Pharmacy and Poisons Board of Kenya

ANNUAL REPORT

2020/2021

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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

Executive Summary

The Pharmacy and Poisons Board (the Board) Financial Year 2020/21 CEO's Annual Report outlines the Board's achievements, which, despite the Covid-19 Pandemic, recorded the highest number of innovative approaches in ensuring business continuity. Significantly, was the successful development and implementation of an online examination management system which resulted to administration of two series (8 sets) of online examination. The exam administration was decentralized from one center in 2019 (manually administered examination) to ten (online examinations) in July 2021. Due to online administration of exams, the Board registered improved efficiency with significant reduction in time taken to release results and optimal utilization of resources due to automated marking.

With a view of aligning Pharmacovigilance to international best practices, the Board, upgraded and launched in March 2021 Kenya Pharmacovigilance Electronic Reporting System (PvERS) version II. The system aims at strengthening reporting of suspected Adverse Drug Reactions and Events related to health products and health technologies.

The Board witnessed an improvement in the various regulatory functions. In particular, dossier evaluation was intensified with reduced registration timelines from approximately 3 years to 15 months. In support of the local pharmaceutical production and in line with the H.E President Big Four Agenda, the Board was able to recommend registration of 53 locally manufactured products through fast-track mechanism. The Emergency Use Authorization pathway and various committees were also introduced in registration process as well as use of reliance and recognition of WHO Emergency Use Listed products in responding to COVID-19 pandemic.

Similarly, the Board expanded the scope of products surveyed under the Joint Post Marketing Surveillance of products for HIV, TB, Malaria and Reproductive Health.

The Department of Inspectorate and Enforcement in an effort to ensuring compliance with regulations and the Law in order to protect and maintain the integrity of the Health Products and Technologies supply chain, conducted routine compliance inspections of the licensed pharmaceutical premises among other activities to reduce incidences of violations. In the same period, there was an increase in the number of Desktop Document reviews of Foreign manufacturing facilities for Health Products and Technologies.

There was a roll out of a new Trade Facilitation Platform (TFP) which is an enhanced format of the previous single window system in conformity to the WTO Kyoto conventions of trade facilitation. The TFP integration with Kenya Revenue Authority (KRA) Custom Management System (iCMS) has improved the Board visibility at the Ports of Entry. Since the automation of the TFP, there was an increase of import permit application in the last 2 months of the year 2021 which represented a revenue increase of 7.35% in 2020/2021 as compared to 2019/2020 FY.

The Board participates in performance contracting and submits quarterly reports on its performance and activities to the Cabinet Secretary and Principal Secretary at the Ministry of Health. Consequently, the Board ensures implementation of the commitments set out in the Annual President's Report on National Values and Principles of Governance and report.

Finally, the services at the Board are funded through financial support from the mother Ministry, Ministry of Health, funds collected as levies and donor funds and it ensures effective internal control in the use of internal resources through Internal Audit Unit and Auditor General audits.

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Chief Executive Officer's Statement

I'm delighted to present Pharmacy and Poisons Board (the Board) Financial Year 2020/21 CEO's Annual Report. This period was characterized by uncertainties around the world mainly due to the COVID-19 Pandemic, with disruptions in health care service delivery. During this period, the Board was not spared either. However, to ensure continued service deliver, the Board was able to leverage on automated systems that were accessible remotely. The Board has also achieved the national requirement of a 1:1 ratio of computer end user devices to users with home and office internet connectivity.

In meeting its harmonization obligations, the Board was ISO certified in 2018 by the Kenya Bureau of Standards and it continually maintains its quality management system through internal audits and management review meetings. Furthermore, Board has been participating in joint activities at the East African Community and Intergovernmental Authority on Development since 2012 and 2016 respectively. 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.

In addition, the national quality assurance scheme within the distribution chain is monitored through the enforcement of Good Distribution Practices, Pharmacovigilance, and Post-marketing Surveillance activities. I'm happy to report that, during the period, the Board registered a slight increase in the number of reports to 1341 reports compared to previous year 629 reports. There was increased reporting because of the expanded scope of reports in PV, availing the online platform for AEFI reports and upscaled training of healthcare providers on the new COVID-19 vaccines that were rolled out in March 2021.

The Board, further, in an effort to increase visibility and improve efficiency in service delivery, commenced the process of decentralizing its services and ensuring adequate linkages with stakeholders by bringing services closer to the people. During this period, the Board established two county offices of Muranga and Kiambu.

In terms of pharmacy practice, there was sustained effort to diversify and increase the human capital base for pharmaceutical services through expanded training opportunities as well as Continuing Professional Development to ensure competence and fitness to practice.

The Board is under obligation to share its annual report with the public as a way of promoting transparency and accountability. Consequently, the Board hereby issues this Chief Executive Officer's Report for the Year 2021.

The development of the report was a consolidated effort of the top management and staff of the Board. Not forgetting the role of the mother ministry, Ministry of Health and our stakeholders. I wish to thank you all for your immense support without whom these achievements wouldn't be possible.

Dr Fred M. Siyoi
CHIEF EXECUTIVE OFFICER

1 Introduction

1.1 Establishment of the 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

a) Regulate the training, continuing professional development (CPD) and practice of pharmacy;

b) Licensing of pharmacists and pharmaceutical technologists and medical representatives;

c) Accreditation of institutions offering pharmacy program;

d) Regulate, monitor and inspect personnel and premises that are involved in training, CPD and pharmacy practice; and

e) 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

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.

2.1 The Board of Directors (BOD)

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:

a) a chairperson who shall be appointed by the President

b) the Director of pharmaceutical services;

c) the Principal Secretary in the ministry for the time being responsible for matters relating to finance or his or her representative;

d) two persons representing the pharmacy training institutions, of which one shall be a pharmacist and one shall be a pharmaceutical technologist;

e) three other persons appointed by the Cabinet Secretary, of whom–

- one person shall be a pharmacist representing institutions of higher learning;
- one person shall be a pharmaceutical technologist representing mid-level colleges; and
- one person shall be an enrolled pharmaceutical technologist with expertise in community pharmacy nominated by the Kenya Pharmaceutical Association;

f) the Chief Executive Officer, who shall be an ex officio member; and one medical practitioner nominated by the Kenya Medical Association and appointed by the Cabinet Secretary.

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 Management Committees

The Management Committee is chaired by the Chief Executive Officer and is composed of 4 Directors, 5 deputy directors and 7 Managers. These are officers at PPB 2 and PPB 3. In the review period FY 2020/2021, the management held a total of 28 meetings to deliberate on key agenda relevant to the functioning of the organization.

2.3 Parliamentary Committees

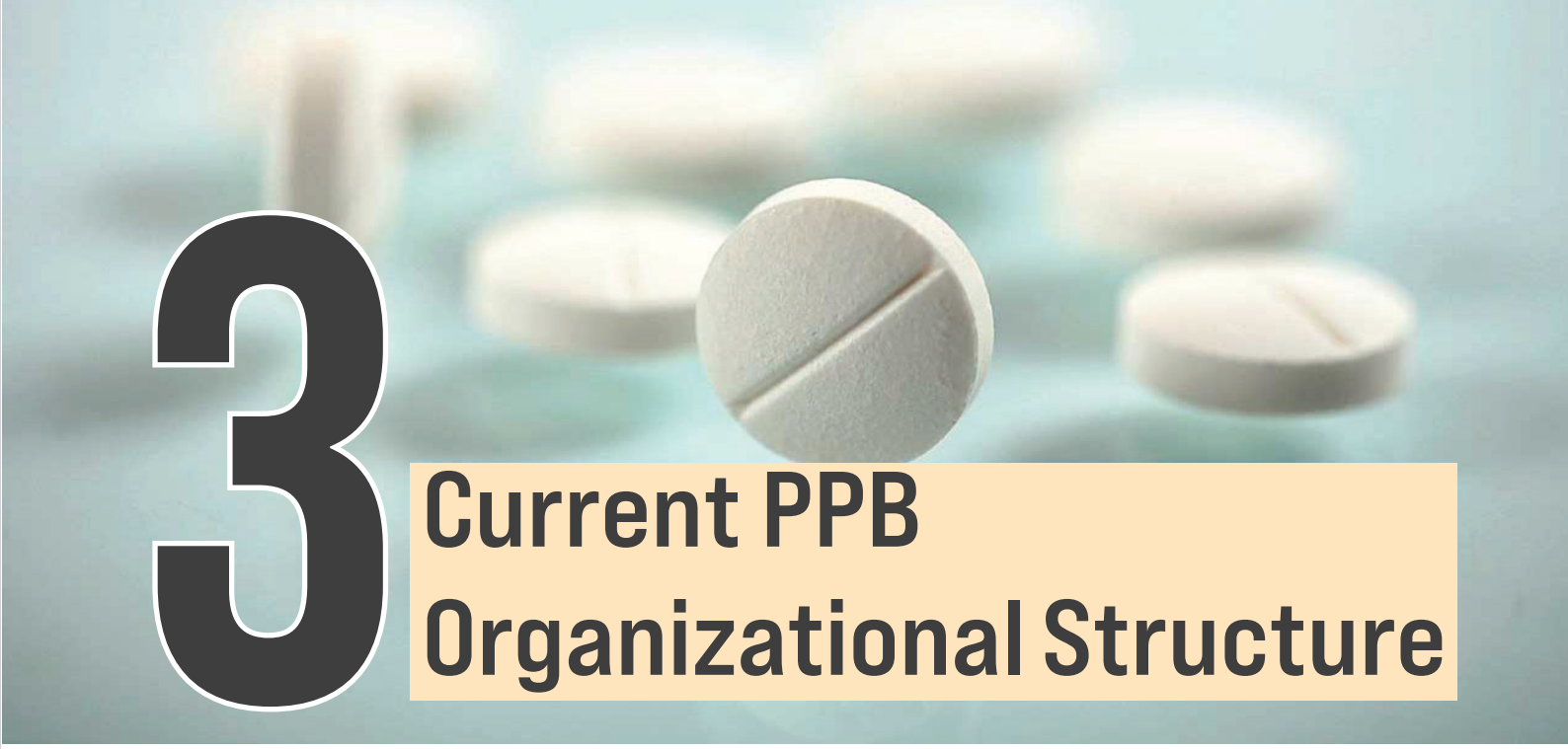
In the FY 2020/2021, the PPB participated in eight (8) meetings of the Committee on Health of the Senate and the National Assembly:

1. Submissions on the Kenya Food and Drug Authority Bill, 2019 – April 2020
2. Submissions to the Senate on the Reproductive Healthcare Bill, 2019 – September 2020
3. SCH Alleged Emergency Authorization for the Importation and Distribution of the Russian-Manufactured Sputnik COVID-19 Vaccine in Kenya – March 2021

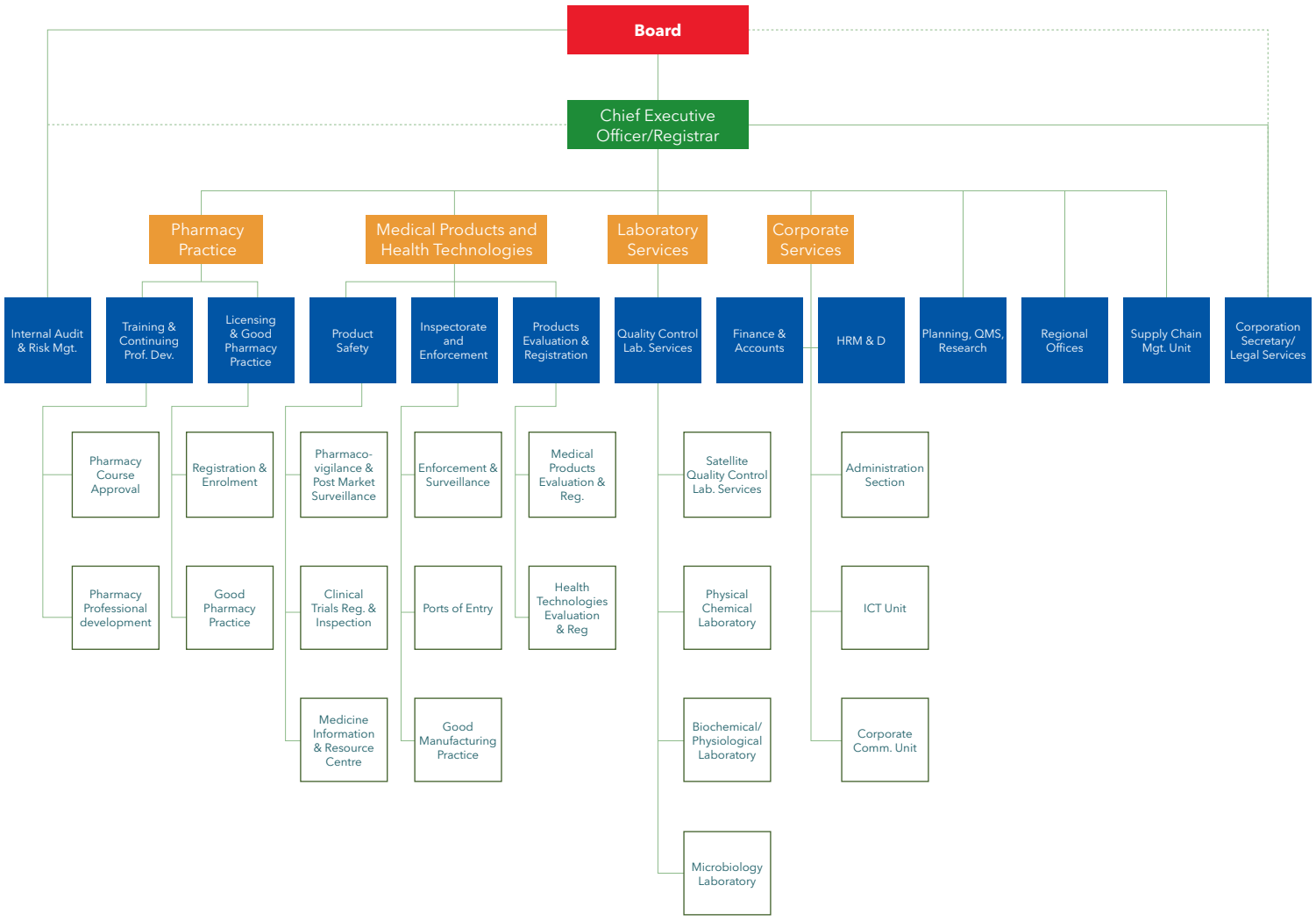
4. The Resurgence of COVID-19 and the Presence of Multiple COVID-19 Vaccines in the Country - March 2021
5. SCH Response to Cancellation of Licences to Private Sector Entities in the Importation, Distribution and Administration of COVID-19 Vaccines into Kenya – April 2021
6. Response to a letter from Office of the Clerk of the Senate on Cancellation of Licences to Private Entities in COVID-19 Vaccines in Kenya – April 2021
7. Public Participation exercise on the Health Laws (Amendment) Bill, 2021 (National Assembly Bills No. 2 of 2021 – April 2021
8. Deliberations on the HIV Stalemate over the HIV/AIDS Commodities, the levels of Medical Oxygen Gas in Hospitals in the Country and Sputnik V Vaccine – April 2021

2.4 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 2020 achieved a score of 100% for this indicator.



3 Current PPB Organizational Structure



3.1. Staff Establishment

S/No.	Designation	Grade	Approved Establishment	In post	Variance
1	CEO	1	1	1	0
2	Directors	2	4	4	0
3	Chief Principal Regulatory Officer	2	3	1	2
4	Senior Principal Regulatory officer	3	6	0	6
5	Technical Assistant/ Senior Principal Regulatory Officer	3	1	0	1
6	Deputy directors	3	6	6	0
7	Managers - HR, Audit, Supply, Planning and Finance	3	5	5	0
8	Regional Regulatory Coordinator	3	14	15	-1
9	Manager, Regional offices	3	1	1	0
10	Corporation secretary	3	1	1	0
11	Principal Legal Officer	4	1	2	-1
12	Principal regulatory officer	4	53	1	52
13	Principal Administrative Officer	4	1	1	0
14	Principal Finance/Accounts Officer	4	1	0	1
15	Principal Human Resource Management Officer	4	1	1	0
16	Principal Corporate Communications officer	4	1	1	0
17	Principal ICT Officer	4	1	1	0
18	Principal Officer (Planning, QMS)	4	1	0	1
19	Principal Officer, Internal Audit & Risk	4	1	0	1
20	County Principal regulatory officer	4	47	2	45
21	Assistant officer / Clerical	8	1	0	1
22	Driver/ Senior	10/9	16	22	-6
23	Clerical Officers/ Senior	10/9	3	18	-15
24	Office Assistant	11/10	1	1	0
25	Finance Officer/ Senior	6/5	1	1	0
26	Planning Officer/Senior	6/5	1	1	0
27	Quality Management Systems Officer/ Senior	6/5	1	0	1
28	Human Resource Management Officer/ Senior	6/5	1	0	1
29	Legal Officer/Senior	6/5	1	0	1
30	ICT Officer/Senior	6/5	4	2	2
31	Finance Officer/Senior	6/5	1	0	1
32	Accountant/Senior	6/5	1	4	-3
33	Research and Development Officer/Senior	6/5	1	0	1
34	Administrative Officer/Senior	6/5	1	0	1
35	Security officer/Senior	6/5	1	0	1
36	Internal Audit & Risk Assurance / Senior	6/5	3	0	3
37	Supply chain Management Officer / Senior	6/5	2	1	1
38	Corporate Communications officer/ senior	6/5	1	2	-1
39	Regulatory Officer/Senior	6/5	85	23	62
40	Assistant Office Administrator / Senior	8/7	3	1	2
41	Assistant HR Officer/Senior	8/7	1	0	1
42	Assistant Regulatory Officers/Senior	8/7	40	34	6

S/No.	Designation	Grade	Approved Establishment	In post	Variance
43	Assistant Administrative Officer / Senior	8/7	1	0	1
44	Assistant Maintenance Officer/ Senior	8/7	1	1	0
45	Assistant Records Manager/Senior	8/7	1	0	1
46	Receptionist	8/7	2	1	1
47	Assistant Customer Care Officer/ Senior	8/7	1	1	0
48	Assistant Security officer/Senior	8/7	1	1	0
49	Senior Assistant Accountant	8/7	1	2	-1
50	Assistant ICT Officer/Senior	8/7	3	4	-1
51	Assistant Corporate Communications Officer/ Senior	8/7	1	2	-1
52	Assistant Supply Chain Management Officer/ Senior	8/7	1	4	-3
53	Assistant Human Resource Management Officer/Senior	8/7	1	0	1
54	Assistant Records Manager/Senior	8/7	1	0	1
55	Assistant Office Administrator	8/7	15	1	14
56	Senior Driver	9	2	0	2
	Total		352	170	182

4. Annual Reports

4.1. Audited Financial Statements

PHARMACY AND POISONS BOARD
ANNUAL REPORT AND FINANCIAL STATEMENTS
FOR THE FINANCIAL YEAR ENDED
30th June 2019

STATEMENT OF FINANCIAL PERFORMANCE FOR THE YEAR ENDED 30TH JUNE 2019

	Note	2018-2019 Kshs	2017-2018 Kshs
Revenue from exchange transactions			
Rendering of services	3	994,047,393	1,091,189,202
Finance Income	4	8,920,560	9,472,342
Other income	5	28,727,899	30,580,291
Total revenue		**1,031,695,852**	**1,131,241,835**
Expenses			
Use of goods and services	6	43,203,983	51,736,947
Employee costs	7	71,404,686	79,152,316
Board expenses	8	7,675,994	4,365,370
Depreciation	9	183,953,287	194,899,722
Repairs and maintenance	10	44,859,020	21,881,005
General expenses	11	691,713,408	441,083,541
Finance costs	12	16,968,097	475,096
Collection cost	13	246,759,679	235,548,972
Total expenses		**1,306,538,154**	**1,029,142,969**
(Deficit)/Surplus before tax		**(274,842,302)**	**102,098,866**
Taxation		-	-
(Deficit)/Surplus for the period		**(274,842,302)**	**102,098,866**

PHARMACY AND POISONS BOARD
ANNUAL REPORT AND FINANCIAL STATEMENTS
FOR THE FINANCIAL YEAR ENDED
30th June 2019

STATEMENT OF FINANCIAL POSITION
AS AT 30TH JUNE 2019

	Note	2018-2019 Kshs	2017-2018 Kshs
Assets			
Current assets			
Cash and cash equivalents	14	761,117,920	1,212,550,005
Trade and Other Receivables	15	40,265,414	33,553,912
		801,383,334	**1,246,103,917**
Non-current assets			
Property, plant and equipment	16	1,374,214,229	1,211,031,748
		1,374,214,229	**1,211,031,748**
Total assets		**2,175,597,563**	**2,457,135,665**
Liabilities			
Current liabilities			
Trade and other payables	17	19,527,411	26,223,211
		19,527,411	**26,223,211**
Total liabilities		**19,527,411**	**26,223,211**
Net assets		**2,156,070,152**	**2,430,912,454**
Reserves	18	6,479,649	6,479,649
Accumulated surplus	19	2,149,590,503	2,424,432,805
Total Reserves		**2,156,070,152**	**2,430,912,454**

PHARMACY AND POISONS BOARD
ANNUAL REPORT AND FINANCIAL STATEMENTS
FOR THE FINANCIAL YEAR ENDED
30th June 2019

STATEMENT OF CHANGES IN NET ASSETS FOR THE YEAR ENDED 30TH JUNE 2019

	Reserves Capital Replacement Reserves Kshs	Accumulated Surplus Kshs	Total Kshs
Balance as at 1 July 2017	**6,479,649**	**2,322,333,939**	**2,328,813,588**
Surplus for the year		102,098,866	102,098,866
Balance as at 30 June 2018	**6,479,649**	**2,424,432,805**	**2,430,912,454**
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 30th June 2019	**6,479,649**	**2,149,590,503**	**2,156,070,152**

PHARMACY AND POISONS BOARD
ANNUAL REPORT AND FINANCIAL STATEMENTS
FOR THE FINANCIAL YEAR ENDED
30th June 2019

STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30TH JUNE 2019

	2018-2019	2017-2018
Cash flows from operating activities		
Receipts	**Kshs.**	**Kshs.**
Rendering of Services	994,047,393	1,091,189,202
Finance Income	8,920,560	9,472,342
Other incomes	28,727,899	30,580,291
Total Receipts	**1,031,695,852**	**1,131,241,835**
Payments		
Compensation to employees	71,404,686	79,152,316
Board Members Expenses	7,675,994	4,365,370
Repairs and Maintenance	44,859,020	21,881,005
General expenses	734,917,391	492,820,488
Finance cost	16,968,097	475,096
Collection cost	246,759,679	235,548,972
Total Payments	**1,122,584,866**	**834,243,247**
Net Cash flow from Operating activities	**(90,889,014)**	**296,998,588**
Cash flow from Investing Activities		
Purchase of Property, Plant, Equipment and intangible assets	(347,135,768)	(691,463,682)
(Increase)/decrease in receivables	(6,711,502)	(10,397,680)
Increase/(decrease) in payables	(6,695,800)	710,909
Net cash flow used in Investing activities	**(360,543,070)**	**(701,150,453)**
Cash flow from financing activities	-	-
NET CASHFLOW FROM FINANCING ACTIVITIES	-	-
Net increase/(decrease) in cash and cash equivalent	**(451,432,085)**	**(404,151,864)**
Cash and Cash Equivalent as at 1st July	1,212,550,005	1,616,701,869
Cash and Cash equivalent as at 30th June	761,117,920	1,212,550,005

PHARMACY AND POISONS BOARD
ANNUAL REPORT AND FINANCIAL STATEMENTS
FOR THE FINANCIAL YEAR ENDED
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STATEMENT OF COMPARISON OF BUDGET AND ACTUAL AMOUNTS FOR THE YEAR ENDED 30TH JUNE 2019

	Approved Budget	Adjustments Reallocations	Final Budget	Actual on comparable basis	Performance difference	
	2018-2019	2018-2019	2018-2019	2018-2019	2018-2019	
Revenue	**Kshs**	**Kshs**	**Kshs**	**Kshs**	**Kshs**	
Rendering of services	1,273,880,000	-	1,273,880,000	1,031,695,852	(242,184,148)	
Total income	**1,273,880,000**	**-**	**1,273,880,000**	**1,031,695,852**	**(242,184,148)**	(a)
		-				
Expenditure		-				
Compensation of employees	72,000,000	-	72,000,000	71,404,686	595,315	(b)
Finance cost	17,000,000	-	17,000,000	16,968,097	31,903	(c)
Board Expenses	8,000,000	-	8,000,000	7,675,994	324,006	(d)
Other payments	1,079,700,000	-	1,079,700,000	1,210,489,377	(130,789,377)	(e)
Total expenditure	**1,176,700,000**	**-**	**1,176,700,000**	**1,306,538,153**	**(129,838,153)**	
		-				
Surplus/ (Deficit) for the period	**97,180,000**	**-**	**97,180,000**	**(274,842,302)**	**(372,022,301)**	

a) Reduction in revenue was due to low trade in medicine in the country, reduced drug registration and evaluations of medical devices.
b) Compensation to employee was due implementation of SRC policy and putting wages well within the budget.
c) Finance cost was within the budget.
d) Reduced board member expenses were due to reduced board activities during the period.
e) Increases in other payments were as a result of depreciation of PPE under budget.

4.2. Annual Technical Reports

4.2.1. Product Evaluation and Registration

Product Evaluation and Registration Department is one of the key departments under the Directorate of Medical Products & Health Technologies. The Department is responsible for using marketing authorization and retention of medical products and health technologies.

Currently the directorate has 12 Dossier assessors engaging in the day to day work but relies on assessors based in other directorates during planned evaluation retreats.

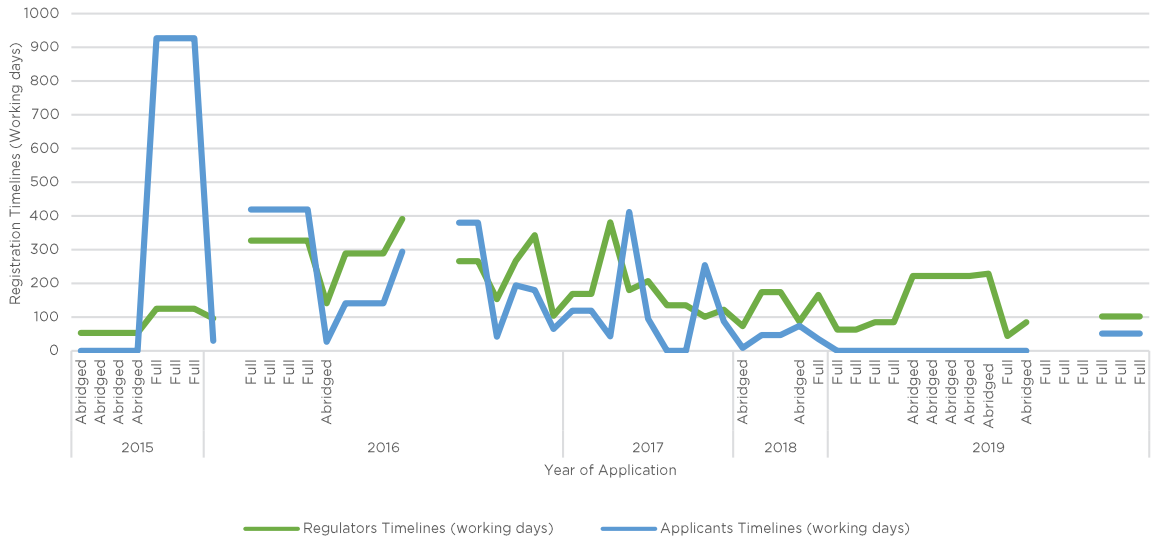
Some key functions of the Directorate include:

a. Formulate, review and implement policies, rules, regulations and strategies for marketing authorization and retention of medical products and health technologies;
b. Coordinate dossier assessment for registration, retention or variations;
c. Collaborate with relevant stakeholders both local and international on product evaluation and registration.

4.2.1.1. Medical Products Evaluation and Registration

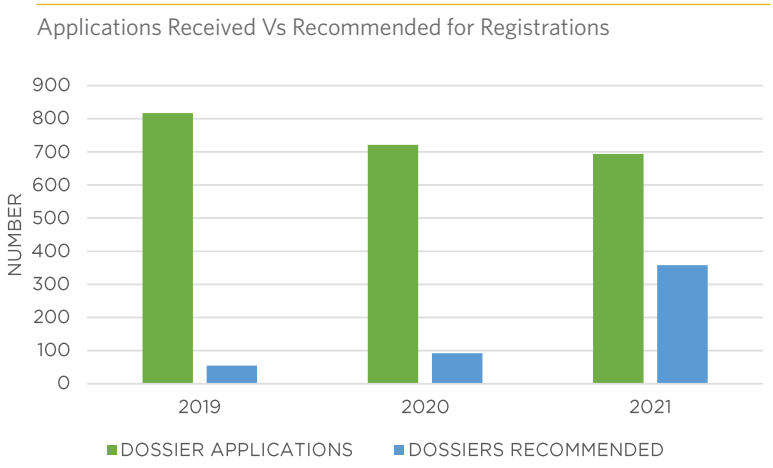
Reduced Registration Timelines

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



The number of dossier applications evaluated and recommended also tripled in 2021 compared to the previous years.

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



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

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

b. Enhanced participation in regional/ international harmonization activities

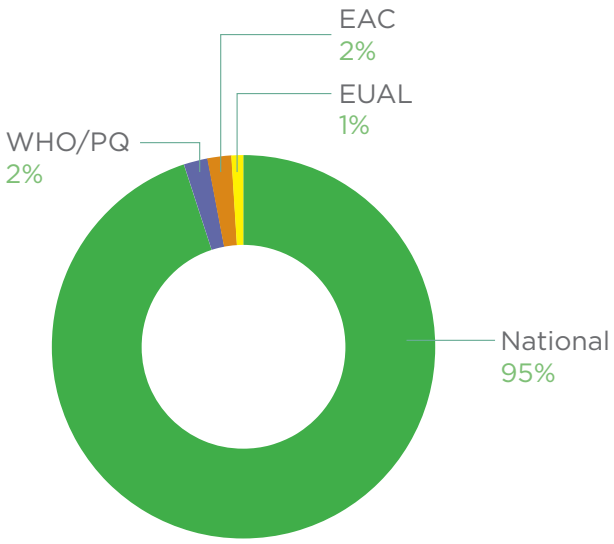
Out of the 358 dossier applications recommended for registration in 2021, 340 were national applications, 7 were WHO/PQ, 6 were EAC and 5 were applied under emergency use Listing procedure.

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

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

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

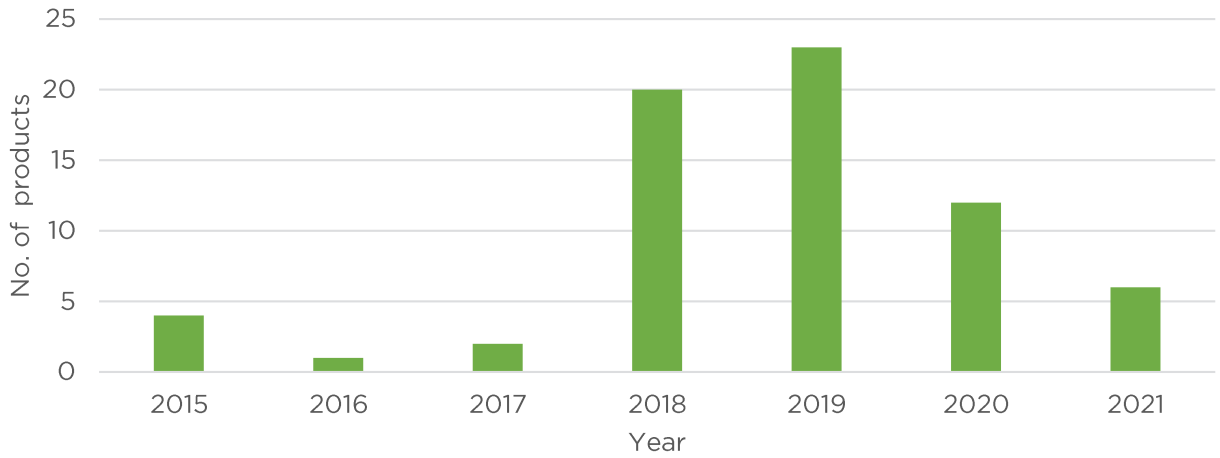
Products Registered in 2021 by Application Path



Products recommended through EAC harmonization over the years

Year	No. of products recommended (EAC)
2015	4
2016	1
2017	2
2018	20
2019	23
2020	12
2021	6
Total	**68**

Products recommended through EAC harmonization

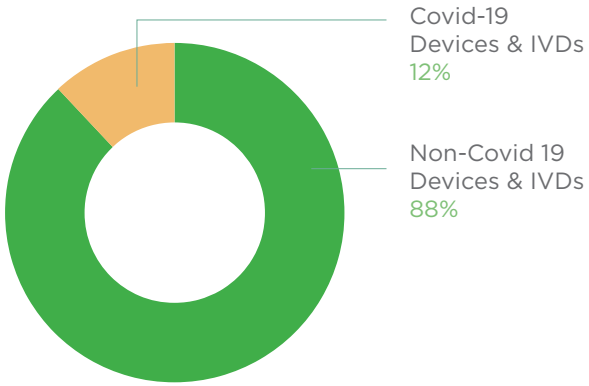


4.2.1.2. Medical Devices Evaluation and In-Vitro Diagnostics

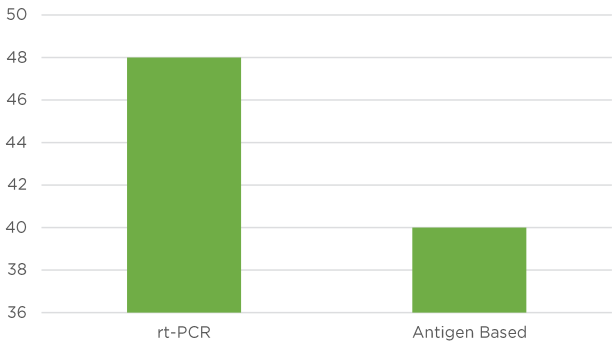
The applications for Medical Devices and In-Vitro Diagnostics increased dramatically in the year 2021 owing to the COVID-19 Pandemic. The total number of applications that were received in this period were 4612; The number of COVID-19 related applications received applications were 560, which were made up of Ventilators, Diagnostics and personal Protective equipment. All the applications submitted were imported from regions outside of Kenya, with the use of reliance and recognition of WHO Emergency Use Listed products having been used with market authorization. 48 Real time Polymerase Chain Reactions (rt-PCR) Tests, and 40 Antigen Tests have been granted market authorization.

As a result of the increased workload owing to the COVID-19 Pandemic, the time taken for the reviewing of application increased to an average of working days 360 days; this being against the backdrop of staffing for the reviewing of medical devices and in-vitro diagnostics having not increased during this time.

Medical Devices & IVD Applications in 2021



Covid-19 Test Kits Granted Marketing Authorization



Emergency Use Authorization pathway

In responding to the COVID-19 Pandemic, the Emergency Use Authorization pathway which incorporate Technical Committee made up of Experts for Medical Devices was instituted. Through this committee, a total of 400 Medical Devices and Personal Protective Equipment applications were reviewed. This pathway provided for a shorter turn-around time for the Medical Devices applications.

For COVID-19 Diagnostics, in-country assessment of both polymerase Chain Reaction Test Kits, as well as Antigen Test Kits by the Kenya Medical Research Institute enhanced the quality assurance aspects for Diagnostics. All incoming COVID-19 Diagnostics undergo performance and validation by the KEMRI Laboratory.

Collaborations with International Harmonization for Medical Devices

Kenya is currently the Chair of the African Medical Devices Forum, under the African Medicines Harmonization initiative of the African Union; in her capacity as Chair of the Forum, Kenya has contributed in capacity building for regulators in Africa through technical file assessment training workshops, development of guidance documents that have supported the post market surveillance and market surveillance of in-vitro diagnostics.

To further leverage on reliance model for regulation of medical devices, staff from the department of medical devices contributed at the Global Harmonization Working Party; International Conference for Drug regulatory Authorities and African Medicines Regulators Conference which are all initiatives seeking to increase harmonized working.

Challenges of the Departmet

Inadequate staff – The department has only 12 evaluators against the recommended staff establishment of 60 evaluators. This has made the Department unable to reduce backlog of pending evaluations.

4.2.2. Product Safety

4.2.2.1. Pharmacovigilance & Post Market Surveillance

Pharmacovigilance

Since the introduction of PV in Kenya (2004), a total of 15,271 individual case safety reports (ICSRs) have been submitted to the global database which presently has a total of 29,577,509 (0.05%) ICSRs. The last financial year of 2020/2021 has seen a slight increase in the number of reports to 1341 reports compared to previous year 629 reports. There was increased reporting because of the expanded scope of reports in PV, availing the online platform for AEFI reports and upscaled training of healthcare providers on the new COVID-19 vaccines that were rolled out in March 2021.

Reports by quarter

Period	No. of ADR reports submitted to PPB
Quarter 1	218
Quarter 2	283
Quarter 3	259
Quarter 4	134
Total reports	**1341**

Type of reports	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21
Suspected Adverse Drug Reaction reports (SADRs)-Reported by healthcare providers	975	1200	1014	1043	629	894
Adverse Events following Immunization reports (AEFI)	-	-	-	-	-	264
Suspected Adverse Drug Reaction reports (SADRs)-Reported by the public/patients	-	-	-	-	-	177
Medication errors reports	-	-	-	-	-	5
Transfusion reaction reports	-	-	-	-	-	1
Total reports	**975**	**1200**	**1014**	**1043**	**629**	**1341**

Below is 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

Number of reports collated per financial year

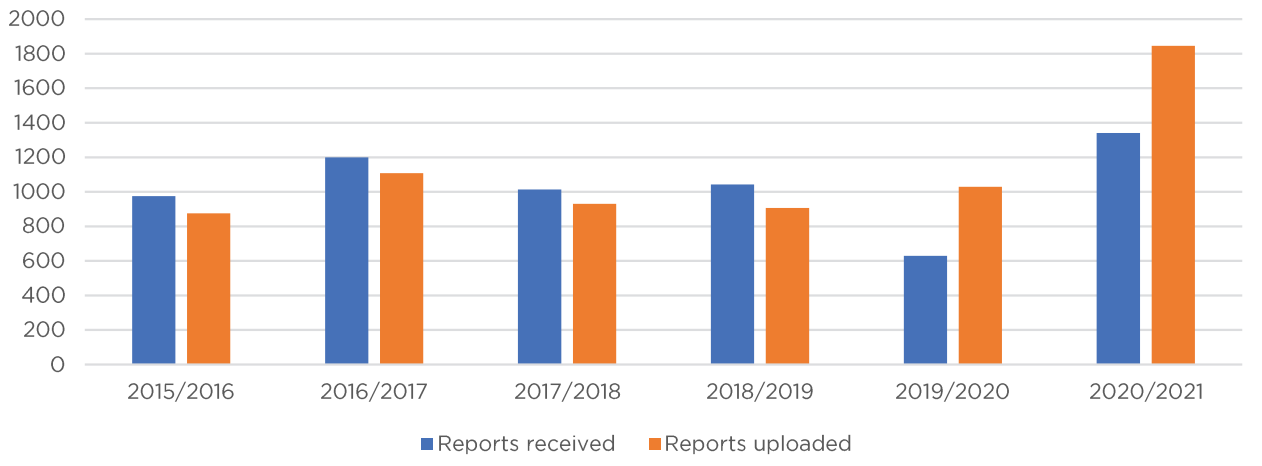
Evaluation of the Adverse Drug Reactions reports

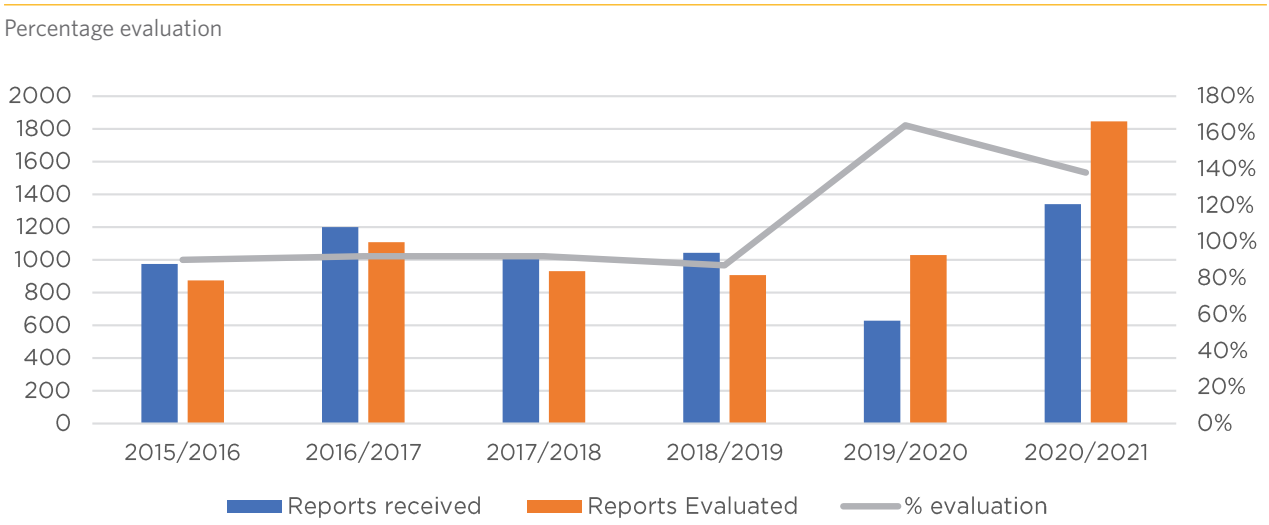
This entails uploading of both the hard copies and online reports from the PV-Electronic Reporting System (PVERs) to Vigi-flow and later downloading the data in an excel sheet and doing some basic statistics on the data in order to give feedback to reporters as a 2 pager.

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

Number of reports received vs uploading to vigiflow





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.

2016/2017

Warning letter

Suspected Isoniazid adverse drug reactions

Reports of suspected deaths and increased hepatotoxicity necessitated some field assessment that led to the recommendation of doing a baseline liver function test before initiating any patient on Isoniazid.

2017/2018

Recall

Gentamicin injection

Adverse drug reaction reports on severe headaches due to gentamicin injection.

Email on concerns

Imatinib suspected therapeutic failures and deaths

Increased reports of death of patients on Imatinib led to a warning letter to Norvatis the MAH of the suspected product.

2018/2019

None

2019/2020

Over the counter purchase of medicines

An alert was issued to the public to warn them to avoid over the counter purchasing of hydroxyquinoline and dexamethasone medicines for management of COVID-19 infections.

Recommended the re-packaging and re-labelling

Chlorhexidine gel used for cleaning of umbilical cord.

Reported medication errors of mistakenly applying it the baby's eyes instead of umbilical cord causing keratitis.

2020/2021

Continued import of chlorhexidine drops

The was revocation of retention license for all chlorhexidine for umbilical cord that were still packed in a bottle that looks like an eye drop.

Number of PV trainings and healthcare workers trained in 2020/2021

The division managed to train 576 healthcare workers on how to identify and report adverse events following immunization on COVID-19 as tabulated below;

Funding	Activity	2020/2021
CIHEB	COVID-19 vaccines roll-out	271
MTAPs	COVID-19 vaccines targeted spontaneous reporting (TSR)	168
MoH	COVID-19 vaccines roll-out	137
	Total trained	**576**

As a baseline KPI for the division, the average time taken to review and take regulatory actions in 2020/2021 is; Approximately 2-3 months. This could probably be explained by the fact that analysis of PV data is done on a quarterly basis and thus signals are picked out at this time or during uploading of data into vigi-flow.

The current backlog

200 Periodic safety update reports, periodic benefits risk evaluation reports, notifications of change of prescribing information and variation reports.

Progress made:

i. Inauguration of the new Pharmacovigilance Experts advisory and Review Committee (PERAC) that will be conducting causality assessment of reported safety serious cases to the Board.
ii. Launch of the Pharmacovigilance Electronic reporting system (PVERs II) that expanded the scope of safety reports submitted to the Board.
iii. Launch of the new pharmacovigilance guidelines on establishment of Qualified Persons for Pharmacovigilance (QPPV).
iv. Lead country in spearheading activities in East Africa Community (EAC) and Inter-Governmental Authority and Developmental (IGAD).
v. Launch of the revised pharmacovigilance guidelines (Guidelines on safety and vigilance of health products and technologies December 2019).

Pharmacovigilance RCORE

Capacity building of other African countries e.g. Ethiopia, Botswana, Malawi

Other relevant PV activities

i. Launch of the new online reporting system (PVERs II) to capture reports on medical devices, medication errors, herbal products, therapeutic ineffectiveness, blood and blood products
ii. 1st review of PV training materials to update the current trend in PV field
iii. Reviewing and development of new reporting tools to capture different events in the field e.g. patient reporting tool, medication errors
iv. Safety monitoring of COVID-19 vaccines throughTargeted Spontaneous Reporting (TSR)
v. Planned active surveillance of COVID-19 vaccines (CEM)
vi. EDCTP Funding projects

- PROFORMA-Involves active surveillance of drugs used in mass administration e.g. Use of IDA vs DA in neglected tropical diseases program. This saw the active follow up of 20,716 participants to monitor adverse events. Data analysis is currently ongoing.
- HATUA-Involves short course trainings in PV to improve reporting of ADRs by health care workers.

Gaps & challenges

Insufficient funding for Pharmacovigilance activities to carry out the following:

1. PV Training and sensitizations (1, 3- & 5-days trainings)
2. Active surveillance of new molecules introduced in the market e.g. COVID-19 vaccines, Bedaquline, delaminid, Anti-malarial vaccine, HPV vaccine etc. through cohort event monitoring (CEM) or targeted spontaneous reporting (TSR)
3. Continual Upgrading of the PvERS to capture all regulated medical products and health technologies and provide a feedback manual.

a) Post market surveillance

1. Compliance rates of medical products and health technologies with specifications and/ or standards, in Kenya

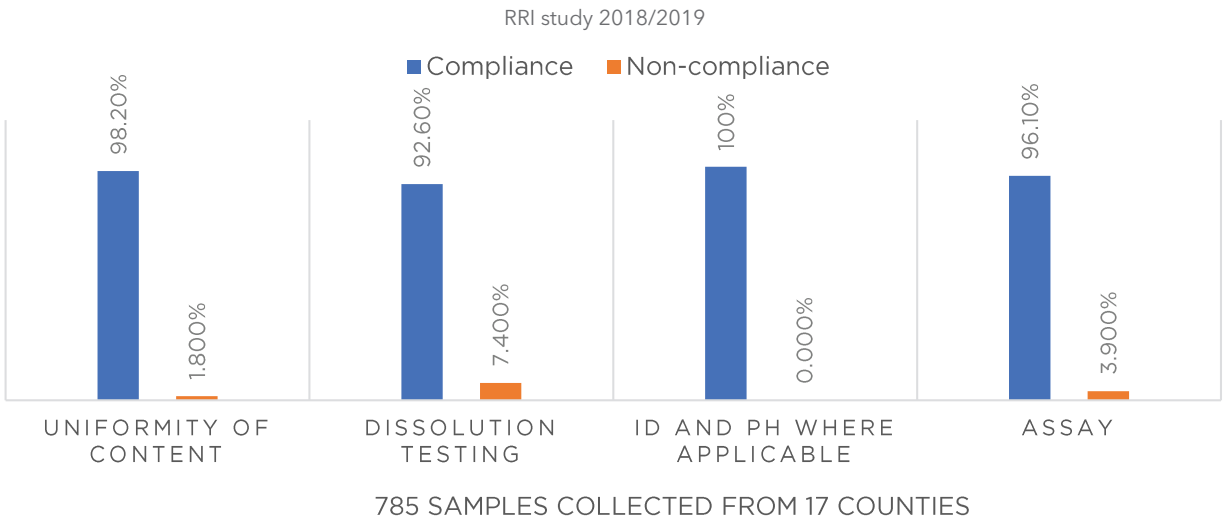
2018/2019 Rapid Results Initiative (RRI) PMS activity

Product categories sampled were Amoxicillin, Folic acid, Folic acid/ Ferrous FDC, Glibenclamide, Hydrochlothiazide, Levonorgestrel, Metformin, Paracetamol, Sildenafil and Herbal preparations for ED.

A total of 785 samples were collected from 17 counties

	Compliance	Non-compliance
Uniformity of content	98.20%	1.80%
Dissolution testing	92.60%	7.40%
ID and PH where applicable	100%	0.00%
Assay	96.10%	3.90%

Compliance vs non-compliance for RRI study



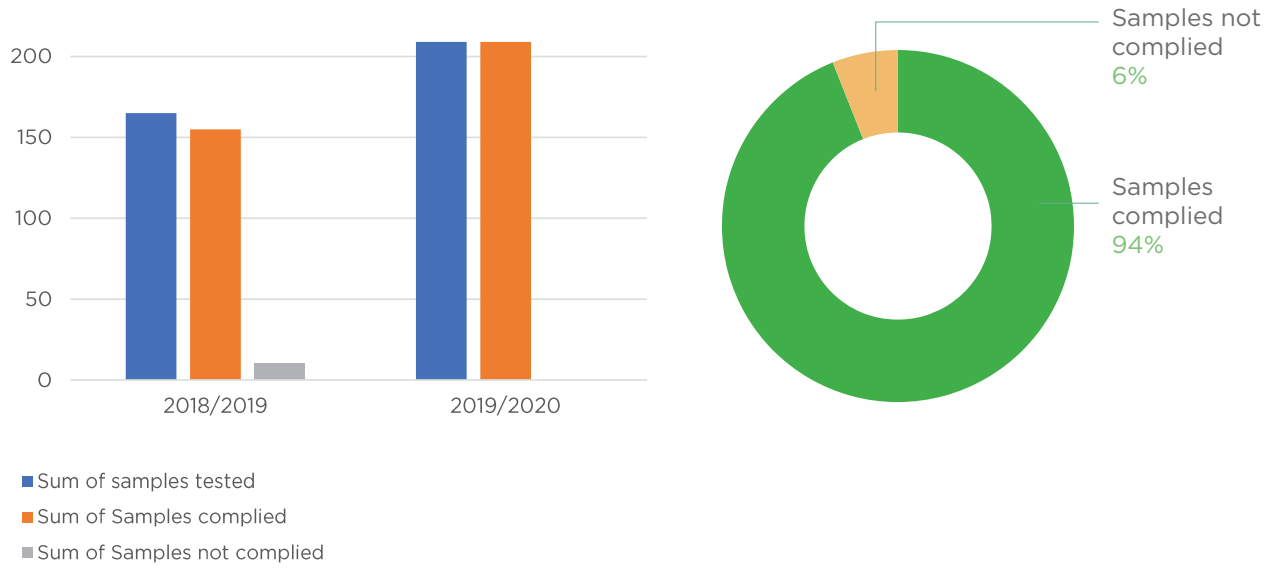
ID- Identification test parameter

Joint Post Marketing Surveillance of products for HIV, TB, Malaria and Reproductive Health

Product categories surveyed were FP products, HIV/AIDS products, TB products, Malaria products and Male latex condoms. Joint 2018/2019 surveyed 165 products while 2019/2020 surveyed 209 products in 47 counties

Year of survey	Total number of samples tested	Number of samples that complied	Number of samples that failed to comply
2018/2019	165	155	10
2019/2020	209	209	0
Total	**374**	**364**	**10**

Graph and Chart showing the compliance rates of medical products and health technologies with specifications and/ or standards



Post- marketing Surveillance of antimalarial products in Kenya, 2019/2020

583 samples were sampled from twelve (12) Counties (Malaria endemic and Malaria epidemic Counties). All samples (100%) complied with the test parameters analyzed.

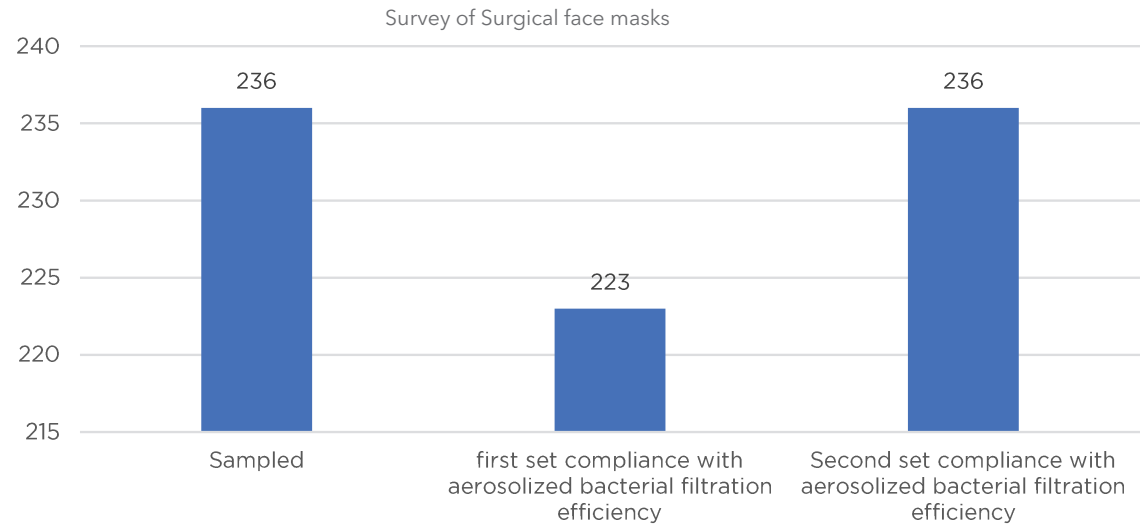
Post marketing Quality surveillance of alcohol-based sanitizers (ABHS)- 2020

The survey found that **98.75%** of the samples collected (n=80), complied with KEBS standard on alcohol concentration. The samples were collected from twenty-one Counties.

Post Marketing Surveillance of surgical face masks, 2020

236 surgical face masks were sampled from 39 counties. They were tested against KS: 2636:2016 on aerosolized bacterial filtration efficiency. The results are as follows;

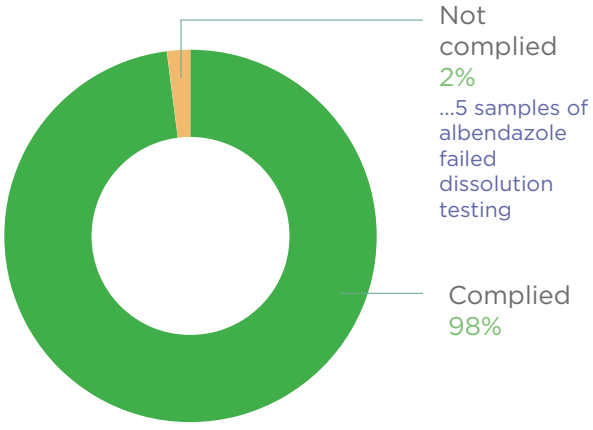
Graph showing compliance of surgical face masks with standards



Risk based post marketing quality surveillance of selected medical products in Kenya, 2021.

309 medical products were sampled from 20 counties and subjected to testing. The drug products included; Albendazole, Azithromycin, Benzylpenicillin, Carbamazepine, Ceftriaxone, Enalapril, Furosemide, Metronidazole and Warfarin.

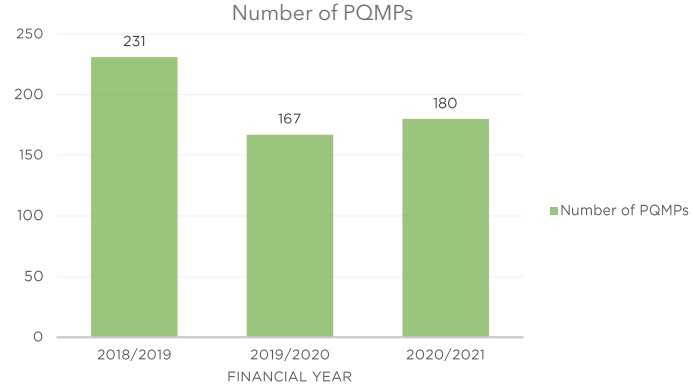
Chart showing percentage compliance of the medical products with specifications



2. Number of Poor-Quality Medical Products (PQMPs) reports disaggregated in years

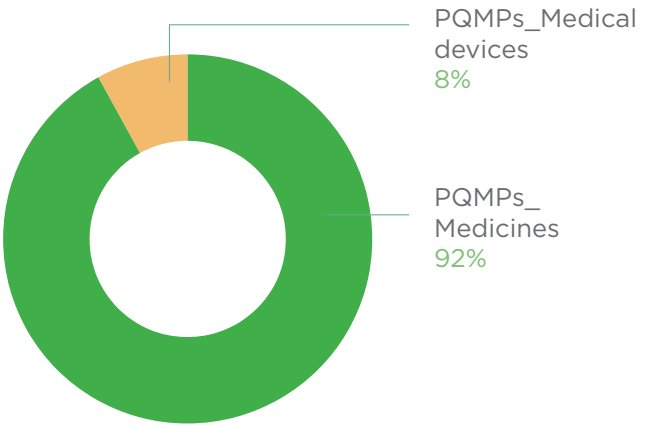
Financial Year	Number of PQMPs	Percent
2018/2019	231	40%
2019/2020	167	29%
2020/2021	180	31%

Graph showing PQMPs disaggregated in years



Disaggregation of PQMPs reported in FY 2020/2021 based on several parameters i.e., type of product, innovator vs generic, imported vs locally manufactured

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



PQMP_Medical devices (n=14), PQMP_Medicines (n=159)

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

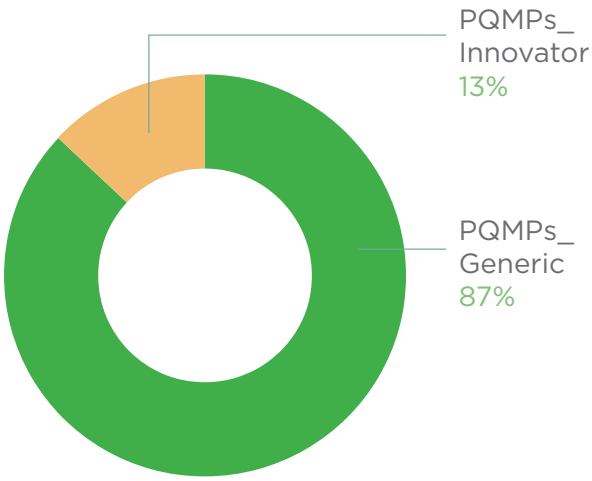
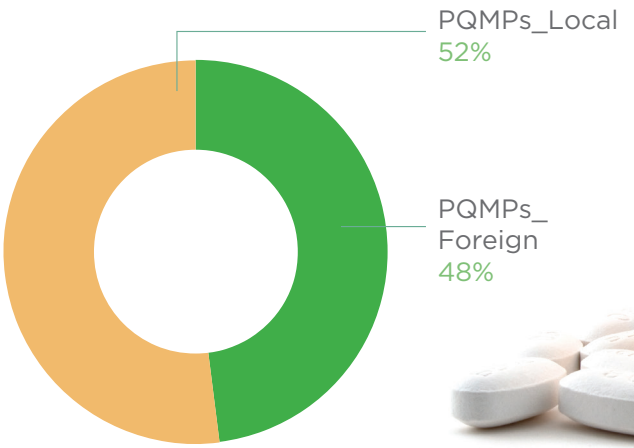


Chart showing proportion of poor-quality reports that comprised medical products that were locally manufactured vs imported.

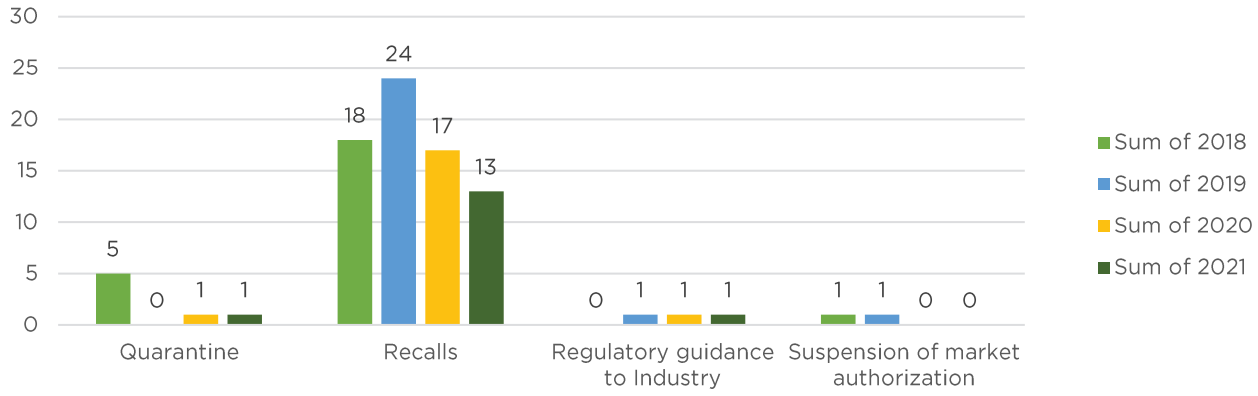


3. Regulatory actions Per Year

Table showing distribution of regulatory actions from 2018 to 2021

Regulatory Action	2018	2019	2020	2021
Quarantine	5	0	1	1
Recalls	18	24	17	13
Regulatory guidance to Industry	0	1	1	1
Suspension of market authorization	1	1	0	0
Total	**24**	**26**	**19**	**15**

Graph showing distribution of regulatory actions from 2018 to 2021



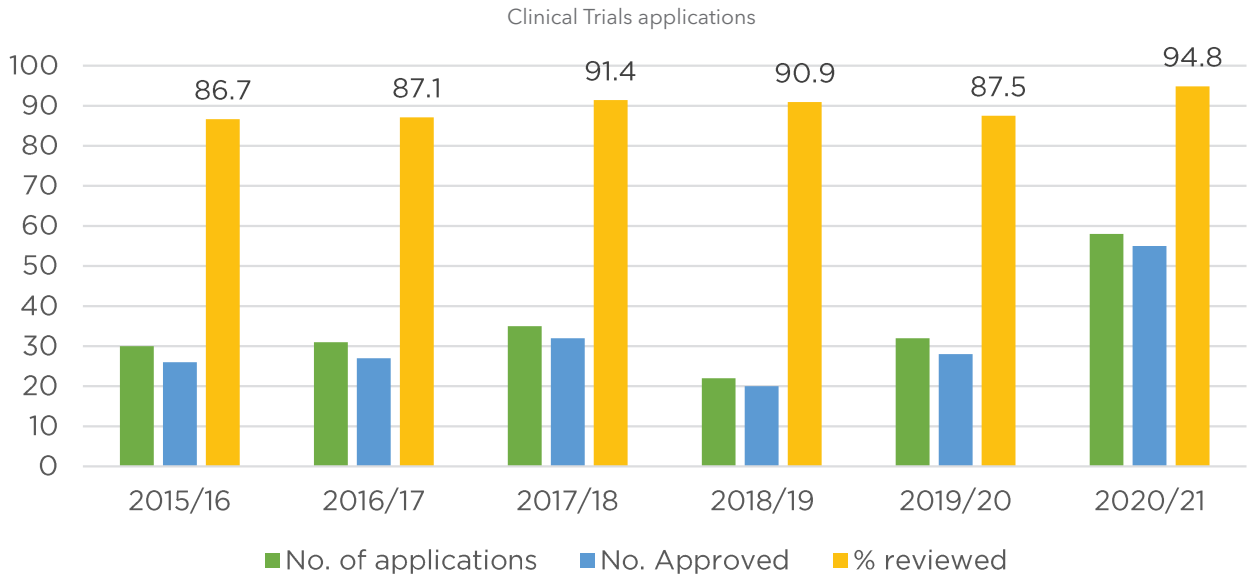
4.2.2.2. Clinical Trials

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 on 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 2020- June 2021), a total of 58 new clinical trial applications were received and reviewed. The details of these clinical trials can be seen at www.ctr.pharmacyboardkenya.org

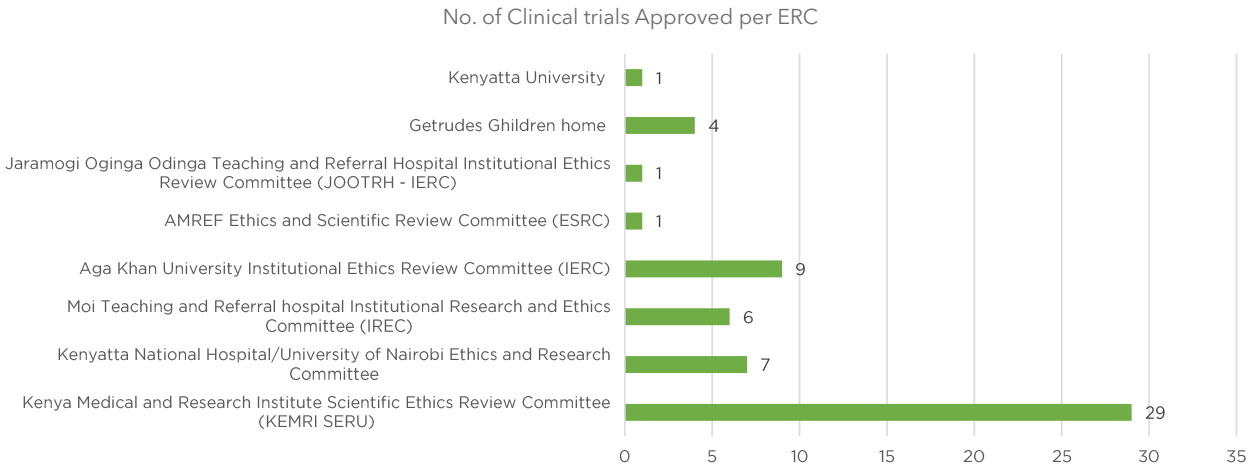
The summary below shows an analysis of this data for the last five years with an indication of compliance to the review timelines.

CT Applications in the last 5 years



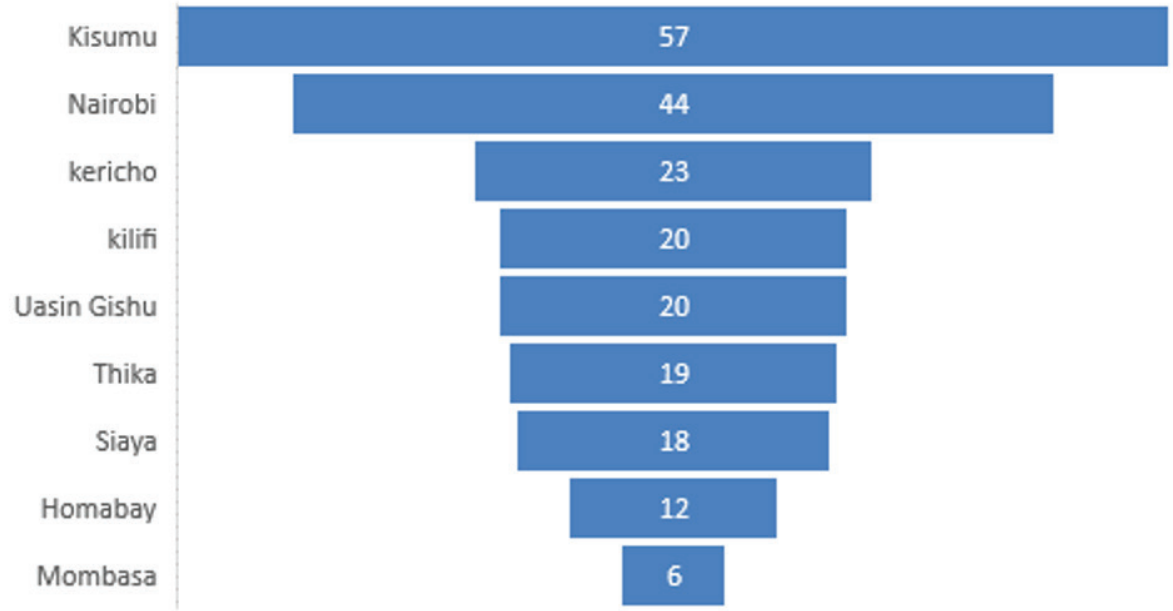
The figure below provides a summary of the of Ethics Review Committees (ERCs) that provided favorable opinions for the conduct of the studies.

Number of Approvals by Ethics Review Committees



The clinical trials were conducted in clinical sites as distributed in the figure below.

Number of Trials per County



During the review period, clinical trials were conducted for various disease conditions, with more attention focused on some disease conditions due to high morbidity, epidemics, or pandemics. The trials were conducted for different objectives with the aim of investigating the therapeutic, prophylactic or testing nature of different product types. Medicines Information and Resource Centre

1. Brief narrative of the total number of applications for advertisements and promotions received, reviewed, and approved in the 2020/2021 financial year disaggregated into;

a) Local and foreign manufactured

Total Number of applications received is 1550
Total Number of applications reviewed are 1138
Total Number of applications queried are 76
Total Number of applications approved are 1062
Total Number of applications not paid for 412

Out of the 1138 products reviewed, the number of local and foreign manufactured products were 109 and 953 respectively.

b) Innovator and generic product

Explainer: For the financial year 2020/21, we did not have data segregated into innovator and generic. This is because;

a) The information had not been populated and uploaded in the drug registration portal so that our online system could pick the information automatically as a drop-down menu when keyed in by the MAH.

b) During development of the online advertisement portal, we did not consider to include innovator and generic parameters.

Next course of action

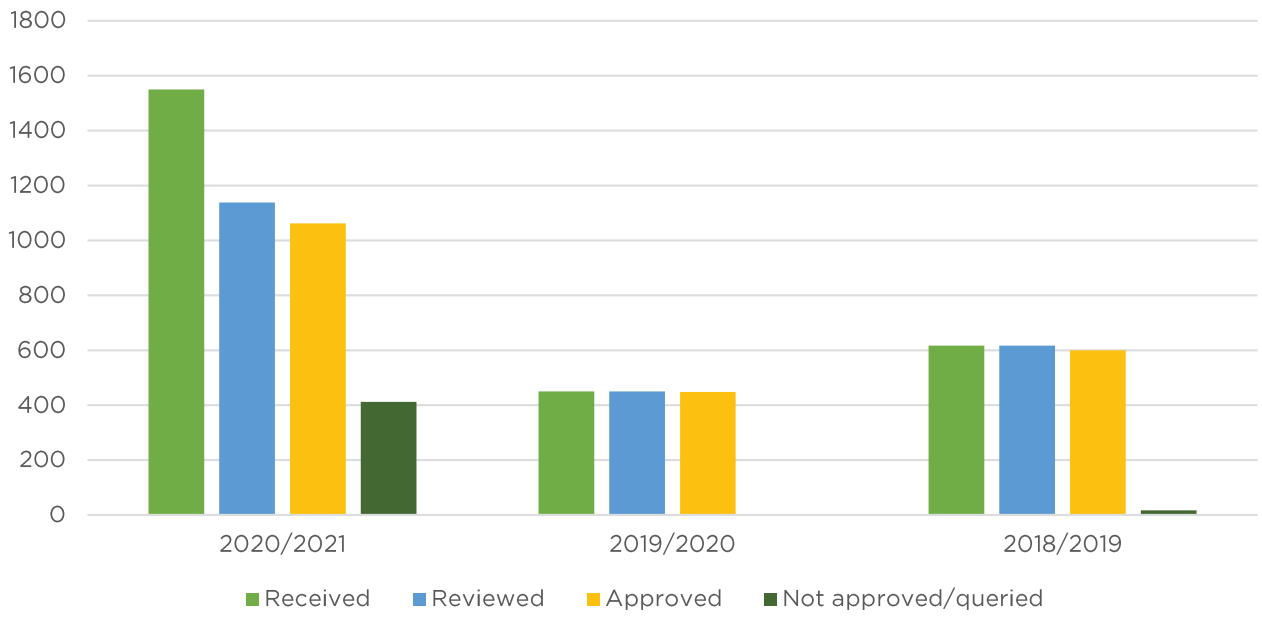
a) Deficiency noted and notified to the developer.

b) Drug registration to fast track completion of the wallets that contain this information.

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

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

Number of adverts received and reviewed



3. As a baseline KPI for this department indicate

a) On average how long, it took for initial review and to approve an application in the 2020/21 FY 7 Days.

b) The current backlog is 150

4. Indicate any progress made on

a) Scheduling guidelines

Draft guidelines have been completed pending QMS review and launch. QMS department are reviewing their SOPs and therefore until approved is when we can use the approved format on the guideline.

b) Setting up a resource centre

Concept note for establishing resource centre and meeting report has been finalized awaiting to be presented to the management

4.2.3. Inspectorate and Enforcement

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

4.2.3.1. Enforcement and Surveillance

I. 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 2020/21FY period DIE implemented activities meant to ensure compliance with regulations and the Law in order to protect and maintain the integrity of the Health Products and Technologies supply chain as per the table below.

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

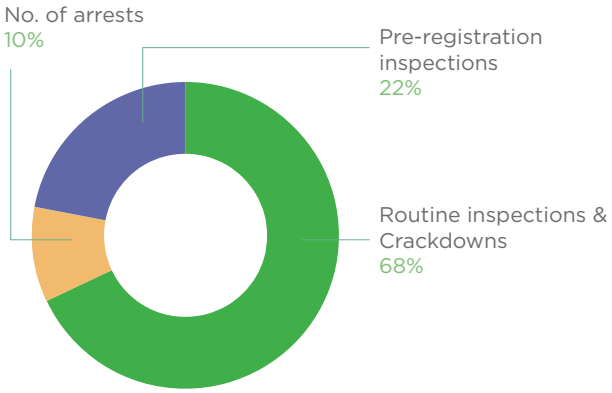
Summary of activities and achievements

S/No.	Activity	Measure	Achievement
1.	Conduct routine compliance inspections of the licensed pharmaceutical premises to reduce incidences of violations	Number	4274
2.	Conduct targeted National crackdowns to weed out illegal pharmaceutical outlets and practitioners	Number	10
3.	Carry out Pre-registration inspections	Number	1405
4.	No. of unauthorized practitioners arrested and prosecuted	Number	600
5.	Verification of all imported/exported HPTs at all Gazetted POEs	Number of inspections	11,053
6.	Stopped consignments at POE	Weight (Kgs)	7,660
7.	To investigate, gather intelligence and take regulatory actions on pharma crime offenders	Number of operations	71
8.	Pharma crime offenders arrested and prosecuted	Number	11
9.	Disposal of Pharmaceutical Waste	No. of certificates	172

Inspection activities

S/No.	Activity	Outcomes (Number)
1	Routine inspections & Crackdowns	4274
2	No. of arrests	600
3	Pre-registration inspections	1405

Diagramatic representation of inspection activities



Disposal of Pharmaceutical waste

In pursuing the aims of reducing health problems, healthcare services inevitably create pharmaceutical 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.

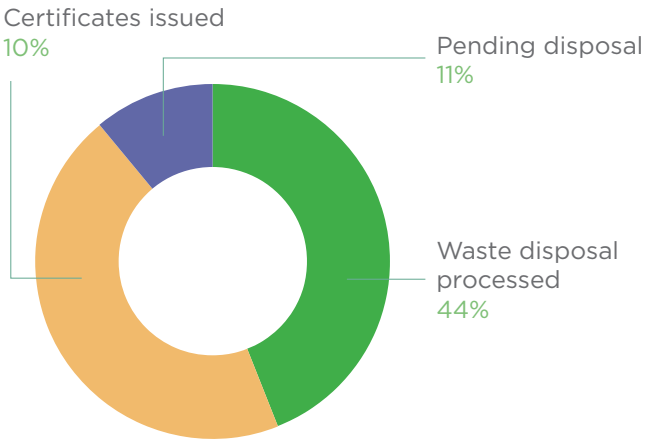
During the year under review, applications, verification and supervision of waste disposal was done as per the table below.

The pending disposals is as a result of factors relating to the capacity of the approved incinerators.

Pharmaceutical waste disposal activities

S/No	Activity	No processed	Certificates issued	Pending disposal
1	Verification and supervision of waste disposal	177	177	43

Pharmaceutical Waste Disposal outcomes



II. Drug Crime Investigations

Office of Drug Crime Investigation (ODCI) is the investigative arm of the DIE responsible for investigating pharma crime offences 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.

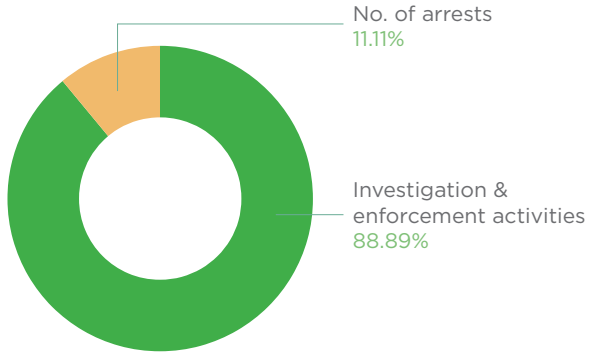
Functions

i. Breaches in the legitimate HPTs supply chain by individuals and organizations dealing in unapproved, counterfeit, falsified and substandard medical products.
ii. Criminal violations in situations where the normal regulatory process has been unable to remedy the problem.
iii. 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.
iv. 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
1	88	11

Summary of investigation and enforcement outcomes



4.2.3.2. 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 medica products and technologies legislations (policies, laws, rules, regulations) to ensure conformity to good manufacturing practice standards and good clinical research practices in line with the mission of PPB Pharmacy and Poisons Act, CAP 244.

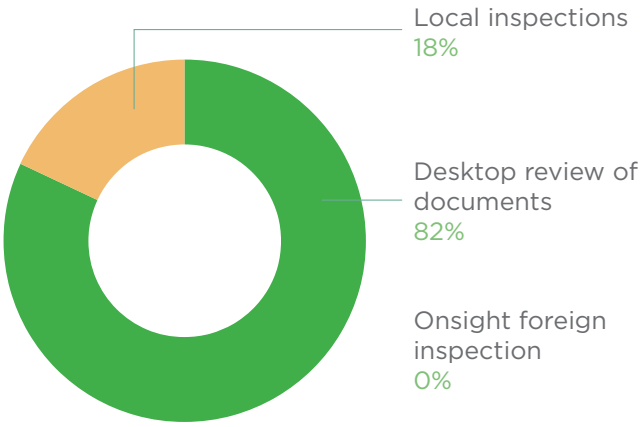
Objective: To foster the integrity of the supply chain of health products and technologies through monitoring, inspection, verification, investigation and enforcement of Pharmacy and Poisons Act, and regulation.

S/No.	Activity	Measure	Achievement
1.	Conduct onsite GMP inspections of Local manufacturing facilities for Health products and Technologies	Number	30
2.	Conduct onsite inspections of Foreign manufacturing facilities for Health Products and Technologies	Number	0
3.	Conduct Desktop Document reviews of Foreign manufacturing facilities for Health Products and Technologies	Number	136

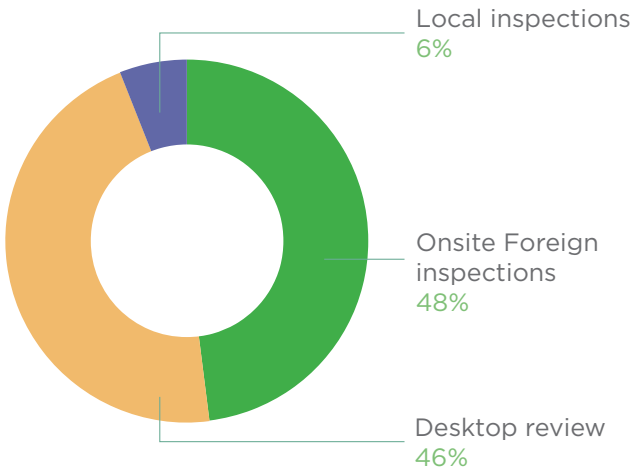
During the financial year 2020 – 2021, there were no onsite inspections carried out for foreign manufacturers of HPT due to travel restrictions imposed because of Covid-19 pandemic.

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

GMP Inspections in the finacial year 2020-2021



GMP Inspections in the financial year 2019-2020



4.2.3.3. 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.

Functions

i To regulate and control the importation of medicinal products, medical devices, Lab reagents, precursors and cosmetics through pre-clearance inspections

ii Verification of import/export documents before issuance of pre-release stamps

iii Conduct surveillance at all inland Ports/ international borders

iv Sampling of profiled products

v Conduct basic screening

Achievements at the two major POEs

a) Jomo Kenyatta International Airport (JKIA)

Total number of verifications conducted=**10,846**

COVID-19 Vaccines report

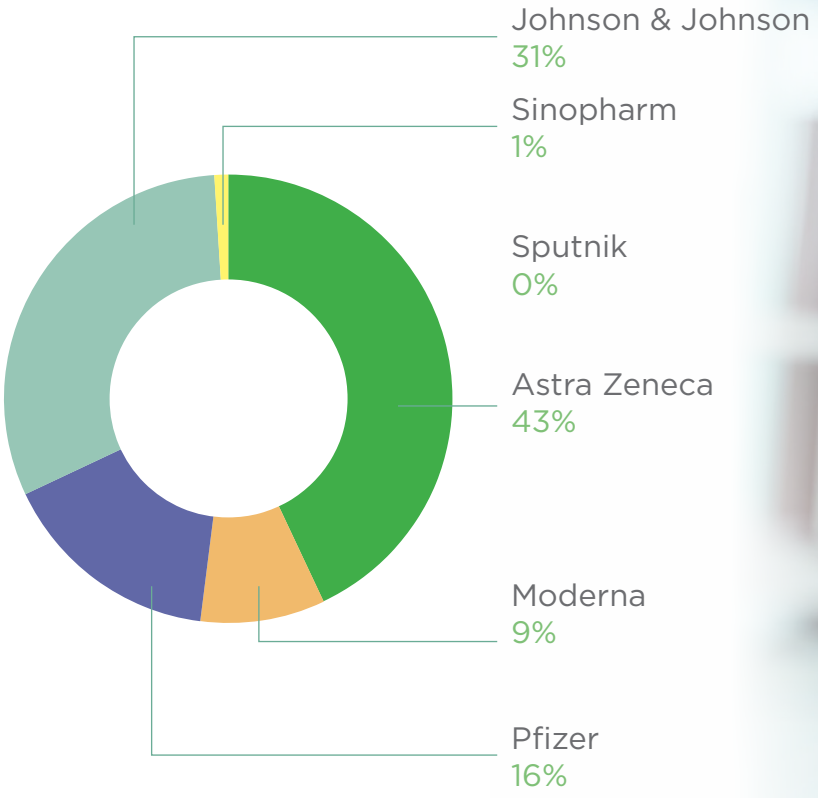
In order to maintain the integrity of the imported vaccines, PPB inspectors at JKIA together with other relevant stakeholders promptly conduct pre-clearance verification through sighting and immediate release of the vaccines for onward delivery to the KEMSA National stores in Kitengela for storage in line with the manufacturer's recommendations.

As of December, 11th December, 2021, POE inspectors at JKIA had sighted and approved for release 23,311,112 assorted doses as per the table below

COVID 19 Vaccines sighted released at JKIA as of 11th Dec 2021

S/NO	VACCINE BRAND	NO OF DOSES	STATUS
1	Astra Zeneca	9,591,760	Released
2	Sputnik	75,000	Released
3	Moderna	1,992,560	Released
4	Pfizer	4,630,442	Released
5	Johnson & Johnson	7,021,350	Released
6	Sinopharm	200,000	Released
Total		22,311,112	

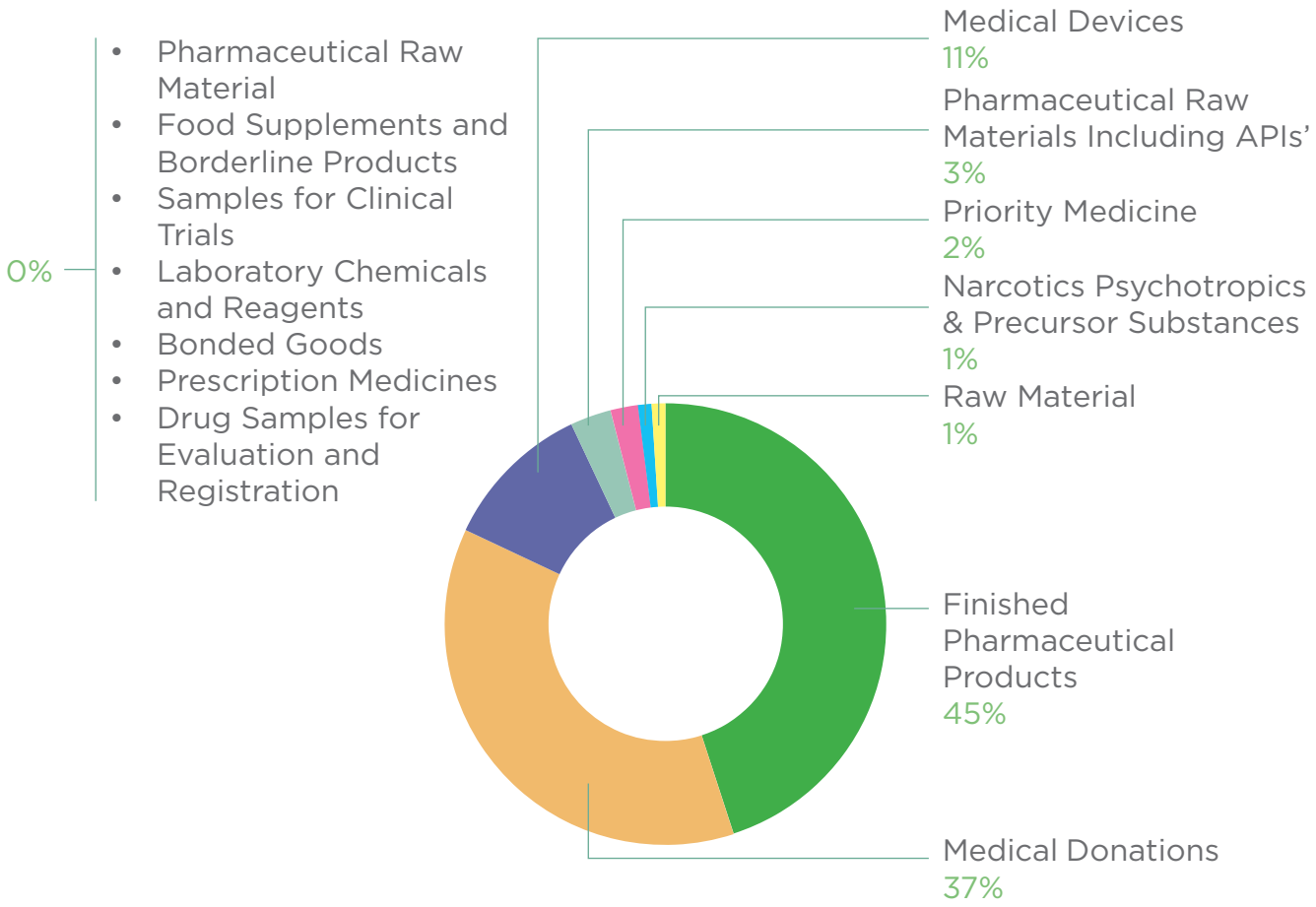
COVID 19 Vaccine representation by Brand and parcentage of imports



Imports

No.	PRODUCT DESCRIPTION	GROSS WEIGHT(Kgs)
1	Finished Pharmaceutical Products	1665061
2	Medical Donations	1380045
3	Medical Devices	410162
4	Pharmaceutical Raw Materials Including APIs'	123882
5	Priority Medicine	56138
6	Narcotics Psychotropics & Precursor Substances	20840
7	Raw Material	14280
8	Pharmaceutical Raw Material	9465
9	Food Supplements and Borderline Products	4843
10	Samples for Clinical Trials	4352
11	Laboratory Chemicals and Reagents	3621
12	Bonded Goods	3049
13	Prescription Medicines	3017
14	Drug Samples for Evaluation and Registration	2786
Total		**3,701,541**

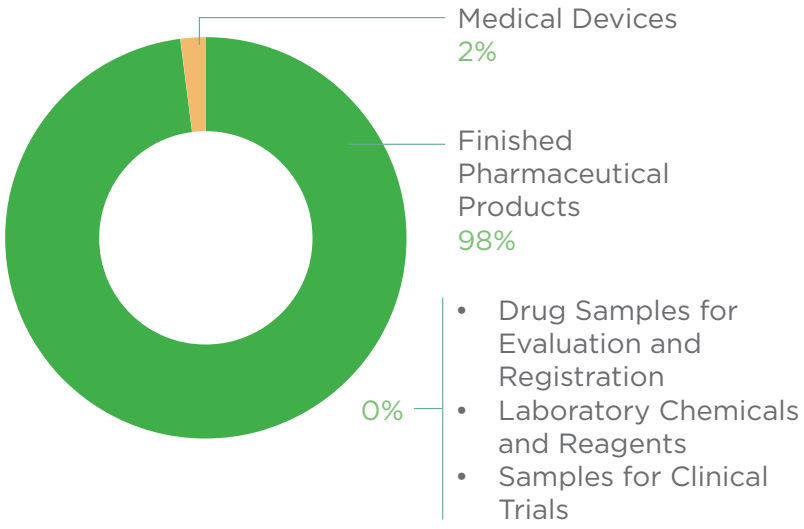
Volume (Kgs) of Imports processed at JKIA by percentage



Exports

No.	PRODUCT DESCRIPTION	GROSS WEIGHT(Kgs)
1	Drug Samples for Evaluation and Registration	112
2	Finished Pharmaceutical Products	334835
3	Laboratory Chemicals and Reagents	388
4	Medical Devices	6448
5	Samples for Clinical Trials	1422
	Grand Total	**343242**

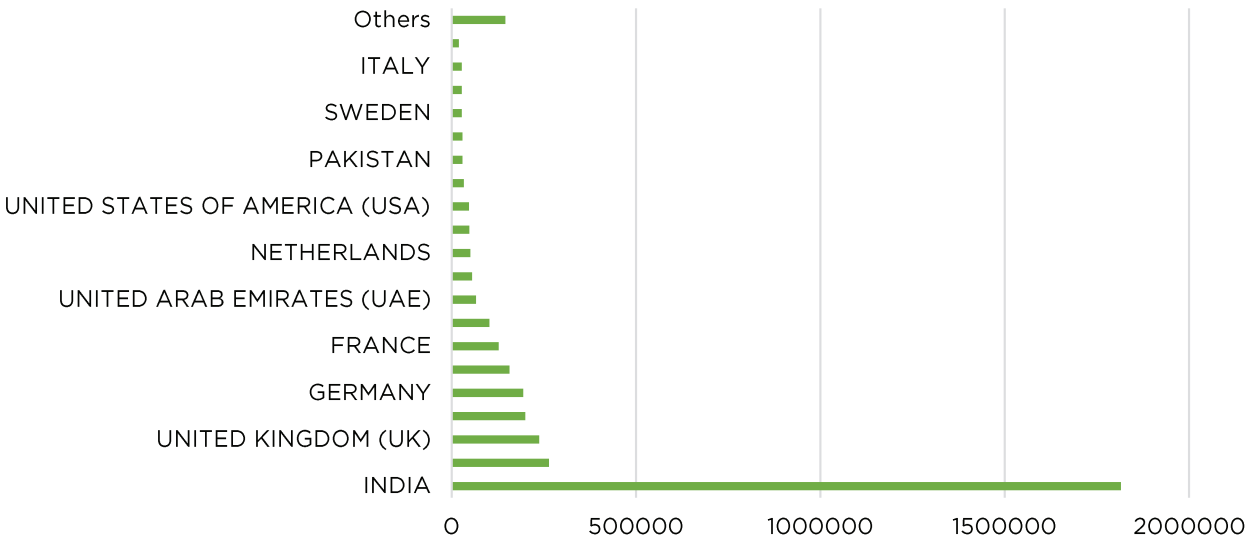
Volume (kgs) of exports by type at JKIA



Listing of country of origin and gross weight received

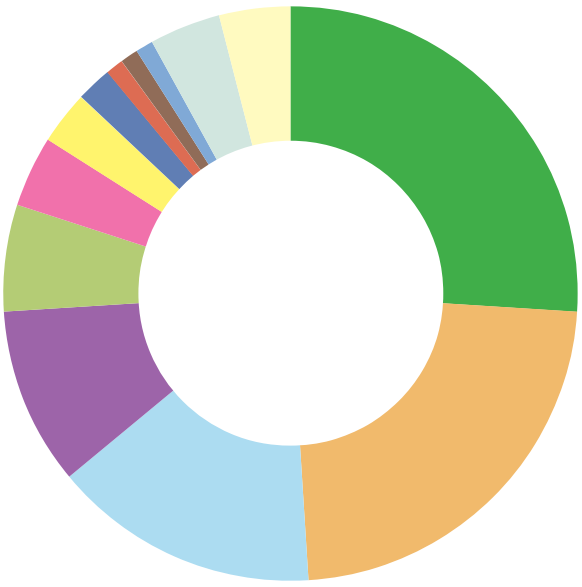
No.	Country of Origin	Gross Weight (Kgs)
1	India	1815451.1
2	South Africa	263754
3	United Kingdom (UK)	237150.5
4	Switzerland	199869
5	Germany	194020
6	Belgium	156900
7	France	127373
8	China	102119
9	United Arab Emirates (UAE)	66097.4
10	Denmark	55397
11	Netherlands	50730
12	Austria	47837
13	United States of America (USA)	47135
14	Bangladesh	33087
15	Pakistan	29443
16	Ireland	29286
17	Sweden	27404
18	Slovenia	27351
19	Italy	27137
20	Hungary	19380
21	Others	145616
	Grand Total	**3702537**

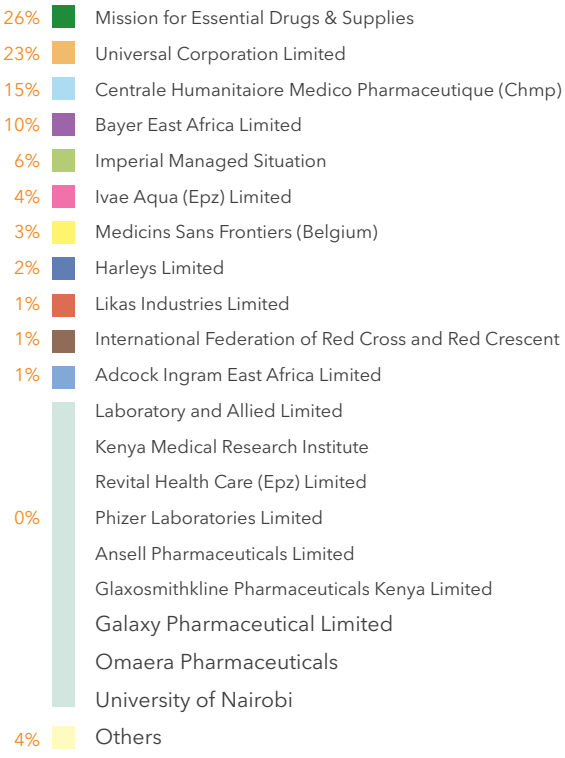
Volume (Kgs) of imports by Country of origin at JKIA



Summary of Exports by Exporter and Total Gross Weight

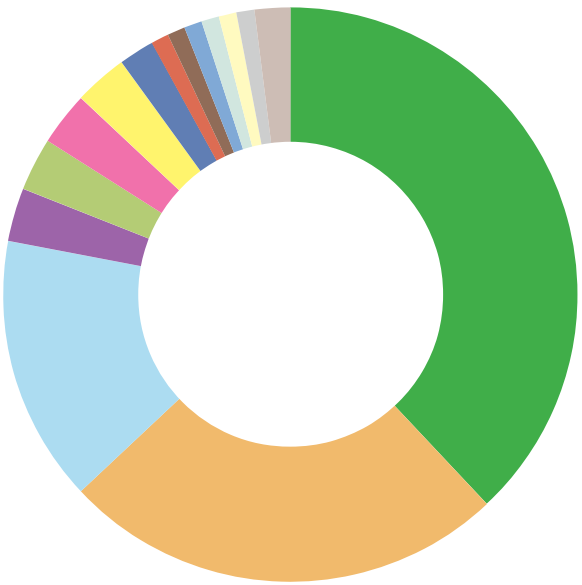
No.	Exporter/Consignor	Gross Weight(Kgs)
1	Mission for Essential Drugs & Supplies	90708
2	Universal Corporation Limited	79878
3	Centrale Humanitaiore Medico Pharmaceutique (Chmp)	53192
4	Bayer East Africa Limited	35328
5	Imperial Managed Solution	19652
6	Ivae Aqua (Epz)Limited	15364
7	Medicins Sans Frontiers (Belgium)	9236
8	Harleys Limited	7323
9	Likas Industries Limited	3180
10	International Federation of Red Cross and Red Crescent	2220
11	Adcock Ingram East Africa Limited	1885
12	Laboratory and Allied Limited	1673
13	Kenya Medical Research Institute	1322
14	Revital Health Care (Epz)Limited	1256
15	Pfizer Laboratories Limited	1115
16	Ansell Pharmaceuticals Limited	1000
17	Glaxosmithkline Pharmaceutical Kenya Limited	963
18	Galaxy Pharmaceutical Limited	952
19	Omaera Pharmaceuticals	845
20	University of Nairobi	732
21	Others	15419
	Grand Total	**343242**





Summary of Country of Destination and Gross weight

No.	Country of Destination	Gross Weight (Kgs)
1	Ethiopia	128912
2	South Africa	84768
3	Niger	51951
4	Iraq	10372
5	Equatorial Guinea	10284
6	Egypt	9307
7	Mauritius	9237
8	Germany	5954
9	Cyprus	4615
10	Denmark	4247
11	Netherlands	2694
12	Malaysia	2654
13	United States of America (USA)	2025
14	India	2013
15	Canada	1375
16	Czech Republic	1091
17	Israel	1054
18	Australia	949
19	Belgium	823
20	Spain	791
21	Others	8125
	Grand Total	**343242**



38% Ethiopia
25% South Africa
15% Niger
3% Iraq
3% Equatorial Guinea
3% Egypt
3% Mauritius
2% Germany
1% Cyprus
1% Denmark
1% Netherlands
1% Malaysia
1% USA
1% India
Canada
Czech Republic
0% Israel
Australia
Belgium
Spain
2% Others

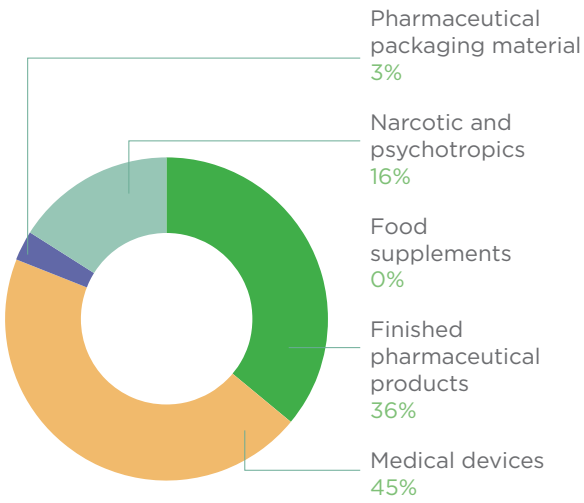
b) Inland Container Depot-Nairobi (ICD-N)

The total number of verifications was **207**

Summary of activities at ICD-N

S/No	Product category	Weight (Kgs)	Approx. Value (USD)
	Finished pharmaceutical products	526941	7159522
	Food supplements	3193	12,330
	Medical devices	662000	1628108
	Pharmaceutical packaging material	39544	54012
	Narcotic and psychotropics	227512	1954683
	Total	**1455997**	**10799518**

Representation of imports by weight(Kgs) at ICD-N



Consignments Stopped/Quarantined at Importers Warehouse

S/No	Importer's Name	Product Description	Batch No.	Remarks
1	Tenwek hospital, Bomet 1x20ft MAGU2491530 CUSTOMS ENTRY 2020ICD250449	Medical Devices		Donation import permit no.CD2074606 All products in the container expired and seized at the port
2	Catholic diocese of Kakamega 1X40FT NWHU 8481284 CUSTOMS ENTRY 2020ICD254099	Medical devices		No Import Permit All products were expired and seized at the port
3	Surgipharm Ltd	Esome 20	302C12	The products were short expiry. Consignee asked to apply and organize for destruction
4	Signature Ltd	Ciprocor 500		Product was not retained, seized from the consignment
5	Imperial managed solutions	Natural latex condoms with reservoir		Released under seal
6	Laborex Kenya	Amlozaah H		Products were short expiry Released vide letter PPB/INS/GDP/LET/273/20-21 dated 18TH FEB 2021

4.2.4. Pharmacy Practice Directorate

4.2.4.1. Training and Continuing professional Development

CPD Unit

Continuing Professional Development (CPD) is an internationally accepted approach that facilitates professionals to gain the knowledge, skills and attitudes to remain current and competent in their practice.

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.

The functions of the unit include

- Regulate, monitor and inspect personnel and premises that are involved in CPD, training and pharmacy practice
- Accreditation of CPD providers
- Approval of CPD programs and events

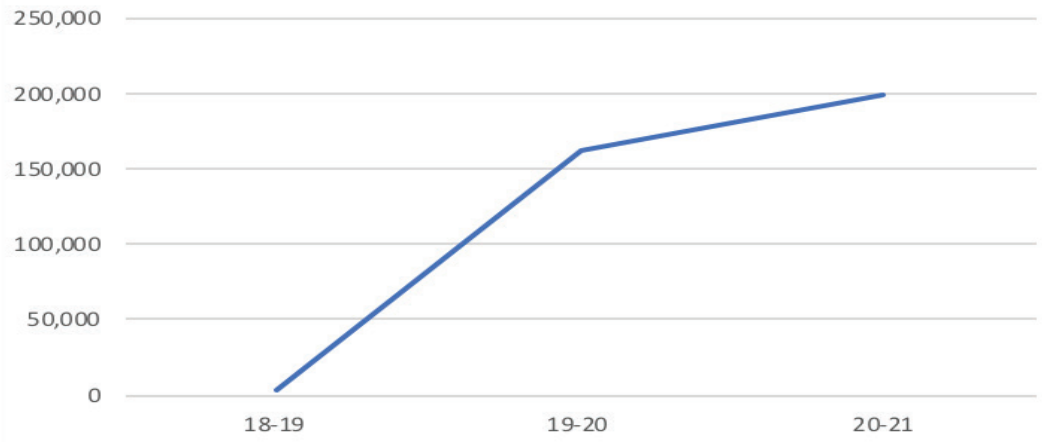
Achievements

- Increase number of CPD providers, programs and events
- Increase number of professionals undertaking CPD

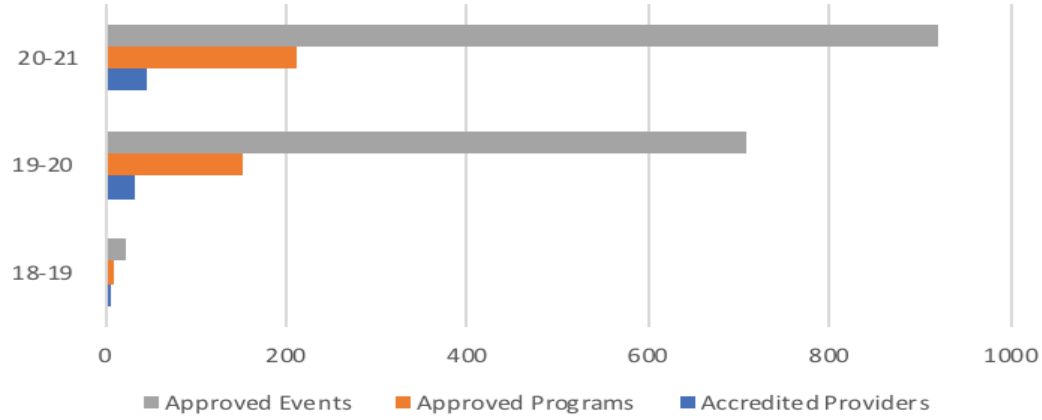
The table below indicates the improvements made in the last three financial years, between July 2018 and June 2021.

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

Trends in CPD Uptake (Participants)



Trends in CPD Provision



Training Unit

The functions of the unit include are to:

- Advance the standards of pharmacy training and practice in Kenya.
- Formulate, implement and review the educational, scientific and professional principles and standards for professional programs in pharmacy
- Evaluate the pharmacy training programmes 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 2021:

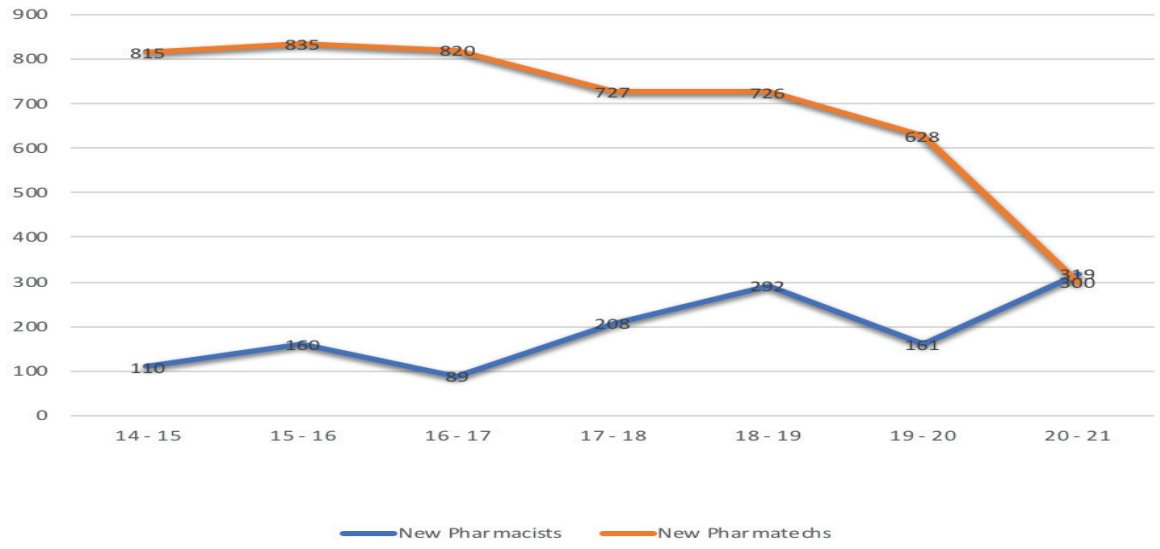
S/No	Course	Public	Private	Total
1	Degree programme	3	4	7
2	Diploma programme	20	2	22

Registration and Enrolment Trends

The table and graph below show the trends in the Registration and Enrolment of pharmacists and pharmaceutical technologists respectively. Whereas there is an increase in pharmacists registered per year, a decline is observed for 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
Cumulative total	**3684**	**10943**

Trends in new registered and enrolled personnel



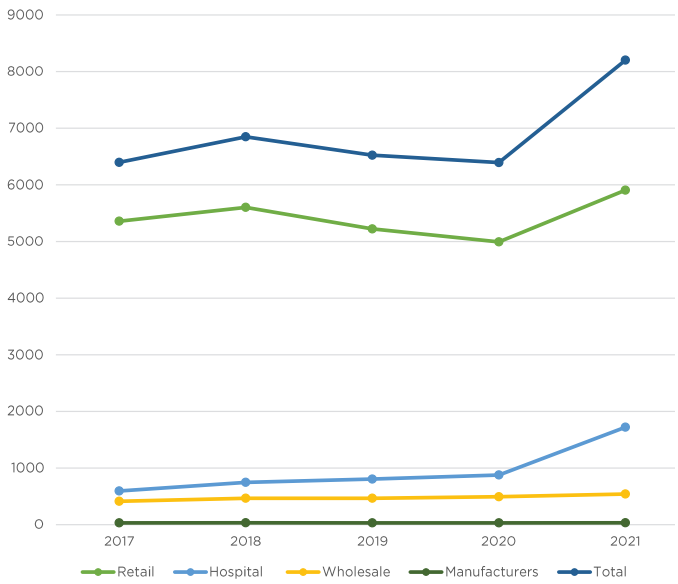
4.2.4.2. Licensing & Good Pharmacy Practice

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. Pharmacy businesses can only operate on registered premises. Registered premises details are entered onto the Register on confirmation of satisfactory inspection of premises. Approval is subject to meeting the requirements provided in Guidelines for Good Distribution Practices for medical products and health technologies in Kenya. Premise licenses are renewable every year. The table below shows the trends in licenses issued over the last five years

Premise licenses issued by year

	2017	2018	2019	2020	2021
Retail	5358	5603	5222	4993	5907
Hospital	595	747	805	877	1721
Wholesale	413	466	466	493	541
Manufacturers	31	33	31	31	33
Total	**6397**	**6849**	**6524**	**6394**	**8202**

Premise licenses issued by year



Trend in new premise applications

2017	2018	2019	2020	2021
1408	1280	606	758	2040

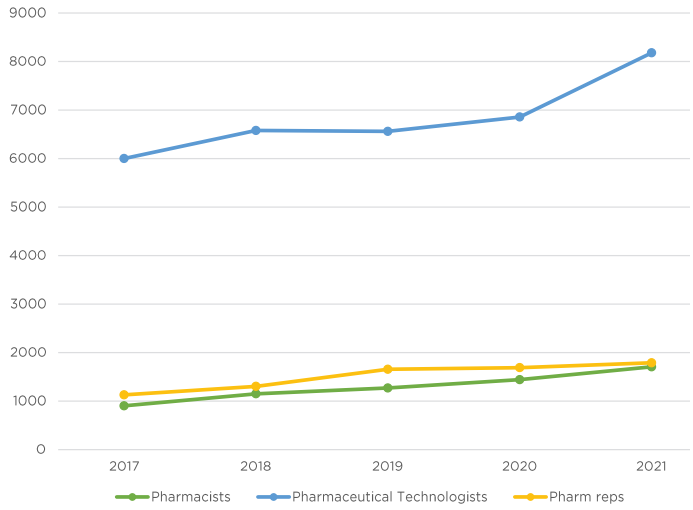
There was a big increase in new premises applications in 2021. This was mainly due to increase in hospital pharmacies getting licenses

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 5 years.

Practice license	2017	2018	2019	2020	2021
Pharmacists	903	1150	1270	1442	1707
Pharmaceutical Technologists	6000	6578	6560	6856	8179
Pharm reps	1129	1304	1656	1690	1790

Practice licenses and pharm rep permits



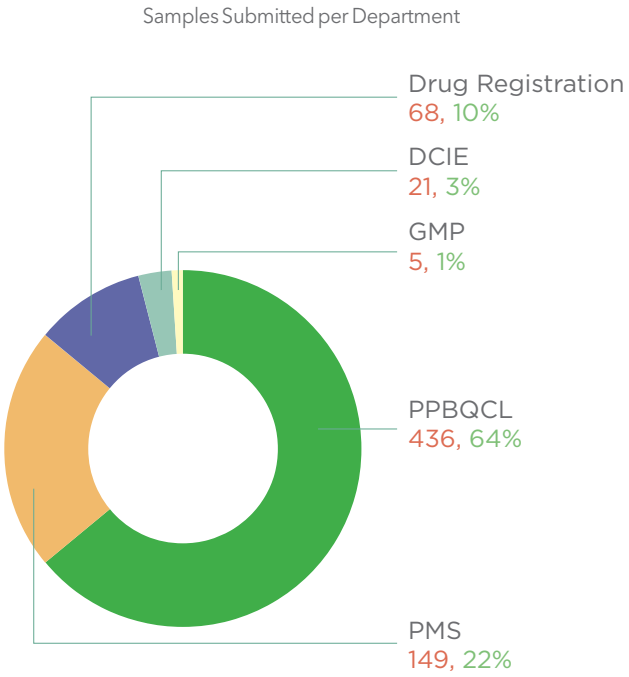
4.2.5. Quality Control Laboratory Directorate

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.

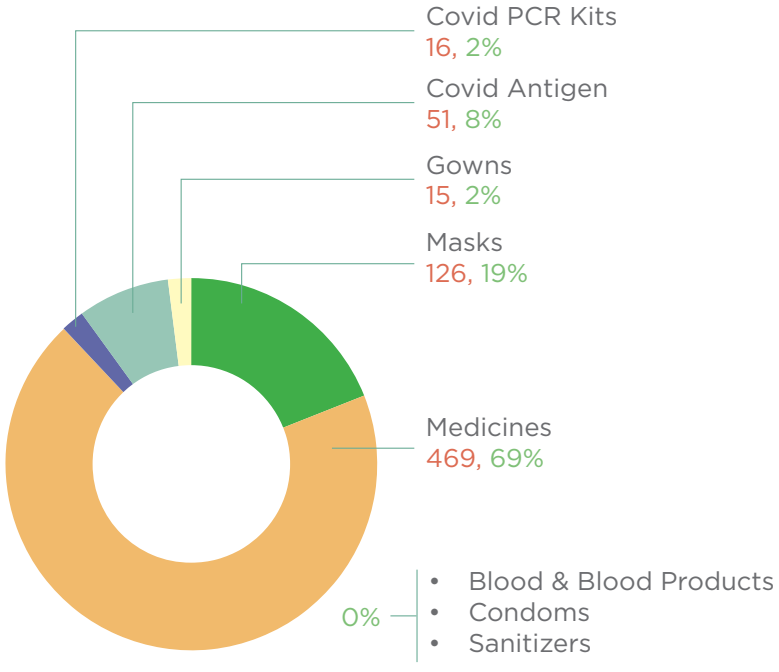
In the FY 2020/2021 the PPBQC laboratory formalized its sampling and testing program while establishing a quality management system appropriate for a National Regulatory Authority analytical testing laboratory. Once its QMS is fully established, the lab expects to be ISO certified in the FY 2021/2022.

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

Samples received disaggregated by departments

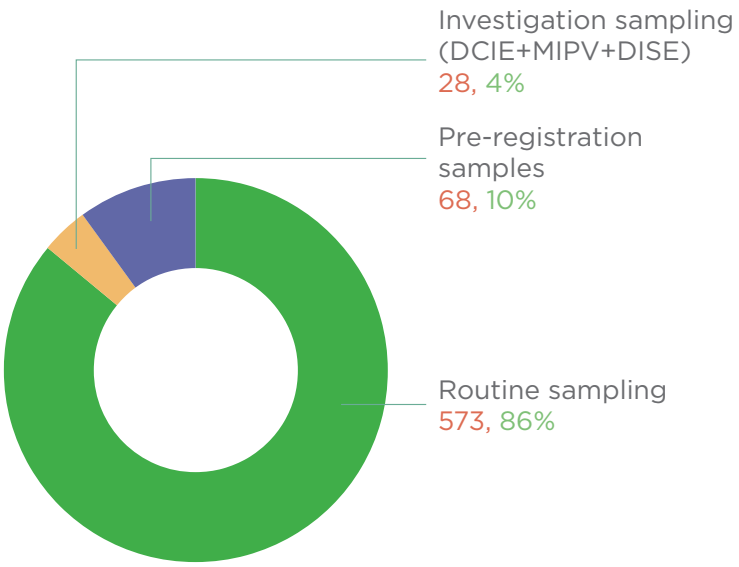


Products evaluated disaggregated by product type



Product evaluated based on objective of sampling

Product evaluated disaggregated by objective of sampling



a) FY2021/2022 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.

4.3. Corporate Affairs Directorate

4.3.1. 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 developing 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;

4.3.2. 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 team work 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.

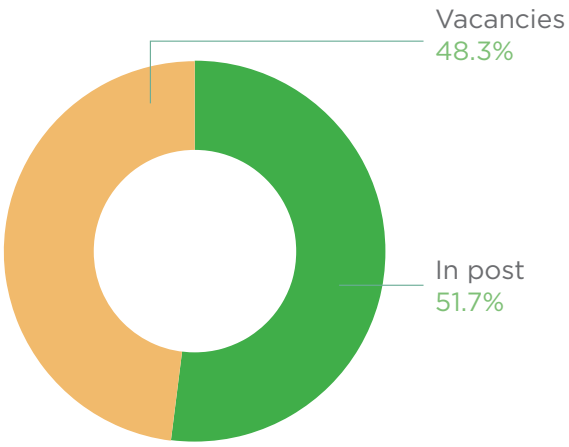
I. Achievements

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

II. Staff establishments

Number	Approved establishment	In-post	Vacancies
All cadres	352	180	172

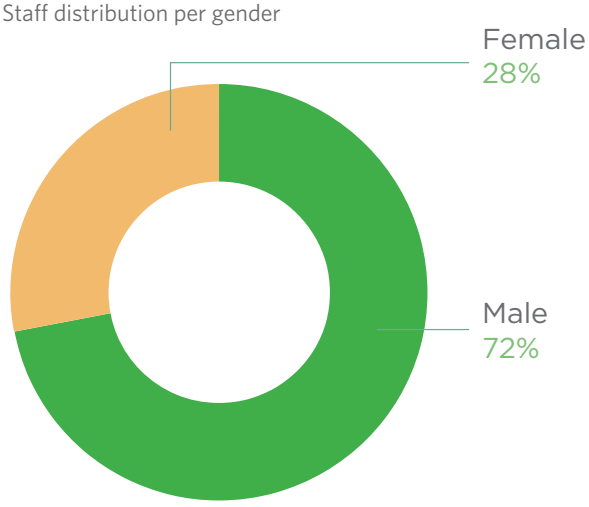
Staff establishment



III. Staff distribution per gender

Staff Gender	Number per gender
Male	129
Female	51
Total	180

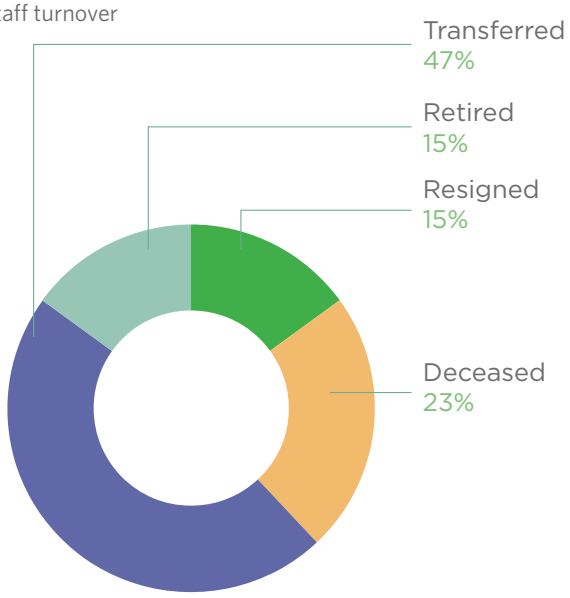
Staff distribution per gender



IV. Staff turnover

S/NO	Number of staffs that have exited	Reasons
	2	Retired
	3	Deceased
	6	Transferred
	2	Resigned
Total	13	

Staff turnover



The department has also made strides in realizing gender mainstreaming as listed below;

1. Constitution of the Gender and Disability Mainstreaming Committee;
2. Sex data disaggregation: The PPB data on sex-disaggregation of all the employee of the Board and other attributes age groups, disability, professional cadres (Pharmacist and Pharmaceutical technologies) and appointed to the management positions were analyzed. The following observations were made;
   i. The ratio of Male to female staff at PPB is 124:46; which translate to 73% males and 27% females
   ii. For staff seconded from Ministry of Health, 77% are males those directly employed by PPB, (68% are males)
   iii. For the regional distribution 82% are males- this means the females are few at the regional offices
3. Draft Policy on Gender Mainstreaming and Gender-Based Violence

Sensitization of PPB members of staff on Gender Mainstreaming; A brief sensitization session was organized for the PPB staff on Gender Mainstreaming through a zoom meeting scheduled for the 25th from 12hrs for 2 hours

4.3.3. 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:

1. PRIMS – PPB Regulatory Information Management Services portal
2. OSS - Online Services Portal
3. Clinical Trials
4. Pharmacovigilance
5. Pharmacy Practice
6. RHRIS – Regulatory Human Resources Information System
7. 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.

4.3.4. Corporate Communications Division

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;

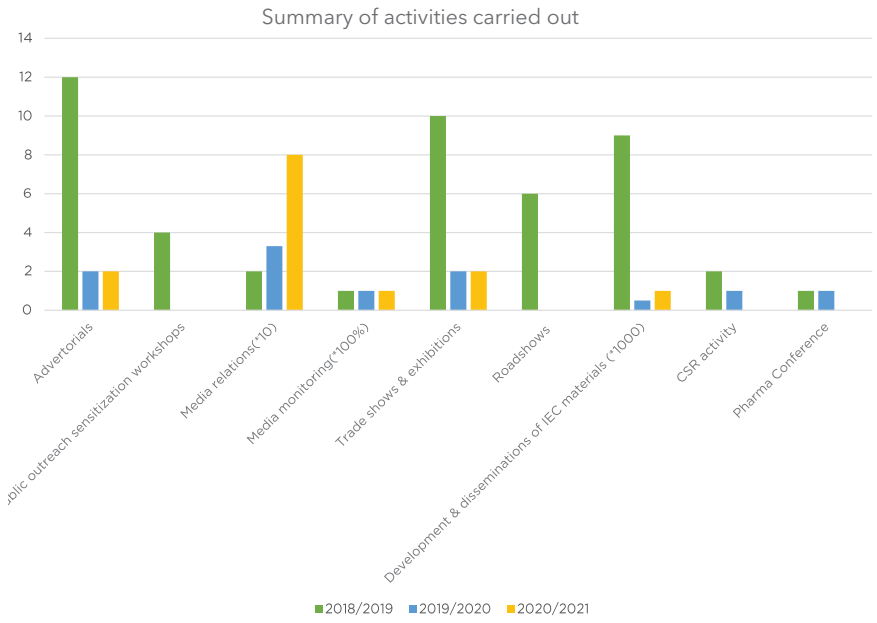
- Developed and implemented a communication and social media strategy
- Launched social media strategies such as #ppbcares, #medsafety #Covid-19 #reportADR #safetycode
- Launched public awareness roadshows in Nairobi, Nakuru, Eldoret, Kisumu and Kisii counties among others
- Organized media training for PPB staff on media handling
- Organized media roundtable with senior staff to build relations
- Initiated Daily media monitoring on health-related issues
- Provide timely responses to media inquiries and interview schedules in issues such as pharmacovigilance, registration of herbal medicines, post marketing surveillance
- Generated public notices on medical recalls, pharmacy practices

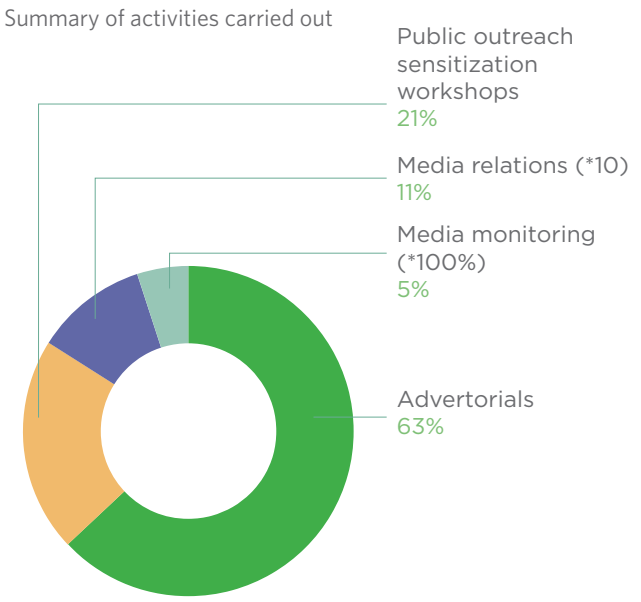
- Developed documentaries on PPB Mandate and ISO certification, PV new systems
- Generated news articles on Medication safety, how to report ADRs, herbal medicine
- Initiated in-house newsletter – PPB Newspaper
- created social media platforms – Twitter, facebook, Youtube, blog
- increased twitter reach from 0 - 10.9 followers, and 28,442 followers in Facebook
- Organised and conducted two Pharma conferences to engage with the Industry players and stakeholders.
- Organised countrywide public outreaches targeting county opinion leaders in Mombasa, Kilifi, Kakamega and Kisumu counties.
- Participated in over 30 trade shows to engage with the public and sensitize them on the PPB mandate.
- Conducted three CSR activities in Nairobi (KNH), Kajiado (Ongata Rongai) and West Pokot
- Street Advertorials at PPB gate, Machakos, Eldoret, Mombasa, Kisumu, and Nakuru
- TV Adverts and info-commercials - Citizen, NTV, KBC, KTN
- Print adverts – Daily Nation, The Standard, Star, People Daily
- Branded all regional offices
- 10,000 IEC production and distribution – newsletters, promotional items
- Carried out public satisfaction survey showing improved satisfaction from 2016 (61%) to 84% 2018
- Participated in events such as KPA, PSK, KHF etc
- 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

Graphical representation of activities carried out





4.4. Independent Units

4.4.1. 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

4.4.2. Internal Audit and Risk Assurance

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

i. Establishment of effective internal control in the use of internal resources.
ii. Reduction of internal control issues raised by the external auditor from seven to four.
iii. Development of a robust Enterprise Risk Management framework that's currently used to establish risk profiles and used perform risk-based audit.
iv. Improvement of controls of regional offices and port of entries operations.
v. Establishment of crisis management framework to help in the management of crises.

As part of fighting corruption, the board has developed a draft anti-corruption policy to help in guiding the fight against corrupt practices in the organization. This is in fulfilment of our obligation on performance contract.

4.4.3. 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 establish linkages with regional and county administrations.

Regional offices locations and hosting

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

Staffing

S/No.	Activity	Indicator
1	Total number of personnel	35
2	No. of pharmacists	8
3	No. of Pharmaceutical Technologists	27
4	No. of administrators	2
5	No. of data clerks	4
6	No. of drivers	11; 1 per region except Mombasa-2

Meetings and capacity building of regional officers

The Department has conducted two capacity building retreats for the regional officers as follows;

No.	Activity	Achievements
1	Development of Decentralization Strategy and training of Regional Heads	February, 2021 The Draft Decentralization Strategy is hereto attached as Annex I: Strategy on Decentralization of Regulatory Services Final Draft Decentralization Strategy June 20_Approval.docx February, 2021
2	Additional services offered at regional offices	1. Two examinations sessions administered at regional offices 2. Four national meetings conducted at the Mombasa Regional Offices
3	Training and development of Inspector's Handbook	October, 2021

Achievements: Infrastructure and Support supervision of regional office

No.	Activity	Dates
1	Capacity assessment of regional offices	May to June 2020
2	Two routine surveillance	March and June 2021
3	Renovations of Nyeri, Eldoret and Mombasa regional offices and Procurement of office furniture	Two (2) contracts signed in favor of regional offices II. Renovation and construction of Guardroom for the Eldoret Regional Office III. Supply of furniture for the regional offices of Eldoret, Mombasa and Nyeri IV. Construction of Perimeter wall for the Eldoret Regional Office
4	Internet connections	Internet connections for 8 out of 9 regional offices

4.4.4. Trade Affairs Unit

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 quality health products and technologies (HPTs) as well as policy coherence along the HPT supply chain. These PGAs and international institutions include: closely with other partner government agencies (PGA's)and international institutions to ensure importation and exportation of safe, efficacious and good quality HPTs.

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 department has witnessed key milestones in its operations. These include:

Automation and roll-out of new Trade Facilitation Platform (TFP)

TFP is an enhanced format of the previous single window system which aims to conform to the WTO Kyoto conventions of trade facilitation. In this regard, the department participated in user specification requirement setting and user acceptability testing and subsequent roll-out.

The TFP integration with the integrated custom management system (iCMS) of KRA has improved the regulatory visibility of the Board at the ports of entry. This is affirmed by the number of increased import permit application in the last 2 months of the year 2021.

Briefly therefore, the various systems used by the department to actualize its role in importation and exportation of HPTs include:

1	TFP format of the Single window system
2	licit control system
3	international import and export system (i2ES) for narcotics, psychotropics and precursors
4	integrated custom management system (iCMS)

The out-puts from the above system(s) feed into the Pre-export verification of conformity (PVoC) program of KEBS for the medical devices and in-vitro diagnostics, food supplements, herbal products, borderline products and medical cosmetics.

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

Current matters

The department 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 Taxation landscape of health products and technologies (HPTs) and proposal for a favorable taxation regime for HPTs in Kenya.	Completed and Published by the MOH.
2.	Development of guidelines on health products and technologies (HPT) pricing and affordability.	Draft guideline development on-going.
3.	Development of guidelines on Generic prescribing and dispensing of health products and technologies.	Draft guideline development on-going.
4.	Development of health products and technologies (HPT) reference database system to anchor the pricing, affordability and transparency elements of HPTs.	Blue print ready and published by the MOH.
5.	Institutionalization of health technology Assessment (HTA).	Development of Draft framework on-going
6.	Promote local manufacturing through preferential treatment during procurement of HPTs locally manufactured	Draft Master Roll 2 which ring-fences locally manufactured HPTs ready and awaiting concurrence between MOH and Ministry of Industrialization before gazettement.

Additionally, the department is involved in various bilateral discussions. These include:

Bilateral Discussions

S/No.	Description	Status
1.	Kenya-USFTA	White paper development, Sectoral annexes on cosmetics developed, compromise paper between the Board and KEBS on Cosmetics developed. Discussions expected to resume soon.
2.	Kenya-India JTC	Discussions on-going
3.	Kenya-Egypt Cooperation	Development of the cooperation framework between the Board and National competent Authority of HPTs in Egypt on-going
4.	Kenya-Jordan Cooperation	Discussions on-going

Trade Statistics

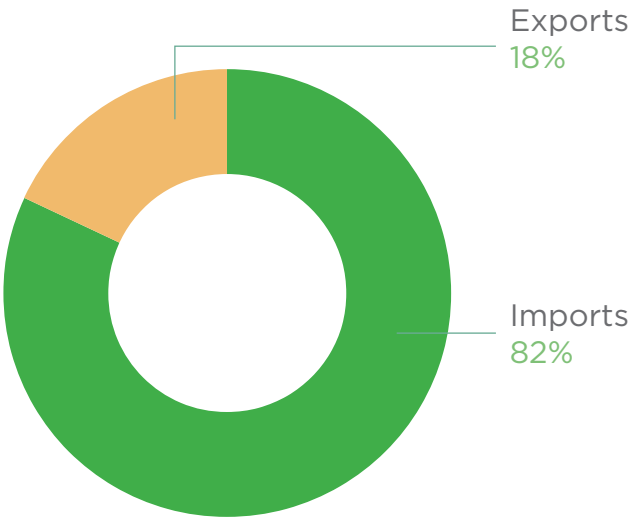
During the year 2021, the department witnessed a 24.8% increase in the number of applications for import and export of HPTs. This was from 21,984 permit applications in the year 2020 to 29,234 applications as of 31st December 2021. This represented a revenue increase of 7.35% in 2020/2021 as compared to 2019/2020 FY. This is attributable to resumption of economic activities following a series of lockdowns and supply chain disruptions as well as integration of the iCMS system of KRA and TFP systems.

However, like the rest of the globe, the number of applications contracted in the year 2020 as compared to 2019 by about 4% from 22,932 applications in 2019 to 21,984 applications in 2020.

Approved permits

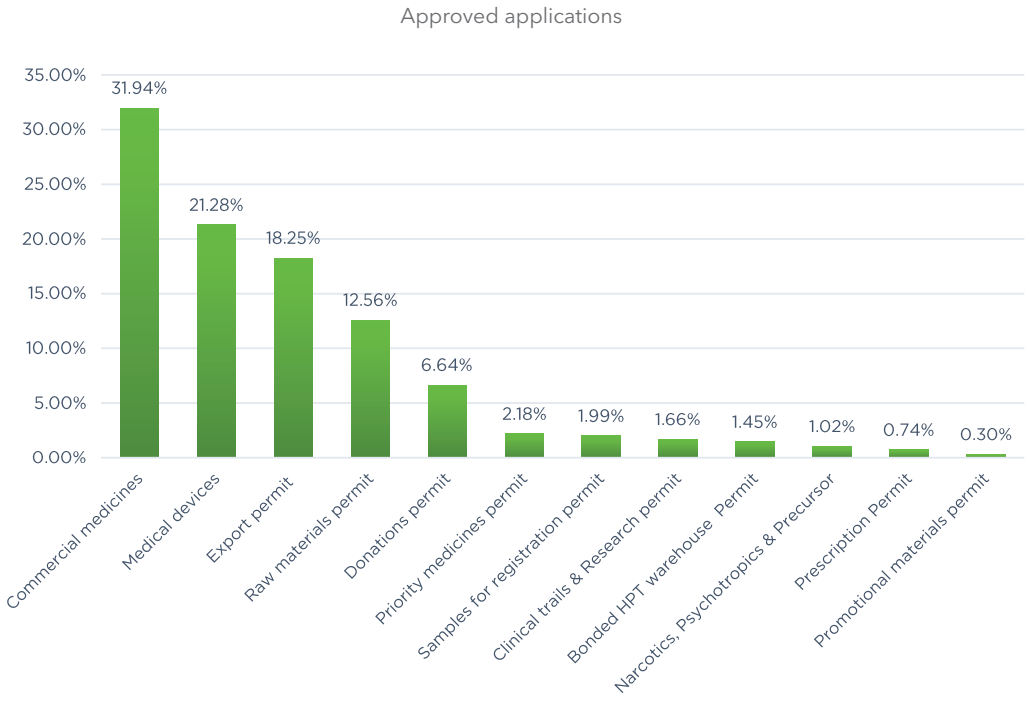
In the year 2020, the approved import permit applications as compared to exports are as represented below:

Approved applications



In respect to the approved import permits, 6, 386 were commercial medicine permits accounting to 32%, 4,255 permits were on medical device permit accounting for 21%, 2, 511 permits were on Raw materials importations accounting for 13%. The below bar graph gives a representation of all the permit application.

Import/Export Permit Distribution



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 850 for imports and 479 for export in 2020.*

Importation Sources

During the 2020 review period, the top 10 import sources included; India accounting for 36.6%, China at 9.29%, Germany at 7.74%, USA at 7.10%, UK at 6.24%, Belgium at 4.98%, France at 3.55%, Switzerland at 3.17%, South Africa at 1.62%, Italy at 1.53%.

Export Destinations

During the 2020 review period, the top 10 export destination included; Tanzania at 27.15%, Uganda at 11.18%, South Sudan at 11.15%, Ethiopia at 8.06%, Somalia at 7.60%, Rwanda at 4.89%, Zambia at 4.70%, Malawi at 4.27%, Cote'd Voire at 3.25%, Nigeria at 2.199%.

Comparison with Preceding years

Over the years, the department has witnessed continued growth of applications for import and export of HPTs. This was however dampened during the year 2020 when COVID-19 struck the Country. For a detailed review, kindly see the below table:

Some Narcotics, Psychotropics and precursor substances (NPP's) were applied under the Commercial medicine

S/No.	Type of Permit	2017	2018	2019	2020	% Difference (+/-)
1.	Commercial Medicine Permit (321C)	7,270	7,475	7,237	6,386	
2.	Medical Device Permit (321V)	3,575	4,574	5,223	4,255	
3.	Raw Materials import Permit (321N)	2,560	2,845	2,629	2,511	
4.	Donation Permit (321F)	1,138	1,294	1,382	1,327	
5.	Priority Permit (321Q)	390	454	421	436	
6.	Prescription Medicine permit (321D)	174	179	169	148	
7.	Narcotics, Psychotropics & Precursors Permit (321U)	63	198	215	203	
8.	Clinical Trials Import Permit (321G)	312	389	439	331	
9.	Drug Registration Samples (321H)	424	424	413	397	
10.	Promotional material permit (321S)	124	144	104	60	
11.	Bonded HPT warehouse permit (321L)	0	0	122	290	
12.	Export Permit (321J)	3,097	3,448	3,349	3,648	
13.	Total No. of approved permits (Imports + Exports)	19,127	21,424	21,703	19,992	

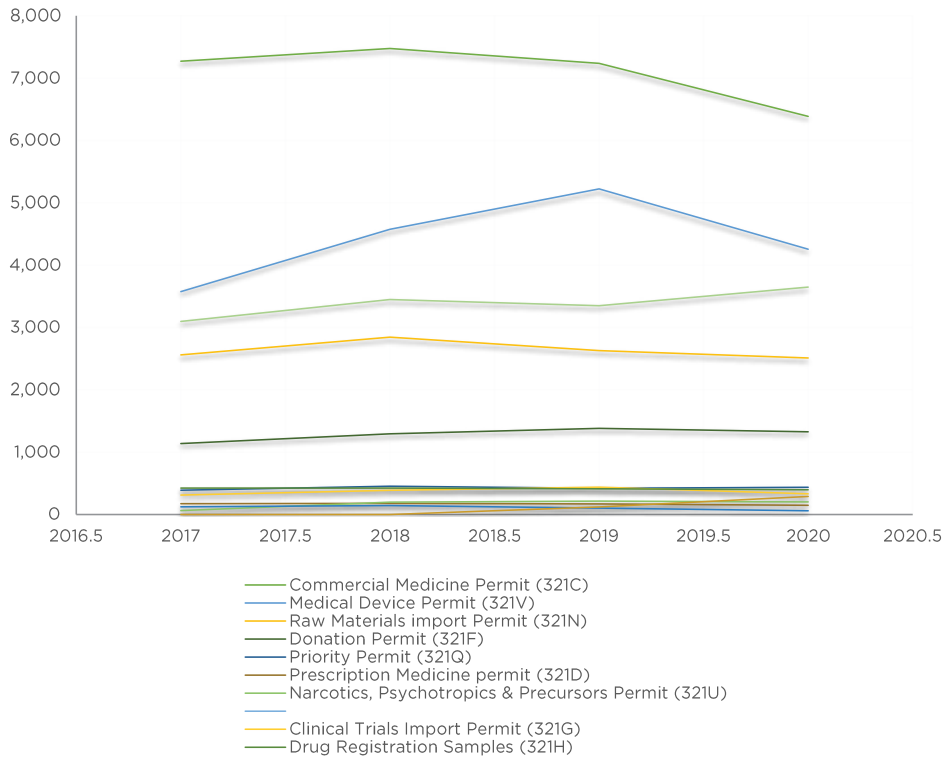
Some Narcotics, Psychotropics and precursor substances (NPP's) were applied under the Commercial medicine permit and Raw materials permit. As a result, the total number of import applications for NPP's in the year 2020 & 2021 were 850 and 944 respectively while export applications for NPP's for the same period were 479 and 507 respectively.

Comparison of permit distribution.

Comparison with the preceding years

Permit Distribution;

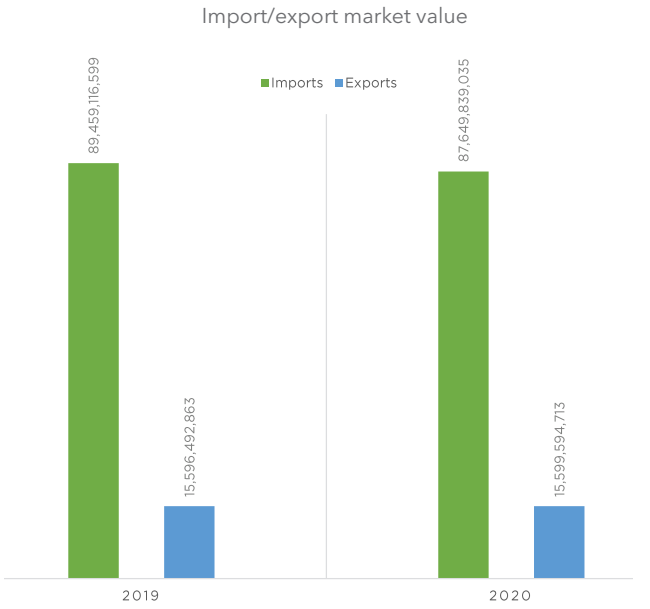
Permit Comparison over the years



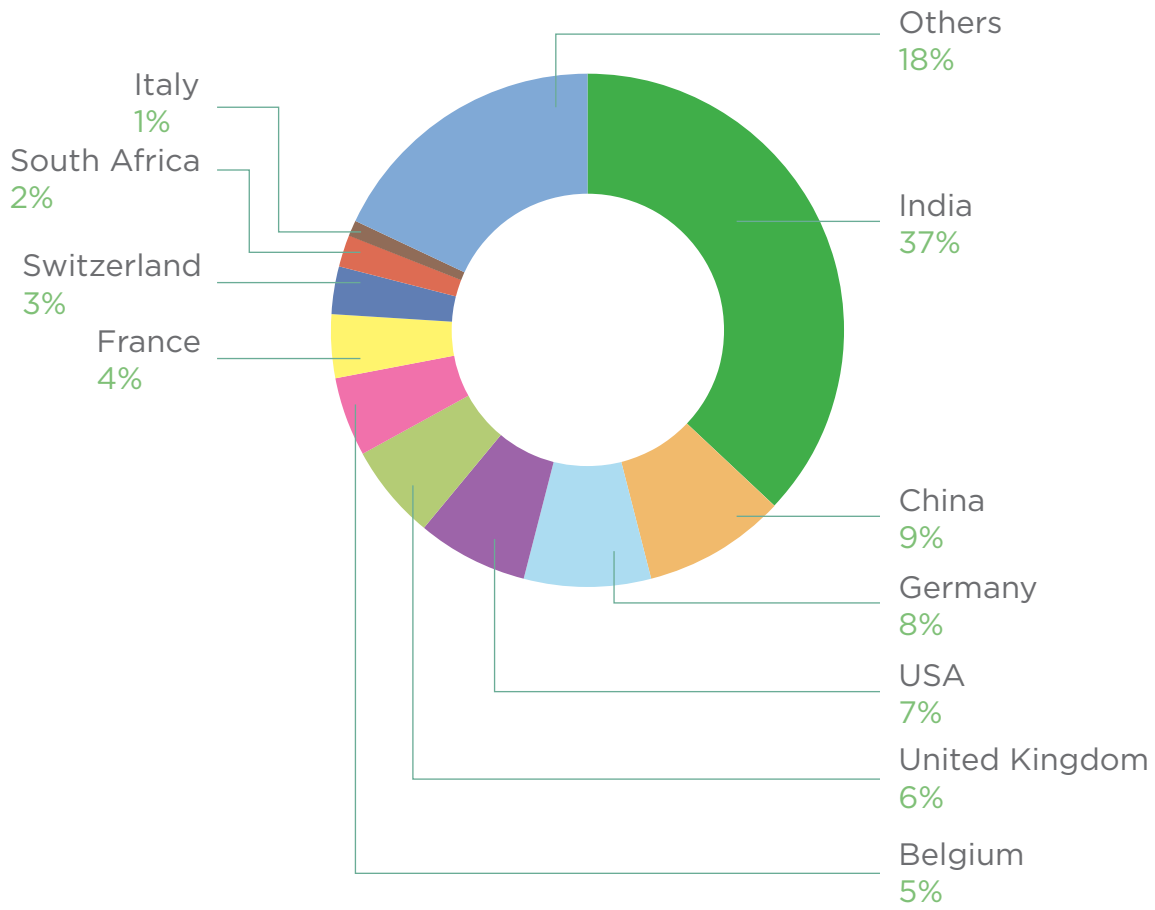
Imports Market Size (Estimated market value in Kshs.) Vs Exports

The imports of health products and technologies decreased by **2%** in the year 2020 from an estimated Ksh,89,459,116,599 in 2019 to Ksh.87,649,839,035 in 2020 while that of exports grew by **0.01%** from an estimated Ksh.15,596,492,863 in 2019 to Ksh.15,599,594,713 in 2020.

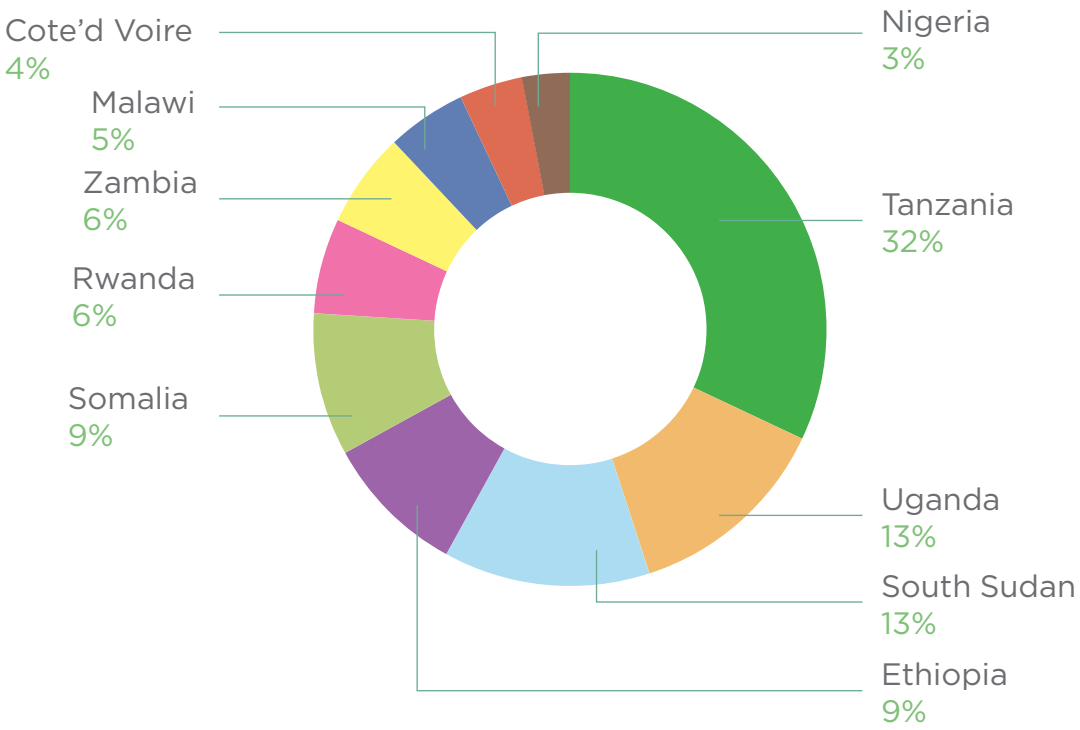
Imports Vs Exports (2019 vs 2020) presentation



Top Importation Sources



Top Export Destination



Permit application Turnaround Time

On average, the turnaround time of the applications has been at 4.54 days. This is based on latest communication by the TFP system host agency.

Workload

Generally, the workload in 2021 increased by **24.8%** based on the last 2 years (2020 and 2021) as evidenced by the number of permits that were evaluated in that period.

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