FOOD AND DRUGS AUTHORITY

2017 ANNUAL REPORT

JULY 2018

FIGURES

TABLES

ACRONYMS AND ABBREVIATIONS

ADRs - Adverse Drug Reactions

BPD - Biological Products Department

BNARI - Bio-Technology and Nuclear Agriculture Research Institute

CEPS	-	Customs Excise and Preventive Service
CID	-	Criminal Investigation Department
CMS	-	Central Medical Stores
CT	-	Clinical Trials
CTAs	-	Clinical Trials Applications
EMEA	-	European Medicine Agency
FDA	-	Food and Drugs Authority
FDL	-	Food and Drugs Law
FSMU	-	Food Safety Management Unit
FPMSU	-	Food Post Market Surveillance Unit
FPIU	-	Food Premises Inspection Unit
GAIN	-	Global Alliance for Improved Nutrition
GAP	-	Good Agricultural Practice
GCMS	-	Ghana Customs Management System
GCNet	-	Ghana Community Network Limited
GCP	-	Good Cold Store Practices
GCP	-	Good Clinical Practice
GDP	-	Good Distribution Practice

GHP	-	Good Hygiene Practice
GM	-	Genetically Modified
GMP	-	Good Manufacturing Practices
GWP	-	Good Warehouse Practice
LMWH	-	Low Molecular Weight Healing
HACCP	-	Hazard Analysis and Critical Control Point
IECD	-	Import and Export Control Department
ICT	-	International Competitive Tender
ISO	-	International Standard Organization
ISOP	-	International Society of Pharmacovigilance
INFOSAN	-	International Food Safety Authorities Network
KNUST	-	Kwame Nkrumah University of Science and Technology
NCB	-	National Competitive Bidding
NFFA	-	National Food Fortification Alliance
NMCP	-	National Malarial Control Programme
NRAs	-	National Regulatory Authorities
PNDC	-	Provisional National Defence Council
PNDCL	-	Provisional National Defence Council Law
PRMISD	-	Projects, Research and Management Information System Department

QAMSA	-	Quality of Anti-malarial Survey Assessment
SAEs	-	Serious Adverse Events
TAC	-	Technical Advisory Committee
TACSM	-	Technical Advisory Committee for Safety Monitoring
MOFA	-	Ministry of Food and Agriculture
U.K	-	United Kingdom
USI	-	Universal Salt Iodation
USP	-	United State Pharmacopeia
WHO	-	World Health Organization
WAHO	-	West Africa Health Organization

EXECUTIVE SUMMARY

In accordance with the Public Health Act 851, 2012, this Report covers activities of the Food and Drugs Authority over the period 1st January 2017 to 31st December, 2017.

The Food and Drugs Authority achieved a momentous feat in the year 2017 and there was a continuation of work to consolidate the instituitional framework for the establishment of the Food and Drugs Authority (FDA) as a Government regulatory body responsible for the control of the manufacture, importation, exportation, distribution, use and advertisement of food, drugs, cosmetics, medical devices and household chemical substances, under the Public Health Act 851, 2012. The Tobacco Control Bill, which forms part of the Public Health Act, 2012 is under the control of the FDA, Ghana. Other policies and guidelines aimed at strengthening the FDA to deliver on its mandate were put in place. These included the guidelines and documents for food and drugs activities and the mandated fee schedule. An inventory of other policies and guidelines already developed,

which have implications for the operations of the FDA, were initiated and steps were taken to review them.

During the year, a range of activities including consumer and public education programmes, regulatory enforcement functions and Good Manufacturing Practices (GMP) training programmes were outlined to support industry and to protect public health and safety.

Applications for the registration of drugs, food, cosmetics, household chemical substances, and Medical devices as well as premises inspections increased by 45% during the year as compared to 40% in 2016. Medicines post market surveillance functions and Food Market Surveillance activities increased by 65% especially on Herbal Medicinal and imported food products, respectively, which have grave consequences on public health and its implications for healthcare delivery. There was an improvement in the operations of the Regional Offices especially during post market surveillance activities over the previous years, which recorded 15,350 in 2017 as compared to 13,253 in 2014; 9,500 in 2016 and 9,200 in 2015. The FDA continued its regulatory control of the exportation of palm oil to the European Union. However, permits issued through the GcNet were nineteen thousand two hundred and forty-two (19,242) as compared to twenty one thousand, three hundred and forty-five (21, 345) in 2017 and eighteen thousand and seventy-one (18,071) in 2016.

CHAPTER ONE

1.0 THE AUTHORITY

1.1 INTRODUCTION

The Food and Drugs Authority (FDA) as a national regulatory body that has the responsibility for the regulatory control of the manufacturing, importation, exportation, distribution, sale and advertisement of food, drugs, cosmetics, medical devices and household chemical substances as enshrined in the Public Health Act, 2012 (ACT 851). This is a very critical role, as misbranding, substandard and/or counterfeit, as well as unsubstantiated product information has very grave consequences on public health and serious implications for healthcare delivery. The FDA, since August 1997, has been pursuing various specific objectives to address issues on regulatory control of products as stated in our mandate.

The following sections deal with the summaries of achievements in 2017.

1.1.0 Governing Board

The Governing Board of the Food and Drugs Authority consists of eleven (11) members appointed by the President of Ghana acting in consultation with the Council of State of the Republic. In making the appointment, the President takes into consideration the knowledge, expertise and experience of the persons so appointed and in particular, their knowledge in matters relevant to the functions of the Authority.

The Chief Exective Officer is responsible for the day-to-day administration of the Food and Drugs Authority and is required to ensure the implementation of the decisions of the Board.

The current composition of the Board is as follows:

No.	NAME	DESIGNATION	POSITION
1	Dr. Sammy Ohene	Head of Psychiatry Department University of Ghana Medical School	Chairman
2	Mrs. Delese A. A Darko	Ag. Chief Executive-Food and Drugs Authority	Member
3	Dr. Alhassan Emil Abdulai	Senior lecturer & Head of Department-Oral and Maxillo-	-do-

No.	NAME	DESIGNATION	POSITION
		Facial Surgery, School of Medicine & Dentistry. University of Ghana. Accra.	
4	Dr. Kenneth Gbeddy	Director – Veterinary Services Directorate	-do-
5	Nana.K. Obiri	National Organiser- Ghana Federation of Traditional Medicine Practioners Association (GHAFTRAM)	-do-
6	Pharm. Audu Rauf	Registrar-Pharmacy Council	-do-
7	Prof. Alex Dodoo	Executive Director Ghana Standard Authority	-do-
8	Dr. Augustine Ocloo	Executive Director Centre for Plant Medicine Research	-do-
9	Mrs. Anna Pearl Akiwuni-Siriboe	Chief State Attorney Ministry of Justice and Attroney General's Department	-do-
10	Dr. Mary Obodai	Principal Research Scientist- Food Research Institution	-do-
11	Madam Rosalind Kainyah	Managing Director- Kina Advisory Limited	-do-

1.1.2 Objectives

The objectives of the Authority is to provide and enforce standards for the sale of food, herbal medicinal products, cosmetics, drugs, medical devices and household chemical substances.

The critical statutory mandate of the FDA as spelt out by the Public Health Act, 2012 (ACT 851) includes the following:

- *Ensure adequate and effective standards for food, drugs, cosmetics, household chemicals and medical devices;*
- *Monitor through the District Assemblies and any other agency of State compliance with the provisions of this Part;*

- *Advise the Minister on measures for the protection of the health of consumers;*
- *Advise the Minister on the preparation of effective Regulations for the implementation of this Part;*
- *Approve the initiation and conduct of clinical trials in the country; and*
- *Perform any other functions that are ancillary to attaining the objects of the Authority.*

1.1.3 STRUCTURE

The Authority's operations are structured under six (6) Divisions as follows:

1. **Drugs Evaluation and Inspectorate Division**. five (5) specialised Departments make up the Division:
    a. Tobacco and Substances of Abuse Department;
    b. Drugs Enforcement Department;
    c. Drugs Registration Department;
    d. Herbal Medicine Department; and
    e. Drugs Industrial Support Department;

    The Drugs Evaluation and Inspectorate Division is responsible for the safeguarding of public health by ensuring that all medicines on the market meet appropriate standards of safety, efficacy, and quality. These functions are carried out by regulating all medicines submitted in the registration dossiers, preregistration inspection, drug quality analysis reports, licensing of manufacturing plants, warehouses and inspections. The Division also controls tobacco, licit narcotic drugs, psychotropic substances and chemical precursors in Ghana.

2. **Medical Device, Cosmetics and Household Chemicals Division**. The Division is made up of three (3) Departments:
    a. Medical Devices Department;
    b. Cosmetics and Household Chemical Substance Department and;

c. Medical Devices, Cosmetics and Household Chemical Substance Enforcement Department.

The Division is responsible for the regulation of all classes of medical devices, cosmetics and household chemicals in Ghana.

3. **Safety Monitoring and Clincial Trials Division**. The following Departments and unit constitute the Division:

   a. Safety Monitoring Department;

   b. Clinical Trial Department and ;

   c. Biological Product Department.

   The Division derived its mandate from the Public Health Act, 2012, Act 851, Part 7 and 8, Section 125 and 150-166 respectively. As part of its mandate, the Division monitors the safety of the medicines analysis of the adverse effect or event reports and by any other means and takes appropriate regulatory action when necessary.

4. **Food Inspectorate Division**. The Division achieved its mandate through the following three (3) Departments:

   a. Food Enforcement Department;

   b. Food Registration Department and;

   c. Food Industrial Support Department.

   This Division contributes to the achievement of the goals of the Food and Drugs Authority for safeguarding public health by ensuring that all food products on the market meet appropriate standards of safety and quality through pre-marketing assessment of food safety and quality. This is achieved by evaluating all samples submitted in the registration process, premises inspection, and meeting labelling requirements. The Division is also mandated to undertake inspection of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify compliance to Good Manufacturing Practices. In addition, the Division ensures that all imported and locally manufactured food products are of good quality and wholesome.

5. **Food Safety Division**. This Division is made up two (2) departments:

a. Food Safety Management Department and;

b. Animal Product and Biosafety Department.

And it's mandated to safeguard public health by ensuring that all restaurants and cold storage facilities are licenced. It also conducts public education to sensitise the public on food safety issues such as Genetically Modified Organisim (GMO).

6. **Monitoring and Evaluation Division**. The following regions make up the Division:

a. Upper West Regional Office;

b. Upper East Regional Ofice;

c. Northern Regional Office

d. Brong Ahafo Regional Office;

e. Ashanti Regional Office;

f. Volta Regional Office;

g. Eastern Regional Office;

h. Central Regional Office and;

i. Western Regional Office.

The Division supervises all the nine (9) regions by preparing indicative plans and making recommendations which would ensure that all demands for activities in the regions are met in an efficient and sustainable manner.

In addition to the above Divisions, there exist six (6) Departments and two (2) specialised Units to augment the work of the Authority.

j. <u>The finance, Administration, Human Resource, Communication and Public Education and PRMIS</u>

They are charged with ensuring that the Authority continuously possesses the needed capacity and the financial, human and technological resources required to effectively and efficiently play its role as Technical regulator within the health sector. The specific tasks of these departments and unit include developing and implementing systems and procedures for the efficient and effective delivery of general administrative services of the

Authority, coordinating the preparation of annual budgets of the Authority, developing a human resource plan to provide the requisite skill levels to meet the Authority's mission and objectives; coordinating the procurement of contracted general services for the Authority; developing and implementing staff performance appraisal and incentive systems; providing stable internet and security; and ensuring that the Food and Drugs Authority is constantly in touch with the public by maintaining healthy relations with the Ghanaian Media and the general Public.

k. Legal Department

As a state institution established by an Act of Parliament, the entire mandate of the Food and Drugs Authority is founded on legal provisions and regulatory boundaries which have to be followed to the letter. The Authority's legal Department is required to make appropriate recommendations relating to the efficiency and effectiveness of established regulatory frameworks and strategies; to serve as the Board Secretariat and in that regards to advise members of the Board on all legal matters, and to represent the Authority on all legal matters.

l. Internal Audit Department

In keeping with the good governance principles of transparency and accountability, the Authority's internal Audit Department is charged with planning, managing, organising and controlling its audit functions as well as ensuring that proper books of accounts are maintained in line with current trends and international best practices. The Department also ensures that standard accounting practices, policies and procedures are adhered to and that adequate producedures have been instituted for the detection of risk and for the prevention or elimination of such risk.

m. Import and Export Control Department (IECD).

The Department is mandated to regulate the importation and exportation of food, drugs, cosmetics, household chemical substances, and medical devices in accordance with the Public Health Act, 2012, (ACT851). The activities of the Department are concentrated at the various entry routes to the Country. The activities of the Department cover the Tema Port, Kotoka

International Airport (KIA), and the Head Office as well as having oversight responsibilities of the all land boarders in the country, for the issuance of electronic permits through the GCNet System. The operational areas of the Department include various freight stations and carrier terminals at the KIA as well as container terminals, freight stations, sheds and wharf sites at the Tema Port.

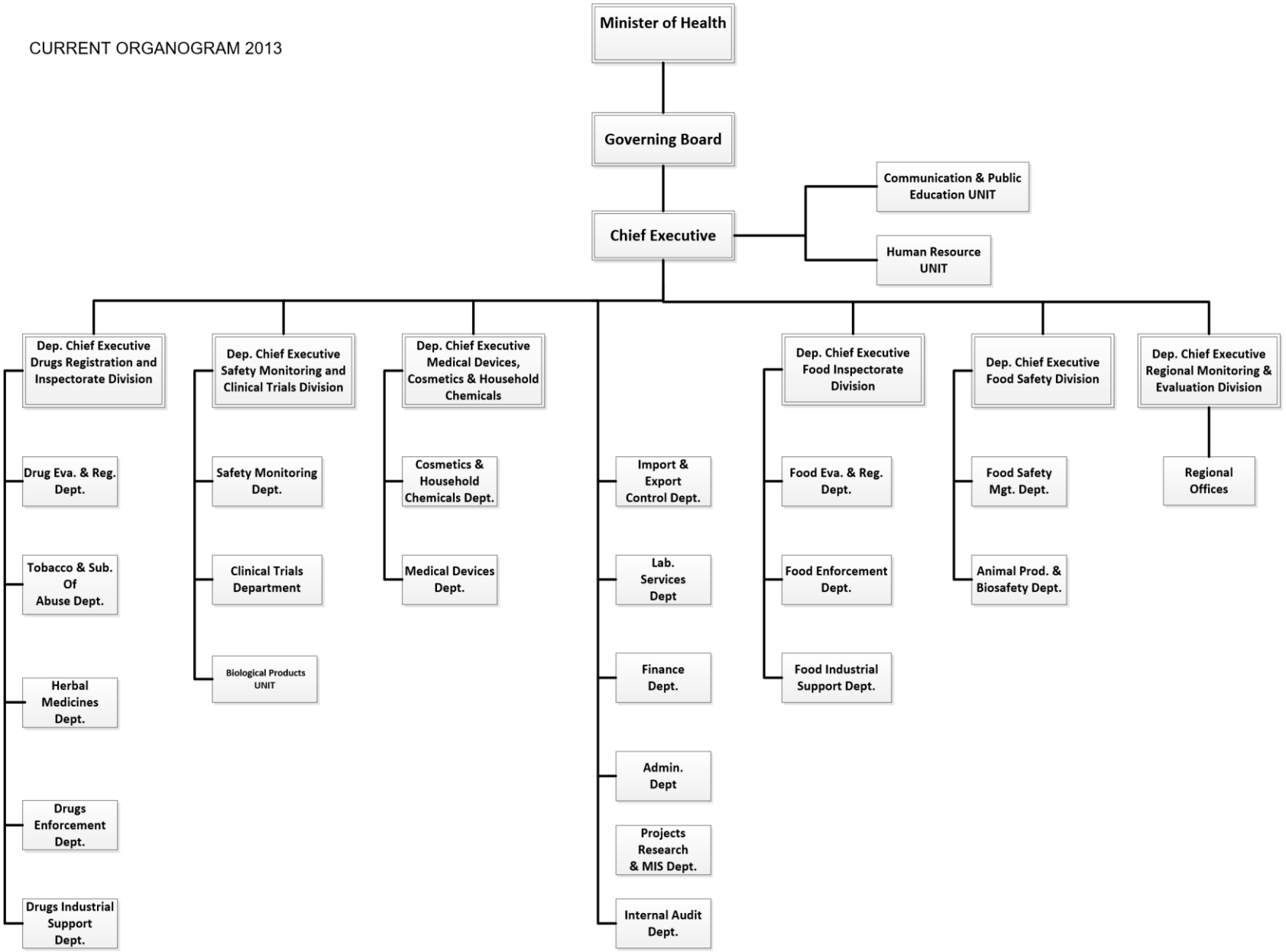
n. Laboratory Services Department

The Quality Control Laboratory provides laboratory services in the form of quality evaluation of food, drugs, cosmetics and household chemical substances. The Laboratory plays the role of determining the quality of these products, thereby enabling the Authority to take regulatory decisions. The laboratory performs chemical, physical and microbiological analysis of chemical and herbal drugs. The quality parameters employed are as established in standard compendia indicated in schedule IV of the Public Health Act, 2012 (ACT 851). The Department also supports both internal and external clients by providing reliable analytical and advisory services.

1.2 ORGANOGRAM OF THE FOOD AND DRUGS AUTHORITY

The current organogram of the FDA is indicated on page 15.

CURRENT ORGANOGRAM 2013



OUR VISION

The vision of the Food and Drugs Authority is to become a centre of excellence in food and drug regulatory affairs on the African continent.

OUR MISSION STATEMENT

The Food and Drugs Authority aims to implement the appropriate regulatory measures to achieve the highest standards of safety, efficacy, and quality for all food, drugs, cosmetics, household chemical substances and medical devices (hereinafter referred to as products) locally manufactured, imported, exported, distributed, sold, or used, to ensure the protection of the consumer as envisaged by the law regulating food and drugs in force in Ghana.

2. 0 **TECHNICAL REGULATION-DRUGS**

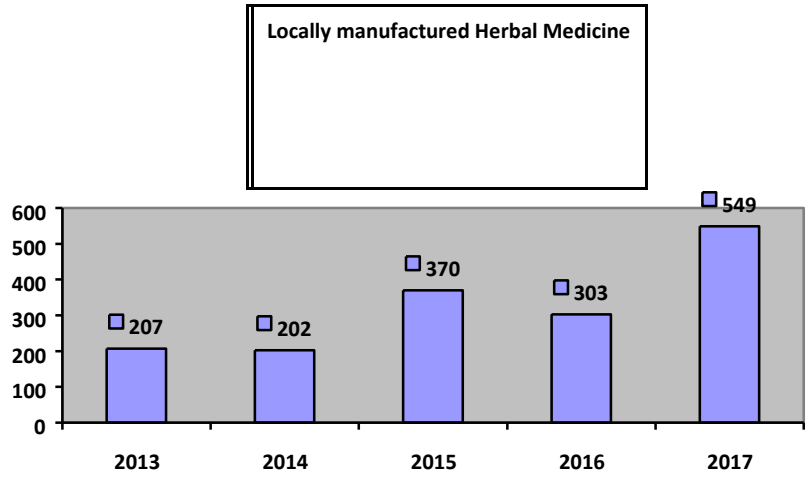
2.1 **REGISTRATION**

Registration provides assurance to the public that all Medicinal and non-medicnal products are well evaluated by all the standard and are certified by the Food and Drugs Authority.

2.1.1 Herbal Medicine

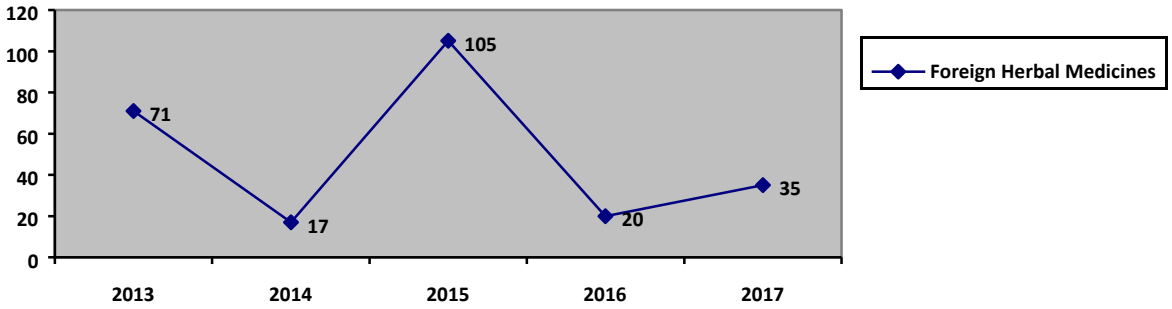
The Department registered a total number of three hundred and three (303) locally manufactured herbal medicines; this includes re-registration. Comparing the 2017 figure to that of 2016, it is indicating that there was a decrease in registration of 27%. Below is the trend for the Department concerning locally, foreign manufactured Herbal Medicine and food supplement registration since 2013 to date.

Figure 1: Locally manufactured Herbal Medcine trend.



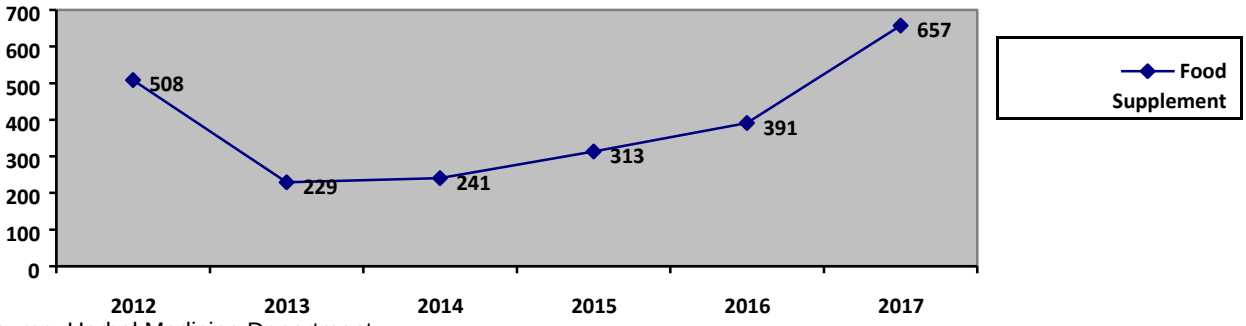
Source: Herbal Medicine Department.

Figure 2: Foreign Herbal Products



Source: Herbal Medicine Department.

Figure 3: Food Supplement registration



Source: Herbal Medicine Department.

The year 2017 saw increase in the in all products being regulated by the Herbal Medicine Department.

2.1.2 Tobacco Registration and Regulation

The year 2017 saw the progress of tobacco regulation and registration. The importing companies furnished the FDA with advice of receipt, annual returns, and the requisitions for the ensuing year. The FDA also received multilateral chemical reporting notification forms for endorsement in connection with the importation and control of precursors. The FDA also sent quarterly and annual returns on the use and importation of narcotics and psychotropic substances to the International Narcotics Control Board (INCB) in Vienna.

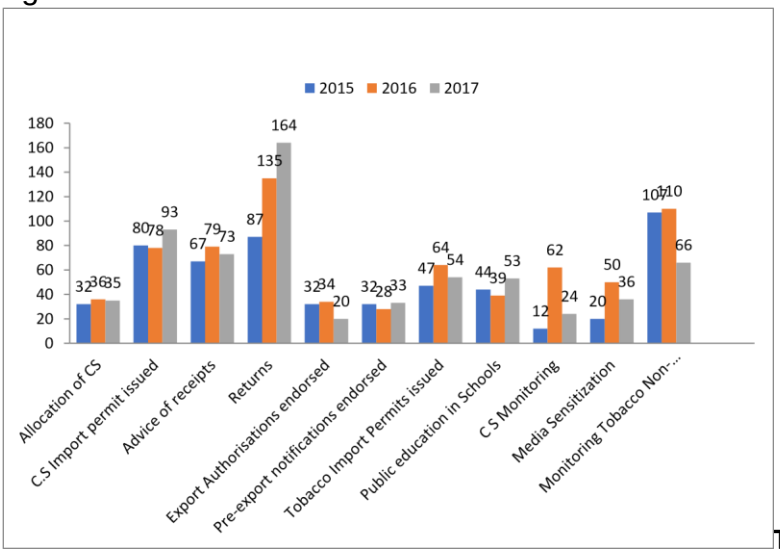
The Department allocated thirty-five (35) controlled substances for manufacturers; and issued ninety-three (93) controlled substances permit. As part of monitoring Control substance in the industry the department conducted twenty-two (22) monitoring visits. The department also had seventy-three (73) receipt of advice with one hundred and sixty-four (164) Returns. Twenty (20) export authorisations endorsed, the same figure was endorsed as pre-export notifications. The department issued fifty-four (54) tobacco import permits. As part of the

mandate of the department, they were able to conduct fifty-three (53) public education in schools in the Greater Accra region.

The department also had twenty (20) sensitization programmes through the media. They also conducted a monitoring visit to about one hundred and seven Pubs, resturants, hotels etc. to check on the compliance of the public smoking prohibition.

The graph below indicates that a lot was achieved in the year 2017 as compare with 2016 and 2015.

Figure 4: Trend of activities for the TSAD from 2015 to 2017



TSAD ACTIVITIES FROM 2015 TO 2017

Source: 2017 Tobacco and Substances of Abuse Department.

2.1.3 Medicines Evaluation and Registration Department

During the year under review, one thousand four hundred and sixty (1460) product applications were submitted to the Drugs Evaluation and Registration Department for registration; the department recorded same figure in 2017. These applications were made up of one thousand, two hundred (1200) imported allopathic drugs (human), sixty (60) allopathic drugs for veterinary use and two hundred (200) for local manufactured drugs allopathic. Eight

hundred and fifty-six (856) were registered as compared to one thousand, four hundred and forty-four (1,444) registered products in 2016. There was a decrease in registration by 68.7% as compared with 2016 registration.

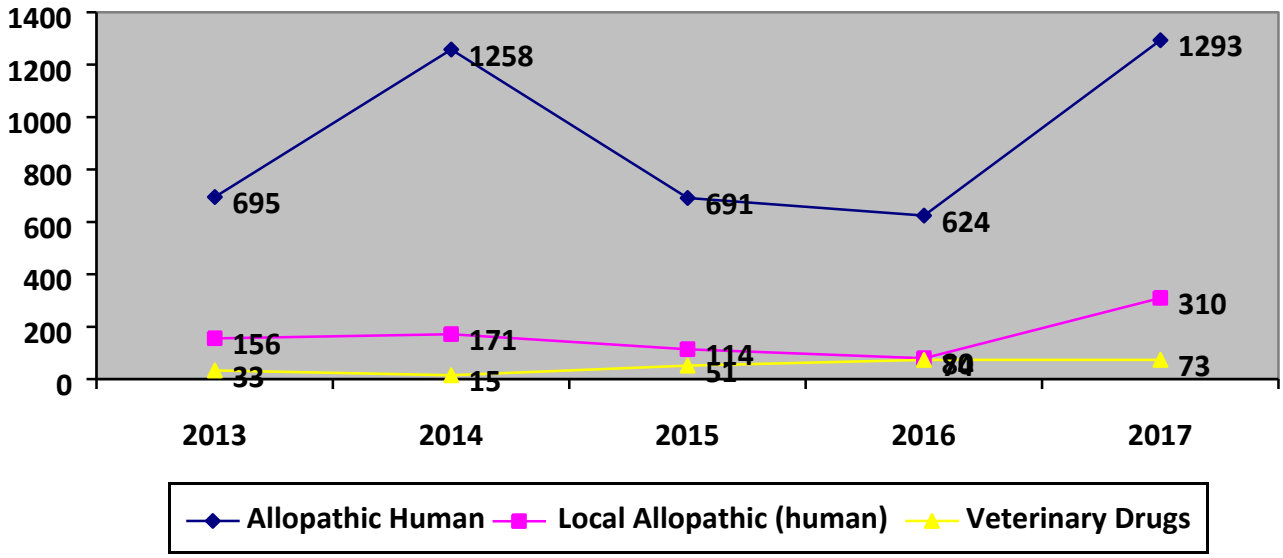
Table 1 gives the summary of applications received for registration during the year under review.

Table 1: Summary of applications received and registered

Product Type	Received 2017	Received 2016	Registered 2017	Registered 2016
Allopathic Drugs (Human)	1,200	1,200	1293	624
Veterinary Drugs	60	60	73	40
Local Allopathic	200	200	310	70
Total	**1,460**	**1,460**	**856**	**1,444**

Source: Drug Evaluation and Registration Department.

Figure 5: trending of Drugs registered since 2013-2017



Source: Drugs Registration Department 2017

Product Registration and Document Reviews

In 2017, twenty-five (25) dossier evaluation meetings and six (6) product registration meetings were held.

Training for Clients and Stakeholders

Training workshops for local pharmaceutical manufacturing companies, importers of medicinal products and key stakeholders from the Ministry of Health were held as follows

- 302 staff of importers and manufacturers of herbal and allopathic medicines trained on new and revised drug guidelines.
- Seventy three (73) Quality Control or /Quality Assurance personnel of pharmaceutical companies trained
- Eighty seven (87) Regulatory Affairs Managers trained and four (4) representatives from the ministry of health.

2.1.4 Enforcement Activities-Drugs

- **Market Surveillance Activities**

The department engaged in the following activities, safely disposed off seventy-one (71) sub-standard, counterfeit and fake drugs. Thirty-seven (37) of the complaints received were investigated. The department also conducted one hundred and fifty-five (155) verification inspections.

The department also conducted raids and swoops at Tuesday Market in Mamprobi and Madina markets. In all eight (8) peddlers were arrested and cautioned, assorted unregistered drugs seized and disposed off. ✦ **Anti-Counterfeiting Activities**

Eleven (11) counterfeit incidences were detected, five (5) batches of fake Vermox detected, the case is in court as at the time of reporting. One thousand one hundred and sixty-one (1161) packs of counterfeit coartem were seized in Ghana and Togo.

- **Product Quality Montoring**

The department purchased five (5) therapeutic line samples from sixteen Districts in Greater Accra, it was indicated that twenty-four (24) of the samples were not registered; these are:

Ambdipine -6;

Metformin-3;

Ciprofloxin-5 and; Diclofenac-10.

Two (2) therapeutic lines (Melformin and Ambdpine) were sent for quality testing, so far, two (2) brands of Ambdipine failed quality analysis. Confirmatory test on Metformin brands is pending.

The same exercise was conducted nationwide for Uterotonics Surveillance, Antimalarial and Analgesics Surveilance. Fifty (50) Uterotonics (oxytocin and ergometrin maleat) were found unregistered, recalled and destroyed. Five (5) Antimalarial and thirteen (13) Analgesic preparations failed quality evaluation, they were recalled and destroyed. The Department notified the regional offices to appropriate regulatory actions.

The department screened forty-two (42) Herbal male vitality products for adulteration with PDE-5 inhibitors, seven (7) products were found adulterated; they were recalled and destroyed. The marketing authorisation of products revoked and administrative charges imposed on the manufacturing company. ✦ **Product Recalls**

Thirty-one (31) products recalled from the market in the 2015, this products are male vitality products, Antimalarial, Analgesics and Uterotonics). All the products were destroyed.

- ✦ **Sanctions**

The Department sanctioned twenty-seven (27) facilities for various regulatory violations such as importation and distribution of non-conforming medicines, manufacturing of nonconforming medicines, adulteration of herbal medicines with PDE-5 inhibitors and manufacturing of substandard medicines. ✦ **Advertisement Control**

The department received two hundred and eighty-four (284) advertisements, out of the total figure received, two hundred and forty-three (243) were approved; thirty-two (32) deffered, eight (8) pending and one (1) rejected due to incomplete script.

- ✦ **Advertisement Monitoring**

The department was able to detect thirty-four (34) unauthorized adverts. Out of this figure, six (6) sponsors and media houses were cautioned. Nine (9) of them were sent to the police for interrogation and prosecution. Nineteen (19) of the unapproved Adverts were being processed for Police action.

Table 2: Summary of activities conducted by Drugs Premises Inspection Unit

Program of Activities	2016	2017
Foreign GMP Audit of Pharmaceutical Plants	30	28
Routine Audit of local Pharmaceutical Plants	27	27
Routine Audit of local Herbal Manufacturing Plants	41	63

Pre-License Inspection of Local Pharmaceutical Manufacturing Plants	1	4

Source: Drugs Enforcement Department

- **Quality Assurance**

In fulfilment of the department's mandate to attain ISO 9001, 2008 Certification by UKAS of UK, the department developed and implemented following quality monitoring system documents:

- Quality Manual
- Quality System Documents ✦ Standard Operating Procedures and; ✦ Forms.

The department sensitised thirty-six (36) FDA staff on ISO 9001:2005 Scheme. Fifteen (15) officers of the department received training on internal Quality Audits. The department conduted two (2) internal audits to address non-conformances. Two (2) management review trainings were conducted.

2.1.5 Industrial Support Services-Drugs

Inspection and issuance of License.

The Department issued license to forty (40) storage facilities, the following inspections were conducted in the year 2017:

- Seventy-four (74) storage facilities for existing importers were inspected;
- Eight (8) cold chain facilities were inspected;
- One (1) hospital storage facility was inspected out of eight (8) and;
- Seventeen (17) pre-licensing of new storage facilities were conducted.

The Department was able to register fifty-three (53) importers. It also conducted six (6) inhouse trainings for technical officers. One stakeholder training on GDP was organised from 25th to 27th March 2015; the focus being on the Central and Regional Medical stores staff. The department conducted thirty-six (36) gap analysis for pharmaceutical manufacturing companies nationwide to identify GMP deficiencies. GMP deficiencies were identified for all the thirty-six companies and communication done.

3.0 TECHNICAL REGULATION-MEDICAL DEVICES, COSMETICS AND HOUSEHOLD CHEMICALS.

3.1 Medical Devices regulation

The department were able to review and draft the following guidelines and SOPs:

- Guidelines for registration as importer of Medical Devices
- Guidelines for registration of Medical Devices (submitted to TAC for comments)
- Completed the Guidelines for registration of combination products
- Completed the Guidelines on donation of medical devices
- SOPs for registration of Class I Medical Devices
- Draft SOP for referring issues to TAC-Medical Devices

The department also achieved the following in the year 2017:

- National Stakeholders meeting-Meeting held in collaboration with the Regional Offices in all the 9 Regions;
- Improved processing of applications
- A new client service - facilitating consultations with clients and improving quality of submissions.
- Fast track registration of Class I medical devices
- Reduced documentation that is facilitating the registration of Class I MDs
- Engaging Class I MD dealers to regularize their activities with FDA
- Working visits to hospitals and diagnostic laboratories
- Visited and interacted with some importers and distributors.

A total number of two hundred and thirteen (213) applications for medical devices were submitted for registration as compared to two hundred and sixty-four (264) applications submitted for registration in 2017, . Out of the total number of applications received, one hundred and sixty-eight (168) as compared with one hundred and seventy-nine (179) applications were registered. There is a decrease of eleven (11) representing 6.5%.

3.2 Cosmetics and Household Chemical Substance

During the year under review, a total of one thousand and forty-one (1041) cosmetics and household chemicals were registered as compared to one thousand two hundred eightyfour

(1,284) cosmetics and Household Chemical products registered in 2017 and six hundred and eighty-one (681) registered in 2016.

Table 3 shows the number of products received and registered during the year under review.

Table 3: Summary of types of Cosmetics products received and registered

Product Type	Received			Registered		
	2017	**2016**	**2015**	**2017**	**2016**	**2015**
Cosmetics	1404	243	559	658	334	**801**
Household Chemicals	224	81	130	138	96	**164**
Cosmetics-Re-registered	171	83	210	191	169	**260**
Household Chemicals-reregistered	47	32	60	54	82	**59**
Total	**1846**	**439**	**959**	**1041**	**681**	**1,284**

Source: Cosmetics and Household Chemical Substance Department.

3.3 Enforcement activities for Medical Devices, Cosmetics and Household Chemicals.

The department achieved the following under GMP inspectons:

- Adoption and commencement of the use of specific Cosmetics GMP inspection Guidelines (GS 22716:2006) to inspect the local cosmetics manufacturing companies.
- Twenty-nine (29) existing cosmetics/household chemicals manufacturing companies and twelve (12) new manufacturing facilities were inspected using this guideline encouraging them to be compliant.
- Eighteen (18) companies were inspected for GDP compliant.

Investigations and Complaints

The Department effectively followed up on various complaints received leading to the seizure, detention and safe disposal of various unwholesome products from the market:

- Sale of expired and tampered Colgate toothpaste (Maximum Cavity Protection)

- Sale of a floor cleaning solution (light Duty Concentrate) to the public as a mouthwash (one touch mouth wash and Samcodent).
- The distribution of three hundred and fifty (350) counterfeit one touch and ultra select Glucose Test kits.

Three companies were given administrative charges.

- **Advertisement Vetting**

The department was able to vet and approve one hundred and eighteen (118) applications on products advertisement.

4.0 TECHNICAL REGULATION-SAFETY MONITORING AND CLINICAL TRIALS

4.1 Safety Monitoring Activities

During the year under review, six (6) Technical Advisory Committee for safety monitoring meetings were held to review six hundred and ninety-seven (697) ADR reports. The following were the outcome from the TAC meeting:

Twenty-seven suspected quality and counterfeit products were reported to the Laboratory Services Department and Drugs Enforcement Department;

- Oxytocin injection was redrawn from the the market and regulatory action taken against the company.
- Tanzite injection was not registered; the case was referred to the Ghana Police Service through the Drugs Enforcement Department. The importer of C-Plus Tablets initiated registration.
- There was a risk Minimization Measure (RMM) for Tot'hema ampoule due to medication error.

The department also undertook the following projects:

- Training for Qualified Person for Pharmacovigilance (QPPV) in collaboration with WHO collaborating center for Advocacy and Training;
- Curriculum review for Training Nurses and Midwives in Ghana to include Pharmacovigilance, Vaccine Vigilance and Patient Safety;
- Provision of IEC Materials such as posters and pull-up Banners, Video and Audio Advertisement, facebook (Patient Safety Ghana), WhatsApp platform etc and;
- A two day training in Southern and Northern sectors were held to introduce Pharmacovigilance Assessment Tool (PAT) into the healthcare delivery system in collaboration with the Ghana Health Service.

Table four (4) below shows the summary of Safety Monitoring Department activities in 2017.

Table 4: Summary of activities conducted by Safety Monitoring Department

PLANNED ACTIVITIES	TARGETS	ACTUALS
Training Programmes *Institutional*	48	29
Professional Associations	2	1
Qualified Person for PV Training in collaboration with WHO CC (RCORE)	1	1
Tertiary Institutions	2	2
Data Entry SWS	801	580
VigiBase	580	580
CEMFlow (WHO and AMFm)	6,441	6,441
TAC Meetings	4	6

Source: Safety Monitoring and Clinical Trials Division.

4.2 Clinical Trials Activities

2015 was generally very challenging; however, CTD carried out most of its activities effectively:

- Development of the Intensive Fellowship Curriculum on CT in collaboration with SPH Course brochure published on the Authority's website
- Development of 2 new guidelines as well as update of 2 existing guidelines for CT
- Collaboration of FDA with Health Canada to organize training on vaccine regulation for CTs for some regulators from African NRAs including Ghana.

The details on performance and figures are captured in table 5.

Table 5: Summary of activities of the Clinical Trials Department

PLANNED ACTIVITIES	TARGETS	ACHIEVEMENTS

Process New Clinical Trial Applications received	Fully evaluate all new applications and issue clinical certificates within FDA timeline	10 new applications received within the year were reviewed within timeline.
Process New Clinical Trial Amendments (CTAm) received	Fully evaluate new amendments and issue appropriate amendment certificates within FDA timeline i.e 30 working days (excludes clock stop time)	5 amendment applications received within the year were reviewed within timeline.
• Evaluation of Progress reports • Safety reports • Final reports • from approved ongoing clinical trial sites	- Process 46 progress reports - Process all close-out reports - Process all SAPs received	- 35 progress reports received and evaluated within timeline: - 2 safety reports received from Mal 063 evaluated within 6 days. - 2 reports received for Mal 055 (Kintampo & Agogo) - 3 SAPs received for AIMS, Mal 063 & 055 (Kintampo)
Processing of SAE reports from approved and active Clinical Trials.	To process all SAE reports received for TAC meetings and update database.	- 168 new SAE reports from ongoing trials were received and processed for TAC meeting
Processing of Import permits/ procurement of Investigational products (excludes clock stop time)	Process all import permits submitted for investigational products within10 working days	All applications reviewed within 2 days • TADO – 6 permits approved • ZEBOV – 3 received, however only 1 approved (dummy shipment)
GCP Inspections 1. Conduct Pre-Trial GCP Inspections for some upcoming studies 2. Conduct Routine GCP Inspections for ongoing trials	Conduct 2 inspections for proposed Ebola trials at • Onchocerciasis Chemo Research Centre, Hohoe • Kintampo Health Research Centre Conduct inspections for 4 ongoing trials and any new trials to be approved within 2015	Pre-Trial GCP Inspections conducted at the 2 sites to ascertain capacity to conduct the trials in compliance with the approved protocol(s), FDA Guidelines, ICH Guidelines and SOPs. - Inspections conducted for 2 ongoing trials and 1 new trial

Trainings organized by FDA 1. Introduce MSc. CT Students from School of Public Health (SPH), UoG to local regulatory system as part programme course curriculum	Met* with the students and introduce FDA's CT requirements through PowerPoint presentations	Presentations made by staff of CTD on topics regarding Regulatory Issues and Good Clinical and Laboratory Practice
2. Annual GCP Training	To organize an annual GCP Training for study investigators and study team	Training came off - 26 participants from research institutions and health facilities across Ghana were trained
3. Training of Pharmacists: Annual General Meeting (AGM)	To train pharmacists at 2015 AGM	Training could not come off though a slot was requested by FDA
RCORE Compliance and Readiness	Prepare and submit Report to NEPAD & development of curriculum	• RCORE Compliance and Readiness Report completed as per format and forwarded to NEPAD • Intensive Fellowship Curriculum on CT developed in collaboration with SPH & course brochure published of FDA website
Ebola related activities On-site GCP training Press Conference Stakeholder meetings/ engagements organized by the MoH	Train Zebov CT study personnel at Hohoe Municipal Hospital. Organize press conference to discuss Ebola trial issues - To educate stakeholders on regulatory issues with respect to CT in Ghana including the proposed Ebola vaccine trials	76 study personnel trained; GCP certificates issued 3 preparatory meetings held; press conference came off with a good number of media personnel attending (FDA conference room) 3 stakeholder engagements held with officers attending as FDA representatives ✦ Civil Servants Auditorium, Accra ✦ Kintampo HRC ✦ Hohoe

Source: Safety Monitoring and Clinical Trials Division

4.3 **Biological Products**

The department accomplished the following during the year 2017:

- ✦ Implementation of the Electronic dossier evaluation system for biological products;
- ✦ Bringing into compliance WHO prequalified vaccines for EPI programmes;
- ✦ Development and publishing of the regulatory framework for blood and Bloodderived medicinal products and;

- ✦ Awareness amongst stakeholders of the existence of a dedicated team for Biological Products evaluation and registration.

The details on performance and figures are captured in table 6.

Table 6: Summary of BPU activities and its achievements

PROGRAMMED ACTIVITY	TARGETS	ACHIEVED
Development of operational documents	To develop new operational documents and update existing ones to address gaps in the regulatory system	Eleven (11) documents developed: (4) documents on Blood regulation and six (6) on Biologics regulation
Stakeholders meeting	To meet and discuss new and revised regulatory documents with stakeholder (NBSG & Importer of Biological Products)	Three (3) meetings were convened and the subjects adequately addressed
Internal Training	To identify training needs and organize training programmes to address needs	A total of five (5) training programmes were organized and the impact evaluated
Development of operational documents	To develop new operational documents and update existing ones to address gaps in the regulatory system	Eleven (11) documents developed: (4) documents on Blood regulation and six (6) on Biologics regulation
Stakeholders meeting	To meet and discuss new and revised regulatory documents with stakeholder (NBSG & Importer of Biological Products)	Three (3) meetings were convened and the subjects adequately addressed
Internal Training	To identify training needs and organize training programmes to address needs	A total of five (5) training programmes were organized and the impact evaluated
Participate in WHO online training (3-months): Cold Chain Management	To complete the on-line training programmes organized by the WHO Cold Chain Management	One (1) officer successfully completed a 3-months course on managing cold-chain biopharmaceutical
Participate in In-country WHO funded regulatory workshop on Biosimilars	To assist in the organization, and to participate in the workshop on Biosimilars	Workshop successfully organized and key learning points incorporated into guidelines
Participate in local/International regulatory workshops/conference/Seminar, and report writing	To participate in selected international regulatory capacity development programmes, and to generate reports with clear findings /recommendations to the CEO's office	Officers successfully participated in seven (7) international conferences/ workshops/seminars, and six (6) local programmes
Review fresh registration applications	To conduct preliminary and full evaluation of all fresh registration application submissions	A total of nineteen (19) registration applications submitted and preliminarily evaluated. Seventeen (17) submissions fully evaluated

Review registration renewal applications	To conduct preliminary and full evaluation of all registration renewal application submissions	A total of twenty-one (21) registration renewal applications submitted and preliminarily evaluated. Twenty-three (23) submissions fully evaluated
Import Permit applications	To process all import permits on-time	A total of one hundred and one (101) import permits processed in accordance with the FDA's requirements. Forty-five (45) permits initially rejected due to inadequate information provided
Additional documentation, Variation/ notification	To evaluate and process all additional documentation and variations (major and minor)	A total of one hundred and twenty-seven (127) additional documentation/variations processed
Correspondence (letters)	To acknowledge and respond to all letters "minuted "to the Unit within specified timelines	A total of two hundred and thirtyeight (238) letters generated and dispatched within specified timelines

Source: Biological Dept

5.0 TECHNICAL REGULATION-FOOD INSPECTORATE

5.1 Food registration

In 2017, a total number of two thousand two hundred and sixty (2,260) applications were received for registration as compared to one thousand seven hundred and thirthy one (1,731) applications received in 2016. Out of this number, two thousand one hundred and sixty-eight (2,168) were processed representing 96% and one thousand five hundred and thirty-two (1,532) were registered representing 68%. The Department attended to four thousand three hundred and sixty-four (4,364) clients. This figure was above that of 2016 of three thousand one hundred and five (3,105). Out of the total figure, two thousand eight hundred and fifty-four (2,854) clients submitted applications whilst one thousand five hundred and ten (1,510) of the clients sort for information pertaining to registration. In total the Department held twenty five (25) registration meetings.

Table 7 shows the activities of the Department under the period under review

Table 7 : Summary of food products submitted and registered

Activity	Submitted	Deferred	Registered	Pending
New Applications for food products	2260	636	1,532	-

Source: Food Registration and Evaluation Department.

5.2 Inspection and Enforcement-Food

The following enforcement activities were undertaken in the year 2017:

Enforcement of Regulations in the Food Manufacturing Plants and Premises.

The department undertook five hundred and twenty two (522) regulatory inspections of operational facilities, which include pre-licensing, follow-ups and routine. Two hundred and thirty (230) food manufacturing premises were issued licenses. This was done to verify compliance with regulatory requirements and conformance to operational objectives. The department also conducted twenty four (24) site verifications of foreign food manufacturing facilities. The countries inspected were the following:

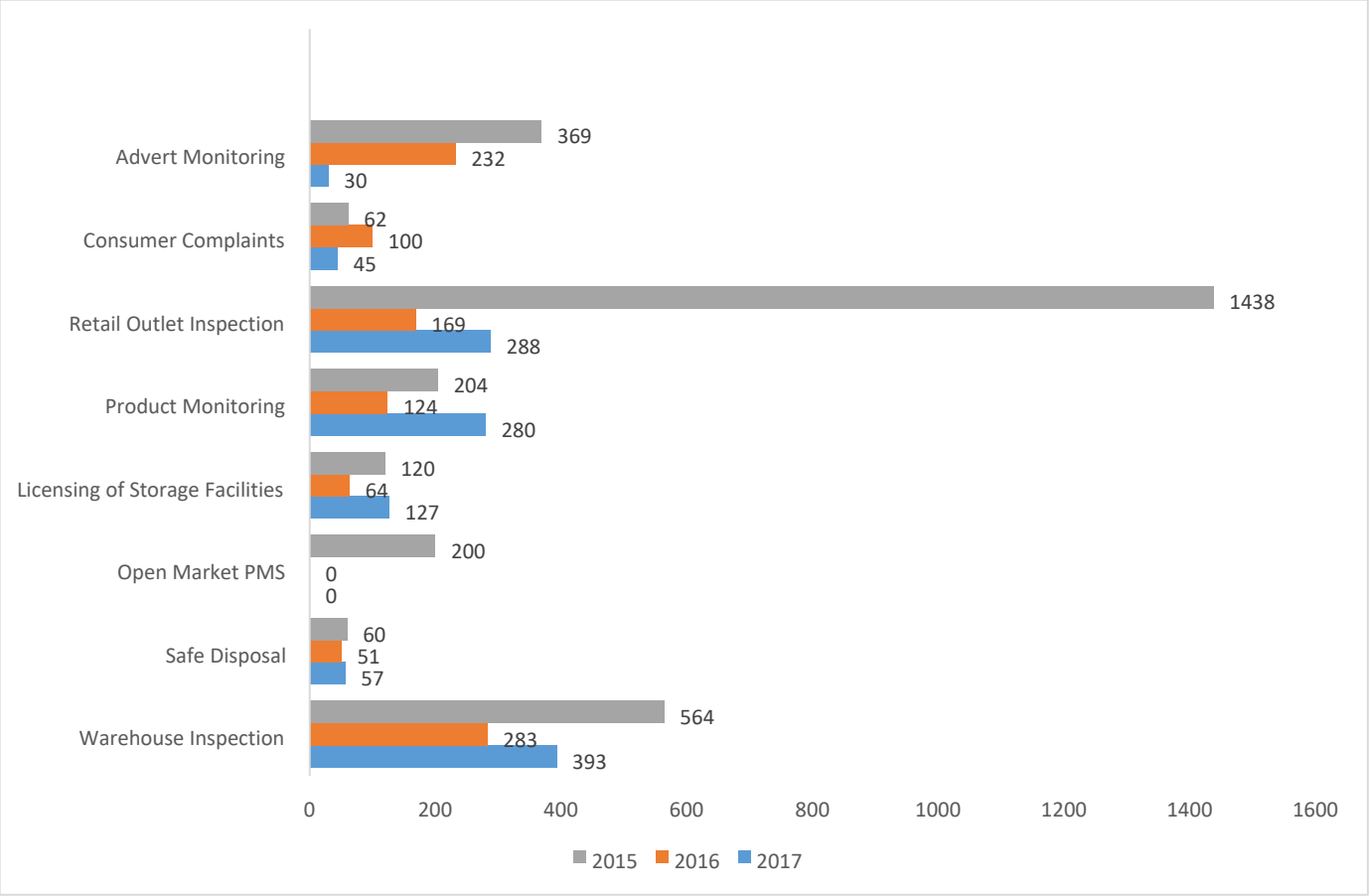
- China -Tomato Paste, Canned Fish Products.
- Nigeria - Cereals, Additives, Bakery Products, confectionery and Drinks.
- France - Meat and Meat products
- Morocco - Fish and Fish products.

In line with compliance monitoring requirements, the department received reliability performance report from the various units and quarterly reports covering performance statistics.

Figure 7: Food Post-Market Surveillance conducted

Source: 2015 Food Post Market-Surveillance Activities

In the course of 2017, the Department processed 363 advertisement applications; 250 applications were approved and 79 applications were deferred. Twenty-six (26)



Advertisement vetting committee meetings were held.

- **Supervision on safe Disposal of Unwholesome Food**

In 2017, 59 applications were received. Fifty-seven (57) destructions were supervised.

- **Supervision of Re-packaging of Damaged Packages of Pre-packaged Foods.**

During the year under review, nine (9) companies requested for supervised pre-packaging and all were approved.

5.3 Food Industrial Support Services

The Department collates information on industry needs and identifies deficiencies which serve as inputs for the adaption of strategies to address these needs. The food

industry is assisted in this regard to implement Good Manufacturing Practices (GMP), Hazard Analysis Critical Control Point (HACCP), ISO 22000 Food Safety Management System, etc. A monitoring mechanism is also put in place through Internal Audit Schemes developed by the Department to ensure continuous application of the principles of food safety and quality management.

The following were achieved as indicated in table below in 2017.

Table 8: Summary of FISSD activites in the year 2017

TARGET	ACTUAL PERFORMANCE	REMARKS
• Train 100% of persons requiring training in GMP • Train 100% of persons requiring training in GWP	100% of all training applications honoured. A total of 316 persons from 107 Food Processing Companies 100% of all training applications honoured. A total of 2 persons from 2 Food Importing Companies	• 54 (50.5%) out of the 107 companies trained have their *premises licensed* • 53 (49.5%) have outstanding GMP issues • 54 (50.5%.) companies have their *products registered.* • 35 (32.7%) companies have their products *conditionally approved* • 11 (10.3%) companies have their products *pending evaluation.* • 7 (6.5%) companies are yet to address infractions observed on products to facilitate registration rehouses (100%) registered Two wa
Assist all companies applying for HACCP training/Installation and award of Certificate	Discussions with 2 new companies (Special Ice Company Limited and Accra Breweries Limited) requiring assistance in HACCP system installation were completed. HACCP PRPs issues identified at Bel Aqua addressed and confirmed. HACCP installation programme to resume.	• Training and all implementation of HACCP systems scheduled to take place in the first quarter of 2017.

Needs Assessments - 20	42 Needs Assessment were* conducted	• Out of the 42 companies, 4 (9.5%) have their premises licensed and products registered. • The other companies are still in the process of implementing corrective actions
Provide Technical support to members of Trade Groups (Technoserve, AWEP and ASSI)	15 Companies supported by Techno serve were* trained in GMP and other regulatory requirements	Five (5) of such companies in the Greater Accra Region have submitted *their applications.
• Audit 10 medium salt production plants (Two times each) and 4 artisanal salt winning sites (8 times) as part of the USI program (Strategy 2/3) • Monitor through the Police Service at Security Checkpoints the status of salt in transit – 24 Visits scheduled	• 4 medium salvation were* plants audited • No inspections were* conducted at artisanal salt winning sites • 18 visits in all were made to Tsopoli, Doboro and Amrahia checkpoints	Salt production and mining activities particularly artisanal salt winning were adversely affected by bad weather. The Doboro and Amrahia police checkpoints were closed down during the second half of the year
• 10 major markets to be visited 30 times to monitor iodine status of salt. • Distribute 92 cartons of RTKits among 4 major institutions in the progarmme • Environmental Health Officers (EHOs) and FDA	• 33 visits were made to 10 markets • FDA, GHS, MLG&RD and Research Institutions (and academia) supplied with RTKits to facilitate rapid analysis of salt for iodization s, 2 Port Health Officers from Upper d West Regions and 2 FDA Officers lta and Central Regions Trained 26 EHO East an involved from Vo USI	13 Photometers with funding from UNICEF distributed to 2 FDA Regional Offices and 11 District/Municipal Assemblies for effective monitoring

	Officers from 13 salt producing areas trained in salt iodation process and use of photometers for quantitative analysis of iodine levels in salt		
	• FDA in-house Codex Committee with internal Subcommittees established • Quarterly Codex Seminars	FDA Codex Committee Inaugurated One Seminar carried out	• Sub-committees proposed for final approval

Develop training manuals Organize training program for FISSD staff Arrange for Industry visits by FISSD staff	Five (5) Tailor-made training manuals developed for food clusters to facilitate training (Water, Alcoholic Beverages, Palm Fruit Extract, Breakfast Cereals and Flavoured Drinks) Three (3) Officers were trained in Risk Analysis Consumer complaints International Food Safety Systems Advanced HACCP/Training of Trainers for HACCP Meat Processing It has not been carried out*	Beneficiaries of the TRAQUE Training Program Industries were in technical distress
Organize/ participate in workshops/ meetings/seminars	Twelve (12) meetings/conferences/seminar/workshops were* attended • Codex (NCC and CCCF) • TC (GSA) • Packaging Policy Working Group(MOTI) • NSIC (MOTI) • EPA	
Support students from Tertiary Institutions on Industrial Attachment	The 5 students were trained on various aspects of Food Regulation including Labelling, GMP Inspections, Development of Inspection Checklists and the Conduct of Needs Assessment.	Tutors from the University of Cape Coast followed up to assess the performance of their students*. The FDA has been asked* to give a lecture to final year students on
	They were also taken on industrial visits, (3 facilities; Milk Powder, Water/Fruit Juice, Mayonnaise/Ketchup) to obtain training on how GMP inspections are conducted. They were each given a project to develop a product with its accompanying labels*	regulation

Source: Food Industrial Support Department activities 2017

6.0 **Technical Regulation - Food Safety Activities**

6.1 **Food Safety Management**

The following activities under the Food Safety Management were undertaken during the period under review.

Table 9: Summary of Activities for Food Safety Department

PLANNED ACTIVITIES	TARGETS	ACTUAL PERFORMANCE LEVELS
1. Inspection & Technical Assistance offered to FSE	192	288

2.	Issuance of Food Hygiene Permit	60% of FSE inspected	73.4% (256 FHP)
3.	Follow-up Inspection to ascertain	61 level of compliance to GCP	75
4.	Hospitality Industry Surveillance	264	99
5.	Applications for FHP	216	271
6.	Consumer Complaint handling	100% of complaints received	100% (3 complaints received and investigated
1.	Quarterly review meetings to ensure safety of food served in the GSFP	4	4
2.	Destruction of expired Premix Vitamins	22,000 cartons	22,000 cartons
1.	Train Street Food Vendors on Food Safety and Hygiene	24	29
2.	Food Safety Awareness among Travellers and Market women	90	106
3.	Mass Media Engagement	200	300
4.	Educate Basic School Pupils on Food Safety and Hygiene	20	15
5.	Stakeholders' workshops on Basic Food Safety and Hygiene	4	4
6.	World Food Day celebrations		
	i. Food safety forum		
	ii. Supervised Traditional food service providers/caterers Cookoff event		
	iii. Participate in Food 4 all Ghana Campaign		
7.	Nationwide Sampling and testing for Sudan dye	0	1,025 samples. of palm oil
8.	Collaborated with Criminal Investigation Department (CID) and Women In Agriculture Development (WIAD) in swoops	0	500 (48.8%) from Greater Accra Region. Dawn swoops, Food safety educational campaigns and food safety education on palm oil adulteration respectively.
1.	Training programmes for* Food Service Establishments	26	11
1.	Development of National Food Safety Policy(NFSP)	1	1
	• Review and adopt policy	1	1

		1	1
• Development of strategic action plan			
• Development of commercial millers Manual			
1. Infosan Alert & Notification		0	3
1. To develop a surveillance system collection of data of all foodborne related cases	1 pilot	4	1 pilot to facilitate the 2 (1st and 2nd quarter)
2. Quarterly Stakeholders' review (1=ER, 2 each from WR &BAR)	0	163 cases	meetings on the surveillance system 0 5
3. Collate data on foodborne diseases reported from the Adentan Municipality			
4. Foodborne disease outbreaks			

Source: 2017 Activities of Food Safety Management Department.

6.2 Animal Products and Biosafety Activities

In 2017, the Department achieved the following as indicated in tables 11.

Table 11: The types of inspections the Department conducted.

ACTIVITY	TARGET	ACTUAL OUTCOME
Conducted		
• Pre-license	1st quarter- 145	101
• Pre-approvals	2nd quarter- 145	190
• Follow-ups	3rd quarter- 140	190
• Routine	4th quarter- 90	115
• Unannounced Inspections	Total – 520	Total – 596
Pre-Christmas inspections	212	200 43 meat shops 26 meat processing facilities 131 cold storage facilities

Post Market Surveillance		2 Cold Storage facilities 5 Egg packing house 8 dog food
Supervision of the process of safe disposal	18-(2014)	16
Supervision of sorting, relabeling and re-packaging exercises	18 (2014)	18
Investigation of complaints received	25 -(2014)	11
Monitoring of products at the warehouses of importers	18 (2014)	32 were received: Dog Food - 9 Feed - 17 Feed Ingredients – 6
Identifying non-conformances at the proposed facilities	2	5

Daily review of print and online media platforms	1770 print media 90 online media	1770 print media 90 online media
Research on risk assessment from countries which have approved GMO	4 crops - maize, soy, cotton, canola	Draft introduction for all four have been developed
Country-wide administration of questionnaires for hazard identification	Hazards as perceived by: Regulators Consumers Shoppers and Farmers from all 10 regions	6 out of the 10 regional offices have returned the completed questionnaires
In-house committee reviewed the parameters and agreed on limits	All categories of feed and feed ingredients	All the categories were covered
Designed flyers on Safe Meat Handling Practices for Consumers and Meat Handlers	To have it uploaded on the website	The flyer has been designed, but is* yet to be finalized.

Presentations from both FDA and the Namibian Biosafety Council	To present the role of FDA	The delegation's feedback indicated they had benefited from the study tour
Meeting with operators: Discussed • licensing as per the PHA • GCSP/GHP	60	48
Meeting with operators: Discussed • licensing as per the PHA • GCSP	15	21
Sampled sausages (local, imported) for analyses at the Department of Food Science, UG	30	15
Sampled from selected fishmeal producers	On-going	13 samples
Training Programme for workers of Cold Storage facilities	4 Companies	3 companies were trained
Training for honey processors	1	1

Source: 2017 Inspections of Animal and Biosafety Department.

7.0 **Import and Export Control Activities**

7.1 Issuance of Permits

In 2017, the Department with the support from the GcNet Unit, issued nineteen thousand two hundred and forty-two (19,242) permits. The department also inspected twelve thousand one hundred and three (12,103) dry containerized cargos at the Tema Port and two thousand three hundred and sixty-six (2,366) at the KIA. One thousand six hundred and six (1,606) inspections conducted on all reefer vessels and containers for frozen Animal products at the Tema port. Two hundred and ninety-one (291) inspections of imported fresh packaged fruits and vegetables conducted. The

department also facilitated the clearance of two hundred and twenty-seven (227) export cargos at Tema.

7.2 Detention

During the period under review, one thousand two hundred and sixty-one (1,261) consignments were detained by the department. Five hundreded and forty-one (541) were unregistered, ninety-nine (99) were non-conforming, three hundred and ninety-nine (399) were in the registration process, thirteen (13) were detained for premises inspection whilst eleven (11) were detained for laboratory analysis (mostly condoms).

7.3 Safe Disposal

The department supervised the safe disposal of several products and consignments which were unwholesome. Twenty thousand two hundred and forty eight (20,248) products were disposed off.

7.4 Licensing of Bonded Warehouse

Eighteen (18) custom bonded warehouses were issued with a license during the period under review. The department will seek deeper collaboration with the Customs Division of the Ghana Revenue Authority to ensure a wider coverage in the year 2017.

7.5 Export

During the period under review, two hundred and twenty-seven (227) export inspections were carried out.

8.0 **Quality Control Laboratory Department**

The Quality control Laboratory Department provides support to all the divisons . In this vein, the total number of samples received for analysis was two thousand eight hundred and ten (2810), this figure represents a decrease of 8.6% from 2016. Out of the above figure two thousand three hundred and thirty two (2332) samples were analysed; of which one thousand seven hundred and seventy-seven (1,777) passed

whilst five hundred and fifty five (555) failed, with four hundred and seventy-eight (478) samples still pending analysis.

Table 10 gives a summary of product categories received for various analytical tests.

Table 10: Summary of product categories received and analysed

Sample Category	Received	Analysed	Passed	Failed	Pending
Allopathic Drugs	704	512	340	172	**192**
Herbal Drugs	554	424	204	220	**130**
Veterinary Drugs	-	-	-	-	**-**
Food	813	751	612	139	**62**
Cosmetics	225	210	190	20	**15**
Household Chemical Substance	71	69	67	2	**2**
Medical Devices	443	366	364	2	**77**
Total	**2810**	**2332**	**1777**	**555**	**478**

Source: 2017 Laboratory Services Department

8.1 **ACCREDITATION TO ISO 17025**

The following under listed Units maintained their scope under the ISO 17025 Accreditation after the surveillance audit conducted by ANAB in May 2017.

1. Drug Physico-Chemical Unit
2. Pharmaceutical Microbiology Unit
3. Medical Devices Unit

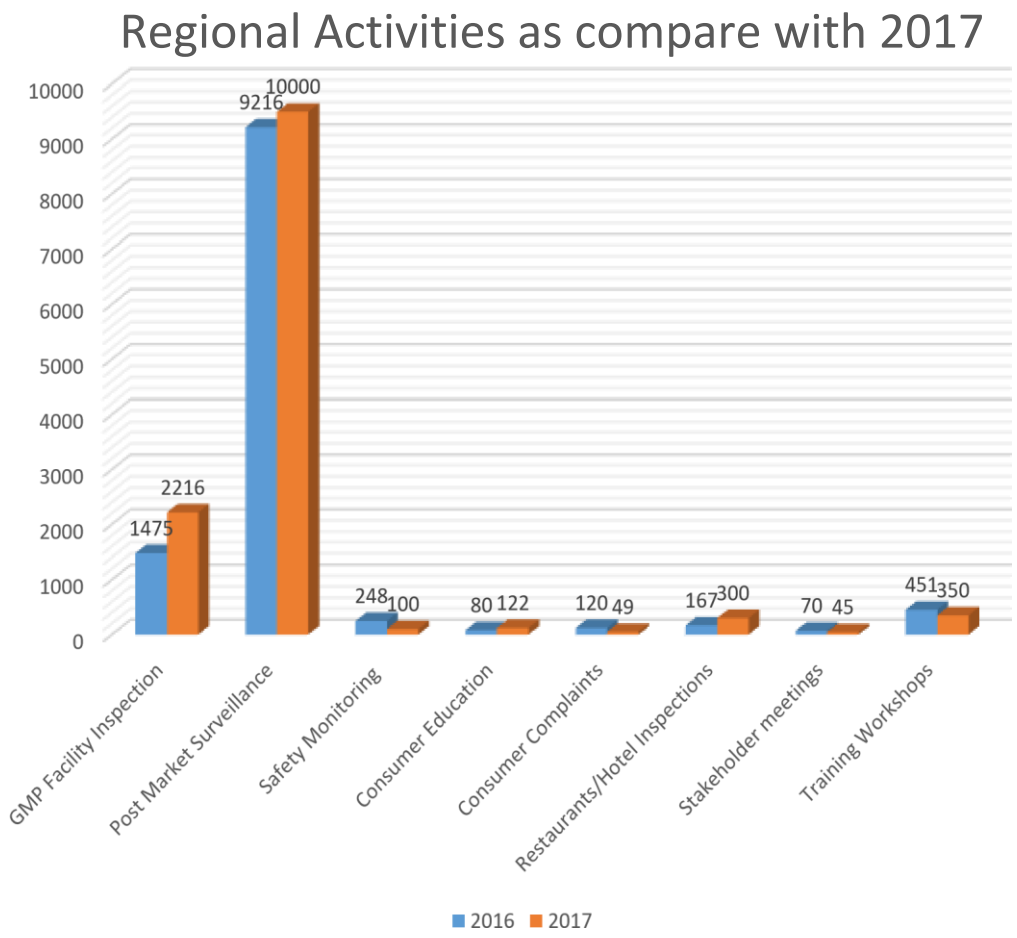
The Objective of getting the Food Microbiology Unit accredited according to ISO 17025 requirements were achieved in May 2017 after a successful audit conducted by ANAB. The Unit was accredited for thirteen Microbiological tests. ○ Aerobic Microbial count in food and animal tests ○ Coliform counts in food and animal feeds ○ Yeast and moulds cunt in food and animal feeds

○ Coagulase positive s.aureas count in food and animal feeds

9.0 **REGIONAL OPERATIONS**

Most of the activities during the year under review centred on pre-licensing inspections of small-scale food producers. The post-market surveillance function was to ensure that expired drugs and food products, unregistered drugs and food, as well as unwholesome food, which were sold to innocent consumers, were taken off from the shops. Meetings, seminars/workshops with stakeholders and media interviews and programmes were some of the prominent activities. Figure 8 shows the combined summary of activities performed by the Regional Offices.

Figure 8: Extent of Performance of Regional Operations.



Source: 2017 Regional Operational data

10.0 **THE FINANCE, ADMINISTRATION, HUMAN RESOURCE, COMMUNICATION AND PUBLIC EDUCATION AND PRMIS**

10.1 **Administration**

10.1.1 Transport Management

The activities performed by the Unit during the period under review were as follows:

- Eighty-nine (89) vehicles documentation renewed.
- The use of forms and logbooks by vehicles operators and users for better data collectively has improved.
- Routine maintenance and repairs were carried out successfully on eighty-nine (89) vehicles.

- Revamping works on seven (7) operational vehicles have been completed and are currently facilitating effective delivery of field operational works both at the head office and some regional offices.

As at 2017, the summary of Vehicles of the FDA is indicated in table 12.

Table 12: **Inventory of FDA Vehicles**

Type	Total number
Saloon Cars	19
Pick-up	60
Station Wagon	5
Motorcycle	3
Buses	2
Total	89

Sources: Transport Unit, 2017

10.1.2 Estate unit

There has not been any significant development with regard to the estates of the Food and Drugs Authority. However, the Unit performed the following activities:

- Gas pipeline installation, fixing of all cylinders in the Laboratory Service Department Annex Project was completed.
- Tema Office complex monitord.

10.1. 4 Dispatch

The unit was able to improve its electronic filing system for both in-coming and out-going mails. This has made tracking and retrival of all documents easier.

10.2Projects, Research and Management Information System Department (PRMISD*)*

During the year under review, the department continued maintaining the Food and Drugs Authority's website and deployed the corporate email system across the FDA. The local area

networks were enhanced to enable management of groups, network resources and users. The dedicated fibre optic bandwidth was enhanced to include fast information search and downloads. The Untangle software ver 9.3 was updated to ver. 10.1 to enable internet connectivity for over 200 desktop and laptop computers and to reduce the incidence of accessing and downloading inappropriate materials, blocking of social networking sites, hackers, etc. that reduce productivity. The webserver was upgraded to host dynamic web pages and a database to accommodate new developments in regulation, especially Patient Reporting of adverse effects of medicines through the website.

The Department also upgraded food application information system to include short message service (SMS) functionality. The Department initiated the procurement of Registration Information System for the registration of Medicines, Biologics, Cosmetics, Household Chemicals and Medical Devices to replace the legacy system from WHO that had its support terminated. 95% of the process has been achieved.

As part of the impending weaning off process from Government payroll, a payroll information system was acquired under the year of review and installed to facilitate the payment of staff salaries. A short messaging service (SMS) code was acquired to facilitate the reporting of adverse drug reactions for the safety monitoring Department. In 2015, the installation of the Ghana Integrated Financial Management Information System (GIFMIS) started; it was to improve budgetary, financial management (record keeping) and reporting in the public sector. The project is 90% completed.

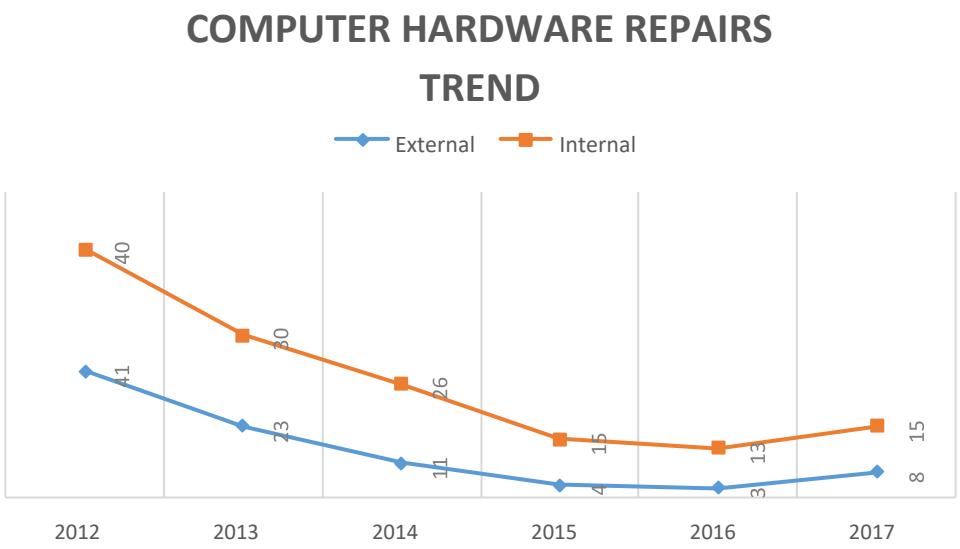
Computer Repairs

During the year under review, the Department undertook 23 hardware repairs for both external and internal repairs indicated in the figure below. The number of both external and internal repairs of computer hardware system have reduced over the period after the installation of corporate anti-virus software and the Department instituting 'green' environment practices on its IT equipments. The figures increased for 2017 since some of the hardware systems were near the end of their life-cycle.

The Department coordinated, prepared and submitted the FDA's quarterly performance reports to the Health Ministry.

Figure 9 below shows the trend of the repairs**.**

Figure 9: Number of Repaired IT Equipments from 2012-2017



10.2 **Communications and Public Education Department**

During the year under review, the key objective was to increase public education to safeguard public health and safety through media interviews. The Unit performance increased significantly over the previous year as indicated in table 13.

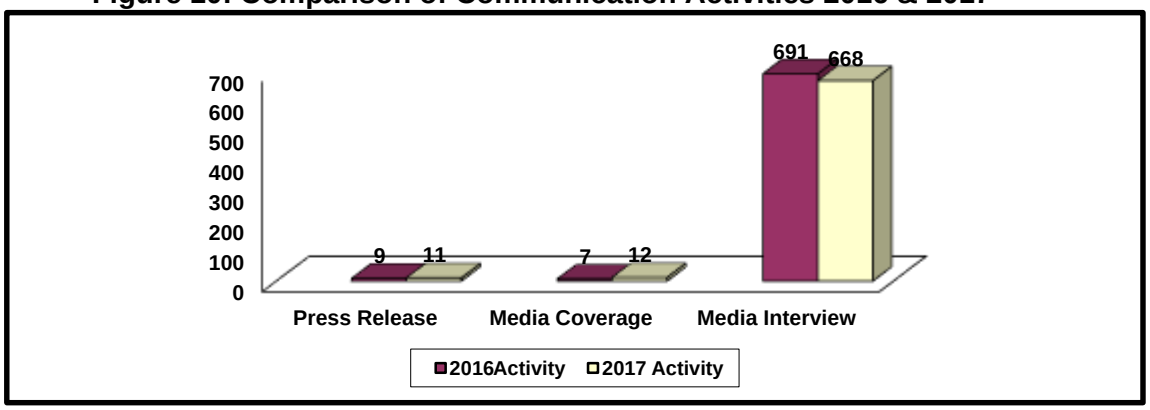
Table 13: Activities conducted by the Communication and Public Education Dept

Planned Activity	Actual Performance
Advise Management on media/communication strategies.	• Palm oil adulteration • Awareness creation
Promotion of interagency collaboration	• Advertising Association of Ghana • Ghana Independent Broadcasters Association • Ghana Standards Authority • Ghana Police Service • Bureau of National Investigations • National Media Commission • Ghana Journalists Association

	• Foreign Affairs • Consulates – U.S.A
To facilitate and coordinate effective Media and Public education	• 521 interviews conducted • Media coverage provided for 12 activities • Ebola vaccine trial • GCP training for research pharmacists • Palm oil adulteration
Regional stakeholder fora.	Successfully organized in 9 regions
Development of Information, Educative and Communication materials	• 11 press releases, disclaimers and notices issued • False information on Ebola virus. • Ghana joins UK, USA and others in search for effective Ebola treatment. • Fovitor Dzomi Palm Oil • Adulteration of palm oil with Sudan IV Dye. • 2017 calendar • Tobacco control • Food safety • Counterfeit products • Good storage practices
Protocol issues Visa acquisition Ticketing	• 139 • 214 • 127
Local accommodation arrangements Travel insurance	• 31
Assist in monitoring and management of airing of unapproved advertisement	• Verbal MOU with security agencies • Stakeholder engagement meeting with media and media regulators • ≈ ……. Adverts monitored and communicated to DRID
Swoops	

Source: 2017 Communication and Public Education Dept

Figure 10: Comparison of Communication Activities 2016 & 2017



Source: 2017 communication data.

11.0 **Human Resource Dept**

10.4.1 Recruitment and Selection

The Authority increased it activities and had constraint in recruiting more staff. The Authority in order to achieve its stated objective of the year recruited fifty-seven (57) staff on temporary to augment its manpower capacity in 2017.

10.4.2 Training and Development

In building the capcity of staff of the Authority, the Human Resource Unit facilitated and supervised series of trainings and conferences in the year 2015. See Appendix 2 for the list of training and conferences attended. The trainigs were either fully or partly sponsored.

The summary of staff strength of the FDA in 2015 is indicated in table 14.

Table 14: Summary of permanent staff

Employee Categories	Total Staff Strength
Permanent	**462**
Temporary	**57**
National Service Personnel	**113**
Seconded Staff	**19**
Total	**651**

Source: 2017 Human Resource Dept

LABOUR TURN OVER RATE

10.4.3 Employee Labour Turnover/Retirement

	RESIGNED	DECEASED	RETIRED				
2017	**4**	**2**	**4**	**2016**	**6**	**2**	**2** **2015**
11	**0**	**1**					

11.1 **Procurement Achievement**

Key Procurement Activities: Goods

Planned	Achieved

Laboratory Chemicals, Microbiology Media, Reference Standards and Consumables	Various Laboratory Chemicals, 2 ISO Microbiology Standards, 36 Chemical Reference Standards and Consumables
Printed materials, Stationery and Office Consumables	Stationery and Office Consumables were procured for routine office work Various publications and forms were printed for various departments
IT Equipment (Laptops, UPSs, Desktop Computers and Accessories, Servers, Printers, and Tablets)	5 Laptops, 43 1500kvA UPSs, 3No. 5000 kVa UPS, 43 Desktop Computers and Accessories, 1 Servers, 4 Printers, 2 Tablets
Television Sets and Electrical Appliances	7 Television Sets and Electrical Appliances
Office, Laboratory and Residential Furniture	24 Laboratory stools, various Office furniture as well as Residential Furniture for Gonokrom
Vehicle Tyres	103 pieces of Vehicle Tyres
Personal Protective Equipment	133 Disposable Overalls, 10 Half Face Respirators, 30 Catridges, Safety Wellington Boots, 50 Hand Gloves
Laboratory Equipment	4 Fridge Thermometer for Sample room
Food Items	640bags Rice, 200cartons Oil and 1200 packs Malta Guinness

Future Direction

The Food and Drugs Authority will continue to confront the challenges presented by the implementation of the Public Health Act, 2012 (Act 857). In particular, steps will be taken to reinforce the corporate identity of the FDA for increased commitment to its mandate of the FDA.

In this regard, the FDA's operational direction for 2018 will focus on the following:

- Intensified Post-market surveillance activities to rid the market of fake, substandard and unwholesome regulated products.
- Commencement of the construction of the Head Office Annex
- Increase presence at the Border Posts.
- Increase fleet of operational vehicles to enhance the mission of FDA.
- Increase collaboration with stakeholders.
- Procument of truscan for enforcement activities.
- Construction and completion of the Tema office complex building.
- Increase staff strength.
- Implementation of condition of Service for Staff.
- Procurement of computers and IT accessories both hard and software to augment the current ones.
- Procurement of Laboratory chemicals, glassware, microbiology media and equipment, as well as the installation of registration information system for the Registration Departments.
- Development of Human Resource policy manual.
- Training of staff in requisite areas of regulation to enhance their output.
- Intensive public education to create consumer awareness for continued protection of public health and safety.
- Continuing dissemination of new Public Health Act.
- Effective monitoring of unapproved advertisement in the media.

ANNEX A.1

FOOD AND DRUGS BOARD MANAGEMENT TEAM AND REGIONAL OFFICES

Strategic Management Team

Chief Executive Mrs Delese Darko

Head, Medical Device, Cosmetics Mr**s** Akua Amartey (Acting) **and**

Household Chemicals Division **Head, Drugs Inspectorate Division**

Mr Seth Seaneke (Acting) **Head, Safety Monitoring Division**

DCE Food Safety Division **Head, Food Inspectorate**

Division Mrs Isabela Mansa Agra (Acting) **Head, Regional**

Monitoring and Evaluation Division Mr Peter Agymang-Dua (Acting) **Head,**

Administration Mr Jones Ofosu

Head, Finance Mrs Perpetual Tawiah

Head, Quality Control Laboratory Mr Karikari Boateng **Head, Project**
Research Management Mr Andrews Boadi **Information Systems**
Head, Internal Audit Mr Edem Kugbey

OFFICE ADDRESSES

Head Office:

Food and Drugs Authority

P O Box CT 2783

Cantonments - Accra, Ghana

Telephone: +233-0302-235100/233200/225502
Fax: +233-0302-229794
URL: http://www.fdaghana.gov.gh

E-mail: fda@fdaghana.gov.gh

Other Locations

Quality Control Laboratory

Tel: +233-0302-673864

Fax: +233-0302-667095

Port Offices

Airport: Tel: 0302-784653

Elubo: Tel: 03122-22538

Tema: Tel: 0303-213418

Regional Offices:

Ashanti

Address: The Regional Office
Food and Drugs Authority
P O Box ST 402, Kumasi.

Location: Regional Coordinating Council, Denyame- Kumasi

Tel/Fax: 03220-36070

Western

Address: The Regional Office
Food and Drugs Authority
P O Box MC 2129, Takoradi.

Location: SSNIT Regional Offices, (Near Central Police Station)

Tel/fax: 0303-27558

Upper East

Address: The Regional Office
Food and Drugs Authority
P O Box 612, Bolgatanga.
Location: Regional Administration Building
Tel: 03820-23727
Fax: 03820-24590

Volta Region

Address: The Regional Office
Food and Drugs Authority
PMB, Ho
Location: Ghana News Agency Building
Tel: 03620-65529
Fax: 091-28411

Northern Region

Address: The Regional Office
Food and Drugs Authority
Tamale
Location: Regional Administration Building
Tel: 03720-24935 Telefax: 032720-24889

Brong Ahafo Region

Address: The Regional Office
Food and Drugs Authority, Sunyani
Location: Sam Bennet Building, Market Square
Tel: 03520-28791

Central Region

Address:The Regional Office
Food and Drugs Authority

P.O. Box CC1373
Cape-Coast
Location: Within the premises of the Regional Administration, Cape-Coast.
Tel: 0322132300/0322090110.

Eastern Region

Address: The Regional Office
Food and Drugs Authority
P.O. KF2431
Koforidua
Location: Hospital Road, Opposite Assemblies of God Church
Tel: 03420 20580/1, Fax: 0342205802

Upper West

Address The Regional Office
Food and Drugs Authority
Box, 291,
Upper West Region
Location: Controller Block, Ministries
Tel: 0392020111 Telefax: 0392020001