22.6 The manufacturing license issued by the board shall be for specific dosage forms and products and the list of authorized products shall be annexed

22.7 A manufacturer may at any time during the license period apply for a variation of license and provide justification/evidence of the same.

23.0 Application for New Premises

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

23.2 The applicant shall declare and provide all the relevant and requested information and documents.

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

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

23.5 The current CR12 or a search showing the directors or shareholders of the company

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

23.7 The National Identity Card of the applicant

23.8 The PIN of the company

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

23.10 Current Certificate of Good Manufacturing Practices for manufacturing premises

23.11 Any partnership agreement for the business

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

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

23.14 A sketch plan setting out all those areas where medicinal products are, or intended to be, sold, supplied, prepared, dispensed, compounded, or stored at the licensed premises. The

sketch plan need not be detailed 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)
d) The premise shall also meet all the other requirements as prescribed by the board. (Guidelines on Good Distribution Practices for Medical Products and Health Technologies in Kenya (HPT/ISE/EFS/GUD/019)

23.15 For manufacturing premises, refer to Guidance Notes for Establishing Medical Products and Health Technologies Manufacturing Facilities in Kenya, document number HPT/ISE/GMP/MAN/006

23.16 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.

23.17 The document to be submitted will vary depending on the nature of the business and the ownership structure. The documents for:

23.17.1 **Retail, Wholesale, Warehouse premises**

a) Business registration certificate for a sole proprietorship or partnership type of business
b) Certificate of incorporation for a limited liability company type of business
c) Signed page of the articles and memorandum of association, or the CR12 Form from the Registrar of Companies
d) KRA PIN

23.17.2 **Scientific office**

a) Business registration certificate for a sole proprietorship or partnership type of business

b) Certificate of incorporation for a limited liability company type of business
c) Signed page of the articles and memorandum of association, or the CR12 Form from the Registrar of Companies
d) Affidavit and/or letter of appointment for the superintendent pharmacist
e) KRA PIN

23.17.3 **Manufacturing Facility**

a) Business registration certificate for a sole proprietorship or partnership type of business
b) Certificate of incorporation for a limited liability company type of business
c) Signed page of the articles and memorandum of association, or the CR12 Form from the Registrar of Companies
d) Affidavit and/or letter of appointment for the superintendent pharmacist
e) List and curriculum vitae of key personnel
f) List of manufactured products
g) GMP certificate from PPB
h) KRA PIN

23.18 Failure to supply the information/documents or knowingly furnishing false information/documents is an offence.

24.0 Evaluation Process for New Premises (Retail, Wholesale, Warehouse, Scientific Office, and Hospital Pharmacy)

24.1 The processing timelines are specified in the Board's Customer Service Charter (PPB/REG/QMS/POL/003).

24.2 Applicants for new facilities shall apply for a license 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.

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

24.4 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. A downloadable receipt is available upon successful submission of payment. Only paid-up applications are available for review.

24.5 The Board may from time to time review the payment methods to facilitate ease of payment by applicants

24.6 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 for inspection.

24.7 The declarations on the application will be verified during the inspection stage. Applicants are required to make accurate and true declarations when applying for new premises.

24.8 After inspection, the inspection report, including photos of the premises, is loaded online (rhris). The report is reviewed by a second reviewer and if satisfactory then the final approval is made, and the applicant is notified by text message and email. The license issued is an electronic document which is downloadable directly from the applicant's portal. (Annex 2, 3, 4, 5 and 6)

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

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

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

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

24.11 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 is notified by text message and email.

24.12 In the case of an unsuccessful application, the applicant will be given a 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, the application shall be reviewed and if satisfactory a license issued

24.13 Unsuccessful applications that are not responded to within a period of one month by the applicant shall be voided and the applicant shall be required to reapply afresh

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

24.15 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.

24.16 Anyone not satisfied with the decision of the Board on licensing has a right to appeal as per Cap 244

24.17 Please see Annex 9: New Premises Approval Flowchart

25.0 Renewal of Licenses

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

25.2 It is in the interest of the licensee to take adequate measures to ensure that they apply for license renewal on time to avoid operating without valid licenses. The Board recommends that the applicants make their requests for renewal of licenses thirty days before the expiry.

25.3 Late applications for license renewals shall attract such penalties as may be prescribed by the Board. Any application done thirty calendar days after the expiry of the license shall be considered late.

25.4 Application for renewal of licenses shall be made to the Board through the online licensing portal (www.practice.pharmacyboardkenya.org) using the "Renewal" tab.

25.5 Notwithstanding licenses having been issued the previous year, the renewal application 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.

25.6 The documents that may change at the end of every renewal year should be attached by the applicant and are subjected to REVIEW to ascertain their validity. These are:

25.6.1 **Retail, Wholesale, Warehouse premises**

a) Business registration certificate for a sole proprietorship or partnership type of business
b) Certificate of incorporation for a limited liability company type of business
c) Signed page of the articles and memorandum of association, or the current CR12 Form from the Registrar of Companies
d) Company PIN Certificate

25.6.2 **Scientific office**

a) Business registration certificate for a sole proprietorship or partnership type of business
b) Certificate of incorporation for a limited liability company type of business
c) Signed page of the articles and memorandum of association, or the current CR12 Form from the Registrar of Companies
d) Affidavit and/or letter of appointment for the superintendent pharmacist
e) Company PIN Certificate

25.6.3 Hospital premises

a) Business registration certificate for a sole proprietorship partnership type of business
b) Certificate of incorporation for a limited liability company type of business
c) Signed page of the articles and memorandum of association, or the current CR12 Form from the Registrar of Companies
d) Company PIN Certificate
e) KenyaMedicalPractitionersandDentistsCouncil(KMPDC) Licence (for Hospitals)

25.6.4 Manufacturing Facility

a) Certificate of incorporation for a limited liability company type of business
f) Signed page of the articles and memorandumof association, or the current CR12 Form from the Registrar of Companies
b) Affidavit and/or letter of appointment for the superintendent pharmacist
c) List and curriculum vitae of key personnel
d) List of manufactured products
e) GMP certificate from PPB
f) Company PIN Certificate

25.7 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 is 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.

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

25.8 Unsuccessful applications that are not responded to within one month shall be voided and the applicant shall be required to reapply afresh

25.9 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.

25.10 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.

25.11 The approvals of renewed licenses shall occur within the timelines prescribed in the service charter from the time of receipt of the application.

25.12 Please refer to Annex 10: Renewal and Variation Approval Flowchart

26.0 Penalty for Renewal

26.1 Any application for renewal of licenses that is lodged later than thirty days after expiry will attract a penalty for late application and this shall be 10% of the standard application fees.

27.0 Notifiable Changes

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

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

27.3 Changes shall be classified as minor or major.

27.4 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

27.5 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.

27.6 For notifiable changes in manufacturing premises refer to GMP guidelines

28.0 Relocation, Change of Address or Name

28.1 A relocated pharmacy or a pharmacy that has changed in name is classified as an existing pharmacy business which has simply relocated from one address to another or changed in name without changing ownership.

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

28.3 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.

28.4 A relocation and change in name can only be done through the variation module in the online platform.

28.5 Change of ownership and name of the premise will be considered as a new premise and must seek approval from the Board.

29.0 Variation of Licenses

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

29.2 For variation of Manufacturing premises, refer to GMP guidelines.

29.3 The GMP department shall evaluate the proposed changes and communicate to the licensing department on any approved changes

29.4 The approvals of variations shall occur within the timelines prescribed in the service charter (PPB/REG/QMS/POL/003) from the time of receipt of the application.

29.5 Please refer to Annex 10: Renewal and Variation Approval Flowchart

30.0 Access to Information by the Public

30.1 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 (www.pharmacyboardkenya.org) by searching directly.

30.2 Each licensed premise will be assigned a unique number (Annex 1: Specimen Health Safety Code) that should be conspicuously displayed and any interested party can verify the real-time status by sending the code to the SMS number provided.

30.3 The database for all licensed premises is available at request subject to the Board's processes.

31.0 Application Fees Structure

31.1 The following fee structure is applicable at the time of approval of these guidelines but may change if and when the need arises:

31.1.1 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
c) Online pharmacy license- Kshs.15,000

31.1.2 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

31.1.3 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

Exemption on fees:

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

31.3 Other exemptions may be for government facilities. The pharmacists and pharmaceutical technologists are however expected to be licensed having paid the annual practice license fees and complied with other licensing requirements.

31.4 And any other exemptions by the Kenyan law.

32.0 Inspections

32.1 The Board shall appoint inspectors under the Pharmacy and Poisons Act, to carry out pre-registration and routine inspections of all premises in Kenya.

32.2 It is an offence under section 48 of Cap 244 for a person to prevent, hinder or obstruct an inspector, or other authorized persons, in the carrying out of their duties.

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

32.4 A pharmacy, and any associated consultation 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 consultation services room.

32.5 It is the responsibility of the superintendent 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 consultation services room. The inspection shall occur within the timelines prescribed in the service charter from the time of receipt of the application.

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

32.7 There is no fee associated with this inspection of the retail, hospital, warehouse, scientific offices, manufacturing, and wholesale premises.

32.8 Routine inspections of licensed establishments will be carried out with the primary objective of assisting superintendents to understand, and comply with, the provisions of the law, regulations, guidelines, and directives of the Board.

33.0 Contraventions and Offenses

33.1 The proprietors of the premises are responsible for ensuring the operation does not contravene the laws and regulations, and that an offence is not committed. Where a contravention or offence is detected, all proprietors and the superintendent shall be held responsible.

33.2 A contravention of the law or regulation may form grounds for a complaint of unsatisfactory professional conduct, and in the case of a statutory offence, the proprietor(s) and the superintendent may be prosecuted in court.

34.0 Closure of Business

34.1 For pharmacy premises, the Board shall be notified: -

a) **When a licensed establishment is to cease operations and close**

b) **Where a pharmacy is closed for any reason for a period longer than three months**

34.2 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.

34.3 Closure may be permanent or temporary.

34.4 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.

34.5 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.

34.6 Where the closure is for a Manufacturing business: -

The Board must be notified when a licensed establishment is to close permanently or temporarily as follows:

a) Where the closure is permanent, a manufacturer must notify the Board three months before the closure
b) Permanent closure will lead to revocation of an issued license
c) For any temporary closure that exceeds six months, notification shall be done one month prior
d) Temporary closure will lead to suspension of an issued license

34.7 No manufacturer is permitted to commence operations following closure that exceeds six months or notification for permanent

closure without clearance from the Department of Inspectorate and Enforcement to ascertain GMP compliance.

35.0 Suspension or Revocation of License

35.1 The Board has the power to suspend or revoke the license of a pharmacy premises if:

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

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

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

35.3 Suspension or revocation of licenses or permits for medical device premises will be handled in accordance with the Guidelines for Registration of Medical Devices Establishments.

36.0 Requirements for Closure of Premises

36.1 Stock management – Finished and raw materials

36.2 Pharmacovigilance

36.3 PMS

36.4 Liability

37.0 Lifting of Suspension and Revocation

37.1 A person or a business whose license is revoked has the right to appeal as provided under Cap 244.

37.2 A person or a business whose license is suspended can have the suspension lifted when they comply with the requirements of the Board.

37.3 The Board shall lift the suspension of the manufacturing license as per Guidance on suspension or revocation of GMP certification (HPT/ISE/GMP/MAN/009)

38.0 References

1. The Constitution of Kenya, 2010
2. Pharmacy and Poisons Act Chapter 244 Laws of Kenya Revised Edition 2019
3. Guidelines for Good Distribution Practices (GDP) for Pharmaceuticals
4. Pharmacy and Poisons Board Customer Service Charter.
5. Joint FIP/WHO Guidelines on Good Pharmacy Practice Available online at: http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf
6. Guidelines for Suspension and Revocation of Marketing Authorization of Health Products and Health Technologies in Kenya.
7. Guidelines for Registration of Medical Devices Establishments.
8. Guidelines for Implementation of Continuing Professional Development in Kenya.
9. Guidelines for Internet Pharmacy Services in Kenya
10. Qualification and Experience Requirements and Responsibilities for Key Personnel of Licensed Manufacturers of Medical Products and Health Technologies Kenya
11. Guidance on suspension or revocation of GMP certification

39.0 Revision History

Revision No:	Date	Sections Revised	Description of change
01	18-11-2022	2.11	Terminologies: ● health products to replace "medical products" ● "key personnel" to replace "qualified person" ● "consultation services room" to replace "professional services room"
		3.	Location and design – referred to GMP and GDP guidelines Amended 3.8
		6	Practice licenses: allows for locum licenses and licenses not attached to specific premises
		9	Equipment and storage facilities – emphasis on addressing safety and well-being of personnel; adequacy of storage space
		11	Premises registration numbers, license numbers and codes – makes display of premise licenses and codes mandatory for the sake of the public
		12	Amended in line with cap 244 to read "display of licenses and certificate of registration of a premise
		13. 13.3 13.4	Rewording: 3.3. A wholesale business shall not retail in the same premise 13.4. A hospital pharmacy shall not do wholesale business.
		17	Scientific offices: reworded to remove "for promotion activities"
		21.14	Added (d) "The premise shall also meet all the other requirements as prescribed by the board. (Guidelines on Good Distribution Practices for Medical Products and Health Technologies in Kenya (HPT/ISE/EFS/GUD/019)"
		21.	Application for new premises: Added several paragraphs detailing the specific documents to be submitted for the following categories of establishments: • 21.17.1. Retail, Wholesale, Warehouse premises • 21.17.2. Scientific office • 21.17.3. Manufacturing Facility

		22.	Expanded scope and reworded to read" Evaluation process for new premises (retail, wholesale, warehouse, scientific office, and hospital pharmacy)" • 22.1 Harmonization of processing timelines with the PPB Customer Service Charter • 22.5 Added "The Board may from time to time review the payment methods to facilitate ease of payment by applicants" • Added 22.16. "Anyone not satisfied with the decision of the Board on licensing has a right to appeal as per Cap 244" to harmonize with the Act • Added 22.17. "Please see Annex 9: New Premises Approval Flowchart"
		23.	Added under 23.2 "The Board recommends that the applicants make their requests for renewal of licenses thirty days before the expiry." • Amended 23.3 "Late applications for license renewals shall attract such penalties as may be prescribed by the Board. Any application done thirty calendar days after the expiry of the license shall be considered as late."
		24	24.1. Any application for renewal of licenses that is lodged later than thirty days after expiry will attract a penalty for late application and this shall be 10% of the standard application fees.
		25.	Added 25.6. "For notifiable changes of manufacturing premises refer to GMP guidelines"
		26.	• 26.4. A relocation and change in name can only be done through the variation module in the online platform. • 26.5. Change of ownership and name of the premise will be considered as a new premise and must seek approval from the Board
		27.	Reworded and added: • 27.2. For variation of Manufacturing premises, refer to GMP guidelines • 27.3. The approvals of variations shall occur within the timelines prescribed in the service charter (PPB/REG/QMS/POL/003) from the time of receipt of the application • Added Annex 10: Renewal and Variation Approval Flowchart
		28.	• 28. Access of information to the public. Reworded • 28.2. Each licensed premise will be assigned a unique number (Annex 1: Specimen Health Safety Code) that should be conspicuously displayed and any

			interested party can verify the real-time status by sending the code to the SMS number provided. • 28.3. The database for all licensed premises is available at request subject to the Board's processes.
		29.	• Exemption on fees: Added 29.4. "And any other exemptions by the Kenyan law."
		30.	• Inspections. Amended 30.1. "The Board shall appoint inspectors under the Pharmacy and Poisons Act, to carry out pre-registration and routine inspections of all premises in Kenya." • 30.5 Harmonization of inspection timelines with the PPB Customer Service Charter
		32.	• Removed the part previously titled "validity of licenses" 32. Closure of business. Reworded and made clearer provisions for pharmacy premises and manufacturing facilities • 32.5. 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. • 32.6 Where the closure is for a Manufacturing business: a. Where the closure is permanent, a manufacturer must notify the Board three months before the closure b. Permanent closure will lead to revocation of an issued license c. For any temporary closure that exceeds six months, notification shall be done one month prior d. Temporary closure will lead to suspension of an issued license
		34	Added 34. "Requirements for closure of premises" 34.1. Stock management – Finished and raw materials 34.2. Pharmacovigilance 34.3. PMS 34.4. Liability
		35	Added 35. "Lifting of suspension and revocation" • 35.1. A person or a business whose license is revoked has the right to appeal as provided under Cap 244. • 35.2. A person or a business whose license is suspended can have the suspension lifted when they comply with the requirements of the Board.

			• 35.3. The Board shall lift the suspension of the manufacturing license as per Guidance on suspension or revocation of GMP certification (HPT/ISE/GMP/MAN/009)
02	27-03-2023		Updated document number to the new format PRA/LPP/GPP/GUD/060
		Glossary	Added the definition of “parallel importation”
		18	Added Certificate of Parallel Importation
		Annexes	Updated the license processing flowchart with timelines as per the Service Charter Updated specimen licenses Updated the format for “License to Manufacture Drugs for Sale”
03	27/11/2023	Section25	Inserted a section numbered as 25.6 specifying documents that should be attached for renewal of licenses.
04	14/10/2024	Section 25	Changed the statement "CR12 form from the Registrar of Companies (not more than 3 months)" to "current CR12 Form from the Registrar of Companies
		Section 29.3	Added "The GMP department shall evaluate the proposed changes and communicate to the licensing department on any approved changes"

40.0 List of Contributors

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

No.	Name	Title
1	Dr.F.M.Siyoi	CEO, Pharmacy and Poisons Board
2	Dr. Wilfred O. Oguta	Director, Pharmacy Practice & Training
3	Dr. Dominic Mutie	Deputy Director, Licensing and GPP
4	Dr. Humphrey Mwavali	Head, Training and Professional Development, PPB
5	Dr. Abdulkadir Omar	Head, Licensing, PPB
6	Dr. Lily Kipkeno	Head, CPD
7	Mr. George Muthuri	Registration & Enrolment/QMS

41.0 Annexes

a. Annex 1: Specimen Health Safety Code

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

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 **JOHN DOE CORPORATION LTD**

of **P.O. BOX 999999, NAIROBI**

Plot No **Plot No. 999/999** is registered to carry on business of a pharmacist as provided for by section 23.

Registered No. of premises **PPB/999**

4th January, 2023	**BU202399999**
Date	*Licence No*

Note: (i) This Registration expires on **31st December, 2023**

(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. 10,000

SR. No: SR No. 00000/23

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

FORM 7

MINISTRY OF HEALTH

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

WHOLESALE DEALER'S LICENCE

Messrs JOHN DOE CORPORATION LTD of P.O. BOX 999999, NAIROBI

carrying on business at Plot No. 999/999, JONH DOE COMPLEX, NAIROBI

are hereby authorized to sell poisons by way of wholesale dealing.

4th January, 2023	BU202399999
Date	*Licence No*

Note: (i) This licence expires on **31st December, 2023**

Fee: KShs. 30,000

SR. No: SR No. 00000/23

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

FORM 31

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	JOHN DOE CHEMIST - NAIROBI		
Registration No of Premises	PPB/R/999		
Location of Premises	P.O BOX 999999 NAIROBI		
Town	Nairobi		
Street	Doe Street		
Plot No.	Plot No. 999/999		
Name of pharmaceutical technologist	JOHN DOE		
ID No	999999	Enrollment No	999999

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

31st January, 2023	BU2023999999
Date	*Licence No*

Note: (i) This Registration expires on **31st December, 2023**

(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. 10,000

SR. No: SR No. 008180/23

e. Annex 5: Specimen Manufacturing License

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

JOHN DOE CORPORATION LTD of **P. O . BOX 999999 - 11111 NAIROBI, KENYA.**

and having premises situated at **JOHN DOE COMPLEX, LENANA STREET, NAIROBI.**

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. 999999 LENANA STREET**

2nd December, 2022	**PPB/999**	**BU20239999**
Date	Registration No	*Licence No*

Note: (i) This licence expires on **31st December, 2023**

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

Fee: KShs. 50,000 Page 4 of 6 **SR. No: SR No. 9999/23**

FORM 22

Note: (iii) This license is valid subject to compliance with Good Manufacturing Practices.

(iv) This license applies only to the attached list of products approved for manufacture.

(v) Any variation or change to be made to the license shall immediately be notified to the Registrar.

(vi) Any deviation from the above conditions will lead to suspension or revocation of this license.

Fee: KShs. 50,000 Page 5 of 6 **SR. No: SR No. 9997/23**

Id	Registration No	Trade Name	Strength	Dosage	INN of API
1	H96/302	PARADOL	500MG	TABLET	PARACETAMOL
2	H96/433	FENPRO	200MG	COATED TABLET	IBUPROFEN
3	H97/174	DANGYL	200MG	TABLET	METRONIDAZOLE
4	H96/655	NEUTRICID	120MG / 250MG	CHEWABLE TABLET	ALUMINIUM HYDROXIDE AND MAGNESIUM TRISILICATE
5	H96/346	DINLACIN	25MG	CAPSULE	INDOMETHACIN
6	H97/191	CPHEN	250MG	CAPSULE	CHLORAMPHENICOL
7	H96/348	FENPRO	100MG	ORAL SUSPENSION	IBUPROFEN
8	H97/074	NEUTRICID	120MG / 250MG	ORAL SUSPENSION	ALUMINIUM HYDROXIDE AND MAGNESIUM TRISILICATE
9	H96/350	DINLAMIN	2MG	SYRUP	CHLORPHENAMINE MALEATE
10	H97/364	SULPHUR	10%	OINTMENT	SULPHUR
11	H96/345	SULTRIM	240MG	ORAL SUSPENSION	TRIMETHOPRIN AND SULPHAMETHOXAZOLE
12	H98/204	ORMIZOLE SUSPENSION	100MG	ORAL SUSPENSION	MEBENDAZOLE
13	H97/357	DANGYL	200MG	ORAL SUSPENSION	METRONIDAZOLE
14	H97/004	CPHEN	125MG	ORAL SUSPENSION	CHLORAMPHENICOL
15	H96/344	PARADOL	120MG	ORAL SUSPENSION	PARACETAMOL
16	H97/231	ASTHADIN	2MG	SYRUP	SALBUTAMOL SULPHATE
17	H97/005	COFZIT	2MG ,15DMG ,5MG AND 1.1MG RESPECTIVELY	SYRUP	CHLORPHENAMINE MALEATE,AMMONIUM CHLORIDE, SODIUM CITRATE AND MENTHOL
18	H2007/470	CANDICLO	1%	CREAM	CLOTRIMAZOLE CREAM
19	H96/351	WHITFIELD	6% / 3%	OINTMENT	BENZOIC ACID AND SALICYLIC ACID
20	H97/169	TETRALINE	3%	OINTMENT	TETRACYCLINE SKIN OINTMENT
21	H96/347	PLAZO	500MG	TABLET	AZITHROMYCIN
22	H98/267	BENZYLBENZOATE	25%	CUTANEOUS SUSPENSION	BENZYLBENZOATE
23	H2009/2014/576	TINDAZ 500MG	500MG,	TABLET	TINIDAZOLE BP
24	H2009/2014/562	NEOCIP-500	500MG	TABLET	CIPROFLOXACIN HYDROCHLORIDE BP
25	H2009/2014/567	OKAGESIC-400	400MG	TABLET	IBUPROFEN BP
26	H96/432	SULTRIM	80MG /400MG	TABLET	TRIMETHOPRIM AND SULPHAMETHOXAZOLE
27	H96/349	TETRALINE	250MG	CAPSULE	TETRACYCLINE

NEX

SR. No:..SR.No..9999/23

f. Annex 6: Specimen Annual Practice License for a Pharmacist

MINISTRY OF HEALTH

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

ANNUAL PRACTICE LICENCE AS A PHARMACIST

Practitioner Details	Licence No: P2023D99999
Name	DR. JOHN DOE
ID Number	999999
Registration Number	999999
Renewal Date	4th January, 2023
Superintendent	YES
Premise	JOHN DOE CORPORATION LTD
Premise Address	Postal Address: P.O. BOX, 999999, NAIROBI Plot No: 999/999 Nairobi

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

Note:

1. This Licence is valid upto **31st December, 2023**, subject to compliance with the provisions of the Act.
2. For superintendents, no change of premises is permitted without authority of the Pharmacy and Poisons Board

Fee: KShs. 5,000 Page 1 of 4 **SR. No: 000485/23**

g. Annex 7: Specimen Annual Practice License for a Pharmaceutical Technologist

MINISTRY OF HEALTH

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

ANNUAL PRACTICE LICENCE AS A PHARMACEUTICAL TECHNOLOGIST

Practitioner Details	Licence No: PT2023D99999
Name	JOHN DOE
ID Number	999999
Enrollment Number	999999
Renewal Date	31st January, 2023
Superintendent	YES
Premise	JOHN DOE CHEMIST - NAIROBI
Premise Address	Postal Address: P.O BOX 999999 NAIROBI Plot No: 999/999 Nairobi

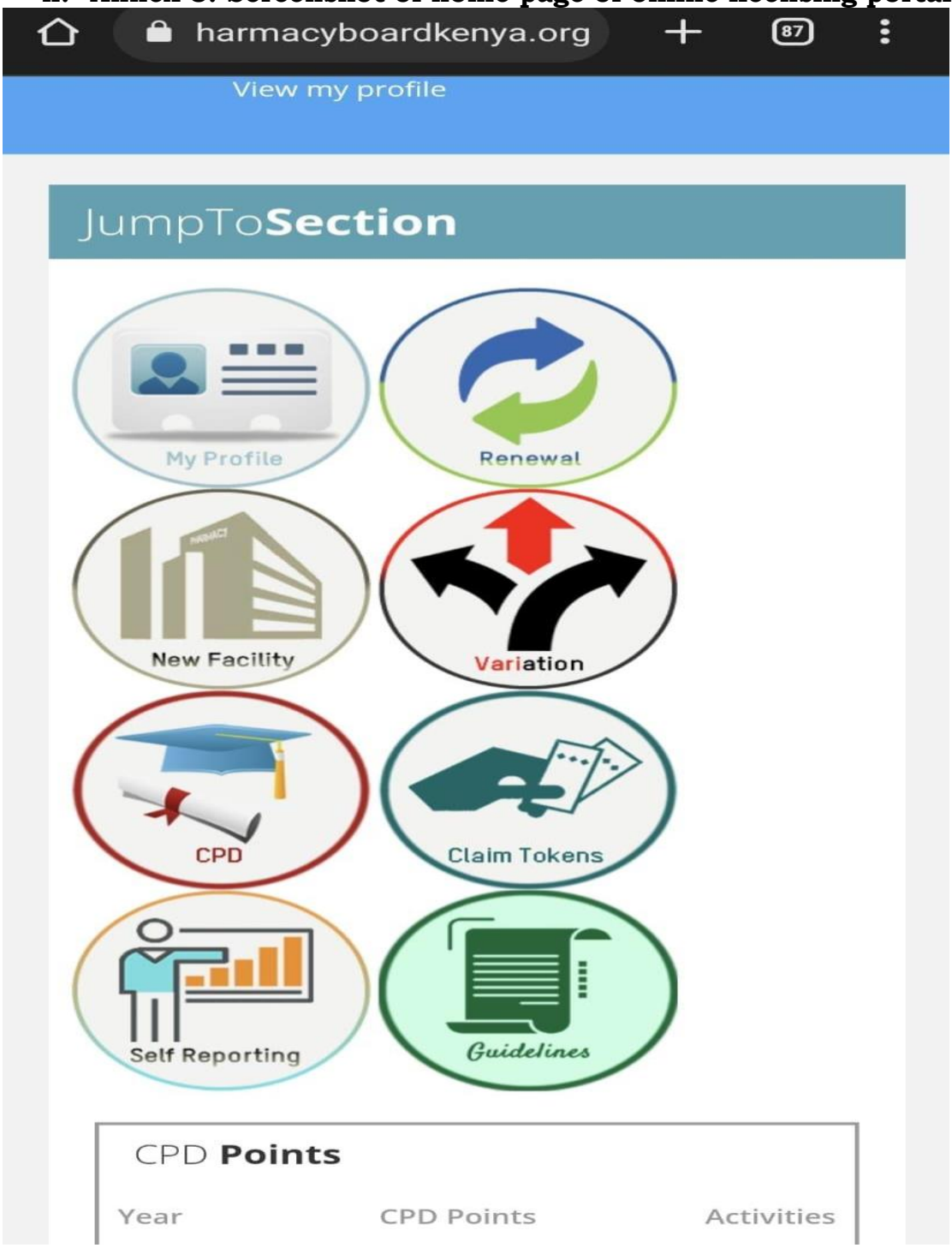
The above named person is hereby licensed to practise as a Pharmaceutical Technologist in accordance with the Pharmacy and Poisons Act

Note:

1. This Licence is valid upto **31st December, 2023**, subject to compliance with the provisions of the Act
2. For superintendents, no change of premises is permitted without authority of the Pharmacy and Poisons Board

Fee: KShs. 5,000 Page 1 of 2 **SR. No: 008179/23**

h. Annex 8: Screenshot of home page of online licensing portal



i. Annex 9: New Premises Approval Flowchart

No	New Premises Application Process	Timelines	Responsibility
1	New Pre-Registration Application Submission/acknowledg ement	1 Day	Applicant/The Board
2	New Premise Pre-registration screening	Within 7 days of receiving application	The Board
3	New Premise Application Submission	0 Days	Applicant/The Board
4	First Review /Approval – forwarding for a second review or decline with a reason	Within 15 days of receiving application	The Board
5	Pre-registration Inspection	14 Days from first reviewer approval	The Board
6	Second Review /Approval - issuance business unit license(s)/ practice license or a decline notification with a reason	Within 15 days of receiving of inspection	The Board
7	Issuance of New License	Downloadable immediately after second reviewer approval	The Board

NB: The total processing time for new establishments is estimated to be **52 days**. **The timelines are exclusive of the time taken by the applicant in responding to queries.**

j. Annex 10: Renewal and Variation Flowchart

No	Process	Timelines	Responsibility
Renewal of Licenses			
1	Renewal Application Submission/ Acknowledgement	1 Day	The Applicant
2	First Review /Approval – forwarding for a second review or a decline notification with a reason	Within 15 days of receiving of application	The Board
3	Second Review /Approval - issuance of business unit license(s)/ practice license or decline notification with a reason	Within 15 days of first reviewer approval	The Board
4	License Issued / Downloaded	Downloadable immediately after second reviewer approval	The Board
Post-licensure variation			
1	Variation Application/ acknowledgement	1 Day	The Applicant
2	Variation First Review /Approval - issuance of license(s), or forwarding for a second review, or a decline notification with a reason	Within 15 days of variation application	The Board
3	Variation Inspection	Within 14 days of first reviewer approval	The Board
4	Variation Second Review /Approval - issuance of a certificate of registration of premises or a letter of rejection	Within 15 days of receiving of inspection report	The Board
5	Issuance of New License, or Addendum to the License post-variation	Downloadable immediately after second reviewer approval	The Board

NB: Total processing time is estimated as **31 days for renewal,** and **45 days for variations requiring inspection**. The timelines are exclusive of the time taken by the applicant in responding to queries.

k. Annex 11: Specimen Parallel Import Certificate

MINISTRY OF HEALTH

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

PARALLEL IMPORT CERTIFICATE

Messrs **JOHN DOE LIMITED of P.O. BOX 999999 - 1111 NAIROBI**

carrying on business at **LR 209/18771 WESTLANDS , 63 WESTLANDS ROAD , NAIROBI**

are hereby authorized to to parallel import medicinal substances.

1st December, 2022	**BU202300157**
Date	*Licence No*

Note: (i) This licence expires on **31st December, 2023**

Fee: KShs. 30,000

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SR. No: 024019/22

Pharmacy and Poisons Board

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