FOOD AND DRUGS AUTHORITY

2022 ANNUAL REPORT

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EXECUTIVE SUMMARY

The Food and Drugs Authority (FDA) is the national regulatory agency in Ghana mandated by Parts 6, 7 and 8 of the Public Health Act, 2012 (Act 851) to assure the safety, quality and efficacy of human and veterinary medicines, food, vaccines, biological products, cosmetics, medical devices, household chemical substances and clinical trials oversight, and the control and use of tobacco and tobacco products, through the enforcement of relevant local and international standards to protect public health in Ghana. This report gives an account of the FDA's performance in the execution of its core mandate for the period January – December 2022.

Product Registration

The FDA in 2022 received a total of Twenty-Two thousand and Sixty-Seven (22,067) product registration applications representing an increase of six percent (6%) over the previous year and processed Nineteen Thousand, Four Hundred Thirty-Five (19,435). Out of the number processed, Seventeen Thousand and Forty-Five (17,045) products were registered, a decrease of 5% from 2021 while Fifteen percent (15%) were deferred due to non-compliance with the registration requirements which include but not limited to labelling and indication issues, and failure of quality control tests. Out of the total number of products registered, sixty-seven percent (67%) were foreign products, and 33% local products.

Facility Licensing

The number of licensing applications received increased from five thousand, and twenty-two (5,022) to six thousand, four-hundred and sixty-eight (6,468). Out of the applications received, five thousand, seven hundred and sixty-three (5,763) licensing inspections were conducted, twenty-six percent (26%) increase over the 2021 performance. Three thousand, three hundred and fifty-one (3,351) facilities were licensed in 2022, one percent (1%) decrease compared to the 2021 performance. A total of nine thousand eight hundred and twenty-nine (9,829) inspections were conducted across the country.

Market Surveillance

In 2022 a total of one thousand, three hundred and thirty (1,330) market surveillance outings were carried out across the country; an increase of 0.5% over the previous year's performance. The number of outlets visited also increased by 0.5% recording fifteen thousand, two hundred and fifteen (15,215) outlets. The number of non-compliant products recorded during surveillance operations was *ninety thousand and ninety-three (90,093)*, a 329.6% increase over the previous year. The high increase in the non-compliance product could be attributed to operational raids conducted on the market. Most of these products seized were drug products. (Aphrodisiac and Body enhancing products, P-One tablet, Postinor 2 (substandard), Abonike and Nazo)

Product Quality Testing

Four thousand five hundred and sixty-two (4,562) samples were available for testing by the Centre for Laboratory Services and Research (CLSR) for testing; a decrease of 24.5% compared to the previous year. Out of this number, 92.5% of the samples available for testing were analyzed representing an increase of 3.3% over the previous year's performance of 89.6%.

Safety Monitoring of Medical Products

The FDA received two thousand eight hundred and twenty-one (2,821) Individual Case Study Reports (ICSRs), representing a decrease of 72% from 2021. Four thousand two hundred and sixty-four (4,264) were entered into the safety watch system in 2022, which included ICSRs received in 2022 and carry overs from the previous period. One thousand six hundred and one (1,601) ICRSs, serious AEFIs were reviewed by TAC SM, TAC VBP and JMVC reports were reviewed by Technical Advisory Committee (TAC) SM.

No signal was identified though a number of events that were reviewed as potential signals.

Food Safety Co-ordination and Consumer Education

The National Food Safety Policy and Food Safety Emergency Response Plan (FoSERP) were launched with its Management Committee inaugurated during the commemoration of the fourth

(4th) World Food Safety Day in the second quarter of 2022. Subsequently, the Food Safety Inter-Sectorial Committee was constituted and inaugurated in the fourth (4^{th}) quarter of 2022.

The National Food Safety Strategic Action Plan was unveiled for implementation of the National Food Safety Policy, at a ceremony organised by the FDA in collaboration with the Ministry of Health. The Committee had its inaugural meeting on the same day.

The number of food-borne disease outbreaks recorded during the year under review was nine (9), the same number as the previous year. The number of people affected, however, increased from seventy (71) in 2021 to one hundred and sixty-four (164) in 2022. There was no death associated with the outbreaks recorded compared to the five (5) deaths recorded in 2021.

Import and Export Control

Out of seventy thousand three hundred and eighty-eight (70,388) permit applications received, sixty-nine thousand four hundred and eighty-nine (69,489) were processed, representing an increase of 78% from the previous year. Sixty-five thousand five hundred and ninety-eight (65,598) permits were approved in 2022, an increase of 86% of permits approved compared to the previous year. The number of import and export consignments inspected increased by 36% from seventeen thousand six hundred and five (17,605) inspections to twenty-three thousand nine hundred and fifty-three (23,953) import and export inspections compared to the previous year.

The FDA does not undertake 100% consignment inspection at the Tema Port. Based on the risk engine categorisation, inspections are conducted for those in the red channel as well as those in the yellow channel that are flag following the container scan. While the red level risk engine indicates on the customs declaration that consignments are of a high risk which require physical inspection before clearance, the yellow channel requires scanning and sampling without physical inspection.

Clinical Trial Authorization

For Clinical Trials, the FDA received a total of fifteen (15) new clinical trial applications, twenty-six (26) amendments and two hundred and forty-eight (248) Ad-Doc applications for consideration; all fifteen (15) applications were approved in 2022. Two hundred and twenty-three (223) Serious Adverse Events (SAE) reports were received and reviewed; eight (8) Good Clinical Practice (GCP) inspections which are primarily inspections conducted to ensure compliance to international set of guidelines that helps make sure that the results of clinical trials are reliable and patients are protected were conducted in the year under review. A total of thirty-nine (39) permits were issued for importation of investigational products out of sixty-four (64) applications.

The FDA in collaboration with the School of Public Health, University of Ghana Legon (SPH), organized the first RCORE Fellowship training in the year 2017, and this has since run through the year 2018, 2019, and 2020 with funds from the International AIDS Vaccine Initiative (IAVI), a non-profit non-governmental organization and additional funding from the Global Health Protection Programme (GHPP). The first Advance RCORE training in 2022 was held in the 4th quarter. This special session was aimed at building capacity and enhancing skills of regulators in effective evaluation of biological products, other new generation investigational products and complex trial designs like adaptive trials. This training also sought to equip regulators with the relevant knowledge and technical skills regarding statistical considerations that form part of Clinical Assessments. A total of 11 international participants from Liberia, Sierra Leone, Nigeria, Zambia, Gambia and Tanzania participated in the Advance RCORE training.

Technical Assistance to Industry

The FDA collaborated with (PUM) Netherlands Senior Experts to organize a fourteen-day (14) marathon training on qualification and validation for pharmaceutical manufacturing plants, manufacturing equipment and utilities and analytical method validation and process validation for twenty-seven (27) local pharmaceutical companies in Ghana. This training was the first of its kind in the history of the Authority, where technical assistance was provided in collaboration with foreign experts. This has improved their compliance levels with respect to Qualification and Validation with 70% having developed the basic documentations such as Validation Master Plans (VMP), User Requirement Specification (URS) and Protocols for validation activities.

A review of twenty-three (23) conceptual designs for proposed new pharmaceutical manufacturing facilities to ensure compliance with Good Manufacturing Practices (GMP) and other relevant regulatory requirements was done during the period. In addition, quarterly monitoring of thirteen (13) new pharmaceutical projects under construction; this led to the provision of timely technical support to avoid potential GMP deficiencies at the various stages of the respective projects was also done.

Capacity Strengthening

One thousand three hundred and ninety-eight (1,398) personnel were trained in Good Manufacturing Practices (GMP), Good Hygienic Practices (GHP),Good Cold Storage Practices (GCSP) and Good Distribution Practices (GDP) /Good Warehouse Practices (GWP)compared to seven hundred and ninety (790) who were trained in 2021.

The FDA successfully intervened to strengthen the capacity of Lee found Foodstuffs Ghana Limited when infractions were observed resulting in its closure and was brought into compliance by way of coordinating trainings in the identified GMP deficiencies.

The installation of Hazzard Analysis and Critical Control Point (HACCP) at KASAPREKO facility in Accra made it easier for it to acquire ISO 22000 Quality Management System certification, and the FDA has begun preparatory process for Hazzard Analysis and Critical Control Point (HACCP) installation at the Kumasi branch.

Tobacco and Controlled Substances Control

Twenty (20) applications were received for registration of tobacco and tobacco products, and all were approved. There was an 18% increase in applications received compared to the previous year. A total of one hundred and seventy-six (176) permit applications were received for tobacco products. One hundred and forty-six (146) of the permits received were approved and thirty (30) rejected.

Controlled substances were issued to twenty-seven (27) importers of raw materials and twenty-four (24) importers of finished pharmaceutical products (FPP); a 13% decrease in the total number of allocations for importers compared to the previous year due to a decrease in requests by manufacturers and importers.

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The FDA received one hundred and seventy-five (175) permit requests for controlled substances. One hundred and fifty-one (151) permits were issued, 10% more than was issued

in the previous year. Twenty-one (21) permits were rejected, and five (5) import permits were returned. There was a 47.5% decrease in import permit applications rejected because agents who put in applications were guided on the requisite protocols of the permit application system. Five (5) import permits were returned because suppliers were not able to supply them with the products.

Public Awareness and Education

One thousand eight hundred and twelve (1,812) educational campaigns were organized at basic and secondary schools, tertiary institutions, marketplaces, transport terminals, non-governmental organizations, religious organizations, publication, and the media (radio, Televison stations and electronic stations with 2,369,666 people reached with these campaigns.

Vaccines and Biological Products

The FDA facilitated the training of Blood service providers in the Northern and Savannah Regions on Good Preparation Practice and a two-day virtual training on blood regulation of Regional Heads and focal persons in the various regions. The institution also participated in the African blood regulators forum to assist in the development of guidelines, the African Vaccine Regulatory Forum (AVAREF) and made contributions to the joint reviews of vaccines on the African continent. A training session was also organized for Rwanda Food and Drugs Authority staff on vaccine regulations and blood and blood products. Drafts for lot release guidelines, lot release protocols and templates of mRNA Covid-19 vaccines were developed during the year under review.

Business Development and International Partnerships

The FDA engaged eighty-seven (87) partners in the year 2022 and undertook ten (10) key projects with partners such as: the European and Developing Countries Clinical Trials Partnership (EDCTP), Africa Union Development Agency (AUDA)-NEPAD, Centre for Disease Control (CDC) / Taskforce for Global Health, PQM+, ePAC among others. Funding was secured towards regulatory systems strengthening and RCORE programmes in excess of USD 700,000 with additional commitments of 5 million US dollars to be fulfilled in 2023.

Finance

A total of One Hundred and Forty-One Million and Seventy-eight Thousand, Three Hundred and Sixty-Three Ghana Cedis, Sixty-Four Pesewas (GH¢ 141,078,363.64) was collected in 2022, an increase of 30% compared to revenue collected in previous year. Out of this amount, Thirty-Six Million, Three Hundred and Twenty-Two Thousand, Four Hundred and Seventy-Seven Ghana Cedis, Twenty-Nine Pesewas (GH¢ 36,322,477.29) was transferred to the consolidated fund.

Internal Audit

The FDA conducted a total of five financial audits at its Head Office, Tema Heights, KIA (Airport) Offices, and Regional Offices during the period with eleven (11) non-compliances observed mostly due to inadequate documentation. Steps have since been initiated to resolve these non-compliances. All payroll reviews were executed within the year. Requests received for review of verification of goods supplied to the FDA stores were also completed.

One hundred and fifty (150) out of two thousand, five hundred and sixty eight (2,568) Pay Vouchers (PV's) reviewed in 2022 financial year were returned for the necessary corrections.

Conclusion

During the year, improvements in performance were translated into corresponding increase in operational and financial performance. The FDA will continue to strengthen its operational activities for product registration, facility licensing, market surveillance as well as the enforcement of the tobacco control regulations to ensure public health and safety.

1.0 INTRODUCTION

The Food and Drugs Authority (FDA) is mandated by Parts 6, 7 & 8 of the Public Health Act 2012, Act 851 to protect public health and safety through the implementation of regulations to ensure quality, safety and efficacy of food, allopathic medicines, herbal medicines, veterinary medicines, vaccines, biological products, medical devices, cosmetics, household chemical substances, tobacco and tobacco products and substances of abuse, and to authorise and manage the conduct of clinical trials. The FDA has evolved over the years in response to emerging threats to public health and safety, as well as technologies in product development and manufacturing.

The Food and Drugs Authority (FDA) continues to improve its internal processes in a bid to protect the health and safety of people in Ghana and be a global center of excellence for food and medical product regulation. The results of the 2021 client satisfaction and public confidence survey conducted in the first quarter of 2022, showed a customer satisfaction index of 76% and Public Confidence Index of 83.6%. As an institution, we continue to deepen our work culture through our core values of accountability, teamwork and integrity to improve the level of confidence our clients and the public have in the Authority. The FDA is poised to improve satisfaction among our clients and consumers by deepening our work culture and conscientiously living up to our core values.

The web-based product registration system developed for processing food product applications has helped reduce processing time for Product registration, decentralize the evaluation process and hence resulted in increased operational efficiency for the Food Evaluation and Registration Department and all Regional Offices of the Authority.

1.1 Vision

To protect the health and safety of people in Ghana and to be a global Centre of excellence for food and medical product regulation

1.2 Mission Statement

The FDA exists to assure the safety, quality and efficacy of human and veterinary drugs, food, biological products, cosmetics, medical devices, household chemical substances and clinical trials, and the control and use of tobacco products, through the enforcement of relevant standards to protect public health.

1.3 Critical Success Factors

The 2020-25 Strategy Compass of the FDA espouses the following critical success factors:

i. Financial Performance - Attain financial sustainability driven by prudent and innovative resource management.
ii. Clients - Achieve the highest quality of service delivery that aligns with our purpose.
iii. Processes - Achieve system-wide effectiveness and efficiency using cutting edge technology as an enabler.
iv. People - Build motivated and highly skilled teams, delivering performance in a model Public Sector institution.
v. Partnerships - Nurture relationships that support our ambition of excellence.

1.4 Core Values

The core values which define the work culture within the organization are as follows:

i. Accountability

ii. Teamwork

iii. Integrity

1.5 Functions of the Food and Drugs Authority

The functions of the FDA as spelt out in parts six (6), seven (7) and eight (8) of the Public Health Act, 2012 (ACT 851) Act 851; these are reflected by the respective Technical Divisions and Departments as well as Regional Offices within the organization. The daily activities of all operational units of the FDA find their place within the following:

1. Enforce standards for human (allopathic and herbal) and veterinary drugs, food, biological products, cosmetics, medical devices, household chemical substances, clinical trials, and the control and use of tobacco products.
2. Register food, human (allopathic and herbal) and veterinary drugs, biological products, cosmetics, household chemical substances and tobacco products.
3. License facilities for manufacture and storage, and vehicles for the transportation of FDA regulated products.
4. Issue food hygiene permit for food service establishments, meat shops, abattoirs and slaughter slabs.
5. Issue import and export permits for FDA regulated products.
6. Free-sale certificate for export of FDA regulated products.
7. Carry out market surveillance of FDA registered products.
8. Monitor adverse effects in the use of FDA regulated products.
9. Approve and monitor advertisement of FDA regulated products.
10. Investigate consumer complaints for FDA regulated products.
11. Provide industrial support services to manufacturers of FDA regulated products.
12. Provide clients services to companies and individuals.
13. Monitor FDA regulated products at all ports of entry.
14. Approve the initiation and conduct of clinical trials.
15. Test all FDA regulated products to ensure conformance to all relevant standards.
16. Educate the public on safe handling and use of FDA regulated products.
17. Monitor through the District Assemblies and any other agency of State, compliance with the provisions of Parts 6, 7 and 8 of Act 851.
18. Develop effective Regulations for the implementation of Parts 6, 7 and 8 of Act 851.

19. Advise the Minister on measures to protect public health.

This report gives an account of the FDA's performance in the execution of its core mandate for the period January – December 2022.

2.0 MANAGEMENT AND STRUCTURE OF FDA

FDA Governing Board

The 6th FDA Governing Board was reconstituted on made up of eleven (11) members. See appendix 1 for updated membership list of the Governing Board.

Management Team

Executive Committee

Mr. Emmanuel Yaw Kwarteng Director, Centre for import and Export Control who served the Authority for fifteen (15) years retired from active service at the Food and Drugs Authority (FDA) on the 27th of December 2022 after reaching the statutory retirement age of sixty (60). Mr. Percy Adomako has since been appointed as Head of the Centre. See appendix II for the list of members of the FDA Executive Committee

Middle Level Management

The following appointments were made in line with the implementation of FDA's new organogram, operationalization of the Western North Regional Office and retirement of the Eastern Regional Head Mr. Samuel Kwakye:

- Mr. John Odai Tettey – Head, Ashanti Regional Office
- Ms. Francisca Obeng – Ag. Head, Central Regional Office
- Mr. Albert Ankomah – Head, Western North Regional Office
- Mr. Kelvin Dafaari Sunkpal - Ag. Head, Upper West Regional Office
- Dr. Martin Kusi - Head, Western Regional Office
- Mr. Zackariah Braimah – Head, Northern Regional Office
- Ms. Anita Kuffour - Ag. Head Eastern Regional Office

See appendix III for the updated list of members of FDA Middle Level Management.

Department Heads

Forty-one (41) Heads of Departments were appointed in line with the implementation of the new organogram of FDA.

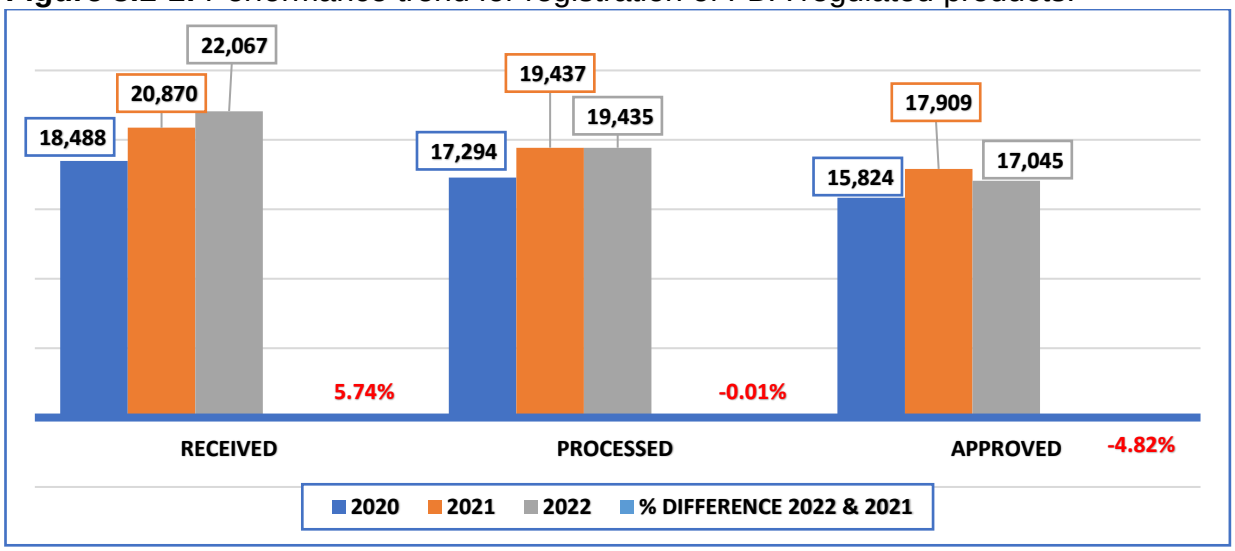
See appendix IV for the list of Department Heads.

3.0 2022 OPERATIONAL PERFORMANCE

3.1 Registration of FDA regulated products.

The FDA has seven (7) Departments that registers products: Food Evaluation and Registration, Drug and Nutraceutical, Vaccines and Biological Products, Herbal and Homeopathic Medicines, Medical Devices, Tobacco and Tobacco Products, and Cosmetics and Household Chemical Substances Departments. The graph below shows the performance of the product registration for all regulated products from 2020-22.

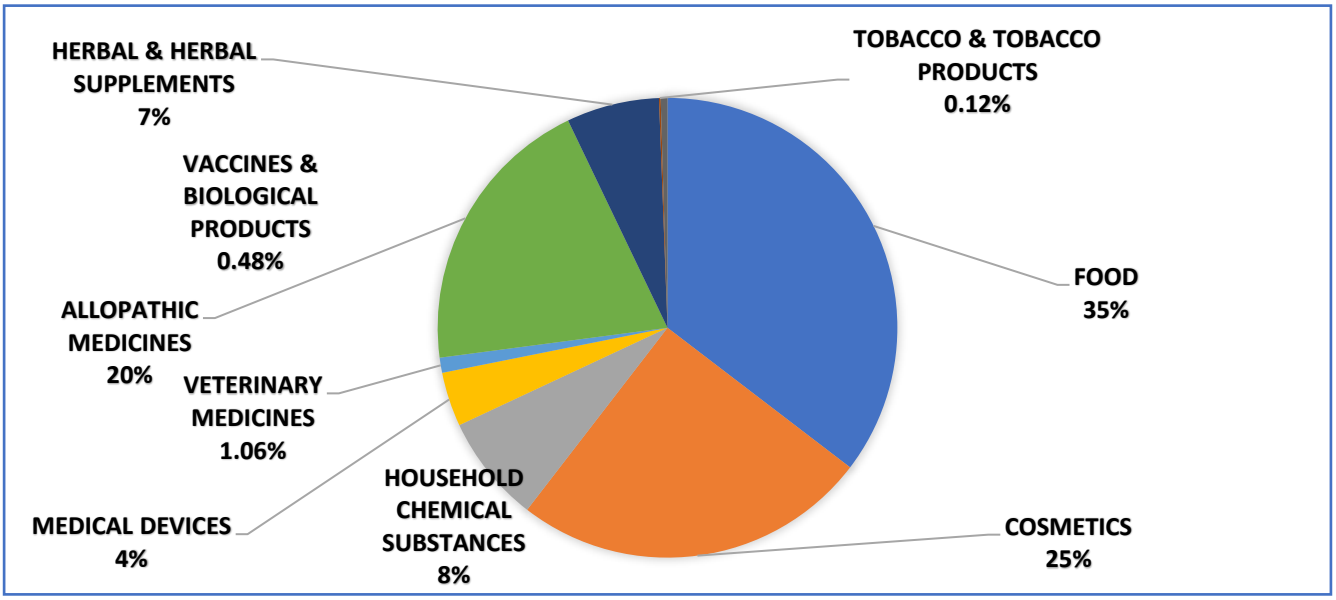
Figure 3.1-1: Performance trend for registration of FDA regulated products.



Source: *FDA Planning, Monitoring and Evaluation Department (2022)*

The 2022 annual targets for the number of product applications received and processed for all FDA regulated products were twenty-two thousand five hundred and ninety-four (22,594) and twenty-one thousand three hundred and eighteen (21,318) respectively. By the end of the year, a total of twenty-two thousand and sixty-seven (22,067) product applications were received for registration, achieving 98% of the annual target. Out of the number of product applications received for registration, nineteen thousand four hundred and thirty-five (19,435) were processed, achieving 91% of its target. There was a 5.7% increase in products received in comparison to the previous year. Seventeen thousand and forty-five (17,045) products were registered as compared to seventeen thousand nine hundred and nine (17,909) products in 2021, representing a decrease of 4.82% over the previous year's performance. Sixty-Seven percent (67%) out of the number approved were foreign products and 33% local products.

Figure 3.1-2: Categories of Products Registered



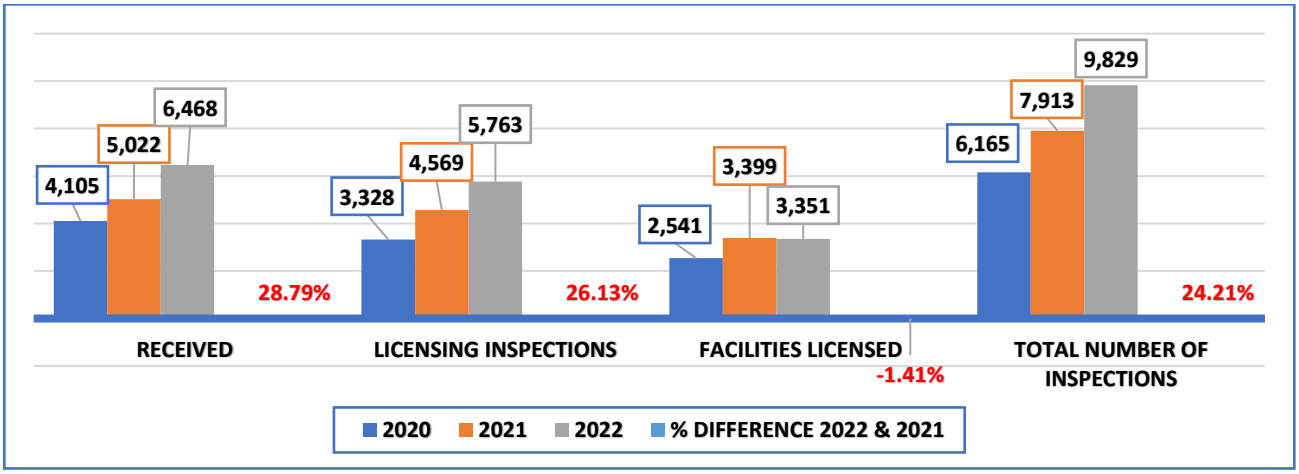
Source: *FDA Planning, Monitoring and Evaluation Department (2022)*

For the categories of products registered during the period under review, food was 35%, cosmetics, 25%, allopathic medicines, 20% with tobacco and tobacco products being the least with 0.12%.

3.2 Licensing of facilities regulated by the FDA.

The Manufacturing facilities, Storage Facilities, Food Services Establishments Departments and the regional offices carry out the licensing of facilities at the FDA. The FDA operates a centralized system of licensure for facilities nationwide at the Head Office in Accra.

Figure 3.2-1*:* Performance trend for licensing of facilities regulated by the FDA***.***

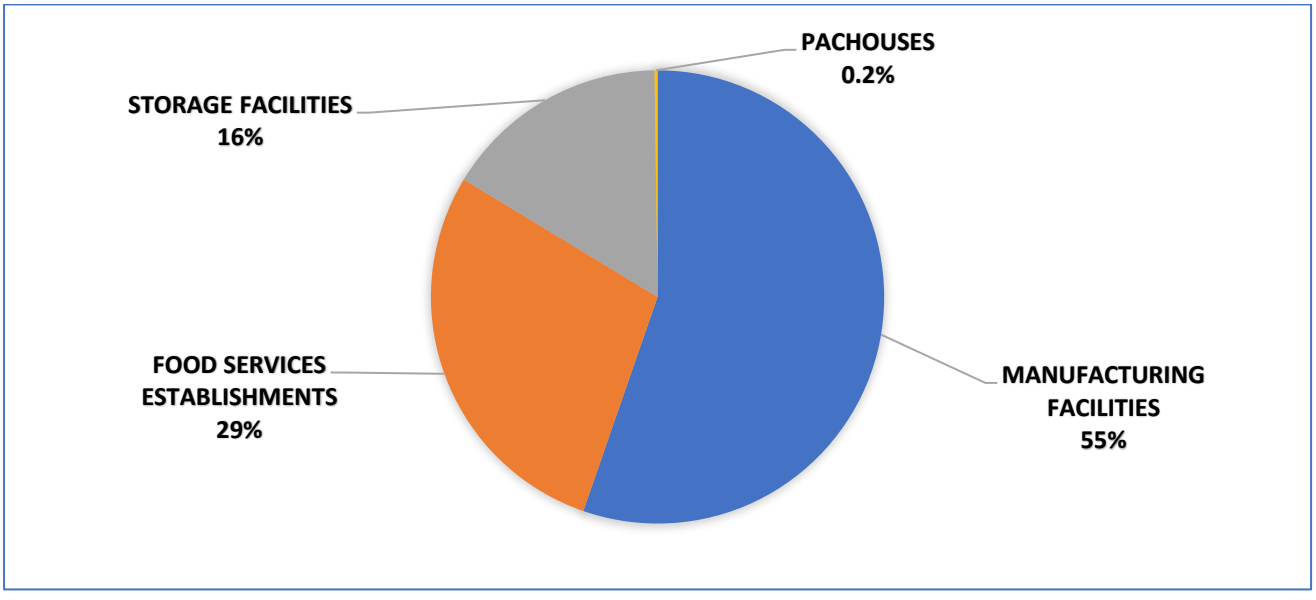


Source: *FDA Planning, Monitoring and Evaluation Department (2022)*

The 2022 annual targets for the number of facility applications received and the number of licensing inspections conducted were five thousand five hundred and twenty-four (5,524) and five thousand and twenty-six (5,026) respectively. By the end of the year 2022, a total of six thousand four hundred and sixty-eight (6,468) applications for facility license were received, achieving 117% of its annual target. Out of the number received, five thousand seven hundred and sixty-three (5,763) licensing inspections were conducted, and three thousand three hundred and fifty-one (3,351) facilities were licensed; a 28.79% increase and 1.41% decrease for the number of licensing inspections and facilities licensed respectively in comparison to performance in 2021. Although there was an increase in the number of inspections conducted, the inability of some manufacturing and storage facilities, and food services establishments to implement corrective actions and preventive actions (CAPA) resulted in the decrease in the number of licenced facilities. The FDA continues to support these industries to bring their facilities to regulatory compliance. In total, nine thousand eight hundred and twenty-nine (9,829) inspections were conducted in 2022 as shown in the graph above, representing a 24.21% increase over the previous year's performance.

The figure below shows the categories of facilities licensed:

Figure 3.2-2: Categories of Facilities Licensed



***Source**: FDA Planning, Monitoring and Evaluation Department (2022)*

For the categories of facilities licensed, manufacturing facilities represented the highest proportion of (55%), with Food Services Establishments having the second highest of (29%),

Storage facilities the third highest (16%) with packhouses being the least with (0.2%). The FDA continues to work assiduously in bringing facilities across all categories into compliance.

Progressive Licensing Scheme

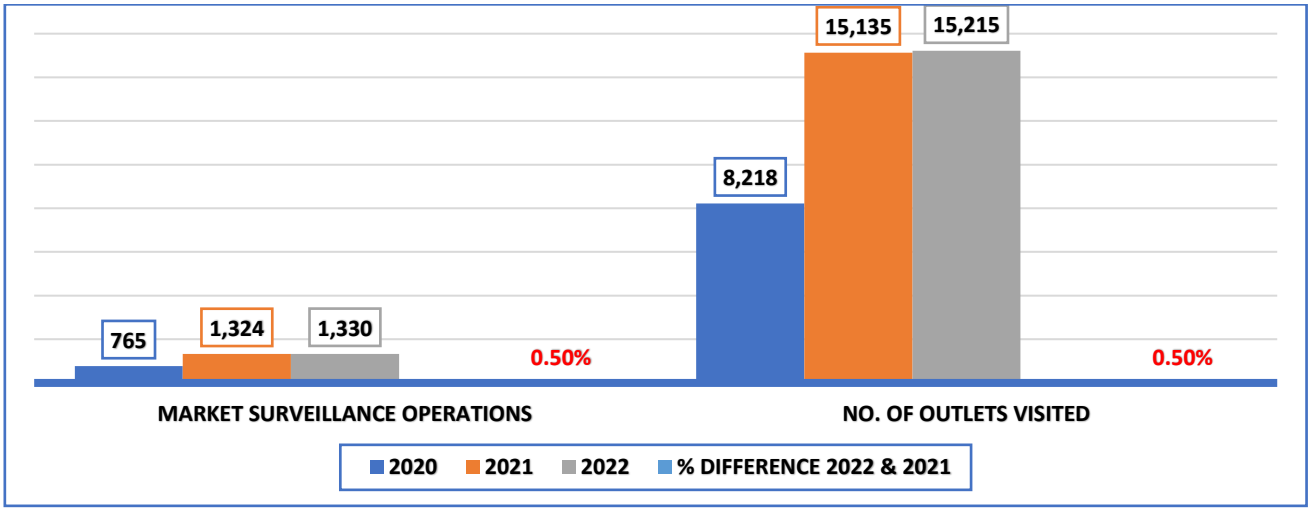
The FDA progressive licensing scheme (PLS) continues to support micro, small and medium scale enterprises (MSMEs) achieve regulatory compliance for quick market access.

Comparing pre PLS to the PLS implementation period, product registration now takes six (6) weeks to be registered and facilities are now licensed upon the first inspection. Since the inception of the programme the total number of products registered under the programme has increased from forty-three (43), pre PLS to two thousand nine hundred and seventeen (2,917) post PLS. The number of facilities licensed has also increased from sixteen (16) to nine hundred and fifty-two (952) pre and post PLS respectively.

The herbal medicine industry is next in line to be included in the scheme to support MSME in the sector. This move is to improve their Good Manufacturing Practices compliance.

3.3 Market surveillance operations

Figure 3.3-1: Performance for market surveillance operations



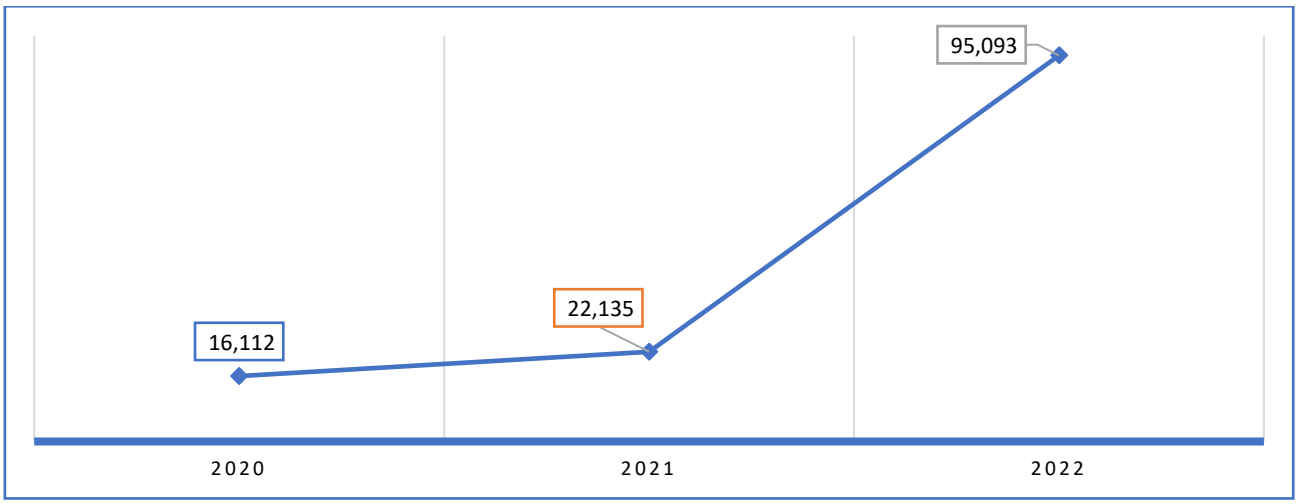
***Source**: FDA Monitoring and Evaluation Department (2022)*

The 2022 annual target for number of market surveillance outings and outlets visited were one thousand four hundred and fifty-six (1,456) and sixteen thousand six hundred and forty-nine (16,649) respectively. As at the end of the year, one thousand three hundred and thirty (1,330) market surveillance outings had been carried out across the country, achieving 91% of its target;

an increase of 0.50% over the previous year's performance. Fifteen thousand, two hundred and fifteen (15,215) outlets were visited in 2022, 91% of its target for the year.

As part of market surveillance operations at the FDA, the Take Back Unwanted Medicines (TBUM) project collected one thousand and ninety-nine (1,099) unwanted medicines from thirty-two (32) pharmaceutical shops in Greater Accra, thirty (30) in Ashanti and thirty-six (36) in Western Region.

Figure 3.3-2*: Non-Compliant Products Identified in Trade*

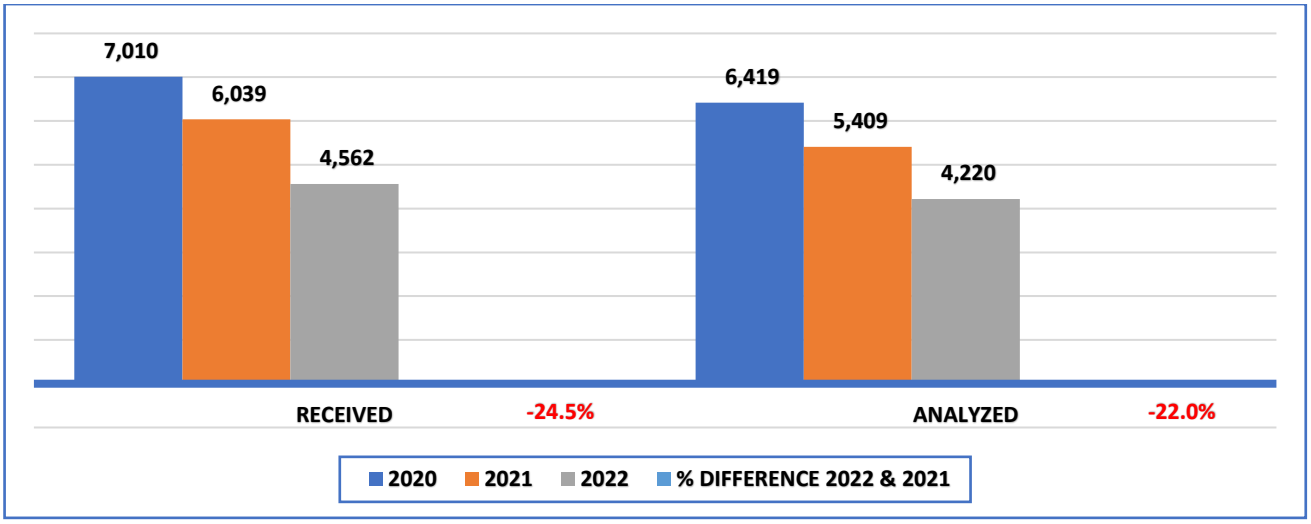


Source*: FDA Planning, Monitoring and Evaluation Department (2022)*

In 2022, a total of ninety-five thousand and ninety-three (95,093) non-compliant products were identified in trade; an increase of 330% over last year's performance. Out of this, 92% of the products identified in trade were substandard and falsified postinor 2 from Nigeria, Procold and Aboniki Ointment.

3.4 Product Quality Testing

Figure 3.4-1: Product Quality Testing Performance

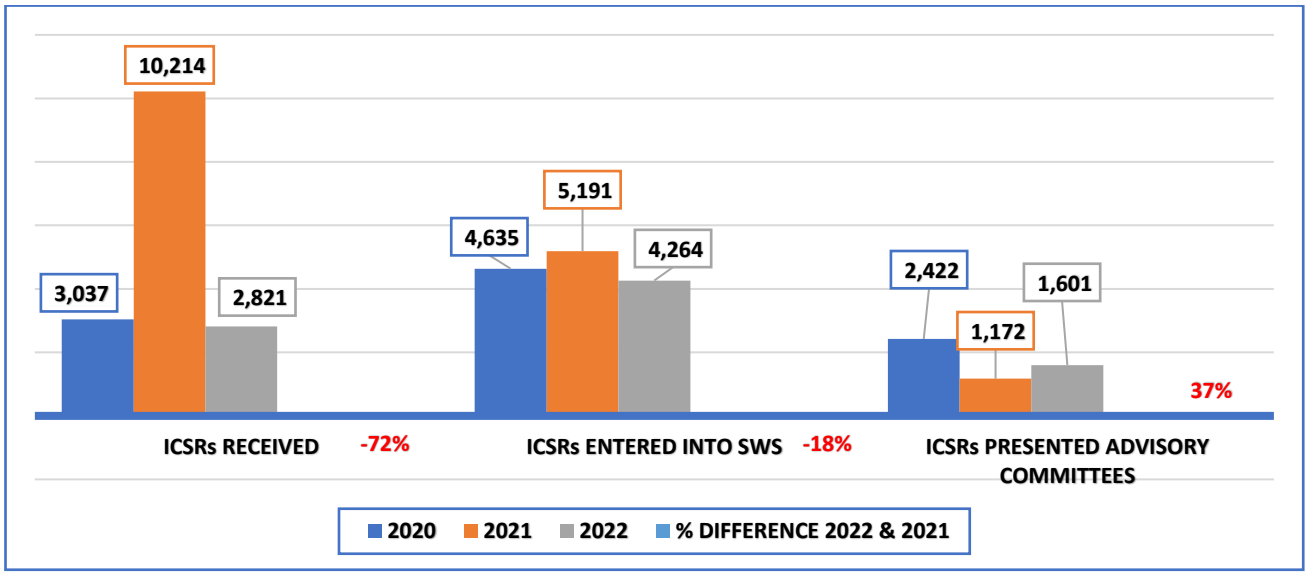


***Source**: FDA Planning, Monitoring and Evaluation Department (2022)*

The Centre for Laboratory Services and Research (CLSR) of the FDA planned to analyze eighty-five (85) percent of all samples submitted to the Centre. A total of four thousand five hundred and sixty-two (4,562) were received by the CLSR for testing; a decrease of 13.9% compared to the previous year. Out of the number received, four thousand two hundred and twenty (4,220) products were analyzed representing 92.5% of samples submitted, a decrease of 22% over the previous year's performance. This was due to the shutdown of the laboratory for renovation works in the last quarter of the year.

3.5 Safety Monitoring of Medical Products

Figure 3.5-1: Trend of safety monitoring performance



***Source**: FDA Planning, Monitoring and Evaluation Department (2022)*

The 2022 annual target for the Individual Case Study Reports (ICSRs) entered into the safety watch system was 100%. By the end of the year, a total of two thousand eight hundred and twenty-one (2,821) Individual Case Study Reports (ICSRs) were received and four thousand two hundred and sixty-four (4,264) including carry overs from the previous period were entered into the safety watch system, achieving 151% of its annual target.

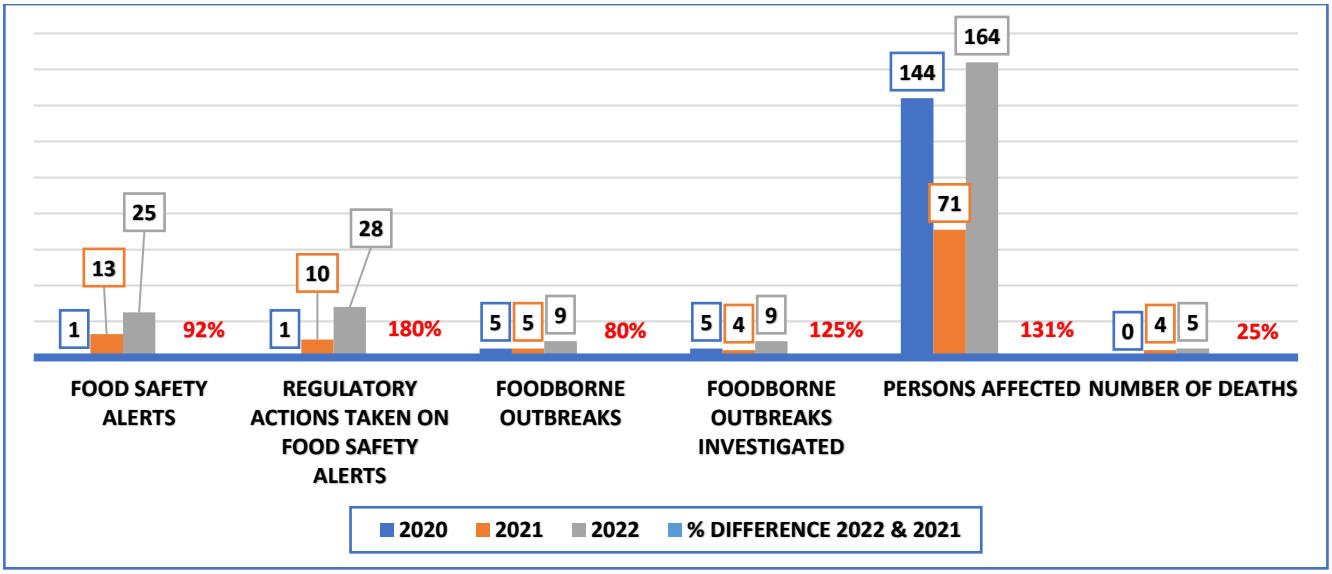
The number of Individual Case Study Reports (ICSRs) presented to Advisory Committees increased by 37% from one thousand one hundred and seventy-two (1,172) to one thousand six hundred and one (1,601). Causality assessment which is only performed for serious AEFI reports (ADRs) represented about 40% of the ICSRs received.
In 2022, five (5) Dear Healthcare Professional letters (DHPLs) were sent out to various health professionals on varying medicine safety issues. No signal was identified though a number of events that were reviewed as potential signals.

For regulatory documents received, 93.1% of Periodic Safety Update Report (PSUR) and Periodic Benefit-Risk Evaluation Report (PBRER) were reviewed and feedback provided to the marketing authorization holders (MAHs). Additionally, all Risk Management Plans (RMPs) were reviewed, and responses provided to the respective MAHs.

3.6 Foodborne disease outbreaks and investigations indicators for 2019-2021

Twenty-five (25) food safety alerts were received comprising of local incidents, imported incidents, local emergency, imported emergency and foodborne outbreak. Twenty-eight (28) regulatory actions were undertaken in response to the twenty-five (25) alerts, as some of the alerts required the deployment of more than one regulatory action.

Figure 3.6-1: Food borne disease outbreaks and investigations for 2020-22.



***Source**: FDA Planning, Monitoring and Evaluation Department (2022)*

Food borne disease outbreak incidents increased from five (5) in 2021 to nine (9) in 2022. All outbreaks were investigated.

Figure 3.6-2: Foodborne Disease Outbreak

NATURE	SUSPECTED FOOD	COMMUNITY	SOURCE	PERSONS AFFECTED	DEATH(s) RECORDED
Suspected food poisoning	Suspected food poisoning	Loggu, Wa east district	Ghana Health Service	7	1
Suspected food poisoning	waakye	lawra municipality, Upper West Regio	FDA Office complainant	4	0
Suspected food poisoning	Fresh fish (Ntsitsie)	Abeadze Kwaakrom in the Mfantseman Municipality of the Central Region	Media	25	0
Suspected food poisoning	waakye	Takoradi, Abeadze Kwaakrom and Lawra Municipality	FDA Office	4	0
Suspected food poisoning	rice boiled with roselle leave and soup prepared with dawadawa	Akoro a suburb of Jirapa	Social media	3	2
Suspected food poisoning	calamari	-	Social media	2	0

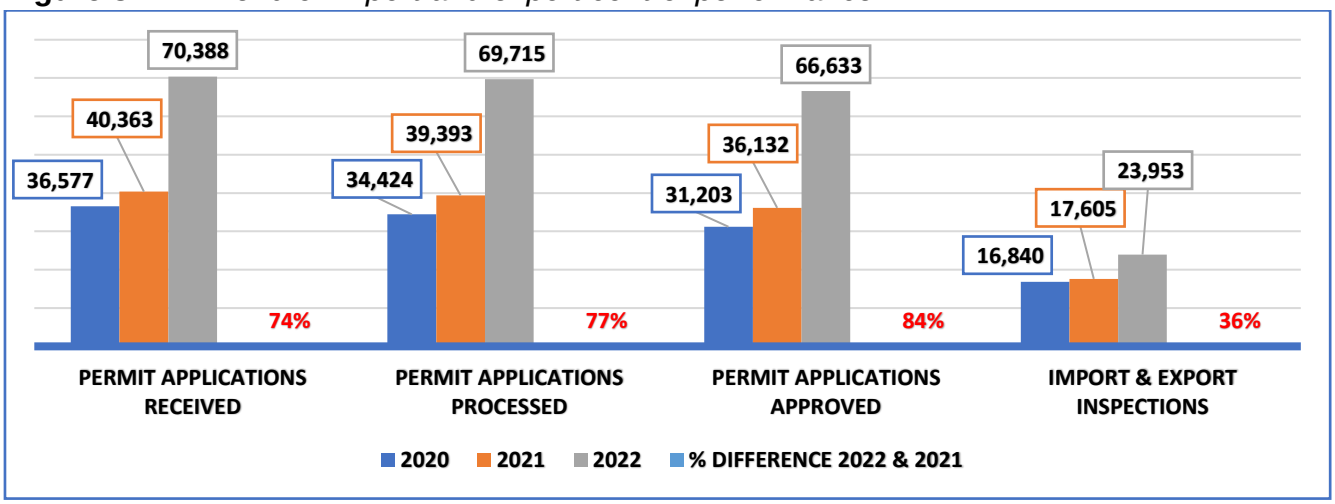
Suspected food poisoning	Fufu and palm nut	Knongunor-Susu in the Lower Manya Krobo Municipal	Ghana Health Service	9	1
Suspected Foodborne disease	Camp meal (groundnut soup)	South Tongu Municipality in the Volta Region	37 Military Hospital	65	1
Suspected food poisoning	fried rice, chicken and jollof rice with coleslaw	Section of the public in east legon	Social media	45	0

***Source**: FDA, Foodborne Disease Surveillance (2022)*

3.7 Import and Export Control

The 2022 annual target for the number of permit applications received was forty-four thousand, three hundred and ninety-nine (44,399). All permit applications received were expected to be processed. By the end of the year, a total of seventy thousand three hundred and eighty-eight (70,388) permit applications were received, 158% of its annual target. Sixty-nine thousand seven hundred and fifteen (69,715) of the permits received were processed exceeding its annual target by 57%. The difference between the applications received and processed was those applications awaiting vetting during the period. During the year, eleven (11) bonded warehouses were inspected, however, twelve (12) bonded warehouses were licensed as a result of licensing of a facility that was inspected in the previous year.

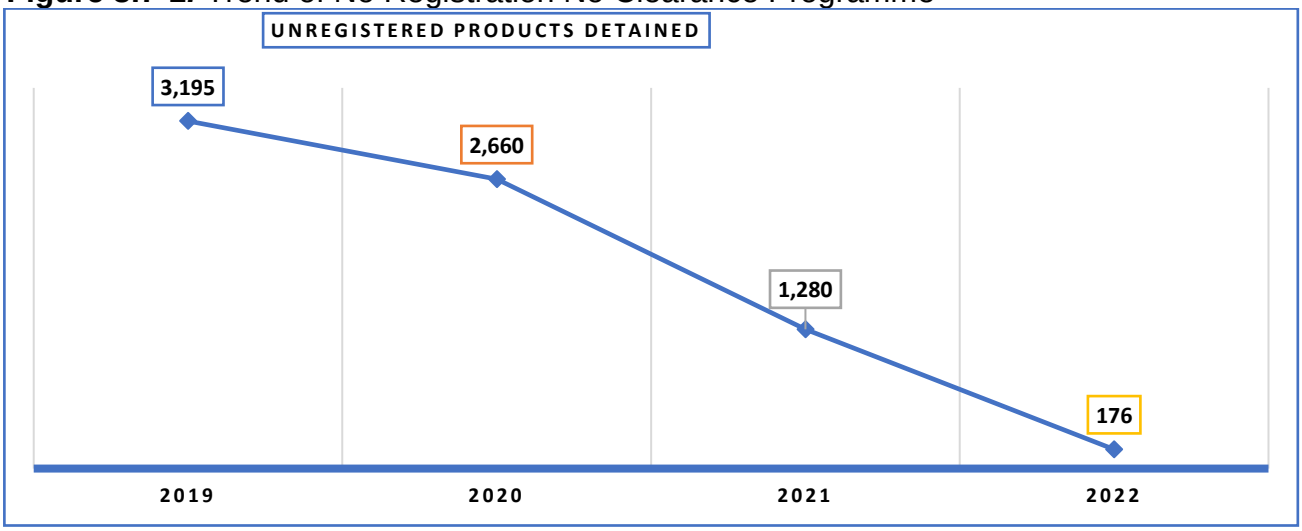
Figure 3.7-1: *Trend of import and export control performance*



***Source**: FDA Planning, Monitoring and Evaluation Department (2022)*

A total of seventy thousand three hundred and eighty-eight (70,388) permits were received and sixty-nine thousand seven hundred and fifteen (69,715) permits processed in 2022; this represents an increase of 74% and 77% respectively from the previous year. Out of this number, sixty-six thousand six hundred and thirty-three (66,633) permits were approved. Twenty-three thousand nine hundred and fifty-three (23,953) consignments were duly inspected, representing a 36% increase compared to the previous year.

Figure 3.7-1*:* Trend of No Registration No Clearance Programme



***Source**: FDA Planning, Monitoring and Evaluation Department (2022)*

To reduce the importation of unregistered products through the Tema Port, the FDA launched the "zero tolerance" for the importation of unregistered products programme. The implementation of 'no registration no clearance policy at the Tema port in May 2021 has led to a cumulative 87% decrease in detention of unregistered consignments, thus reducing the pressure of work on the enforcement teams and thus enabling them to focus on other key regulatory assignments.

3.8 Clinical Trial Authorization

A total of fifteen (15) new clinical trial applications were approved. Twenty-six (26) amendments and two hundred and forty-eight (248) Ad-Docs were also received during the year.

A total of Two hundred and twenty-three (223) Serious Adverse Events (SAE) reports were received. All the SAE reports received were reviewed by the Technical Advisory Committee (TAC). Eight (8) Good Clinical Practice (GCP) inspections were conducted during the reporting period.

Regional Centre of Regulatory Excellence (RCORE) training in Clinical Trials is organized to strengthen capacity of regulators, academics and health professionals' in clinical trials within the Africa region to enhance the conduct of clinical trials. The overall objective is to ensure that African citizens have access to quality, safe and efficacious medication, medical devices and health claimed products. A total of 69 persons participated in the training, 46 were international participants, and 23 local participants including FDA staff across the country involved in clinical trial monitoring.

3.9 Support for Local Industry

3.9.1 Technical support to Industry

Twenty-four (24) applications were received for review of conceptual designs for the year under review. A total of twenty-three (23) applications were reviewed, of which four (4) were approved. The FDA planned to conduct thirty (30) technical assistance programmes for industries in 2022. As at the end of the year, eighty-two (82) technical assistance programmes had been carried out, a 26% increase in performance compared to the previous year.

3.9.2 Capacity Strengthening

3.9.2.1 Training Programmes

The 2022 annual target for the number of participants trained in Good Manufacturing Practices and Good Hygiene Practices was four hundred (400) and three hundred (300) respectively. By the end of the year, a total of four hundred and twenty (420) and eight hundred and thirty (830) participants had been trained in Good Manufacturing Practices and Good Hygiene Practices respectively, representing an achievement of 105% and 277% of the annual targets. In total, four hundred and twenty (420) participants from two hundred and four (204) Food manufacturing companies were trained in various aspects of the current codes of Good Manufacturing Practices compared to one hundred and thirty-nine (139) participants 2021 and sixty-one (61) participants in 2020.

Due to an increase in requests for training from clients following intensive surveillance activities, eight hundred and thirty (830) participants from one hundred and thirty-one (131) Food Service Establishments (FSEs) were trained in the Principles of Food Safety and Good Hygiene Practices. An improvement, compared to one hundred and five (105) participants in 2021 and ten (10) participants in 2020.

Forty-one (41) participants from six (6) Pharmaceutical Companies were trained in the current codes of Good Storage and Distribution Practices in the fourth quarter of 2022.

3.10 Tobacco and Substances of Abuse Control

3.10.1 Tobacco Control

The 2022 annual target for the number of tobacco product applications received and processed was twenty (20). By the end of the year, the FDA received twenty (20) applications were received. All applications processed were approved, a 43% increase compared to the previous year. One hundred and Seventy-Six (176) permit applications received were processed for tobacco products, out of this, one hundred and forty-six (146) were approved and thirty (30) were rejected. This is a 25% increase in permits issued compared to the previous year.

The WHO Framework Convention on Tobacco Control (FCTC) project 2030 was duly launched in 2022 by the Minister of Health. The project will provide support and technical direction to propel the comprehensive implementation of the FCTC in strengthening tobacco control in the country.

The official launch of the 2022 World No Tobacco Day (WNTD) was held at the GNAT Hall, Bolgatanga on the 31st of May 2022. Traditional leaders present at the launch showed commitment to the possible replacement of tobacco in customary practices. The paramount Chief of the Sakoti traditional area in the Nabdam District of the Region, Naaba Sigri Bewong in his speech during the launching explained how influential members of society were expected to own tobacco (pipes), as a sign of higher status. He further outlined the use of raw tobacco for marriage dowry in parts of the Northern belt of Ghana, more specifically in the Upper East amongst the Kusasis and Frafras. He reiterated his commitment to the replacement of tobacco in customary practices to other alternatives like money. According to the paramount chief, the House of Chiefs for the Region had held Traditional Council sessions over the period to discuss the prohibition of tobacco as dowry requirements. He referenced the Chieftaincy law Act 759

which gives them the mandate to modify aspects of their custom, which seem to be outmoded. Naaba finally encouraged people who cultivate tobacco to grow other crops.

3.10.2 Controlled Substances Control

The Institution planned to issue a total of forty-five (45) controlled substances of finished products and raw materials to importers and manufacturers in 2022. By the end of the year, the FDA had achieved 113% of its annual target issuing controlled substances to twenty-four (24) importers of finished products and twenty-seven (27) importers of raw materials. This was a 14% decrease in allocation compared to the previous year.

Fifty-four (54) facilities were scheduled to be visited to monitor compliances with controlled substances regulation. 54 inspections were conducted, 22 announced inspections for importers and 34 unannounced inspections. Out of this, 32 were for wholesalers / retailers and 2 were importers of controlled substances.

A total of one hundred and seventy-five (175) permit applications were received and vetted for controlled substances, out of this, one hundred and fifty-one (151) permits were issued, twenty-one (21) rejected and five (5) import permits were returned. This represents a 10% and 51% decrease in permits issued and rejected over the previous year.

Say No to Drug Abuse (Daabi) music video campaign for secondary schools was successfully launched at the Achimota secondary school and subsequently follow up programmes organized at Wesley Grammer and Accra Academy Senior High School and all FDA social media platforms and currently has twenty-five thousand (25,000) views on YouTube. This initiative is to increase coverage of substance abuse awareness nationwide and develop the youth as ambassadors in disseminating the dangers associated with drug abuse.

3.11 Public Awareness and Education

The annual target for the number of persons to be reached with training programmes was two million six hundred forty-six thousand seven hundred and thirty-five (2,646,735), by the end of the year two million three hundred and sixty-nine thousand six hundred and sixty-six (2,369,666) persons had been reached an achievement of 90% of the annual target set.

One thousand eight hundred and twelve (1,812) educational campaigns were organized for basic and secondary schools, tertiary institutions, marketplaces, transport terminals, non-governmental organizations, religious organizations and the media (radio, TV stations and

electronic stations); an increase in public education on key and emerging safety issues compared to previous years. 2369666

3.*11* Communication and Public Education

The 2022 annual target for the number of press releases issued was twenty (20). By the end of the year however, a total of sixteen (16) press releases had been issued.

Online activities in 2022 improved as compared to the previous years. There was an increase in the social media engagements, publications posted on the FDA social media handles, and online stories monitored over the period. The number of social media engagements as at the end of the year was three hundred and eighteen thousand four hundred and seventy-nine (318,479) engagements which was an astronomical increase of 1393% compared to the previous year's engagements. New followers across the various social media handles (Facebook, twitter, LinkedIn and Instagram) were forty-two thousand eight hundred and sixty-eight (42,868) an increase of 77% compared to the previous year's figure of twenty-four thousand one hundred and ninety-seven (24,197). Out of this number, Facebook, Twitter, LinkedIn and Instagram, constituted 18%, 9%, 4% and 69% respectively of the number of new followers attained in 2022.

The FDA was recognized as part of the first ten (10) public sector institutions that effectively deployed the tools of digital media to reach the public.

3.12 Donor Funded Projects

The following activities were undertaken by the institution for the various donor-funded projects during the year under review:

- **The BERC-Africa Project**; a 36-month project sponsored by European and Developing countries Clinical Trials Partnership (EDCTP) with the aim of building and enhancing capacity of regulators in clinical trials in Africa through short training programmes and courses commenced in October 2020 and expected to end in September 2023

- The Malaria Vaccine Implementation Programme launched on 30th April 2019 with a total of 898,208 doses of Mosquirix given as of 31st December 2022

- The Implementation Research training as part of SAVING Consortium capacity building, at Aburi, Eastern Region

- Commencement of Implementation Research on the uptake of the Med Safety App titled "Identifying and addressing challenges with uptake of mobile application for reporting adverse reactions in Ghana.

- Nationwide testing of Sudan dyes in palm oil project.

4.0 2021 FINANCIAL PERFORMANCE

The FDA targeted to collected revenue of One Hundred and Twenty-Five Million, One Hundred and Fifty-Eight Thousand, Three Hundred and Forty-Eight Ghana Cedis Thirty-Six Pesewas (GH¢125,158,348.36) for the year 2022. By the end of the year, a total of One Hundred and Forty-One Million, and Seventy-Eight Thousand, Three Hundred and Sixty-Three Ghana Cedis, Sixty-Four Pesewas (GH¢141,078,363.64) had been collected, an increase of 30% compared to One Hundred and Eight Million, Six Hundred and Sixty-Seven Thousand, One Hundred and Ninety-Five Ghana Cedis and Sixty-Nine Pesewas (GH¢108,667,195.69) generated the previous year. Out of this amount, thirty-six million, Three Hundred and Twenty-Two Thousand, Four Hundred and Seventy-Seven Ghana Cedis and Twenty-Nine pesewas (GH¢36,322,477.29) was transferred to the consolidated fund while One Hundred and Four Million, Seven Hundred and Fifty-Five Thousand, Eight Hundred and Eighty-Six Ghana Cedis and Thirty-Five Pesewas (GH¢104,755,886.35) was spent on operational activities.

Table *4.0*-1: Revenue Budget and Actual Performance

2022 ANNUAL BUDGET (GHS)			
	BUDGETED	**ACTUAL**	**VARIANCE**
Total Revenue	125,158,348.36	141,078,363.64	15,920,015.28
FDA Retention	87,610,843.85	104,755,886.35	17,145,042.50
Transfer to Consolidated Fund	37,547,504.51	36,322,477.29	(1,225,027.22)

***Source**: FDA Financial Report (2022)*

Table *4.0-2:* Expenditure Budget Performance

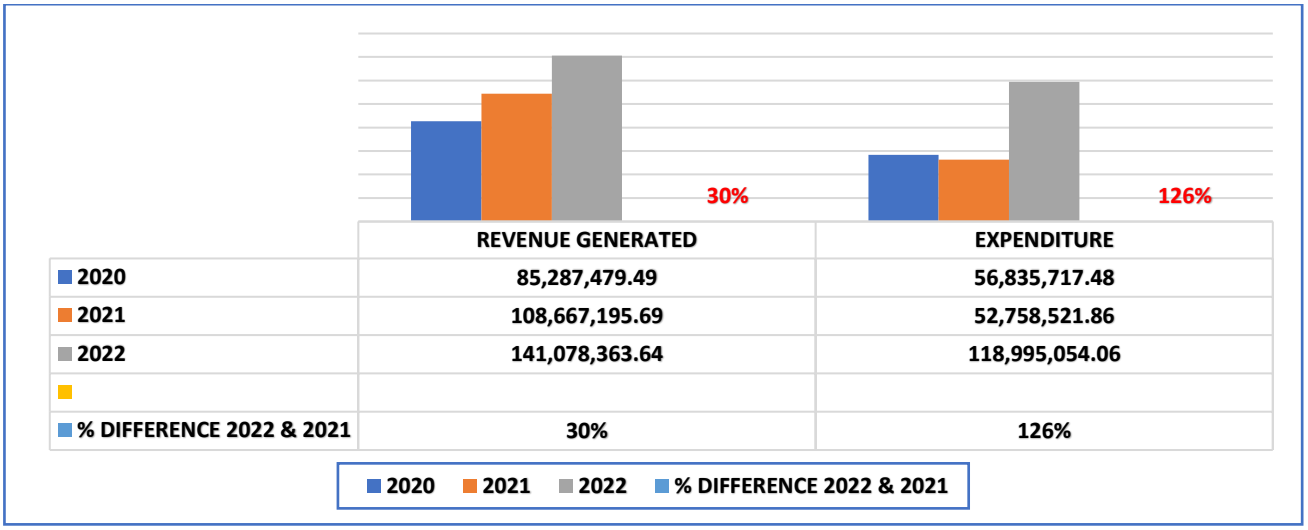
EXPENDITURE ITEMS	**BUDGET(GHS)**	**ACTUAL (GHS)**	**VARIANCE (GHS)**
IGF Compensation	40,012,632.00	34,245,242.37	(5,767,389.63)
GOG Compensation	23,540,067.00	28,506,439.85	4,966,372.85
Goods & services	49,886,005.00	70,715,398.77	20,829,393.77
Capital expenditure	16,646,060.00	14,034,412.92	(2,611,547.08)

Total	**130,084,765.00**	147,501,493.91	**17,416,728.91**

Source: *FDA Financial Report (2022)*

In 2022 the FDA exceeded its GoG Compensation and Goods and Services budget by 21% and 42% respectively as indicated in table 4.0-2 above. The year also recorded 14% and 16% less of the IGF Compensation and capital expenditure budget respectively. The entire expenditure budget for 2022 exceeded its target by 13% due to the general increase in the prices of goods and services, increase in staff strength, increase in exchange rate and upward review of contracts the Institution previously entered into.

Figure 4-*0-1: Revenue and Expenditure Performance*



Source*: FDA Financial Report (2022)*

The Authority exceeded its revenue target by 13% in the year under review and increased revenue collection by 30% compared with 2021 figures. However, the institution exceeded its IGF expenditure by 12% and performed 126% over 2021 expenditure figures due the general increase in the prices of goods and services, increase in exchange rates and upward review of contracts. Due to funds allocated to the FDA Ministry of Finance, as a result of the increased IGF retention for 2021, from 50% to 70%.

4.1 Internal Audit

The Internal Audit Directorate (IAD) in line with its key role as set out in sections 16 (3&4) and 83 of the Internal Audit Agency Act, 2003 and Public Financial Management Act, 2016 (Act 921) respectively, submitted an annual audit plan to management and the audit committee of the

board which was approved for the year under review. In pursuant to the 2022 annual audit plan, five (5) financial audits were conducted with eleven non-compliances observed. The coverage of required financial audit executed for 2022 financial year included the Head Office, Tema Office, KIA Office, and the nine (9) Regional Offices. The directorate could not achieve its target of visiting the regions twice in the year, due to manpower constraints. A review of financial audit findings for the past three (3) years shows a significant improvement in internal controls. The institution recorded 100% lodgment of all collected revenues, timely lodgment of collected revenues including appropriate recording and accounting for all received revenues in the year 2022. Expenditure transactions also saw thorough pre and post audits by the Internal Audit Directorate. All post payment non-compliances were referred to appropriate directorates or departments for redress. However, no major financial risk incident was recorded for the year under review.

Pre-audit and verification activities, which focused on pre-expenditure payments and payroll vouching, ensured that all payments and payrolls were reviewed before payments were effected. Overall, 97% of all payments and all payroll requests received were processed for payments. Transactions which did not meet the required payment process were referred to the user departments for appropriate action. Procured items and supplies to the FDA Stores were verified accordingly with no exceptions observed for the period under review.
On performance audit, the directorate executed three (3) out of four (4) planned audits due to changes in planned man hour requirement for both financial and performance audit. The executed performance audits resulted in improved operational controls in respective audited units.

In staff development, the Authority sponsored some staff of the directorate to attend the international conference of Global Institute of Internal Auditors and the Internal Audit Agency Conference for 2022.
Overall, we expect the directorate to be provided audit software, additional staff, and continued staff development to enable it to deliver its mandate.

5.0 SUMMARY OF KEY ACHIEVEMENTS FOR 2022

5.1. ACCREDITATIONS

1. The Centre for Laboratory Services and Research (CLSR) expanded its ISO 17025:2017 accreditation from 48 to 58 tests for drugs, medical devices, cosmetics, household chemical substances and food laboratories. The food lab was accredited for the first time for 5 tests.

2. The Drugs Laboratory of the CLSR achieved WHO ML4 vaccine procuring and was awarded a WHO-Prequalified Quality Control Laboratory (QCL) status. Implying that that results of analysis from the CLSR are acceptable globally. It is the first lab in West and Central Africa to achieve this feat.

3. FDA supported Nigeria, South Africa and Rwanda through its capacity strengthening programmes including training courses, assisted self-benchmarking and study tours in their preparation for their formal WHO benchmarking for Maturity Level 3 in 2022.

5.4 P*ARTNERSHIPS & INTERNATIONAL COLLABORATIONS*

1. The FDA in collaboration with MUSIGA released an all-star anti-drug abuse campaign music video in the fight against substance abuse among the youth of Ghana.

2. FDA implemented a conceptual framework to strengthen its collaboration with Research and Academic Institutions to drive evidence-based regulatory policy and decisions to protect public health.

3. A national food safety emergency response plan (FoSERP) was developed and launched, and its nine (9) member Management Committee inaugurated to ensure quick, effective and coordinated response to food safety emergencies.

4. The National Food Safety Policy was launched to facilitate effective coordination of stakeholders in the food control system to ensure food safety from farm to fork- Committee representatives are drawn from the FDA, PPRSD, VSD, GSA, Disease Surveillance Department, GHS, National Security Secretariat, Fisheries Commission, Customs Division and Public Health Directorate of 37 Military Hospital.

5. FDA implemented a conceptual framework to strengthen its collaboration with Research and Academic Institutions to drive evidence-based regulatory policy and decisions to protect public health.

6. The FDA-GSA joint application system was operationalised to enable applicants obtain the FDA registration and GSA certification simultaneously with a single application. The first ten (10) product applications were successfully processed via this system which aims to save our applicant's valuable time.

7. The FDA in collaboration with ProPer Alliance, launched the ProPerSeals Platform to enable consumers verify registration status of FDA regulated products and to support Intelligence gathering and investigation of complaints to enhance supply chain security and counteract the incidence of substandard and falsified FDA regulated products.

8. FDA signed an MOU with the Ministry of Trade and Industry to increase our presence at the district level through their Business Resource Centres; providing essential services to FDA clients.

9. FDA participated in the 2nd Intra-African Trade Fair, 2021, organised under the auspices of the Africa Continental Free Trade Area (AfCFTA) to facilitate IntraAfrica trade in line with the AfCFTA vision.

10. FDA participated in a Paul Ehrlich Institute sponsored training for 10 regulators from Gambia (5), Sierra Leone (3) and Liberia (2) in Clinical Trials Oversight and Pharmacovigilance.

11. The FDA has been accepted as an associate member of the International Collation of Medicines Regulatory Authorities (ICMRA). It is a voluntary, executive-level, strategic coordinating, advocacy and leadership entity of regulatory authorities working together on emerging regulatory issues.

12. The FDA as a Regional Centre for Regulatory Excellence (RCORE) in collaboration with the School of Public Health of the University of Ghana organised the following in 2022:

    a. The first Advanced RCORE Fellowship Training Programme in Clinical Trials Oversight for Eleven (11) African regulators.

b. The first RCORE Fellowship Training Programme that included participants from francophone West Africa (Gabon, Senegal, Cameroon and Guinea Conakry and Benin).

The programme has since 2014 strengthened the capacity of more than 80 regulators and researchers on the African continent to ensure access to quality safe and efficacious medicines.

OPERATIONAL ACHIEVEMENTS

1. The FDA opened new offices bringing its services closer to its clients and consumers by operationalising the Western North Regional Office in Sefwi Wiawso, two district offices in the Central Region, at Kasoa in the Ewutu Senya East District and at Assin Fosu in Assin Central District. Furthermore, the FDA obtained office spaces at Nalerigu in the Northeast Region and Kade in the Eastern Region to operationalise a regional office and district office respectively in 2023.

2. FDA inspected two thousand eight hundred (2,800) food service establishments comprising restaurants, fast food joint and catering facilities for compliance to current Good Hygiene Practices to safeguard public health. The perennial backlog of inspections for food service establishments has been eliminated and client waiting time for inspections has reduced from 5 months to 3 weeks. Additionally, three thousand and thirty seven (3,037) previously unknown facilities were identified as part of this programme aimed at unearthing facilities operating without hygiene permit. This was achieved using trained national service persons supervised by permanent staff and the use of public transport services to address the challenge of inadequate staffing and transportation.

3. Under the FDA's Progressive Licensing Scheme (PLS) which utilises a 3-tiered approach for licensing micro and small-scale manufacturing facilities; Fifty-six (56) cosmetics and household chemical substances and two hundred and thirty-seven (237) food manufacturing facilities were licensed. In addition, Two Hundred and fifty-two (252) cosmetics and household chemical substances and nine hundred and thirty-four (934) food products were registered. The PLS coupled with other risk-based product

registration, supports micro and small-scale enterprises to access market quicker with quality and safe products.

4. Under the Street Food Vending Permit (SFVP) initiative, four thousand nine hundred and fifty-eight (4,958) street food vendors were identified and trained in Good Hygienic Practices (GHP) to safeguard public health and safety. Five hundred and eight-one (581) street food vendors who met basic requirements of safety were issued with hygiene permits for display at the point of sale to boost consumer confidence. The public have been sensitized to authenticate validity of these hygiene permits before patronising vendors. \

5. AWARDS

i. The FDA received the Most Financially Sustainable Regulator and the Best Inter-Trading Specified Entity of the year 2022 during the 1st Public Enterprise League Table Awards ceremony organized by Ministry of Public Enterprises, State Interests and Governance Authority and Ministry of Finance.

ii. The FDA received the Industry Leadership Award by the Ghana –West Africa Healthcare Excellence Awards ceremony held by the Unique Communications.

iii. The Institution's Communication Team received the Corporate Communications Team of the Year (Government Regulations) award during the 4th National Communications Awards ceremony which was organized by the Africa Digitization Impact Project and RAD Communications.

iv. The Institution received the Customer Service Focused, Public Sector Institution for the year 2022 – 2023 award during the Ghana Customer Service Excellence Recognition Scheme organized by the National Customer Service Advocate, GLOBAL PLUS CO. LTD & Ghana Customer Service Development Initiative.

v. The FDA was awarded with the Gold Label Seal of Good Standing in the Delivery of Customer Service and Consumer Relations Excellence at the Ghana Customer Service Excellence Recognition Scheme organized by the National Customer Service Advocate, GLOBAL PLUS CO. LTD & Ghana Customer Service Development Initiative.

vi. The FDA received an Excellence in Government Regulatory and Standards award during the 2nd National Governance & Business Leadership Awards 2022.

vii. The FDA received the National Government Agency of the year award during the National Business Honors award ceremony.

6.0. CHALLENGES

a. Renumeration at the FDA is less competitive compared to the industry and other analogous agencies and this affects the morale of staff and exposes them to pressures from the industry resulting in the loss of trained and experienced staff to industry and other organizations.

b. The retention of 30% of service charges by MOF affects operational efficiency.

c. Inadequate vehicles for operational activities resulting in long inspection waiting times and inspection backlogs.

6.1 MANAGEMENT OF CHALLENGES

a. Management continues to engage MOH, MOF, FWSC and other stakeholders on competitive staff renumeration.

b. The institution prioritizes expenditure to deliver services to clients.

c. The Use of risk-based scheduling of inspections and use of commercial transport for inspections.

d. Continuous dialogue with MOF for further assistance in IGF retention

e. Continuous dialogue with Donor Partners for funding to support key activities.

a. Staff use of personal laptops.

7.0 PRIORITIES AND OUTLOOK FOR 2023

OPERATIONAL ACTIVITIES

a. FDA will continue to strengthen its ***operational activities for*** product registration, facility licensing, market surveillance as well as the enforcement of the tobacco.

b. Remodeling of existing office space at FDA Heights at Tema into a Molecular Microbiology Laboratory

Technical Regulations Operational Activities

The FDA will continue to strengthen the following key activities; product registration, facility registration, market surveillance, product quality monitoring, product quality testing, safety monitoring of regulated products, clinical trials and control of substances of abuse as well as the enforcement of the tobacco control regulations (LI 2247).

Enforcement of Sections 106 and 115 of Part 7 of Act 851

The FDA will finalize the accreditation processes with COTVET for its Qualified Supervisors Courses developed with the support from Skills Development Fund and start running the same in Technical Universities and Private Consulting Firms across the country. This will ensure micro, small and medium scale enterprises (MSME) have easy access to accredited training institutions who will offer these for the food, cosmetics, household chemical substances and herbal medicine MSMEs.

Administration

Projects

The FDA will continue to strengthen its operational activities by creating conducive working atmosphere in all its offices by undertaking the following capital intensive projects in the year 2023.

a. Construction of Fence wall around the Food and Drugs Authority's Land located at Ho in the Volta Region, Tamale in the Northern Region, WA in the Upper West Region and Sunyani in the Bono Region.
b. Rehabilitations of mechanical and electrical fixtures at the Food and Drugs Authority official residence at the Western Region and Official Residence at Cantonments- Accra
c. Construction of access road from meridian road to the FDA office complex in Tema
d. Construction of Roof top bar, servery and store at Tema office complex of the for Food and Drugs Authority
e. Furnishing of FDA Regional Office at Bolgatanga in the Upper East Region
f. Construction of Security Post and Outhouse at the FDA Official Residence at Bolgatanga in the Upper East Region.
g. Construction of Water Tanks Platforms at FDA Heights
h. Construction of 2-Storey Office Complex for the FDA at Wa in the Upper West Region
i. Construction of 3-Storey Office Complex for the FDA at Ho in the Volta Region, Kumasi in the Ashanti Region
j. Construction of Remedial Civil Works on the food micro-biology LAB at the TUC office in Accra

Logistics

The FDA will procure additional motor bikes, ICT equipments, stationaries, and other logistics to support its operational activities.

Human Resource Management

Recruitment of Additional Staff

The FDA will recruit additional staff to strengthen its inspection and market surveillance activities across the country.

Partnerships and International Collaborations

- The FDA will fully operationalize FDA-GSA Operational Harmonisation Proposals with the establishment of systems to facilitate joint handling of client requests for registration, certification and export permits.

- The FDA intends to maintain its collaboration with the 1D1F secretariat in order to assist manufacturing facilities in obtaining regulatory approval for the production, distribution, and sale of FDA regulated products.
- The collaboration with Ghana Enterprises Agency (GEA) will be strengthened to support micro, small and medium-scale enterprises to comply with Good Manufacturing Practices using FDA's Progressive Licensing Scheme.

8.0 WAY FORWARD

Product registration targets for applications received are a combination of new and renewal applications; both are dependent on applicant decisions to submit application. Strengthening enforcement activities in the markets, seaports, airports, and border posts will contribute to an increase in applications submitted for products registration as well as facility licensing. An online systems and strategies will be developed to alert FDA of registered products due for re-registration but are still on the Ghanaian market.

The expansion of scope for the FDA progressive licensing scheme to include herbal medicine and small-scale pharmaceutical medicines manufacturers is in progress; this will increase our performance in product registration, facility licensing and industrial support services.

The strengthening of capacity of Centre for Import and Export Centre's for import data mining will facilitate the recovery of lost revenue from companies avoiding FDA regulation at the Tema Port and consequently increased performance in revenue collection, product registration and facility licensing.

There will be deployment of additional manpower and resources to support surveillance, inspections, public education, monitoring, and enforcement activities. National service personnel have been key to our performance for the past couple of years, thus with the commencement of the 2021/22 national service period, the additional manpower of the national service persons will be used to bridge the gaps in the FDA's operational areas.

9.0 APPENDICES

APPENDIX I – LIST OF GOVERNING BOARD MEMBERS

FDA GOVERNING BOARD MEMBERS				
S/N	**NAME**	**INSTITUTION**	**POSITION IN INSTITUTION**	**POSITION ON THE BOARD**
1	Dr. Sammy Ohene	University of Ghana Medical School	Head of Psychiatry Department	Chairman
2	Mrs. Delese A. A. Darko	Food and Drugs Authority	Chief Executive Officer	Member
3	Dr. Audu Rauf	Pharmacy Council	Registrar	Member
4	Professor Alex Asase	Centre for Plant Medicine and Research	Executive Director	Member
5	Prof. Charles Tortoe	CSIR- Food Research Institute	Acting Executive Director, CSIR-Food Research Institute	Member
6	Dr. Joyce Dontwi	Veterinary Services Directorate	Director	Member
7	Nana. K. Obiri	Ghana Federation of Traditional Medicine Practitioners Association (GHAFTRAM)	National Organizer	Member
8	Dr. Alhassan Emil Abdulai	University of Ghana. Accra.	Senior lecturer & Head of Departmental and Maxillo-Facial Surgery, School of Medicine & Dentistry	Member
9	Mrs. Martha Osei	Communication for Development Centre	CEO, Communication for Development Centre	Member
10	Prof. Alexander Dodoo	Ghana Standards Authority	Executive Director	Member
11	Mrs. Anna Pearl Akiwuni-Siriboe	Ministry of Justice and Attorney General's Department	Chief State Attorney	Member
12	Mrs. Yvonne Nkrumah	Food and Drugs Authority	Deputy Chief Executive Officer	Board Secretary

***APPENDIX II – LIST OF* EXECUTIVE COMMITTEE MEMBERS**

EXECUTIVE COMMITTEE MEMBERS				
S/N	**NAME**	**DIVISION/CENTRE/DIRECTORATE**	**POSITION IN DIVISION/ DIRECTORATE**	**POSITION ON** STRATEGIC **MANAGEMENT**
1	Mrs. Delese A. A. Darko		Chief Executive Officer	Chairman
2	Mr. Seth K. Seaneke	Health Products & Technologies Division	Deputy Chief Executive Officer	Member
3	Mrs. Akua O. Amartey	Technical Operations Division	Deputy Chief Executive Officer	Member
4	Mrs. Yvonne Nkrumah	Corporate Services Division	Deputy Chief Executive Officer	Member
5	Mr. Roderick Daddey Adjei	Food Division	Deputy Chief Executive Officer	Member
6	Mr. Eric Karikari-Boateng	Centre for Laboratory Services and Research	Director	Member
7	Emmanuel Yaw Kwarteng	Centre for Import & Export Control	Director	Member
8	Mr. Nicholas Agbomadzi	Finance Directorate	Director	Member
9.	Mr. Edem Kofi Kugbey	Internal Audit Directorate	Director	Member
10	Mr. Joseph Yaw-Bernie Bennie	Legal and Corporate Affairs Directorate	Director	Member
11	Mr. Kwame Dei Asamoah-Okyere	Business Development & International Partnership Directorate	Director	Secretary

APPENDIX III – LIST OF MIDDLE LEVEL MANAGEMENT

DIRECTORS/REGIONAL HEADS				
S/N	**NAME**	**DIRECTORATE/REGION/DEPARTMENT**	**POSITION**	**POSITION ON MLM**
1	Mr. Joseph Bernie Bennie	Legal and Corporate Services Directorate	Director	Chairman
2	Mrs. Faustina Atupra	Food Safety and Consumer Education Directorate	Director	Member
3	Mr. Thomas Amedzro	Enforcement Directorate	Director	Member
4	Ms. Maria Lovelace-Johnson	Inspectorate Directorate	Director	Member
5	Mr. Ebenezer Kofi Essel	Industrial Support Services Directorate	Director	Member
6	Ms. Nora Narkie Terlabie	Regional Operations Directorate	Director	Member
7	Mr. Samuel Asante Boateng	Drug and Herbal Medicine Registration Directorate	Director	Member
8	Mr. Emmanuel Nkrumah	Medical Devices, Cosmetics and Household Chemicals Directorate	Director	Member
9	Dr. Edwin Nkansah	Clinical Trials and Safety Monitoring Directorate	Director	Member
10	Mr. James Y. Lartey	Administration Directorate	Director	Member
11	Dr. Mrs. Olivia Agyekumwaa Boateng	Tobacco and Substances of Abuse Directorate	Director	Member
12	Mrs. Maureen Lartey	Food Registration and Applied Nutrition Directorate	Director	Member
13	Kwame Dei Asamoah Okyere	Business Development and International Partnership Directorate	Director	Member
15	Ms. Francisca Obeng	Central Regional Office	Ag. Regional Head	Member
16	Mr. Gorden Akurugu	Volta Regional Office	Regional Head	Member

17	Dr. Martin Kusi	Western Regional Office	Regional Head	Member
18	Mr. John Odai Tettey	Ashanti Region	Regional Head	Member
19	Ms. Akua Amponsaa Owusu-Antwi	Bono Regional Office	Regional Head	Member
20	Ms. Anita Kuffour	Eastern Regional Office	Ag. Regional Head	Member
21	Mr. Albert Ankomah	Western North Regional Office	Regional Head	Member
22	Mr. Zackariah Braimah	Northern Regional Office	Regional Head	Member
23	Mr. Sebastian Hotor	Upper East Regional Office	Regional Head	Member
24	Mr. Kelvin Dafaari Sunkpal	Upper West Regional Office	Ag. Regional Head	Member
25	Mrs. Naana Afrakoma Yawson	Supply Chain Department	Head of Department	Member
26	Mr. Prince Oduro	Financial Audit and Compliance	Head of Department	Member
27	Mrs. Jennifer Bonnah	Data Management Department	Head of Department	Member
28	Mrs. Harriet Ofori Antwi	Microbiology Laboratory Department	Head of Department	Member/ Secretary
29	Samuel Adom Siaw	Expenditure Department	Head of Department	Member
30	William Agbavitor	Legal Department	Head of Department	Member

APPENDIX IV – LIST OF HEADS OF DEPARTMENTS

DEPARTMENTS			
S/N	**NAME**	**DEPARTMENT**	**POSITION**
1	Jacob Amoako-Mensah	Import Control	Head of Department
2	Gloria Asum-Kwarteng	Export Control	Head of Department
3	Jennifer Bonnah	Data Management	Head of Department
4	Marian Kommey	Food Laboratory	Head of Department
5	Patrick Owusu-Danso	Drug Laboratory	Head of Department
6	Frederica Liz Hayford	Veterinary	Head of Department
7	Harriet Ofori-Antwi	Microbiology	Head of Department
8	Ishmael Larkai	Medical Devices	Head of Department
9	Prince Oduro	Financial Audit and Compliance	Head of Department
10	Emmanuel Aguedzi Tetteh	Revenue	Head of Department
11	Samuel Adom Siaw	Expenditure & Reporting	Head of Department
12	Nana Serwah Boateng	Strategy, Partnerships & International Collaboration	Head of Department
13	Joseph Ofosu Siaw	Quality Management System	Head of Department
14	Afua Amoako-Mensah	Planning, Monitoring and Evaluation	Head of Department
15	Mercy A. Owusu-Asante	Technical Support	Head of Department
16	Abu Sumaila	Capacity Strengthening	Head of Department
17	Vigil Edward Ashun-Prah	Intelligence	Head of Department
18	Daniel Teye	Operations	Head of Department
19	Mathew Gyan Nkum	Investigations	Head of Department
20	Geoffrey Victor	Manufacturing Facilities	Head of Department
21	Yvonne Miguela Osei	Storage Facilities	Head of Department

22	Andrew Manomey	Career Development	Head of Department
23	Bright Seyram Attakpah	Staff Welfare	Ag. Head of Department
24	Pascal Fosu	Administration	Head of Department
25	Naana Afrakoma Yawson	Supply Chain	Head of Department
26	William Korbla Agbavitor, Esq	Legal	Head of Department
27	Rhoda E. Appiah	Communication & Public Education	Head of Department
28	Isaac Marful Dapaah	Information Management & Technology Solutions	Head of Department
29	Eric Owusu	Drugs & Nutraceuticals	Head of Department
30	Ernest Afesey	Herbal & Homeopathic medicine	Head of Department
31	Roland Sefakor	Medical Devices	Head of Department
32	Victor Ofori Antwi	Cosmetics & Household Chemical Substance	Head of Department
33	George Tsey Sabblah	Safety Monitoring	Head of Department
34	Yvonne Ayongo Adu Boahen	Clinical Trial	Head of Department
35	Nathaniel Nkrumah	Vaccines and Biological Products	Head of Department
36	Adah Allotey Pappoe	Substances of Abuse	Head of Department
37	Jemima Donkor	Tobacco and Tobacco Products	Head of Department
38	Percy Adomako	Food Evaluation and Registration	Head of Department
39	Cheetham Mingle	Applied Research and Nutrition	Head of Department
40	Wilhemina Nyanta Quarcoopome	Food Service Establishment	Head of Department
41	Jocelyn Adeline Naa Koshie Egyakwa-Amusah	Food Safety Coordination & Consumer Education	Head of Department