FOOD AND DRUGS AUTHORITY

2020 ANNUAL REPORT

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EXECUTIVE SUMMARY

The Food and Drugs Authority (FDA) is the national regulatory body 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, biological products, cosmetics, medical devices, household chemical substances and clinical trials, and the control and use of tobacco products, through the enforcement of relevant local and international standards to protect public health of the people in Ghana. This report gives account of the FDA's performance in the execution of its core mandate for the period January – December 2020.

Product Registration

A total of eighteen thousand, three hundred and seventy-four (18,374) applications were received for the year under review; this represents an increase of 39% from the previous year, 2019. The number of processed applications increased to seventeen thousand seven hundred and forty-one (17,741) representing 38%. Out of this, fifteen thousand nine hundred and eighty-four (15,984) products were registered, representing an increase of 37% from 2019 while, a total of one thousand, five hundred and ten (1,510) applications were deferred, representing an increase of 3% as compared to total products deferred in 2019.

Facility Licensing

A total of five thousand, one hundred and fifty (5,150) applications were received for the year under review; this represents a zero percent (0%) increase from the previous year 2019. A total of six thousand, eight hundred and fifty-four (6,854) inspections were carried out in 2020; this represents 20% increase from the previous year. Three thousand nine hundred and four (3,904) facilities were licensed, representing an increase of 16% from 2019.

Market Surveillance

A total of nine hundred and twenty (920) market surveillance operations were carried out across the country; this marked a decrease of over 7% in the previous year's performance. Number of retail outlets that were visited decreased by 12%. A total of twenty-six thousand six hundred and sixty (26,660) non-compliant products were identified in trade; indicating a decrease of over 79% in last year's performance.

As an organization, the FDA undertook an average of three (3) market surveillance operations each week for the year under review which represents a decrease of over 7% in performance compared to the previous year, 2019.

Product Testing

The laboratory received seven thousand and ten (7,010) products; representing an increase of 142% in products received compared to that of the year 2019. Out of this number, six thousand four hundred and eighteen (6,418) products representing 170% were analyzed; this reflected a decreased of 13.74% compared to the number of products analyzed in 2019. In comparison to the 2019 data, the number of products that passed increased by 160% in 2020.

Adverse Drug Reaction Monitoring

The FDA received three thousand three hundred and seven (3,307) Adverse Drug Reaction (ADR) reports, representing an increase of 19% from 2019. One thousand three hundred and three (1,303) reports were however submitted to the Technical Advisory Committee (TAC) representing a decrease of 25% compared to 2019. All ADR submitted to the TAC were reviewed which represents a decrease of 46% from 2019.

Food Borne Disease Surveillance & Investigation

The number of outbreaks recorded decreased by 71.4%. There was no death associated with outbreaks recorded in 2019. Due to the absence of sentinel sites, there was no data collected on incident cases. The breakthrough partnership with Ghana Health Service (GHS) however, allowed FDA to incorporate its data needs into their Integrated Disease Surveillance and Response System thereby affording FDA to collect data on incident cases of food borne illness across the country.

Import and Export Control

Out of thirty-six, five hundred and seventy-seven (36,577) permit applications received, twenty-nine thousand two hundred and fifty (29,250) permits were issued in 2020, this represented a decrease of 21.8% of permit issued in 2019. Applications received for inspection decreased to 19.5% with a total of twenty-eight thousand, seven hundred fifty (28,750) applications submitted; out of this figure, sixteen thousand, four hundred and twelve consignments were duly inspected. This represents 8.8% decrease in the number of import inspections approved in 2020 compared to 2019. For export control operations, the number of applications received for inspections was five hundred and thirty-seven (537), representing an increase of 5.3% as compared to five hundred and ten (510) applications received in 2019.

Clinical Trial Authorization

The Clinical Trials Department received a total of fifteen (15) new clinical trial applications, seven (7) amendment and eighty-nine (89) Ad-Doc applications for consideration; (12) twelve out of the fifteen (15) new applications were deferred while the seven (7) amendment applications were approved. Three hundred and twenty-nine (329) serious Adverse Events (SAE) reports were submitted to the Technical Advisory Committee (TAC); Three (3) GCP inspections were conducted in the year under review. Out of which forty percent (40%) had minor non-compliance, forty-three (43) percent were major and no critical non-compliance was observed. A total of thirteen (13) permits were issued for importation of investigational products out of eighteen (18) applications.

Support for Local Industry

As a result of the 2020 GMP compliance road map, 6 Local Pharmaceutical companies have completed all outstanding GMP non-compliances and their manufacturing facilities commissioned in the middle of the year under review.

The Food Industrial Support Service Department of The FDA received two hundred and thirty-seven (237) training requests, representing a 6% decrease in performance. The FDA organized twenty-four (24) training programmes, a decrease of 33% compared to 2019; and trained four hundred and seventy-one (471) participants from two hundred and twenty-three (223) companies which represents a decrease of 52% and 28% respectively from last years. A total of one hundred and twenty-seven (127) companies had their facilities licensed based on the support they received from the Food Industrial Support Service Department.

Tobacco and Substance of Abuse Control

Fifteen (15) applications for registration of tobacco products were received, representing a decrease of 25% compared to 2019; fourteen (14) applications were approved and one (1) rejected. A total of one hundred and ninety-five (195) permit applications for controlled substances were received, representing an increase of 8% compared to 2019. one hundred and forty-eight (148) applications were approved and forty-seven (47) rejected. Twenty-eight (28) facilities that use controlled substances were audited indicating a 75% increase compared to the previous year; eight (8) non-compliances were observed, a decrease of 56% compared to 2019.

In the wake of the pandemic, World No Tobacco Day (WNTD) was successfully organised virtually with massive participation from stakeholders, National Union of Ghana Students (NUGS), some FDA staffs and media. Guidelines for control and supply of Controlled drugs were developed for sale.

Finance

The FDA through its Fees and Charges generated a total of one hundred and fifteen million, five hundred and seventeen thousand, seven hundred and fifty-seven cedis and seventy pesewas. (GH¢115,517,757.70) out of this, internally generated revenue amounted to eighty-five million, two hundred and eighty-seven thousand, four hundred and seventy-nine cedis and forty-nine pesewas (GH¢ 85,287,479.49). This represents an increase of 43.67% over the 2019 collections. The expenditure for 2020 is sixty-six million, two hundred thousand and eighty-four hundred cedis and thirty-five pesewas (GH¢ 66,200,084.35) indicating an increase of 11% over that of 2019.

Internal Audit

For the period under review, there were no infractions recorded for revenue, expenditure and payroll audits. This is a tremendous improvement for the organization and demonstrates the impact of internal audit on continuous improvement.

The performance of the FDA in respect of its regulatory functions of product registration, facility licensing, market surveillance, import and export control, product testing and safety monitoring increased. This follows the trend of the past two years – 2018 and 2019. There was, however, a 7% decrease in market surveillance activities. This notwithstanding, there are still gains to be made regarding process indicators such as the percentage of product applications processed, percentage of license inspections conducted, and percentage of submitted products tested. These gains appear to be locked up by resource constraints: human resource, vehicles, computers, application software and laboratory consumables and materials. Addressing these will enhance the Institution's performance in the respective areas. This will ensure that issues that limited performance in 2020 will be addressed to enhance performance in 2021.

1 INTRODUCTION

The Food and Drugs Authority 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 for food, allopathic, herbal and veterinary medicines, biological products, medical devices, cosmetics, household chemical substances, clinical trials, tobacco, tobacco products and substances of abuse. 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.

In 2020 the COVID-19 pandemic presented challenges and opportunity to FDA operations. With restrictions on public gatherings our training programmes and stakeholder engagements were postponed for some of our planned activities. The implementation of our planned 2020 programme of work has been adversely affected as a result of the current situation. The situation however, accelerated plans for implementation of a web-based registration application management system, the adoption of risk-based strategies and desk audits for facility inspection which will be used even after the COVID-19 pandemic as these have proven to be effective and efficient. The FDA has increased market surveillance of COVID-19 related products to ensure they meet quality and safety requirements. The FDA maintains 25% of its staff strength at its offices across the country. Staff work from home undertaking monitoring of advertisement, desk audits, and writing of reports and letters amongst other functions.

The FDA played a key role in the Ministry of Health's response to this pandemic by implementing measures to expedite approval of COVID-19 related medicines (2 days), household chemicals substances (2 days) and medical devices (2 days for PPEs and 30 – 40 days and Devices). The FDA released requirements for expedited approval of COVID-19 related products, locally made face masks, face shields and hand sanitizers. Guidelines for authorisation of emergency use of Antigen/Antibody RDTs for Sars-Cov-2 Virus was also released. The FDA implemented a safety monitoring plan to guide healthcare professionals to follow up patients with COVID-19 being treated with any of the medicines issued with "Emergency Use Authorization".

As an agency of the Ministry of Health, the FDA contributed to the implementation of 2018-2021 Heath Sector Medium Term Development Plan (HSMTDP) in 2020 under the *Health Sector Regulation Programme* and two related Sub-Programmes

i. Regulation of Pharmaceutical and Medicinal Health Products.
ii. Regulation of Food and Non-Medicinal Products.

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 defines the work culture within the organization are as follows:

i. Accountability
ii. Teamwork
iii. Integrity

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 organisation. 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. Carryout 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 account of the FDA's performance in the execution of its core mandate for the period January – December 2020.

2 MANAGEMENT AND STRUCTURE OF FDA

The Food and Drugs Authority has initiated the process of implementing its new organisational structure following approval from the Public Services Commission (PSC). The new structure has reduced the Deputy Chief Executive positions from six (6) to four (4); namely the DCEO Food Division, DCEO Health Products and Technologies Division, DCEO Technical Operations Division and DCEO Corporate Service Division. A directorship level comprising twenty (20) directorates has been introduced between the Departmental and the Deputy Chief Executive Officer levels. See appendix xx for new FDA organogram (Director level).

FDA Governing Board

The following member of the FDA Governing Board ended her tenure in 2020 after attaining the statutory retirement age:

NO.	NAME	POSITION	DATE OF APPOINTMENT	END OF TENURE
1.	Mary Obodai (Prof.)	Member	3rd April, 2018	November, 2020

An official communication of her successor is yet to be received from Food Research Institution. See appendix I for updated list of members of the Governing Board.

Management Team

Strategic Management

The following members of the FDA Strategic Management team retired from active service in 2020:

NO.	NAME	POSITION	DATE OF APPOINTMENT	DATE OF RETIREMENT
1.	Jones Ofosu (Mr.)	Head, Administration	1st November, 2006	5th June, 2020
2	Solomon Agampim (Mr.)	Head, Import and Export Control Department	14th February 2003	15th September 2020

Mr. Jones Ofosu and Mr. Solomon Agampim have since been replaced by their successors, Mr. James Lartey and Mr. Emmanuel Yaw Kwarteng respectively.

See appendix II for updated list of members of the Strategic Management team

Middle Level Management

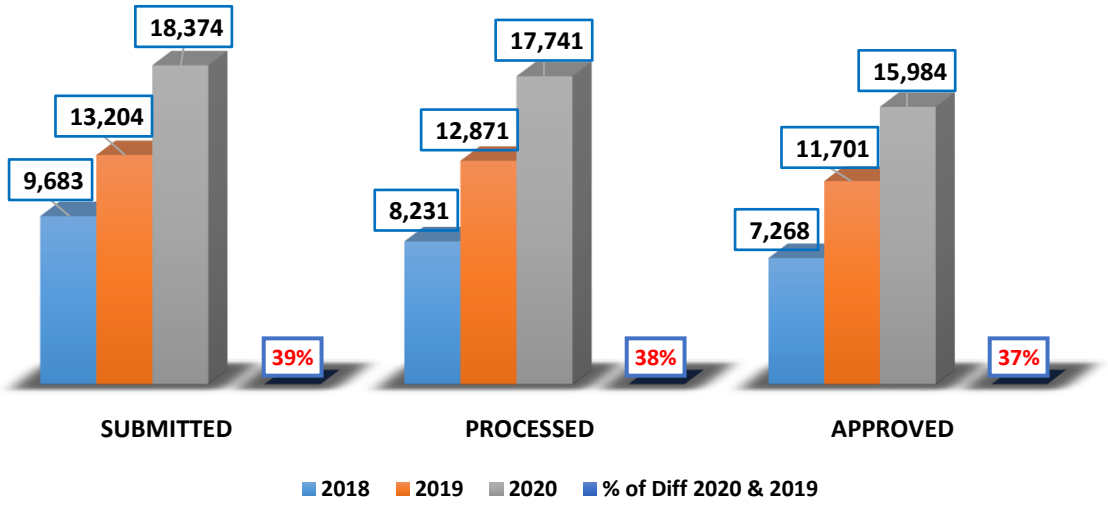
Nana Serwaa Boateng, a representative from the Project Research and Management Information Systems (PRMIS) was appointed as a member of the middle Level Management team in the year 2020. See appendix III for updated list of members of the Middle Level Management team.

3 2020 OPERATIONAL PERFROMANCE

3.1 Registration of FDA regulated products

The FDA has six (6) registration departments as follows: Food Evaluation and Registration, Drug Evaluation and Registration, Biological Products, Herbal Medicine, Medical Devices, and Cosmetics and Household Chemical Substances Departments. The graph above shows a representation of all products registered in the years 2018-20.

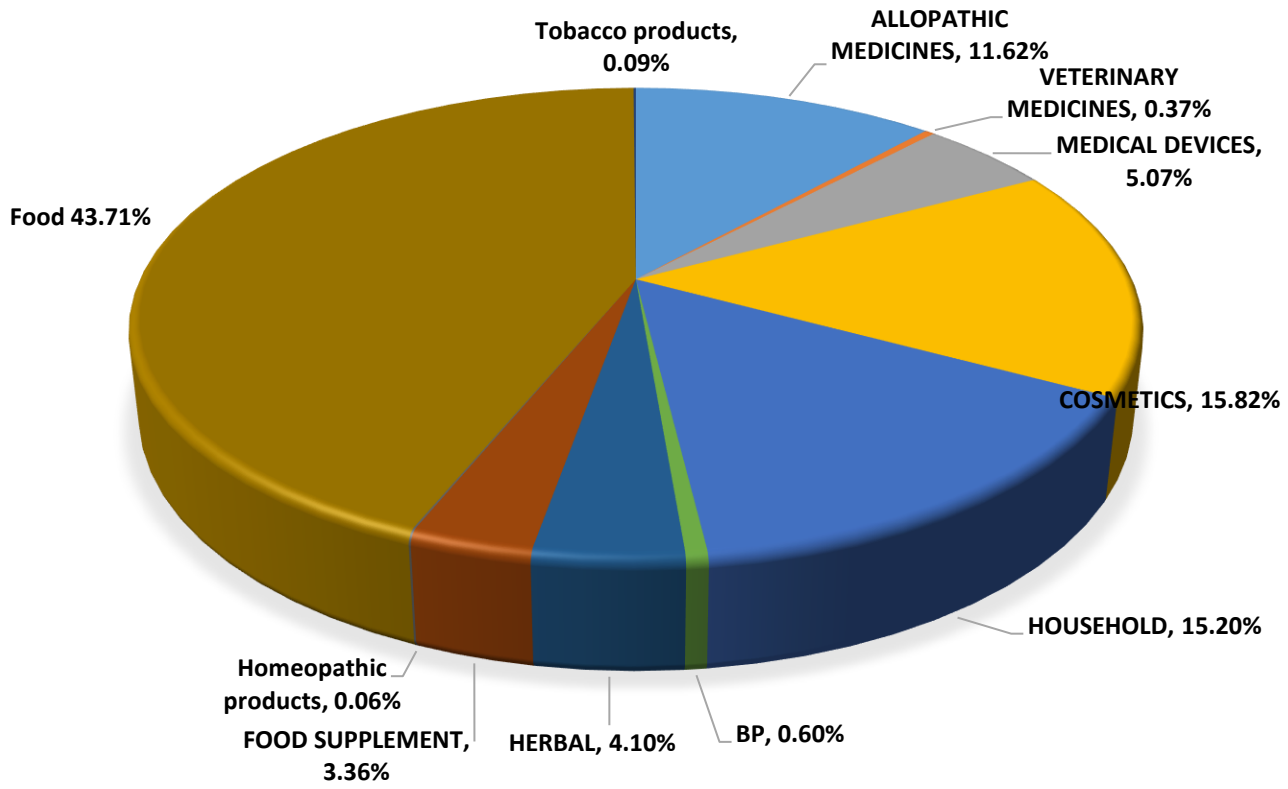
Figure 3.1-1: Performance trend for registration of FDA regulated products



Source: FDA Monitoring and Evaluation Division

The FDA in 2020 received a total of eighteen thousand three hundred and seventy-four (18, 374) products for registration, which represents an increase of 39% from the previous year. Out of that, a total of fifteen thousand nine hundred and eighty-four (15,984) products were registered as compared to that of eleven thousand seven hundred and one (11,701) in 2019; representing an increase of 37% from the previous year. Out of this number 58% were foreign products, and 42% local products.

Figure 3.1-2 Categories of Products Registered

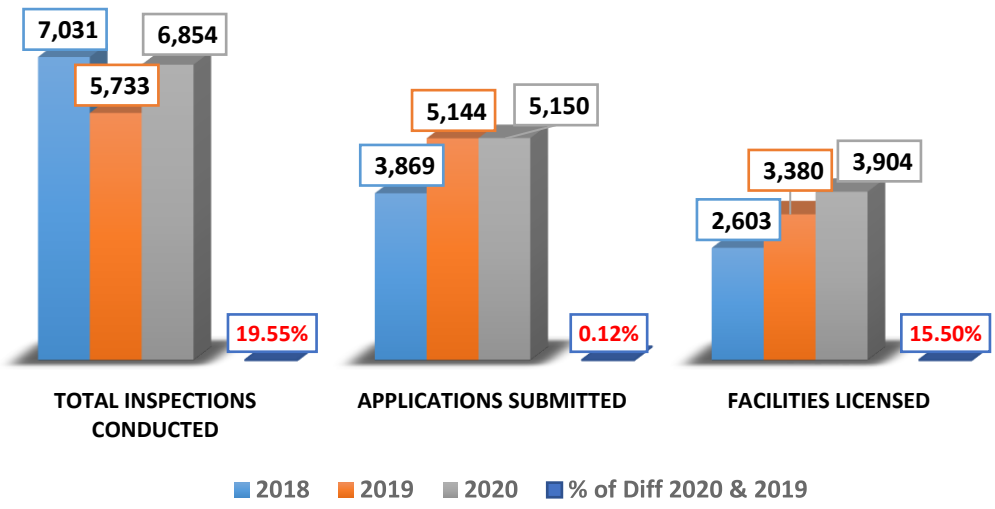


***Source**: FDA Monitoring and Evaluation Division (2020)*

3.2 Licensing of facilities regulated by the FDA.

The FDA has the following departments involved in the licensing of facilities: The Drug Inspectorate, Food Enforcement, Medical Devices, Cosmetics, Household Chemical Substances, Food Safety Management, Animal Products, and Agro-Produce and Biosafety Departments. The FDA operates a centralised system of licensure so all licenses for facilities in the Regions are issued by the relevant Departments at the Head Office in Accra.

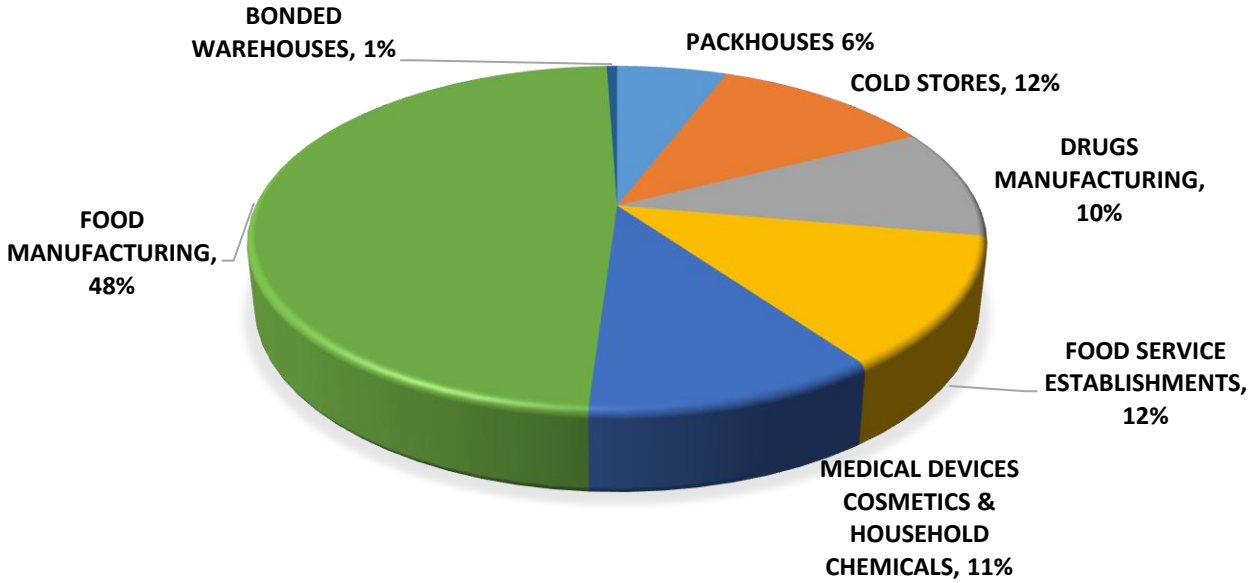
Figure 3.2-1*:* Performance trend for licensing of facilities regulated by the FDA**.**



***Source**: Monitoring and Evaluation Division (2020)*

A total of six thousand eight hundred and fifty-four (6,854) inspections were conducted in 2020 as shown in the graph above representing 20% increase from the previous year. The number of applications received also increased from five thousand one hundred and forty-four (5,144) to five thousand one hundred and fifty (5,150). Three thousand nine hundred and four (3,904) facilities were licensed in 2020 a 15.5% increase in compared to the 2019 performance.

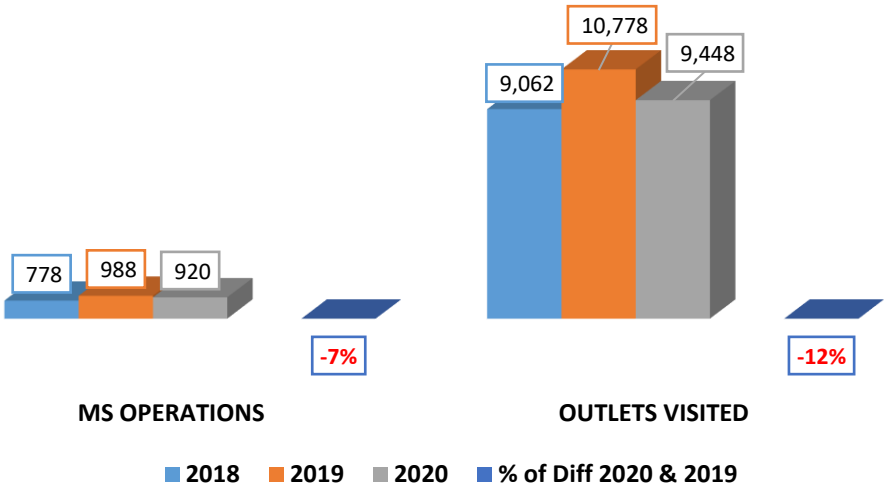
Figure 3.2-2: Categories of Facilities Licensed



***Source**: Monitoring and Evaluation Division (2020)*

3.3 Market surveillance operations

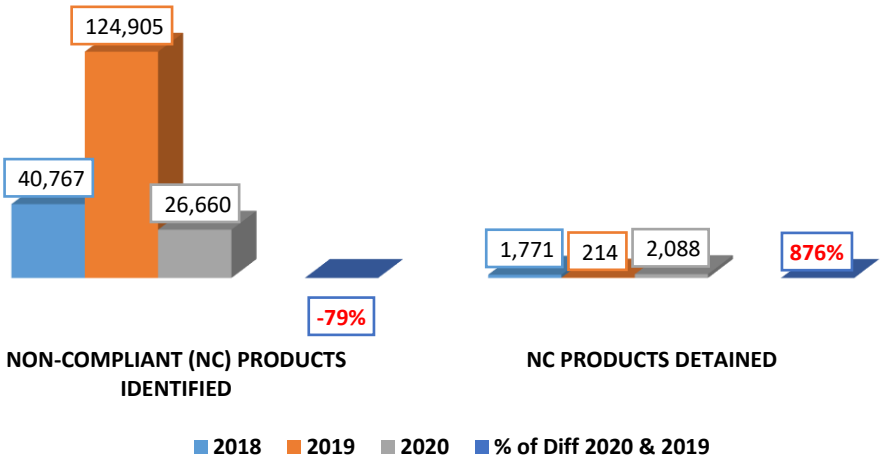
Figure 3.3-1: Performance for market surveillance operations



***Source**: Monitoring and Evaluation Division (2020)*

In 2020 a total of nine hundred and twenty (920) market surveillance operations were carried out across the country; a decrease of 7% over the previous year's performance as result of the reduction in the number of surveillance activities because of the COVID-19 restrictions. This led to a decrease in the number of outlets visited by 12% to nine thousand four hundred and forty-eight (9,448) outlets. This also led to a reduction in the number of non-compliant products identified during surveillance by 79%. This notwithstanding, products detained during this period were two thousand and eighty-eight (2,088) representing a significant jump of about 876% compared to last year.

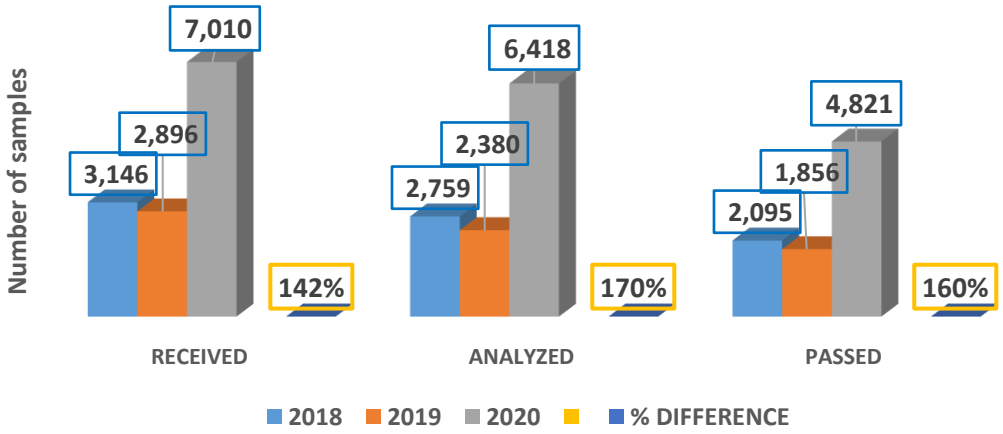
Figure 3.3-2: Non-compliant product identified in trade



***Source**: Monitoring and Evaluation Division (2020)*

3.4 Product Quality Testing

Figure 3.4-1: Product Quality Testing Performance

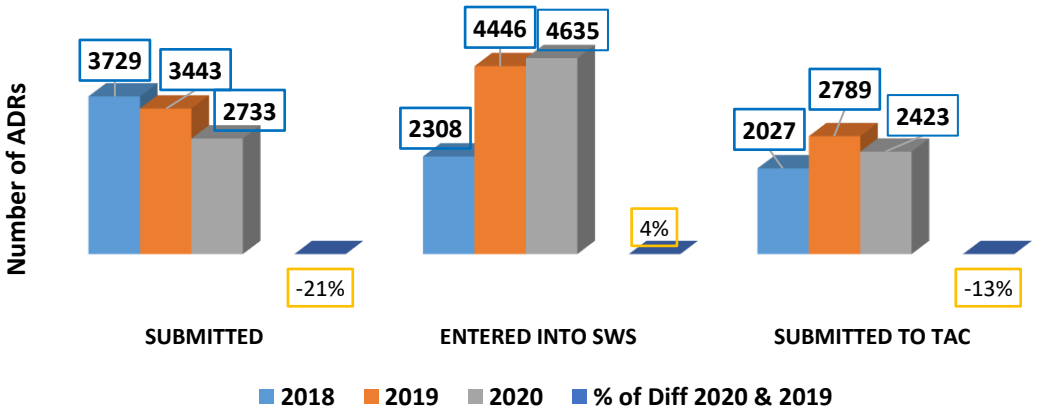


***Source**: Monitoring and Evaluation Division (2020)*

Seven thousand and ten products were received by the lab for testing; an increase of 142% compared to the previous year. Six thousand four hundred and eighteen (6,418) products were analysed; an increase of 170% over the previous year's performance. Four thousand eight hundred and twenty-one (4,821) products passed whilst one thousand five hundred and fifty-three (1,553) products failed. Five hundred and ninety-one (591) products could not be analysed for the year under review, due to logistic and personnel constraints. The increased number of requests and consequently analysis conducted is attributed to the increased number of COVID-19 related products that were submitted for registration.

3.5 Safety Monitoring performance

Figure 3.5-1: Trend of safety monitoring performance



***Source**: Monitoring and Evaluation Division (2020)*

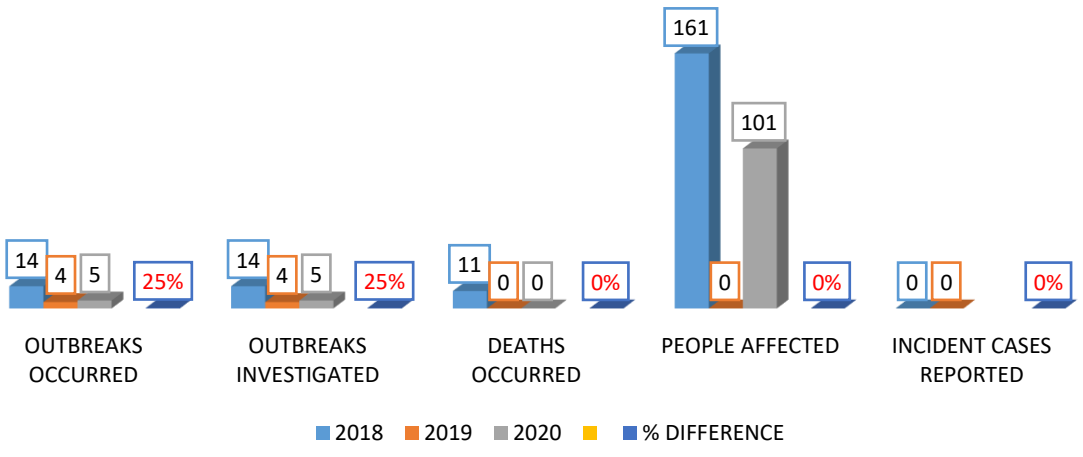
The FDA received two thousand seven hundred and thirty-three (2,733) adverse drug reaction reports; this was 21% less than was submitted in 2019. This is attributed to decreased hospital attendance due to COVID-19 restrictions introduced at health facilities; as they admitted only patients with emergencies. Four thousand six hundred and thirty-five (4,635) ADR reports were entered into the Safety Watch System (SWS); this was 4% more than was achieved in 2019. The variation between the ADRs submitted and those entered into the safety watch is accounted for by backlog of entries arising from manpower constraints from previous years, and the entry of forms that were previously exempted because they were classified as incomplete, but now have been cleared to be entered.

The number of ADR reports submitted to the TAC reduced by 13% to two thousand four hundred and twenty-three (2,423); as a result of a reduction in the frequency of meetings due to the COVID-19 pandemic restrictions.

3.6 Foodborne disease outbreaks and investigations indicators for 2018-20

Food borne disease outbreaks increased by 25% indicating a figure of five (5). The number of people affected by the outbreaks dropped by 6% to one hundred and one (101) from one hundred and eight. (108).

Figure 3.6-1: Food borne disease outbreaks and investigations indicators for 2018-20



***Source**: Monitoring and Evaluation Division (2020)*

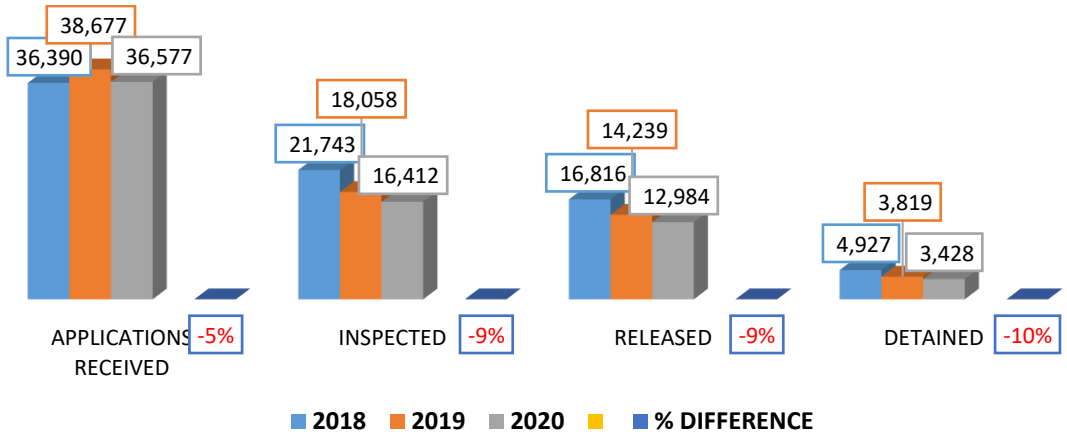
There was no death associated with the outbreaks investigated in 2020. No record of incident cases was collected for 2019 as well as 2020. Currently, no data is being collected on incident cases because there are no data sources. Through our partnership with Ghana Health

Service (GHS) the requisite FDA indicators have been approved for incorporation into the Integrated Disease Surveillance and Response System (IDSRS). This will enable the FDA to collect data on incident cases of food borne illnesses across the country. This is expected to commence following training of GHS staff from the FDA.

3.7 Import export control performance

A total of twenty-eight thousand seven hundred and fifty (28,750) permits were received and processed in 2020; this represents an increase of 6% from the previous year. Out of this number, thirty-four thousand one hundred and twelve (34,112) permits were approved. Regarding Applications; out of the total applications received for inspections, sixteen thousand, four hundred and twelve (16,412) consignments were duly inspected, representing 22% of total applications received.

Figure 3.7-1: Trend of import control performance



***Source**: Monitoring and Evaluation Division (2020)*

The number of consignments released decreased by 9% representing twelve thousand nine hundred and eighty-four (12,984); the number of consignments detained also decreased by 10% with a figure of three thousand four hundred and twenty-eight (3,428) in 2020, but in 2020, out of the total consignment inspected 9% were detained. The level of compliance by importers improved invariably in 2020 thus, resulting in low level records of detentions at the port as compared to 2019 detention records. There is a need to put interventions in place to curb this problem; as it would make more time and resources available to deal with other pertinent issues by the market surveillance teams.

Comparing the performance of work output for 2019 with 2020, the number of consignments inspected decreased by 9%, those released decreased by 9%, those that were detained decreased by 10% and those not inspected increased by 30%. There was however a constant decrease in consignments received, inspected, released, detained and not inspected when compared to the year 2019. This is attributed to the red, yellow and green channel system used at the Tema Port. Products that go through the green channel are not inspected. Over the period the number of products in this category has increased accounting for the observed trend.

Five hundred and thirty-seven (537) applications for export were received, inspected and approved; an increase of 5.3% compared to 2019. A total of two thousand four hundred and fifty-six (2,456) certificates of free sale were issued in 2020; a decrease of 27.4% compared to 2019.

3.8 Clinical Trial Authorisation

The Clinical Trials Department received a total of ten (10) new clinical trial applications, five (5) amendment and eighty-three (83) Ad-Doc applications for consideration; two (2) fresh and five (5) amendment applications were approved. Three hundred and fifty-one (351) Serious Adverse Events (SAE) reports were received and submitted to the Technical Advisory Committee. Five (5) GCP inspections were conducted over the period under review; eighty-one (81) percent of non-compliances observed were minor, nineteen (19) percent were major and no critical non-compliance was observed. A total of seven (7) permits were issued for importation of investigational products out of fourteen (14) applications.

The following notable achievements were chalked by the Department:

i. Organized RCORE and GCP training virtually using the moodle platform.
ii. Secured EDCTP grant.
iii. Organized virtual TAC-CT training.
iv. Online GCP training organized for Clinical Trials researchers (3 different groups from KCCR, 1 from Kintampo, One group from Korle-Bu and one group from Hohoe to:
    - Discuss impact of the principles of GCP on the quality of clinical trials.
    - Emphasize local regulatory requirements for conduct of trials as mandated by FDA.
    - Describe the roles of stakeholders in clinical trials.
    - Outline some key elements required to achieve quality in clinical trials while protecting study participants.

- Provide a platform for all stakeholders to engage and network with each other as well as discuss ways to help in improving general conduct of clinical trials in Ghana.

A 4-week RCORE Training for African Clinical Trial Regulators from 7 African countries to:

- Build capacity and enhance skills of regulators in the area of effective clinical trial regulation through hands-on training and exchange programs to help improve their output.
- Increase regulatory workforce to facilitate quality review of clinical trials conducted in Africa.
- Provide a platform for regulators and researchers to continually share ideas, knowledge and experiences over the years in the aim of improving their activities.

3.9 Support for Local Industry

3.9.1 Pharmaceutical Industry

None of the thirty (30) Pharmaceuticals manufacturing facilities under the Ghana 2020 GMP roadmap achieved a graded A status within the year. This is because the progress of the near completion new GMP compliant facilities were stalled by the novel COVID-19 pandemic travel restrictions. It is estimated that 5 facilities would be graded A in 2021 barring all unplanned eventualities. Three (3) facilities have been graded B whilst the rest of companies are graded C.

Twenty-five (25) CAPAs relating to the Ghana UNIDO Roadmap were received and reviewed by the department in 2021. CAPA verification exercises have been carried out for 16 companies. The remaining fourteen companies have been scheduled for first quarter 2021.

3.9.2 Food Industry

Training Programmes

A total of Two hundred and Eighty -One (281) participants from One Hundred and Eighty-Nine (189) Food Processing Companies were trained in various aspects of Good Manufacturing Practices (GMP) compared to two previous years, which recorded Two Hundred and Twenty-four (244) participants in 2018andTwo Hundred and Ninety-eight (298) participants in 2019. The target for 2020 was Four Hundred (400) participants. The target was not achieved due to a low number of requests for training from clients and also the challenges presented by the COVID-19 pandemic.

One Hundred and Ninety (190) staff from Thirty-Four (34) Food Service Establishments were trained in Food Safety and Hygiene practices (GHP). Compared to the two previous years, which recorded Three Hundred and Thirty-eight (338) participants in 2018 and Three

Hundred and Twenty-Six (326) participants in 2019, performance in 2020 saw a decrease in request for training from clients possibly as a result of the COVID-19 pandemic. The target for 2020 was Four Hundred (400) participants.

Needs Assessments

Fifteen (15) Needs Assessments were carried out in different food processing companies. Compared to the two previous years which recorded Thirty-five (35) companies in 2018 and Forty (40) companies in 2019. The target for 2020 of Forty (40) facilities was not achieved due to the COVID -19 pandemic. The Department however carried out Eighty-Seven (87) specialized Needs Assessments as part of the on-going progressive licensing program aimed at accelerating the growth of the local food industry. This specialized Needs Assessment were coupled with on-site training in Good Manufacturing Practices (GMP).

A total of one hundred and twenty-seven (127) companies had their facilities licensed based on the support they received from the Food Industrial Support Service Department; this represents a 19% decrease compared to 2019 performance.

3.10 Tobacco and Substances of Abuse Control

Tobacco Control

Fifteen (15) applications were received for registration of tobacco and tobacco products. Fourteen (14) were approved and (1) deferred. There was a 25% decrease in applications received as compared to the previous year. The department received 96 import permit applications for tobacco products. Eighty-nine (89) import permits were issued and seven (7) were rejected. There was 18% decrease in permit issued over the previous year because the department received fewer applications from importer.

Controlled Substances Control

Controlled substances were issued to twenty-two (22) importers of raw materials and eleven (11) importers of finished pharmaceutical products (FPP). There was a 15% decrease in allocation because some companies still had quantities of controlled substance unused.

The department received one hundred and ninety-five (195) import permit applications for controlled substances. One hundred and forty-eight (148) import permits were issued, forty-seven (47) were rejected and seven (7) import permits were returned. There was 10%

increase in permit issued over the previous year because most of the importers put in an application each for the different controlled substance imported. There was a 4% increase in import permit applications rejected because of errors made by agents due to lack of better understanding of the new Food and Drugs Authority Integrated Custom Management System (ICUMS). Seven (7) import permits were returned since the suppliers of the controlled substances were not able to supply the products to the importers.

Public Awareness and Education

Forty-three (43) educational campaigns were organized for basic and secondary schools, tertiary institutions, market places, transport terminals, non-governmental organizations, religious organizations and the media (radio, TV stations and electronic stations). There was 75% decrease in this activity due to the upsurge of COVID – 19 infections, thus schools were closed, however public education campaign was carried out on the various social media platforms like Facebook, Twitter, and WhatsApp.

3.11 2020 FINANCIAL PERFORMANCE

A total of eighty-five million two hundred and eighty-seven thousand, four hundred and seventy-nine Ghana Cedis forty-nine Pesewas (GHS85,287,479.49) was collected in 2020, an increase of 15% compared to the revenue collected during the previous year. Twenty-eight million, six hundred and fifty-one thousand, one hundred and fifty-eight Ghana Cedis and twenty-four pesewas (GHS28,651,158.24) was transferred to the consolidated fund. Fifty-six million, four hundred and twenty-four thousand, four hundred and sixty-three Ghana Cedis and three pesewas (GHS56,424,463.03) was spent on operations.

Figure 3.11-1 : Revenue Budget and Actual Performance

2020 ANNUAL BUDGET (GHS)				
	ORIGINAL	**REVISED @ MID-YEAR**	**ACTUAL**	**VARIANCE**
Total Revenue	100,573,597.90	70,000,000.00	85,287,479.49	15,287,479.49
FDA Retention	50,286,798.95	35,000,000.00	56,424,463.03	21,424,463.03
Transfer to Consolidated Fund	50,286,798.95	35,000,000.00	28,651,158.20	(6,348,841.76)

***Source**: FDA Financial Report (2020)*

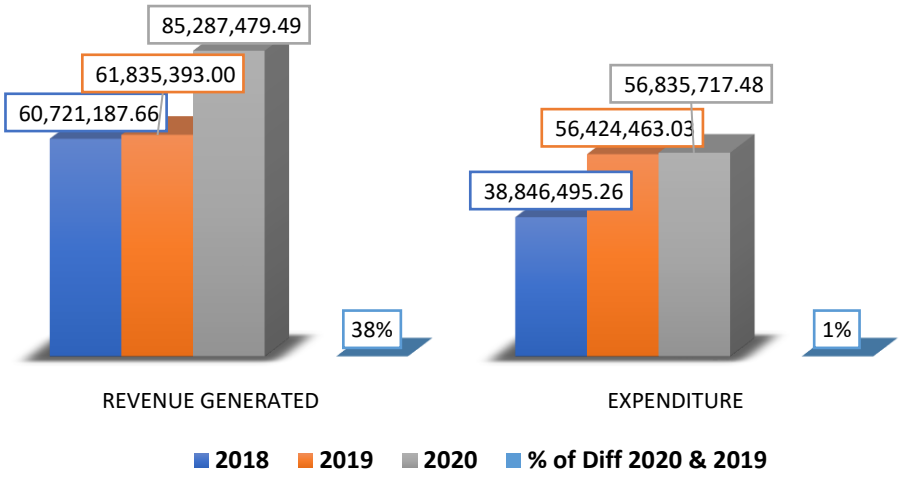
On all three expenditure classifications of IGF Compensation, Goods & Services and Capital Expenditure actual expenditure exceeded budgeted amounts by 5.56%, 6% & 136% respectively. The entire expenditure budget was exceeded by 25.68%. The variance observed in the FDA 2020 expenditure budget reflects the FDA Governing Board and Management's effort at ensuring public health and safety was not compromised in the face of challenges presented by the COVID-19 pandemic which affected all aspects of the Ghanaian economy. The FDA received 1.5 Million Ghana Cedis from the MOH for COVID-19 emergency preparedness and response project (EPRP) was not part of the 2020 approved budget. Thus, expenditure from the COVID-19 EPRP contributed to variances across the relevant expenditure areas.

Figure 3.11-2: Expenditure Budget Performance

EXPENDITURE ITEMS	BUDGET(GHS)	ACTUAL (GHS)	VARIANCE (GHS)
IGF Compensation	16,254,318.61	17,265,536.82	(1,011,218.21)
Goods & services	21,796,983.49	23,009,015.67	(1,212,032.18)
Capital expenditure	6,842,753.42	16,149,910.54	(9,307,157.12)
Total	**44,894,055.52**	**56,424,463.03**	**(11,530,407.51)**

Source: Monitoring and Evaluation Division

Figure 3.11-3 Trend of FDA revenue and expenditure performance



Source: Monitoring and Evaluation Division

3.12 Internal Audit

The internal audit conducted five financial audits, out of these audits, seven non-compliance were observed by the department. The institution has recorded 100% lodgment for the past 3 years. In 2020, they executed all required financial (revenue and expenditure) audits; this included the Head Office, Tema and KIA Offices, and the nine (9) Regional Offices. The following training were organized in 2020; training on GIFMIS, GHANEPS and QAIP and performance audit. All requests received for review of payrolls, payment vouchers and verification of goods supplied to the FDA stores were completed.

On revenue audit infractions, the issue of non-timely lodging of money was not experienced in the year 2020 same as for 2019. In respect of maintenaning proper records i.e. receipt book capturing, there were no incidence for the year under review. On expenditure audits infractions, review of payment vouchers showed all payment vouchers were pre-audited, for 2020. There was no incidence of payment vouchers approved without requisite supporting documents. There was no incidence of un-retired funds. Compliance to financial regulations has improved tremendously. On payroll audit, there were no infractions observed for promotion updates, annual increments and presence of resigned staff on payroll. No other infractions were observed for the period under review. For the period under review, there was no infraction recorded for revenue, expenditure and payroll audits. This is a tremendous improvement for the organization and demonstrates the impact of effective internal audit on continuous improvement.

4 SUMMARY OF KEY ACHIEVEMENTS FOR 2020

1. The FDA regulatory system for medicines has been rated maturity level 3 based on the WHO Global Benchmarking Tool (GBT).
2. The FDA received approval for its new organisational structure from the Public Services Commission.
3. Desk audits have been introduced in place of onsite inspection of manufacturing and storage facilities for low risk products.
4. As part of the national response to combat COVID-19 in Ghana, the FDA reduced the processing times for COVID-19 related FDA regulated products; 2 – 5 days for medicines, household chemical substances and PPEs; and 30 – 40 days for COVID-19 detection kits and ventilators.
5. The FDA developed guidelines and requirements for expedited registration of COVID-19 related products.
6. The FDA launched the progressive license scheme for micro, small and medium scale enterprises (MSMEs) in the manufacturing sector of the food industry.
7. The FDA with support from the Skills Development Fund developed four (4) curricula for Qualified Supervisor Courses for MSMEs in the food, cosmetics, household chemical substances and herbal medicines industries.
8. The scope of ISO 9001:2015 certification at the FDA which is currently at the Head Office and Tema Office has been expanded to include the Ashanti and Volta Regions.
9. The CIF based fees and charges for imported products has been successfully implemented at the Tema Port.
10. The FDA received approval for its new organisational structure from the Public Services Commission.
11. The FDA and GSA commenced harmonisation of their operational activities to promote safe, quality and efficacious/effective FDA regulated products; locally manufactured, imported or exported.
12. The FDA signed an MOU with the National Board for Small Scale Industries (NBSSI) to support the growth and development of MSMEs in Ghana.

13. The FDA's new office complex at Tema has been completed and handed over to management by the contractor.
14. The FDA website has been upgraded to give it a new look and additional functions to meet consumer, client and international partner requirements.
15. FDA signed a memorandum of understanding (MOU) with the Center for State Control of Drugs and Medical Devices (CECMED) of the Ministry of Public Health of the Republic of Cuba (MINSAP) on developing cooperative relations between the two regulatory authorities.
16. FDA in collaboration with PUM Netherlands organized a training to build the capacity of both regulators and members of cosmetic manufacturing industry in Ghana.
17. The FDA developed guidelines for emergency use authorisation of medical products for control and management of COVID-19.
18. FDA supported the first-ever factory of physically challenged persons.

5 KEY CHALLENGES

1. The primary challenge to date has been the impact of the COVID-19 pandemic on our operational activities. The most affected operational activity was market surveillance outings. The FDA has evolved in several respects to mitigate the effects of the pandemic on the execution of its mandate.

    i. PPEs comprising gowns, face masks, and head covers have been provided for staff to enable the FDA to inspect facilities for manufacture and/or storage of high-risk products.

    ii. The FDA has increased market surveillance of COVID-19 related products to ensure they meet quality and safety requirements.

    iii. Desk audits have been introduced in place of onsite inspection of manufacturing and storage facilities for low risk products.

    iv. The FDA maintains 25% of its staff strength at its offices across the country. The staff who stay at home undertake monitoring of advertisement, desk audits, and writing of reports and letters.

    v. The FDA has adopted the use of virtual meeting tools including the Microsoft Teams to reduce interpersonal contact for routine meetings and training workshops.

2. The FDA has access to only the 50% of its IGF as remitted by the MOF. This has affected the flexibility of FDA in managing its expenditure budget; with serious implications for implementation of our planned programmes and activities as we have spent more than 50% of our IGF for the past three years.

3. Inadequate logistics (vehicles and computers) continue to limit operational performance in spite of the recent acquisition of new vehicles and computers. The disposal of old vehicles and computers and the operation of the Tema Office increases the need for extra logistics.

6 PRIORITIES AND OUTLOOK FOR 2021

6.1 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 secure accreditation from COTVET for its Qualified Supervisors Courses developed with the support from Skills Development Fund. This will enable FDA run 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.

6.2 Administration

Estate Management

1. All Regional Offices have been informed by management to locate a well-placed parcel of land for construction of offices in sixteen (16) Regions. The following lands that have been purchased will be fenced in 2021:
    i. Volta Region
    ii. Bono Region
    iii. Ashanti Region
2. The following buildings will be renovated:
    i. Ashanti Regional office
    ii. Northern Regional Officer's residence
    iii. Upper East Regional Office
3. Installation of lift at the Head Office.

Transport Management

The FDA will procure additional vehicles to augment its fleet to support its operational activities.

6.3 Human Resource Management

Implementation of new organogram

The FDA has received Public Services Commission approval for its new organogram. Implementation of the organogram and its associated scheme of service will commence in 2021.

Recruitment of Additional Staff

The FDA following financial clearance will recruit additional staff to support the expanding scope of its regulatory activities.

6.4 Legal

To aid expeditious and successful prosecution of FDA cases in court, the legal department will undertake the following in 2021 to strengthen the capabilities of FDA Staff as well as Circuit and High Court Judges.

i. Forty (40) staff of the FDA will be trained as prosecutors.
ii. Sixty (60) staff of the FDA will be trained as investigators.
iii. One hundred (100) Circuit and High Court Judges will be sensitized on the activities of the FDA.
iv. Forty (40) prosecutors of the JUPOL will be trained in prosecution of regulatory crimes.

6.5 Management Information Systems

Online Product Registration System

The FDA commenced the development of systems to facilitate online product registration of all its regulated products. This system will go live this year. It will enable clients to make online submissions and follow up on progress of applications submitted.

Automation of Work Processes

The FDA will automate is administrative and operational work processes using the GOG Smart Workplace Platform.

6.6 Business Partnerships

1. The FDA will fully operationalise FDA-GSA Operational Harmonisation Proposals with the establishment of application software to facilitate collaboration in jointly handling client requests for registration, certification and export permits.
2. The FDA will continue to collaborate with the 1D1F secretariat to support manufacturing facilities to manufacture, distribute and sell FDA regulated products attain regulatory approval.
3. Strengthen collaboration with Ghana Enterprises Agency (erstwhile NBSSI) to support micro, small and medium scale enterprises comply with codes Good Manufacturing practices using FDA's Progressive Licensing Scheme.
4. The FDA in collaboration with Afrochampions Initiative:
    1. Will integrate its digital services with the AfCFTA Super App to promote AfCFTA Vision and provide market opportunity for micro, small and medium scale enterprises across Africa by facilitating access to regulatory services.
    2. Establish bilateral relations to drive reciprocal regulatory approvals with Nigeria to drive the AfCFTA Vision.

7 WAY FORWARD

The FDA will continue to intensify core regulatory activities of product registration, facility licensing, market surveillance, product quality testing, clinical trials and safety monitoring, control of tobacco and substance of abuse and related auxiliary functions. Additionally, the organization will

- Continue to support the local industry through capacity building and will pursue donor support in this regard towards the strengthening of same.
- Pursue financial clearance for recruitment of additional staff.
- Continue to work with the Fair Wages and Salaries Commission on the approval of the FDA's Conditions of Service.
- Procure additional logistics – vehicles and ICT equipment to enhance operational efficiency.
- Work with the Ministry of Finance to categorize the source of IGF into service and non-service charges; to allow us retain fully service charges to enable the FDA fulfil its obligations to its clients.
- Maintain the respective ISO accreditation for the FDA Laboratory and the Head Office and expand scope of accreditation to the Ashanti and Volta Regional Offices.
- Maintain maturity level 3 WHO listed National Regulatory Agency for Medicines regulation.
- Continuation of the focus on winning public confidence through increased engagement and responsiveness to their needs.
- Zero Tolerance Policy on The Importation of Unregistered Products – Effective February, 2021, all imported regulated products to be registered prior to their importation.

- Intensified Public Education – The FDA shall intensify public education and sensitization activities in all regions of the country. This is to ensure better understanding of our mandate and encourage self-regulation among consumers. We require the support of the media to complement our efforts.

- FDA New Advertisement Statement-In response to industry's concerns about the length of the FDA's advertisement approval statement and its implications to cost of air time, it has reviewed the statement from "This advertisement has been vetted and approved by the FDA" to "This advert is FDA approved".

- Introduction of the Food and Drugs Safety Line-to address general myths and misconceptions about food and drugs in the public domain eg-Plastic Olonka bags and fried plantain chips...

8 . APPENDIXES

APPENDIX I – LIST OF GOVERNING BOARD MEMBERS

FDA GOVERNING BOARD MEMBERS				
	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. Alhassan Emil Abdulai	University of Ghana. Accra.	Senior lecturer & Head of Department-Oral and Maxillo-Facial Surgery, School of Medicine & Dentistry	Member
4	Dr. Joyce Dontwi	Veterinary Services Directorate	Director	Member
5	Nana. K. Obiri	Ghana Federation of Traditional Medicine Practioners Association (GHAFTRAM)	National Organiser	Member
6	Pharm. Audu Rauf	-Pharmacy Council	Registrar	Member
7	Prof. Alexander Dodoo	Ghana Standard Authority	Executive Director	Member
8	Dr. Kofi Bobi Barimah	Centre for Plant Medicine Research	Ag. Executive Director	Member
9	Mrs. Anna Pearl Akiwuni-Siriboe	Ministry of Justice and Attroney General's Department	Chief State Attorney	Member
10	Dr. Mary Obodai	Food Research Institution	Director	Member

APPENDIX II – LIST OF STRATEGIC MANAGEMENT MEMBERS

STRATEGIC MANAGEMENT MEMBERS				
S/N	**NAME**	**DEPARTMENT/DIVISION**	**POSITION IN DEPARTMENT/ DIVISION**	**POSITION ON STRATEGIC MANAGEMENT**
1	Mrs. Delese A. A. Darko	Food and Drugs Authority	Chief Executive Officer	Chairman
2	Mr. Seth K. Seaneke	Drug Registration and Inspectorate Division Safety Monitoring and Clinical Trial Division	Ag. Deputy Chief Executive Ag. Deputy Chief Executive	Member Member
3	Mrs. Akua O. Amartey	Medical Devices Cosmetics and Household Chemical Substances Division	Ag. Deputy Chief Executive	Member
4	Mrs. Roderick Daddey Adjei	Food Division	Head of Division	Member
4	Mr. James Lartey	Administration Department Communications and Public Education Department	Head of Department Ag. Head of Department	Secretary/Member Member
5	Mr. Nicholas Agbomadzi	Finance Department	Head of Department	Member
6	Mr. Eric Karikari-Boateng	Head, Laboratory Services Department	Head of Department	Member
7	Mr. Isaac Dapaah	Projects Research & Management Information Systems Department	Head of Department	Member
8.	Mr. Emmanuel Yaw Kwarteng	Import and Export Control Department	Head of Department	Member
8	Mr. Edem Kofi Kugbey	Internal Audit Department	Head of Department	Member
9	Ms. Mary Mintah	Human Resource Department	Head of Department	Member
10	Mrs. Cynthia Dapaah Ntow	Head Legal Department	Head of Department	Member

APPENDIX III – LIST OF MIDDLE LEVEL MANAGEMENT MEMBERS

MIDDLE LEVEL MANAGEMENT				
	NAME	**DEPARTMENT/REGION**	**POSITION IN DEPARTMENT/ REGION**	**POSITION ON MIDDLE LEVEL MANAGEMENT**
1	Mr. Joseph Yaw-Bernie Bennie	Medical Devices Department	Head of Department	Chairman
2	Mrs. Harriet Ofori-Antwi	Food Microbiology Unit	Head of Unit	Secretary/Member
3	Mrs. Faustina Atupra	Agro Products and Biosafety Department	Head of Department	Member
4	Mr. Percy Adomako Agyekum	Food Evaluation and Registration Department	Head of Department	Member
5	Mrs. Wilhemina Quarcoopome	Food Market Surveillance Department	Head of Department	Member
6	Ms. Maria Lovelace-Johnson	Food Inspectorate Department	Head of Department	Member
7	Mr. Ebenezer Kofi Essel	Food Industrial Support Department	Head of Department	Member
8	Mrs. Jocelyn Adeline Egyakwa-Amusah	Food Safety Management Department	Head of Department	Member
9	Mr. Emmanuel Nkrumah	Cosmetics & Household Chemical Substances Department	Head of Department	Member
10	Mr. Jacob Amoako-Mensah	Import Export Control Department	Principal Regulatory Officer	Member
11	Mr. Geoffrey Victor Arthur	Medical Devices, Cosmetics & Household Chemical Substances Inspectorate Department	Head of Department	Member
12	Mr. Matthew Gyang-Nkum	Medical Devices, Cosmetics & Household Chemical Substances Market Surveillance Department	Head of Department	Member
13	Mr. Samuel Asante-Boateng	Drug Evaluation and Registration Department	Head of Department	Member
14	Mr. Thomas Amedzro	Drug Inspectorate Department	Head of Department	Member
15	Mr. Vigil Edward Prah-Ashun	Drug Market Surveillance Department	Head of Department	Member
16	Dr. Mrs. Olivia Agyekumwaa Boateng	Tobacco & Substance of Abuse Department	Head of Department	Member
17	Mr. Ernest Delali Afesey	Herbal Medicines Department	Head of Department	Member

MIDDLE LEVEL MANAGEMENT				
	NAME	**DEPARTMENT/REGION**	**POSITION IN DEPARTMENT/ REGION**	**POSITION ON MIDDLE LEVEL MANAGEMENT**
18	Mrs. Mercy Owusu-Asante	Drug Industrial Support Department	Head of Department	Member
19	Dr. Edwin Nkansah	Biological Products Department	Head of Department	Member
20	Mr. George Sabblah	Safety Monitoring Department	Head of Department	Member
21	Dr. Mrs. Yvonne Adu Boahen	Clinical Trials Department	Head of Department	Member
22	Mrs. Naana Afrakoma Yawson	Procurement Department	Head of Department	Member
23	Mrs. Nora Narkie Terlabie	Ashanti Regional Office	Regional Head	Member
24	Mr. John Odai-Tettey	Central Regional Office	Regional Head	Member
25	Mr. Gorden Akurugu	Volta Regional Office	Regional Head	Member
26	Mr. Abu Sumaila	Western Regional Office	Regional Head	Member
27	Ms. Akua Amponsaa Owusu-Antwi	Bono Regional Office	Regional Head	Member
28	Mr. Samuel Kwakye	Eastern Regional Office	Regional Head	Member
29	Mr. Martin Kusi	Northern Regional Office	Regional Head	Member
30	Mr. Sebastian Hotor	Upper East Regional Office	Regional Head	Member
31	Mr. Albert Ankomah	Upper West Regional Office	Regional Head	Member
32	Mr. Cheetham Mingle	Food Physico-Chemical Unit	Head of Unit	Member
33	Patrick Owusu-Danso	Drug Physico-Chemical Unit	Head of Unit	Member
34	Mrs. Delali Dei-Tutu	Pharmaceutical Microbiology Unit	Head of Unit	Member
35	Mr. Joseph Ofosu Siaw	Quality Assurance Unit	Head of Unit	Member
36	Mrs. Maureen Lartey	Animal Products Department	Head of Department	Member
37	Mr. Roland Sefakor	Medical Devices Unit	Head of Unit	Member
38	Mr. Ishmael Larkai	Cosmetics and Household Chemicals Unit	Head of Unit	Member
39	Mr. Kwame Dei Asamoah-Okyere	Monitoring and Evaluation Division	Chief Regulatory Officer	Member
40	Nana Serwaa Boateng	Project Research and Management Information Systems	Senior Regulatory Officer	Member