FOOD AND DRUGS AUTHORITY

2018 ANNUAL REPORT

JULY 2019

TABLE OF CONTENTS

LIST OF FIGURES

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 the 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 2018.

Product Registration

A total of nine thousand, six hundred and eighty-three (9,683) applications were received for the year under review; this represents an increase of 19% from the previous year, 2017. In Figure 3, the number of processed applications increased by 41% to eight thousand, two hundred and thirty-one (8,231) applications. A total of seven thousand, two hundred and sixty-eight (7,268) products were registered out of this number; this marks an increase of 11.4% (745 products) from 2017.

Facility Licensing

A total of seven thousand and thirty-one (7,031) facilities were inspected in 2018; this represents 32% increase from the previous year. The number of pre-licensing inspections conducted increased by 5% to three thousand, two hundred and seven (3,207) facilities. Two thousand, six hundred and three (2,603) facilities were licensed, representing an increase of 22% from 2017. Comparing performance of 2018 to 2017, the percentage of pre-licensing inspections conducted increased by 45%, whilst that for facilities licensed increased by 16%.

Market Surveillance

A total of seven hundred and seventy-eight (778) market surveillance operations were carried out across the country; this marked an increase of 35% over the previous year's performance. The number of outlets that were visited increased by 21% to nine thousand and sixty-two (9,062) outlets. A total of forty thousand, seven hundred and sixty-seven (40,767) non-compliant products were identified in trade; an increase of 157% over last year's performance. The number of detentions increased by 98% to one thousand, seven hundred and seventy-one (1,771) in 2018.

As an organisation, the FDA undertook an average of fifteen (15) market surveillance operations each week for the year under review, representing an increase of 42% over the performance of the previous year, 2017. This translates to one (1) market surveillance operation in four (4) and five (5) working days respectively for the relevant Departments/Units at the Head Office and the Regions.

Product Testing

The Laboratory received three thousand, one hundred and forty-six (3,146) products; this was 0.13% lower than was submitted in the previous year. Out of this number, two thousand, seven hundred and fifty-nine (2,759) products representing 88% were analysed; the number of products analysed increased by 4% compared to 2017. Seventy-six (76) percent (2,095 products) of analysed products passed; however, the number of products that passed reduced by 0.24%.

Adverse Drug Reaction Monitoring

The FDA received three thousand, seven hundred and twenty-nine (3,729) adverse drug reaction reports; this was 37% more than was submitted in 2017. Out of this number, two thousand, three hundred and eight (2,308) Adverse Drug Reaction (ADR) reports were entered into the Safety Watch System (SWS); this was 1211% more than was achieved in 2017. The number of ADR reports submitted to the TAC reduced by 4% to two thousand and twenty-seven (2,027); the number reviewed by the TAC also reduced by 29% compared to the previous year.

Import and Export Control

The total number of permits issued increased by 50% in 2018 to thirty-four thousand, nine hundred and five (34,905) permits. Applications received for inspection increased by 32% to twenty-six thousand, six hundred and twenty-eight (26,628); all these consignments were duly inspected, thus, maintaining a 100% work output performance level. For export control operations, applications received for inspections reduced by 6% to two hundred and forty-six (246). This percentage reduction also reflects in the number of inspected and released consignments, as IECD has a 100% execution of all request for inspections for export consignments.

Clinical Trial Authorisation

The Clinical Trials Department received a total of six (6) new clinical trial applications, three (3) amendment and twenty-four (24) Ad-Doc applications for consideration; three (3) fresh and two (2) amendment applications were approved. Three hundred and two (302) Serious Adverse Events (SAE) reports were submitted to the Clinical Trials Technical Advisory Committee. Three (3) GCP inspections were conducted over the period under review; sixty-nine (69) percent of non-compliances observed were minor, twenty-nine (29) percent were major and two (2) percent were critical in nature. A total of thirteen (13) permits were issued for importation of investigational products out of eighteen (18) received.

Support for Local Industry

Fifteen (15) Pharmaceutical manufacturing companies representing 48% of Drug (Allopathic) manufacturing companies in Ghana are at various stages of constructing new manufacturing facilities because of the implementation of the FDA-UNIDO sponsored GMP Compliance Road Map Project for large scale pharmaceutical companies.

The Food Industrial Support Service Department of The FDA received two hundred and seventeen (217) training requests. The FDA organised forty (40) training programmes and trained seven hundred and thirteen (713) people from two hundred and thirty-one (231) companies. A total of one hundred and forty-seven (147) 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, an increase of 7% compared to 2018; seventeen (13) applications were approved and three (3) deferred. A total of one hundred and forty-six (146) permit applications for controlled substances were received, an increase of 19% compared to 2018; seventy-six (76) applications were approved and fifty (50) rejected. Eighteen (18) facilities that use controlled substances were audited; thirty-two (32) non-compliances were observed, an increase of 23% compared to 2018.

The FDA successfully organised the 2019 World No Tobacco Day celebrations across the country with support from the Regional Offices. One hundred and eighty-nine (189) public education programmes on tobacco use and substance of abuse.

The FDA implemented the Pictorial Health Warnings (PHW) on Tobacco and tobacco product packages; this took effect on the 1st November 2018. All imported registered tobacco products now have the PHWs imprinted on their packages.

The FDA through the Hon. Minister of Health passed the following Executive Instruments:

- 'Instructions for the restriction of importation, manufacture and registration of codeine-containing cough syrups
- Instrument, 2018'. 'Instructions for the control of the importation, manufacture and sale of tramadol and tramadol containing products instrument, 2018'

Finance

The FDA through its Fees, Charges and Administrative Fines collected a total of sixty million, seven hundred and twenty-one thousand, one hundred and eighty-seven Ghana Cedis and sixty-six Pesewas (GHS 60,721,187.66). This represents an increase of 21% over the 2017 collections. A similar margin of increase in revenue collection was observed for 2017. This confirms the increase observed in applications received for product registration and facility licensing.

The expenditure for 2018 increased by 48% to thirty-six million, seven hundred and sixty thousand, six hundred and twenty-five Ghana Cedis and nine Pesewas (GHS 36,760,625.09); this reflects a 5% increase over the previous year's expenditure. The FDA spent 22% more of its collected revenue in 2018 compared to 2017.

Internal Audit

For the year under review, nine (9) out of the ten (10) audit thrusts were executed by the Internal Audit Department. In 2018, they executed 100% of financial audits (revenue and expenditure) from 83% in 2017; this included the Head Office, Tema and KIA Offices, and the nine (9) Regional Offices.

On revenue audit infractions, issues relating to non-timely lodging of money reduced from 25% in 2017 to 15% in 2018, representing 40% reduction in its incidence. This year's performance reflects an overall 75% reduction since 2016. In respect of maintenance of proper records, i.e. receipt book capturing, there was a 20% increase in incidents for this issue relative to its performance for 2017. The non-compliance incidents, therefore, increased from 25% to 30%.

For expenditure audit infractions, review of payment vouchers showed no change in performance at 30% for non-pre-audited payment vouchers. There were 25% incidents of

unretired funds; this was a drop from 40% in the previous year, representing a 38% decline in this infraction. Payment vouchers not supported by adequate documentation was 32% down from 33% the previous year; this infraction has seen very little change for the past three years.

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 across the organization as reflected in the process and output indicators. This follows the trend of the past two years – 2016-17. This notwithstanding, there are still gains to be made with regard to process indicators such as the percentage of product applications processed, percentage of pre-licensing inspections conducted, percentage of submitted products tested, and the number of weekly market surveillance operations conducted. These gains appear to be locked up by resource constraints - people, vehicles, computers and application software. Addressing these will enhance our performance in the respective areas.

1 INTRODUCTION

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 the health of the people in Ghana.

The role of the FDA in the national health delivery system in Ghana cannot be overemphasized as the medical products it regulates are essential in the diagnosis, treatment and/or management of diseases. The importance of food in our lives is summed up by this Hippocrates quote: *"Let food be thy medicine and medicine be thy food."* The FDA ensures that the consumption of food does not contribute to the disease burden by ensuring sound food control practices. The effectiveness and efficiency of the FDA in execution of its mandate is, therefore, critical to the health of the Nation.

Functions of the FDA

Parts six (6), seven (7) and eight (8) of Act 851 stipulate nineteen (19) functions for the FDA; these are in turn 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 functions:

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, homeopathic, and herbal) and veterinary medicines, biological products, cosmetics, household chemical substances and tobacco products.
3. Register facilities for manufacture and storage, and vehicles for the transportation of products regulated by the FDA.
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. Issue 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 of Health 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 2018.

2 MANAGEMENT AND STRUCTURE OF FDA

FDA Governing Board

The membership of the FDA Governing Board remained unchanged – see appendix I for list of members.

Management Team

The Head of the Monitoring and Evaluation Division and a member of Strategic Management of the FDA, Mr. Peter Kwasi Agyeman-Duah, retired after 19 years of service to the FDA. See appendix II for current list of management members.

Creation of New Departments

As part of FDA's plans to strengthen market surveillance operations to ensure post registration compliance and enforcement of regulation on product safety, quality and efficacy in the retail segment of the food and medical product industry, the FDA separated the functions of the Enforcement Depart into Market Surveillance and inspectorate. This resulted in the creation of two (2) new Departments, Food Market Surveillance Department and Medical Devices, Cosmetics and Household Chemical Substance (MDCHC) Market Surveillance Department. This has increased the total number of Departments at the FDA from twenty-one (21) to twenty-three (23). These two Departments were created late in 2018 and thus became fully functional in January 2019.

3 TECHNICAL REGULATIONS

3.1 Product Registration

The FDA has six (6) registration Departments: Food Evaluation and Registration, Drug Evaluation and Registration, Biological Products, Herbal Medicine, Medical Devices, and Cosmetics and Household Chemical Substances.

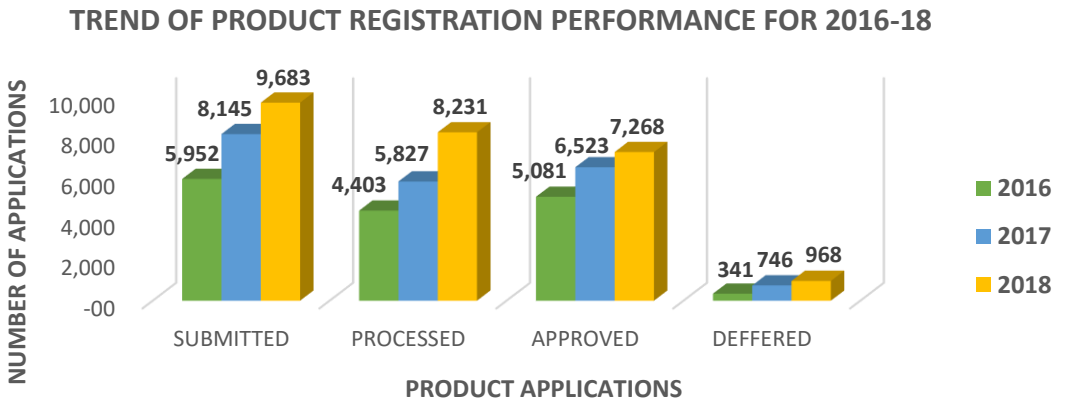


Figure 3.1-1: Performance trend for registration of FDA regulated products for 2016-18.

Figure 3.1-1 shows a total of nine thousand, six hundred and eighty-three (9,683) applications were received for the year under review; this represents an increase of 19% from the previous year, 2017. In Figure 3.1-2 the number of processed applications increased by 41% to eight thousand, two hundred and thirty-one (8,231) applications in 2018. A total of seven thousand, two hundred and sixty-eight (7,268) products were registered out of this number; this marks an increase of 11.4% (745 products) from 2017.

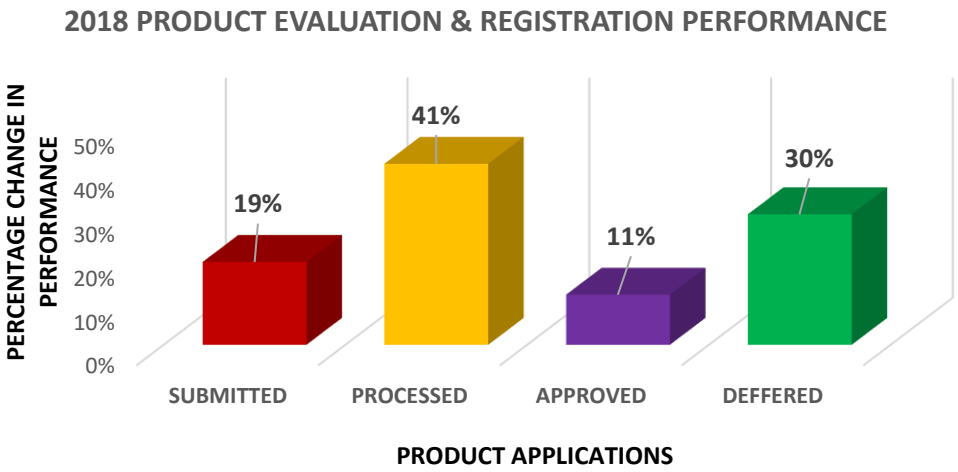


Figure 3.1-2: Performance of product evaluation and registration operations for 2018

According to *Figure 3.1-2* the percentage of processed applications to submitted applications for 2018 increased by 19% as compared to 2017; this represents increased work output by the registration departments over the period.

The number of deferred applications increased by 30% for 2018 as shown in *Figure 3.1-2.* However, comparing the percentage of applications deferred for 2017 and 2018 in *Figure 3.1-3,* it shows an 8% decrease in the total number of applications deferred for 2018; this suggests an increase in the quality of applications submitted possibly due to increased applicant knowledge of application requirements. There is the need to identify driving factors and reinforce them to ensure a continuous downward trend of deferrals.

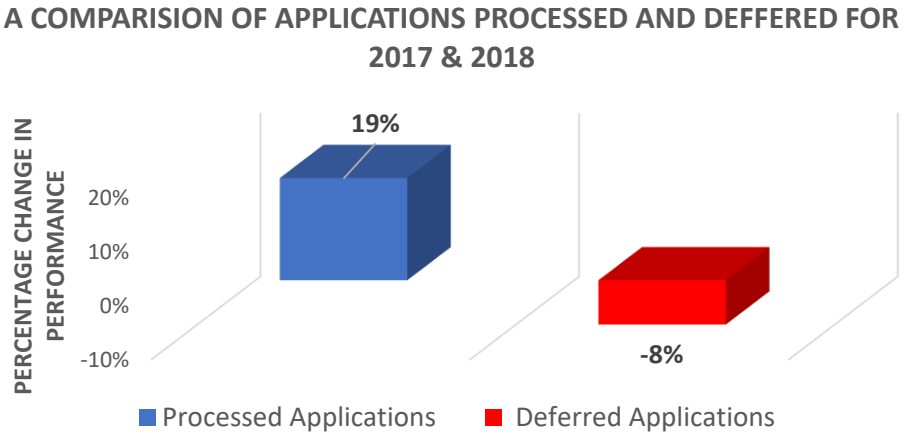


Figure 3.1-3: A comparison of the percentage of applications for 2017 & 2018 for processed and deferred applications.

3.2 Facility Licensing

In 2018, the FDA had six (6) 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.

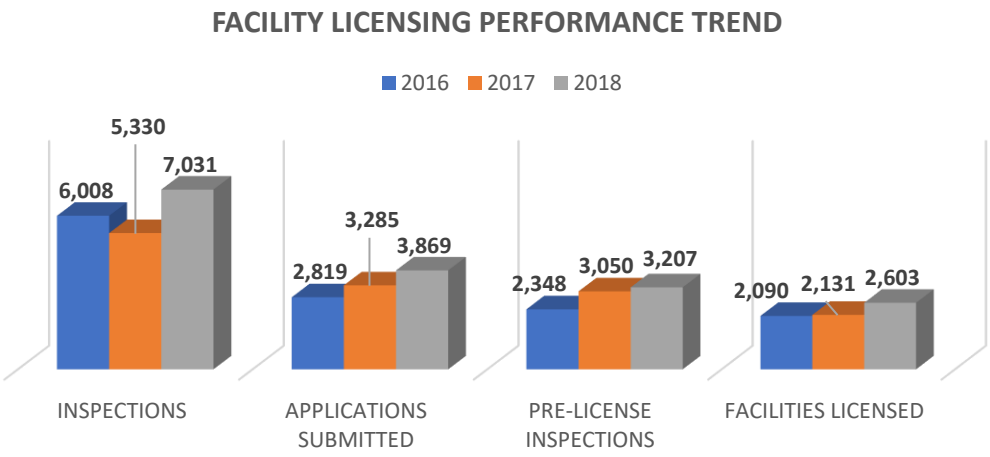


Figure 3.2-1: Performance trend for licensing of facilities regulated by the FDA for 2016-18.

A total of seven thousand and thirty-one (7,031) facilities were inspected in 2018 as shown in Figure 4 above; this represents 32% increase from the previous year. The number of pre-

licensing inspections conducted increased by 5% to three thousand, two hundred and seven (3,207) facilities.

A total of two thousand, six hundred and three (2,603) facilities were licensed, representing an increase of 22% from 2017. Comparing performance of 2018 to 2017, the percentage of pre-licensing inspections conducted increased by 45%, whilst that for facilities licensed increased by 16%. Going forward, it would be necessary to analyse the number of follow-up inspections undertaken per application to ensure value for money for services rendered.

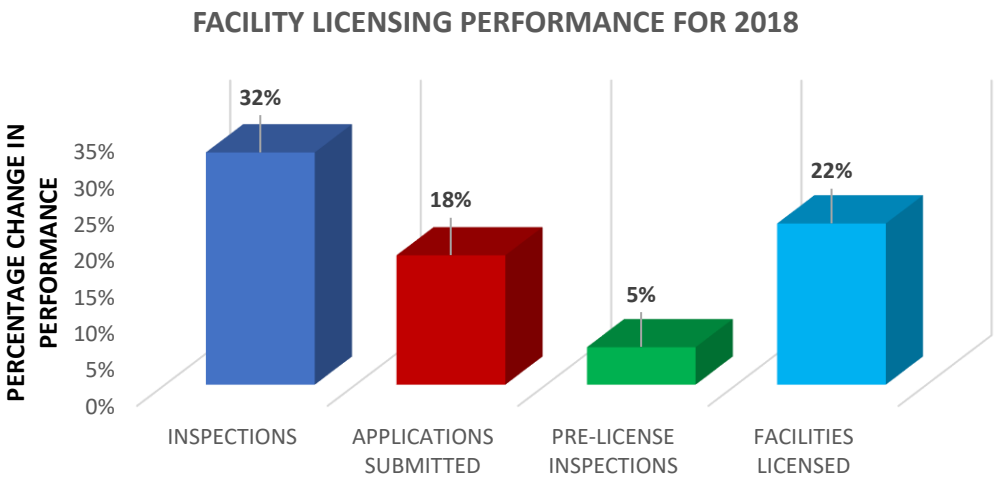


Figure 3.2-2: 2018 Performance for facility inspections and licensing.

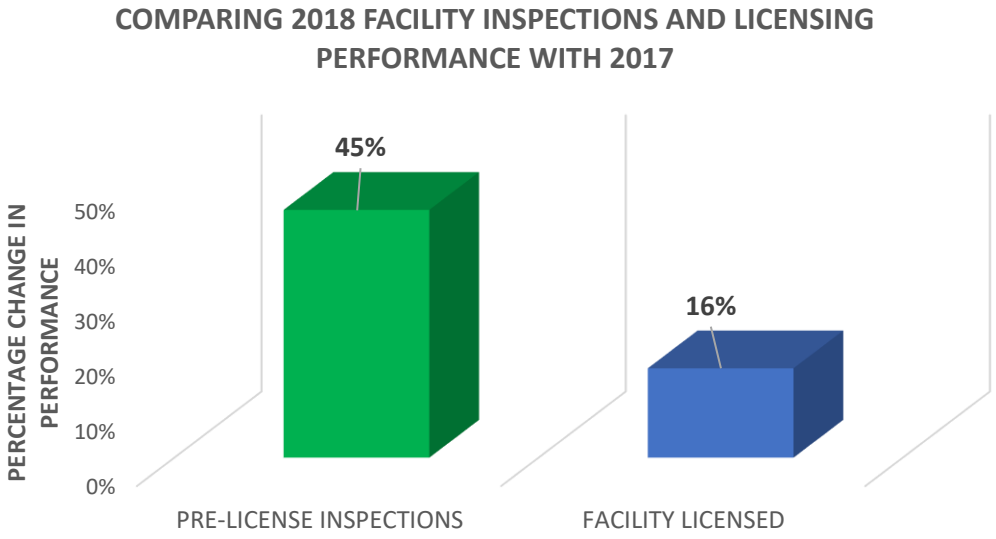


Figure 3.2-3: A comparison of 2018 performance for inspections and licensing for facilities regulated by the FDA compared to 2017.

3.3 Market Surveillance

In 2018 a total of seven hundred and seventy-eight (778) market surveillance operations were carried out across the country; this marked an increase of 35% over the previous year's

performance. The number of outlets that were visited increased by 21% to nine thousand and sixty-two (9,062) outlets. A total of forty thousand, seven hundred and sixty-seven (40,767) non-compliant products were identified in trade, an increase of 157% over last year's performance. The number of detentions increased by 98% to one thousand, seven hundred and seventy-one (1,771) in 2018. See *Figure 3.3-1*.

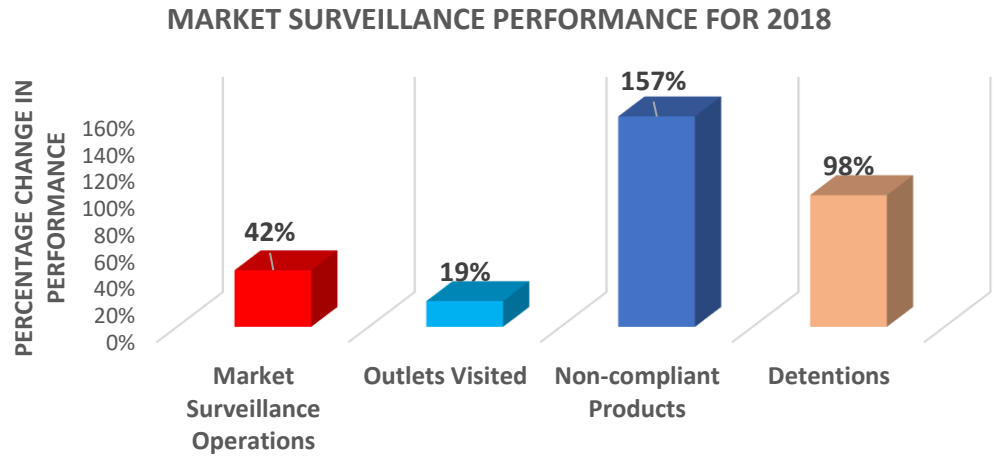


Figure 3.3-1: Performance for 2018 market surveillance operations

Further analysis of the data as shown in *Figure 3.1-2* indicates that the average number of outlets visited per market surveillance operation reduced by 16% for the year under review to 12 outlets. This notwithstanding, the average number of non-compliant products identified per outlet increased by 116% to four (4) non-compliant products. The number of non-compliant products per market surveillance operation consequently increased by 81% to fifty-two (52) non-compliant products. This observation is most likely due to the work in the large supermarket chains in Accra.

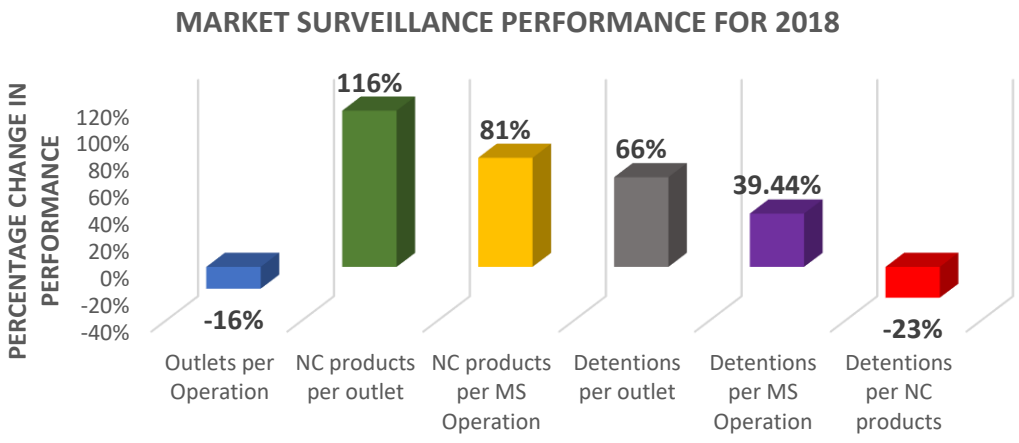


Figure 3.3-2: An analysis of the 2018 output performance for market surveillance operations

In the case of detentions, from *Figure 3.3-2*, the average number of detentions per outlet visited increased by 66% in 2018, whilst the average number of detentions per market surveillance operations reduced by 23% compared to performance observed in 2017. Average number of detentions per non-compliant products reduced by 52% in 2018 compared to 2017. *There is the need to understand what other regulatory actions are being taken in respect of non-compliant products other than detentions, by collecting additional data.*

According to *Figure 3.3-3*, in 2018, the FDA undertook fifteen (15) market surveillance operations each week; an increase of 42% over the performance of the previous year, 2017. This translates to one (1) market surveillance operation in four (4) and five (5) working days respectively for the relevant Departments/Units at the Head Office and the Regional Offices. Though these results confirm the increased focus on market surveillance by the FDA, they also indicate that the FDA is present in the market place about 25% each week in Accra and 20% in the Regions.

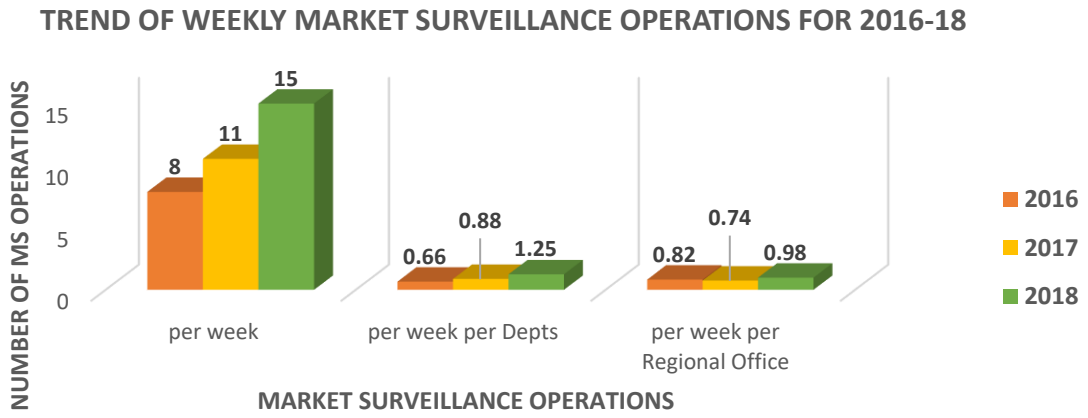


Figure 3.3-3: Trend of weekly performance of market surveillance operations for the FDA from 2016-18.

3.4 Product Quality Testing

The Laboratory received three thousand, one hundred and forty-six (3,146) products; this was 0.13% lower than was submitted in the previous year. Out of this number, two thousand, seven hundred and fifty-nine (2,759) products representing 88% were analysed; the number of products analysed increased by 4% compared to 2017. Seventy-six (76) percent (2,095 products) of analysed products passed; however, the number of products that passed reduced by 0.24%. See *Figure 3.4-1* & **Error! Reference source not found.**. Twenty-four (24) percent (664 products) of analysed products failed; an increase of 18% compared to 2017 – *Figure 3.4-2*.

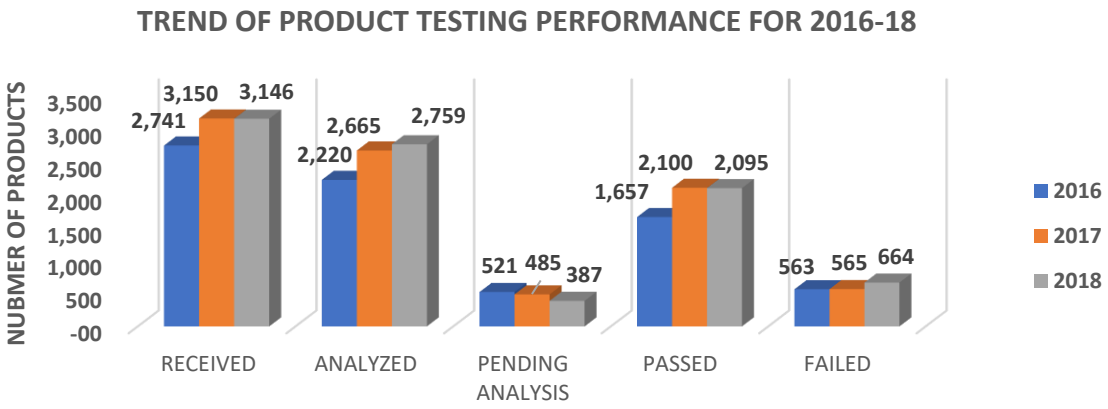


Figure 3.4-1: Trend of performance for product testing for 2016-18

Three hundred and eighty-seven (387) products representing 12% could not be analysed for the year under review; this is a 20% reduction compared to the performance for 2017. This suggests an increased output by the Laboratory.

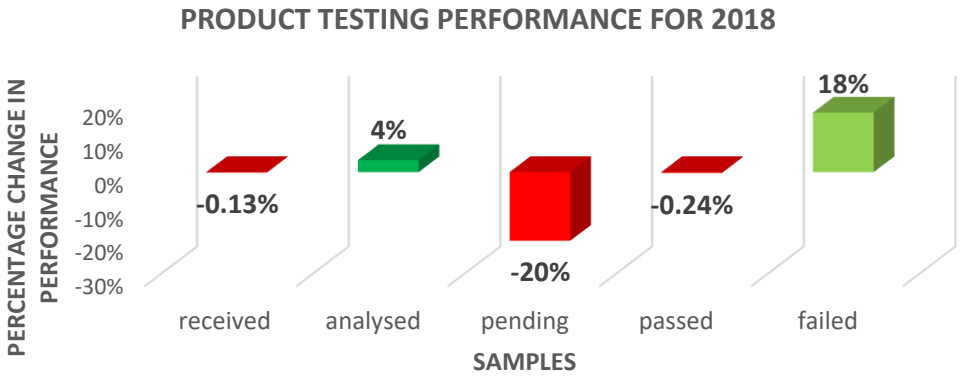
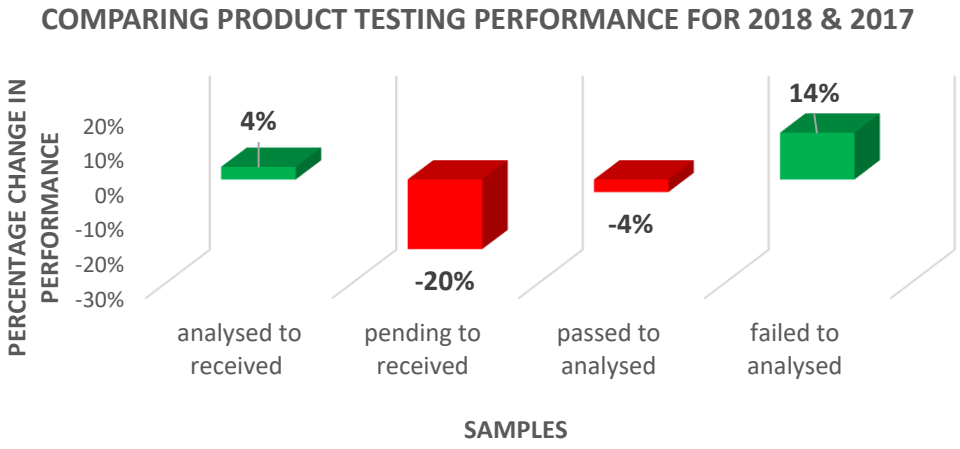


Figure 3.4-2: Analysis of product testing performance for 2018

As shown in

Figure **3.4-3**, for the year under review, the percentage of products analysed increased by 4%



compared to 2017. There was a 20% reduction in the percentage of products

Figure 3.4-3: Comparing 2018 performance of product testing with 2017

pending analysis for the same period. The percentage of products that passed reduced by 4%, whilst the percentage of products that failed increased by 14%.

3.5 Adverse Drug Reaction Monitoring

The FDA received three thousand, seven hundred and twenty-nine (3,729) adverse drug reaction reports; this was 37% more than was submitted in 2017. Out of this number, two thousand, three hundred and eight (2,308) ADR reports were entered into the Safety Watch System (SWS); this was 1211% more than was achieved in 2017.

The number of ADR reports submitted to the TAC reduced by 4% to two thousand and twenty-seven (2,027); the number reviewed by the TAC also reduced by 29% compared to the previous year. See *Figure 3.5-1* & *Figure 3.5-2*.

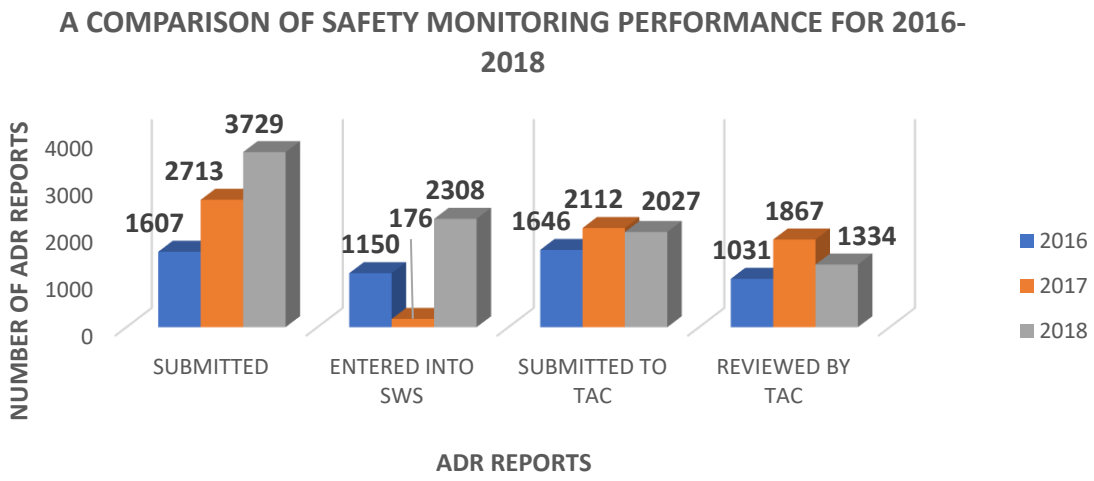


Figure 3.5-1: Trend of safety monitoring performance from 2016-18.

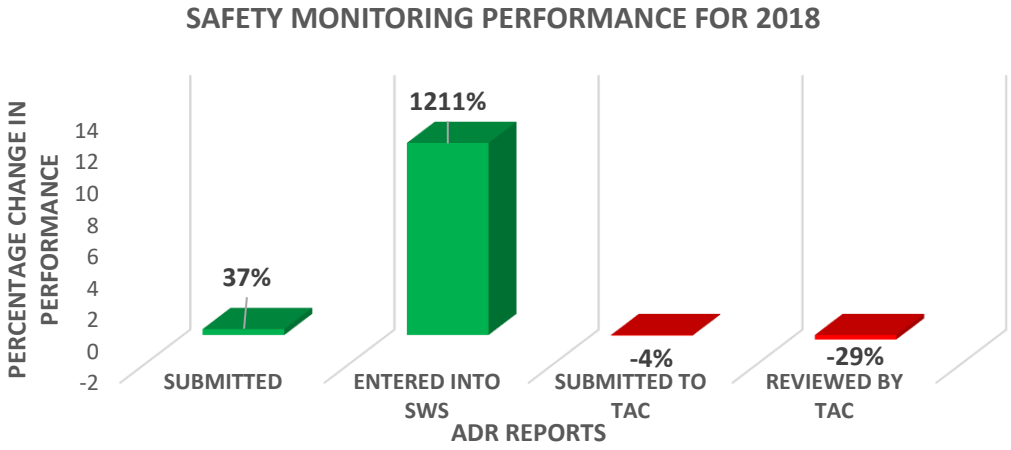


Figure 3.5-2: 2018 performance for safety monitoring activities

Comparing performance of 2018 to 2017, the percentage of ADR reports entered into the SWS in 2018 increased by 854%; whilst the percentage submitted to and reviewed by the TAC reduced by 30% and 26% respectively.

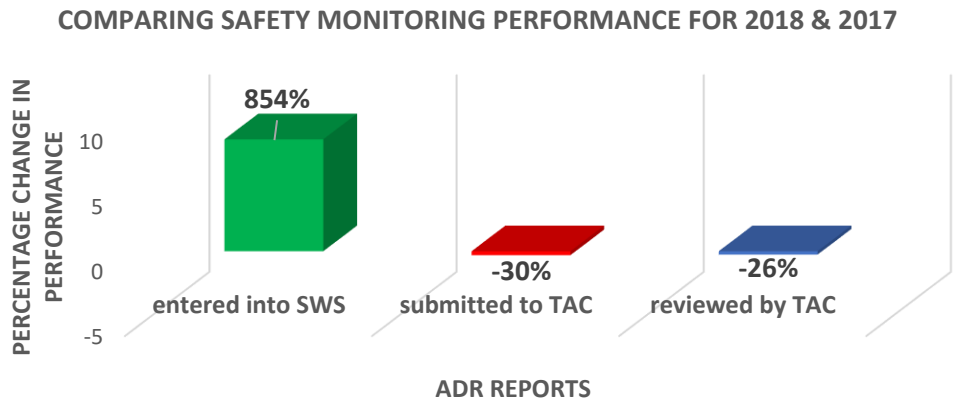


Figure 3.5-3: A comparison of 2018 performance of safety monitoring with 2017

3.6 Food borne Disease Surveillance

The food-borne disease outbreaks increased by 113% to fourteen (14) outbreaks from six (6) in 2018; all these were investigated. The number of people affected by the outbreaks dropped by 36% to one hundred and sixty-one (161) from two hundred and fifty (250).

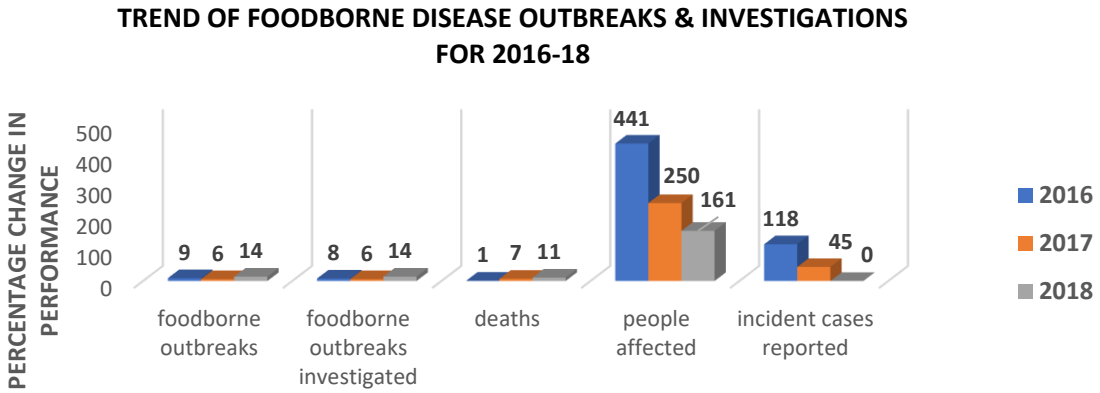


Figure 3.6-1: Trend of food borne disease outbreaks and investigations for 2016-18

The number of recorded deaths increased by 57% to eleven (11). No record of incident cases was collected for 2018; this is not because they did not occur, but because the Food Safety Management Department did not collect data. From the data available, it shows that though the number of outbreaks are increasing, the number of persons affected are dropping.

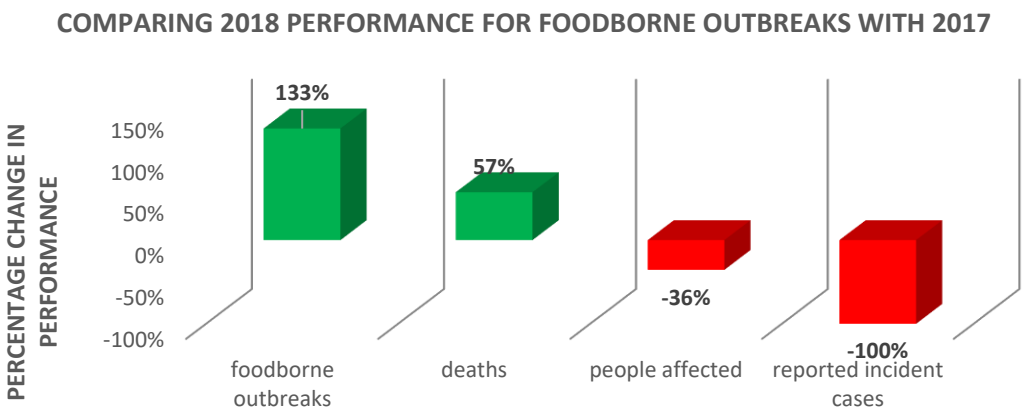


Figure 3.6-2: A comparison of the 2018 performance for food borne disease outbreaks and investigations with 2017

3.7 Import and Export Control

The total number of permits issued increased by 50% in 2018 to thirty-four thousand, nine hundred and five (34,905) permits. Applications received for inspection increased by 32% to twenty-six thousand, six hundred and twenty-eight (26,628); all these consignments were duly inspected, thus, maintaining a 100% work output performance level. See *Figure 3.7-1* & *Figure 3.7-2*.

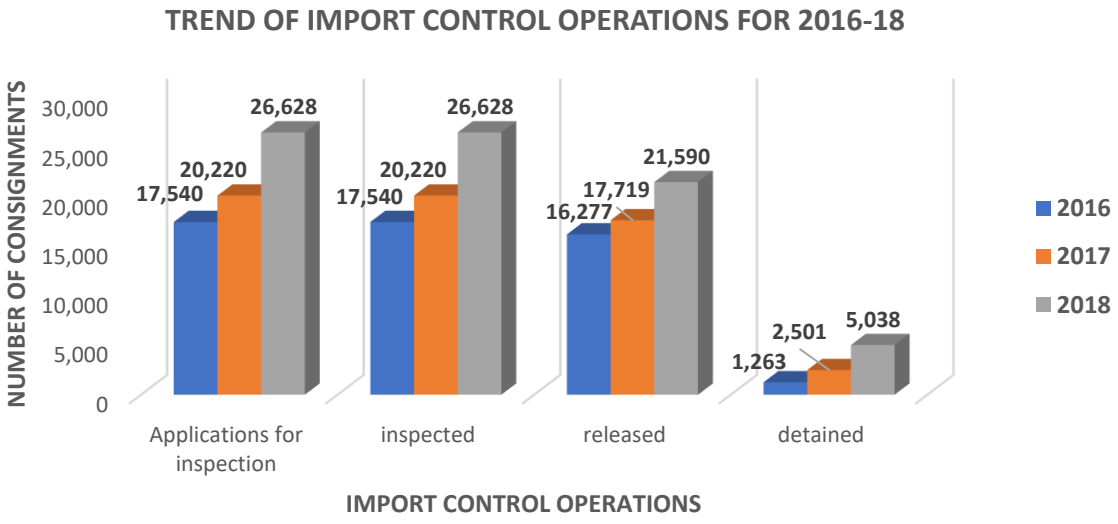


Figure 3.7-1: Trend of import control operations performance for 2016-18

The number of consignments released increased by 22% to twenty-one thousand, five hundred and ninety (21,590) for the year under review. This notwithstanding, the number of consignments detained increased by 101% in 2018 as compared to 2017 to five thousand and thirty-eight (5,038) consignments as compared to 2017; due in part to a 7% decrease in number of products released relative to 2017.

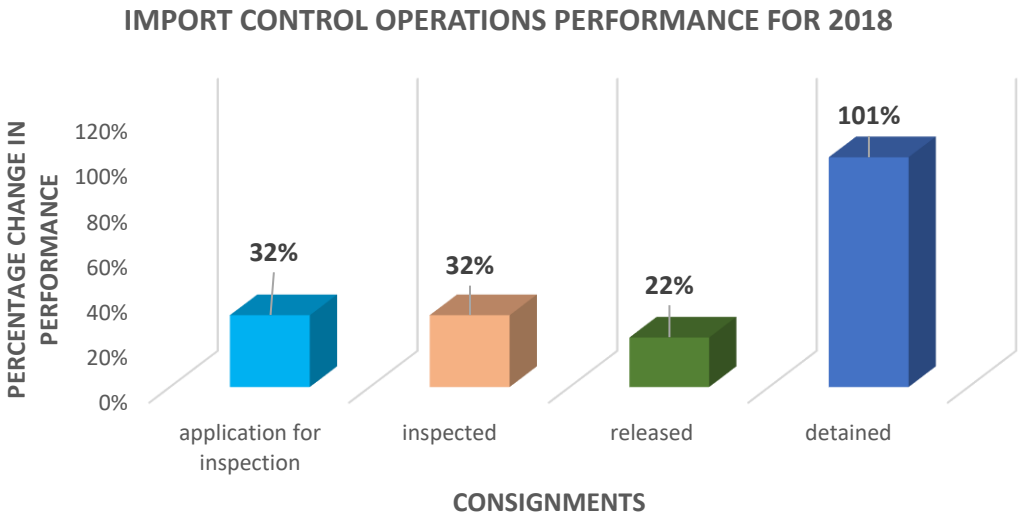


Figure 3.7-2: 2018 performance for import control operations.

Comparing the performance of work output for 2018 with 2017, IECD maintained a 100% execution of all inspection applications. The number of products released reduced by 7% whilst that for detentions increased by 53%. The level of compliance by importers continued to decline from 2017; thus, resulting in record high level of detentions at the port. This situation puts enormous pressure on the market surveillance teams.

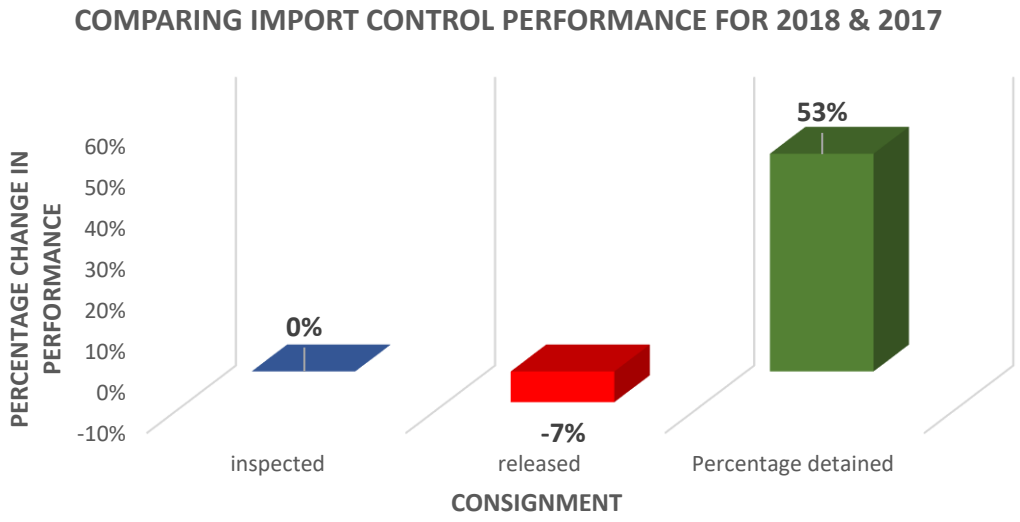


Figure 3.7-3: A comparison of 2018 performance for import control operations with 2017 performance.

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.

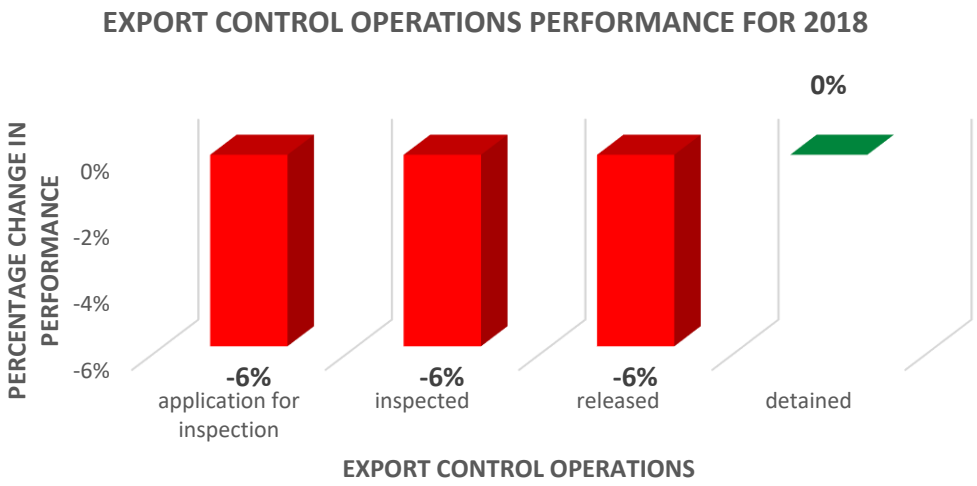


Figure 3.7-4: 2018 performance for Export control operations

According to *Figure 3.7-4*, export control operations applications received for inspections, reduced by 6% to two hundred and forty-six (246). This percentage reduction also reflects in the number of inspected and released consignments, as IECD had a 100% execution rate of all request for inspections for export consignments.

3.8 Clinical Trial Authorisation

The Clinical Trials Department received a total of six (6) new clinical trial applications, three (3) amendment and twenty-four (24) Ad-Doc applications for consideration; three (3) fresh and two (2) amendment applications were approved. Three hundred and two (302) Serious Adverse Events (SAE) reports were submitted to the Clinical Trials Technical Advisory Committee. Three (3) GCP inspections were conducted over the period under review; sixty-nine (69) percent of non-compliances observed were minor, twenty-nine (29) percent were major and two (2) percent were critical in nature. A total of thirteen (13) permits were issued for importation of investigational products out of eighteen (18) received.

The following notable achievements were chalked by the Department:

- Development of Guidelines for Assessment and Registration of Herbal Products for Selected Diseases using Basic Pharmacological Procedures.
- Organisation of capacity building programmes for RCORE Fellows from eight (8) African countries; eight (8) regulators from the National Health Regulatory Authority (NHRA) of Zambia and staff of Korle Bu and Komfo Anokye Teaching Hospitals as well as their respective Medical Schools.

Two stakeholder engagement meetings were organised for Clinical Trial researchers at Komfo Anokye and Korle Bu Teaching Hospitals to introduce and solicit feedback on clinical trials regulatory framework, and existing clinical trials guidelines

3.9 Support for Local Industry

3.9.1 Pharmaceutical Industry

Fifteen (15) Pharmaceutical manufacturing companies representing 48% of Drug (Allopathic) manufacturing companies in Ghana are at various stages of constructing new manufacturing facilities because of the implementation of the FDA-UNIDO sponsored GMP Compliance Road Map Project for large scale pharmaceutical companies. Currently there are three (3) companies rated Grade B and twenty-four (24) rated Grade C, same as in 2017. Two (2) companies have achieved compliance to the quality management system requirements.

3.9.2 Food Industry

Training Programmes

The Food Industrial Support Service Department of The FDA received two hundred and seventeen (217) training requests. The FDA organised forty (40) training programmes and trained seven hundred and thirteen (713) people from two hundred and thirty-one (231) companies. A total of one hundred and forty-seven (147) companies had their facilities licensed based on the support they received from the Food Industrial Support Service Department.

The FDA developed an introductory level Food Safety Supervisors' Course. The course was oversubscribed in its maiden session organised in 2018. A total number of one hundred (100) participants were trained.

The FDA supported the following companies to successfully implement HACCP for their manufacturing facilities: Piccadilly Biscuits GH Ltd, Accra Breweries Ltd, Special Ice Ltd and Kasapreko Co. Ltd

3.10 Tobacco and Substances of Abuse Control

Tobacco Control

Fifteen (15) applications for registration of tobacco products were received, an increase of 7% compared to 2018; seventeen (13) applications were approved and three (3) deferred. Ninety-

four (94) permit applications were received; an increase of 74% compared to 2018. Out of this number eighty-five (85) applications were approved and three (3) rejected.

Controlled Substances Control

A total of one hundred and forty-six (146) permit applications for controlled substances were received, an increase of 19% compared to 2018; seventy-six (76) applications were approved and fifty (50) rejected. Eighteen (18) facilities that use controlled substances were audited; thirty-two (32) non-compliances were observed, an increase of 23% compared to 2018.

Public Awareness and Education

The FDA successfully organised the 2019 World No Tobacco Day celebrations across the country with support from the Regional Offices. One hundred and eighty-nine (189) public education programmes on tobacco use and substance of abuse. The following educational materials were developed to support the public education campaigns:

- Be an ambassador for a tobacco-free society.
- What you need to know about drug abuse.
- Stop tramadol and codeine abuse now.

The Department organised one hundred and seventy-three (173) public education programmes on tobacco use and substance of abuse. The FDA collaborated with MUSIGA to compose a song on drug abuse.

Pictorial Health Warnings on Tobacco and Tobacco Products

The FDA has implemented the Pictorial Health Warnings (PHW) on Tobacco and tobacco product packages; this took effect on the 1st November 2018. All imported registered tobacco products now have the PHWs imprinted on their packages.

Executive Instrument on Tramadol and Codeine-based Cough Syrups

The FDA, through the Hon. Minister for Health, passed the following Executive Instruments:

- **Banned codeine-based cough syrups** according to an Executive Instrument: 'Instructions for the restriction of importation, manufacture and registration of codeine-containing cough syrups instrument, 2018.'

- **Restricted control on tramadol** according to the Executive Instrument: 'Instructions for the control of the importation, manufacture and sale of tramadol and tramadol containing products instrument, 2018.'

3.11 Finance

The FDA through its Fees, Charges and Administrative Fines collected a total of sixty million, seven hundred and twenty-one thousand, one hundred and eighty-seven Ghana Cedis and sixty-six Pesewas (GHS 60,721,187.66). This represents an increase of 21% over the 2017 collections. A similar margin of increase in revenue collection was observed for 2017. This confirms the increases observed in applications received for product registration and facility licensing. The revenue collected for 2018 exceed the target estimate by 12%.

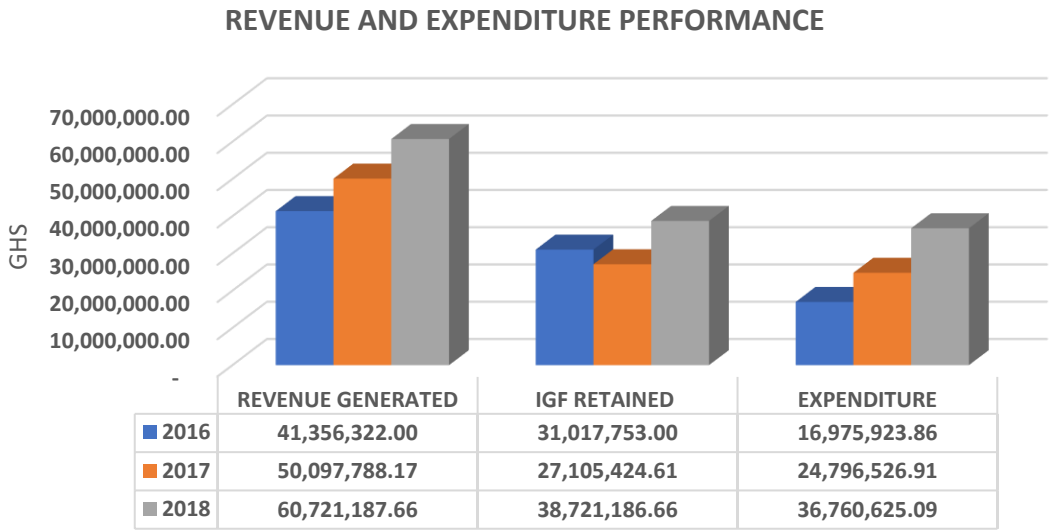


Figure 3.11-1: Trend of FDA revenue and expenditure performance for 2016-18.

In 2018, the Head Office collected 62% of the total revenue collections; this was 14.1% more than was achieved in the previous year; however, its contribution towards the total revenue collected fell by 6.5% compared to 2017.

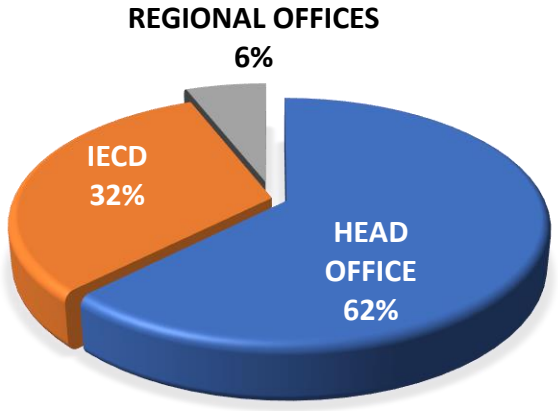


Figure 3.11-2: 2018 Revenue Collection Performance for Head Office, IECD and Regional Offices.

The IECD offices at Tema and KIA collected 32% of the revenue, representing an increase of 12.9% in their contribution towards total revenue collected. The Regional offices contributed 6% to the total revenue collected; an increase of 8.4% from 2017. Increase in revenue was experienced across the entire organization.

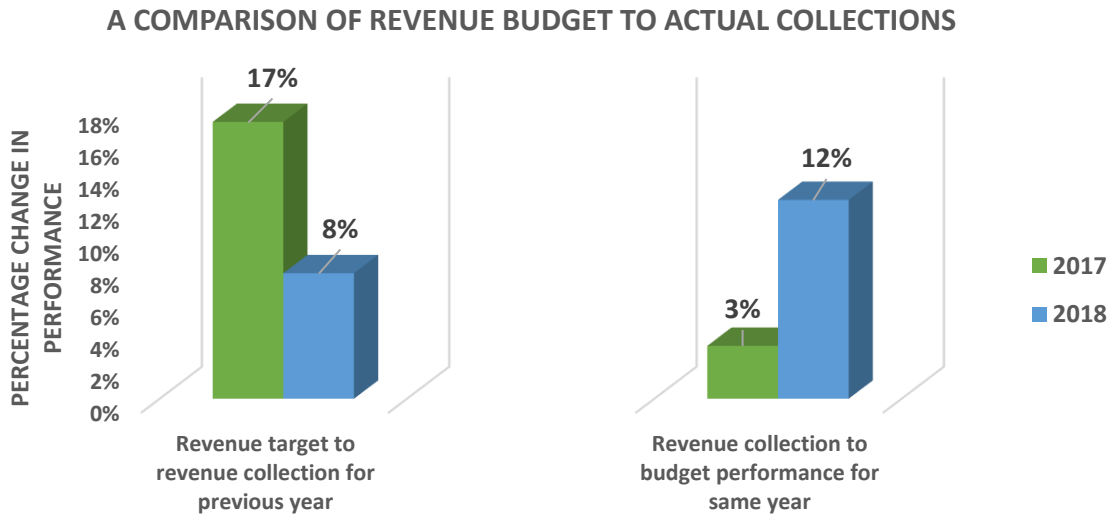


Figure 3.11-3: A Comparison of Revenue Budget to actual revenue collected for 2017 and 2018.

The expenditure for 2018 increased by 48% to thirty-six million, seven hundred and sixty thousand, six hundred and twenty-five Ghana Cedis and nine Pesewas (GHS 36,760,625.09); this reflects a 5% increase over the previous year's expenditure. The FDA spent 22% more of its collected revenue in 2018 compared to 2017.

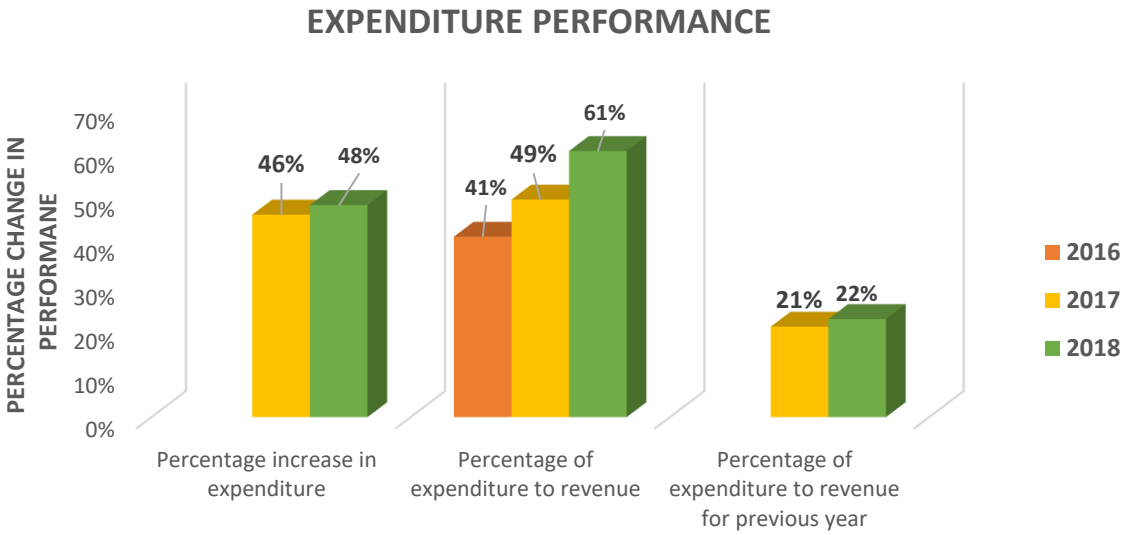


Figure 3.11-4: Trend of Expenditure Performance for the periods 2016-18.

The percentage of IGF spent increased from 54% in 2017 to 64% in 2018. Thus, the FDA in 2018 required about 93% more than was allocated per the capping level of 33%. This shows the current increased capping level of 50% will still not be adequate to support the organisation's expenditure.

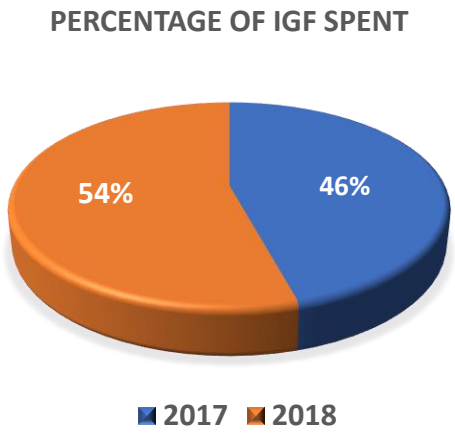


Figure 3.11-5: A comparison of percentage of internally generated funds (IGF) spent for 2017 and 2018.

3.12 Internal Audit

For the year under review, nine (9) out of the ten (10) audit thrusts were executed by the Internal Audit Department. In 2018, they executed 100% of financial audits (revenue and expenditure) from 83% in 2017; this included the Head Office, Tema and KIA Offices, and the nine (9) Regional Offices.

Out of two planned performance audits, the operations of the Procurement Department were executed. This leaves the other twenty-eight (28) Departments at the Head Office and nine (9) Regional Offices out of the performance audit programme.

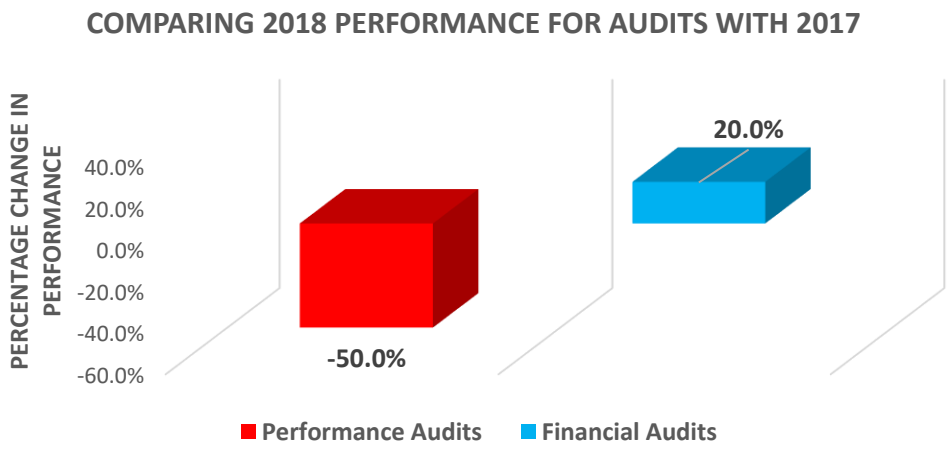


Figure 3.12-1: A comparison of 2018 performance and financial audits with 2017 and

Thus, in respect of the performance audits, the current coverage is 2.6%. For the past three (3) years, the Internal Audit Department has completed all requested reviews for payrolls, payment vouchers and verification of goods supplied to the FDA stores.

On revenue audit infractions, issues relating to non-timely lodging of money reduced from 25% in 2017 to 15% in 2018, representing 40% reduction in its incidence. This year's performance reflects an overall 75% reduction since 2016. In respect of maintenance of proper records, i.e. receipt book capturing, there was a 20% increase in incidents for this issue relative to its performance for 2017. The non-compliance incidents, therefore, increased from 25% to 30%.

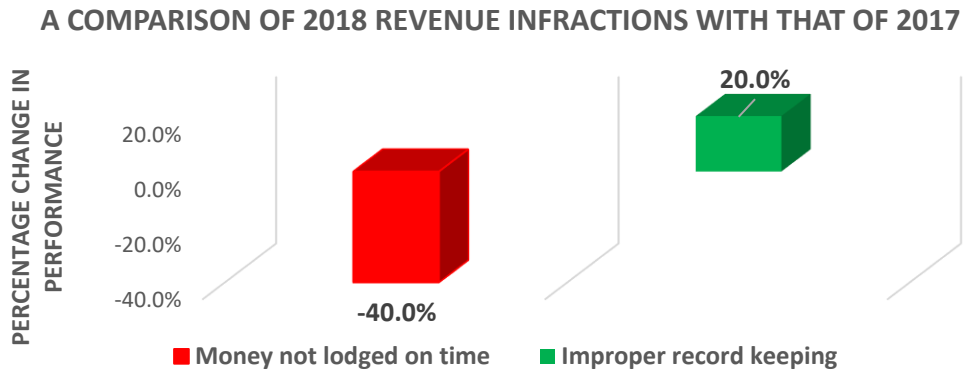


Figure 3.12-2: A comparison of revenue infractions observed during the 2018 financial audits with that of 2017

On expenditure audit infractions, review of payment vouchers showed no change in performance at 30% for non-pre-audited payment vouchers. There were 25% incidents of unretired funds; this was a drop from 40% in the previous year, representing a 38% decline in

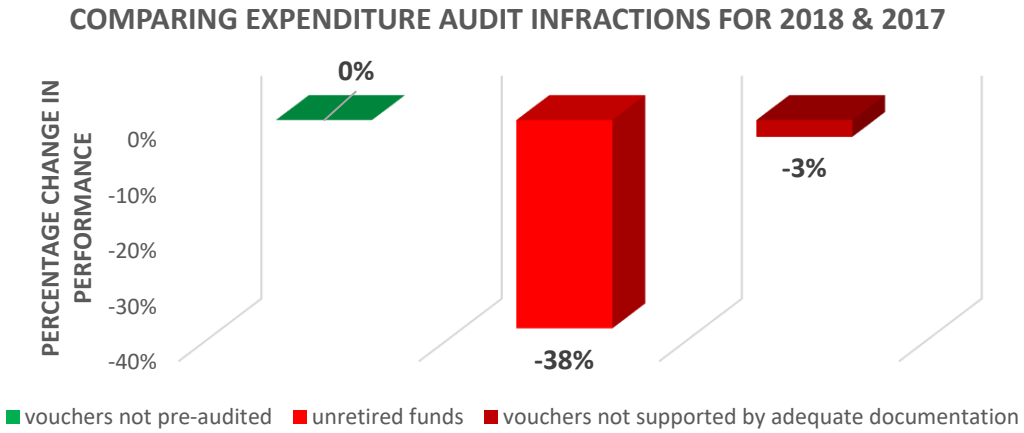


Figure 3.12-3: A comparison of expenditure infractions observed during financial audits for 2017 and 2018

this infraction. Payment vouchers not supported by adequate documentation was 32% down from 33% the previous year; this infraction has seen very little change for the past three years.

On payroll audit infractions, *Figure 3.12-4*, promotion updates by controller are delayed consistently; the 2018 incident level of 33% is similar to what was observed in 2017. Non-reflection of annual increment reduced from 32% to 28%, whilst names of resigned staff on payroll reduced from 34% to 26%.

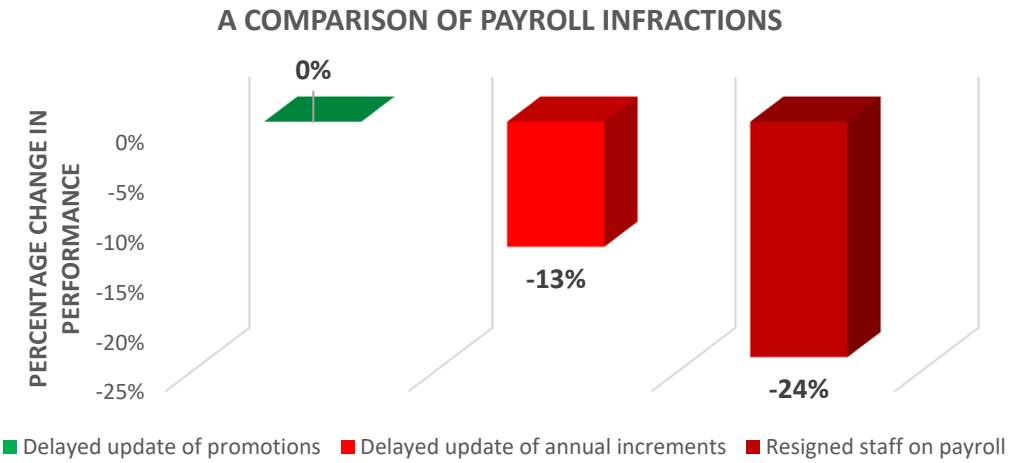


Figure 3.12-4: A comparison of payroll infractions observed during payroll reviews for 2017 and 2018

4 OTHER KEY ACHIEVEMENTS FOR 2018

The following are highlights for the year under review;

Public Education

For the year under review the FDA was in the media spotlight in the line of duty educating clients and the general public. A major high point was the tramadol and codeine containing cough syrup abuse campaign that was replicated across the country to conscientize the public on the dangers associated with the abuse of these medicines.

The FDA installed a wide screen TV at the reception showing content to inform clients on the registration process as well as safe handling of FDA regulated products. The *food safety watch* project was launched; a series of 2 -3-minute videos on topical food safety issues to educate the general public via the various social media platforms. This should be adopted for other FDA regulated product categories. These messages should be released in a timely manner and consistently to sustain FDA visibility and public interest.

Construction of Office Complex

Construction of the FDA Office Complex is in progress and works currently stands at 90% completion.

The FDA completed the refurbishment of its testing laboratory at the Tema port. This will facilitate decision making by reducing turnaround time on testing.

Recovery of Fines

The FDA has developed a digital database of correspondence on fines; this led to the retrieval of six hundred and seventy-eight thousand Ghana Cedis (GHC 678,000) in the third and fourth quarters of 2018.

Technical Advisory Committee on Nutrition

The FDA, established a Technical Advisory Committee on Nutrition (TAC-NU) to provide advice on matters related to nutrition.

Advertisement of FDA Regulated Products

There has been strict enforcement of the airing time for alcoholic beverage advertisements. The introduction of the tagline “This advertisement has been vetted and approved by the FDA”

has revolutionized the advertisement landscape for FDA regulated products, and made FDA a household name in Ghana.

Labelling of Foods Derived from GMOs

The FDA concluded stakeholder consultations on the labelling of foods derived from GMOs; stakeholders proposed the labelling of such foods, paving the way for the revision of the FDA's labelling guidelines for food.

Registration of Frozen Animal Products

The FDA successfully concluded consultations with importers of frozen animal products on the impending requirement.

Regulation of Street Food Vendors

The FDA signed an MoU with FAO to implement the Healthy Street Food Incentives (HSFI) project to enable FDA to collaborate with MMDAs to regulate street food vendors.

Recognition and Awards

The CEO of the FDA won the United Nations Inter-Agency Task-Force award on the Prevention and Control of Non-Communicable Diseases.

ISO Implementation

FDA retained its ISO/IEC 17025:2005 accreditation for its Laboratory; it is accredited to 40 tests, the highest scope in Africa. FDA retained its ISO 9001:2015 accreditation – technical and administrative functions at the FDA Head Office.

5 CHALLENGES

This year, challenges which Departments and Regional Offices could not surmount include inadequate staff, vehicles, office equipment, computers and accessories, workstations, and office space. The rising cost of rentals across the country for office accommodation increases the cost of FDA's operations.

The FDA is required by Ministry of Finance to retain 50% of IGF generated. This affects FDA's ability to provide the requisite services to our clients as 50% of service charges is retained by Government.

Departments and Regional Offices lack the requisite application software required to facilitate execution of their operational activities. The food functionality system and DREGSYS system which are used for the processing of registration application for food and allopathic medicines respectively, require upgrades to meet facilitate processing of registration applications as well as provide vital monitoring and evaluation data for performance measurements. There are currently no official applications for evaluation and registration of medical devices, cosmetics, and household chemical substances. The inspectorate and market surveillance operational activities also do not have an official application software. In the absence of these application softwares, some staff developed database applications to bridge the gap. It is important to note that these applications are at several levels of sophistication across similar regulatory functions, and independent of each other. This affects quality of data collected, and consequently, the decisions made based on such data.

6 CONCLUSION

On performance of the FDA, in respect of its regulatory functions of product registration, facility licensing, market surveillance, product testing and safety monitoring, increased performance in process and output indicators were observed across the organization as depicted in the earlier discussions. This follows the trend of the past two years – 2016-17. This notwithstanding, there are still gains to be made with regard to process indicators such as the percentage of product applications processed, percentage of pre-licensing inspections conducted, percentage of submitted products tested, and the number of weekly market surveillance operations. These gains appear to be locked up by resource constraints - people, vehicles, computers and application software.

Addressing resource constraint of transportation and computers would increase performance for the Inspectorate and Market Surveillance operations. Human resource and computers for product registration operations; and securing of service contracts for equipment and availability of consumables for product quality testing would increase process and output performance.

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:

i. Continue to support the local industry through capacity building, and will pursue donor support in this regard towards the strengthening of same.
ii. Pursue financial clearance for recruitment of seventy-five (75) additional staff.
iii. Continue to work with Public Services Commission on the approval of the FDA's new Organizational Structure.
iv. Continue to work with the Fair Wages and Salaries Commission on the approval of the FDA's Conditions of Service.
v. Procure additional logistics – vehicles and ICT equipment to enhance operational efficiency.
vi. Continue to work with the Ministry of Finance to increase the percentage of IGF retained for operational activities.
vii. Rebranding its image to reflect the diversity and dynamism of its operations as well as project a new corporate image to its stakeholders.
viii. Complete the FDA Office complex construction.
ix. Maintain the respective ISO accreditation for the FDA Laboratory and the Head Office.
x. Attain maturity level 3 WHO listed National Regulatory Agency status for Medicines

8 ANNEX I – LIST OF STRATEGIC MANAGEMENT MEMBERS

STRATEGIC MANAGEMENT MEMBERS		
	NAME	**DEPARTMENT/DIVISION**
1	Mrs. Delese A. A. Darko	Chief Executive Officer
2	Mr. Seth K. Seaneke	Ag. Deputy Chief Executive (DRID)
3	Mrs. Akua O. Amartey	Ag. Deputy Chief Executive (MDCHCD)
4	Mrs. Isabella Mansa Agra	Ag. Deputy Chief Executive (FID & FSD)
5	Mr. Jones Ofosu	Head, Administration
6	Mr. Nicholas Agbomadzi	Head, Finance
7	Mr. Eric Karikari-Boateng	Head, Laboratory Services
8	Mr. Andrew Boadi	Head, Projects Research & Mgt Info. Systems
9	Mr. Solomon Agampim	Head, Import & Export Control
10	Mr. Edem Kofi Kugbey	Head, Internal Audit
11	Ms. Mary Mintah	Head, Human Resource
12	Mrs. Cynthia Dapaah-Ntow	Head, Legal
13	Mr. James Lartey	Head, Communications and Public Education

9 ANNEX II – LIST OF GOVERNING BOARD MEMBERS

FDA GOVERNING BOARD MEMBERS			
	NAME	**DEPARTMENT/DIVISION**	**POSITION**
1	Dr. Sammy Ohene	Head of Psychiatry Department University of Ghana Medical School	Chairman
2	Mrs. Delese A. A. Darko	Chief Executive Officer	Member
3	Dr. Alhassan Emil Abdulai	Senior lecturer & Head of Department-Oral and Maxillo-Facial Surgery, School of Medicine & Dentistry. University of Ghana. Accra.	Member
4	Dr. Kenneth Gbeddy	Director – Veterinary Services Directorate	Member
5	Nana. K. Obiri	National Organiser- Ghana Federation of Traditional Medicine Practioners Association (GHAFTRAM)	Member
6	Pharm. Audu Rauf	Registrar-Pharmacy Council	Member
7	Prof. Alex Dodoo	Executive Director Ghana Standard Authority	Member
8	Dr. Augustine Ocloo	Executive Director Centre for Plant Medicine Research	Member
9	Mrs. Anna Pearl Akiwuni-Siriboe	Chief State Attorney Ministry of Justice and Attroney General's Department	Member
10	Dr. Mary Obodai	Principal Research Scientist Food Research Institution	Member
11	Madam Rosalind Kainyah	Managing Director- Kina Advisory Limited	Member