MINISTRY OF HEALTH
PHARMACY & POISONS BOARD

ANNUAL REPORT

2021/2022

Pharmacy and Poisons Board of Kenya

ANNUAL REPORT 2021/2022

Pharmacy and Poisons Board @ppbkenya info@pharmacyboardkenya.org

web.pharmacyboardkenya.org

Acronyms and Abbreviations

ANU	Anti-Narcotics Police Unit
BTA's	Bilateral Trade Agreements
CEO	Chief Executive Officer
CPD	Continuous Professional Development
DCI	Drug Crime Unit
EAC	East African Community
EDCTP	European & Developing Countries Clinical Trials Partnership
FDC	Fixed Dose Combination
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
i2ES	International Import and Export System
iCMS	Integrated Custom Management System
IDA	International Development Association
IGAD	Intergovernmental Authority on Development
INCB	International Narcotics Control Board
ISO	International Organization for Standardization
JKIA	Jomo Kenyatta International Airport
KEBS	Kenya Bureau of Standards
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Agency
KenTrade	Kenya Trade Network Agency
KNBS	Kenya National Bureau of Statistics
KNESWS	National electronic single window system
KRA	Kenya Revenue Authority
MAH	Market Authorization Holder
MoH	Ministry of Health
NACADA	National Agency for the Campaign against Drug Abuse
PPB	Pharmacy and Poisons Board
PPBQCL	Pharmacy and Poisons Board, Quality Control Laboratory
MPHT	Medical Products and Health Technologies
MTaPs	The Medicines, Technologies and Pharmaceutical Services
ODCI	Office of Drug Crime Investigation
PGA	Partner Government Agencies
PV	Pharmacovigilance
PvERS	Pharmacovigilance Electronic Reporting System
PSC	Public Service Commission
QPPV	Qualified Persons for Pharmacovigilance
Rt-PCR	Polymerase Chain Reaction
SDT	State department of Trade
SHC	Senatorial Health Committee
SRC	Salaries and Remuneration Commission
TFP	Trade Facilitation Platform
TSR	Targeted Spontaneous Reporting
UNCTAD	United Nations Conference on Trade and Development
UNODC	United Nations Office on Drugs Crime
USAID	United States Agency for International Development (USAID)
WHO	World Health Organization
WHO/PQ	WHO Prequalification

Chief Executive Officer's Statement

The Pharmacy and Poisons Board, under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya is mandated to regulate the profession of Pharmacy, the manufacture and trade in medical products and health technologies through regulation of marketing authorization, licensing, market control, ensuring product safety, clinical trials oversight, manufacturing and pharmacy practice. This means creating confidence among the public about the Health Products they consume, the regulatory agencies in the region in support of harmonization and adoption of international best practices. The Board's financial year was marked by intense workload and efforts towards attainment of WHO Assessment rating of Maturity Level 3. This process has contributed immensely to regulatory systems strengthening and improvement of service delivery, which is summarized in this CEOs Annual Report FY 2021/2022. The WHO assessment came about the same time the country was preparing to establish vaccine manufacturing and capacity building in vaccine assessment and testing. This period also presented uncertainty around political transition in the country and economic recession affecting the whole world brought about mainly due to the COVID-19 Pandemic with disruptions in health care service delivery.

In spite of this the Board is delighted to highlight the major milestones in advancing its regulatory system notably; enactment of rules to better implement the Pharmacy and Poisons Act, the WHO assessment against the Global Benchmarking Tool (GBT), development of collaboration framework to guide cooperation with other government agencies and training of staff in vaccine regulation and testing.

To further strengthen governance, the first Board of Directors following amendment of the Pharmacy and Poisons Act was appointed in March 2022 and inauguration planned for 1st July 2022. In terms of legislative framework, the Board developed six sets of Pharmacy and Poisons Rules, 2022 that were enacted by Parliament in June 2022 to implement, interpret or prescribe the Pharmacy and Poisons Act.

In its effort to keep abreast with international initiatives and emerging trends, the Board participated in workshops, conferences and meetings organized both nationally and internationally; international workshop in Vienna for piloting an Online system for the control of Narcotics and psychoactive substances coordinated by the International Narcotics Control Board, WHO/AVAREF Safety Updates Meeting in Addis Ababa, Vaccine Manufacturing in South Korea,

The last financial year has seen concerted efforts from the Board of Management, government agencies and development partners in achieving the goals of regulation through collaborative efforts and financial support respectively. To this end, the Board sincerely appreciates the contributions from the stakeholders, the development partners, and the World Health Organization for being part of the success registered in the period.

During the same period, the Board conducted Post-Marketing Surveillance of maternal, neonatal and child health products and antimalarials in Kenya, 2021/2022. The Risk Based PMS samples were collected from 17 counties across the country. The total number of samples collected were 285, 176 tested and two (2) samples failed labeling requirements

Since the development and implementation of an online examination management system, in 2020, five series (20 sets) of online examinations have been successfully conducted with regard to Registration and Enrolment examination.

The Board prides itself in the improvement of the security, integrity, and efficiency of the online exam system due to the incorporation of Safe Exam Browser, and integration with the Regulatory Human Resource Information system (RHRIS) in the FY 2021-22. Consequently, automation has led to improved efficiency in exam administration as evidenced by a significant reduction in the time taken to release results. In addition, there has been Improved objectivity due to automated marking.

Further, exam administration has been decentralized, improving service delivery at regional level, improving access and fairness, while using resources within the PPB regional offices.

The Board endeavors to improve its regulatory system through benchmarking with WHO, regional economic Communities, internal audits, quality audits and through performance contracting and submits quarterly reports on its performance and activities to the Cabinet Secretary and Principal Secretary at the Ministry of Health. The Board ensures implementation of the commitments set out in the Annual President's Report on National Values and Principles of Governance and report and the current rating is at 100%. The services at the Board are funded through funds collected as levies and donor funds. The Boards' Internal Audit Unit ensures effective internal control in the use of internal resources.

In conclusion, I wish to thank the Board of Management, the management team, all staff members and stakeholders for their invaluable support without whom these achievements wouldn't be possible.

Dr Fred M. Siyoi
CHIEF EXECUTIVE OFFICER

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1 Introduction

1.1 Establishment of the Kenya, Pharmacy and Poisons Board

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.

1.2 Powers of the Pharmacy and Poisons Board

The powers of the Board are stipulated under Section 3A of the Pharmacy and Poisons Act (Cap 244) as follows:

(a) formulate guidelines for regulating the manufacture, import and export, distribution, sale and use of medical products;

(b) grant or withdraw authorization for conducting clinical trials of medical products;

(c) grant or withdraw marketing authorization for medical products subject to appropriate conditions and revise such conditions for marketing authorization as necessary;

(d) recall medical products from the market;

(e) grant or withdraw licenses to manufacturers, wholesalers, retailers, importers, exporters and distributors;

(f) investigate conduct related to the manufacture, import, export storage, distribution, sale and use of medical products;

(g) levy, collect and utilize fees for services rendered;

(h) prescribe the standards appropriate for new medical products; new uses, dosages, and formulations of existing medical products; and such other categories as may be appropriate;

(i) constitute technical and expert advisory committees;

(j) institute administrative, civil and criminal proceedings and such other powers necessary for the performance of its functions

1.3 Functions of the Pharmacy and Poisons Board

The functions of the Board are envisaged under Section 3B of the Pharmacy and Poisons Act, Cap 244. The specific functions of the Board in relation to regulation of health products and technologies and the profession of pharmacy are summarized as follows:

Part 1: Medical products and Health Technologies

a) Registration of health products and health technologies

b) Import and export control of health products and technologies

c) Licensing of manufacturers and distributors of health products and health technologies

d) Licit control of narcotics and psychotropic substances in line with the International Conventions

e) Conduct regulatory inspections of manufacturers and distributors of health products and technologies

f) Conduct laboratory testing and inspection of manufacturing, storage and distribution facilities of health products and technologies

g) Oversight of clinical trials

h) Control promotion and advertising of health products and health technologies

i) Conduct post marketing surveillance for quality, safety and disposal of health products and health technologies;

j) Conduct Pharmacovigilance of health products and technologies

k) Regulate contractors for medical devices and physical security for products including radioactive materials and biological products

Part 2: Profession of Pharmacy

d) Regulate the training, continuing professional development (CPD) and practice of pharmacy;
e) Licensing of pharmacists and pharmaceutical technologists and medical representatives
f) Accreditation of institutions offering pharmacy program
g) Regulate, monitor and inspect personnel and premises that are involved in training, CPD and pharmacy practice; and
h) Maintain a register of pharmacy practitioners for which licensure or authorization has been granted

Part 3: General functions

a) Advice the Cabinet Secretary of Health on all matters relating to administration and implementation of the Act;
b) Levy, collect and utilize fees for services rendered
c) Collaborate with other national, regional and international institutions on regulation of medical products, health technologies and the profession of pharmacy.

1.4 Vision, Mission and Core Values

Vision:

To be a global leader in promoting and protecting public health.

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

Core Values:

- Commitment to public health
- Professionalism
- Accountability and Transparency
- Integrity and Respect
- Quality
- Diversity and inclusion

1.5 Strategic Overview

Goals – Key Result Areas (KRAs)

Goal 1: Ensure access to safe, quality, efficacious and affordable health Products and technologies;

Goal 2: Leverage on research, innovation and technologies in the delivery of products and services;

Goal 3: Promote organizational stewardship, partnership and Accountability;

Goal 4: Promote a pharmacy practice that provides the highest attainable Standards of healthcare.

The third Strategic Plan for the Pharmacy and Poisons Board leverages opportunities in the pharmaceutical sector for optimizing Universal Health Coverage as a right for all Kenyans. It focuses on broad policy interventions and initiatives for securing the health of Kenyans within its mandate as stipulated in the Pharmacy and Poisons Act, Cap 244.

Kenya's national commitments and obligations as outlined in the Kenya Vision 2030, Third Medium Term Plan; and, the Big Four Agenda are critical drivers of the choice of initiatives to be implemented during the next five years. The Strategic Plan is also aligned to Kenya Health Policy 2014-2030 and National Pharmaceutical Policy 2012. The Plan also takes cognisance of regional and international policy and legal documents, declarations and aspirations, including +the African Union Model Law on regulation of medicines and the Sustainable Development Goals, specifically SDG 3

1.6 Key Strategy deliverables;

The organization is in the process of implementing its 2020-2025 strategic plan and the following outcomes have been delivered in the two years of implementation.

1. Developed USSD code *271# and mobile app mPvERs for the public to report on safety and quality issues of the medicines.
2. Undertook capacity building to five (5) local manufacturing companies as listed below;
   a. Kenyatta University Teaching and Referral Hospital (KUTRH) and Aga Khan University Hospital Tracer Center Facility; manufacturing Radiopharmaceuticals for cancer diagnosis treatment.
   b Square pharmaceuticals, True Pharma, and Questa; Manufacturing general products
3. Undertook evaluation of health products dossiers and a total of **1117** new products have been registered in the Kenyan Market in the two years of strategy implementation to enhance the accessibility of the health products to the Kenyan public;

4. Sensitized fifteen (15) clinical trial sites personnel on safety detection and reporting on clinical trials;
5. A refreshed public website was launched in June 2022 which includes resources and information for our stakeholders and the general public.
6. Some operational systems were developed and others reviewed in June 2022 resulting in the implementation of simplified, contemporary processes and practices to support transparent progress tracking and reporting.

a. Automated the review of applications on health products and technologies advertisements and promotional materials;

7. Reviewed Clinical trials' legal regulations and guidelines based on WHO GBT requirements;
8. Enhanced post-market surveillance of the health products and regulatory actions were taken on products found to fail safety and quality standards. Seven (7) health products batches were recalled from the markets;
9. The board's Quality control Laboratory entered into an agreement with other WHO prequalified labs (NQCL & MEDS) for health products testing and other laboratories (KEMRI, National Public Health, and KEBS) for health technologies testing especially testing kits to build testing capacity;
10. Conducted six (6) clinical trial site inspections in the period of implementation of the strategy.

1.7 Future Key Deliverables

Future phases of the transformation project will include internal and external priorities that will deliver value to the Pharmacy Poisons Board. Key deliverables which are currently in progress for the new Financial Year include:

1. The Board is in the process of attaining Maturity Level III by WHO, so as to allow the country to manufacture vaccines for its population.
2. Mid-term review of the strategy to record the milestones achieved, challenges experienced, environment analysis, and Strengths & weaknesses in the two-year implementation of the strategy;
3. Inspection of six (6) clinical trial sites to enhance compliance with Good Clinical trial Practices;
4. Review and implement mechanisms to enhance compliance with Good Manufacturing Practices by the local manufacturers;

2 Governance of The Board

The role of governance is critical to the efficient and effective functioning of the regulator. The PPB is governed by a Board of Directors that provides oversight over the performance of its functions. The current Board of Directors was appointed on 25th March, 2022 vide Gazette Notice No. 3202 of 2022 for the Chairman and 4th March, 2022, Gazette Notice number 3379 of 2022 for the members.

2.1 The Board of Directors (BOD)

The Board


Dr. Rogers Atebe – Chairman of the Board


Miriam Ndirangu


Stephens Oyaya


Dr. Paul Njaria


Dorcas Ngechu


Dr. John Kisengi


Dr. Diana Marion


Muleli Mutuku

Dr. Fred Siyoi – CEO

The Board of Directors consists of nine (9) members appointed by the Cabinet Secretary for Health for a period of three (3) years by dint of Section 3 of the Pharmacy and Poisons Act (Cap 244). The Board is composed of:

S/N	CATEGORY	NAME
1	Chairman	Dr. Rogers Atebe
2	Director of pharmaceutical services	N/A
3	Principal Secretary, National Treasury or representative	Mr. Muleli Mutuku
4	Pharmacist representing pharmacy training institutions	Dr. Paul Magutu Njaria
5	Pharmaceutical technologist representing pharmacy training institutions	Dorcas Wanjiru Ngechu
6	Pharmacist representing institutions of higher learning	Dr. John Munguti Kisengi
7	Pharmaceutical technologist representing mid-level colleges	Miriam Wairimu Ndirangu
8	Pharmaceutical technologist with expertise in community pharmacy nominated by the Kenya Pharmaceutical Association (KPA)	Stephens Ogutu Oyaya
9	Medical practitioner representing Kenya Medical Association (KMA)	Dr. Diana Marion
10	Chief Executive Officer	Dr. Fred Siyoi

The Chief Executive Officer is responsible for the day-day administration of the PPB and is required to ensure the implementation of the strategy as set by the Board of Directors.

The PPB submits quarterly reports on its performance and activities to the Cabinet Secretary and Principal Secretary at the Ministry of Health.

2.2 Parliamentary Committees

In the FY 2021/2022, the PPB participated in eight (8) meetings of the Committee on Health of the Senate and the National Assembly and one meeting with the Delegated Legislation Committee summarized as follows:

1. Submissions during the public hearings on Health Laws (Amendment) Bill and Pharmacy and Poisons (Amendment) Bill - July 2021
2. Submissions on the Kenya Food and Drugs Authority Bill - July 2021
3. Submissions on the Kenya Food and Drug Authority Bill, 2019 sponsored by Hon. Robert Pukose - September 2021
4. Meeting to deliberate on the cost, safety and regulation of health products and technologies - September 2021
5. Workshop on the Cost of Healthcare in the Country - November 2021
6. Meeting to consider the Health Laws (Amendment) Bill, 2021 - November 2021
7. Meeting to consider the stakeholders recommendations on the cost of healthcare in Kenya
8. Submissions on the Statute Law (Miscellaneous Amendments) Bill, 2022 - June 2022
9. Submissions to the Parliamentary Committee on Delegated legislation on six (6) Pharmacy and Poisons Act Rules, 2022 - 3rd June 2022

2.3 National Values & Principles of Governance

The Board executes its functions in compliance with the values and principles of public service stipulated under Article 232 of the Constitution of Kenya and reports annually to the Public Service Commission (PSC). Additionally, the Board is required to implement the commitments set out in the Annual President's Report on National Values and Principles of Governance and report on the measures taken in the realization of National Values and Principles of Governance stipulated under Article 10 of the Constitution. The Board in the year 2021 achieved a score of 100% for this indicator.

2.4 Regulatory System Strengthening, WHO Benchmarking using Global Benchmarking Tool

The formal benchmarking assessment on the status of the Kenyan regulatory system against the WHO's Global Benchmarking Tool (GBT) was successfully conducted at the Pharmacy and Poisons Board

(PPB) from 21st June 2022 to 1st July 2022. Kenya underwent WHO GBT Assessment (medicines and Vaccine Non-producing) from 21st June to 01st July 2022 in a bid to attain the WHO maturity level three (ML3)–the third of four levels in the WHO's classification. Maturity level four (ML4) is the highest.

A total of eight functions (medicines & Vaccine non-producing) were assessed resulting in 71 sub indicators to ML.3 (3 sub-indicators at ML.2) seen not fully implemented. There were 119 recommendations (IDPs) against the 71 sub-indicators needed to be fully implemented to attain ML.3 (medicines & vaccine non-producing) status.

Further, the WHO between 29th November to 01st December 2022 held a virtual meeting with PPB, 35 out of the 119 recommendations were marked as resolved (please refer to the table below). The PPB is working to ensure the 84 recommendations are resolved by the next virtual meeting with WHO scheduled for the end of February 2023. The WHO shall schedule a final onsite assessment if they are satisfied with the level of implementation of the remaining recommendations.

Function	Pending Recommendations Critical to ML3-01st Dec 2022	Recommendations Critical to ML3-July 2022	Recommendations critical to ML.2
RS (Regulatory System)	10	14	Two
MA (Marketing Authorization)	10	19	None
VL (Vigilance)	15	15	None
MC (Marketing Control)	7	9	One
LI (Licensing)	9	14	None
RI (regulatory Inspections)	19	20	None
LT (Laboratory Testing (NQCL and PPB QC)	14	16	None
CT (Clinical Trials Oversight)	11	12	None
Total Ongoing implementation recommendations	**84**		
Total recommendations to ML3 as at July 2022	119		
Implemented IDPs (to ML.3)	**35**		
Total recommendations to ML4 as at July 2022	165		
Total recommendations to ML4 + recommendation for improvement as at July 2022	247		
Subindicators to ML.3 as at July 2022	71		
Subindicators to ML.4 as at July 2022	111		

Figure 1

WHO GBT Status as of December, 2022

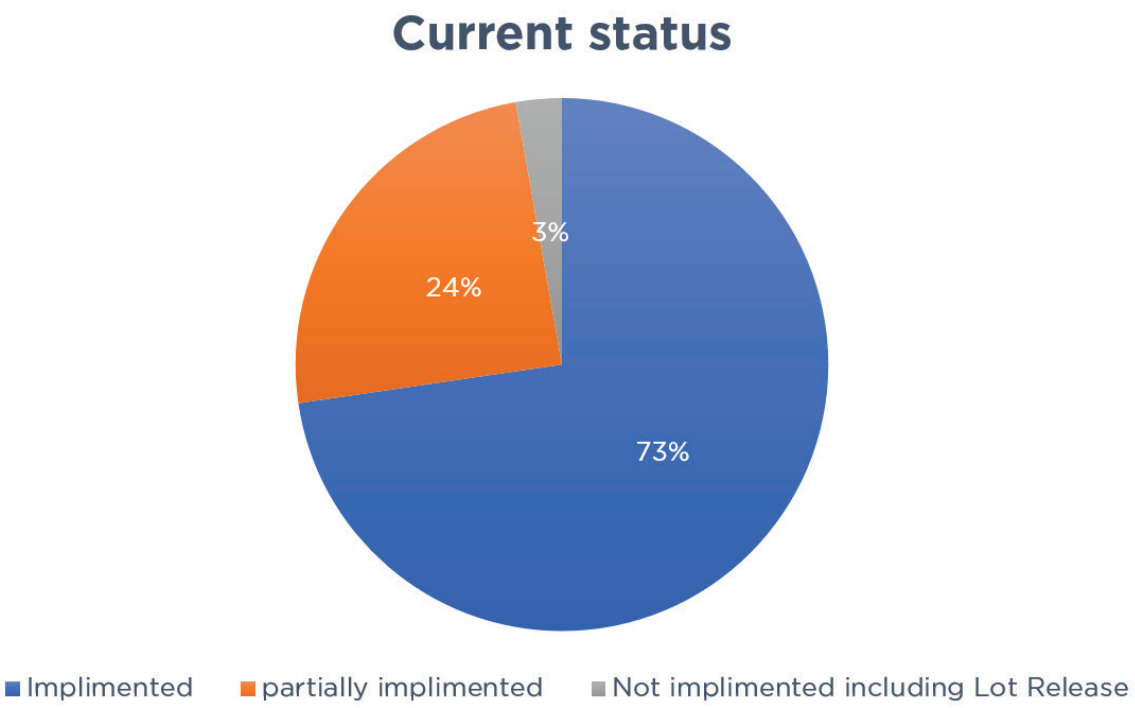
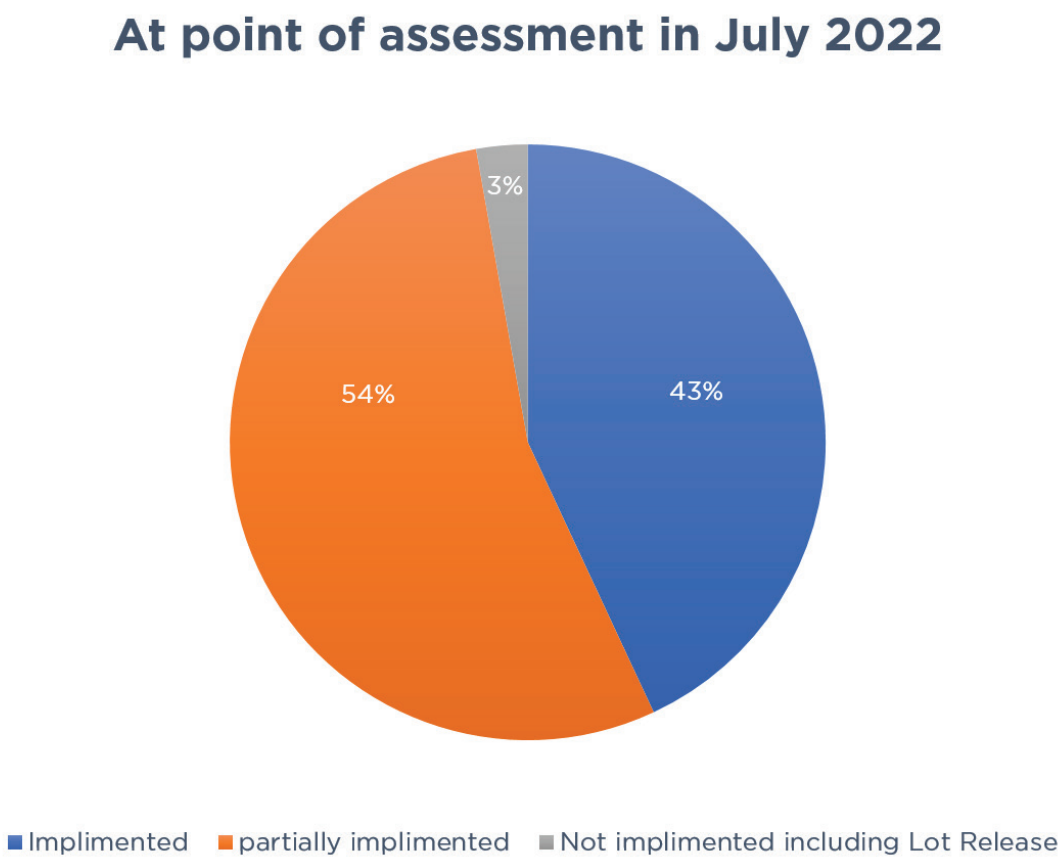


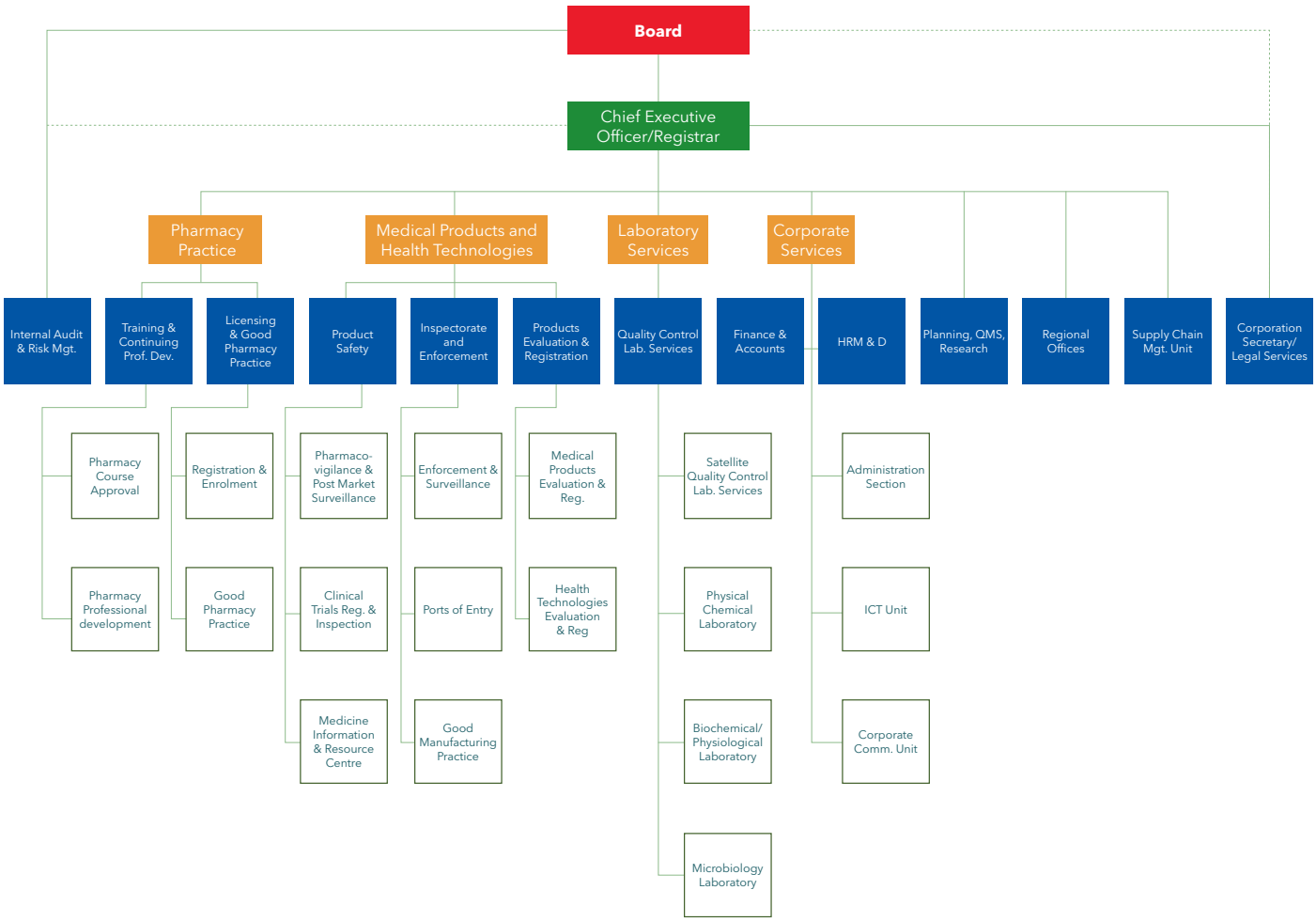
Figure 2

WHO GBT Report as of July 2022



3 Current PPB Organizational Structure

Figure 3



4. Annual Reports

4.1. Audited Financial Statements

PHARMACY AND POISONS BOARD
ANNUAL REPORT AND FINANCIAL STATEMENTS
FOR THE FINANCIAL YEAR ENDED
30th June 2020

STATEMENT OF FINANCIAL PERFORMANCE FOR THE YEAR ENDED 30TH JUNE 2020

	Note	2019-2020 Kshs	2018-2019 Kshs
Revenue from exchange transactions			
Rendering of services	3	1,124,990,214	994,047,393
Finance Income	4	6,838,817	8,920,560
Other income	5	40,221,753	28,727,899
Total revenue		1,172,050,784	1,031,695,852
Expenses			
Use of goods and services	6	30,395,077	43,203,983
Employee costs	7	81,915,758	71,404,686
Board expenses	8	5,679,809	7,675,994
Depreciation	9	181,630,452	183,953,287
Repairs and maintenance	10	28,235,388	44,859,020
General expenses	11	590,706,075	691,713,408
Finance costs	12	938,775	16,968,097
Collection cost	13	193,554,574	246,759,679
Total expenses		1,113,055,907	1,306,538,154
Surplus / (Deficit) for the year		58,994,877	(274,842,302)

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STATEMENT OF FINANCIAL POSITION
AS AT 30TH JUNE 2020

	Note	2019-2020 Kshs	2018-2019 Kshs
Assets			
Current assets			
Cash and cash equivalents	14	287,611,055	761,117,920
Trade and Other Receivables	15	66,249,791	40,265,414
		353,860,846	**801,383,334**
Non-current assets			
Property, plant and equipment	16	1,406,573,095	1,374,214,229
		1,406,573,095	1,374,214,229
Total assets		1,760,433,941	**2,175,597,563**
Liabilities			
Current liabilities			
Trade and other payables	17	16,368,912	19,527,411
		16,368,912	**19,527,411**
Total liabilities		**16,368,912**	**19,527,411**
Net assets		**1,744,065,029**	**2,156,070,152**
Reserves	18	6,479,649	6,479,649
Accumulated surplus	19	1,737,585,380	2,149,590,503
Total Reserves		**1,744,065,029**	**2,156,070,152**

PHARMACY AND POISONS BOARD
ANNUAL REPORT AND FINANCIAL STATEMENTS
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STATEMENT OF CHANGES IN NET ASSETS FOR THE YEAR ENDED 30TH JUNE 2020

	Reserves Capital Replacement Reserves Kshs	Accumulated Surplus Kshs	Total Kshs
Balance as at 1 July 2018	6,479,649	2,424,432,805	2,430,912,454
Deficit for the year		(274,842,302)	(274,842,302)
Balance as at 30 June 2019	6,479,649	2,149,590,503	2,156,070,152
Balance as at 1 July 2019	6,479,649	2,149,590,503	2,156,070,152
Transfer to the National Treasury		(471,000,000)	(471,000,000)
Surplus for the year		58,994,877	58,994,877
Balance as at 30th June 2020	6,479,649	1,737,585,380	1,744,065,029

PHARMACY AND POISONS BOARD
ANNUAL REPORT AND FINANCIAL STATEMENTS
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30th June 2020

STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30TH JUNE 2020

Cash flows from operating activities	2019-2020 Kshs.	2018-2019 Kshs.
Receipts		
Rendering of Services	1,124,990,214	994,047,393
Finance Income	6,838,817	8,920,560
Other incomes	40,221,753	28,727,899
Total Receipts	**1,172,050,784**	**1,031,695,852**
Payments		
Compensation to employees	81,915,758	71,404,686
Board Members Expenses	5,679,809	7,675,994
Use of Goods and Services	30,395,077	43,203,983
Transfer to the National Treasury	471,000000	-
Repairs and maintenance	28,235,388	44,859,020
General expenses	590,706,075	691,713,408
Finance cost	938,775	16,968,097
Collection cost	193,554,574	246,759,679
Total Payments	**1,402,425,455**	**1,122,584,866**
Net Cash flow from Operating activities	**(230,374,671)**	**(90,889,015)**
Cash flow from Investing Activities		
Purchase of Property, Plant, Equipment	(213,989,318)	(347,135,768)
(Increase)/decrease in receivables	(25,984,377)	(6,711,502)
Increase/(decrease) in payables	(3,158,499)	(6,695,800)
Net cash flow used in Investing activities	**(243,132,194)**	**(360,543,070)**
Cash flow from financing activities	-	-
NET CASHFLOW FROM FINANCING ACTIVITIES	-	-
Net increase/(decrease) in cash and cash equivalent	**(473,506,865)**	**(451,432,085)**
Cash and Cash Equivalent as at 1st July 2019	761,117,920	1,212,550,005
Cash and Cash equivalent as at 30th June 2020	287,611,055	761,117,920

PHARMACY AND POISONS BOARD
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STATEMENT OF COMPARISON OF BUDGET AND ACTUAL AMOUNTS FOR THE YEAR ENDED 30TH JUNE 2020

	Approved Budget 2019-2020	Adjustments Reallocations 2019-2020	Final Budget 2019-2020	Actual on comparable basis 2019-2020	Performance difference 2019-2020	
Revenue	**Kshs**	**Kshs**	**Kshs**	**Kshs**	**Kshs**	
Rendering of services	1,286,120,000	-	1,286,120,000	1,172,050,784	(114,069,216)	
Total income	**1,286,120,000**	-	**1,286,120,000**	**1,172,050,784**	**(114,069,216)**	(a)
		-				
Expenditure		-				
Compensation of employees	85,000,000	-	85,000,000	81,915,758	3,084,242	(b)
Finance cost	1,000,000	-	1,000,000	938,775	61,225	(c)
Board Expenses	8,000,000	-	8,000,000	5,679,809	2,320,191	(d)
Other payments	1,100,000,000	-	1,100,000,000	1,024,521,566	75,478,434	(e)
Total expenditure	**1,194,000,000**	-	**1,194,000,000**	**1,113,055,907**	**80,944,093)**	
		-				
Surplus/ (Deficit) for the period	**92,120,000**	-	**92,120,000**	**58,994,877**	**(33,125,123)**	

a) Reduction in revenue was due to effects of Covid 19 pandemic worldwide
b) The Board's Personnel cost was within the approved budgeted amount.
c) Finance cost – underutilization of finance cost was due to increase in efficiency in financial management
d) Reduced board member expenses were due to reduced board activities during the period.
e) Other payments- underutilized due to inability to carry out all activities caused by the Covid 19 scourge.

5 Annual Technical Reports

5.1 Product Evaluation and Registration

Product Evaluation and Registration is a department under the Directorate of HPTs. The Department is responsible for assessing applications (dossier) towards marketing authorization and retention of medical products and health technologies.

Currently, the department has twelve (12) dedicated Dossier assessors doing the day-to-day work but relies on assessors based in other departments during planned evaluation retreats.

5.1.1 Medical Products Evaluation and Registration

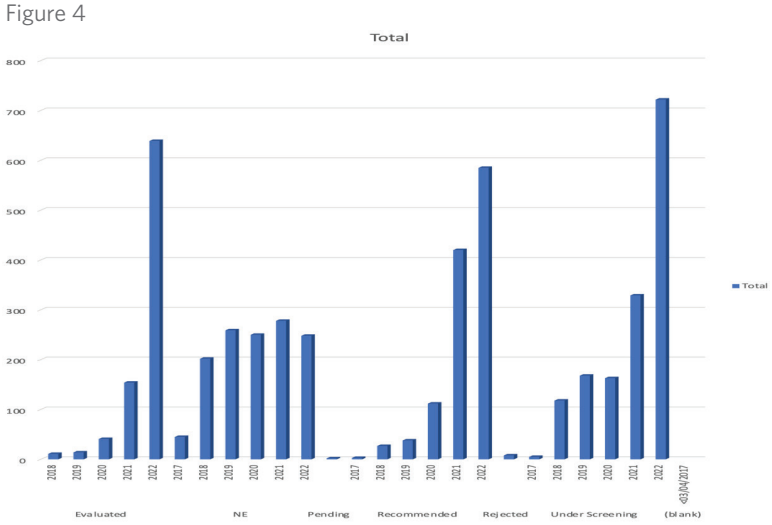
The number of dossier applications evaluated and recommended increased in 2022 compared to the previous years as per table below:

Year	New dossier applications	Dossiers recommended
2019	817	55
2020	721	92
2021	694	358
2022	639	585

Under Screening	1505
2017	5
2018	118
2019	168
2020	163
2021	329
2022	722

The number of applications that have undergone successful screening per year

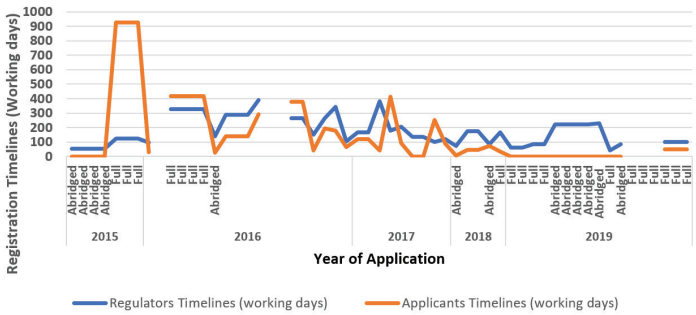
Figure 4



Reduced Registration Timelines

Since 2019, the department has streamlined and intensified evaluation of dossier applications received. The registration timelines have since been reduced from about three (3) years to less than fifteen (15) months for most of the products

Figure 5



a. In line with big four Presidential agenda initiative, the department set up mechanisms for fast tracking registration of locally manufactured products

The department evaluated and recommended registration of **53** locally manufactured products through a fast track mechanism aimed at supporting local manufacturing.

b. Enhanced participation in regional/ international harmonization activities

Application Pathway	Year	No
EAC - (Joint Assessment)	2017	1
	2018	7
	2019	5
	2020	6
	2021	1
	2022	25
Total		45
IGAD - (Joint Assessment)	2019	6
	2020	2
Total		8
MAGHP - Recognition (Swissmedic)	2020	1
Total		1
National (Full Assessment)	2016	1
	2017	386
	2018	803
	2019	813
	2020	727
	2021	929
	2022	993
Total		4652
SRA (Abbreviated)	2020	1
	2021	2
	2022	33
Total		36
WHO PQ CRP (Recognition)	2019	2
	2020	11
	2021	51
	2022	21
Total		85
WHO SRA CRP - (Recognition)	2022	1
Total		1
Total		4828

Out of the **358** dossier applications recommended for registration in 2021, **340** were national applications, **7** were WHO/PQ, **6** were EAC and **5** were applied under emergency use Listing procedure.

Since January 2021, the Directorate evaluated and recommended registration of **7** products through WHO /PQ abridged procedure

Since January 2021, the Directorate evaluated and recommended registration of **6** products through EAC medicine's harmonization program

Since January 2021, the Directorate evaluated and recommended registration of **5** biologicals (Vaccines) through EUAL procedures

5.2 Product Safety

5.2.1 Pharmacovigilance (PV)

Since the introduction of PV in Kenya (2004), a total of **16,607** individual case safety reports (ICSRs) have been submitted to the global database which presently has a total of **33,850,091 (0.05%)** ICSRs.

The last financial year of 2021/2022 has seen an increase in the number of reports to **3299** (146% increase) compared to previous year 1341 reports. This increase in reporting is attributable to the expanded scope of reports in PV from adverse drug reactions to also include reports of medication errors, transfusion reactions and medical devices events. Also availing the online platform for reporting adverse events following immunizations (AEFI), launch of mobile application mPvERS and USSD code *271# also expanded the platforms for reporting safety issues. Finally, the upscaling of training of healthcare providers on how to identify, manage and report safety issues also contributed to the increase in reports received in this financial year.

Reports by quarter

Report type	Q 1	Q 2	Q 3	Q 4	Total reports
sADRs	167	192	242	238	**839**
AEFI	174	407	932	48	**1561**
Medication errors	180	168	134	165	**647**
Medical devices	1	8	0	1	**10**
Transfusion reactions	0	2	1	1	**4**
PADRs	58	63	31	86	238
Total reports	580	840	1340	539	3299

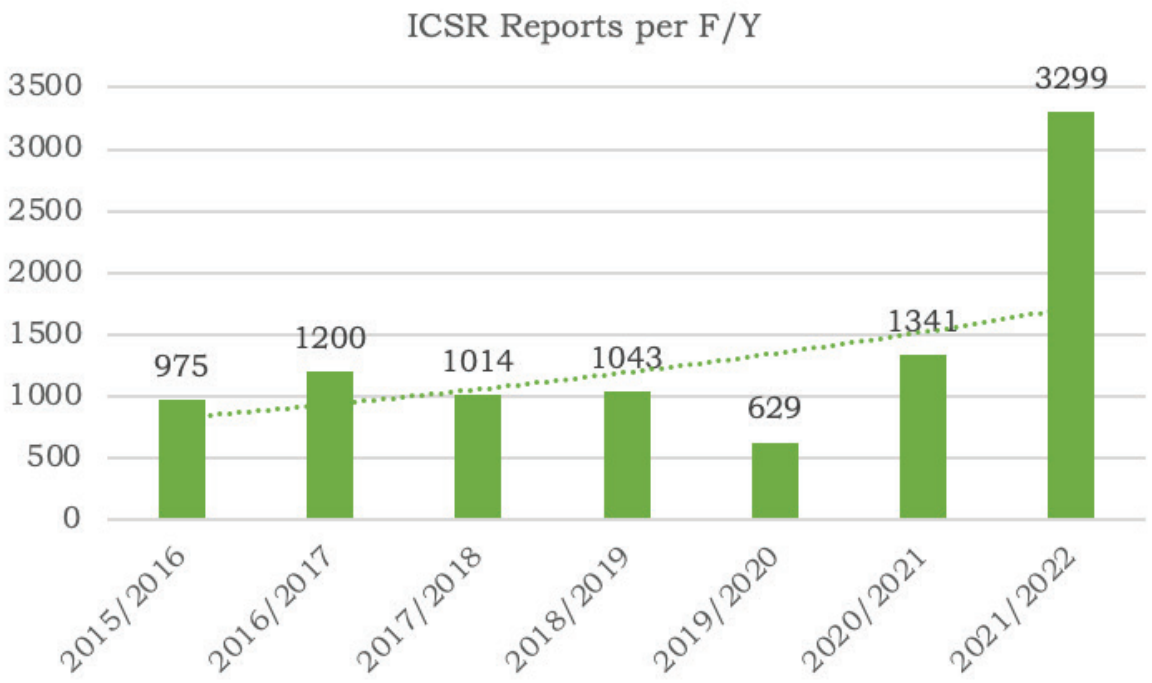
Type of reports	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22
Suspected Adverse Drug Reaction reports (SADRs)- Reported by healthcare providers	975	1200	1014	1043	629	894	839
Adverse Events following Immunization reports (AEFI)	-	-	-	-	-	264	1561
Suspected Adverse Drug Reaction reports (PADRs)- Reported by the public/ patients	-	-	-	-	-	177	238
Medication errors reports	-	-	-	-	-	5	647

Type of reports	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22
Medical devices incidences	-	-	-	-	-	-	10
Transfusion reaction reports	-	-	-	-	-	1	4
Total reports	975	1200	1014	1043	629	1341	3299

Below is a comparison of safety reports received and evaluated in the last six years.

Year	Hard copies	PVERs/Online	Total no.
2015/2016	475	500	975
2016/2017	300	900	1200
2017/2018	67	947	1014
2018/2019	96	951	1043
2019/2020	-	629	629
2020/2021	-	1341	1341
2021/2022	-	3299	3299

Figure 6: Number of reports collated per financial year



5.2.1.2 Evaluation of the Adverse Drug Reactions reports

This entails uploading of both the hard copies and online reports from the **PV-Electronic Reporting System (PVERs)** to Vigi-flow and later downloading the data in an excel sheet and doing some basic statistics on the data in order to give feedback to reporters as a 2 pager.

During the uploading of reports, causality assessment is carried out on each report to ensure that minimum requirements for a valid report are met.

Year	PVERs	Vigi-flow
2015/2016	975	875
2016/2017	1200	1108
2017/2018	1014	931
2018/2019	1047	907
2019/2020	629	1029
2020/2021	1341	1846
2021/2022	3299	1688

Figure 7

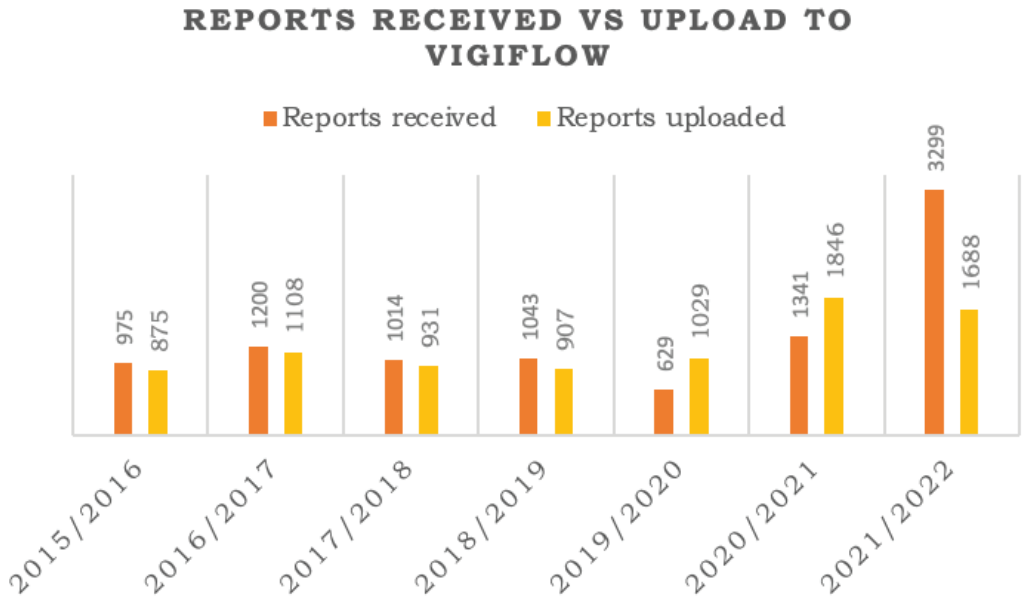
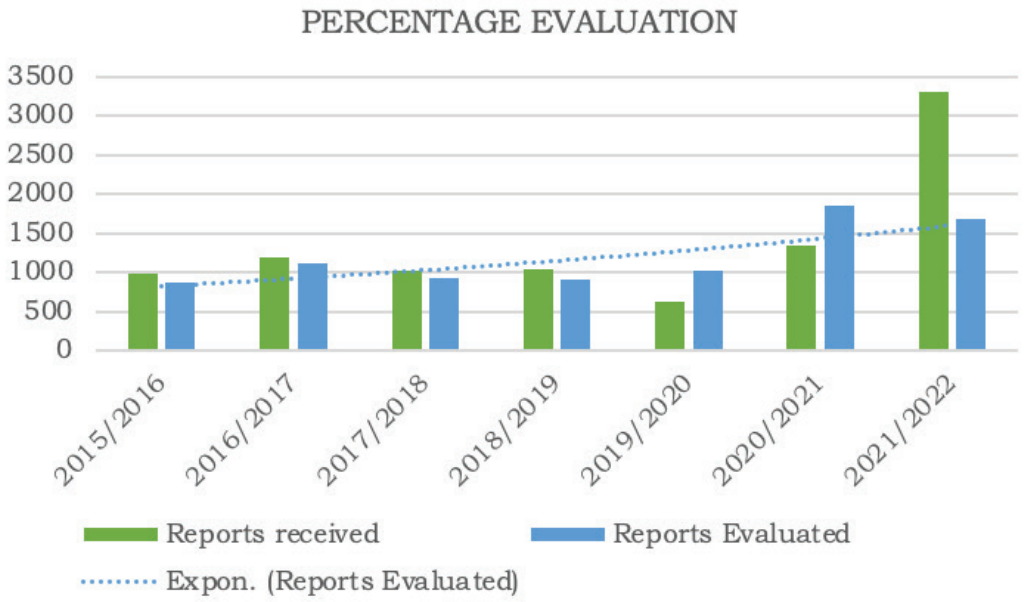


Figure 8



The bar graph above shows the number of reports received at the PV Centre and evaluated. On average 90% of the reports received are evaluated and any follow up needed is then initiated. In 2019/2020 and 2020/2021, percentage evaluations of the reports were at 164% and 138% respectively. This is explained

by the backlog reports (905 reports) from the previous years. This figure dropped significantly in this financial year of 2021/2022 to 51%.

5.2.1.3 Safety advisory committee meetings

The Pharmacy and Poisons Board has two technical committees (Pharmacovigilance Experts Review and Advisory Committee & National Vaccine Safety Advisory Committee) that evaluate serious individual case safety reports and makes recommendations on appropriate actions to be taken by relevant stakeholders. In the F/Y 2021/2022, the PERAC committee reviewed serious cases and issued safety alerts to healthcare providers on use measures to be undertaken when using combined central nervous system drugs. Members of the public were also cautioned on the use of diclofenac as over the counter medicines and the risks involved in abuse of the same painkillers.

5.2.1.4 WHO GBT assessment-Vigilance

The Board in the F/Y 2021/2022 underwent the WHO global benchmarking assessment to assess its maturity level in terms of regulation of its functions. Vigilance function was classified to be at maturity level 2 at 88% implementation of the indicators at that level.

5.2.1.5 USSD Code launch

In line with its mandate in protecting public health and promoting patient safety, the PPB has leveraged on mobile solutions as a means to further engage the public in reporting of adverse events. The PPB therefore, through support from the USAID Medicines, Technologies and Pharmaceutical Services (MTaPS) Program developed a mPvERS system, a mobile based solution that provides a reporting platform for adverse events and suspected poor quality health products and technologies. This mobile solution is in the form of a mobile application for both android and iOS and an Unstructured Supplementary Service Data (USSD) solution. The solution supports the reporting of the adverse events following immunization, adverse drug reactions, suspected poor quality medical products and technologies, medication errors, transfusion reactions, medical devices incidents and public reporting via the USSD (*271#). The solution was developed to supplement the existing national reporting system Pharmacovigilance Electronic Reporting System (PvERS II) that was launched in March 2021 to increase and improve consumer reporting and AEFI reporting.This was a successful investment as we saw an increase in reporting by 146%.

5.2.2 Post-Marketing Quality Surveillance Report, FY 2021/2022

5.2.2.1 Post-Marketing Surveillance of Maternal, neonatal and child health products and anti-malarial in Kenya, 2021/2022

The Risk Based (RB) PMS samples were collected from 17 counties across the country as indicated below. The total number of samples collected were 285.

Number Sampled	Number tested	Compliance status
285	176	Two (2) samples failed labeling requirements

5.2.2.2 Joint IGAD cross-border post-marketing quality surveillance of maternal, neonatal and child (MNCH) health products

Number Sampled	Number tested	Compliance status
147	88	100%

5.2.2.3 Post-Marketing Surveillance of Public Health Program (PHPs) products, (ARVs, anti-malarial, anti-TBs and mRDTs)

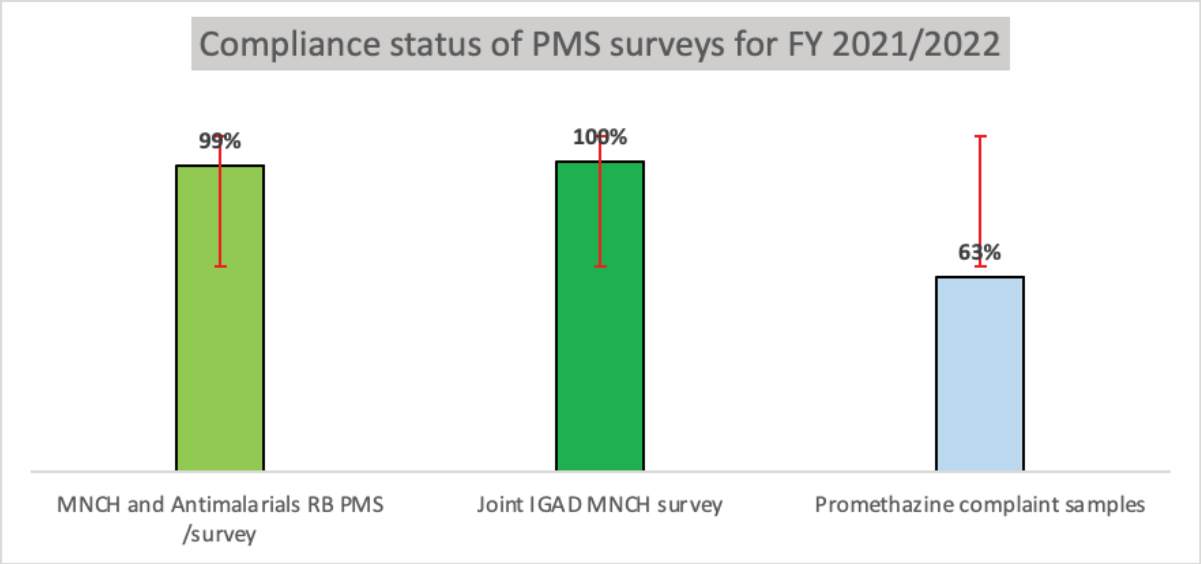
Number Sampled	**Number under testing**
219	219

5.2.2.4 Complaint samples collected and tested for investigational purposes

Promethazine products

Number Sampled	**Number tested**	**Compliance status**
37	8	Three (3) samples failed to comply

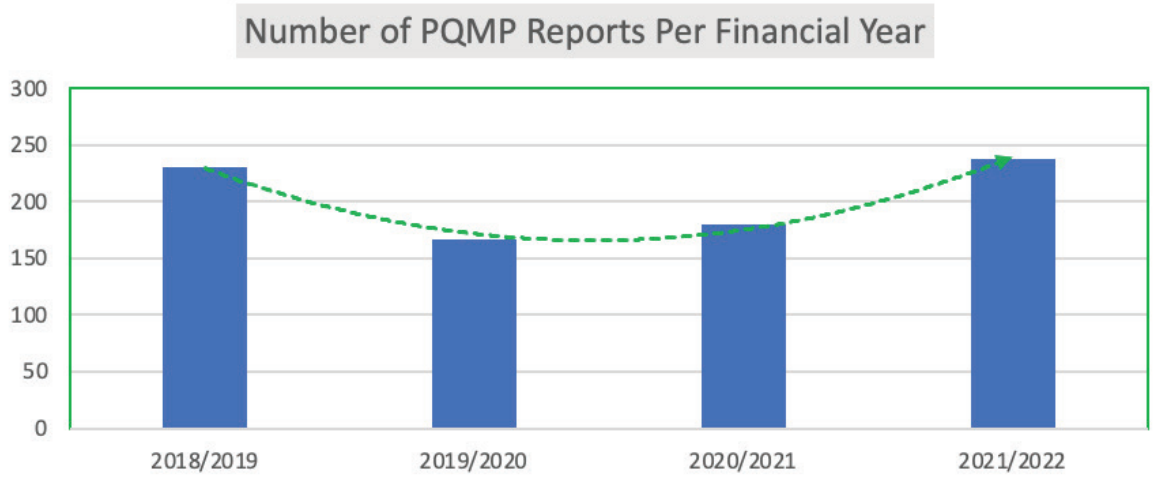
Figure 9: Graph showing Compliance status of PMS surveys for FY 2021/2022



5.2.2.6 Number of Poor-Quality Medical Products (PQMPs) Reports Disaggregated in Years

Financial Year	**Number of PQMP Reports**	**Percentage of PQMP Reports**
2018/2019	231	28.31%
2019/2020	167	20.47%
2020/2021	180	22.06%
2021/2022	238	29.19%
Total	**816**	100%

Figure 10: Graph showing PQMPs disaggregated in years

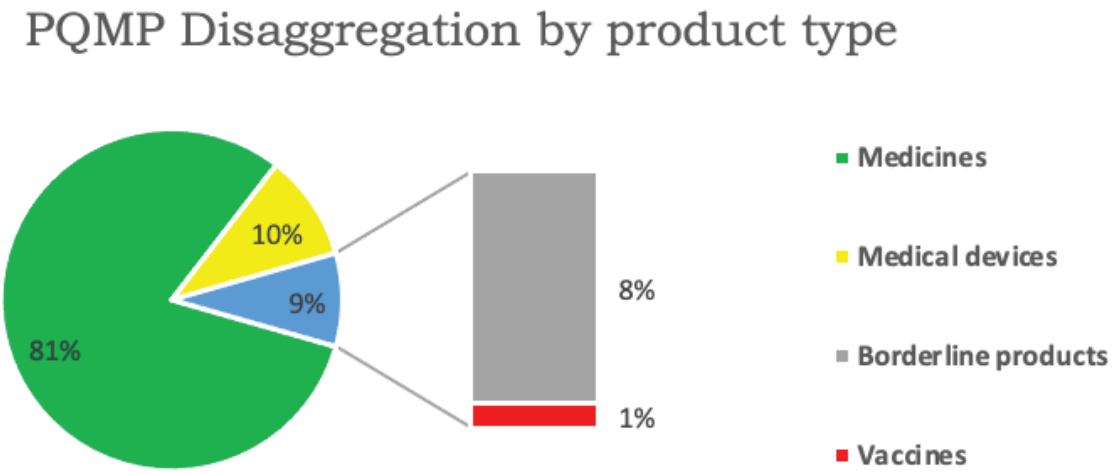


5.2.2.6 Disaggregation of PQMPs reported in FY 2021/2022 based on several parameters i.e., type of product, innovator vs generic, imported vs locally manufactured

Disaggregation of PQMPs, type of product (2021/2022)

Total number of PQMPs	Medicines	Vaccines	Medical devices	Borderline products
238	193	2	24	19

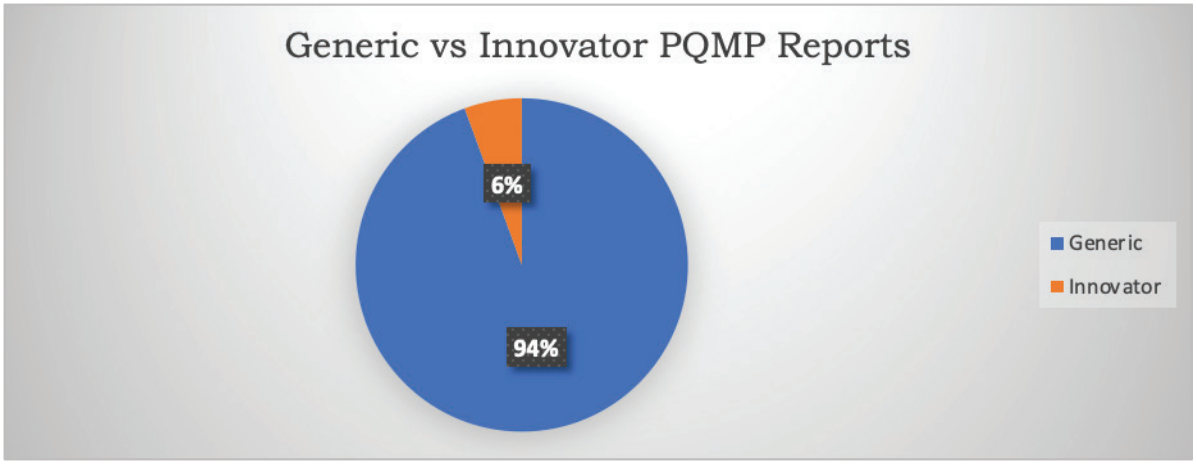
Figure 11: Chart showing proportion of poor-quality medical products reports that comprised medicines vs medical devices



5.2.2.7 Disaggregation of PQMPs, innovator vs generic products

Total number of PQMPs for medicines	Generic	Innovator
238	223	15

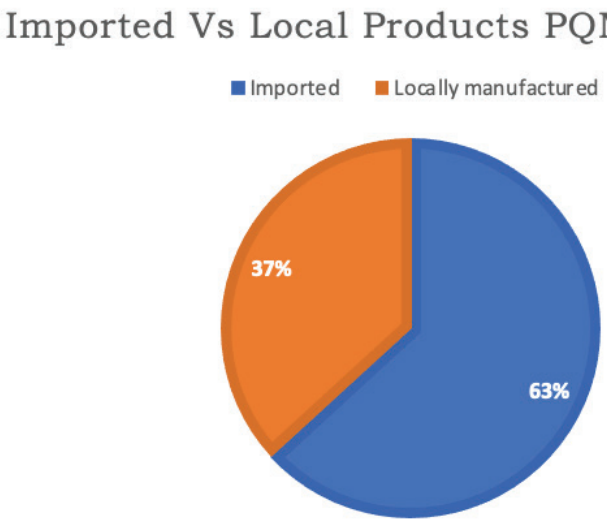
Figure 12: Chart showing proportion of poor-quality reports that comprised innovator products vs generic medical products.



5.2.2.8 Disaggregation of PQMPs, imported vs locally manufactured products

Total number of PQMPs	Imported	Locally manufactured
238	150	88

Figure 13: Chart showing proportion of poor-quality reports that comprised medical products that were locally manufactured vs imported.



5.2.2.9 Regulatory actions per year

Table showing distribution of regulatory actions from 2018 to 2022

Regulatory Action	2018	2019	2020	2021	2022	Total
Quarantine	5	0	1	1	6	13
Recalls	18	24	17	13	8	80
Regulatory guidance to industry	0	1	1	1	1	4
Suspension of market authorization	1	1	0	0	1	3
Total	**24**	**26**	**19**	**15**	**16**	100

Figure 14: Graph showing distribution of regulatory actions from 2018 to 2021

5.2.3 Clinical Trials

The Pharmacy and Poisons Board started regulation of clinical trials in 2008 and set up an Expert Committee on Clinical Trials (ECCT). The ECCT is made up of broad expertise spanning Pharmacology, immunology, clinical trials, Statistics, vaccinology, Pharmacokinetics, Pediatrics, Public Health, Tropical Medicines, molecular medicines and recombinant technology. From the inception of the regulation of clinical trials by PPB, safety monitoring of study participants has been at the forefront. Before the approval of a clinical trial, the Pharmacy and Poisons Board Expert Committee of Clinical Trials (PPB ECCT) reviews the protocol to ascertain that the investigational product under study is safe and of good quality for use by the proposed participants.

For the period under review (July 2021- June 2022), a total of 60 new clinical trial applications were received and reviewed. The details of these clinical trials can be seen at www.ctr.pharmacyboardkenya.org

The summary below shows an analysis of this data for the last five years with an indication of compliance to the review timelines.

5.2.3.1 Status of ECCT protocols 2018-2022

1. Trend of ECCT protocols received and approved

The Expert Committee on Clinical Trials received a total of 196 protocols between January 2019 and 30th June 2022.

YEAR	ECCT PROTOCOLS RECEIVED	ECCT PROTOCOLS APPROVED	ECCT PROTOCOLS WAITING APPROVAL	ECCT PROTOCOLS STOPPED	APPLICATION WITHDRAWN
2019	34	32	0	0	0
2020	46	43	0	0	0
2021	72	61	2	2	3
2022	44	31	13	0	0

Figure 15

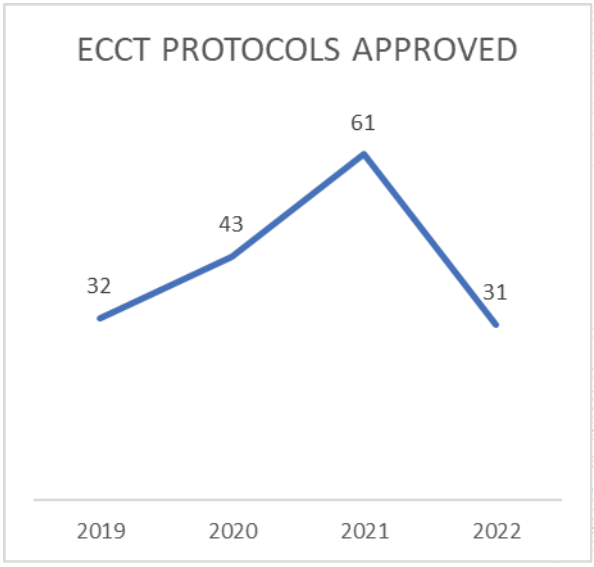
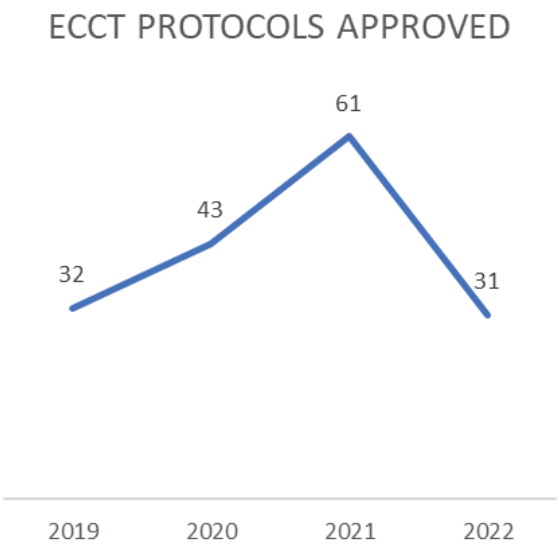


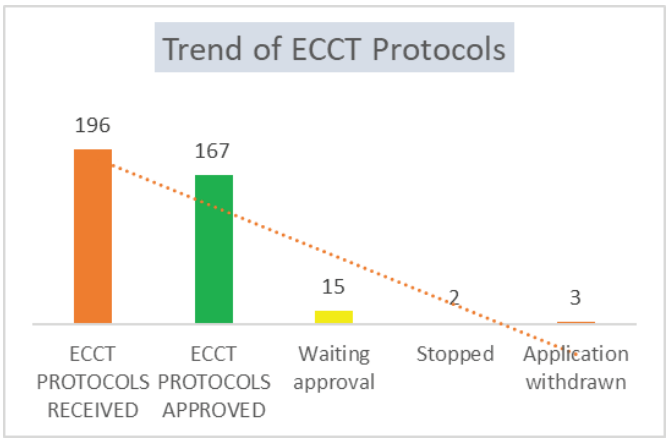
Figure 16

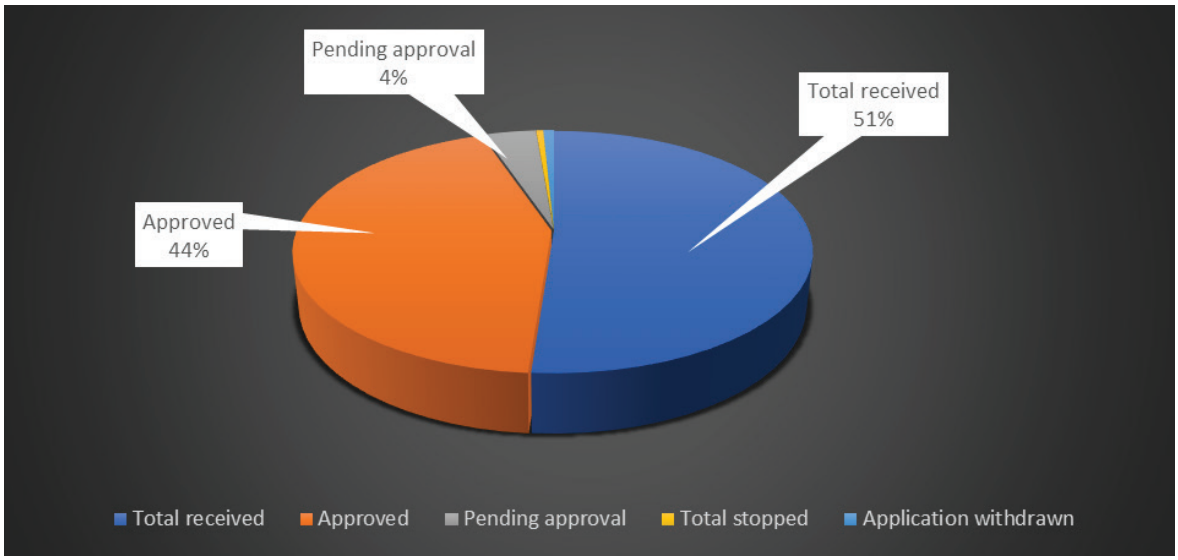


5.2.3.2 Trend of ECCT protocol status

Overall, the Pharmacy and Poisons Board has received a total of 196 protocols for review between 2019 and 2022

The ECCT approved 167 protocols, stopped 2 protocols while 15 were pending approval as at 30th June 2022.

PROTOCOL STATUS	RECEIVED VS APPROVED PROTOCOLS
	Total received: 196 Approved: 167 Pending approval:15 Total stopped: 2 Application withdrawn:3



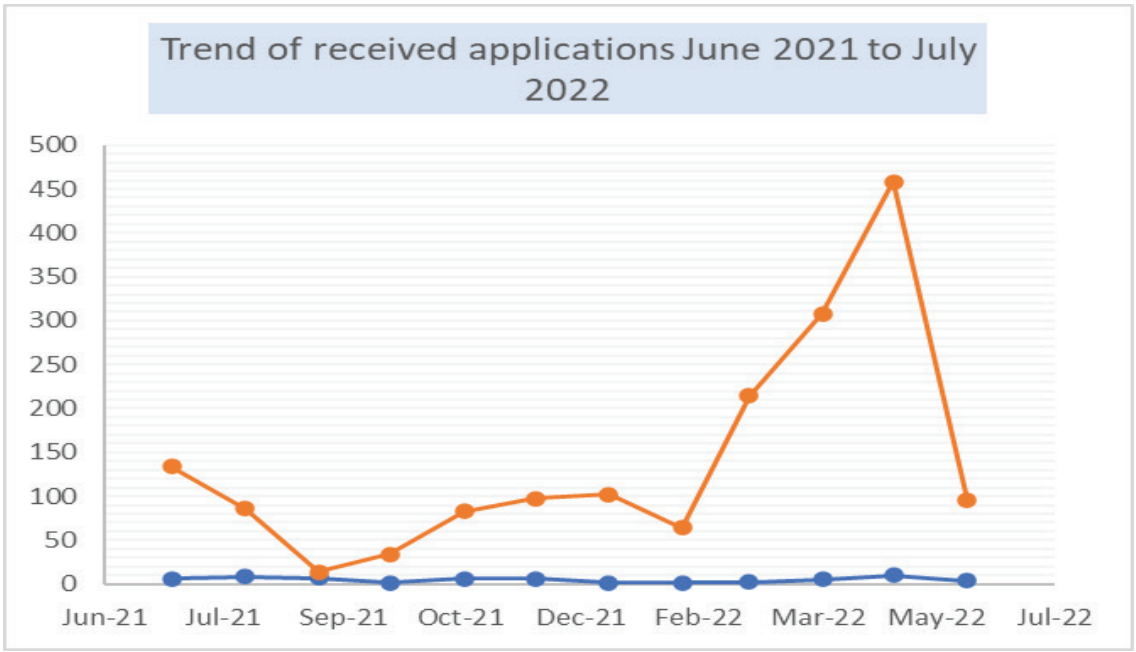
5.2.4 Medicines Information and Resource Centre

The Medicines Information and Resource Unit received a total of 1746 applications for advertisement / promotion of Health Products and Technologies in Kenya between 1st July 2021 to 30th June 2022. Majority of the applications were submitted online via https://prims.pharmacyboardkenya.org/ .

Online applications contributed 96.73% (1689 applications) of all reports in this reporting period. Of the 1689 online applications received, 565 applications (33.45%) were queried while 1124 applications (66.54%) were approved without queries. All but 4 received manual applications (99.92%) were not approved.

	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Tot
Online	134	86	14	34	83	97	102	64	214	308	458	95	1689
Manual	6	8	7	1	6	6	1	1	2	5	10	4	57
Total													1746

Figure 17



Most of the online applicants (22.26%) selected "Others" as the media of the promotion/ advertisement in this reporting period. Leaf behind literature, Branded items and calendars were among the top advertisements/promotions approved between June 2021 and July 2022, contributing 19.54% (416), 14.37% (306) and 5.92% (126) of the total applications approved.

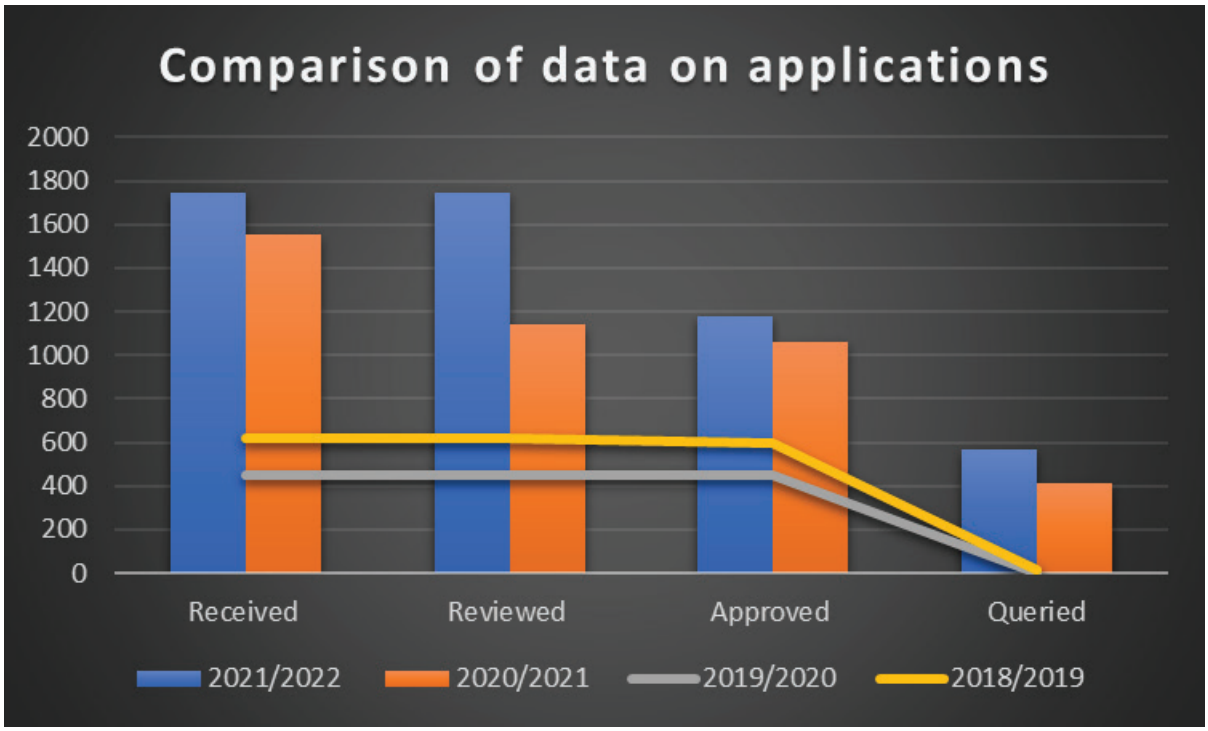
Most manual applications received were applications for promotion/advertisement of borderline products, medical devices and herbal products via leaf behind literatures, posters and branded items. The summary of applications evaluated and approved via the online platform https://prims.pharmacyboardkenya.org/ is as intimated below by type of media.

S/No	Row Labels	Sum of Applications	Proportion
1	RADIO SCRIPT	24	1.13%
2	DANGLERS	25	1.17%
3	PICK UP LEAFLET	30	1.41%
4	POSTERS	42	1.97%
5	TV SCRIPT	48	2.25%
6	YOUTUBE	50	2.35%
7	BANNERS	54	2.54%
8	STICKERS	66	3.10%
9	INSTAGRAM	78	3.66%
10	FACEBOOK	90	4.23%
11	PRESCRIPTION PADS	103	4.84%
12	DETAIL AID	112	5.26%
13	CALENDERS	126	5.92%
14	BRANDED ITEMS	306	14.37%
15	LEAF BEHIND LITERATURE (LBL)	416	19.54%
16	OTHERS	559	26.26%

Comparison number of applications received, reviewed and approved in years, 2018/2019, 2019/2020, 2020/2021 and 2021/2022.

Applications	Year			
	2021/2022	2020/2021	2019/2020	2018/2019
Received	1746	1550	450	617
Reviewed	1746	1138	450	617
Approved	1179	1062	448	600
Not approved/queried	569	412	2	17

Figure 18



Apart from reporting on advertisements and promotions, the medicines Information unit has been developing the guidelines on scheduling and rescheduling and reviewing the poison list. The guideline and schedules were subjected to stakeholder engagement and have been finalized. Operationalization of the schedules is awaiting amendment of the Act, Cap 244 to incorporate the new schedules.

Application for Rescheduling

Two applications for two products have been received for rescheduling; Omeprazole 20mg and Ibuprofen gelatin capsules.

Resource and Poisons Centre

The concept note for establishment of the resource and poisons center and a request to refurbish and procure furniture and IT equipment was developed and presented to the top management for action. The unit is in the process of developing a policy that will guide the operation of the committee to spearhead the establishment of the center.

5.3 Department of Inspectorate and Enforcement (DIE)

5.3.1 Functions

i. Regulate the manufacture, import/ export, storage, distribution, sale and use of health products;
ii. Regulate, monitor and inspect personnel and premises that are involved in the manufacture, import/export, storage, distribution, sale, use and disposal of health products;
iii. Disseminate information on health products to health professionals and to the public in order to promote their responsible use; and
iv. Collaborate with other national, regional and international institutions on health products regulation.

The Department coordinates activities of the following functional divisions/units:

1. Enforcement and Surveillance
   i. Good Distribution Practices (GDP) Division
   ii. Drug Crime (DCI) Unit
2. Good Manufacturing Practices (GMP) Division
3. Ports of Entry (POE) Division

5.3.2 Good Distribution Practices (GDP)

This is part of quality assurance system that ensures that the quality of HPTs is maintained by means of adequate control and implementation of numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from unapproved, illegally imported, stolen, substandard, falsified/adulterated, and/or misbranded medical products and health technologies.

During the 2021/22FY period, DIE planned and implemented activities meant to ensure compliance with regulations and the Law in order to:

1. Protect and maintain the integrity of the supply chain of health products and technologies
2. Protect Public Safety

Objective: To foster the integrity of the supply chain of health products and

Technologies through monitoring, inspection, verification investigation and enforcement of Pharmacy and Poisons Act, and regulation.

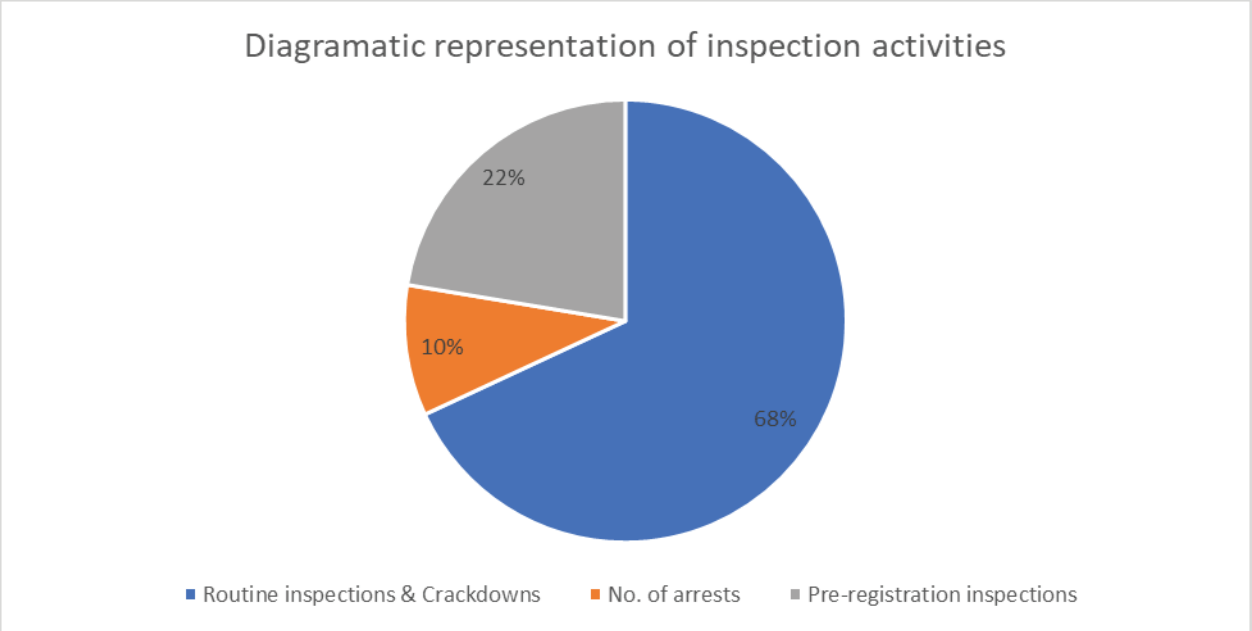
Summary of activities and achievements

S/No.	Activity	Measure	Achievement	
			2020/21FY	**2021/22FY**
1.	Conduct routine compliance inspections of the licensed pharmaceutical premises to reduce incidences of violations	Number	4274	4393
2.	Conduct targeted National crackdowns to weed out illegal pharmaceutical outlets and practitioners	Number	10	18
3.	Carry out Pre-registration inspections	Number	1405	2554
4.	No. of unauthorized practitioners arrested and prosecuted	Number	600	1302
5.	Verification of all imported/ exported HPTs at all Gazetted POEs	Number of inspections	11,053	22,004
6.	Stopped consignments at POE	Weight (Kgs)	7,660	1780
7.	To investigate, gather intelligence and take regulatory actions on pharma crime offenders	Number of operations	71	143
8.	Pharma crime offenders arrested and prosecuted	Number	11	220
9.	Disposal of Pharmaceutical Waste	No. of certificates	177	457
10	Court Users Committee (CUC) meetings participated	Number	10	4

Inspection activities

S/No.	**Activity**	**Outcomes (Number)**	
		2020/21FY	**2021/22FY**
1	Routine inspections & Crackdowns	4274	4393
2	No. of arrests	600	1302
3	Pre-registration inspections	1405	2554

Figure 19



5.3.3 Disposal of Pharmaceutical waste

In pursuing the aims of reducing health problems, healthcare services inevitably create pharmaceutical and related waste that may itself be hazardous to public health and the environment. Safe methods for managing pharmaceutical waste are therefore essential and should be an integral feature of healthcare services.

Safe management of pharmaceutical waste entails taking all practical steps to ensure that pharmaceutical waste is managed in a manner that protects human health and the environment against the adverse effects which may result from the pharmaceutical waste.

The Department of Inspection & Enforcement implements the Guidelines for safe disposal of pharmaceutical waste and ensures waste generators adhere to the same.

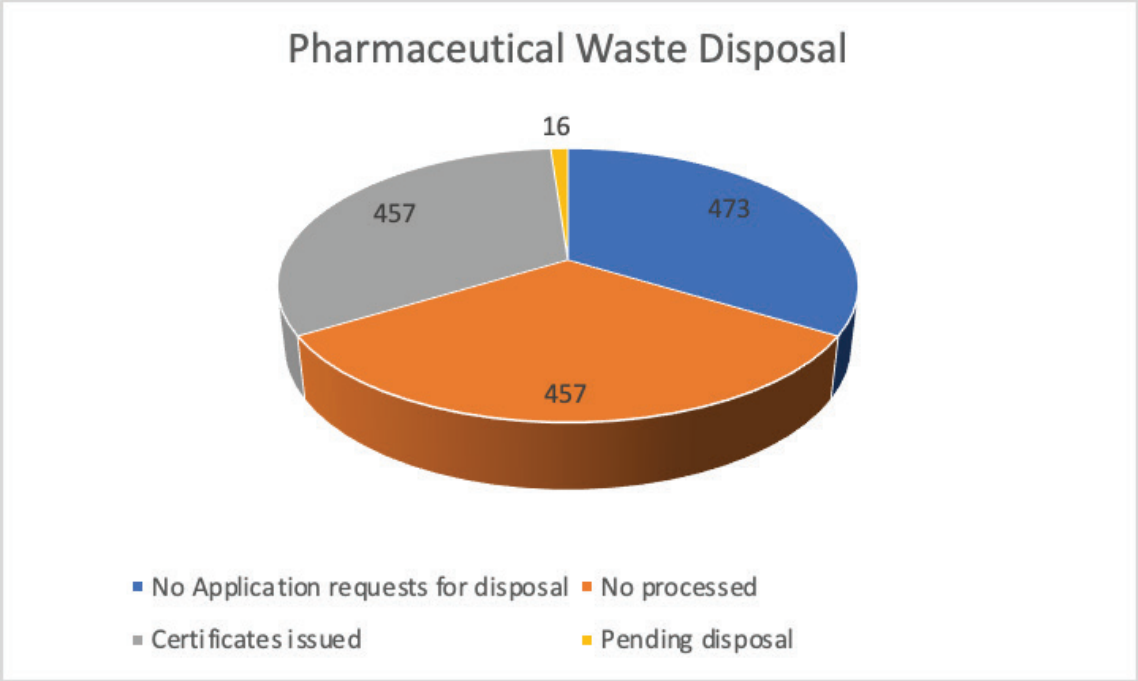
During the year under review, applications, verification and supervision of waste disposal was done as per the table below.

The pending disposals (16 applications out of which 10 are from one applicant) are as a result of the applicant not ready as per the terms of service of the incinerator. Once the applicant clears with the incineration service provider, the disposal will be done immediately.

Pharmaceutical waste disposal activities

S/No	Activity	No Application requests for disposal	No processed	Certificates issued	Pending disposal
2020/21FY	Verification and supervision of waste disposal	220	177	177	43
2021/22FY	Verification and supervision of waste disposal	473	457	457	16

Figure 20



5.3.4 Drug Crime Investigations

Office of Drug Crime Investigation (ODCI) is the investigative arm of the DIE responsible for investigating pharma crime offenses and other significant health related criminal violations which include theft, fraud, diversion, smuggling, substandard/falsified HPTs and illicit trade practices that pose danger to public health.

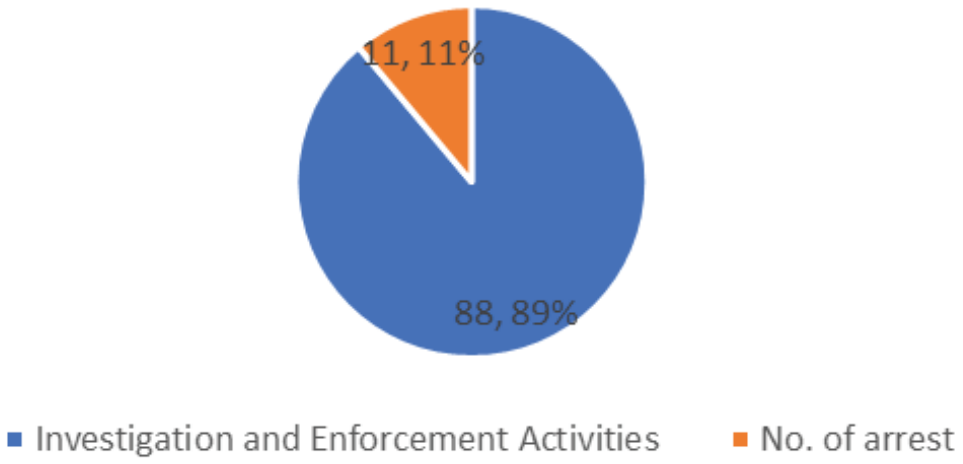
Functions

1. Breaches in the legitimate HPTs supply chain by individuals and organizations dealing in unapproved, counterfeit, falsified and substandard medical products.
2. Criminal violations in situations where the normal regulatory process has been unable to remedy the problem.
3. Criminal violations where the risk of harm to the public health is particularly significant and the only remedy appears to be through the criminal process.
4. Criminal conduct that prevents the PPB from being able to properly regulate including false statements to the PPB during the regulatory process and obstruction of due process.

Summary of activities

S/No	Investigation and Enforcement Activities	No. of arrest
2020/21FY	88	11
2021/22FY	51	4

Figure 21: Summary of investigation enforcement outcomes



5.3.5 Good Manufacturing Practices (GMP)

This is part of quality assurance system that ensures that the personnel, premises and practices employed in the manufacturing of medicinal substances and clinical Research organizations comply with the defined codes of practice and other prescribed requirements by Overseeing inspection of Active Pharmaceutical Ingredients manufacturing facilities, Finished Pharmaceutical products manufacturing premises of Medical products and health technologies and Clinical Research organizations. It enforces drug legislations (policies, laws, rules, regulations) to ensure conformity to good manufacturing practice standards and good clinical research practices to ensure their quality, safety and efficacy as defined in the Pharmacy and Poisons Act, CAP 244.

Objective: To foster the integrity of the supply chain of health products and technologies through monitoring, inspection, verification, investigation and enforcement of Pharmacy and Poisons Act, and regulation.

S/No.	Activity	Measure	Achievement	
			2020/21FY	2021/22FY
1.	Conduct onsite GMP inspections of Local manufacturing facilities for Health products and Technologies	Number	30	14
	No of compliant Local manufacturing facilities	Number	30	14
2.	Conduct onsite inspections of foreign manufacturing facilities for Health Products and Technologies			
	No of applications received for Foreign GXP inspections	Number		217
	Backlog of applications from previous year	Number	83	300
	No of compliant Foreign Local manufacturing facilities	Number		298
	No of non-compliant Foreign Local manufacturing facilities	Number	0	2
3.	Conduct Desktop Document reviews of foreign manufacturing facilities for Health Products and Technologies	Number	136	0
TOTAL				

During the financial year 2020 – 2021, there were no onsite inspections carried out for foreign manufacturers of HPT due to travel restrictions imposed because of Covid-19 pandemic.

The charts below illustrate the comparison between GMP inspections in the financial year 2020-2021 and the financial year 2019-2020.

Figure 22

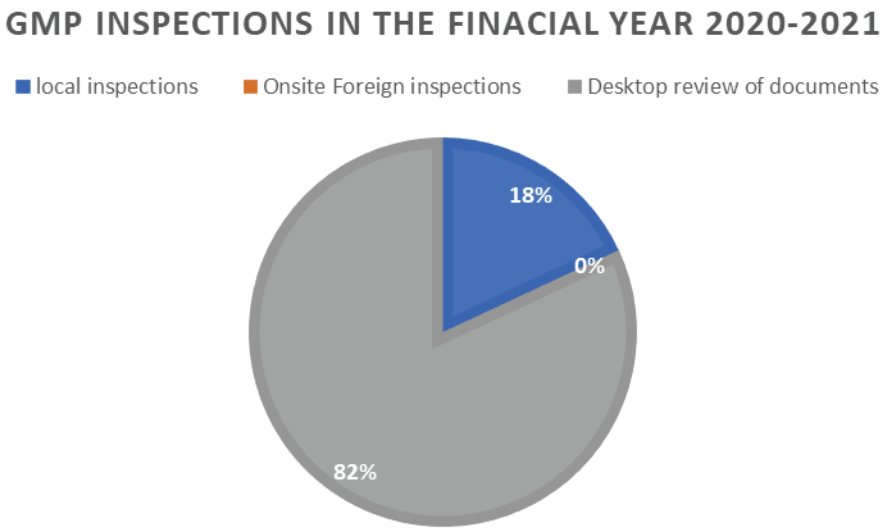
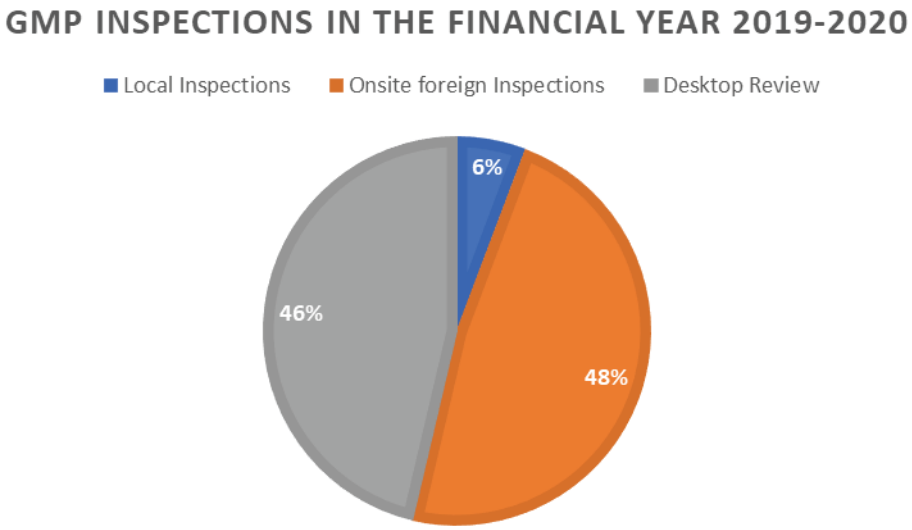


Figure 23



5.3.6 Ports of Entry

Ports of Entry inspectors enforce GDP through inspection and verification of all imported/exported HPTs at Ports of Entry before a consignment is either released for marketing or rejected.

5.3.6.1 Functions

- To regulate and control the importation of medicinal products, medical devices, Lab reagents, precursors and cosmetics through pre-clearance inspections
- Verification of import/export documents before issuance of pre-release stamps
- Conduct surveillance at all inland Ports/ international borders
- Sampling of profiled products
- Conduct basic screening

5.3.6.2 Achievements at the three major POEs

Summary of inspection and verification of health products and technologies at the three major ports of entry; Inland Container Deport-Nairobi, Jomo Kenyatta International Airport and Kilindini Sea Port

a) Inland Container Depot-Nairobi (ICDN)

Analysis of products cleared in the FY 2021/2022

S/N	Product description	Q1	Q2	Q3	Q4	Total Weight In Kgs
1	Finished pharmaceutical products	23497	792881	2470576	1995756	5282711
2	Medical donations	0	0	61627	46615	108242
3.	Medical devices	9701	212037	450353	731862.26	1119003
4.	pharmaceutical raw materials including APIs	650	146934	3378597	1828713	4191270
5.	Pharmaceutical packaging material	0	0	0	53570	53570
6	Promotional material	0	0	0	56	56
7	Narcotics Psychotropics & Precursor substances	0	39263	265685	118120	423068
Total						11,177,920

Figure 24: Health Products and Technologies (HPTs) processed by weight in Kgs per quarter

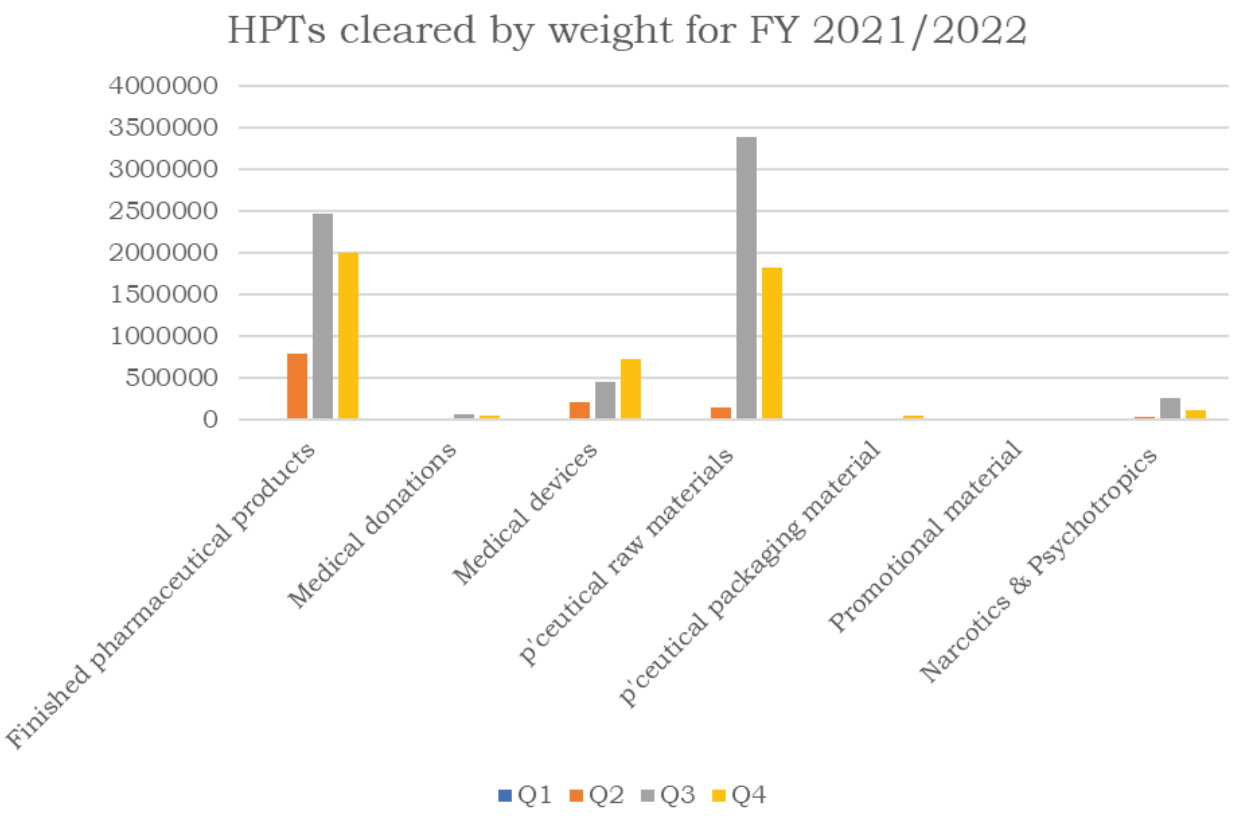
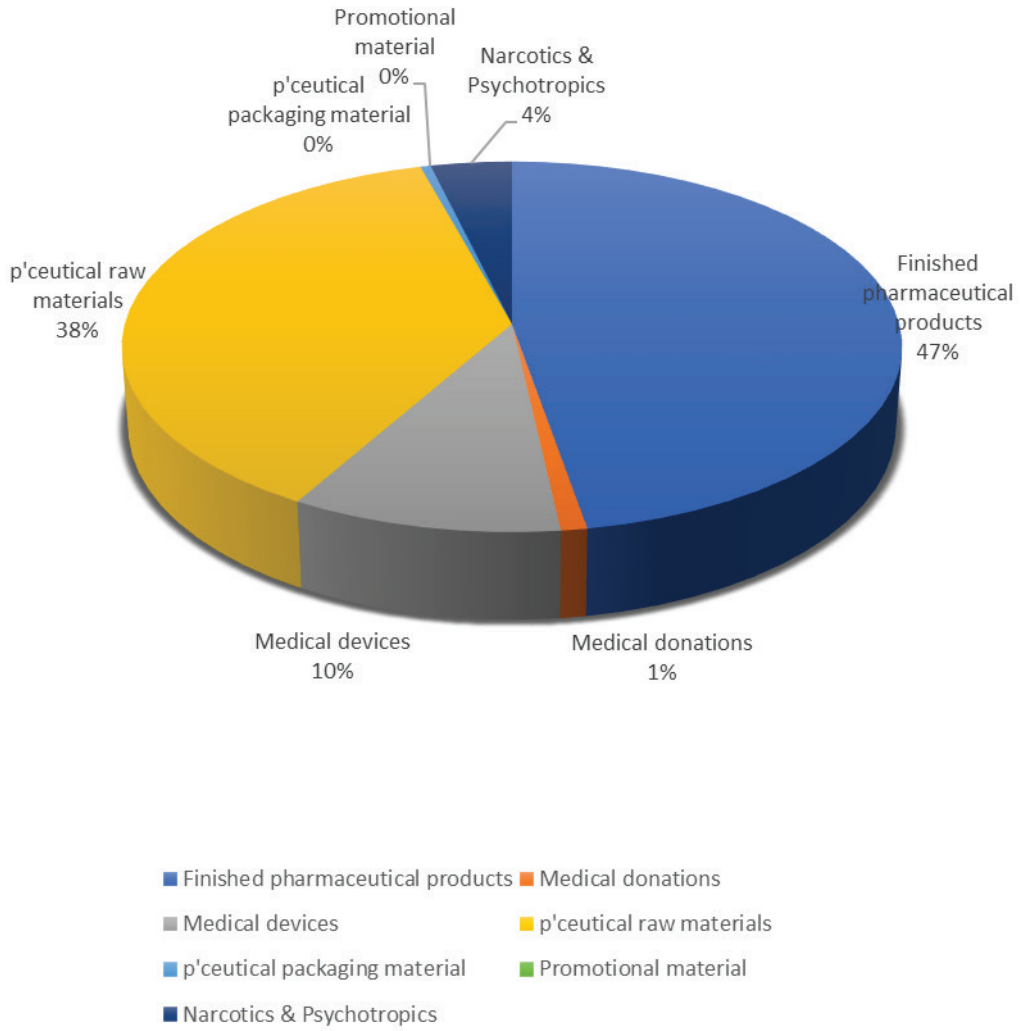


Figure 25: Total weight per product description in Kgs by percentage



Stopped consignments

One consignment was stopped belonging to Pan pharmaceuticals ltd, during transportation the vessel had mechanical problems in the sea causing leakage of sea water into some of the containers which caused medicines to be soaked in sea water. The stopped medicines were stored at the customs bonded warehouse awaiting destruction.

b) Jomo Kenyatta International Airport (JKIA)

Summary of activities performed and outcomes

1	Pre-clearance inspection of consignment imports and exports	20,268
2	Narcotics and psychotropic substance	217,798
3	Covid 19 vaccines (different types) doses	21,207,140
4	Consignment stopped	1,780
5	Total weight of consignment released: imports	5,211,090
	Exports	380.883

The different types of consignment processed at the port were; Medical Devices, finished Pharmaceutical Products, Raw Materials, narcotics, donations, sample for registration, sample for clinical trials. as illustrated by the charts and tables in the report.

Stopped consignment/quarantined

During this period consignments were stopped and quarantined at customs cage for poor / lack of proper documentation among other noted non-conformities

These comprised of pharmaceuticals, medical devices and lab reagents.

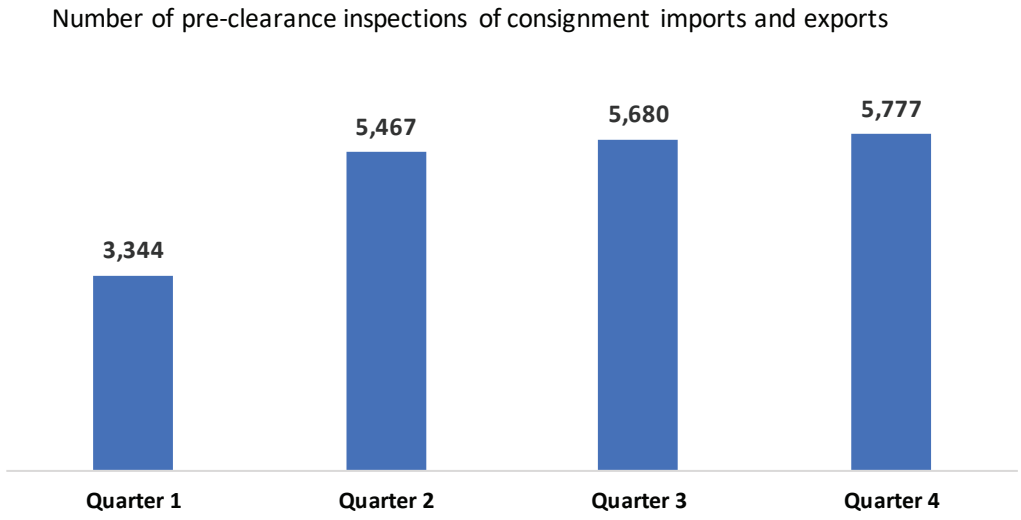
Summary of activities performed

S/NO	ACTIVITIES	RESULTS
1.	Verification of Imports and Exports	100% Verification of all imports and exports achieved refer to Annex
2.	Conduct Surveillance of Satellite entry/exit points	Programmed surveillance at passenger terminal and baggage hall
4.	Sampling of profiled products	Sampling was done for new products being imported
5.	Identify training needs of inspectors to enhance capacity	Training needs assessment conducted and forwarded for action
6.	Supervised disposal of pharmaceutical wastes	Supervised complete disposal of stopped, quarantined and condemned Health products and technologies at Forodha House
7.	Risk profiling of clients	Developed daily client profiling matrix based on the risk assessment matrix as per the SOP and intelligence gathered.
8.	Attend Stakeholders meetings and multi-agency collaboration	Attended JKIA stakeholders meeting on trade facilitation Participated in joint multiagency verification

Number of pre-clearance inspections of consignment imports and exports

Quarter 1	3,344
Quarter 2	5,467
Quarter 3	5,680
Quarter 4	5,777
Total	20,268

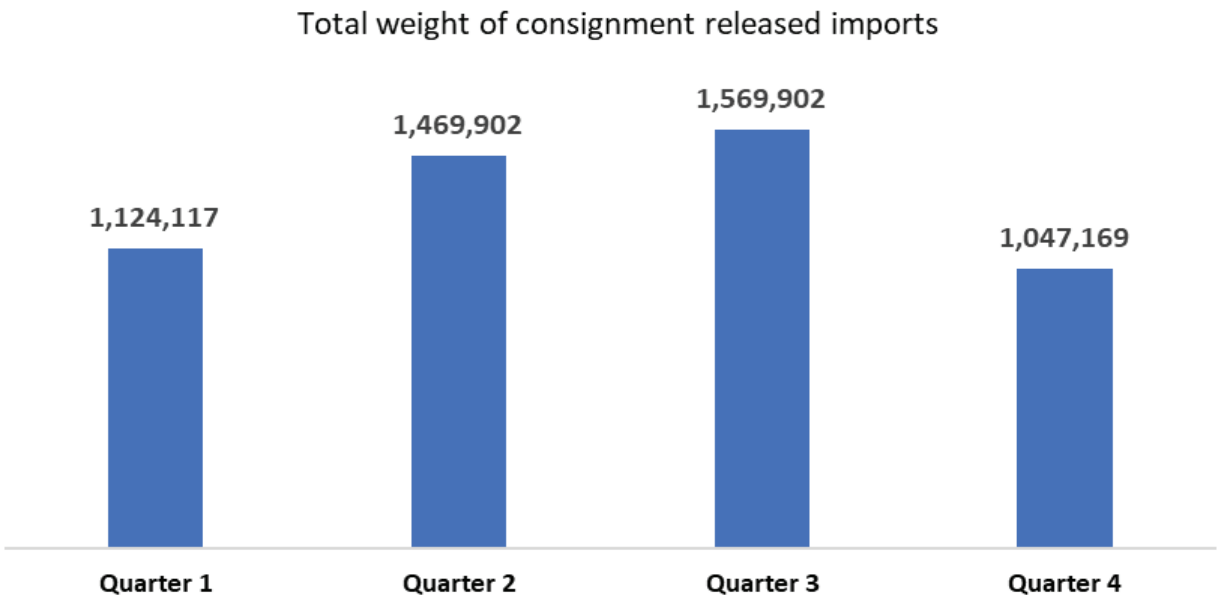
Figure 26: Diagrammatic representation of number of pre-clearance inspections of HPTs performed per quarter



Total weight of HPTs imports consignment released per quarter

Quarter 1	1,124,117
Quarter 2	1,469,902
Quarter 3	1,569,902
Quarter 4	1,047169
Total	**5,211,090**

Figure 27: Diagramatic representation by weight of HPTs released per quarter



Types of consignment released by weight

	Consignment type	Weight
1.	Finished pharmaceutical product	2,361,929
2..	Medical devices	1,037,735
3	Sample for registration and evaluation	20,177
4	Medical donations	914,586
4.	Pharmaceutical raw materials	181,948
5.	Prescription medicines	3,693
6.	Priority medicines	43,178
7.	Promotional materials	5,371
8.	Samples for clinical trials	19,075
9.	Narcotics and psychotropic substance	217,798
10.	COVID 19 vaccines	405,600
	Total	**5,211,090**

Figure 28

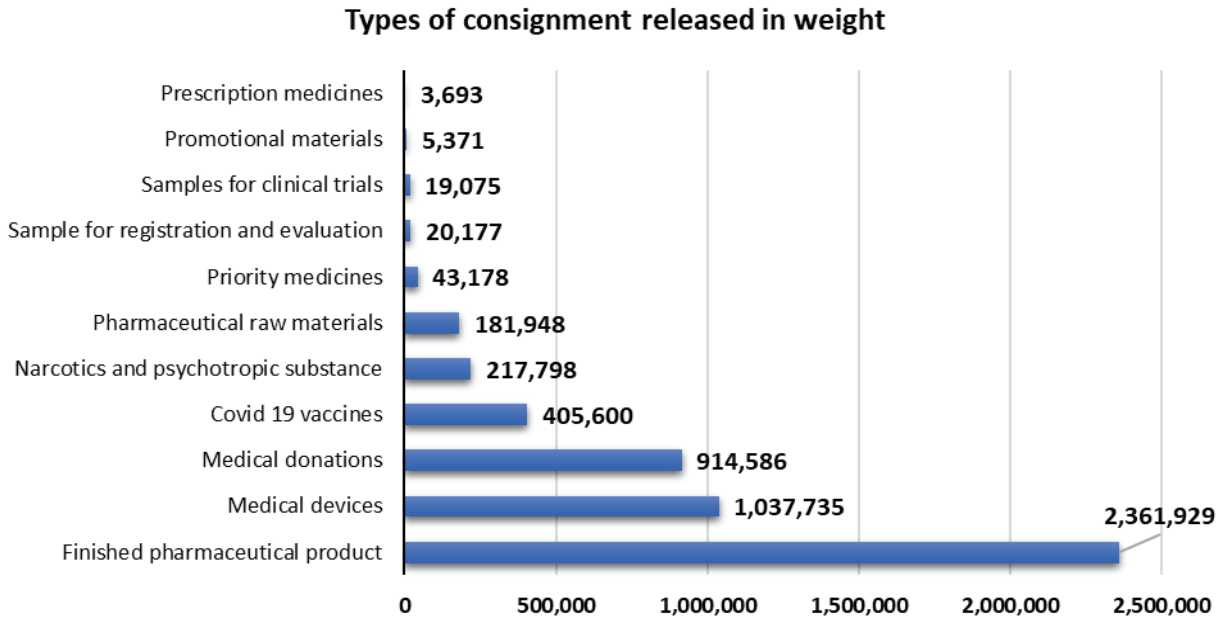
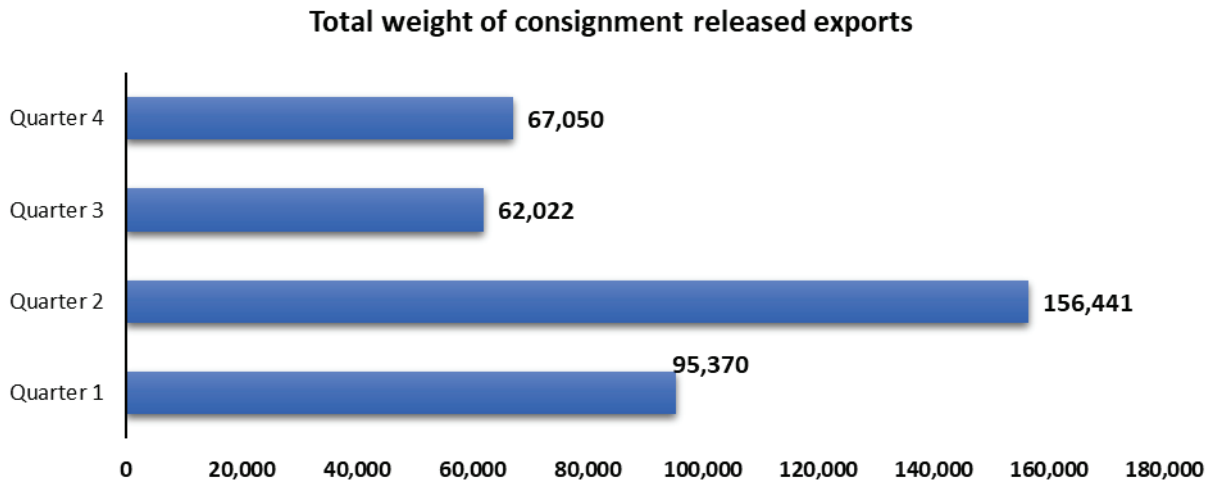


Table 8: Total weight of exported HPT consignments released

Quarter 1	95,370
Quarter 2	156,441
Quarter 3	62,022
Quarter 4	67,050
Total	380,883

Figure 29: Total weight of export HPTs released per quarter

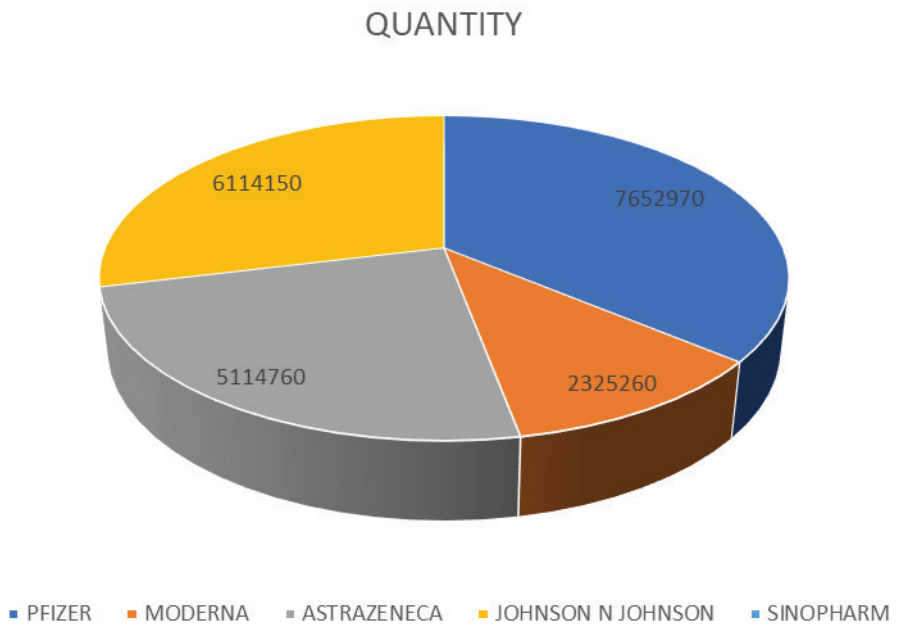


COVID 19 Vaccines

Number of doses of vaccines sighted and released

Vaccine type	Pfizer	Moderna	AstraZeneca	Johnson n Johnson	Sinopharm
Quarter 1	795600	1760780	740360	141600	0
Quarter 2	4185000	564480	3834400	5972550	0
Quarter 3	2415910	0	540000	0	0
Quarter 4	256460	0	0	0	0
TOTAL	**7652970**	2325260	5114760	6114150	0

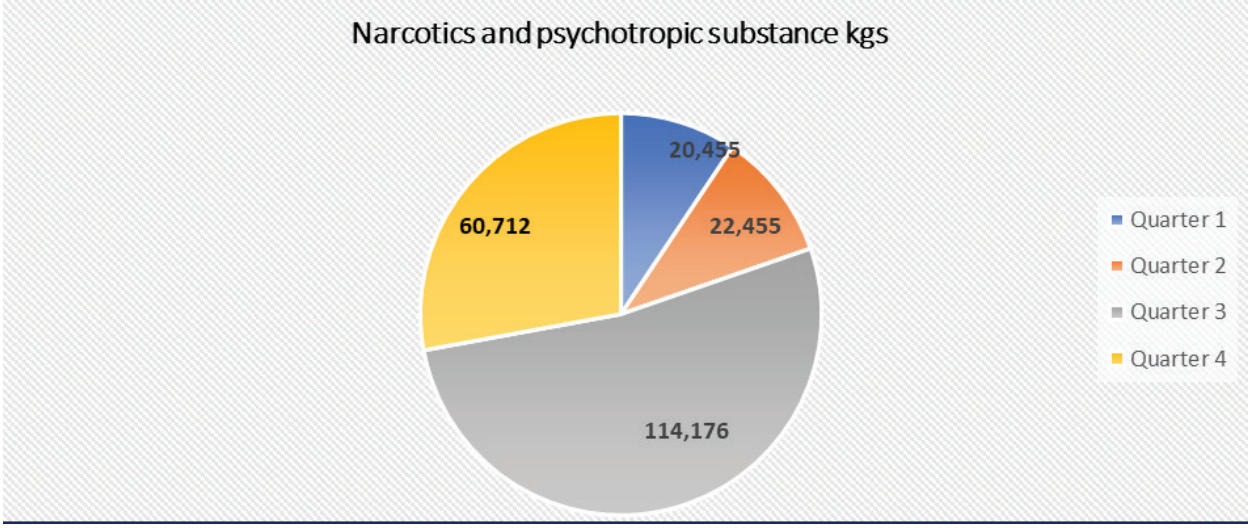
Figure 30: Diagrammatic representation of quantity of doses of COVID 19 vaccines released



Narcotics and psychoactive substances by weight in kgs

Quarter 1	20,455
Quarter 2	22,455
Quarter 3	114,176
Quarter 4	60,712
Total	**217,798**

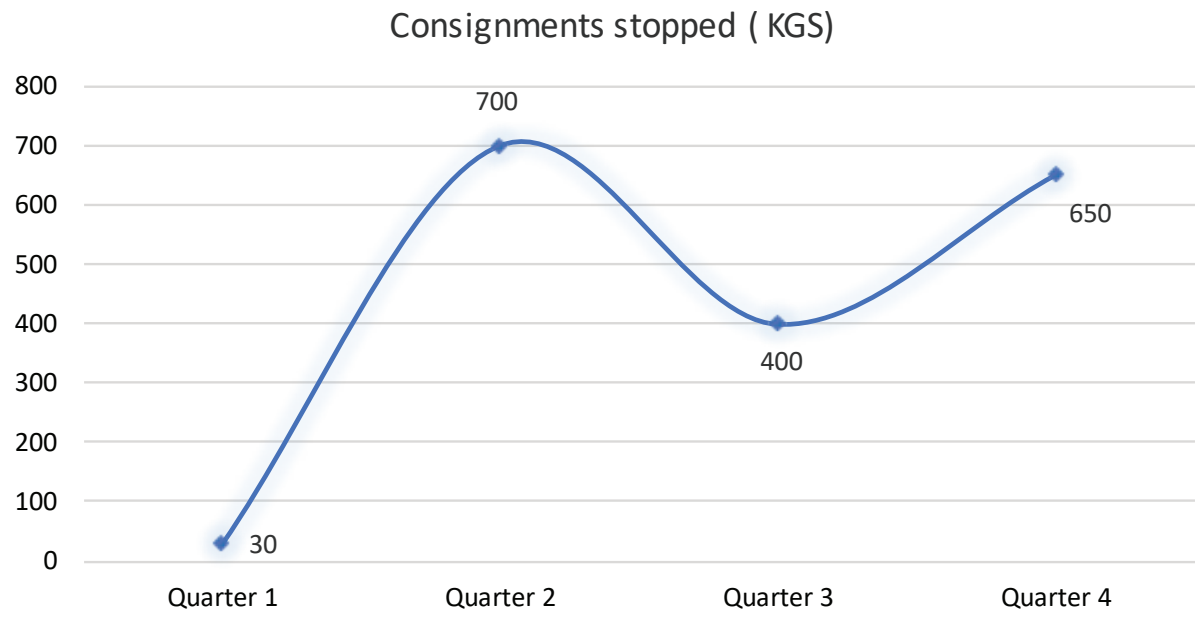
Figure 31: Diagrammatic representation by weight of narcotics released



Consignments rejected (KGS)

Quarter 1	30
Quarter 2	700
Quarter 3	400
Quarter 4	650
Total	1780

Figure 32: Graphical representation of HPT consignments rejected due to various non-conformities



c) Kilindini Sea Port PPB Office

Summary of inspection and verification

S/No	HPT consignment Type	No. of Verifications	No of Packages	Weight (Kgs)
1	Finished Pharmaceutical products	336	42,960	429,744
2	Pharmaceutical Raw materials	39	16,520	601,516
3	Medical Devices	48	5988	93,208
4	Medical Donations	101	47776	778,760
5	Laboratory Reagents and Chemicals	4	26	13,775
6	Narcotics, Psychotropics and precursor substances	8	11,550	289,052
TOTAL		536	124,820	2,206,055

Figure 33: Diagramatic representation by number of verification for different HPT types

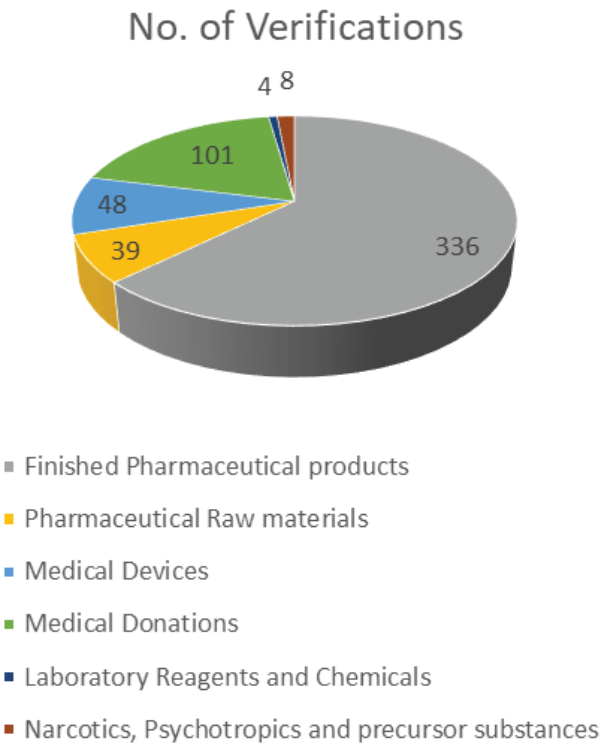
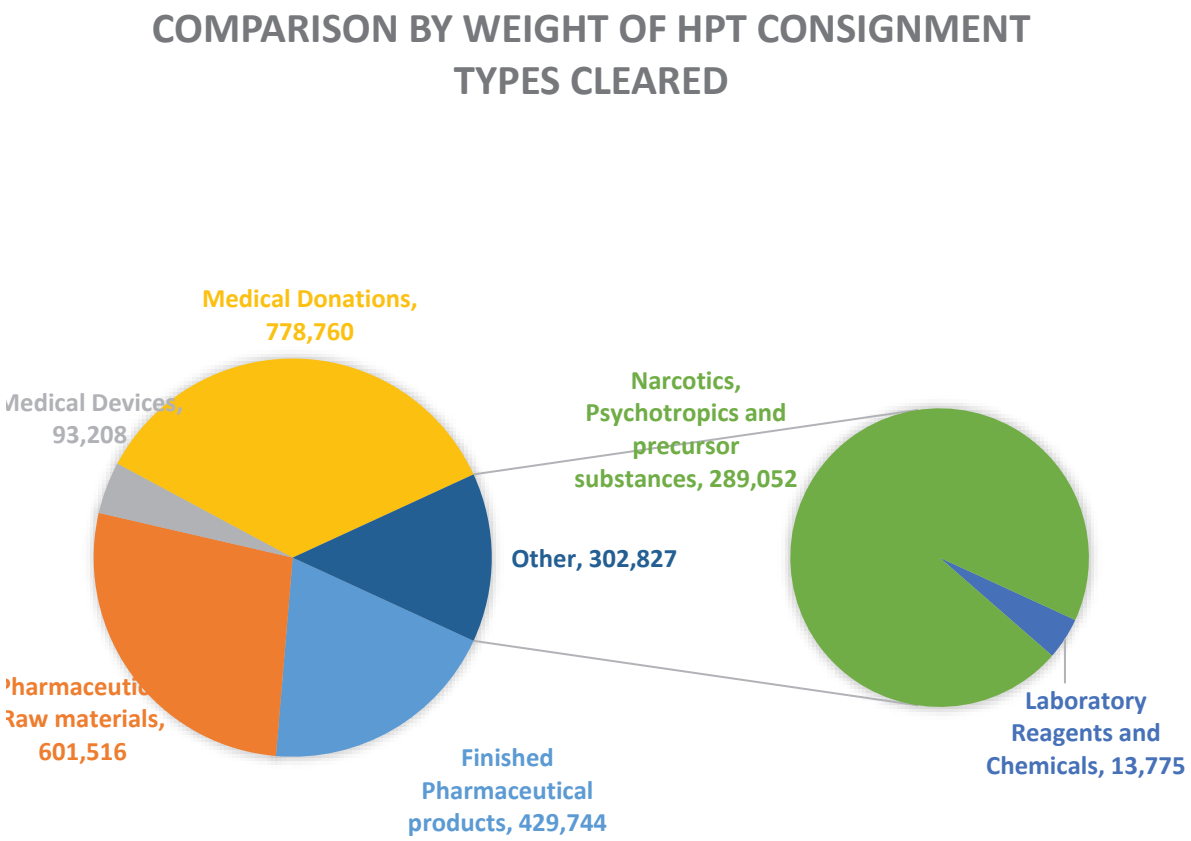


Figure 34: Comparison by weight



5.4 Pharmacy Practice Directorate

5.4.1 Continuing Professional Development

The main objective of the CPD unit is to maintain and enhance the competency of pharmacy professionals to improve practice and health outcomes. This enables pharmacy professionals to keep their knowledge and skills up to date to provide the best pharmaceutical practices, improve treatment outcomes and protect patient safety.

Functions;

a) Regulate, monitor, and inspect personnel and premises that are involved in CPD, training, and pharmacy practice
b) Accredit CPD providers and
c) Approve CPD programs and events

Achievements;

Since inception in 2018, there has been a tremendous increase in the number of CPD providers, programs, and events. The increased availability of CPD and the requirement for licensure have led to an increase in the number of pharmacy professionals undertaking CPD. The table below indicates the improvements made in the last three financial years, between July 2018 and June 2022.

Year	Providers	Programs	Events	Participants
2018-2019	7	11	22	3,000
2019-2020	33	152	707	162,792
2020-2021	46	210	919	199,494
2021-2022	62	203	1043	198,365

Figure 35

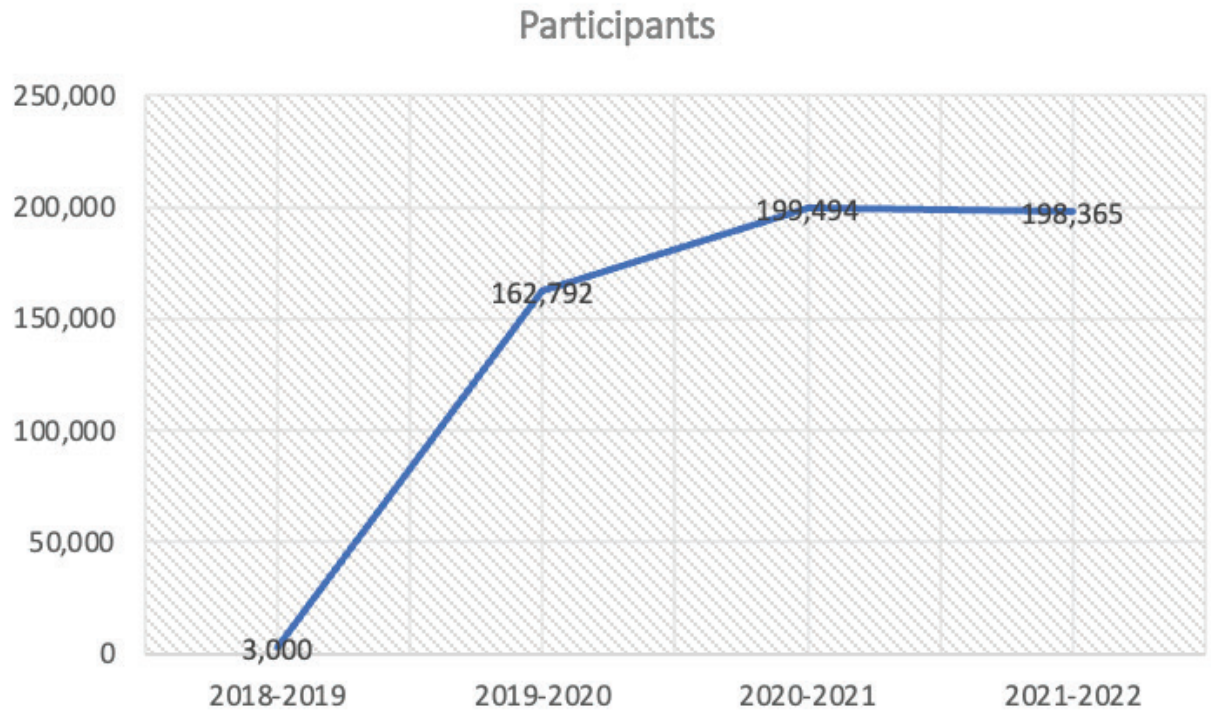
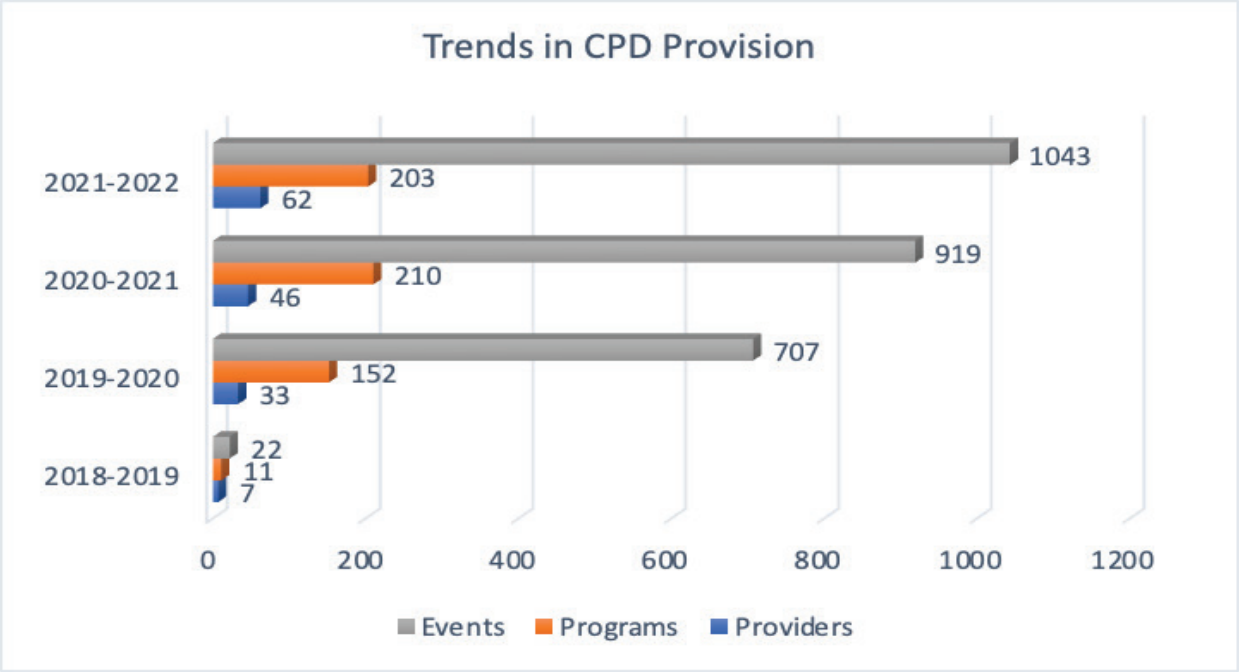


Figure 36



5.4.2 Regulation of Training

The unit's functions include:

Advance pharmacy training standards in Kenya.

Formulate, implement and review the educational, scientific, and professional principles and standards for professional programs in pharmacy

Evaluate the pharmacy training programs for purposes of approval or accreditation

Publish a directory of approved and accredited professional programs of pharmacy for use by stakeholders and other relevant authorities

The table below shows the number of approved pharmacy training programs as at 30th June 2022:

No	Course	Public	Private	Total
1	Degree programs	3	4	7
2	Diploma programs	20	2	22

Achievements during FY 2021/2022:

The current core/model curricula of PPB have been revised with the objectives of

a) aligning pharmacy training in Kenya to global trends and Global competence framework for pharmacists

b) re-orienting pharmacy training, consistent with Kenya's policy direction, Universal Health Coverage (UHC), and the overall health needs of the country including the provision of Family Planning [1] and Immunization

c) redesigning the curricula to be more competence-based and skills-based.

With this regard, emerging courses or content were incorporated into the revised curriculum including, clinical skills, pharmacy practice experience, National Values, Gender and Health, family planning, vaccinology, pharmaco-economics, Pharmacovigilance, regulatory affairs, medical supplies, equipment, and laboratory reagents, among others.

[1] Expanding access and choice to family planning services in Kenya, Ministry of Health, 2019

Challenges: Due to the provisions in the Universities Act, the PPB's role in regulating pharmacists' training is limited.

5.4.3 Registration and Enrolment

The unit's functions include:

a) prescribe the minimum requirements and evaluate the qualifications of persons wishing to be registered as pharmacists;
b) prescribe the minimum requirements and evaluate the qualifications of persons wishing to be enrolled as pharmaceutical technologists;
c) prescribe, supervise and evaluate internship programs as a prerequisite for recognition, registration or enrolment;
d) prescribe and conduct examinations for purposes of recognition, registration or enrolment;
e) maintain a Register of pharmacists and a Roll of pharmaceutical technologists.

Achievements:

Since the development and implementation of an online examination management system, in 2020, Five series (20 sets) of online examinations have been successfully conducted.

In the FY 2021-22, the security, integrity, and efficiency of the online exam system have been improved by the incorporation of Safe Exam Browser, and integration with the regulatory human resource information system (RHRIS). Due to the automation, there has been improved efficiency in exam administration as evidenced by a significant reduction in the time taken to release results. In addition, there has been Improved objectivity due to automated marking.

Further, exam administration has been decentralized, improving access and fairness, while using resources within the PPB regional offices.

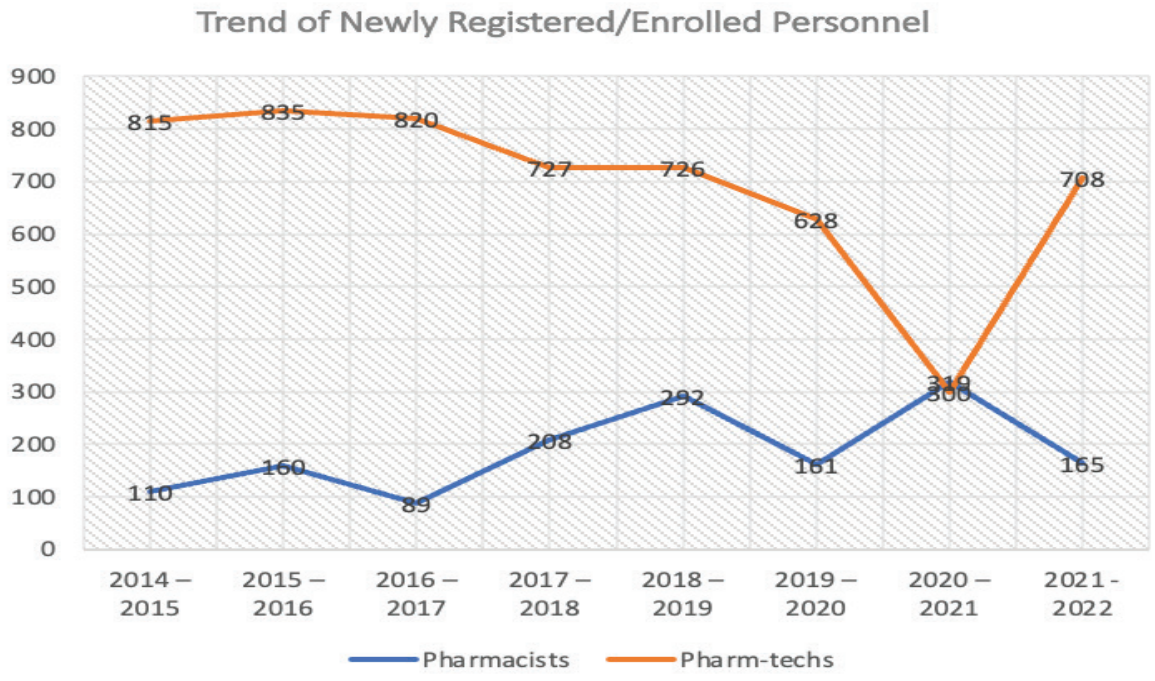
Registration and Enrolment Trends

The table and graph below show the trends in the Registration and Enrolment of pharmacists and pharmaceutical technologists respectively.

Trends in the Registration and Enrolment of pharmacists and pharmaceutical technologists

Year	Pharmacists	Pharm-techs
2014 – 2015	110	815
2015 – 2016	160	835
2016 – 2017	89	820
2017 – 2018	208	727
2018 – 2019	292	726
2019 – 2020	161	628
2020 – 2021	319	300
2021 - 2022	165	708

Figure 37



The decrease in Enrolment of Pharmaceutical Technologists in 2020-21 is due to inability to graduate caused by the COVID-19 pandemic. The Pharmacists were less affected as the Universities were able to hold online graduation events.

5.4.4 Licensing & Good pharmacy practice

Section 3B (2)(j) of the Pharmacy and Poisons Act 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.

Through regulation of pharmacy practice, the Board aims to ensure that pharmaceutical services available in Kenya satisfy the needs of all for the prevention, diagnosis, and treatment of diseases using safe, efficacious, high-quality, and cost-effective pharmaceutical products

The key functions of the department include

a) Registration and annual licensing of Manufacturers, Distributors, Wholesalers, Retail outlets. The scope has now been expanded to include licensing of scientific offices, warehouses, hospital pharmacies, and internet pharmacies
b) Issuance of practice licenses to pharmacists and pharmaceutical technologists
c) Issuance of recognition to specialist pharmacists
d) Issuance of pharmaceutical representative permits

Guidelines

The guidelines that are currently in use at the unit are: -

- Guidelines for Registration and Licensing of premises last revised in November 2022
- Guidelines on Internet Pharmacy Services in Kenya - last revised in November 2022 and implementation is ongoing
- Guidelines on Recognition of Pharmacy Specialties

Online Licensing Platform

The PPB undertook to automate the licensing activities for premises and practice licenses to ease the process and enhance efficiency. A platform was developed in 2014 and launched in 2015 to serve this purpose. All applications for premise and practice licenses are done online through the PPB practice portal where all practitioners have unique login credentials. This system has undergone several upgrading and the addition of more modules to make it more user-friendly and automate all services at the Unit.

Achievements

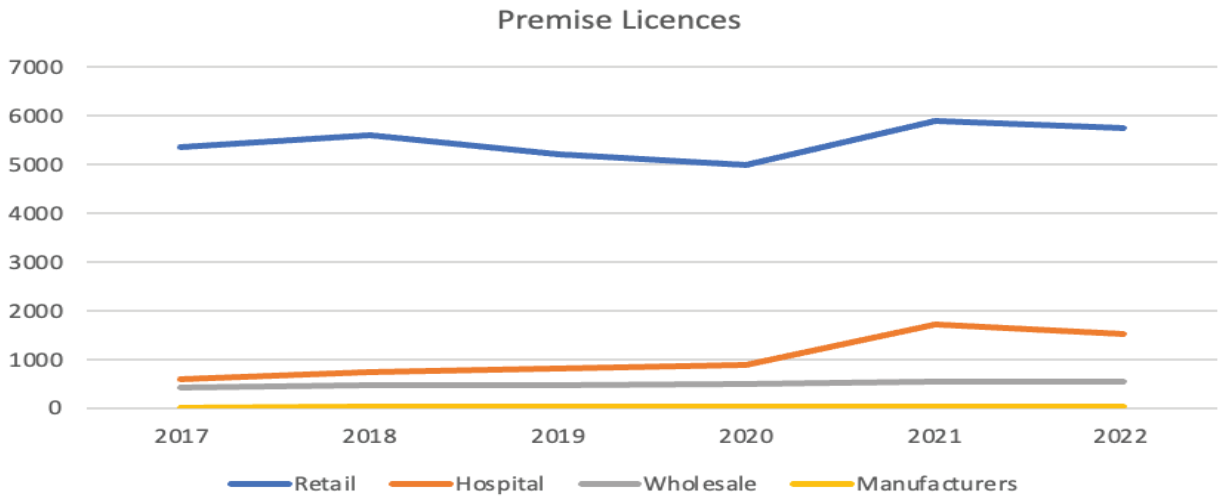
a) The first process to be automated at the Board. The regulatory human resource system (RHRIS) is still being improved and new modules are being developed to better support the licensing function
b) Increased revenue collection and accountability
c) Reduction of approval timelines for licenses
d) Ease of renewal and new applications for practitioners at the comfort of their workplaces
e) Linked licensure to CPD (Licenses not issued without a practitioner gaining the required CPD points)
f) Initiated the process of recognition of Pharmacy Specialists and issuance of first 100 recognitions

The table below shows the trends in licenses issued over the last six years

Premise licenses

	2017	2018	2019	2020	2021	2022
Retail	5358	5603	5222	4993	5907	5755
Hospital	595	747	805	877	1721	1535
Wholesale	413	466	466	493	541	538
Manufacturers	33	36	34	34	37	38
Total	**6399**	**6852**	**6527**	**6397**	**8206**	7866

Figure 38



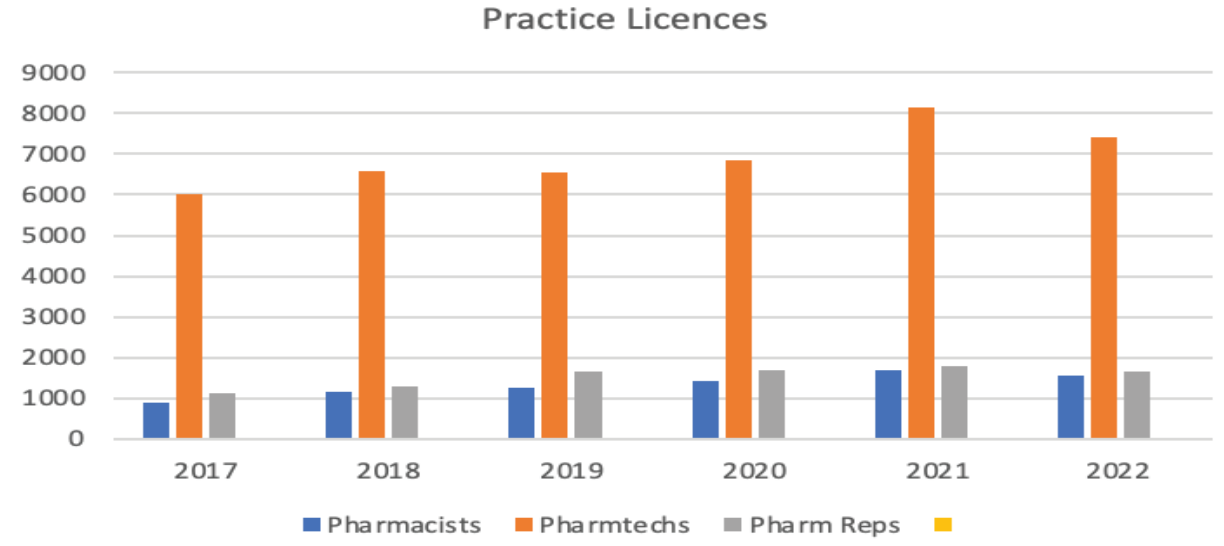
In 2021, there was a significant increase in number of licensed premises and licensed practitioners, this is due to NHIF making it mandatory for hospitals to have licenses from PPB to make claims.

5.4.5 Practice licenses and pharmaceutical representative permits

Every pharmacist or pharmaceutical technologist practicing in Kenya is required by law to have a valid annual practice license as well as pharmaceutical representatives. The table below shows the trend in practice licenses issued by the Board over the last 6 years.

	2017	2018	2019	2020	2021	2022
Pharmacists	903	1149	1270	1442	1707	1551
Pharmtechs	6000	6578	6560	6856	8156	7412
Pharm Reps	1129	1304	1652	1690	1789	1675
Total	8032	9031	9482	9988	11652	10638

Figure 39



Recommendations and work in progress

a) Introduce penalties for late applications to harmonize renewal times to improve compliance
b) Operationalize Guidelines on Internet Pharmacy Services in Kenya
c) Finalize the regulations and issue formal recognition certificates to specialists
d) Review the scope of pharmacy services
e) Licensing of pharmacy specialists' centers
f) Develop a Guideline for licensing of Pharm Reps
g) Develop and maintain a National Pharmacy Care system

5.5 Quality Control Laboratory Directorate

The Pharmacy and Poisons Board Quality Control Laboratory (PPBQCL) was established to undertake conformity evaluation of medical products against their claimed (pre-market) or authorized (post-market) specifications under the PPB sampling and testing programme. The program is part of post marketing surveillance activities involved in quality assurance of marketed products.

In the FY 2020/2021 the PPBQC laboratory formalized its sampling and testing program while establishing a quality management system appropriate for a National Regulatory Authority analytical testing laboratory. Once its QMS is fully established, the lab expects to be ISO certified in the FY 2021/2022.

This report summaries the FY 2020/2021 performance with respect sampling, sample handling, internal and external analytical testing and the results of analysis.

Figure 40

Samples received disaggregated by departments

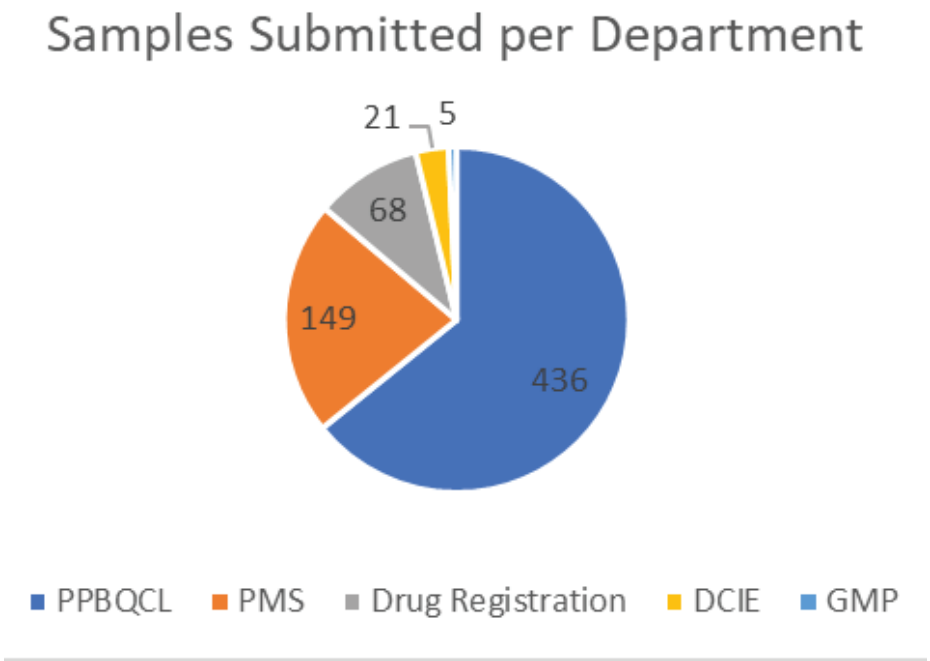


Figure 41

Products evaluated disaggregated by product type

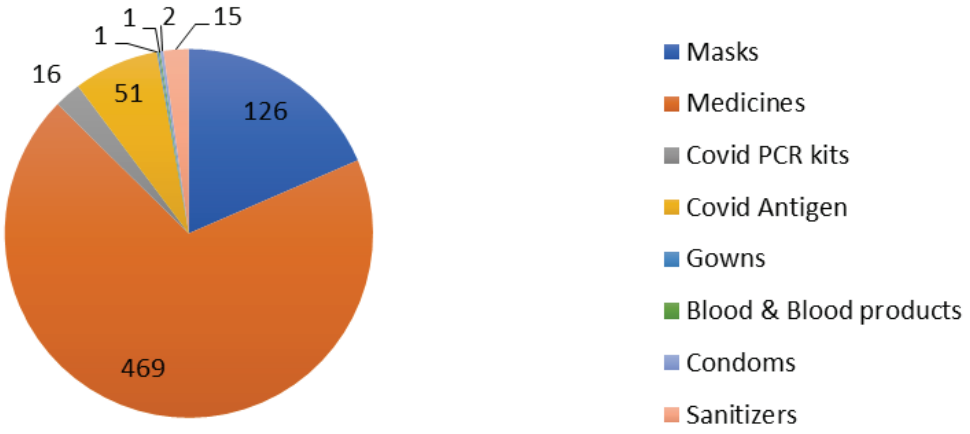
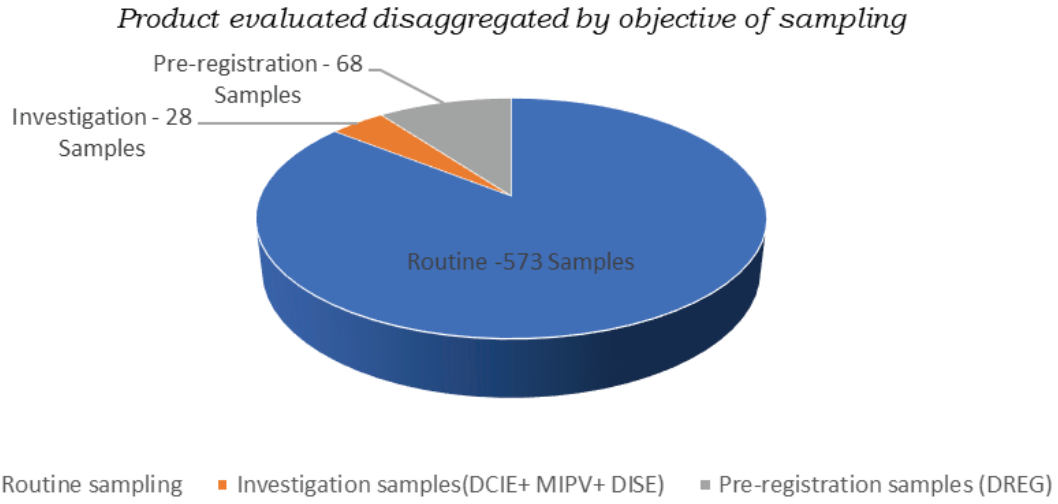


Figure 42

Product evaluated based on objective of sampling



a) FY 2021/2022 projections

Currently the PPBQCL does not hold any accreditation although it is currently establishing a Quality Management System appropriate for Quality Control Laboratory for a National Regulatory Authority. It is expected to attain ISO/IEC 17025:2017 international standard accreditation in the FY 2021/2022.

5.6 Corporate Affairs Directorate

5.6.1 Administration Department

The Administration department is one of the units under the Directorate of Corporate Affairs services, and is responsible for offering support services to the Board by ensuring the overall management of administrative services. This involves the development of policies and guidelines, annual operation plans and budgets for all administrative functions, overseeing the management of assets, registry services, safe custody and management of records, transport & logistics, security, maintenance and supervision of customer care staff

Achievements;

i. Development of Fire Safety Policy and guidelines

ii. Establishment of a fleet of twenty-eight motor vehicles serving the Board headquarters and the regional offices and one motorcycle dedicated to delivering services within the headquarters' environs as per the table below;

iii. Establishment of walkthrough and gate scanner as part of security system measures;

5.6.2 Human Resource Management & Development Department

Functions;

Human Resource Management and Development Department is responsible for the following functions:

1. Developing, reviewing and implementing policies, rules, regulations and corporate strategies for sound human resource management and development;
2. Developing, reviewing and implementing guidelines, standards, infrastructure, tools, management strategies with regard to human resource management and development;
3. Developing employee relations that promotes teamwork and productive partnership;
4. Developing human resource strategies and strategic action plans to ensure that the Board has in place the right personnel with the right skills that will enable them deliver high quality service;
5. Developing, interpreting and implementing the career progression guidelines of staff;
6. Selection and recruitment of Human Resource;
7. Training and development of staff;
8. Keeping Human Resource records;
9. Managing staff payroll;
10. Maintaining overall discipline of the Staff;
11. Coordinating performance management and staff appraisal;
12. Managing staff separation;
13. Developing, reviewing and implementing quality management system and risk.

I. Achievements

i. Job Evaluation for all staff

ii. Received Job evaluation results from Salary and Remuneration Commission (SRC)

iii. Reviewed Human Resource policies, organizational structure and career progression guidelines

iv. Spearheaded the development of an online self-directed learning system, USTADI

v. Developed the Draft PPB Competency Matrix

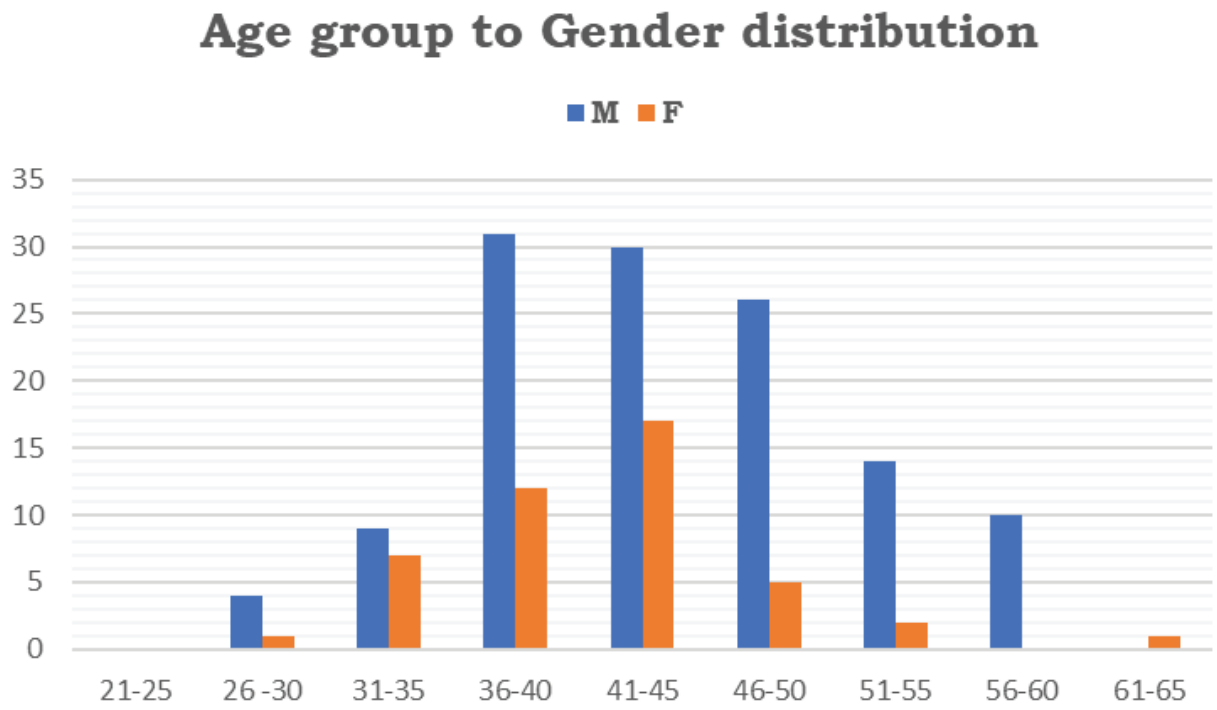
II. Staff establishments

Number	Approved establishment	In-post	Vacancies
All cadres	352	169	183

Age group to Gender distribution

S/No.	Age Group	Gender	
		M	F
	21-25	0	0
	26 -30	4	1
	31-35	9	7
	36-40	31	12
	41-45	30	17
	46-50	26	5
	51-55	14	2
	56-60	10	0
	61-65	0	1
Sub-Total		**124**	**45**
Total		169	

Figure 43



5.6.3 Information and Communication Technology Department

Information Communication Technology (ICT) has become the backbone of the day-to-day operations in all organizations. Pharmacy and Poisons Board is not an exception. While the board and the management of the Board recognize this fact, organizations all over the world, including Pharmacy and Poisons Board are faced with the challenges of ICT security and establishment of acceptable use of ICT as well as legal compliance.

The Information Communication Technology (ICT) section administers PPB online portals, websites, intranet and provides internal ICT training. The section also provides specific technical services to all departments at headquarters and the requisite ICT services user support by way of trouble-shooting and limited maintenance services.

End User Devices

The Board has achieved the national requirement for a 1:1 ratio of computer end user devices to users. All users have a laptop computer or desktop computer or tablet computer or a combination of the three.

Network

The Board has over 600 network nodes. These nodes are used for end user devices, server equipment, shared devices like printers, security equipment like cameras. All the nodes are linked via a Fiber Optic link. Board's intranet is linked to the internet via a fiber optic connection and a radio backup connection.

Service Portals

The Board has moved its services online and they are accessible from anywhere. Portals that are active are:

a) PRIMS – PPB Regulatory Information Management Services portal
b) OSS - Online Services Portal
c) Clinical Trials
d) Pharmacovigilance
e) Pharmacy Practice
f) RHRIS – Regulatory Human Resources Information System
g) Post Market Surveillance

Mobile Services

The Board has partnered with MTAPS and USAID to develop mobile applications that provide access to Pharmacovigilance services on USSD and mobile apps. These are under development and will be launched in 2022.

5.6.4 Corporate Communications Department

The function of the corporate communications department is to enhance the visibility of the Board and manage its branding.

The Division's responsible is to;

- Develop, review and implement Public Relations policies and strategies;

- improve the image and raise the Boards profile internally and externally.
- generate wide public awareness on the services, achievements, challenges and plans of PPB for the stakeholders
- influence attitudes of policy makers, stakeholders and the public in general regarding the issues related to pharmaceutical regulation.
- provide a mechanism that enables the Board to communicate effectively and receive feedback internally and externally with its stakeholders.
- influence policy related to and complementing the pharmaceutical industry to enhance the health of the public

The Division has initiated a number of strategies to support the implementation of the Pharmacy and Poisons Board Strategic plan. These includes Media relations, Advertorials, social media, Outreach events, Marketing and Branding.

Since inception in 2013 the division has realized the following achievements;

1. Developed and implemented a communication and social media strategy
2. Launched social media strategies such as #ppbcares, #medsafety #Covid-19 #reportADR #safetycode
3. Launched public awareness roadshows in Nairobi, Nakuru, Eldoret, Kisumu and Kisii counties among others
4. Organized media training for PPB staff on media handling
5. Organized media roundtable with senior staff to build relations
6. Initiated Daily media monitoring on health-related issues
7. Provide timely responses to media inquiries and interview schedules in issues such as pharmacovigilance, registration of herbal medicines, post marketing surveillance
8. Generated public notices on medical recalls, pharmacy practices
9. Developed documentaries on PPB Mandate and ISO certification, PV new systems
10. Generated news articles on Medication safety, how to report ADRs, herbal medicine
11. Initiated in-house newsletter – PPB Newspaper
12. created social media platforms – Twitter, facebook, Youtube, blog
13. increased twitter reach from 0 - 10.9 followers, and 28,442 followers in Facebook
14. Organised and conducted two Pharma conferences to engage with the Industry players and stakeholders.
15. Organised countrywide public outreaches targeting county opinion leaders in Mombasa, Kilifi, Kakamega and Kisumu counties.
16. Participated in over 30 trade shows to engage with the public and sensitize them on the PPB mandate.
17. Conducted three CSR activities in Nairobi (KNH), Kajiado (Ongata Rongai) and West Pokot
18. Street Advertorials at PPB gate, Machakos, Eldoret, Mombasa, Kisumu, and Nakuru
19. TV Adverts and info-commercials - Citizen, NTV, KBC, KTN
20. Print adverts – Daily Nation, The Standard, Star, People Daily
21. Branded all regional offices
22. 10,000 IEC production and distribution – newsletters, promotional items
23. Carried out public satisfaction survey showing improved satisfaction from 2016 (61%) to 84% 2018
24. Participated in events such as KPA, PSK, KHF etc
25. Aided in the publication of PPB supplements- Star, Daily Nation

Summary of activities carried out

Activities	2018/2019	2019/2020	2020/2021
Advertorials	12	2	2
Public outreach sensitization workshops	4	0	0
Media relations	20	33	80
Media monitoring	100%	100%	100%
Trade shows & exhibitions	10	2	2
Roadshows	6	0	0
Development & disseminations of IEC materials	9000	500	1000
CSR activity	2	1	0
Pharma Conference	1	1	0

Figure 44

Graphical representation of activities carried out

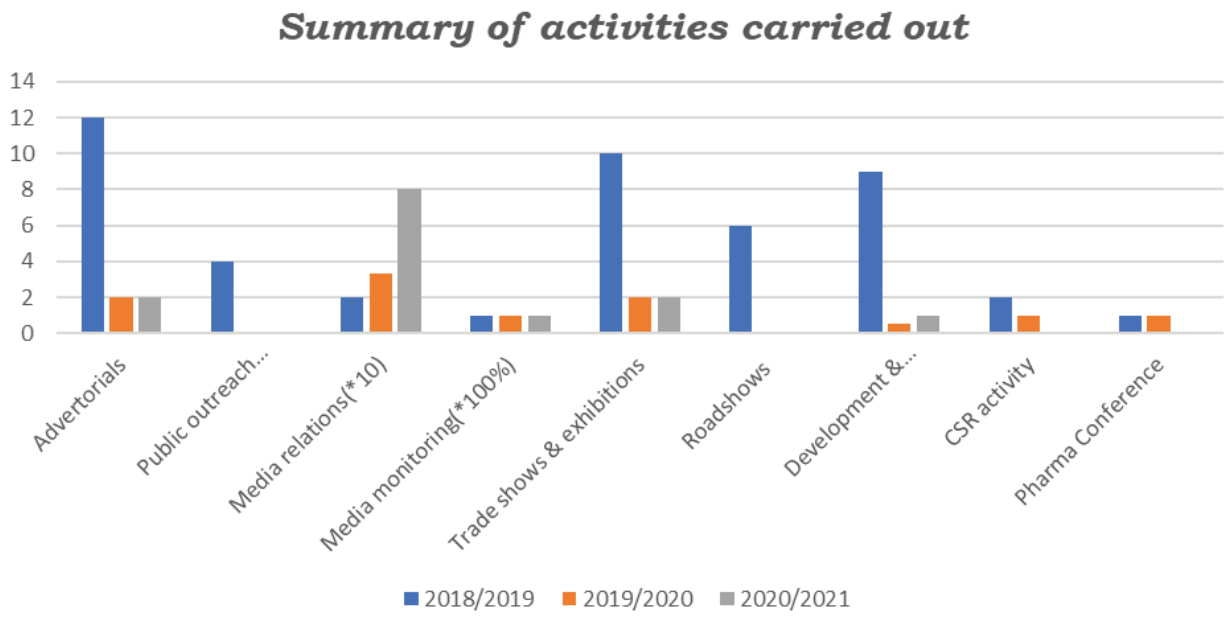
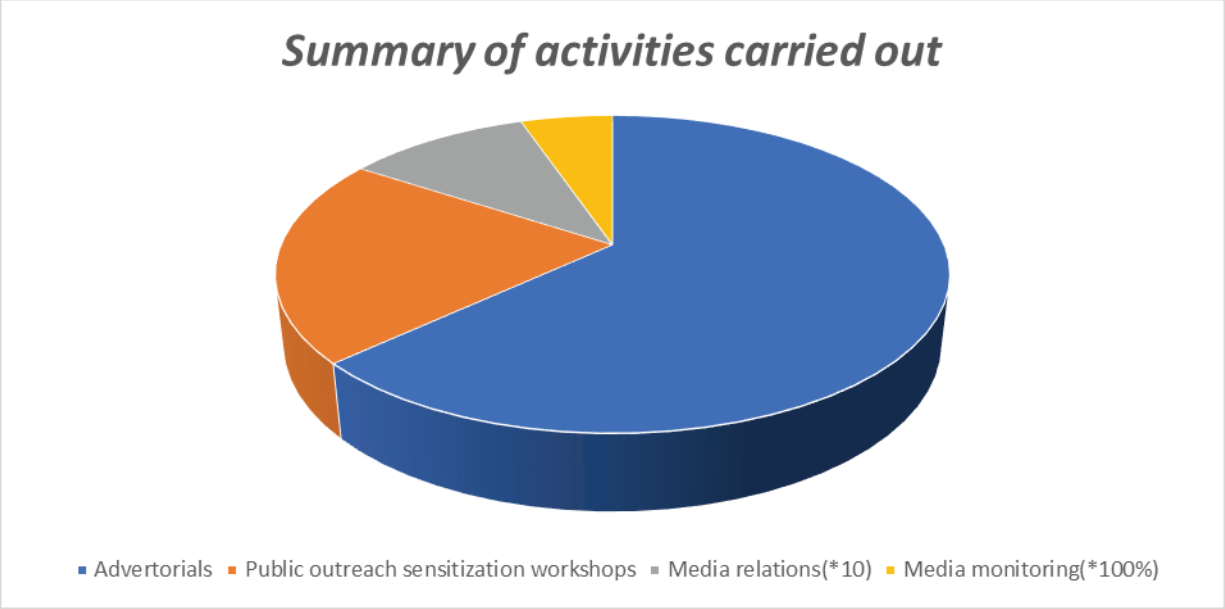


Figure 45



5.7 Independent Units

5.7.1 Office of the Corporation Secretary/ Legal Services

The mandate of this department is to provide Board's Secretariat and Legal Services to the institution. Additionally, the department provides secretariat to the Management meetings. The Department ensures that the Board adheres to the tenets of the constitution of Kenya and complies with the provisions of the relevant statutes amongst others the Pharmacy and Poisons Act (Cap 244), the Health Act, 2017, Public Procurement and Asset Disposal Act 2015, Public Finance Management Act 2015, Employment Act 2007, State Corporations Act, the Advocates Act among others.

Key Achievements in the FY 2020/2021

1. Significant reduction of litigations
    - There was no new litigation during the financial year 2020/2021
    - The pending matter in the Court of Appeal being Civil Appeal No 211 of 2017; PPB Vs Ministry of health & 8 Others. The successful appeal enables the Board to effectively discharge her functions which had been impugned.
    - Nairobi Employment and Labour Relations Court Petition No 186 of 2019; Dr. Fred Siyoi Vs PPB the department actively participated in seeking an out-of-court consent judgement on the disputed employment matter. A consent was duly entered upon on 19th October 2020
2. Participated in the review and development of several bills to be tabled before parliament: Blood Products Bill, Kenya Food and Drugs Authority Bill
3. The department was appointed to represent the institution in the legal Technical working group (TWG) on the Integrated Product Management System (IPMAS) that culminated in the development of the Integrated Government of Kenya Mark Bill, 2020
4. The department membership was co-opted into the Intellectual Property technical negotiation team. This has seen the representation on the pharmaceutical sector interest in the negotiation document which would be beneficial to the sector and the economy in general.
5. Active participation in the Court Users Committee throughout the country where emerging issues regarding prosecution of pharmaceutical related offences have been ventilated. This has effectively improved the relations of the participating agencies leading to successful prosecutions

5.7.2 Internal Audit and Risk Assurance

The internal audit and risk function is carried out by the Internal Audit Unit based on an Internal Audit Charter that's approved by the Audit and Risk Committee. The Internal Audit and Risk Assurance Unit provides independent, objective assurance and consulting services designed to add value and improve operations at the Board. It's through internal audit and risk assurance recommendations that the board has achieved below;

i. Establishment of effective internal control in the use of internal resources. Reduction of internal control issues raised by the external auditor from five (5) to three (3).
ii. Improvement of controls of regional offices

and port of entries operations. All regional offices were audited on efficiency on Inspectorate function.

iii. Establishment of the crisis management framework to help in the management of crises.

iv. Development of a robust Enterprise Risk Management framework that's currently used to establish risk ranks and enhance risk-based approach in all regulatory functions.

Risk management Training 2022

Group	Type	Number
Senior management	Sensitization- Virtual	25
Risk Champions	Training- In person	18
Staff	Sensitization- Virtual	85

As part of preventing corruption and fraud, the board is in the process of developing an Ethics and Integrity framework that will support the fight on corruption.

5.7.3 Regional Coordination Unit

The department was established with the aim of developing and implementing policies, rules, regulations and corporate strategies for administration of PPB regulatory functions at the regional and county levels and establishing linkages with regional and county administrations.

Regional office's locations and hosting;

S/No.	Activity	Indicator/number
	Number of regional offices	10
	Number of regional offices establishment owned by the Board	4 (North rift -Eldoret, Coastal Region-Mombasa, Central Region-Nyeri and Lower Eastern- Machakos
	Regional PPB offices hosted within government facilities	2: Western- Kakamega, New Nyanza-Kisumu, Garissa
	Regional Offices hosted with PPB Headquarters	1-Nairobi
	County offices hosted within County Commissioner's Headquarter	4-Kiambu, Murang'a, Kisii, and Kitale

Achievements: Infrastructure and Support supervision of regional offices;

No.	Activity	Dates
	Equipping of the regional and county offices	Two (2) contracts signed in favor of regional offices Renovation and construction of Guardroom for the Central Regional Office Supply of conference facilities for the regional office of South-rift, Kisii County and Western Regional Office
	Internet connections	Internet connections for all the 9 regional offices

5.7.4 Trade Affairs Unit

5.7.4.1 Introduction

The trade unit of the Pharmacy and Poisons Board draws its mandate from section 44 subsection 1 (f), (ff) as read with the pharmacy and poisons rules section 3. The department works closely with other partner government agencies (PGA's)and international institutions to ensure importation and exportation of safe, efficacious and quality health products and technologies (HPT's) as well as policy coherence along the HPT supply chain. These PGAs and international institutions include:

National agencies & Ministries	International agencies
Ministry of Health (MoH) & related HPT programs such as NASCOP, Cancer program, Reproductive health program, Malaria program, TB program, KEPI.	World Health Organization (WHO)
Kenya Trade Network Agency (Kentrade),	International Narcotics Control Board (INCB),
State department of Trade (SDT) in the Ministry of trade and Industrialization,	United Nations Office on Drugs Crime (UNODC),
Kenya Revenue Authority (KRA),	United Nations Conference on Trade and Development (UNCTAD)
National Agency for the Campaign against Drug Abuse (NACADA)	United Nations Population Fund (UNFPA)
Kenya National Bureau of Statistics (KNBS),	United Nations Children Fund (UNICEF)
Kenya Bureau of Standards (KEBS),	International Organization of Migration (IOM)
Ministry of foreign affairs (MFA),	United States Agency for International Development (USAID)
KenInvest	Diplomatic missions
The National Treasury	

In the recent past, the unit has witnessed key milestones in its operations. These include:

Roll-out of Unified Billing System (MPESA function) for payment of import permits

This functionality will enable clients to make payments without necessary appearing at PPB for such payments.

In its timeline, together with other departments at the Board as well as MDA's, the Unit hopes to finalize and roll-out the below systems to optimize its functions. These include:

1. The Trade module;
2. The Cargo release module;
3. The Manufactures System;
4. The Donation System;

Once in place, these systems will bolster the Board's reporting mechanisms, Regulatory oversight, strategic and operational HPT intelligence.

5.7.4.2 Current matters

The unit is currently participating and working with other Ministries, Departments and Agencies (MDA's) to support realization of Universal Health Coverage (UHC) and Vision 2030. Some of the activities its being involved with include:

Support of UHC and Vision 2030		
S/No.	**Activity Description**	**Status**
1.	Survey on the Prices of various HPTs in the Market place.	Proposed to start 3rd Quarter of FY 2022/23.
2.	Development of guidelines on health products and technologies (HPT) pricing and affordability.	At internal stakeholder Review stage.
3.	Development of guidelines on Generic prescribing and dispensing of health products and technologies.	At internal stakeholder Review stage.
4.	Development of health products and technologies (HPT) reference database system to anchor the pricing, affordability and transparency elements of HPTs.	Finalization of various data sets that will inform the database system.
5.	Institutionalization of health technology Assessment (HTA).	Review for adoption of the strategic framework on-going
6.	Promote local manufacturing through preferential treatment during procurement of HPTs locally manufactured	Local Manufacturers Taskforce created under MoH to oversee appropriate operationalization of Master Roll-2

Additionally, the department is involved in various bilateral discussions which are at various levels of consideration and review.

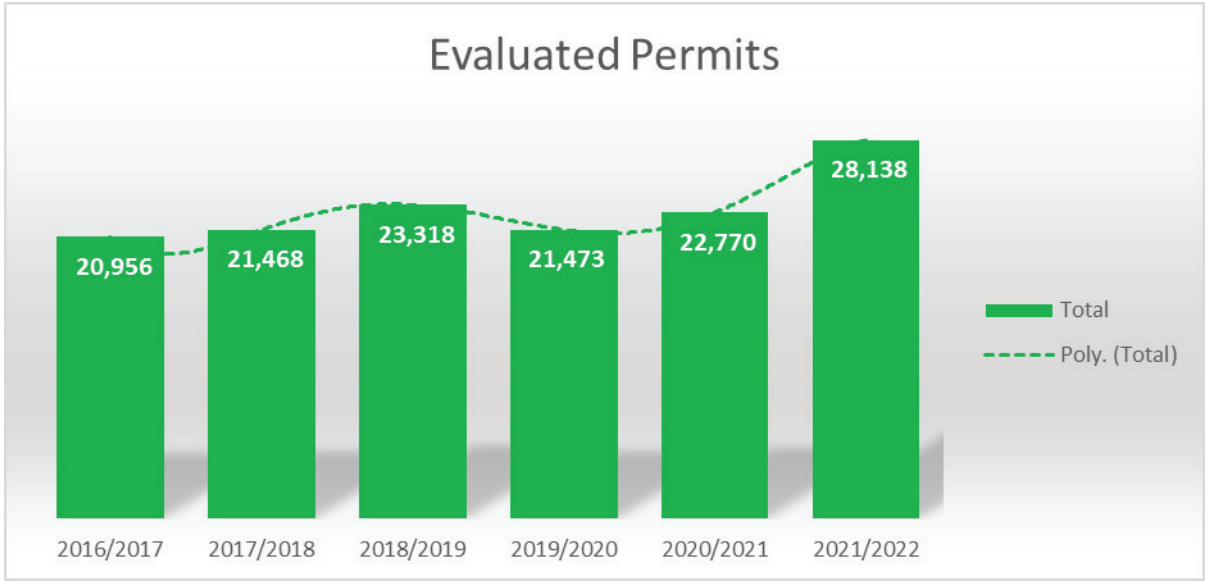
5.7.4.3 Trade Statistics

In the FY 2021/2022, the Unit witnessed an estimated 19% increase in the number of import and export applications from 22,770 applications in FY 2020/2021 to 28,138 applications in FY 2021/2022 (See the graph below). This represented a 8.6% revenue growth in FY 2021/2022 as compared to 7.4% in FY 2020/2021.

This is attributable to resumption of economic activities post COVID-19 lockdowns in various global markets.

Figure 46

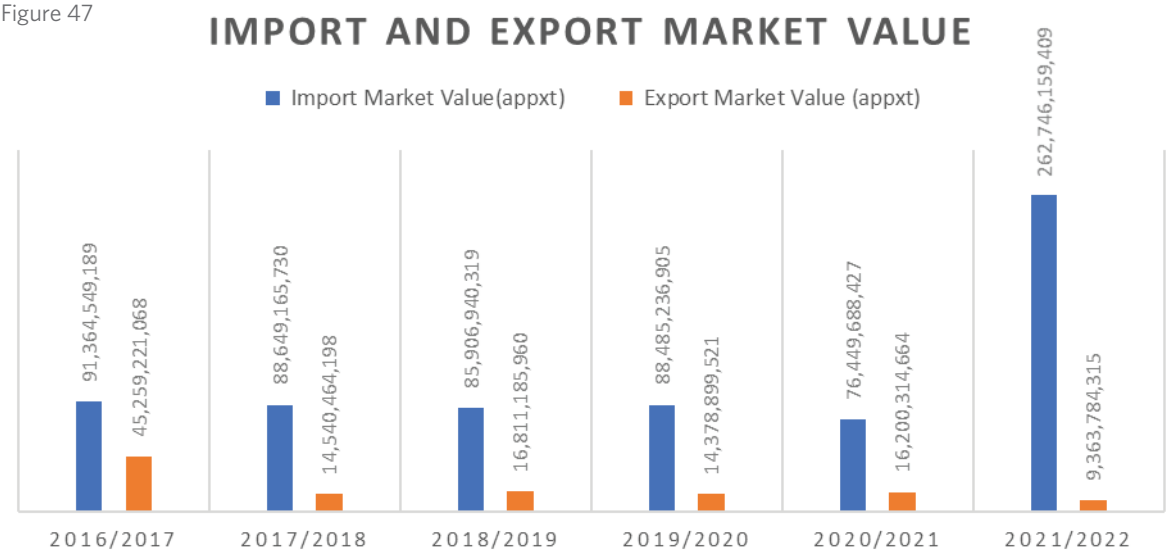
Evaluated import and export applications.



Market Value of Imported and Exported HPTs

Over the same period, the unit witnessed increase in the market value of imported HPTs. See the graph below;

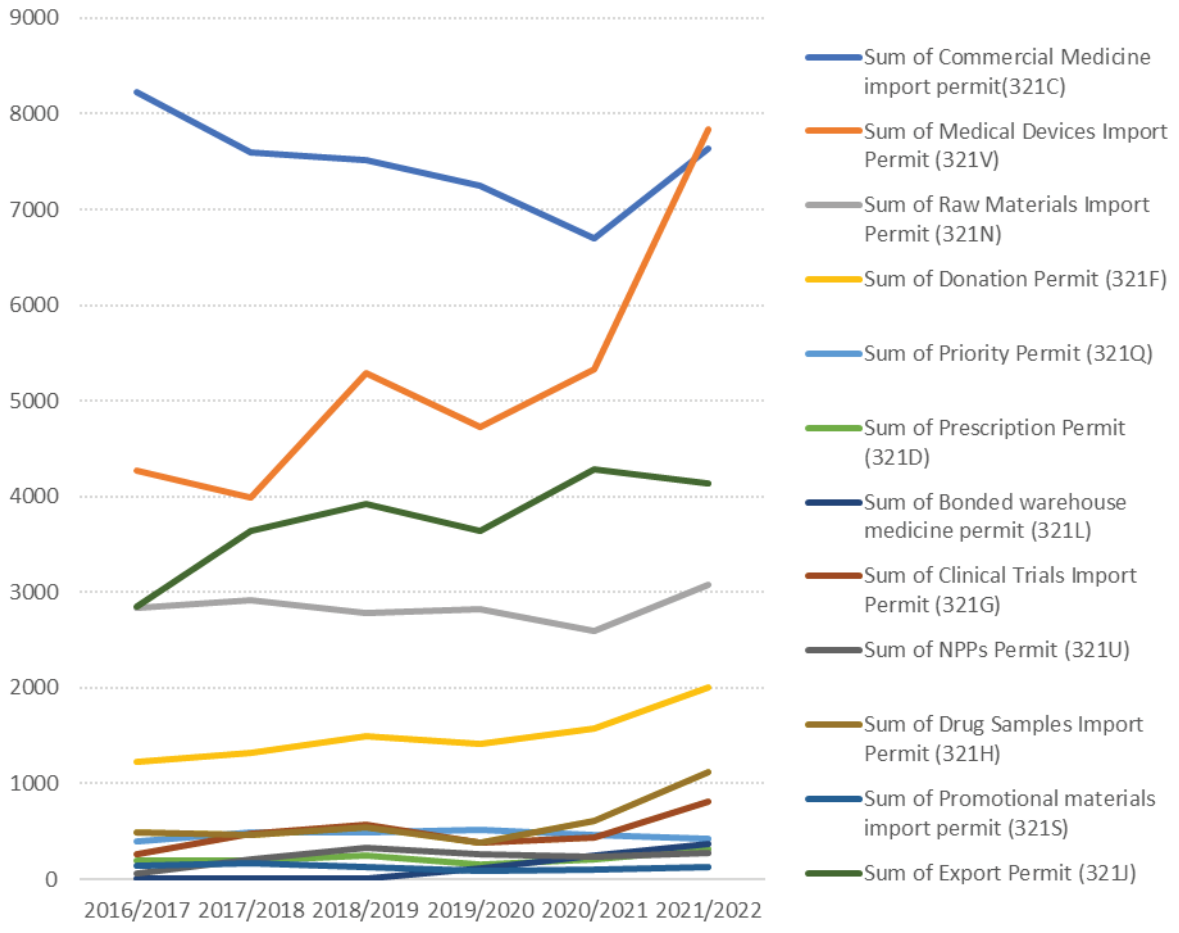
Figure 47



a) Import/Export Permit Distribution

In respect to evaluated applications, the commercial medicine import permits are back to an upward trajectory in the FY 2021/2022 after witnessing a decline in the last two (2) financial years. Worth noting is that medical devices permit applications surpassed the commercial medicine import permits. See the graph below:

Figure 48



Comparison of permit distribution

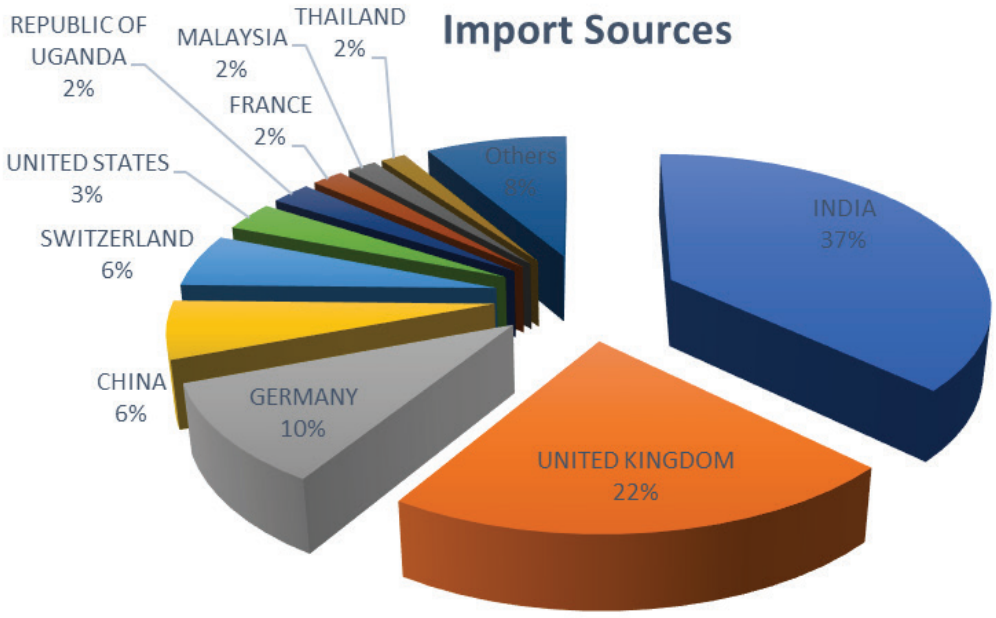
FY	Commercial Medicine import permit(321C)	Medical Devices Import Permit (321V)	Raw Materials Import Permit (321N)	Donation Permit (321F)	Priority Permit (321Q)	Prescription Permit (321D)	Bonded warehouse medicine permit (321L)	Clinical Trials Import Permit (321G)	NPPs Permit (321U)	Drug Samples Import Permit (321H)	Promotional materials import permit (321S)	Export Permit (321J)
2016/17	8230	4274	2840	1229	391	189	0	267	65	493	135	2843
2017/18	7597	3992	2912	1321	484	198	0	475	211	465	168	3645
2018/19	7514	5294	2788	1490	493	254	0	574	326	539	121	3925
2019/20	7247	4731	2825	1421	511	157	109	380	255	376	91	3638
2020/21	6701	5332	2589	1578	457	210	244	434	228	607	104	4286
2021/22	7640	7843	3076	2002	418	317	372	806	281	1118	131	4134

Note: *Some Narcotics, Psychotropics and Precursor (NPP's) Chemicals were applied under commercial permits and raw materials, as a result the total number of applications covering NPP's 950 for imports and 497 for export in the FY 2021/2022.*

Figure 49

Importation Sources.

During the 2021[1] review period, the top 3 import sources included; India accounting for about 37.6%, UK at about 22%, and Germany at about 10%.

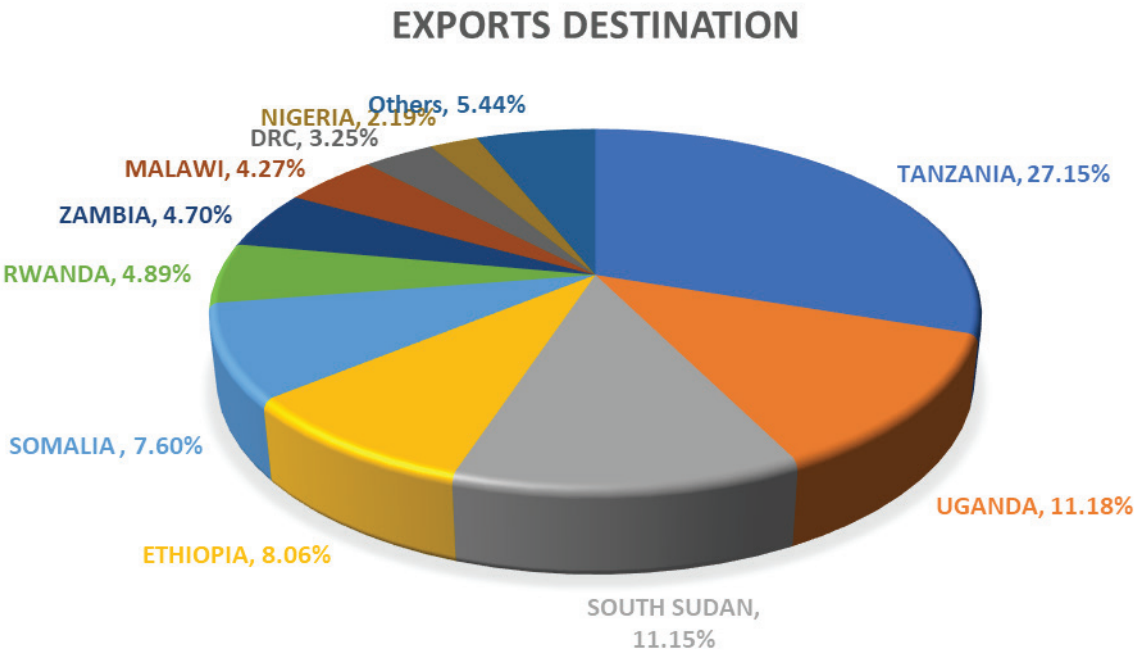


[1] The SQL for the FY 2021/2022 had an error message at the time of preparing this report thus the use of the 2021 data. This is occasioned by the new TFP system rolled out in 23rd August 2021.

Figure 50

Export Destinations.

During the 2020[2] review period, the top 3 export destination included; Tanzania at 27.15%, Uganda at 11.18% and South Sudan at about 11.15%.



5.7.4.4 Permit application Turnaround Time (TAT)

On average, as at 31st December 2022, the turnaround time of the applications that require payment was at 5 days. This includes the time taken by clients to make payments and respond to queries.

On average, as at the same period, the turnaround time of applications that do not require payment was at 4.8 days. This includes the time taken by clients to respond to queries.

Source: National TFP System (Popularly referred to as Kentrade)

5.7.4.5 Visibility

The importation and export procedures can be accessed at the Board's website as well as the website at: www.infotradekenya.go.ke

5.7.5 Performance Improvement – PPB Quality Management System

The Pharmacy and Poisons Board has implemented a quality management system (QMS) based on ISO 9001 International Standard. The overall purpose of implementation of the quality management system was to ensure overall quality and enhanced performance. This ensures that every time a process is performed, consistency is ensured in the information produced, methods, skills and controls applied.

Following implementation of QMS, the Board has improved its processes in terms of timeliness and effectiveness, resulting in improved customer satisfaction. This is attributed to automation and aligning of day-to-day operations with the strategic objectives that has resulted in reduced wastage of time and resources as most of our services were available to the clients online.

In the 2021 /2022 financial year, the PPB conducted several audits, internal and external, to check on the performance for various regulatory functions and departments. This included the periodic internal audits, management review meeting, ISO certification external audit by Kenya Bureau of Standards (KEBS) and the WHO assessment against the Global Benchmarking Tool (GBT). It is notable that the resulting recommendations from the management review meeting were addressed successfully and the non-conformities identified during external audits reduced from seven in 2018 to two in 2022. The Board is committed to addressing the gaps and areas of improvement raised by the WHO towards a robust regulatory system.

[2] The SQL for the 2021/2022 for export destination had an error message at the time of preparing this report thus the reference to the 2020 data. This is occasioned by the new TFP system launched on 23rd August 2021.

Pharmacy and Poisons Board of Kenya

info@pharmacyboardkenya.org

Pharmacy and Poisons Board

@ppbkenya

web.pharmacyboardkenya.org