REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

CUSTOMER SERVICE DELIVERY CHARTER

October 2023

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CEO/PQR/QMS/POL/003	Customer Service Delivery Charter	Revision No. 3	Effective Date: 26/10/2023 Review Date: 26/10/2028

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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
ICSR	Individual Case Safety Report
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
PSUR	Periodic Safety Update Report
PBRER	Periodic Benefit Risk Evaluation Report
QMS	Quality Management System
R&D	Research and Development
REG	Registrar
RMP	Risk Management Plan
SCAC	State Corporations Advisory Committee
SRC	Salaries and Remuneration Commission
TMF	Technical Master File
TRA	Trade Affairs
WHO	World Health Organization

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 role 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.

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 Health products and 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 a 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

1.0 INTRODUCTION:

1.1 Background

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 Health products and technologies. The functions of the Board are envisaged under section 3B of the Pharmacy and Poisons Act, Cap 244.

The review of the service charter is informed by the enactment of the Pharmacy and Poisons Rules, 2022, compliance with the requirements of the World Health Organization Global Benchmarking Tool (WHO-GBT), Good Regulatory Practices, quality management systems and current Strategic Plan 2020 to 2025. The charter aligns with our goals of achieving Universal Health Coverage (UHC) and advancing the Government's Bottom-up Economic Transformation Agenda (BETA).

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 across the organization.

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.

1.2 **Vision**

To be a global leader in promoting and protecting public health

1.3 **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 Health products and technologies

1.4 **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

1.5 **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. Further, the Constitution under Article 10 and Article 232 provides for the values and principles of public service including the principles of transparency, accountability, and public participation. A customer service charter aligns with these principles by ensuring transparency, responsive and prompt provision of services provided by Pharmacy and Poisons Board ("the Board").

These principles are further expounded under Section 7 of the Public Service (Values and Principles) Act, 2015 which makes it a

requirement for public service to ensure that public services are provided promptly, effectively, impartially and equitably, without unreasonable delay. It emphasizes the importance of providing responsive customer service in public institutions in compliance with the period provided for in the service charter of the institution.

The Access to Information Act, 2016 mandates transparency and access to information held by public bodies. The customer service charter serves as a tool for disseminating information about the services offered by the Board, to make it easier for the public to access relevant information enhancing public trust.

The Pharmacy and Poisons Act (Cap 244) provides the legal framework for regulation of health products and technologies in Kenya. It stipulates the functions of the Board in regulation of the profession of Pharmacy and ensuring the safety, quality and efficacy of HPTs in Kenya. The Customer Service Charter outlines the Board's commitment to fulfilling its responsibilities within prescribed timelines.

1.6 **Core Functions**

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

2.0 PRODUCTS AND SERVICES

We offer the following products and services to our clients:

2.1 **Health Products and Health Technologies**

1. Registration and marketing authorization of Health products and technologies
2. Control of import and export for Health products and technologies
3. Licensing of manufacturers and distributors of Health products and 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 Health products and technologies
6. Conduct laboratory testing of samples collected during post market surveillance and investigations.
7. Approve and regulate clinical trials on Health products and 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 Health products and technologies
10. Promotion of rational use of Health products and technologies
11. Control and supervision of disposal of pharmaceutical waste.
12. Conduct Pharmacovigilance of Health products and 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 Health products and technologies

2.2 **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

2.3 **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 Health products and technologies

3.0 CLIENTS AND STAKEHOLDERS

3.1 **Clients**

1. Health products and technologies manufacturing companies
2. Health products and technologies importers, exporters, distributors, wholesalers and retailers
3. Hospitals
4. HPT Procurement agencies
5. Healthcare providers
6. Pharmacists and Pharmaceutical Technologists
7. Researchers
8. Institutions offering pharmacy training
9. Public
10. Students pursuing training in pharmacy
11. Suppliers
12. Members of Staff

3.2 **Stakeholders and Partners**

1. Board of Directors
2. PPB staff
3. Pharmacy Practitioners
4. Pharmacy 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 organizations such as WHO, AU, EAC, IGAD, SWISS MEDIC and NEPAD
12. Collaborating institutions such as National Public Health
13. Institutions offering pharmacy training
14. Laboratories, KEMRI, NASCOP and National Radiation Protection Board
15. CPD providers and Professional bodies
16. Media
17. Law enforcement agencies
18. Trade Unions such as KMPDU, COTU, KUDHEHIA and PUSETU
19. Politicians
20. County governments
21. Public/Patients
22. Inspectorate of State Corporations
23. Financial Institutions
24. Foreign Countries Embassies
25. Pharmaceutical Manufacturers
26. Pharmacy Outlets, distributors and hospitals
27. HPT Procurement agencies
28. Ministry for Higher education
29. Quality assurance agencies

4.0 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.

4.1 **Office of the Chief Executive Officer**

No.	Service/activity	Requirements to obtain service	Charges	Timeline
Corporation Secretary & Legal Services				
1.	Public participation in policy-making process	Familiarization with issues and active participation	Free	1 day
2.	Draw agreements/contracts/ MOUs	a. For contracts resulting from a tender process under the PPAD Act, submit the communication from the head of supply chain department b. For MOUs and other agreements, submit communication from the User department	Free	30 days from date of receipt of instructions
3.	Legal advisory services	Memo/communication from the user department seeking legal advice	Free	14 days from date of receipt of the date of receipt of request
4.	Respond to the legal demand notices	Handling demand notices	Free	14 days from date of receipt of the demand notice
5.	Lodging of appeals	Letter of appeal	Free	Within 14 days after the decision
6.	Respond to appeal for rejected application	letter of appeal, payment of appeal fee, Response to rejected queries	300 (Foreign and Local)	Within 90 days from the date of receipt of appeal
7.	Respond to appeal for rejected CUA/EUA application	letter of appeal, payment of appeal fee, Response to rejected queries	300	Within 7 days
8.	Respond to appeal for rejected HPT application	letter of appeal, payment of appeal fee, Response to rejected queries	300USD	30 days
9.	Respond to appeal for rejected application	letter of appeal, payment of appeal fee, Response to rejected queries	300 (PDMPs)	Within 30 days from the date of receipt of appeal

10.				
Trade Affairs				
	Processing of Import and Export permit applications			
1.	Evaluation of permits	Requirements as outlined in the import and export guideline	Free	8 days
2.	Evaluation of narcotics, psychotropic and precursors substances permit	Requirements as outlined in the Import and export guideline and Narcotics, Psychotropic and Precursors substances guideline	Free	14 days upon payment
Quality Management System				
Handling complaints of customer				
	Acknowledgement of public complaints and grievances	Make a complaint	F r e e	1 day
	Resolution of complaints	Make a verbal or written complaint	Free	14 days
	Processing of request for information	Make a request for free information	Free	21 days
Supply Chain Management				
1.	Registration of Suppliers	Duly filled application form Company profile Certificate of Incorporation Registration PIN Certificate Valid Tax Compliance Certificate/Exempt ions Original Bank Statement Copy of certificate of registration with relevant regulatory bodies Non-refundable fee payment receipt copies of annual return forms filed by company registry National ID/Passport	Free	14 days
2.	Processing of tenders	Submit bids for good and services	Free	90 days
3.	Notification of successful and unsuccessful bidders	Access e- procurement portal for notification	Free	1day
4.	Payment for goods and services received	L.P.O / Invoice Certificate of Completion / Goods /Services Received	Free	60 days from the date of receipt of the invoice
5.	Disposal of obsolete stores	Submission of bids	Free	60 days from the date of advertisement

4.2 **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	Requirements to obtain Service	Charges	Timeline
Human Resource Management & Development				
	Recruitment & selection			
1.	Recruitment of staff	Make formal Free application based on the advert	Free	90 days
2.	Payroll processing	Employee payment records	Free	20th of Every Month
Finance & Accounts Department				
1.	Processing of payment for goods and services	Evidence of service offered or goods provided	Free	30 days upon receipt of invoices
2.	Verification, validation and approval for payment of permits	Proof of payment (PPB/ecitizen receipt), commercial invoice and permit application	0.75% of FOB value	1 day upon submission
Administration				
1.	Response to phone calls (Landline or any other official line)	Phone call	Free	15 seconds
2.	Response to enquiry by Walk-in clients	Walk-in and make the enquiry	Free	1 minute
3.	Response to correspondence	Written correspondence (letters)	Free	5 days
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	Within 24 hours
		Training on new and existing online Services	Free	Within 90 days of introduction of a new service
2.	Updating of PPB website	Approved content	Free	Within 24 hours upon receipt of approved content
Corporate Communication				
	Media handling			
	Response to correspondence	Email and Social media (Twitter, Facebook & YouTube	Free	1 day

4.3 Health Products and Technologies Directorate

4.3.1 Product Evaluation and Registration Department

The Department of Product Evaluation and Registration (PER), performs an essential public health task by making sure that the health products and 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	Requirements to obtain Service	Charges (USD)	Timeline
1.	**Routine Normal Market Authorization of Medicinal Products (Human) and Alternative or Herbal/Complementary Products**			
	Screening of application and allocation of CTD number	Payment of application fees, Valid cGMP certificate or payment for inspection/reinspection Complete Dossier	1000 Foreign 500 Local	80 days from the time of paying
	Evaluation of screening questions	Response to screening questions	Free	28 days
	Issuance of CTD number	Samples where applicable	Free	24 hours upon receipt of the samples
	Evaluation after issuance of CTD number	N/A	Free	Within 18 months
	Evaluation of additional data	Response to queries	Free	Within 90 days
	Final Decision and issuance of registration certificate	N/A	Free	Within 90 days after evaluation of additional data
	Publish list of registered medical Products	N/A	Free	At least once in every 3 months
2.	**Fast Track Registration of Medicinal Product (on request)**			
	Screening of application	Payment of application fees Valid cGMP certificate or payment for inspection/reinspection Complete Dossier	Additional 2000 (Foreign & Local)	Within 14 days
	Evaluation of screening questions	Response to screening questions	Free	Within 14 days

	Issuance of CTD Number	Samples where applicable	Free	Within 24 hours upon receipt of the samples
	Evaluation after issuance of CTD number	N/A	Free	Within 6 months
	Evaluation of additional data	Response to queries	Free	Within 45 days
	Final Decision and issuance of registration certificate	N/A	Free	Within 45 days after evaluation of additional data
3.	**Emergency and Compassionate use for Health Products and Technologies**			
	Screening of application	□Payment of application fees, □Complete Dossier	1000 for Health Products 2500 for medical devices and IVDs	Within 7 days
	Evaluation of screening questions	Response to screening questions	Free	Within 3 days
	Issuance of CUA/EUA number	Samples where applicable	Free	Within 24 hours upon receipt of samples
	Evaluation after issuance of CUA/EUA number	N/A	Free	Within 30 days
	Evaluation of additional data	Response to queries	Free	Within 30 days
	Final Decision and issuance of registration certificate	N/A	Free	Within 7 days
4.	**Registration of medicines, and Vaccines through Reliance Mechanism (SRA/WHO-PQ)**			
	Screening of application and allocation of CTD number	Proof of payment, Application form, Dossier and Sample if applicable	1000	10 days
	Evaluation of screening questions	Response to screening questions	Free	10 days
	Evaluation after issuance of CTD number	N/A	Free	30 days
	Evaluation of additional data	Response to queries	Free	30 days
	Final Decision and issuance of registration certificate	N/A	Free	10 days
5.	**Registration of medicines, and Vaccines through regional Reliance Mechanism EAC-MRH & IGAD-)**			
	Screening of application and allocation of CTD number	Proof of payment, Application form, Dossier and Sample if applicable	1000 (Foreign) 500 (Local)	10 days

	Evaluation of screening questions	Response to screening questions	Free	10 days
	Evaluation after issuance of CTD number	N/A	Free	30 days
	Evaluation of additional data	Response to queries	Free	30 days
	Final Decision and issuance of registration certificate	N/A	Free	10 days
6.	**Notifications to Registered Medicines and Vaccines**			
	Screening of applications for variation	Application form, required documents and Sample if applicable	Free	30 days
	Final Decision on the Notification	N/A	Free	30 days
7.	**Minor Variations of Registered Medicines and Vaccines**			
	Screening of applications for variation	Payment, Application form required documents and; Sample if applicable	300 (Foreign and Local)	30 Days
	Evaluation of additional data	Response to Queries	Free	30 days
	Final Decision and issuance of registration certificate	N/A	Free	30 days
8.	**Major Variations of Registered Medicines and Vaccines**			
	Screening for major variation	Payment, Application form required documents and; Sample if applicable	300 (Foreign and Local)	30 days
	Evaluation of additional data	Response to queries	Free	60 days
	Final Decision and issuance of registration certificate	N/A	Free	60 days
9.	**Renewal of Marketing Authorization**			
	Screening of application	Payment, Application form, Renewal Dossier and Sample if applicable	1000 Foreign 500 Local	30 days
	Evaluation of screening questions	Response to screening questions	Free	30 days
	Evaluation after acceptance of application	N//A	Free	90 days

	Evaluation of additional data	Response to queries	Free	45 days
	Final Decision and issuance of registration renewal certificate	N/A	Free	30 days
10.	**Evaluation of Donations**			
	Screening of application	Application, required documents and Sample if applicable	Free	4 days
	Application Review	Response to queries	Free	7 days
	Final Decision and issuance of donation certificate	N/A	Free	3 days
11.	**Unregistered Health Products**			
	Screening of application	Application, required documents and Sample if applicable	Free	4 days
	Application Review	Response to queries	Free	4 days
	Final Decision and issuance of authorization	-N/A	Free	3 days
12.	**Certificate of Pharmaceutical Product (CoPP)**			
	Review of CoPP Application	Application	Free	14 days
	Approval of CoPP.	N/A	Free	3 days
13.	**Annual Retention of Registered Products by 31st Dec of every year**			
	Screening of annual retention	Payment Application and required documents	300 Foreign 150 Local	15 days
	Review of annual retention	N/A	Free	45 days
	Evaluation of Annual retention queries	Response to queries	Free	15 days
	Final Decision and issuance of retention certificate	N/A	Free	15 days
14.	**Listing of Food Supplements, Medical cosmetics & Borderline Products**			
	Screening of applications for listing	Payment Application and required documents	100 (Foreign & local)	10 days
	Evaluation of screening questions	Response to screening questions	Free	3 days
	Evaluation after acceptance of application	N//A	Free	4 days
	Evaluation of additional data	Response to queries	Free	3 days

	Final Decision and issuance of listing certificate	N/A	Free	10 days
15.	**Registration of Medical Device including In-Vitro Diagnostics**			
	Screening of application	□Payment □Complete application	Class A: 100, Class B: 200, Class C: 1000, Class D: 1000	60 days
	Evaluation after issuance of product ID number	N/A	Free	18 Months
	Evaluation of additional data	Response to queries	Free	30 days
	Final Decision and issuance of registration certificate	N/A	Free	24 days after evaluation of additional data
	Publish list of registered medical device	N/A	Free	At least once in every 3 months
16.	**Routine Market Authorization for Whole Blood, Blood components and Plasma derived Blood Products (PDMPs)**			
	Screening of application and allocation of TMF number	□ Payment of application fees, □ Complete Dossier	500 whole blood 500 blood components each(local) 500 Blood components each (foreign) 500 PDMP local 1000 PDMP foreign	Within 30 days from the time of payment
	Evaluation of screening questions	Response to screening questions	Free	Within 14 Days after screening.
	Issuance of TMF number	Sample where applicable	Free	Within 24 hours upon receipt of the sample
	Evaluation after issuance of TMF number	N/A	Free	Within 24 months
	Evaluation of additional data	Response to queries	Free	Within days 30 days
	Final Decision and issuance of registration certificate	N/A	Free	Within 30 days after evaluation of additional data

4.3.2 **Product Safety Department**

The department is responsible for ensuring safety, quality effectiveness and fit for purpose of HPTs during product development and after-market authorization. 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**	**Requirements to obtain service**	**Charges**	**Timeline**
1.	Evaluation of advertisements for Health Products and Technologies	1.Duly filled application 2.Samples/artwork 3.Payment of application fee	Ksh. 5000 Per product per medium	30 Days
Pharmacovigilance				
1.	Acknowledgement of receipt of ICSR.	Valid reports from individual, healthcare workers, or MAH	Free	7 days
	Provide feedback after processing of ICSR	N/A	Free	7 days after processing
2	Acknowledgement of: 1. PSUR/PBRER 2. RMP	1. Aggregated product safety reports by MAH 2. RMP by MAH	Free	14 days
	Evaluation of PSUR/PBRER/RMP	N/A	Free	60 days
	Evaluation of additional data on PSUR/PBRER/RMP	Response to queries	Free	30 days
	Final Decision on Evaluation of PSUR/PBRER/RMP	N/A	Free	30 days after evaluation
3	Acknowledgement of field safety corrective actions of Medical Devices and IVDs	1. Field safety corrective action reports by MAH	Free	14 days
	Evaluation of field safety corrective actions of Medical Devices and IVDs	N/A	Free	60 days
	Evaluation of additional data on field safety corrective actions of Medical Devices and IVDs	Response to queries	Free	30 days
	Final Decision on Evaluation of field	N/A	Free	30 days after evaluation

	safety corrective actions of Medical Devices and IVDs			
4	Publication of safety data	N/A	Free	Quarterly
Post Market Surveillance				
1	Acknowledgement of HPT quality complaints	Valid complaint report	Free	24 hours
2	Investigation of HPT quality complaints	Samples where applicable	Free	30 days
3	Feedback to the reporter	N/A	Free	5 days
4	Publication of PMS reports	N/A	Free	Quarterly
Clinical Trials				
1.	Acknowledgement and screening of clinical trial applications	1. Duly filled online clinical trial application 2. Payment	USD1000 – Application fee	5 days
	Clinical trial protocol evaluation and feedback to the applicant.	1. Duly filled application form 2. Clinical trial protocol 3. screening responses (Where applicable)	Free	30 days
	Review of clinical trial safety reports	Duly filled clinical trial Safety reports	Free	14 days
	Evaluation of proposed protocol amendments	1. Protocol amendment application 2. Ethics approval of amendment	Free	21 days
	Approval of annual renewal of clinical trials	1. Duly filled annual approval checklist 2. Participants flow 3. Ethics approval	Free	Within 30 days from day of application

4.3.3 **Inspection and Enforcement Department**

This is the enforcement arm of Pharmacy and Poisons Board 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**	**Requirements to obtain service**	**Charges**	**Timeline**
GMP inspections of manufacturers				
1.	Acknowledge application for GMP inspection	Duly filled online application form Payment of application fee	4000 Foreign 1000 Local	7 days
	cGMP Onsite inspection of the local manufacturing sites	Site master file		30 days from the date of application
	cGMP Onsite inspection of the foreign manufacturing sites	Site master file		360 days from the date of application
	Desktop review applications	1. Request for desk top review 2. Site master file 3. Required Stringent Regulatory Authority documents		90 days from the date of application
	Issuance of inspection report and certificate to the applicant	N/A	Free	60 days from the date of inspection
Good Distribution Practice (GDP)				
1.	Pre-registration Inspection	Notification for pre-registration inspection	Free	Within 14 days of notification
2.	Verification and supervision of all applications for disposal of pharmaceutical waste	1.Duly filled online application for disposal form 2.List of Pharmaceutical waste 3. Payment 4.Identified NEMA certified site	Ksh. 2500 per application	21 days from the date of receiving application
3	Variation Inspection	Variation with changes that require inspection	Free	Within 14 days of notification
4	Inspection of Pharmaceutical transporters	1.Duly filled online application for disposal form 2. Payment	Ksh 20,000 per application	21 days upon approval of online application
Ports of Entry (POE)				
1.	Document verification and consignment release	Online document declaration with all attachments (Import/Export permit Entry form Release order Airway bill/Bill of lading/Parcel Number among others)	free	I day from notification
2.	Physical inspection of HPT and	Notification to inspect consignment and	free	2 days upon notification

	consignments release	Scheduled inspection by customs department		
3.	Sampling, basic screening/testing at site of profiled medical products and release	Samples for testing	free	within 8hrs of sampling
Drug Crime Investigation (DCI)				
No.	**Activity/Service**	**Requirement to obtain service**	**Charges**	**Timeline**
1.	Feedback on customer complaints on pharma related crimes	Make a complaint	Free	7 days after receipt of complaint

4.4 Pharmacy Practice Directorate

4.4.1 Licensing and Good Pharmacy Practice

a) 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.

b) 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.

c) Pharmaceutical representatives' permits

A representative of a person engaged in the sale and supply of pharmaceuticals containing a poison requires a permit to, in the course of business, give free samples of such products to persons who may lawfully possess Part I poisons. The process involves application and review of the qualifications and final issuance of the permit.

d) Registration and Licensing of Premises/ Establishments

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

1. Premises for Wholesale (for carrying on the business of a pharmacist)
2. 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)
3. Hospital pharmacies
4. Telehealth, telemedicine, and online/internet pharmacy services
5. Warehouses where medical products are stored
6. Manufacturing premises
7. Establishments for Medical Devices
8. Scientific Offices

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

4.4.2 **Training and Continuing Professional Development**

a) Approval of institutions offering training in Pharmacy

Institutions offering training in pharmacy, either at diploma or degree level, must have valid course 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) 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.

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 the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya.

d) 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 events entails the submission of CPD programs and events, evaluating and making recommendations or approving applications for accreditation of CPD programs and activities.

No.	Service/ Activity	Requirements to obtain service	Charges	Timeline
	Training and Continuing Professional Development			
1.	**Approval of institutions offering training in pharmacy**			
	Inspection of training institution	Completed application payment as per the guideline	Ksh. 230,000 For Diploma, Ksh 460,000 for Degree	Two (2) months
	Issue an inspection report and approval certificate	N/A	Free	Three (3) months after inspection
2.	**Renewal of Course Approval**			
	Acknowledgement of application for	Letter of request for	Ksh.30,000 for Diploma,	5 days

	renewal of Course approval of training institution	renewal □ Payment	Ksh 60,000 for Degree courses	
3.	**Indexing of Students**			
	Issue index numbers to students	□Completed application □payment as per the guideline	Application fee Ksh.1000	Two (2) months after receipt of application
4.	**Accreditation of continuing professional development providers and approval of programs and Events**			
	Evaluate the application and approve/reject programs	□Completed application □payment as per the guideline	Application fee Ksh.22,000	30 days after receipt of application
	Issue letter of accreditation to CPD providers	N/A	Free	30 days after evaluation
	Evaluate the application and approve/reject events	Completed application as per the guideline	Free	5 days
	Evaluate the application for self-directed learning and approve/reject	Completed application as per the guidelines	Free	Two (2) months after receipt of application
5.	**Frequency of administering examination for registration as a pharmacist and enrolment as a pharmaceutical technologist**			
	Acknowledgement of application for examination	□ Completed application □ Payment	As per gazetted application fee	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	□ National ID/Passport □ Examination card	Free	□ October/November series □ April/May series
	Release the results of pre-registration and pre- enrollment examination	N/A	Free	Within two (2) months after sitting the examination
6.	**Registration of pharmacists and enrolment of pharmaceutical technologists**			
	Issue certificate of registration as a pharmacist or enrollment as a pharmaceutical technologist	Completed application as per guideline	As per the legal notice	Thirty (30) days after receipt of application

Licensing and Good Pharmacy Practice Department				
1.	**Registration of new establishments/premises**			
	New Premise Pre-registration screening	□Completed application	Free	7 days
	New Premise Application acknowledgement	□Completed application □Payment	As per the legal notice	1 day
	First Review Approval/rejection			15 days
	Approval/rejection of business unit license(s)/ Annual practice license	□Completed application □Payment □Approved inspection report	Free	Within 15 days of receiving of inspection report
	Issuance of New License	□Approved application by first reviewer; □Approved inspection report	Free	Immediately after second reviewer approval
2.	**Renewal of licenses**			
	Acknowledgement of Renewal Application	□Completed application □Payment	As per the legal notice	Within 1 day of receiving of application
	First Review of the application		Free	Within 15 days of receiving of application
	Second Review /Approval - issuance of business unit license(s)/ practice license or decline notification with a reason		Free	Within 15 days of first review
3.	**Post-licensure variation of licenses**			
	Acknowledgement of Variation Application	□Completed application □Payment where applicable	Free or As per the legal notice	Within 1 day of receiving of application
	Variation First Review /Approval - issuance of license(s), or forwarding for a second review, or a decline notification with a reason		Free	Within 15 days of variation application
	Variation Second Review /Approval - issuance of a certificate of registration of premises or a letter of rejection	□Completed application □Payment where applicable □Approved inspection report	Free	Within 15 days of receiving of inspection report
	Issuance of New	□Recommended	Free	Immediate

	License, or Addendum to the License post-variation	application by first reviewer; Approved inspection report		after second reviewer approval
4.	**Pharmaceutical representative permit**			
	New pharmaceutical representative screening	Completed application	Free	Within 1 day of receiving of application
	New pharmaceutical representative application acknowledgement	Completed application Payment	As per the legal notice – Kshs.5,000	Within 1 day of receiving of application
	First Review /Approval – forwarding for a second review or decline with a reason		Free	Within 15 days of receiving application
	Second Review /Approval – pharm rep permit or decline notification with a reason		Free	Within 15 days of receiving of application
5.	**Resubmitting edited applications**			
	Review of re-submitted application as per category of license	Completed application Response to previous queries	Free	The process to follow similar timelines as Initial applications

4.5 Laboratory Services Directorate

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

No.	Activity/Service	Requirements to obtain service	Charges	Timelines
	Sample testing and reporting			
1.	Acknowledge sample receipt upon submission.	1. Samples 2. Duly filed Analysis request form	Free	Immediately
	Release of analysis report to the clients		Free	42 days
	Release of analysis report to clients for samples/products that require urgent regulatory action, with market complaints, poor quality products		Free	10 days
	Outsourcing of laboratory testing service			

2.	Submission of samples to external laboratories	1. Samples 2. Duly filed Analysis request form	Free	10 days
	Submission of samples to external laboratories (for samples that require urgent regulatory action, with reported ADRs)	none	Free	5 days
	Reporting to clients after receipt of Certificate(s) of Analysis from external laboratories.	none	Free	2 days

5.0 OBLIGATIONS TO CLIENTS

5.1 Service Standards

The Board is committed to ensure provision of quality health 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.

In line with quality policy, the Board will consistently meet and exceed customer expectations. To ensure efficiency, PPB 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. Further, the board offices have ramps and lifts to enable the physically challenged persons to access services. Washrooms are also available on ground floor.

Customers can lodge complaints manually or online via the website, using the complaints form. Complaint/compliment boxes are also strategically placed at all PPB offices and are opened at least once a week to retrieve and address the contents. Customers can also send the complaints via complaints@pharmacyboardkenya.org, or via telephone, +2547097700100.

Customers are directed to the relevant service points from the reception. 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. To achieve this;

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.
5. Be transparent and ethical

b) **The premises of the Board will be:**

1. Accessible and welcoming
2. Drug free zone
3. Corruption free zone

5.2 **Customer Rights and Responsibilities**

a) **Customers' rights**

Customers have the right to:

1. Privacy and confidentiality;
2. Access services;
3. Access facilities;
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.

5.3 Location and how to contact us

Mode of Contact	**How to Contact Us**
Telephone: Twitter: Facebook: Email Website	Head Office +2547097700100 @ppbkenya www.facebook.com/pharmacyboardkenya info@pharmacyboardkenya.org admin@pharmacyboardkenya.org www.pharmacyboardkenya.org
In person	PPB Head office is located at Lenana Road opposite Russian Embassy Nairobi. Mombasa Regional office Kisumu Regional office Kakamega Regional office Nakuru Eldoret Machakos Nyeri Embu
In writing	Chief Executive Officer, Pharmacy and Poisons Board P.O Box 27663 Lenana Road, 00506 Nairobi
Working hours	Office Hours: 8:00 a.m. to 5. 00 p.m. Monday to Friday (Weekdays and public Holidays excluded)

6.0 AMENDMENTS TO THE SERVICE CHARTER

This service charter is subject to review due to the emerging trends. 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 five (5) years.Customer satisfaction

surveys will be carried out annually.

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

Pharmacy and Poisons Board is a non-discriminatory and corruption free organization. Customers are advised to report any form of corruption or harassment through +2547097700100, info@pharmacyboardkenya.org , complaints@pharmacyboardkenya.org,

7.0 MONITORING OF IMPLEMENTATION OF SERVICE CHARTER

Compliance with the service charter timelines will be monitored on quarterly basis by heads of departments/divisions using the template provided under Annex 2.

The monitoring reports will be sent to quality management system division for review and analysis. The analyzed reports will be submitted to the management to inform decision making and continuous improvement in service delivery.

8.0 REFERENCES

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

9.0 REVISION HISTORY

Revision No:	Date	Author	Section(s) revised	Description of change
1.	20/08/2017	HQM	Entire Document	To align with ISO 9001:2015
2.	23/12/2020	HQM	Entire Document	Reviewed the functions to align with the amended CAP 244 and the organogram Reviewed mission, vision and core values to align with the current strategic plan
3.	08/09/2023	HQM	1.0,2.0,4.0,5.0, 7.0, 8.2(b)	Deleted health laws 2019' from the introduction section. Added the compliance with QMS and WHO-GBT requirements to the introduction section Removed SCAC and SRC from introduction and added the aspect of SP, PC, BETA, GRaP Included marketing authorization to 'Health products and technologies' section Added quality assurance agencies to stakeholders Changed duration to timelines and; obligation to requirements to obtain service in the service standards section Changed resolution off customer complaints to communication of the outcome and changed timelines to 14 days Procurement timelines on forwarding invoices changed to 10 days from 30 days Changed response time for inquiries through correspondence from 10 to 7 days to align to public service standards Incorporated the common service standards as per the public service commission directive. Added monitoring implementation of customer service delivery charter section.

10.0ANNEXES

Annex 1: List of Contributors

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;

Dr. Fred M. Siyoi	Chief Executive Officer
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Dr. Anthony Toroitich	Deputy Director, Product Safety
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Dr. Ali Arale	Product Evaluation & Registration
Dr. Samuel Kerama	Clinical Trials
Dr.Karim Wanga	Post Marketing Surveillance
Dr. Pamela Nambwa	Pharmacovigilance
Dr.Nancy Cherotich	Medicines Information
Dr. Lorna Wangari	Quality Control Laboratory
Dr. Allan Kyalo	Exports and Imports
Mr.Peter Kiptoo	Ports of Entry
Mr. George Muthuri	Quality Management System
Ms. Jerop Too	Quality Management System
Ms. Immaculate Naibei	Internal Audit
Mr. Kibet Kisorio	Legal services

Ms. Ednah Menach	Human Resource Management & Development
Ms. Nelly Sinja	Supply Chain Management
Ms. Gladys Gitahi	Planning
Ms.Odongo Dorine	Administration
Ms. Nancy Arunga	Legal Services
Mr. Anthony Kemboi	Quality Management System
Ms. Hellen Odundo	Quality Management System

Annex 2: Service Charter Implementation Monitoring Matrix

Directorate…… Department……

Quarter…… Date……

SERVICE	TIMELINE	SERVICES OFFERED	ADHERENCE TO SERVICE CHARTER	REASON FOR VARIANCE
Acknowledgement of receipt of application in the 30 minutes	Within 30 minutes	X applications received and acknowledged	Compliant	No variance
Issuance of certificates of compliance and reports to successful applicants and a letter of rejection to unsuccessful applicants within 30 days after inspections	Within 30 days	X inspections done and certificate of compliance issued	Compliant (indicate level of achievement eg 4 out of 10 certificates issued within timelines	No variance
			Non-Compliant 6 out of 10 certificates issued beyond the timelines	This is caused by the inspectors being engaged with other duties hence they do not finish the reports in the stipulated time.

Compiled by (Designation)

Name: ……

Signature……

Date: ……

Reviewed by (Designation)

Name: ……

Signature……

Date: ……