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MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINES FOR REGISTRATION AND LICENSING OF PREMISES

OCTOBER, 2026

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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
CAPA	Corrective and Preventive Action
CR12	Document indicating particulars of ownership and shareholding of a limited liability company
KRA PIN	Kenya Revenue Authority Personal Identification Number
PRIMS	Pharmaceutical Regulatory Information Management System (GMP portal)
RHRIS	Regulatory Human Resource Information System
SMF	Site Master File
VMP	Validation Master Plan

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.

Controlled Manufacturing: A regulatory arrangement under which a manufacturer holding a Temporary Manufacturing Licence is permitted to undertake specified manufacturing operations subject to predefined limitations, conditions, risk-control measures, regulatory monitoring, and corrective action requirements pending achievement of full compliance with licensing and GMP requirements.

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
b) 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: Any building, part of a building, warehouse or other fixed location owned, leased, used or controlled by an applicant or licensee for the conduct of an activity regulated by the Board under the Pharmacy and Poisons Act, at the specific address for which registration or a licence has been issued, and includes all areas within that location where medicinal products or medicinal substances are manufactured, processed, packaged, stored, handled, prepared, compounded, dispensed, sold or supplied.

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 4 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.

Complete application: An application containing all mandatory information, required supporting documents, applicable fees and other prerequisites necessary for the relevant regulatory assessment to commence.

Manufacturing Facility: The premise used for making medicinal products or medicinal substances, 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.

Notifiable change: A change to a registered or licensed premise, or to the particulars, scope, conditions or authorised activities of an issued licence, which must be notified to the Board and classified as minor or major under the applicable change-control criteria.

Renewal: The regulatory process through which a current manufacturing licence is continued for a further period, following assessment of the application and the applicable compliance status.

Revocation: A final regulatory action terminating a manufacturing licence in accordance with applicable law and the prescribed regulatory process.

Site Master File (SMF): A document prepared by the manufacturer containing specific and factual information about the quality management policies and activities of the site, and the production and quality control of manufacturing operations carried out at the named site.

Suspension: An interim regulatory action that restricts or stops all or specified manufacturing activities to control an identified risk while the

underlying facts, corrective action or compliance status are addressed. A suspension may be full or partial.

Temporary/Conditional Authorisation: An exceptional, time-limited regulatory tool permitting controlled manufacture while defined non-critical requirements are being completed, subject to specified scope, conditions, duration, monitoring and exit criteria.

Validation Master Plan (VMP): A document that summarises the manufacturer's overall philosophy, intentions and approach to validation, including the validation activities to be performed at the site.

Variation: A regulatory change to an existing valid manufacturing licence, based on an application and supporting evidence, excluding suspension or revocation.

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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 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. Ahmed Mohamed

CHIEF EXECUTIVE OFFICER

1. INTRODUCTION

1.1. 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.

1.2. 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".

1.3. **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

In relation to manufacturing facilities in (f) above, these guidelines are applied together with the Guidance Notes for Establishing Health Products and Technologies Manufacturing Facilities in Kenya (HPT/ISE/GMP/MAN/006) and other related guidelines issued by the Board. They cover the following regulatory processes:

i. Registration and licensing of a new manufacturing facility;
ii. Renewal of a manufacturing licence;
iii. Variation of an issued manufacturing licence;
iv. Temporary/conditional manufacturing authorization;
v. Suspension of an issued manufacturing licence;
vi. Lifting or reinstatement of a suspended manufacturing licence;
vii. Revocation of an issued manufacturing licence; and
viii. Notifiable changes and change control.

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

2. REQUIREMENTS FOR PREMISES

2.1 General Requirements for Premises

a) 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).

b) 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.

c) 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.

d) 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/

e) 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

f) 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.

g) The Board's registration, licensing, inspection, renewal, variation, and compliance requirements shall apply uniformly to all pharmaceutical establishments, whether domestic, public, or private, and regardless of ownership. The same licensing criteria and regulatory standards shall be applied without distinction based on the ownership, management, or funding of an establishment.

2.2 **Location and Design**

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

b) 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.

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

d) Every part of the pharmacy's operations must be on approved premises, following a satisfactory inspection by the 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.

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

f) 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 the dispensation process in the pharmacy. The premises shall be required to address, among other issues, the fire prevention facilities.

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

h) 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.

i) In the case of pharmacies that operate within proximity to, or within a medical center or a hospital, the pharmacy premises must be

j) separate or distinct from the rest of the medical center and the premises must be approved by the Board.

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

2.3 **Ownership and Beneficial Interests**

a) The ownership of pharmacies may be:

i. A sole proprietor, or.

ii. A partnership, or.

iii. A limited company/body corporate, or.

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

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

c) 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

d) 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.

2.4 **Personnel**

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

b) 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).

c) 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.

d) 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.

e) 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

f) The superintendent shall be available to oversee the handling of medical products at the facility.

g) 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

h) The owner and superintendent shall individually and jointly ensure that only qualified personnel have access to handling or dispensing of pharmaceuticals.

i) 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.

j) 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).

2.5 **Practice Licenses**

a) 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.

b) 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.

c) 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

d) For avoidance of doubt, practice variation evidence shall be, based on the variation type, as follows

2.5.1 **Moving to an existing premise**

a) Duly signed letter of appointment and acceptance (if not a shareholder)

b) Duly signed and acknowledged letter of resignation from current position

c) Duly signed and acknowledged letter of resignation from current position

2.5.2 **Termination of contract**

a) Duly signed and acknowledged letter of resignation from current position

b) Copy of the terminated contract

2.5.3 **Termination of practice license**

a) Letter of intention stating the reasons for asking to terminate the license

2.5.4 **Business closure**

a) Letter of intention to close the business/ branch

b) Letter of cessation of the business from the Registrar of Companies (where applicable)

c) Letter from the shareholders/ directors authorizing the action

e) 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.

f) 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.

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

2.6 **Eligibility to Superintend**

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

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

i. Holds a valid license to practice as a pharmaceutical technologist and

ii. 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.

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

2.7 **Business Names**

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

b) 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.

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

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

e) 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

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

g) 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:
   i. All signage inside or outside of the pharmacy
   ii. Advertisements, including telephone directories
   iii. Business cards, labels, stationery, prescription stamps, envelopes and computer-generated documents, including repeat authorizations.

2.8 **Equipment and Storage Facilities**

a) 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.

b) There should be adequate storage space. The premises are to be laid out and equipped so that:
   i. Any medical product stored in the premises should be stored per the manufacturers and the Board's recommended storage conditions.
   ii. The safety and well-being of the personnel are adequately addressed
   iii. There is adequate space for quarantined health products and technologies

2.9 **Resources for Pharmacy Premises**

a) 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.

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

2.10 **Premises Registration Numbers, License Numbers and Codes**

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

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

c) 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.

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

2.11 **Display of Licenses and Certificate of Registration of a Premise**

a) 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.

b) 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.

c) 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.

d) 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.

2.12 **Premises for Pharmacists**

a) 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).**

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

c) A wholesale business shall not retail on the same premises

d) A hospital pharmacy shall not do wholesale business.

e) 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.

2.13 **Premises for Pharmaceutical Technologists**

a) 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).**

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

c) 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.

2.14 **Online/Internet Pharmacies**

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

b) 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.
c) 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).
d) The Guidelines for Internet Pharmacy Services in Kenya shall also apply to telehealth or telemedicine establishments.
e) 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.

2.15 **Wholesale Premises**

a) 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).**
b) 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.
c) A pharmaceutical technologist is not eligible for a Wholesale Dealers' License.
d) The Wholesale Dealers License automatically expires on the 31st day of December in the year it is issued.

2.16 **Certificate of Parallel Importation**

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

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

2.17 **Scientific Offices**

a) 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.

b) 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.

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

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

2.18 **Medical Devices Establishments**

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

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

2.19 **Warehouses**

a) 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)

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

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

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

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

f) A warehouse shall only be used for storage purposes, and no retail sales shall be allowed.

2.20 **Manufacturing Facilities**

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

b) 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).

c) 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 shall be attached to the application for evaluation.

d) 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

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

f) The manufacturing license issued by the board shall be for specific dosage forms and product types, and the list of authorized products, list of authorized manufacturing operations and list of key personnel shall be annexed

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

h) A manufacturing licence shall not be issued, varied or reinstated on the basis of administrative review alone; confirmation of an acceptable Good Manufacturing Practice (GMP) compliance status is required in every case.

i) Every application for a new manufacturing licence, and every decision to vary, suspend or reinstate an existing licence, shall be independently reviewed at two levels before a decision is issued. Where an application is declined, the reasons given shall be specific enough to enable the applicant to address the deficiency.

j) The Board may issue a temporary manufacturing licence authorizing limited and controlled manufacturing activities where the completion of specific GMP compliance requirements can only be demonstrated or verified through actual manufacture, including process validation, equipment qualification, cleaning validation, media fills, validation batches, or other comparable activities. Such authorization shall specify its scope, conditions, duration, monitoring and reporting obligations, and exit criteria, and shall be granted only where all critical quality, safety, personnel and facility requirements have already been satisfied

3. APPLICANT GUIDE FOR PREMISES LICENSING

3.1 Application for a New Premises Licence

a) Applicants intending to register and license a new pharmaceutical premises shall follow the steps below.

Step 1: Access the PPB Practice Portal

Access the Pharmacy and Poisons Board Practice Portal:

https://practice.pharmacyboardkenya.org/

Sign in using your **registration or enrolment number and password**.

Step 2: Start a New Facility Application

From the dashboard:

1. Click **"New Facility"**
2. Enter the required details of the proposed premises.
3. Select the appropriate premises type.
4. Provide the required details of the proprietor and superintendent.
5. Upload the required supporting documents.

   The documents should include, as applicable:

   - **E-Citizen business name search**; and
   - Valid KMPDC licence where the proposed premises is a hospital pharmacy.

b) Applicants should ensure that the proposed premises, ownership, superintendent, location, layout, equipment and storage facilities comply with the applicable PPB requirements before submitting the application.

Step 3: Submit the Application for Review

Review the information entered and documents uploaded to ensure that they are accurate and complete.

Submit the application and wait for communication from the Board regarding the review process.

Step 4: Complete the Application After Approval

Where the initial application is approved:

1. Log in to the PPB Practice Portal.
2. Follow the instructions provided by the Board.
3. Complete the remaining application requirements based on the type of premises applied for**.**
4. Submit the completed application for payment.

Step 5: Make Payment

Once directed to the payment page:

1. Follow the payment instructions provided on the portal.
2. Make the required payment.
3. Confirm successful payment.
4. Download and retain the payment receipt.

Step 6: Premises Inspection

Following approval of the application, the relevant regional PPB office will contact the applicant regarding inspection of the proposed premises.

The applicant shall ensure that the premises are fully prepared and comply with the applicable requirements before inspection.

Inspection of the premises shall be conducted in accordance with the applicable PPB guidelines:

c) For premises subject to Good Storage and Distribution Practices (GSDP): the inspection shall be conducted in accordance with the Guidelines on Good Distribution Practices for Medical Products and Health Technologies in Kenya (HPT/ISE/EFS/GUD/019). The outcome of the inspection shall be documented in a GDP Inspection Report.

d) For premises subject to Good Manufacturing Practices (GMP), the inspection shall be conducted in accordance with the applicable GMP requirements and the Guidance Notes for Establishing Medical Products and Health Technologies Manufacturing Facilities in Kenya (HPT/ISE/GMP/MAN/006). If the premises are found to comply with the applicable GMP requirements, the outcome shall be reflected in the issuance of a GMP Certificate.

Step 7: Final Review

A final review of the application will be undertaken after the inspection.

Where deficiencies are identified, the applicant shall address them as directed by the Board.

Step 8: Download and Display the Licence

Once the application has been approved:

1. Log into the PPB Practice Portal.

2. Download the issued premises licence.

3. Print the licence.

4. Conspicuously display the licence at the licensed premises.

The licence and registration information should remain clearly visible and available for verification.

3.2 **Renewal of a Premises Licence as a Superintendent**

a) A superintendent applying for renewal of a premises licence shall follow the steps below.

Step 1: Log into the PPB Practice Portal Access:

https://practice.pharmacyboardkenya.org/

Sign in using your registration or enrolment number and password**.**

Step 2: Start a Renewal Application

From the dashboard:

1. Click “Renewal.”
2. Select “New Renewal Application.”

Step 3: Select the Premises

1. Enter the name of the premises.
2. Wait for the premises to appear in the drop-down list.
3. Select the correct premises from the list.
4. Select “YES” under the superintendent option.

Step 4: Upload the Required Documents

The supporting documents will depend on the type of premises.

A. Retail or Wholesale Premises

- Add the name of the director in the designated section.
- Submit the application for payment.

B. Hospital Pharmacy

- Attach the valid KMPDC licence.
- Add the name of the director in the designated section.
- Submit the application for payment.

C. Manufacturing Premises

- Attach the valid GMP Certificate issued by PPB.
- Add the name of the director in the designated section.
- Submit the application for payment.

Step 5: Make Payment

Once directed to the payment page:

1. Follow the payment instructions.
2. Make the required payment.
3. Download and retain the payment receipt.

Step 6: Await Board Review

After payment, wait for communication from the Board regarding the review of the renewal application.

b) The applicant should monitor the PPB Practice Portal and any communication from the Board for further instructions.

3.3 **Variation of an Issued Licence**

a) Where a licensee needs to change information or conditions relating to an issued licence, an application for variation shall be made through the PPB Practice Portal.

Step 1: Log into the PPB Practice Portal Access:

https://practice.pharmacyboardkenya.org/

Sign in using your **registration or enrolment number and password**.

Step 2: Select Variation

From the dashboard:

1. Click **"Variation."**
2. Select the appropriate **type of variation** from the drop-down menu.

Step 3: Provide Details of the Variation

1. State the reason(s) for requesting the variation.
2. Upload the appropriate supporting evidence for the requested variation.
3. Review the information and documents provided.

b) The evidence required will depend on the type of variation being requested.

Step 4: Submit and Pay, Where Applicable

1. Submit the variation application.
2. Make payment where a fee is applicable.
3. Download and retain the payment receipt.

Step 5: Await Board Review

c) Wait for communication from the Board regarding the review and outcome of the variation application.

d) Where additional information or supporting documentation is required, the applicant shall provide it as directed by the Board.

3.4 Important Requirements for Applicants

Before submitting an application, applicants should ensure that:

a) The information provided on the portal is accurate and complete.
b) All uploaded documents are valid, current and legible.
c) The proposed premises comply with the applicable PPB premises requirements, GSDP and GPP standards**.**
d) The proposed superintendent is appropriately registered/enrolled and holds a valid practice licence.
e) A superintendent does not simultaneously superintend another registered premises.
f) All pharmaceutical activities are conducted within the premises approved by the Board.
g) The premises are adequately equipped and have appropriate storage facilities.
h) Required safety and fire-prevention measures are in place.
i) The premises are ready for inspection before the inspection date.
j) The licence is displayed conspicuously once issued.

3.5 PPB Online Licensing Portal

a) Practice Portal:
https://practice.pharmacyboardkenya.org/
b) Licence Status Verification:
https://practice.pharmacyboardkenya.org/LicenseStatus

4. APPLICATION FOR NEW PREMISES

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

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

c) The applicable supporting documents include copies of the following:

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

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

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

iv. The National Identity Card of the applicant

v. The Company KRA PIN Certificate

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

vii. Any partnership agreement for the business

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

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

x. 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:

- The location and overall floor area of the dispensary.
- The bench area, including sink, refrigerator, barcode scanner(s) and work areas.
- Direct public access (for pharmacy premises only)
- 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) (Requirements for retailers & wholesalers)

d) 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.

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

4.1 **Retail, Wholesale, Warehouse premises, Hospital**

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) Company KRA PIN Certificate

4.2 **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) Company KRA PIN Certificate

4.3 Manufacturing Facility

4.3.1 General Application Requirements and Documentation for a Manufacturing Licence

Applicants shall submit applications for a manufacturing licence through the PPB online portal and upload all required documentation under the relevant sections of the portal before submission.

The applicant shall provide the following documents, as applicable:

a. Certificate of Incorporation for limited liability companies;
b. Signed Memorandum and Articles of Association or a current CR12 Form issued by the Registrar of Companies;
c. Company KRA PIN Certificate;
d. Affidavit and/or letter of appointment of the Superintendent Pharmacist, where applicable;
e. List and curricula vitae (CVs) of key technical personnel; and
f. Any other documents that may be specified by the Board based on the nature and scope of the proposed manufacturing activities.

The applicant shall ensure that all submitted information and documentation is complete, accurate, valid and current.

4.3.2 Manufacturing Scope and Product Declarations

Applicants and licence holders shall declare the proposed and/or actual manufacturing activities in accordance with the applicable requirements and the manufacturing scope approved by the Board and reflected in the PPB GMP Certificate on the PRIMS Portal.

The manufacturing scope shall include, as applicable:

a. Dosage forms manufactured, such as oral solids and oral liquids;
b. Broad product categories, such as sterile, non-sterile and biological medicinal products;
c. Specific product categories, such as general products, cephalosporins, penicillins and other beta-lactams;
d. Product types, such as hard gelatin capsules, dry syrups in glass bottles and oral powders;
e. The specific products manufactured or proposed to be manufactured; and
f. Activities undertaken at the site, including manufacturing, processing, batch certification, primary packaging, secondary packaging, testing and storage.

The declared manufacturing scope shall be consistent with the scope approved by the Board. No manufacturing activity or product category outside the approved scope shall be undertaken without prior approval by the Board.

For declaration of manufactured products, the applicant initialy declares export only products (not registered in Kenya) on the GMP portal and submits for verification by GMP Division. Once the final approval of the license is done, the applicant is able to download the manufacturing license with an annexed export only list of products.

This action of downloading the license, will consequently allow the applicant to retain products that have MA as per compedium of guidelines for medicine registration. The list of the retained products will undergo review and verification against MA database for approval. Once approved, the applicant shall be notified to redownload the license that will have a second annex that has a list of Products with MA.

If the retained products information have discrepancies from the MA database after review and verification, the applicant will receive notification to correct and resubmit in liason with MA department.

4.3.3 Criteria for Issuance of a Temporary Manufacturing Licence

An applicant shall be eligible for a temporary manufacturing License after meeting the following criteria:

a) The applicant is a new manufacturer that has not yet commenced commercial production of pharmaceutical products at the site.
b) The manufacturing site is not yet fully operational for commercial manufacture.
c) The site is at a stage of qualification and validation (equipment, utilities, systems, processes).
d) Physical infrastructure and systems are sufficiently established to support validation activities under GMP-compliant conditions.
e) The applicant intends to conduct qualification and validation activities (process validation, cleaning validation, analytical method validation, stability studies) before commercial production.
f) The applicant demonstrates the intent and technical/financial capability to progress to full manufacturing authorization

4.3.4 Specific Requirements for a Temporary Manufacturing Licence

An applicant seeking a Temporary Manufacturing Licence shall, in addition to the requirements specified under Section 4.3.1, provide evidence that the facility has satisfactorily progressed through the applicable establishment and readiness assessment stages, including:

a. Letter of No Objection to the Execution of the Proposed Layout Plan from GMP division;
b. Letter of Satisfactory Completion of Site Verification Assessment from GMP division;
c. Letter of Satisfactory Completion of Operational Readiness Assessment from GMP division;
d. Any other information or documentation required by the Board to demonstrate readiness for controlled manufacturing activities.

Following satisfactory review of the application and supporting documentation, the Board may issue a Temporary Manufacturing Licence where the facility has substantially complied with the applicable Good Manufacturing Practice (GMP) requirements, but specific requirements remain to be completed, demonstrated or verified through controlled manufacturing activities.

The Temporary Manufacturing Licence shall specify the approved manufacturing scope, conditions, restrictions, regulatory milestones and validity period.

4.3.5 **Issuance, Scope, Conditions and Restrictions of a Temporary Manufacturing Licence**

a) **Scope of the licence**

A Temporary Manufacturing Licence shall:

i. Be issued only for the specific manufacturing site, dosage forms, product types, manufacturing operations and activities expressly authorised by the Board;
ii. Clearly specify the activities and products permitted under the licence;
iii. Be limited to activities necessary to complete or verify outstanding GMP requirements, including, where applicable:

- Process validation;

- Cleaning validation;
- Media fills for sterile manufacturing;
- Process performance qualification;
- Hold-time studies;
- Stability studies; and
- Other controlled manufacturing activities specifically approved by the Board.

A Temporary Manufacturing Licence shall not be construed as confirmation of full GMP compliance or as a substitute for a Routine Manufacturing Licence or GMP Certificate.

b) **Conditions and restrictions**

The holder of a Temporary Manufacturing Licence shall:

i. Operate only within the manufacturing scope, conditions and restrictions specified in the licence;
ii. Undertake only the manufacturing activities authorised by the Board and maintain accurate records of all activities conducted under the licence;
iii. Not manufacture products outside the scope specified in the licence;
iv. Not introduce additional products, dosage forms, manufacturing operations or production lines without prior written approval from the Board;
v. Not transfer manufacturing activities to another site or premises without prior approval from the Board;
vi. Not release or supply products manufactured under the licence for commercial distribution unless expressly authorised by the Board;
vii. Notify the Board of changes to ownership, business name, premises, Superintendent Pharmacist or other particulars relevant to the licence;
viii. Not make significant changes to the premises, equipment, utilities, processes, key personnel or other particulars

affecting the licence without notifying the Board and obtaining prior approval where required; and

ix. Comply with all other conditions imposed by the Board as part of the licence.

4.3.6 Validity, Timelines and Extension of a Temporary Manufacturing Licence

A Temporary Manufacturing Licence shall be valid for a maximum period of six (6) months from the date of issuance. The expiry date shall be clearly stated on the licence.

The following regulatory milestones shall apply:

Regulatory milestone	**Required timeline**
Commencement of authorised activities	Only after issuance of the Temporary Manufacturing Licence
Completion of authorised manufacturing, validation and qualification activities	Within the six-month validity period
Submission of evidence demonstrating completion of outstanding GMP requirements	Within the period specified by the Board and before expiry of the licence
Application for a Routine Manufacturing Licence	Before expiry of the Temporary Manufacturing Licence
Issuance of a Routine Manufacturing Licence	Upon verification of satisfactory GMP compliance and fulfilment of the applicable licensing requirements

A Temporary Manufacturing Licence shall not be renewable as a routine administrative or licensing mechanism and shall not automatically convert into a Routine Manufacturing Licence upon expiry.

Where exceptional circumstances prevent completion of the authorised activities within the six months, the licence holder shall submit a written request to the Board before expiry, providing justification, progress made, outstanding activities and a proposed completion plan.

Any extension shall be subject to specific written approval by the Board following a risk-based assessment. An extension shall not authorise activities beyond the scope of the original licence. Where an extension is not granted, the licence shall expire at the end of its validity period.

4.3.7 Transition from a Temporary Manufacturing Licence to a Routine Manufacturing Licence

A holder of a Temporary Manufacturing Licence seeking to transition to a Routine Manufacturing Licence shall demonstrate that the facility has achieved the required level of GMP compliance and fulfilled the conditions specified in the Temporary Manufacturing Licence.

The holder shall complete the applicable manufacturing, validation, qualification and other outstanding activities and undergo the applicable GMP inspection and certification process.

The applicant shall submit, through the PPB online portal, the following documents:

a. A valid GMP Certificate issued by the Pharmacy and Poisons Board and verifiable through the GMP PRIMS Portal;
b. Declaration of Manufacturing Scope;
c. Declaration of Products Manufactured;
d. An updated list of Key personnel
e. Any other information or documentation required by the Board to support the transition to routine manufacturing.

The Board shall review the submitted documentation and verify that the proposed manufacturing activities are consistent with the approved GMP scope.

A valid GMP Certificate shall be a prerequisite for transition from a Temporary Manufacturing Licence to a Routine Manufacturing Licence. Where the requirements have been satisfactorily fulfilled, the Board shall issue the Routine Manufacturing Licence.

Where the requirements for transition have not been fulfilled before expiry of the Temporary Manufacturing Licence, the licence shall expire unless an extension has been expressly approved by the Board in accordance with Section 4.3.5.

A Routine Manufacturing Licence shall be issued upon satisfactory fulfilment of the applicable licensing requirements and verification of GMP compliance, including possession of a valid GMP Certificate covering the approved manufacturing scope.

A Routine Manufacturing Licence shall:

a. Authorise manufacturing only within the scope approved by the Board;
b. Be valid for one (1) calendar year and expire on 31 December of each year, irrespective of the date on which it was issued;
c. Be subject to renewal within the period specified by the Board, with all applicable renewal requirements satisfied before expiry; and
d. Remain subject to continued compliance with applicable GMP requirements, the approved manufacturing scope and all conditions imposed by the Board.

The Board may suspend, vary or revoke the licence in accordance with applicable law where the licence holder fails to maintain the required standards or breaches the conditions of the licence.

4.3.8 **Review and Decision-Making Process**

The regulatory review outcome shall be determined based on the completeness, accuracy, consistency, and compliance of the application and supporting documentation with applicable legal and regulatory requirements, relevant PPB procedures, and the requirements applicable to the specific licensing stage.

The regulatory review shall result in one of the following decisions:

Decision	**Decision-Making Criterion**	**Regulatory Action/Outcome**

Approve	The application and supporting documentation are complete, accurate, satisfactory, and compliant with all applicable legal, regulatory, and PPB requirements. No outstanding deficiency that would prevent approval has been identified.	The application shall be approved and applicant notified through the designated electronic communication channel and making the electronically generated licence available for download through the PPB portal.
Reject	The application does not meet applicable legal, regulatory, or PPB requirements, or identified deficiencies remain unresolved following regulatory review.	The application shall be declined and the reasons for the decline shall be communicated to the applicant. Where applicable, the applicant may address the identified deficiencies and resubmit the application through the PPB portal.

4.3.9 **Manufacturing Licence Decision Pathway**

For manufacturing facilities, the regulatory decision shall follow the applicable licensing stage and shall be based on the evidence available at each stage.

Stage 1: Application Submission and Regulatory Assessment

Application submitted → Regulatory assessment → Have the applicable requirements been satisfactorily met?

- **No:** Decline the application and communicate the reasons to the applicant.
- **Yes:** Determine the applicable licensing stage and proceed to the relevant assessment.

Stage 2: Temporary Manufacturing Licence

Is the facility sufficiently ready for controlled manufacturing, with outstanding GMP requirements suitable for controlled verification?

- **No:** Decline the application or withhold approval of the Temporary Manufacturing Licence, as applicable, and communicate the reasons to the applicant.

- **Yes:** Approve the **Temporary Manufacturing Licence**, subject to the applicable conditions and restrictions, for a period of up to six (6) months.

Stage 3: Transition to a Routine Manufacturing Licence

After completing the required controlled manufacturing activities, fulfilling the applicable GMP requirements, and obtaining a satisfactory GMP inspection and GMP Certificate, assess whether the proposed manufacturing scope aligns with the scope covered by the GMP Certificate and whether the applicant has fulfilled all applicable conditions and restrictions of the Temporary Manufacturing Licence.

- **No:** Decline the application for a Routine Manufacturing Licence and communicate the reasons to the applicant.
- **Yes:** Approve the **Routine Manufacturing Licence** for the manufacturing scope authorised by the Board and supported by the applicable GMP Certificate.

The Routine Manufacturing Licence shall be valid for the applicable calendar year and shall expire on 31 December of that year, irrespective of the date of issue. Renewal shall be subject to fulfilment of the applicable renewal requirements and shall be undertaken in accordance with the prescribed regulatory process.

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

a) 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.

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

c) 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.

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

e) 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.

f) 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.

g) 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)

h) Having considered all factors and matters relating to the application, the Board will either:

i) Issue a certificate of registration of premises under Part II of the Pharmacy and Poisons Act, Cap 244, Laws of Kenya; or

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

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

l) 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.

m) The processing timelines are specified in the Board's Customer Service Delivery Charter (CEO/PQR/QMS/POL/003).

n) 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 shall be issued

o) 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

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

q) 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.

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

s) Please see Annex 9: New Premises Approval Flowchart

4.5 **Renewal of Licenses**

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

b) 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.

c) 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.

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

e) 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.

f) 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:

4.5.1 **Retail, Hospital, 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 KRA PIN Certificate

4.5.2 **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 KRA PIN Certificate

4.5.3 **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 KRA PIN Certificate
e) Kenya Medical Practitioners and Dentists Council (KMPDC) Licence (for Hospitals)

4.5.4 **Manufacturing Facility**

a) Certificate of incorporation for a limited liability company type of business
b) Signed page of the articles and memorandum of association, or the current CR12 Form from the Registrar of Companies
c) Affidavit and/or letter of appointment for the superintendent pharmacist
d) List and curriculum vitae of key personnel
e) List of manufactured products
f) Company KRA PIN Certificate
g) Annual declaration of continued compliance
h) The applicant shall select the following as relevant to the facility and the GMP certificate

i. Dosage forms manufactured, e.g. Oral solids, oral liquids, etc.
ii. Broad categories of products manufactured, i.e., sterile, non-sterile and biological medicinal products
iii. Categories of products manufactured, e.g., General, cephalosporin, penicillin, etc.

iv. Product type, e.g. hard gelatin capsules, dry syrups in glass bottles, oral powders in glass, etc.

v. Activities carried out on the site, i.e., processing operations, batch certification, primary & secondary packaging

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
e) 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.
f) 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 will automatically become void.
g) The approvals of renewed licenses shall occur within the timelines prescribed in the service charter from the time of receipt of the application.
h) Please refer to Annex 10: Renewal and Variation Approval Flowchart

4.6 **Penalty for late Renewal**

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.

4.7 **Notifiable Changes**

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

b) The changes may lead to a variation of the license or issuance of a fresh registration of premises.

c) Changes shall be classified as minor or major.

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

i. Business name
ii. Postal address and/or email address
iii. Change of ownership - including the acquisition or disposal of a financial interest in a pharmacy business, change in share distribution, change of directors, partners/owner's/ members
iv. Superintendent/ responsible pharmacist/ pharmaceutical technologist

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

i. Change of premise location, i.e., change in location, plot number, building, or floor in the same building
ii. Nature of business, e.g., from wholesale to retail
iii. Change from the business of a pharmacist to the business of a pharmaceutical technologist and vice versa

iv. Altering (including expansion or reduction in size) and renovating substantially without relocating the pharmacy business and without changing the ownership or address
v. Deferment (inactive business without cessation of business registration)
vi. Cessation/Business closure
vii. Any other significant changes

f) For notifiable changes in manufacturing premises, refer to changes that may affect the scope, validity, or conditions under which the GMP certificate was issued. Such variations may arise from modifications in:
i. Manufacturing site, name, address
ii. Dosage forms manufactured
iii. Categories of products manufactured
iv. Subcategories of the dose forms
v. Key personnel
vi. Manufacturing activities
vii. Other activities carried out on the site

4.7.1 **Relocation, Change of Address or Name**

a) 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.

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

c) 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.

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

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

4.7.2 **Variation of licenses**

A duly registered or licensed premise can apply for a 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.

For avoidance of doubt, the following evidence will be required to support different types of variation applications

a) **Change of business name**

i. Business Registration Certificate (for sole proprietorships or partnerships)
ii. Certificate of Incorporation (for a Limited Liability Company)
iii. Current CR12 - Showing a list of directors and shareholders
iv. Certificate of Change of Particulars
v. Other Relevant Documents

b) **Change of Postal Address and/or Email Address/Contact Details**

i. Duly signed request letter with the details to be changed
ii. Other Relevant Documents

c) **Change of Ownership**

i. Business Registration Certificate (for sole proprietorships or partnerships)
ii. Certificate of Incorporation (for a Limited Liability Company)
iii. Current CR12 - Showing a list of directors and shareholders
iv. Certificate of Change of Particulars

v. The minutes of the Board of Directors with details of proposed changes

vi. Other Relevant Documents

d) **Change of premise location, i.e., change in location, plot number, building, or floor in the same building**

i. To attach as new premises under 4.0 above

ii. Other Relevant Documents

e) **Nature of business e.g., from wholesale to retail**

i. Attached as new premises under 4.0 above

ii. Sketch and Dimensions in meters

iii. Other Relevant Documents

f) **Change from the business of a pharmacist to the business of a pharmaceutical technologist and vice versa**

i. Duly signed request letter with the details to be changed

ii. Duly executed Contract Agreement or Letter of Appointment or Termination Letter

iii. Other Relevant Documents

g) **Altering (including expansion or reduction in size) and renovating substantially without relocating the pharmacy business and without changing the ownership or address**

i. Duly signed request letter

ii. Sketch and Dimensions in meters

iii. Other Relevant Documents

h) **Deferment (inactive business without cessation of business registration)**

i. Duly signed request letter with reasons for deferment

ii. Other Relevant Documents

i) **Cessation/Business Closure**

i. Duly signed request letter with reasons for cessation

ii. Cessation of Business from Registrar of Companies

iii. Other Relevant Documents

4.7.3 **Variation of Manufacturing Licences**

For the variation of manufacturing licenses, a manufacturer may at any time during the license period apply for a variation through the **PPB online portal** and provide supporting documentation relevant to the proposed change.

Any manufacturer intending to implement any change that affects the particulars, scope, conditions, or authorized activities under an existing Manufacturing Licence shall submit an application for a **Licence Variation** to PPB through the PPB online portal.

No variation shall be implemented before receiving approval from the PPB.

Where the proposed change also impacts the GMP status, the applicant shall first obtain approval from the GMP Department before submitting the corresponding application for variation of the Manufacturing Licence.

The following guidance applies to specific categories of variations that may affect the GMP status:

a) **Manufacturing site, name, and address**

i. Change of Name of Manufacturing Facility

Where there is a change in the name of the manufacturing facility, the applicant shall upload the following updated documents:

- Certificate of Incorporation.
- Signed page of the Memorandum and Articles of Association (or current CR12 Form); and

- Company KRA PIN Certificate.

ii. Change of Physical Address / Relocation

Where there is a change in the physical address or relocation of the facility, the Licensing Department shall confirm the GMP compliance status of the new or modified site in the GMP online system prior to review of the application.

b) **Production lines**

i. Where there is an addition of a new production line, decommissioning of an existing line, or significant modification of an approved production line, the Licensing Department shall confirm GMP compliance status in the GMP online system before review.

ii. Production lines may include, but are not limited to:
- Solid dosage production lines.
- Liquid dosage production lines.
- Semi-solid dosage production lines.

c) **Categories of products manufactured**

i. Where there is an addition or removal of product categories, the Licensing Department shall confirm GMP compliance status in the GMP online system before review.

ii. Product categories may include:
- General products.
- Cephalosporins.
- Cytotoxic products.

d) **Subcategories of the dosage forms**

i. Where there is an addition or removal of product subcategories, the Licensing Department shall confirm GMP compliance status in the GMP online system before review.

ii. Subcategories may include:
- General
- Cephalosporins

- Cytotoxic
- Hormones
- Beta-lactams

e) **Key personnel**

i. Where there are changes to key technical personnel, the applicant shall select and input the respective nominee(s) in the PPB Online Portal.

ii. Key personnel positions include:
   - Quality Assurance
   - Head of Quality Unit
   - Head of Production Unit
   - Head of Quality Control Unit
   - Qualified Person for Pharmacovigilance (QPPV)

iii. A consolidated PDF document containing the list of key personnel and their respective Curriculum Vitae (CVs) shall be uploaded.

f) **Manufacturing activities**

i. Where there is an addition, removal, or significant modification of authorized manufacturing operations, the Licensing Department shall confirm GMP compliance status in the GMP online system before review.

ii. Manufacturing activities may include:
   - Granulation
   - Sterilization
   - Blending
   - Tableting

g) Other Activities Conducted at the Site

i. Where there is a change to authorized operational responsibilities, the Licensing Department shall confirm GMP compliance status in the GMP online system before review.

ii. Operational responsibilities may include:

- Batch certification
- Packaging and labelling
- Quality control testing
- Storage and distribution

Once the proposed changes are selected in the PPB online practice portal, the applicant shall submit the application for review. Where prior approval is required, the variation shall not be implemented until approval is issued.

All variation applications shall be subject to review and, where necessary, inspection; approval shall only be granted upon confirmation that GMP compliance is maintained.

The review process shall include assessment of application completeness and verification of alignment between the proposed variation and the newly approved GMP Certificate as reflected in the GMP PRIMS system.

Applicants shall at all times ensure consistency between the Manufacturing Licence and the GMP Certificate.

Upon completion of the review process, the Licensing Department shall communicate its decision to the applicant via email.

Where approved:

- An updated Manufacturing Licence reflecting the approved amendment shall be made available for download on the applicant's portal; and
- A revised scope of authorized activities shall be annexed to the Licence.

Where rejected:

- Reasons for rejection shall be communicated via email; and
- The applicant shall be required to resubmit the application with the necessary corrections or additional information.

The approvals of variations shall occur within the timelines prescribed in the service charter, Customer Service Delivery Charter (**CEO/PQR/QMS/POL/003**) from the time of receipt of the application.

Please refer to Annex 11: Variation Approval Flowchart

5. ACCESS TO INFORMATION BY THE PUBLIC

a) 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.

b) 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.

c) The database for all licensed premises is available on request, subject to the Board's processes.

6. APPLICATION FEE'S STRUCTURE

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

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

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

   i. Annual practice license- Kshs. 5,000

   ii. Premises registration fee-KShs.10,000

   iii. Online pharmacy license- KShs. 15,000

b) Wholesale Pharmacy premises

   i. Annual practice license -Kshs. 5,000

   ii. Premises registration fee-KShs.10,000

   iii. Wholesale dealer's license -Kshs 30,000

c) Manufacturing premises

   i. Annual practice license -Kshs 5,000

   ii. Premises registration fee - Kshs 10,000

   iii. Wholesale dealer's license -Kshs 30,000

   iv. Manufacturing License- Kshs. 50,000

Exemption on fees:

a) 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.

b) 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.

c) And any other exemptions under the Kenyan law.

7. INSPECTIONS

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

b) 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.

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

d) 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.

e) 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.

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

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

h) 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.

8. CONTRAVENTIONS AND OFFENCES

a) The proprietors of the premises are responsible for ensuring the operation does not contravene the laws and regulations, and that no offence is committed. Where a contravention or offence is detected, all proprietors and the superintendent shall be held responsible.

b) 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.

8.1 Closure of Business

a) For pharmacy premises, the Board shall be notified: -

i. When a licensed establishment is to cease operations and close

ii. Where a pharmacy is closed for any reason for a period longer than three months

b) 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.

c) Closure may be permanent or temporary.

d) 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 occur during 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.

e) 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.

f) 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:

i. Where the closure is permanent, a manufacturer must notify the Board three months before the closure
ii. Permanent closure will lead to the revocation of an issued license
iii. For any temporary closure that exceeds six months, notification shall be made one month prior
iv. Temporary closure will lead to the suspension of an issued license

g) No manufacturer is permitted to commence operations following a closure that exceeds six months or notification for permanent closure without clearance from the Department of Inspectorate and Enforcement to ascertain GMP compliance.

8.2 **Suspension or Revocation of License**

a) The Board has the power to suspend or revoke the license of a pharmacy premises if:
   i. It is closed or no longer being used to conduct a pharmacy business.
   ii. The conditions under which the business was licensed are no longer being met.

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

c) 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.

d) For manufacturing licences, a suspension shall clearly record the grounds for the action and identify the affected products,

manufacturing lines, dosage forms, processes or activities, and shall specify whether the suspension is full or partial, together with the conditions for lifting or reinstatement.

e) The suspension and revocation of a manufacturing licence shall comply with applicable statutory requirements, including notice, reasons, opportunity to respond and any applicable review or appeal rights, except where urgent protective action is legally justified.

f) On revocation, arrangements shall be made for the disposition of affected stock, including recall or quarantine where necessary, and the public regulatory record shall be updated promptly, subject to applicable confidentiality and legal requirements.

8.3 **Requirements for Closure of Premises**

a) Stock management – Finished and raw materials
b) Pharmacovigilance
c) PMS
d) Liability

8.4 **Lifting of Suspension and Revocation**

a) A person or a business whose license is revoked has the right to appeal as provided under Cap 244.
b) A person or a business whose license is suspended can have the suspension lifted when they comply with the requirements of the Board.
c) 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).
d) An application for lifting or reinstatement shall be supported by evidence demonstrating that the identified deficiencies have been corrected and that corrective and preventive measures have been effectively implemented. For significant or critical deficiencies, on-site verification shall be required before reinstatement, and the

Board may impose a defined period of enhanced inspection or reporting based on risk.

9. 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 Device 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 in Kenya
11. Guidance on suspension or revocation of GMP certification
12. Guidance Notes for Establishing Medical Products and Health Technologies Manufacturing Facilities in Kenya, HPT/ISE/GMP/MAN/006.

10. 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”
		2.2.	Location and design – referred to GMP and GDP guidelines Amended 3.8
		2.5	Practice licenses: allows for locum licenses and licenses not attached to specific premises
		2.8	Equipment and storage facilities – emphasis on addressing safety and well-being of personnel; adequacy of storage space
		2.10	Premises registration numbers, license numbers and codes – makes display of premise licenses and codes mandatory for the sake of the public
		2.11	Amended in line with cap 244 to read “display of licenses and certificate of registration of a premise
		2.12	Rewording: 3.12 to include 3.12 (d) A hospital pharmacy shall not do wholesale business.
		2.17	Scientific offices: reworded to remove “for promotion activities”
		4	Added (n) “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)”
			Application for new premises: Added several paragraphs detailing the specific documents to be submitted for the following categories of establishments: 3.1. Retail, Wholesale, Warehouse premises 4.1.2. Scientific office 4.1.3. Manufacturing Facility
		4.2	Expanded scope and reworded to read” Evaluation process for new premises (retail, wholesale, warehouse, scientific office, and hospital pharmacy)”

			4.2.(a) Harmonization of processing timelines with the PPB Customer Service Charter (e) Added "The Board may from time to time review the payment methods to facilitate ease of payment by applicants" Added (p) "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 (q). "Please see Annex 9: New Premises Approval Flowchart"
		3.5.1	Added under 4.3.b "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."
		3.6	(a)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.
		4.5	Added 4.5 (f). "For notifiable changes of manufacturing premises refer to GMP guidelines"
		4.6.	4.6 (d) A relocation and change in name can only be done through the variation module in the online platform. 4.6 (e) Change of ownership and name of the premise will be considered as a new premise and must seek approval from the Board
		3.7.3	Added: For variation of Manufacturing premises, refer to GMP guidelines 5.4 The approvals of variations shall occur within the timelines prescribed in the service charter Customer Service Delivery Charter (**CEO/PQR/QMS/POL/003**). from the time of receipt of the application Added Annex 10: Renewal and Variation Approval Flowchart
		4.0	Added: Access of information to the public. (b)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.

			(c) The database for all licensed premises is available at request subject to the Board's processes.
		5.0	Exemption on fees: Added (c). "And any other exemptions by the Kenyan law."
		6.0	Inspections. Amended 6.0. (a) "The Board shall appoint inspectors under the Pharmacy and Poisons Act, to carry out pre-registration and routine inspections of all premises in Kenya." (e) Harmonization of inspection timelines with the PPB Customer
		7.1.	Removed the part previously titled "validity of license Closure of business. Reworded and made clearer provisions for pharmacy premises and manufacturing facilities (e)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. (f)Where the closure is for a Manufacturing business: i. Where the closure is permanent, a manufacturer must notify the Board three months before the closure ii. Permanent closure will lead to revocation of an issued license iii. For any temporary closure that exceeds six months, notification shall be done one month prior iv. Temporary closure will lead to suspension of an issued license
		7.3	Added 7.3. "Requirements for closure of premises" i. Stock management – Finished and raw materials ii. Pharmacovigilance iii. PMS iv. Liability
		7.4	Added 7.4 . "Lifting of suspension and revocation" 7.4.(a). A person or a business whose license is revoked has the right to appeal as provided under Cap 244. 7.4.(b). A person or a business whose license is suspended can have the suspension lifted when they comply with the requirements of the Board. 7.4.(c). 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	Document Number	Updated document number to the new format PRA/LPP/GPP/GUD/060
		Glossary	Added the definition of “parallel importation”
		2.16	Added a section on ; 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	Section 4 b	Inserted a section numbered as 25.6 specifying documents that should be attached for renewal of licenses.
04	14/10/2024	Section 4b	Changed the statement "CR12 form from the Registrar of Companies (not more than 3 months)" to "current CR12 Form from the Registrar of Companies
05	09/05/2025	Sections 3.5 (c)and 5.3	Added the list of documents required for different types of variations.
		Sections 4.5 (f)	Added. 4.5 (f) For notifiable changes in manufacturing premises, refer to changes that may affect the scope, validity, or conditions under which the certificate was issued. Such variations may arise from modifications in: i. Manufacturing site, name, address ii. Facility layout iii. Production lines iv. Product categories v. Critical equipment vi. Production capacity vii. Key personnel
		Sections 5.3	Added. 5.3 For variation of manufacturing license’s, a manufacturer may at any time during the licence period apply for a variation of the manufacturing licence through the PPB online portal and shall provide evidence of the approved changes by the GMP department

06	16/10/2025	3.3.	Added - (j) Current Certificate of Good Manufacturing Practices for manufacturing premises. The applicant shall select the following as is relevant to the facility and the GMP certificate i. Dosage forms manufactured ii. Subcategories of the dosage forms iii. Categories of products manufactured iv. Product type v. Activities carried on the site
		3.3	Added - (f)The applicant shall select the following as is relevant to the facility and the GMP certificate i. Dosage forms manufactured ii. Subcategories of the dosage forms iii. Categories of products manufactured iv. Product type v. Activities carried on the site Updated the license to manufacture drugs for sale with an annexure specifying authorized dosage forms, product categories and manufacturing activities
		Annexes Annex 2	Premises registration certificate, Wholesale Dealers' Licence updated with conditions. Licence to Manufacture Drugs for Sale updated with conditions, authorized activities and list of products
07	14/10/2026	Scope	Added the eight manufacturing regulatory processes covered and cross-referenced HPT/ISE/GMP/MAN/006.
		Abbreviations	Added CAPA, CR12, KRA PIN, PRIMS, RHRIS, SMF and VMP.
		Glossary of Terms	Added Complete application, Manufacturing Facility, Notifiable change, Renewal, Revocation, Site Master File, Suspension, Temporary/Conditional Authorisation, Validation Master Plan and Variation; refined the definition of Premises to cover all categories of registered and licensed premises, not only pharmacy premises registered under section 4.
		Applicant Guide for Premises Licensing	Added a new section providing step-by-step guidance to applicants on the premises licensing process, including application submission, supporting documentation, regulatory assessment, payment, inspection, approval and issuance of the licence. Added a section on how to add Export only Products and Products with MA during the submission of applications.
		Manufacturing Facilities	Revised and expanded the requirements and regulatory procedures for licensing manufacturing facilities, including the temporary/conditional manufacturing authorisation pathway, completion of

			applicable GMP requirements, GMP inspection and certification, and issuance of the Routine Manufacturing Licence. Clarified the applicable licensing conditions, restrictions, review requirements and regulatory decision-making process.
		Suspension or Revocation of Licence; Lifting of Suspension	Added scope and grounds recording for full or partial suspension, statutory due-process requirements, disposition and public-record update on revocation, and the reinstatement evidence and enhanced-oversight requirements.

11. LIST OF CONTRIBUTORS

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

1	Dr. Ahmed Mohamed	CEO, Pharmacy and Poisons Board
3	Dr. Wilfred O. Oguta	Director, Pharmacy Practice & Training
4	Dr. Dominic Mutie	Deputy Director, Licensing and GPP
5	Dr. Humphrey Mwavali	Head, Training and Professional Development, PPB
6	Dr. Abdulkadir Omar	Head, Licensing, PPB
7	Dr. Lily Kipkeno	Head, CPD
8	Mr. George Muthuri	Registration & Enrolment/QMS
9	Dr. Washington Oyoo	Registration & Enrolment/Licensing
10	Dr. Sylvia Ndegwa	Registration & Enrolment/Licensing
11	Dr. Chebor Chumo	Registration & Enrolment/Licensing

12. ANNEXES

Annex 1: Specimen Health Safety Code



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 XXX

of **XX NAIROBI**

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

Registered No. of premises XXXX

13th November, 2025	**XXXXXXXXX**
Date	*Licence No*

Note:
(i) This Registration is valid until **31st December, 2026**.
(ii) The authorized premises may not be altered or relocated without the prior written approval of the Board.
(iii) This registration becomes **automatically void 30 days after any change in business ownership.**
(iv) This license is **contingent upon strict adherence to Good Storage and Distribution Practices.**
(v) The sale of unregistered or unauthorized health products and technologies, or engagement in any prohibited activity, shall result in license suspension, revocation, and/or legal action.



Fee: KShs. 10,000

SR. No: SR No. 023537/25

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 **XXXXX** of **XXX NAIROBI**

carrying on business at **Plot No. XXX, XXX Street, Nairobi**

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

13th November, 2025	**XXXXXXXX**
Date	*Licence No*

Note:
(i) This licence expires on **31st December, 2026**
(ii) This license is valid subject to compliance with Good Distribution and Storage Practices.
(iii) Sale of unregistered/unauthorized health products and technologies or dealings with unlicensed entities shall result in license suspension, revocation, or legal action.
(iv) This license is valid only for the specified premise and location.

Fee: KShs. 30,000

SR. No: SR No. 023537/25

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	XXXXXX XXXXXXXX		
Registration No of Premises	**PPB/X/1870**		
Location of Premises	**P.O BOX** XXXXXXX		
Town	XXXX		
Street	XXXXXXX		
Plot No.	**Plot No.**		
Name of pharmaceutical technologist	XXXXXXXXXXXXX		
ID No	XXXXX	Enrollment No	**8553**

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

4th December, 2025	**BU202600028**
Date	*Licence No*



Fee: KShs. 10,000

SR. No: SR No. 023635/25

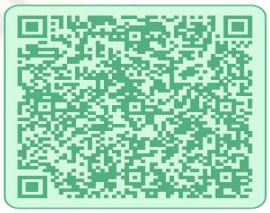
Note: (i) This Registration is valid until **31st December, 2026**. **FORM 31**

(ii) The authorized premises may not be altered or relocated without the prior written approval of the Board.

(iii) This registration becomes **automatically void 30 days after any change in business ownership.**

(iv) This license is **contingent upon strict adherence to Good Storage and Distribution Practices.**

(v) The sale of unregistered or unauthorized health products and technologies, or engagement in any prohibited activity, shall result in license suspension, revocation, and/or legal action.



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

XXXX of **XXX NAIROBI**

and having premises situated at **XXX Building, Ground Floor, XXX 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. XXX XXXX**

at **Plot No. XXXX, XXX Street, Nairobi**

X

13th November, 2025 — *Date*

XXXXX — Registration No

XXXXXXX — *Licence No*

Fee: KShs. 50,000

SR. No: SR No. 023537/25

FORM 22

Note:

(i) This licence expires on **31st December, 2026**

(ii) 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.

(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.

ANNEX

Authorized Manufacturing Operations

Broad Category	Sub Category	Category	Product Type	Activities
Non-Sterile Products	Nasal	Cytotoxic	Tablets, Hard Gelatin Capsules, Soft Gelatin Capsules	Processing operations , Batch certification
Sterile Products	Terminally	General	Small Volume Parenteral Liquids in Ampoules, Small Volume Parenteral Liquids in Vials, Small Volume Parenteral Liquids in Cartridges, Small Volume Parenteral Liquids in Prefilled Syringes, Large Volume Parenteral Liquids in Glass Bottles, Large Volume Parenteral Liquids in Plastic Bottles	Processing operations , Batch certification

Pharmacy and Poisons Board
HARAMBEE

SR. No: SR No. 023537/25

ANNEX

Id	Registration No	Trade Name	Strength	Dosage	INN of API
1	H99/302	PARADOL	500MG	TABLET	PARACETAMOL
2	H96/433	FENPRO	200MG	COATED TABLET	IBUPROFEN
3	H97/174	DANGYL	200MG	TABLET	METRONIDAZOLE
4	H96/665	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	TRIMETHOPRIM AND SULPHAMETHOXAZOLE
12	H99/204	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	H2009/2014/376	TINDAZ 500MG	500MG,	TABLET	TINIDAZOLE BP
24	H2009/2014/0662	NEOCIP-500	500MG	TABLET	CIPROFLOXACIN HYDROCHLORIDE BP
25	H2009/2014/1567	OKAGESIC-400	400MG	TABLET	IBUPROFEN BP
26	H96/432	SULTRIM	80MG / 400MG	TABLET	TRIMETHOPRIM AND SULPHAMETHOXAZOLE
27	H96/349	TETRALINE	250MG	CAPSULE	TETRACYCLINE

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

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 up to **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**

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

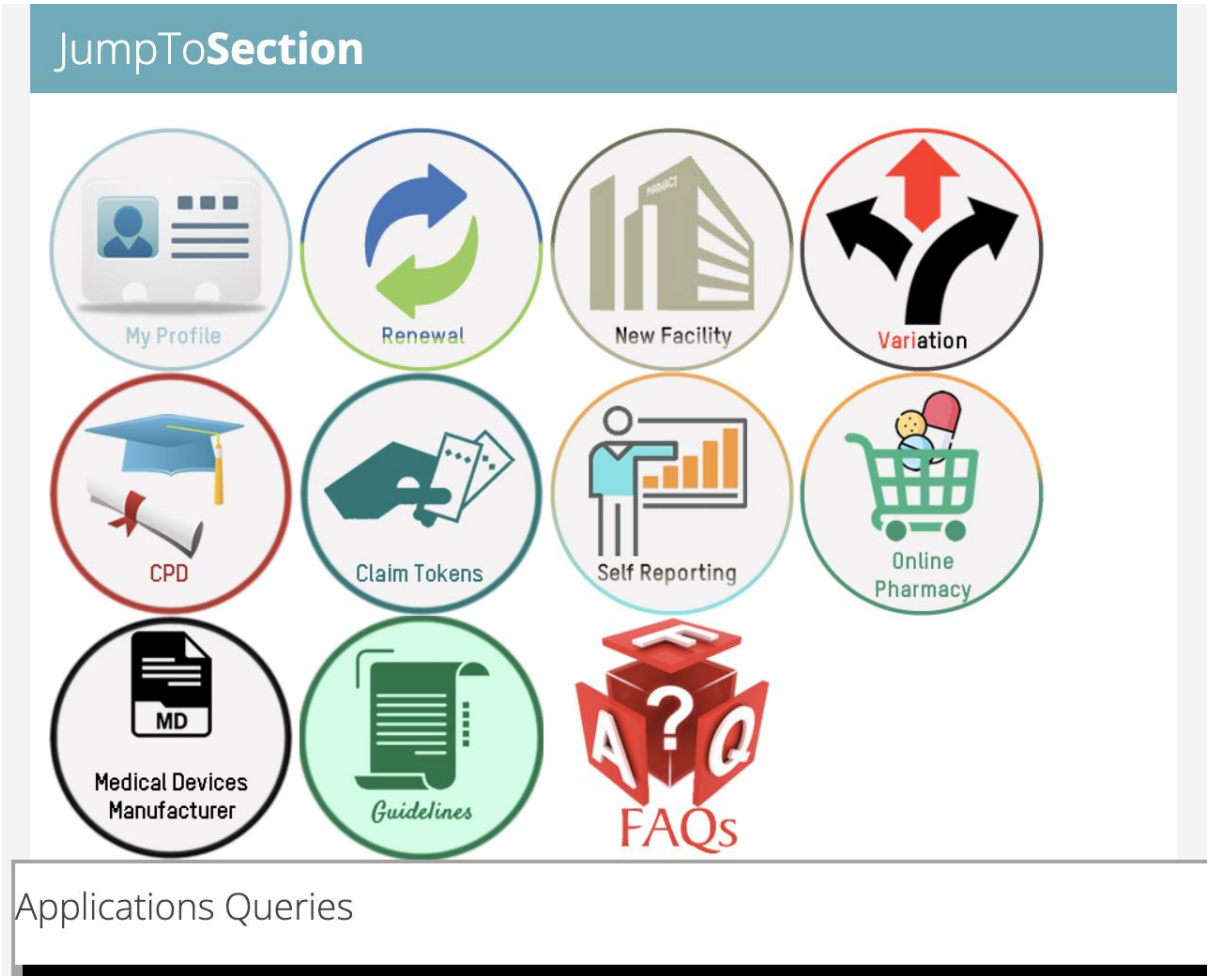
The above named person is hereby licensed to practise as a Pharmaceutical Technologist in accordance with the Pharmacy and Poisons Act

Note:

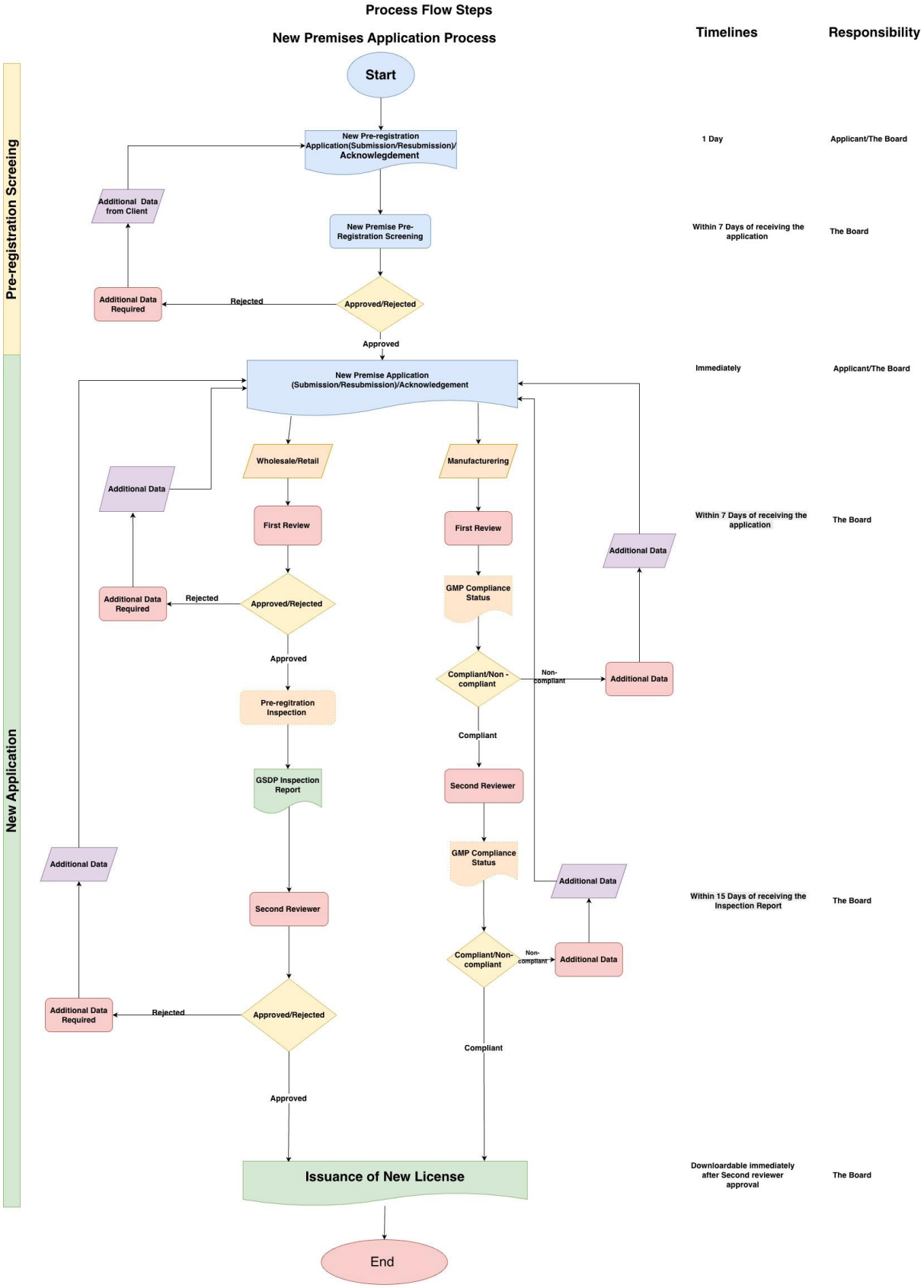
1. This Licence is valid up to **31st December, 2023**, subject to compliance with the provisions of the Act
2. For superintendents, no change of premises is permitted without authority of the Pharmacy and Poisons Board

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

Annex 8: Screenshot of home page of online licensing portal

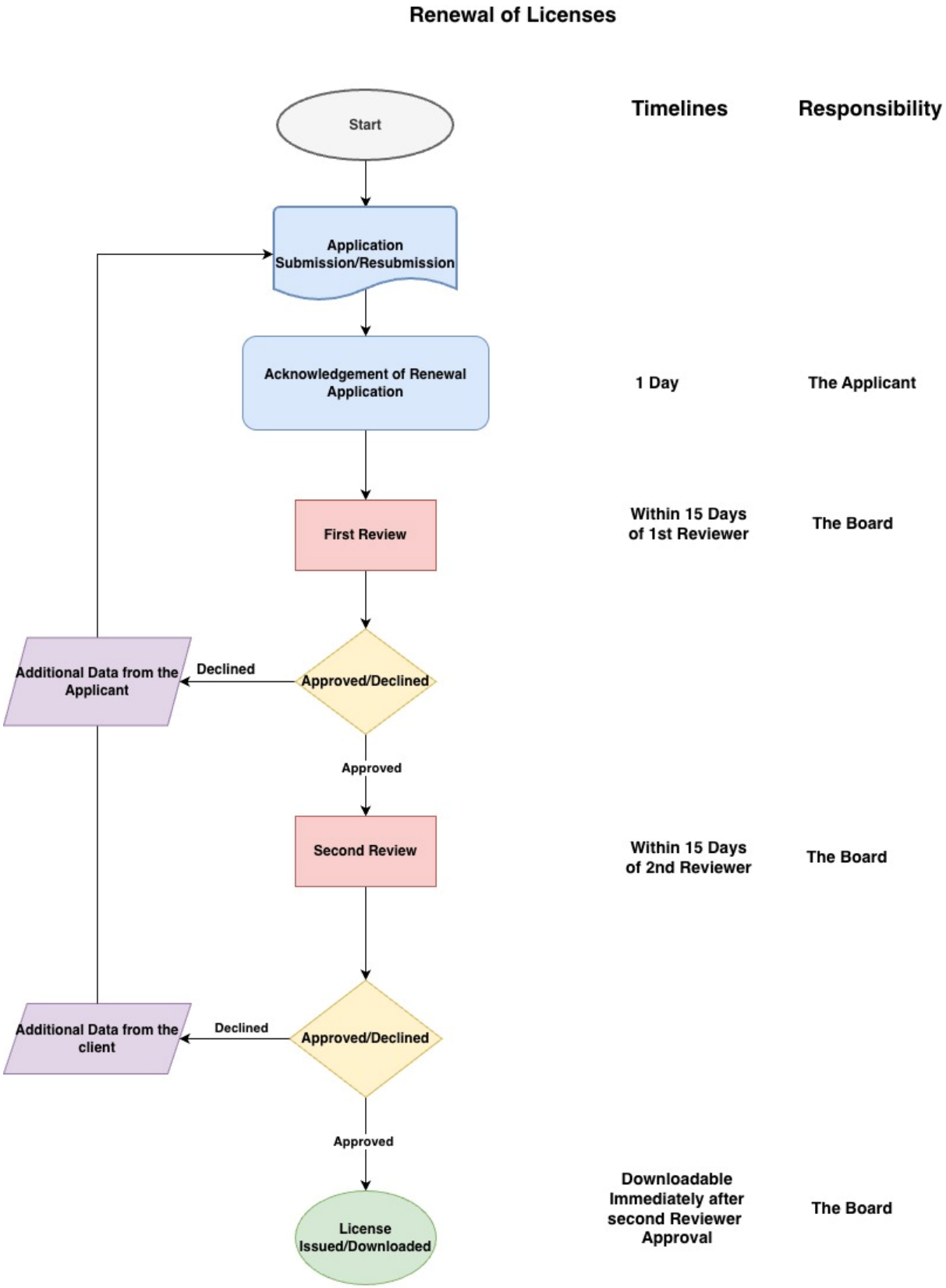


Annex 9: New Premises Application Process Flowchart



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.

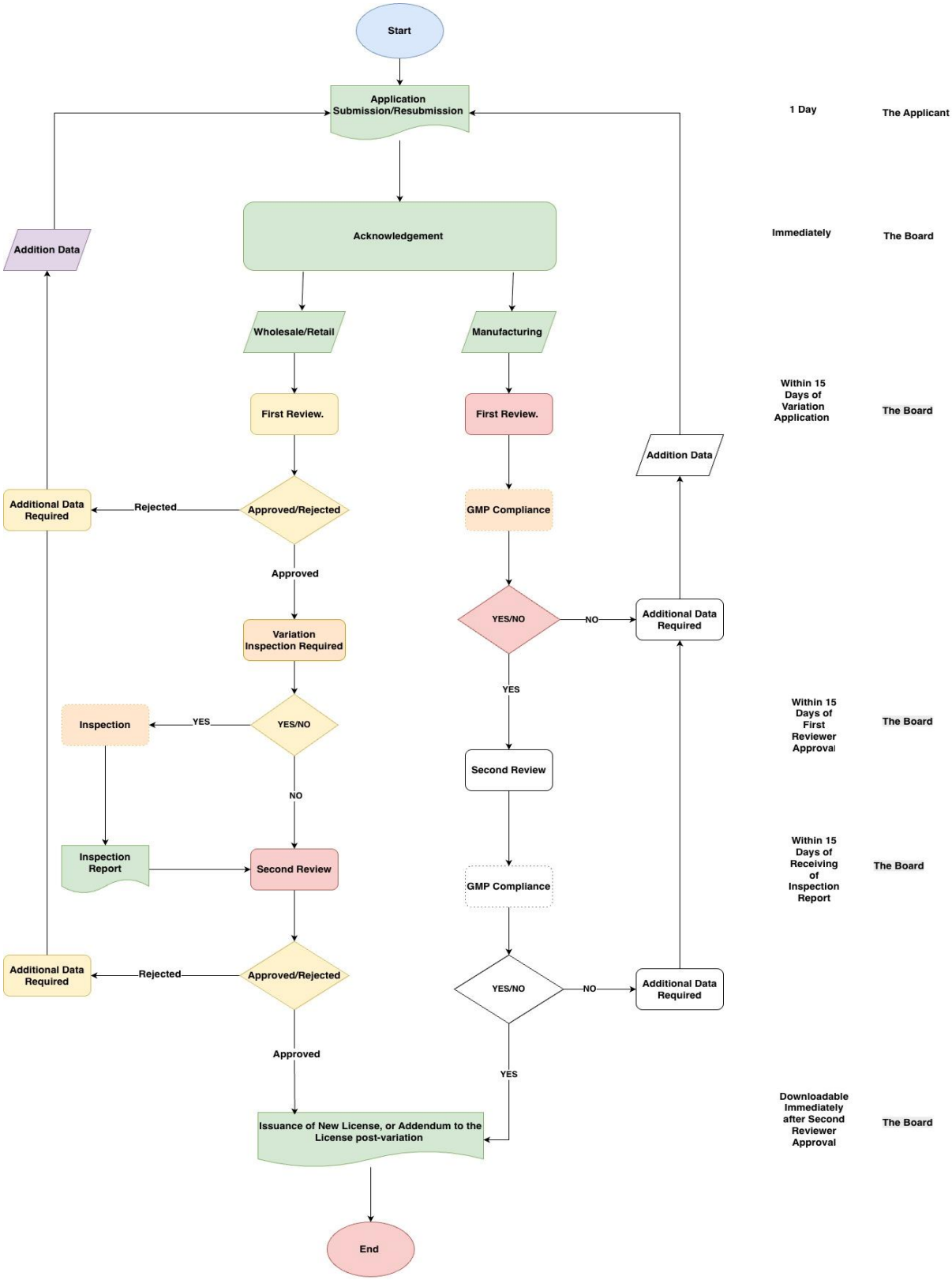
Annex 10: Renewal Application Process Flowchart



Text

NB: Total processing time is estimated as 31 days for renewal. The timelines are exclusive of the time taken by the applicant in responding to queries

Annex 11: Variation Application Process Flowchart



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

Annex 12: 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

Page 1 of 1

SR. No: 024019/22

Pharmacy and Poisons Board
P. O. Box 27663- 00506 Lenana Road Opposite Russian Embassy Nairobi,
Tel: +254 709 770 100
Website: webmaster@ppb.go.ke
Email: info@ppb.go.ke