REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

CUSTOMER'S SERVICE DELIVERY CHARTER

December 2020

PPB/REG/QMS/POL/003	CUSTOMER SERVICE CHARTER	Revision No: 2	Effective date 31/12/2020 Review Date: 05/01/2023

Prepared by Quality Assurance Officer - QMS

Sign.....

Date: 23/12/2020.....

Reviewed by Director Corporate Services

Sign.....

Date: 28/12/2020.....

Checked by HQM

Sign.....

Date: 28/12/2020.....

Authorized by Chief Executive Officer

Sign.....

Date: 28/12/2020.....

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ABBREVIATIONS AND ACRONYMS

ADR	Adverse Drug Reactions
AU	African Union
CEO	Chief Executive Officer
cGMP	Current Good Manufacturing Practices
COTU	Central Organizations of Trade Unions
CPD	Continuing Professional Development
CTD	Common Technical Document
EAC	East African Community
FOB	Free on Board
HQM	Head, Quality Management System
HRM & D	Human Resource Management and Development
ICT	Information, Communication and Technology
IGAD	Intergovernmental Authority on Development
KEMRI	Kenya Medical Research Institute
KMPDU	Kenya Medical Practitioners, Pharmacists and Dentists Union
KRA	Kenya Revenue Authority
KUDHEHIA	Kenya Union of Domestic, Hotels, Education Institutions, Hospitals and Allied Workers
LPO/LSO	Local Purchase Order/ Local Service Order
NASCOP	National AIDS/STI Control Program
NEPAD	New Partnership for Africa's Development
NHIF	National Health Insurance Fund
NSSF	National Social Security Fund

PGA's	Partner Government Agencies
PER	Product Evaluation and Registration
POE	Ports of Entry
POL	Policy
PPB	Pharmacy and Poisons Board
PR	Public Relations
QMS	Quality Management System
R&D	Research and Development
REG	Registrar
SCAC	State Corporations Advisory Committee
SRC	Salaries and Remuneration Commission
TRA	Trade Affairs
WHO	World Health Organization

ACKNOWLEDGEMENT:

This Customer Service Charter presents the Pharmacy and Poisons Board's commitment to effectively and timely offer service delivery to its clients. The following members are recognized for their participation in development of the document;

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FOREWORD:

The Pharmacy and Poisons Board (hereinafter referred to as "*The Board")* has developed this Customer Service Charter pursuant to the provisions of Article 43 (1) (a) of the Constitution and the government commitment to its citizens on provision of the highest attainable standard of healthcare.

The mandate 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 and efficacious medical products and health technologies.

The Board acknowledges that customer service charter is a key element towards timely and consistent service provision and an important strategy for the achievement of its mission and supporting objectives. Further, this customer service charter is a holistic management process that is to be applied at all levels of activity across the institution.

All stakeholders and interested parties are recognized in the course of service delivery to ensure equal treatment with respect and courtesy. The Management will, on continuous basis, identify customer requirements, evaluate and review the service charter to ensure satisfactory service delivery.

The Board assures the customers and stakeholders of its commitment to meet and exceed their expectations. The implementation of this Customer Service Charter will therefore enhance service delivery, accountability while ensuring its contribution in protecting and promoting public health.

Dr. F. M. Siyoi

CHIEF EXECUTIVE OFFICE

LEGAL FRAMEWORK

The Constitution of Kenya, 2010 Article 43 (1) (a) guarantees its citizens the right to the highest attainable standard of health care. In this regard, the Pharmacy and Poisons Board aspires to promote a pharmacy practice that provides the highest attainable standards of healthcare.

The Ministry of Health in response to the ever-changing environment and constitutional reforms in the country, adopted Sessional Paper No. 4 of 2012 on the National Pharmaceutical Policy. This was targeted at crafting the policy direction to inform reforms in the pharmaceutical sector so as to ensure equitable access to quality essential medical products and health technologies for all Kenyans.

The Pharmacy and Poisons Act, Cap 244 Laws of Kenya (hereinafter referred to as "the Act"), mandates the Board to make better provision for the control of the profession of pharmacy and the trade in drugs and poisons. This customer service charter demonstrates our commitment to customers in the provision of timely and quality pharmaceutical services towards the realization of the aforementioned constitutional requirement.

GLOSSARY OF TERMS

Advertisement: Includes a notice, circular, label, wrapper or other document and an announcement made orally or by means of producing or transmitting light or sound;

Organization: Unless otherwise stated means the 'Pharmacy & Poisons Board.

Day: Unless otherwise stated means working day.

Working day: Monday – Friday from 8am to 5pm excluding public holidays

Medical Product: Includes human and veterinary medicines, medical products, medicinal substances, vaccines, diagnostics, medical devices, blood products, traditional and alternative medicine, therapeutic feeds and nutritional formulations, cosmetics and related products

Health Technologies: Application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health programme and improve quality of life (WHO)

Enrolled pharmaceutical technologist: Means a person whose name appears on the roll of pharmaceutical technologists in accordance with section 6(2), Cap 244

Investigational Medicinal Substance: Means a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorization but used or assembled (formulated or packaged) in a way different from the authorized form, or when used for an unauthorized indication, or when used to gain further information about the authorized form;

Manufacture: Means any process carried out in the course of making a product or medicinal substance and includes, packaging, blending, mixing, assembling, distillation, processing, changing of form or

application of any chemical or physical process in the preparation of a medicinal substance or product; but does not include dissolving or dispensing the product by diluting or mixing it with some other substances used as vehicle for administration;

Medicinal substance: Means any medicine, product, article, or substance which is claimed to be useful for any of the following purposes; treating, preventing or alleviating disease or symptoms of disease; diagnosing disease or ascertaining the existence, degree or extent of a physiological condition; or preventing and interfering with the normal operation of a physiological function whether permanently or temporarily and whether by way of terminating, reducing, postponing or increasing or accelerating the operation of the function in human beings or animals;

Medicine: Means any medicament or curative or preventive substance, whether proprietary or in the form of preparation;

Poison: Means a substance included in the Part I and II Poisons List referred to in section 25, Cap 244;

Registered pharmacist: Means a person whose name is entered in the register of Pharmacists in accordance with section 6(1), Cap 244;

Registrar: Means the person appointed under the provisions of section 5(1), Cap 244.

1. INTRODUCTION:

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 functions of the Board are envisaged under the Pharmacy and Poisons Act, Cap 244 that was recently amended vide the Health Laws (Amendment) 2019 to expand the roles of the Board to conform with Section 63 of the Health Act, 2017.

The second review of the service charter is informed by the CAP 244 amendments vide the Health Laws 2019, current Strategic Plan 2020 to 2025 and job evaluations by the Salaries and Remuneration Commission (SRC) in line with the State Corporations Advisory Committee (SCAC).

The Board acknowledges that customer service charter is a key element towards timely and consistent service provision and an important strategy for the achievement of its mission and supporting objectives. Further, this customer service charter is a holistic management process that is to be applied at all levels of activity across the institution.

The Board assures the customers and stakeholders of its commitment to meet and exceed their expectations. The implementation of this Customer Service Charter will therefore enhance service delivery, accountability while ensuring its contribution in protecting and promoting public health.

1.1. VISION

To be a global leader in promoting and protecting public health

1.2. MISSION

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

1.3. CORPORATE VALUES AND PRINCIPLES

The board seeks to cultivate a conducive and responsive organizational culture for both internal and external stakeholders and enhance service delivery by embracing the following core values;

a) Commitment to public health

b) Professionalism

c) Accountability and transparency

d) Integrity and respect

e) Quality

f) Diversity and Inclusion

1.4. CORE FUNCTIONS

1. Ensure the quality, safety and efficacy of medical products and health technologies.
2. Regulation of training and practice of pharmacy.
3. Advising the government on any matter relating to the regulation of medical products, health technologies and pharmaceutical services.

2. PRODUCTS AND SERVICES

We offer the following products and services to our clients:

Part 1: Medical products and Health Technologies

1. Registration of medical products and health technologies
2. Control of import and export for medical products and health technologies
3. Licensing of manufacturers and distributors of medical products and health technologies
4. Licit control of narcotics and psychotropic substances in line with the International Conventions
5. Conduct regulatory inspections of manufacturers, storage facilities and distributors of medical products and health technologies

6. Conduct laboratory testing of samples collected during post market surveillance and investigations.
7. Approve and regulate clinical trials on medical products and health technologies
8. Regulate the promotion, advertising and marketing of medicinal substances in accordance with approved product information
9. Conduct post marketing surveillance of safety and quality of medical products and health technologies
10. Promotion of rational use of medical products and health technologies
11. Control and supervision of disposal of pharmaceutical waste.
12. Conduct Pharmacovigilance of medical products and health technologies
13. Regulate contractors for medical devices and physical security for products including radioactive materials and biological products
14. Providing technical support for local manufacturing of medical products and health technologies

Part 2: Profession of Pharmacy

1. Prescribe the minimum requirements and approve qualifications of persons wishing to be registered or enrolled as pharmacists or pharmaceutical technologists respectively
2. Maintain a register of all persons registered or enrolled under the Act
3. Prescribe and conduct examinations for purposes of recognition, registration or enrollment
4. Establish/prescribe different categories of pharmacy businesses and the scope of practice of persons registered or enrolled as per the CAP 244
5. Approve institutions to be established or accredited for training of pharmacists and pharmaceutical technologists

6. Regulate, monitor and inspect personnel and premises that are involved in training, Continuous Professional Development and pharmacy practice;
7. Licensing of pharmacists and pharmaceutical technologists and medical representatives
8. Approve and license the premises for the practice of pharmacists and pharmaceutical technologists
9. Establish, approve and accredited continuing professional educational programs for pharmacists and pharmaceutical technologists
10. Establish and maintain a professional code of conduct for pharmacists and pharmaceutical technologists

Part 3: General functions

1. Advice the Cabinet Secretary of Health on all matters relating to administration and implementation of the Act;
2. Levy, collect and utilize fees for services rendered
3. Collaborate with other national, regional and international institutions on regulation of medical products, health technologies and the profession of pharmacy
4. Leverage on research, innovation and technologies in the delivery of products and services
5. Participating in policy formulation regarding the profession of pharmacy and regulation of medical products and health technologies

3. CLIENTS

1. Medical Products and health technologies manufacturing companies
2. Medical Products and health technologies importers,

exporters, distributors, wholesalers and retailers

3. Hospitals
4. Healthcare providers
5. Pharmacists and Pharmaceutical Technologists
6. Researchers
7. Institutions offering pharmacy training
8. Public
9. Students pursuing training in pharmacy
10. Suppliers
11. Members of Staff

4. STAKEHOLDERS AND PARTNERS

1. Board of Directors
2. PPB staff
3. Pharmacy Practitioners
4. Students
5. Licensed laboratories
6. Ministry of Health
7. Government of Kenya
8. Development partners
9. Suppliers
10. Statutory bodies such NSSF, NHIF and KRA
11. Regional economic blocks and International organisations such as WHO, AU, EAC, IGAD, SWISS MEDIC and NEPAD
12. Collaborating institutions such as National Public Health

Laboratories, KEMRI, NASCOP and National Radiation Protection Board

13. CPD providers and Professional bodies
14. Media
15. Law enforcement agencies
16. Trade Unions such as KMPDU, COTU, KUDHEHIA and PUSETU
17. Politicians
18. County governments
19. Public/Patients
20. Inspectorate of State Corporations
21. Financial Institutions
22. Foreign Countries Embassies
23. Pharmaceutical Manufacturers
24. Pharmacy Outlets, distributers and hospitals
25. Ministry for Higher education

5. SERVICE STANDARDS

This service charter is an expression of our commitment to align our services to customer requirements as stipulated in the Pharmacy and Poisons Board's Act and relevant statutory requirements. The following sections contain services, obligations, duration and the user charges for the services rendered.

5.1. OFFICE OF THE CHIEF EXECUTIVE OFFICER

No.	Service/activity	Obligation	Charges	Duration
Corporation Secretary & Legal Services				
1	Draw agreements/contracts/MOU's	Draft and agreement/contracts/MOU's	Free	30 days from receipt of instructions
2.	Legal advisory services	Render legal guidance on enquiries	Free	Within14 days date of receipt from
3.	Respond to the notices	Handling demand notices	Free	14 days from date of receipt
Trade Affairs				
1	Processing permits of general	Verification of permits for payment	Free	1 working day submission upon
		Approval of payments	Free	1working day approval upon
		Approval of permits	0.75% of FOB value	6 working days
2	Processing of chemicals and raw materials permits	Issuance of permits for sale of chemicals	0.75% of FOB value	4 working days payment upon
		Issuance of permits for sale of chemicals and raw materials for manufacturing	Free	4 working days upon payment

3	Processing of narcotics, psychotropic and precursors substances permits	Issuance of permits for sale of narcotics, psychotropic and precursors substances	0.75% of FOB value	14 working days upon payment
		Issuance of permits for manufacturing substances	Free	14 working days upon payment
Quality Management System				
1.	Handling complaints of customer	Receiving and acknowledging customer complaints	Free	2 days from receipt
		Resolution of a customer complaint and communication of the outcome	Free	30 days depending on the nature of complaint
		Lodging of appeals	Free	Within 14 working days after the decision
		Closure of the appeal	Free	Within 21 days after decision is made
Supply Chain Management				
1.	Meeting with customers	Adhere to agreed appointment time	Free	Within 30 minutes-with appointment
2	Listing of suppliers	Presentation of mandatory documents	Free	As stipulated in the public procurement regulation,2020
3	Evaluation of bids/quotations	As stipulated in the tender/quotation documents	As stipulated in the PPDA-2015 and PPAR- 2020	Within 30 days
4	Awarding of tender	Approval/feedback from C.E. O	Free	Within 14 days
5	Processing of suppliers Payment	Provision of all necessary documents	Free	Within 30days of receipt of invoice

5.2. CORPORATE SERVICES DIRECTORATE

This Directorate provides support services to the organization. Primarily it will be responsible for ensuring effective management of the Board's resources. The Directorate has five (5) departments.

No.	Service/activity	Obligation	Charges	Duration
Human Resource Management & Development				
1	Recruitment & selection	Advertisement of vacant positions	Free	21days of receiving applications from the date of advert
		Invitation for interviews	Free	14days after closure of the advert
		Communication of interview results	Free	14days after the last day of the interview
2	Handling letters and correspondences	Respond to external letters and correspondences	Free	Within 14 days of receipt
Finance & Accounts Department				
1	Processing of payment for goods and services	Payment upon verification of documents	Free	30days upon receipt of invoices
Administration				
1	Provide clean and safe environment	Ensuring clean and safe environment	Free	Daily
2	Security	provide security to clients and their properties	Free	Daily
3	Registry	Receiving of external letters	Free	Immediately
		Dispatch	Free	daily
Information Communication Technology				
1	Support the provision of online services	Ensuring accessibility of PPB online services	Free	Continuous
		Respond to system downtime and queries	Free	Immediately
		Training on new and existing online Services	Free	Continuous
		Handling ICT security breaches	Free	Immediately
2	Maintenance of	Update the website as per	Free	Continuous

	PPB website	ICT policy		
Corporate Communications				
1	Media handling	Responding to media enquiries	Free	Immediately
		Responding to the social media	Free	within one day
2	Publicity and events management	Public Awareness	Free	Quarterly

5.3. HEALTH PRODUCTS AND TECHNOLOGIES DIRECTORATE

5.3.1 PRODUCT EVALUATION AND REGISTRATION DEPARTMENT

The Department of Product Evaluation and Registration (PER), performs an essential public health task by making sure that the medical products and health technologies registered by the Pharmacy and Poisons Board are of good quality, safe and effective for the improvement of the health of the public.

No.	Service/Activity	Obligation/ Commitment	Charges	Duration
1	Routine Market Authorization of Medicinal Products (Human) and Alternative or Herbal/Complementary Products	Screening of application and allocation of CTD number	USD1000 Foreign products/U SD 500 for local products	Within 90 days from the time of paying
		Evaluation after issuance of CTD number	Free	Within 24 months
		Evaluation of additional data	Free	Within 90 days
		Final Decision and issuance of registration certificate	Free	Within 90 days after evaluation of additional data
		Consider and respond to appeal for rejected application	USD 300 as an appeal fee for both local and foreign products	Within 90 days from the date of receipt of appeal
		Publish list of registered medical Products	Payment of applicable fee	At least once in every 3 months
2	Fast Track Registration of Medicinal Product	Screening of application and allocation of CTD	USD 1000 Foreign products/USD 500	Within 30 days

	(Human)	number	for local products	
		Evaluation after issuance of CTD number	Free	Within 6 months
		Evaluation of additional data	Free	Within 60 days
		Final Decision and issuance of registration certificate	Free	Within 90 days after evaluation of additional data
		Consider and respond to appeal for rejected application	Free	Within 90 days from the date of receipt of appeal
3	Emergency and Compassionate use Product and Technologies Registration	Screening of application and allocation of CTD number	Payment of applicable fee	Within 3 days
		Evaluation after issuance of CTD number	Free	Within 30 days
		Evaluation of additional data	Free	Within 30 days
		Final Decision and issuance of registration certificate	Free	Within 7 days
		Consider and respond to appeal for rejected application	free	Within 7 days
4	Registration of medicines, and Medical Products through Reliance Mechanism (SRA/WHO-PQ, CEP/WHO-PQ, EAC-MRH & IGAD-MRH Project)	Screening of application and allocation of CTD number	USD1000	Within 30 days
		Evaluation after issuance of CTD number	Free	Within 90 days
		Evaluation of additional data	Free	Within 30 days
		Final Decision and issuance of registration certificate	Free	Within 90 days after evaluation of additional data
5	Variation of registered products	Review of applications for variation and issuance of certificates	USD 300 as an appeal fee for both local and foreign products	180 days for major variations and 90 days for Minor variations & notifications
6	Certificate of Pharmaceutical Product (CoPP)	Review & Approval of CoPP.	Free	Within 14 days from the date of submission

7	Annual Retention of Registered Products by 31st Dec of every year	Review & Approval of annual retention certificate	USD 300Foreign products and USD 150 for local products	Within 90 days
8	Listing of Food Supplements, Medical cosmetics & Borderline Products	Assessment & Approval of Listing Certificate	As per applica ble fee	Within 30 days
9	Listing & Registration of In-Vitro & Medical Device	Evaluation after issuance of product ID number	Payment of applicable fee: (ClassA:USD100,ClassB:USD200, Class C: USD1000, & Class D: 1000)	Within 24 months
		Evaluation of additional data	Free	Within 30 days
		Final Decision and issuance of registration certificate	Free	Within 90 days after evaluation of additional data
		Consider and respond to appeal for rejected application	free	Within 7 days
		Publish list of registered medical device	Payment of applicable fee	At least once in every 3 months
10	Emergency use Authorization of Medical Devices/IVDs	Screening of application and allocation of CTD number	Payment of applicable fee	Within 3 days
		Evaluation after issuance of CTD number	Free	Within 30 days
		Evaluation of additional data	Free	Within 30 days
		Final Decision and issuance of registration certificate	Free	Within 7 days
		Consider and respond to appeal for rejected application	free	Within 7 days

5.3.2 PRODUCT SAFETY DEPARTMENT

For effective service delivery, it is organized into three (3) technical Divisions namely:

1. Pharmacovigilance and Post Market Surveillance
2. Medicine Information and Resource Centre
3. Clinical Trials Authorization and Inspection

Medicines Information and Resource Center				
No.	**Service/Activity**	**Obligation/Commitment**	**Charges**	**Duration**
1.	Approval of advertisements for medicines and Health technologies	Evaluation of application the	Ksh. 5000 Per product per medium	Within 30 Days
		Giving feedback on approved or rejected application in writing	Free	Within 14 days after evaluation
Pharmacovigilance and Post Market Surveillance				
1	Monitoring quality, safety, and efficacy of medical products and Health Technologies	Acknowledge receipt of ADRs and suspected sub-standard and falsified medical products	Free	Within 7 days
		Providing feedback (for poor quality products complaints) to the reporter	Free	Within 7 working days once a decision is made.
	Analysis of ADR report	Dissemination of ADR assessment report	Free	Quarterly
Clinical Trials				
1	Authorization of clinical trials	Acknowledgement screening of application and the	USD 1000 – Application fee	Within 5 days
		Evaluate the application and provide feedback to the applicant.	Free	Within 30 days
		Provide feedback clarification on reporting and safety	Free	Within 14 days
		Evaluate proposed amendments	Free	Within 21 days
		Approval of annual renewal of clinical trials	Free	Within 30 days from day of application

5.3.3 INSPECTION AND ENFORCEMENT DEPARTMENT

For effective service delivery, it is organized into four (4) technical Divisions namely:

1. Good Manufacturing Practices
2. Good Distribution Practices
3. Ports of Entry
4. Drug Crime Investigation

Good Manufacturing Practice (GMP)				
No.	Activity/Service	Obligation/Commitment	Charges	Duration
1	GMP inspections of manufacturers	Acknowledge application	USD 4,000 Foreign & USD 1000	Within 14 working days from the date of application
		cGMP Onsite inspection of the manufacturing sites		Within 12 months from the date of application
		Desktop review applications		Within 90 working days from the date of application
		Issuance of inspection report and certificate to the applicant		Within 60 working days from the date of inspection

Good Distribution Practice (GDP)				
1	Inspection of premises	Conducting pre-registration inspection of new premises	Free	14 working days from the time of receiving an alert
2	Disposal of pharmaceutical wastes	Verification of all applications for disposal of pharmaceutical waste	Ksh. 2500 per application	14 working days from the date of receiving application
		Supervision of disposal of pharmaceutical waste	Free	20 working days upon being notified by MAH or owner of products

Ports of Entry (POE)				
1	Clearance of consignments	Pre-clearance inspection and verification of consignments of interest	Free	3 working days

		Responding to consignment alerts /emails/ queries or information from Partner Government Agencies (PGA's)	Free	1 working day
Drug Crime Investigation (DCI)				
No.	Activity/Service	Obligation/Commitment	Charges	Duration
1	Investigation of Pharma crimes	Initiation of investigations of all pharma related crimes	Free	Immediately
2	Handling of customer complaints on pharma related crimes	Promptly investigates and responds to customers complaints on pharma related crimes	Free	Within 14 working Days after receipt of complaints

6. PHARMACY PRACTICE DIRECTORATE

6.1. LICENSING AND GOOD PHARMACY PRACTICE

a) Registration of pharmacists

A pharmacist must be registered by PPB before he/she can engage in pharmacy practice in Kenya as spelt out in Cap 244 of the Laws of Kenya.

b) Licensing of pharmacists

In order to practice as a pharmacist in Kenya, one must have a valid Annual Practice License issued by PPB. The process of licensing entails submission of a duly filled application in the prescribed format accompanied by the necessary documents.

c) Enrolment of pharmaceutical technologists

A pharmaceutical technologist must be enrolled by PPB before he/she can engage in practice as a pharmaceutical technologist in Kenya as spelt out in Cap 244 of the Laws of Kenya.

d) Licensing of Pharmaceutical Technologists

In order to practice as a pharmaceutical technologist in Kenya, one must possess a valid Annual Practice License issued by the Board. The process of licensing entails submission of a duly filled application in the prescribed format accompanied by the necessary documents.

6.2. TRAINING DIVISION

a) Approval of Institutions Offering Training in Pharmacy

Institutions offering training in pharmacy (either at Diploma or Degree level) must have valid approval from the Board.

Following successful application in the prescribed format, expressing intention to offer the training, the Board commits to evaluate, inspect and approve successful applicants.

b) Accreditation of Continuing Professional Development (CPD) Providers and approval of CPD Programs

The process for accreditation of CPD providers entails submission of a duly filled application form for accreditation as a CPD provider or re-licensure.

The process for approval of CPD programs and activities entails the submission of CPD programs and activities.

No.	Service/ Activity	Obligation/Commitment	Charges	Duration
Licensing and Good Pharmacy Practice Division				
1	Frequency of administering examination for registration as a pharmacist and enrolment as a pharmaceutical technologist	Receipt and acknowledgement of application for examination	As per the gazette application fee	Within 1 day
		Evaluate the application and provide feedback to the applicant	Free	Within twenty-one (21) days of receipt
		Conduct pre-Registration and pre-enrolment examinations	Free	October/November series and April/May series
		Release the results of pre-registration and pre-enrollment examination	Free	Withintwo (2) months after sitting the examination
2	Registration of pharmacists and enrolment of pharmaceutical technologists	Issue certificate of registration as a pharmacist or enrollment as a pharmaceutical technologist	As per the gazette notice	Within thirty (30) days after receipt of application
3	Registration and licensing of pharmaceutical premises	Issuance of a certificate of registration of premises or a letter of rejection	As per the gazette notice	Within 90 working days ofreceiving of application
4	Licensing of pharmaceutical representatives	Issue a pharmaceutical representative permit	Application fee Ksh. 5,000	Within thirty (30days after receipt of application
Training, Assessment and Continuing Professional Development Division				
1	Approval of institutions offering training in pharmacy	Inspection of training institution	Ksh. 230,000 For Diploma, Ksh 460,000 for Degree	Within two (2) months
		Issue an inspection report and approval certificate	Free	Within two (2) months after inspection
2	Renewal of course approval	Receipt and acknowledgement of application for renewal of Course approval of training institution	Ksh. 30,000 for Diploma, Ksh 60,000 for Degree courses	Within 5 working days
3.	Indexing of students	Issue index numbers to all students	Application fee Ksh. 1000	Within 3 months on admission

	Accreditation of continuing professional development providers	Issue letter of accreditation to CPD providers	Application fee Ksh. 22,000	Within two (2) months of receipt
	Approval of CPD programs and events	Evaluate the application and approve/reject programs	Free	Within 30 days
		Evaluate the application and approve/reject events	Free	Within 5 days

7. LABORATORY SERVICES DIRECTORATE

The directorate consists of one department namely, Quality control and four divisions

No.	Activity/Service	Obligation/Commitment	Charges	Duration
1	Sample testing and reporting	Acknowledge sample receipt upon submission.	Free	Immediately
		Internal analysis for bulk batches from internal departments/clients.	Free	42 working days
		Internal analysis for samples/products that require urgent regulatory action, with market complaints, poor quality products	Free	10 working days
2	Outsourcing of laboratory testing service	Submission of samples to external laboratories	Free	10 working days
		Submission of samples to external laboratories (for samples that require urgent regulatory action, with reported ADRs)	Free	5 working days
		Reporting to clients after receipt of Certificate(s) of Analysis from external laboratories.	Free	2 working days
3.	Lot release	Acknowledgement of successful application	Free	Within 1 hour
		Screening	-	Within 1 hour

		Notification about a) incomplete or, b) queries or, c) inconsistencies or, clarification regarding the	-	Within 24 hours of screening.
		Notification of rejection of application when an applicant/MAH is unable to provide the needed clarification	-	Within 24 hours
		Evaluation of a screened application and submitted samples	-	Within 14 calendar days
		Issue of Lot release upon successful evaluation of application and submitted sample and having confirmed that all the Lot Release requirements have been fulfilled	-	Within 24 hours.

8. OBLIGATIONS TO CLIENTS

8.1. SERVICE STANDARDS

The Board is committed to ensure provision of quality medical products and pharmaceutical services through teamwork and partnership. It endeavors to deliver its services in a timely and efficient manner, in an atmosphere that ensures transparency, integrity, accountability and good governance. The Board respects the principles of professionalism, rule of law and conformity to set international standards.

The Board places high value on relationships with its customers and will build strong relationships to better understand their needs and strive for best outcomes in service delivery.

a) The staff will:

1. Be friendly, helpful and treat its clients with respect
2. Behave professionally and politely
3. Dress appropriately and wear an identification tag

4. Be available at all times.

b) The premises of the Board shall be:

1. Accessible and welcoming
2. Smoking, alcohol and drug free zone
3. Corruption free zone

8.2. CUSTOMERS' RIGHTS AND RESPONSIBILITIES

a) Customers' rights

Customers have the right to:

1. Privacy and confidentiality;
2. Access services; the Board also has counter services at the reception desk, which operates from 8. 00a.m to 1.00 pm and 2.00 p.m to 5.00p.m. on working days. Customers are directed to the relevant service points from the counter.
3. Access facilities; board offices will have ramps to enable the physically challenged persons to access services.
4. Lodge complaints through laid down procedures.

b) Customers' responsibilities

Customers are obliged to:

1. Be courteous and respectful;
2. Adhere to rules and regulations at all times;
3. Abide by the legal provisions governing pharmaceutical sector;
4. Respond promptly and effectively to clarifications on the issues raised in the process of attending to their request for services;

5. Respond to requests for information accurately and thoroughly and in a timely manner;
6. Uphold integrity and not to offer inducement by way of gifts and favors in return for services.

c) Shared Responsibilities

1. The board expects mutual respect, attention and patience to be sustained by both parties.
2. Board's staff will always wear staff identification tags conspicuously displayed. Likewise, visitors will be required to wear the visitors' pass provided at the security desk.
3. To attend meetings punctually.

How to contact us

Mode of Contact	How to Contact Us	Our contact Standards
Telephone	**Head Office** +2547097700100 **Our Hotline:** +254 20 2713538	We will answer calls promptly and try to resolve inquiries immediately. When your inquiry needs special attention, we will endeavor not to transfer your call more than once. When we are unable to answer your inquiry immediately, we will advise when you can expect a comprehensive reply
In person	The Board is located at Lenana Road opposite Russian Embassy Nairobi. Office Hours: 8:00 a.m. to 5. 00 p.m. Monday to Friday (Weekdays and public Holidays excluded)	We aim to resolve face-to-face inquiries immediately. When this is not possible, we may request to call or respond to you in writing later
In writing	Chief Executive Officer, Pharmacy and Poisons Board P.O Box 27663 Lenana Road, 00506 Nairobi	**For general inquiries;** We will acknowledge or resolve your inquiry within 3 working days. We will reply to your correspondence within 10 working days. If we are unable to respond within 10 working days, we will inform you on the 11th day on the progress and when you can expect a comprehensive reply
Email	info@pharmacyboardkenya.org admin@pharmacyboardkenya.org	Within 24hours (Monday to Friday). **For general inquiries;** We will acknowledge or resolve your inquiry within two (2) working days. If an inquiry cannot be resolved within two

		working days, we will send you an email to inform you of the department handling your inquiry and when we expect to resolve it.
Website	www.pharmacyboardkenya.org	The Board's website will provide comprehensive, accurate, relevant and timely information to our stakeholders

9. AMENDMENTS TO THE SERVICE CHARTER

This service charter is subject to review due to the changing circumstances. The Board will, in consultation with customers, partners and stakeholders, review and amend as appropriate the service charter to ensure continued improvement of services **within three (3) years**.

Customer satisfaction surveys will be carried out annually.

Feedback on this Service Charter shall be addressed to the CEO in writing, on phone or face-to-face presentations.

Pharmacy and Poisons Board is non-discriminatory and corruption free. Report any form of corruption on +254202713409.

10. REFERENCES

1. Constitution of Kenya, 2010
2. Pharmacy and Poisons Act, CAP 244
3. Health Laws (Amendment) 2019
4. Strategic Plan 2020-2025