FOOD AND DRUGS AUTHORITY

ANNUAL REPORT

2016

FIGURES

TABLES

ACRONYMS AND ABBREVIATIONS

ADRs	-	Adverse Drug Reactions
BPU	-	Biological Products Unit
BBBPERU	-	Biologics, Blood and Blood Products Evaluation and Regulation Unit
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 the year 2016, the Authority took more pragmatic steps to fulfil its regulatory mandate. The following are the achievements of the Authority concerning the promotion and protection of Public Health and Safety in the country:

- Received a total number of 2,082 application (food products), this figure is made up of new applications totalling 1,714 representing 82% and renewals of 368 applications representing 18%, 1,544 of the applications received were approved, with the department deferring 580 applications and rejecting one application;

- A total number of medicinal products received was 1,400, out of which 995 was approved, this includes both Allopathic for human and veterinary drugs. A total of 1,089 herbal medicines and food supplements were approved for the year;

- The total number of cosmetics and household chemicals approved for the year 2016 was 1,205.

- A total number of 2,220 samples received for analysis by the laboratory service, out of this figure, 1,657 samples analysed passed with only 563 samples failing.

- Intensified Post Market Surveillance with a total of 7,666 visits carried in the country.

- Intensified public education in public schools, markets, lorry stations, church, mosques etc. with a total of 22,803 educational, sensitisation programmes carried out;

- The passage of legislative instrument on Tobacco Control Regulations, 2016 (L.I 2247) which entered into force 4th January, 2017.

The Authority continued to strengthen its administrative oversight role by facilitating the procurement of ten (10) operational vehicles and two (2) HCPL for laboratory activities. and facilitate public service improvement. In that regard, the Authority embarked on a number of media engagement campaigns with the help of the media to improve its visibility and broaden the knowledge of its public health and safety mandate among consumers, public and the citizenry; and engaged in 668 media interview, twelve media coverages and eleven press releases, disclaimer and notice. The FDA introduced toll free line and a hotline for FDA's activities.

The Food and Drugs Authority in September 2016 created a new Unit for Monitoring and Evaluation to support the Monitoring and Evaluation Division for effective monitoring of the Institution's activities.

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 2016.

1.1.0 Governing Board

The Governing Board of the Food and Drugs Authority consists of twelve (12) 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 composition of the Board for the year in reveiew is as follows:

1.	Mr Totobi Quakyi	Chairman, Government Representative
2.	Mr Hudu Mogtari	Chief Executive, Food and Drugs Authority
3.	Dr George Ben Crentsil	Executive Director, Ghana Standards Authority
4.	Mrs Grace Issahaque	Representative, Attorney General's Department.
5.	Dr Bashiru Boi Kikimoto	Ministry of Food and Agriculture (VSD)
6.	Mr Joseph K. N Nyoagbe	Registrar, Pharmacy Council
7.	Dr Belinda Afriyie Nimako	University of Health/Allied Sciences - Volta Region
8.	Togbega Dabra VI	Traditional and Alternative Medicines Practice Council
9.	Dr Nanam Tay Dziedzoave	CSIR, Food Research Institute
10.	Mrs Angela J. Owusu	CEPS Laboratory
11.	Prof Dominic Adotei Edo	CSRIPM

12. Ms Cynthia Adwoa Dapaah Food and Drugs Authority.

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, pre-registration 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. Blood and Blood Products Unit.

    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 three (3) departments:

   a. Food Safety Management Department and;

   b. Agro Product and Biosafety Department.

   c. Animal Product 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).

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

d. <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.

e. 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.

f. 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.

g. 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.

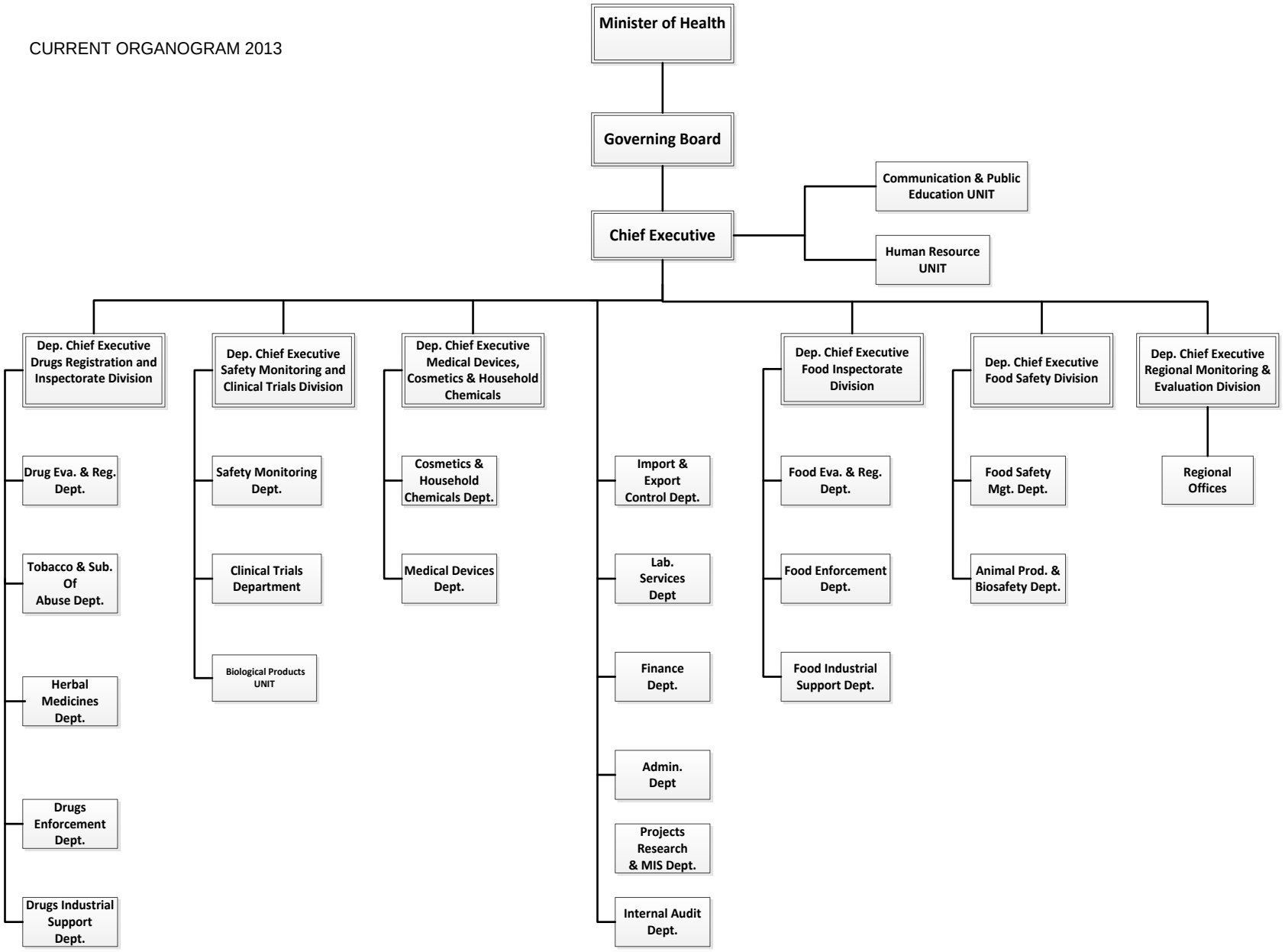
h. Laboratory Services Department

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**

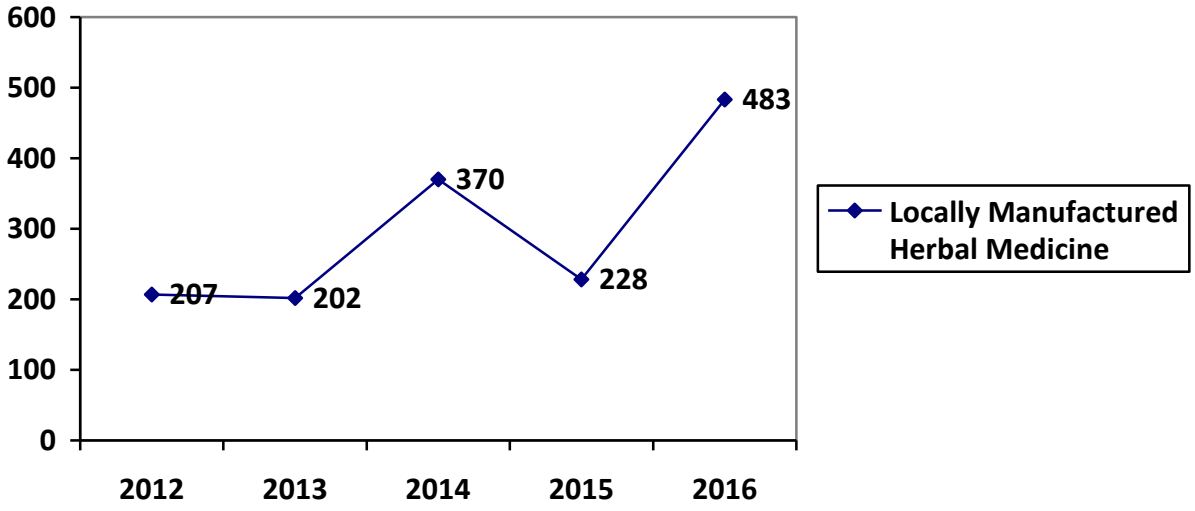
Registration provides assurance to the public that all Medicinal and non-medicnal products are well evaluated by all the standard and are certified by the Food and Drugs Authority.

2.1.1 Herbal Medicine

The Department in 2016 registered a total number of three hundred and three (303) locally manufactured herbal medicines; this includes re-registration. Comparing the 2015 figure to that of 2014, it is indicating that there was a decrease in registration of 27%.

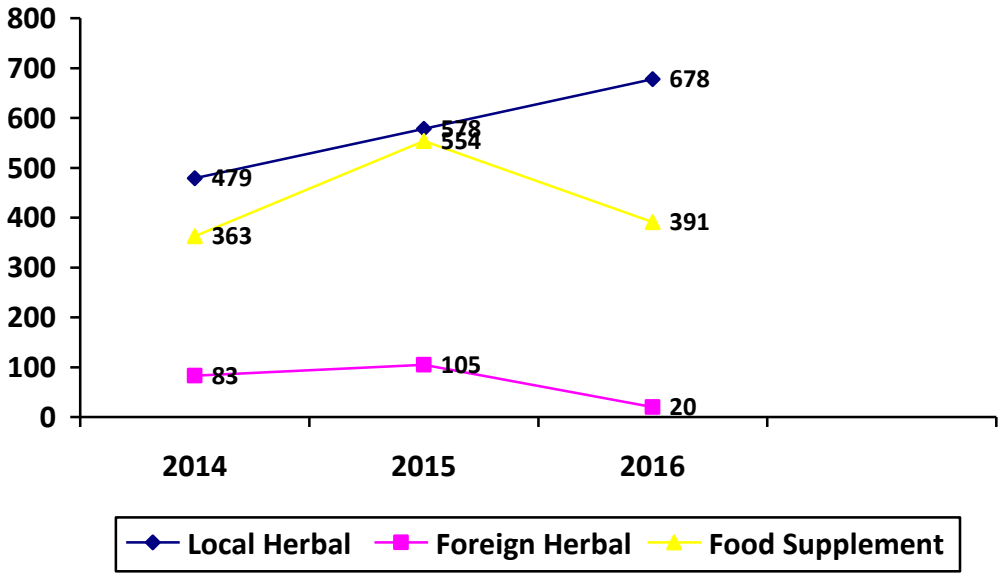
Below is the trend for the Department concerning locally, foreign manufactured Herbal Medicine and food supplement registration since 2012 to 2016.

Figure 1: Locally manufactured Herbal Medcine trend.



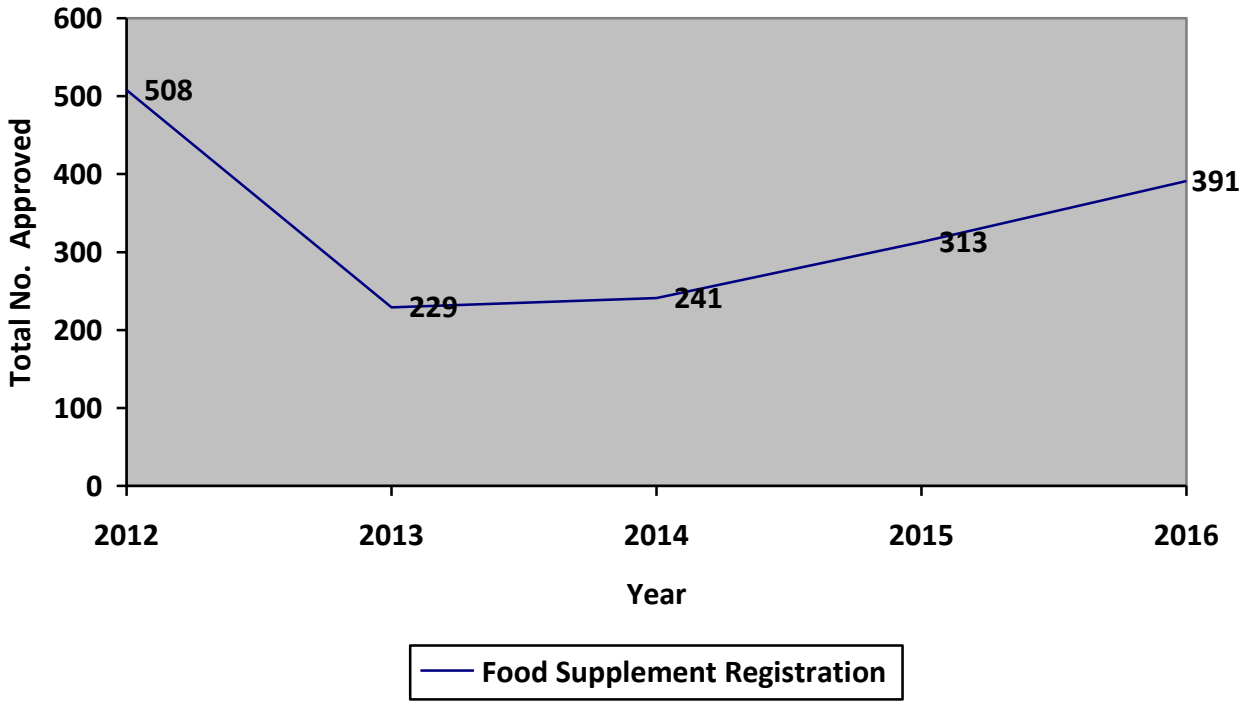
Source: Herbal Medicine Department.

Figure 2: Trend Analysis of Herbal Department Activities



Source: Herbal Medicine Department.

Figure 3: Food Supplement registration



Source: Herbal Medicine Department.

The year 2016 saw increase in the food supplement registration and local herbal medicine. The department recorded low registration in foreign herbal as compare to 2014 figure.

2.1.2 Tobacco Registration and Regulation

The year 2016 saw progress in 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.

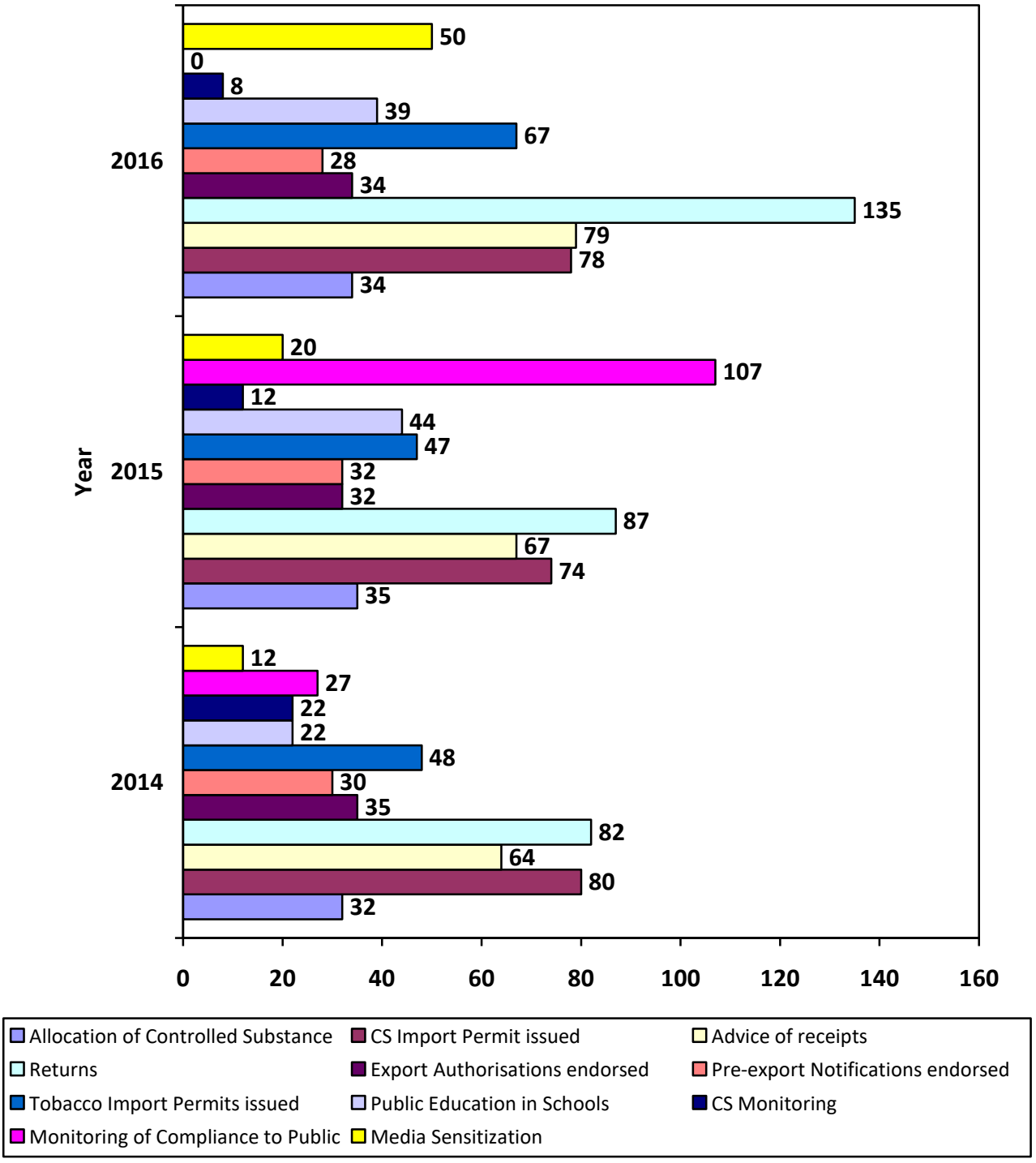
The department facilitated the passage of Legislative instrument on Tobacco Control Regulations, 2016 (L.I. 2247) which will be in force from 4th January, 2017. The department also monitored controlled substancece at the retail level.

The Department allocated thirty-four (34) controlled substances for manufacturers; and issued seventy-eight (78) controlled substances permit. As part of monitoring Control substance in the industry the department conducted eight (8) monitoring visits. The department also had seventy-nine (79) receipt of advice with one hundred and thirty-five (135) Returns. Thirty-four (34) export authorisations endorsed, twenty-eight endorsement of pre-export notifications. The department issued sixty-four (67) tobacco import permits. As part of the mandate of the department, they were able to conduct thirty-nine (39) public education for fourteen thousand and ninety-six (14,096) student in thirty-four (34) basic schools, four secondary schools and one tertiary all in the Greater Accra region. Two hundred and fifty-five posters of Smokers body were distributed to these schools.

The department also had fifty (50) sensitization programmes through the media specifically forty-four (44) radio stations and six TV stations. 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 2016 as compare with 2014 and 2015.

Figure 4: Trend of activities for the TSAD from 2014 to 2016



Source: 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 targeted to the Drugs Evaluation and Registration Department for registration; the department recorded same figure in 2015. 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.Nine hundred and ninety-five were registered as compared to eight hundred and fifty-six (856) registered products in 2015. There was an increase in registration by by 16.23% as compared with 2015 registration.

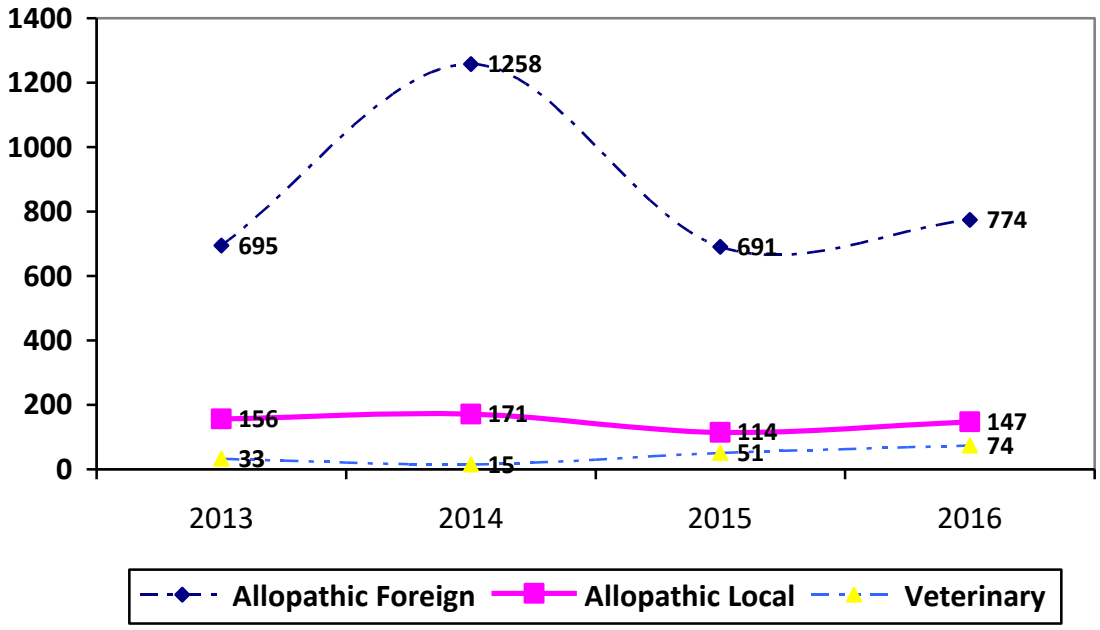
Table 1 gives the summary of applications received for registration during the year under review.

Table 1: Summary of applications received and registered

Product Type	Target 2015	Target 2016	Registered 2015	Registered 2016
Allopathic Drugs (Human)	1,200	1,200	691	774
Veterinary Drugs	60	60	51	74
Local Allopathic	200	200	114	147
Total	**1,460**	**1,460**	**856**	**995**

Source: Drug Evaluation and Registration Department.

Figure 5: trending of Drugs registered since 2013-2016



Source: Drugs Registration Department

Product Registration and Document Reviews

In 2016, nineteen (19) dossier evaluation meetings and seven product registration meetings were held.

2.1.4 Enforcement Activities-Drugs

- **Market Surveillance Activities**

The department conducted engaged in the following activities, safely disposed off sixty (60) sub-standard, counterfeit and fake drugs, investigated twenty-seven (270 consumer complaints received for 2016. The department also conducted one hundred and sixty-nine (169) verification inspections. The department also conducted three (3) raids and swoops at Kasseh Market, Okaishie Drug lane and James Town.

Anti-Counterfeiting Activities

The department detected about fifteen (15) counterfeit incidences, below are some of the products:

- Xiaoke pills and other Chinese medicines smuggled in a consignment of biscuit;
- Unregistered products labelled Miso, Mife and SS imported by DKT International;
- Unregistered rabies vaccines (cross and crown, speeda) smuggled into the country by a Nigerian and;
- Unregistered and substandard Oxytocin (Phylo-Oxy).

- **Product Quality Montoring**

The department purchased two (2) therapeutic line samples nationwide categories into 28 ARVs and 12 anti-TB medicines. All samples passed as per respective compendia.

- Anti-hypertensiv**e:**

The department visited twenty-six (26) facilities were eleven (11) unregistered products were identified all of which were "UK generics".

- Anti-Diabetics & Oral Contraceptives:

Seven (7) facilities visited to monitoring anti-diabetic and oral contraceptives, thirteen (13) pieces of counterfeited Postinor 2 were seized, 4 brands of unregistered anti-diabetic products (Glibenclamide 5mg manufactured by CP Pharmaceuticals, Metformin 500mg by Teva, UK, Pioglitazone 30mg by Accord Healthcare Ltd and LG Glitazone by Madras Pharmaceuticals India) identified.

Regulatory Sanctions were applied.

Product Recalls

Seven (7) products recalled from the market in the 2016, which are:

- Alkafen Nasal Soft Capsules (8,798 products recalled)
- Diclo-Dor 75 Injection (3,245 products recalled)
- Mincid Susp ension
- Ceta- Ibu Suspension
- Kefrox Oral Suspension
- Tumiwura Herbal

All the products were destroyed.

- **Sanctions**

The Department sanctioned four (4) companies and a Swiss National issued with Administrative charges for importation of unregistered products.

- Kojach Limited (Artesunate Inj.)
- Ansapharma (unregistered medicines)
- DKT International (Unregistered products)
- Akwa Pharmacy (Philo-Oxy)

- **Advertisement Control**

The department received two hundred and seventeen (217) advertisements, out of the total figure received, one hundred and sixt-nine (169) were approved and forty-eight (48) deffered due to incomplete script.

- **Advertisement Monitoring**

The department was able to detect thirty-five (35) unauthorized adverts. Out of this figure, fifteen (15) sponsors and media houses were cautioned. two (2) of them sanctioned and eighteen (18) reported to the police police for interrogation and prosecution.

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

Program of Activities	2015	2016
Foreign GMP Audit of Pharmaceutical Plants	28	29
Routine Audit of local Pharmaceutical Plants	27	29
Routine Audit of local Herbal Manufacturing Plants	63	67
Pre-License Inspection of Local Pharmaceutical Manufacturing Plants	4	12

Source: Drugs Enforcement Department

- **Quality Assurance**

In fulfilment of the department's mandate to sustain its ISO 9001, 2008 Certification by UKAS of UK, the department conducted one internal audit and management review meeting. The department was able to sustain its ISO 9001, 2008 certification with the support of DFID. The department in the year 2016 was able to transited to ISO 9001: 2015 by developing a d operationalising all documents.

2.1.5 Industrial Support Services-Drugs

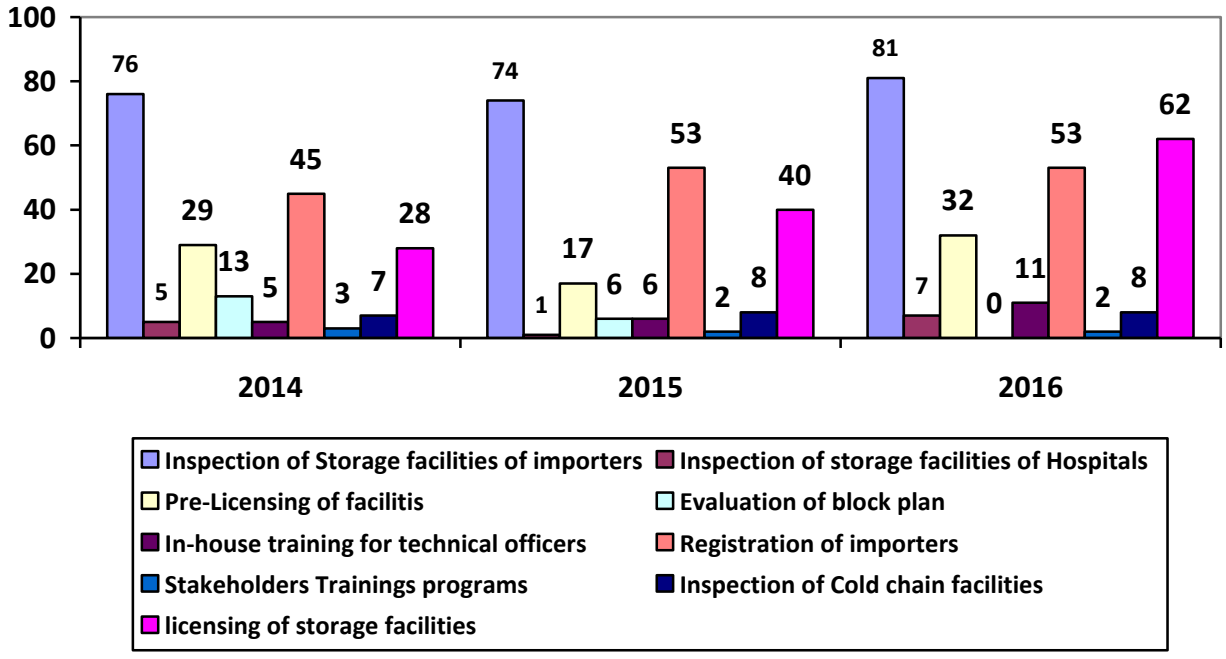
Inspection and issuance of License.

The Department issued license to sixty-two (62) storage facilities, the following inspections were conducted in the year 2016:

- Eighty-one (81) storage facilities for existing importers were inspected;
- Eight (8) cold chain facilities were inspected;
- Seven (7) hospital storage facility was inspected out of fifteen (15) and;
- Thirty-two (32) pre-licensing of new storage facilities were conducted.

The Department was able to register fifty-three (53) importers. It also conducted eleven (11) in-house trainings for technical officers.

Figure 6: comparing activities of DISSD for 2014,2015 and 2016



Source: Drugs Industrial Support Services Department.

3.0 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 2016:

- 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.
- The department in collaboration with the Biomedical Department, at University of Ghana did a presentation to the students on the regulation of medical devices in Ghana.
- Invitation to forum at the Biomedical Engineering Department at University of Ghana was honoured.

A total number of three hundred and eighty-six (386) applications were submitted for registration as compared to two hundred and thirteen (213) applications submitted for registration in 2015. Out of the total number of applications received, three hundred and sixty-eight (378) as compared with one hundred and sixty-eight (168) applications were registered. In total three hundred and nineteen (319) dossiers were evaluated

3.2 Cosmetics and Household Chemical Substance

During the year under review, a total of one thousand, two hundred and three (1,203) cosmetics and household chemicals were registered as compared to one thousand and forty-one (1041) cosmetics and household chemicals products registered in 2015 and one thousand two hundred eighty-four (1,284) cosmetics and Household Chemical products registered in 2014.

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		
	2016	**2015**	**2014**	**2016**	**2015**	**2014**
Cosmetics	1047	1404	559	1007	658	801
Household Chemicals	184	224	130	196	138	164
Total	**1,231**	**1628**	**689**	**1203**	**796**	**965**

Source: Cosmetics and Household Chemical Substance Department.

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

In fulfilment of its mandate, the division advocated for the creation of the enforcement department for MDCHC in March 2015.

The department achieved the following under GMP inspectons:

- Ten (10) safe disposal conducted
- One hundred and nineteen (119) verification inspection conducted, some of the companies could not be located coupled with other regulatory engagement
- Seventy (70) existing cosmetics/household chemicals manufacturing companies and forty (40) new manufacturing facilities were inspected using this guideline encouraging them to be compliant.
- Sixty (60) 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:

- Fake So Klin Detergents powder
- Sale of fake Makari Range of Cosmetics products.
- The distribution of counterfeit Quick lady Lady Sanitary Pad.

Three companies were given administrative charges.

- **Advertisement Vetting**

The department was able to vet and approve one hundred and thirty-nine (139) applications on products advertisement.

4.0 SAFETY MONITORING AND CLINICAL TRIALS

4.1 Safety Monitoring Activities

During the year under review, twelve (12) Technical Advisory Committee for safety monitoring meetings were held to review one thousand six hundred and seven (1,607) ADR reports. The following were the outcome from the TAC meeting:

- Banned of Fixed-dose combinations (FDCs)
  - Withdrawal not necessary because the FDA has not received any safety reports for any of the FDCs
- Oral skin whitening products containing Glutathione and Cysteine
  - Approval should not be granted because there is no evidence of efficacy and safety.
- 1, 4-para-dichlorobenzene (p-DCB) in air-fresheners and deodorizers
  - FDA to collaborate with EPA and GSA to find out the acceptable environmental concentration of products containing p-DCB before any action is taken. In the interim, there should be public education on the correct use of this product.
- Training on correct dosage of Anti Snake Venom
  - Health workers to be educated on the correct dosage of Anti Snake Venom through training.

The department also undertook the following projects:

- Launch of Patient Engagement in Medicine Safety
- Roll-out of Pharmacovigilance Assessment Tool (PAT) in all regions
- Training-of-Trainers workshop for Lecturers and Tutors from Nursing and Midwifery Training Institutions in Ghana (in collaboration with the Nursing and Midwifery Council of Ghana)

Table four (4) below shows the summary of Safety Monitoring Department activities in 2016.

Table 4: Summary of activities conducted by Safety Monitoring Department

PLANNED ACTIVITIES	TARGETS	ACTUALS
PV inspection	13	13
PV Awareness	48	48
Data Entry SWS	801	1152
VigiBase	580	354

TAC Meetings	6	12

Source: Safety Monitoring and Clinical Trials Division.

4.2 Clinical Trials Activities

2016 was generally very challenging; however, CTD carried out most of its activities effectively:

- Amendament 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	To process all SAE reports received for TAC meetings and update	- 168 new SAE reports from on-going trials were received and processed for

Trials.	database.	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 on-going 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 on-going 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 2016:

- 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 Blood-derived 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

PLANNED ACTIVITY	TARGETS	ACHIEVED
Development of operational documents	To develop twenty-two (22) new operational documents and update existing ones	Twenty (20) documents developed: three (3) master SOPs and seventeen (17) operational aids developed
Stakeholders /collaborators meeting and interactions	To meet and discuss new and revised regulatory initiatives	One - days meetings convened to discuss the regulatory process and framework for blood facility regulation
Staff Capacity Building	To develop capacity in the area of regulating BBC/develop competence to regulate Biotechnology-derived medicines/regulation of vaccines and vaccine related products	-Three (3) officers participated in an ECOWAS vaccines workshop -Two (2) officers participated in a CePAT training on Medicine Registration and Dossier Compilation (CePAT Training Centre) -Three (3) officers participated in a workshop on Blood regulation at National Blood Service.

Blood Facilities Exploratory Assessment Exercise	To Introduce stakeholders to the published regulatory documents that contain the minimum requirements needed to license blood facilities and list blood products manufactured in the facilities.	Thirty-nine (39) Blood facilities assessed nation –wide for the purposes of processes classification and facility location.
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 successful generated seven (7) reports
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. Sixteen (16) submissions fully evaluated
Registration renewal applications	To conduct preliminary and full evaluation of all registration renewal application submissions	A total of twenty-two (22) registration renewal applications submitted and preliminarily evaluated. Twenty-one (21) submissions fully evaluated
Import permit applications	To evaluate and process all import permits on-time	A total of forty (40) import permits processed in accordance with the FDA's requirements.
Additional documentation/ variation/ notification	To evaluate and process all additional documentation and variations (major and minor)	A total of one hundred and four (104) additional documentation/variations processed
Correspondence (letters)	To acknowledge and respond to all letters "minuted "to the Unit within specified timelines	A total of one hundred and eighty-six (186) letters generated and dispatched within specified timelines
Blood Donation Drive	To complement the stock levels of blood in the National Blood banks and also to sensitize the public on the need to voluntarily donate blood regularly. 150 Units	Successfully executed. 82 units collected

Source: Biological Unit

5.0 FOOD INSPECTORATE

5.1 Food registration

In 2016, a total number of two thousand and eighty-two (2082) applications were received for registration as compare to two thousand two hundred and sixty (2,260) application receid in 2015. Out of this number, two thousand one hundred and twenty-five were processed. The spill over from the appliations received in December 2015. The Department attended to four thousand eight hundred and seventy-five (4,875) clients.

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	Rejected
New Applications for food products	2,082	580	1,544	1

Source: Food Registration and Evaluation Department.

5.2 Food Enforcement.

The following enforcement activities were undertaken in the year 2016:

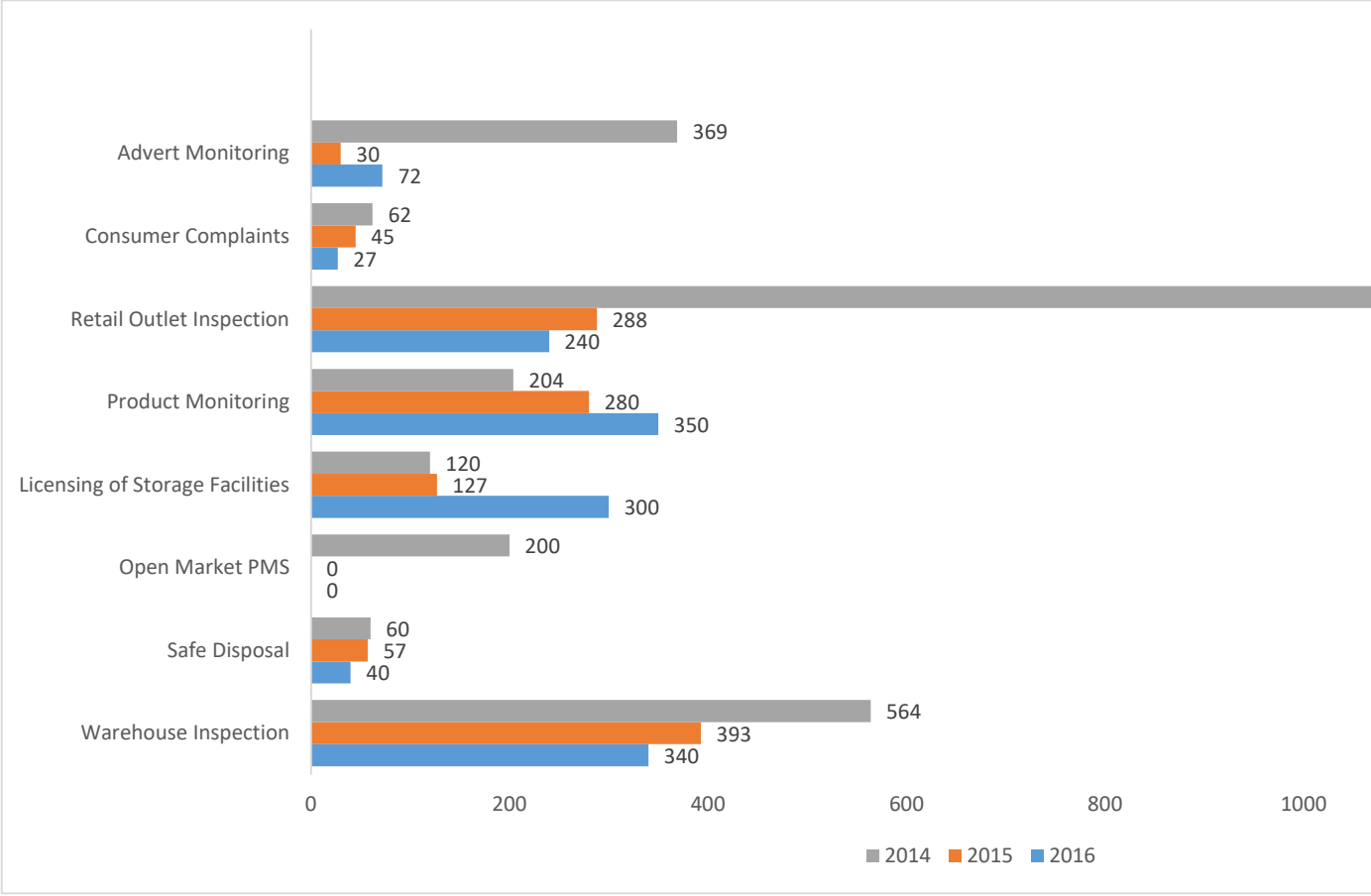
<u>Enforcement of Regulations in the Food Manufacturing Plants and Premises.</u>

The department undertook five hundred and ninety-three (593) regulatory inspections of operational facilities, which include pre-licensing, follow-ups and routine. Three hundred and twenty-eight (328) 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-eight (28) site verifications of foreign food manufacturing facilities.

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: 2016 Food Post Market-Surveillance Activities

In the course of 2016, the Department processed 434 advertisement applications; 255 applications were approved and 95 applications were deferred. Twenty-six (26) Advertisement vetting committee meetings were held.

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 2015.

Table 8: Summary of FISSD activites in the year 2016

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 222 persons from 128 Food Processing Companies No application for training in GWP was received during the period.	▪ 74 (58%) out of the 128 companies trained have their premises licensed ▪ 54 (42%) have outstanding GMP issues ▪ 75 (58.6%.) companies have their products registered. ▪ 30 (23.4%) companies have their products conditionally approved ▪ 13 (10.2%) companies have their products pending evaluation. ▪ 10 (7.8%) companies are yet to address infractions observed on products to facilitate registration
Assist 5 companies applying for HACCP training/Installation and award of Certificate	Nine (9) new applications were received. Implementation of the HACCP system is at the final stages in Three (3) companies (Kasapreko, Accra Brewery and Special Ice Company). The installation of HACCP systems of Two (2) companies (A2 Innovations and GN Foods) is scheduled to commence in February, 2017. Four (4) companies (Home Foods, Twellium, Ghana Nuts and Usibras Gh. Ltd.) are yet to respond to the HACCP proposals submitted to them and initiate payments. Re-audit of the HACCP system of Aqua fresh is completed and Certificate renewed	Blow-Chem Industries Limited suspended their HACCP Programme in view of installation of new production lines. The HACCP programme will be revived and completed in 2017
Needs Assessments - 100	38 Needs Assessments conducted	Needs assessments are carried out as and when the requests are made. Some of the companies supported are in the process of registering their products and premises.
All salt mining and producing sites, schools and major markets in 13 districts were to be monitored	A collaborative monitoring of 14 mining sites, 113 traders in all the major Markets and 62 eateries was done by the FDA and Environmental Health Officers of the Ministry of Local Government and Rural Development in 12 Salt mining districts.	The Salt producing factories continued to comply with GMP requirements and were registered with the FDA. Inspections have now been absorbed as part of the routine schedule of the Premises Inspection Unit The market monitoring has now been undertaken by the MLGRD as part of

		the National Salt Iodization Committee's (NSIC) strategy for resource management
Organize/ participate in workshops/ meetings/seminars	Ten (10) meetings/conferences/seminar/workshops attended Codex (NCC and CCCF) TC (GSA) West African Quality Systems Food Safety Policy Raw Water Quality Criteria – Water Resources Commission ECOWAS Technical Management Committee for Standards Harmonization Enhanced Nutrition and Value Chain in Ghana Inception Refresher Training for EHO Sanitation Prosecutors and USI Focal Persons	Organize/ participate in workshops/ meetings/seminars
Organize/ participate in workshops/ meetings/seminars	3 International Food Safety Workshops organized Microbiological Risk Assessment Follow up Microbiological Risk Assessment Chemical Risk Assessment	FAO sponsored the organization of 3 international workshops in Ghana.

Source: Food Industrial Support Department activities 2016

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**	**Remarks**
1. Development of National Food Safety Policy(NFSP) • Development of strategic action plan • Public sensitization on the NSFP.	1 1	1 1	Strategic action plan developed for implementation A public sensitization workshop was organized.
2. Visit to Market places for Food Safety Awareness among Street Food Vendors, Travellers and Market women 3. Mass Media Engagement	56 60	56 53	5, 430 street Food Vendors, Travelers and Market women were trained Successful
4. Visits to Basic Schools to educate Pupils on Food Safety and Hygiene 5. Visits to Market places to investigate food adulteration	35 10	35 10	7,983 pupils were educated. Discovery of the adulteration of powdered pepper and tomato powder.
6. World Food Day celebrations i. Food safety forum	1	1	200 people participated in workshop
7. Nationwide Sampling and testing of palm oil for Sudan dye	120 samples	278 samples tested	Successful (Currently 98% compliance)
8. Destruction of Adulterated palm oil	60 barrels	Sixty (60) barrels	Successful
9. Sensitization workshop for palm oil sellers 10. Training programmes for Food	1 20	1 7	32 palm oil sensitized on Laboratory results of adulterated palm oil

	Service Establishments			52 food handlers were trained.
1.	Infosan Alert & Notification	Nil	2	Successful. Alerts forwarded to all Regional Heads and Departmental heads in the 2 food divisions.
1.	To develop a surveillance system to facilitate the collection of data of all foodborne related cases 2. Organize One- day Technical Advisory Committee Meeting on the National Foodborne Disease Surveillance	0 1	1 1	A two-day Training of Trainers programme on Integrated Foodborne Disease Surveillance was organized for 20 FDA Regional Focal Persons and Regional Disease Surveillance Officers of GHS One- day Technical Advisory Committee Meeting organized
3.	Enroll Greater Accra Regional Hospital (Ridge hospital) into the system	1	Ridge hospital enrolled	Successful
4.	To organize 4 sensitization workshops for clinicians of the Obstetric/Gynecology, Medical, Surgical and Pediatric Departments of the Ridge Hospital 5. Routine visits to all health facilities involve in the Foodborne Disease Surveillance 6. Foodborne disease outbreaks	4 4 0	4 4 9 outbreaks (796 cases) 1 Outbreak W/R (5 cases) 4 Outbreaks C/R (656 cases) 2 Outbreaks GAR (64 cases) 2 Outbreaks BA (71 cases)	successful Successful Investigated

7.	Foodborne disease incidences	0	147 cases	Successful
8.	Special activities (Palm Oil samples received for testing for Sudan IV dye)	-	128 samples received, 115 (89.8%) of the samples analyzed tested negative for Sudan dye	Successful

Source: 2016 Activities of Food Safety Management Department.

6.2 Agro Products and Biosafety Activities

In 2016, the Department achieved the following as indicated in tables 11.

Table 11: The types of inspections the Department conducted.

ACTIVITY	TARGET	ACTUAL	REMARKS
Food Safety Stake-holders Collaboration	98	95	-
Inspections/PMS	288	235 Break down Feed Mill-60 Warehouse-121 PMS-3 Farm Visits-2 Renegades -12 Call-offs -12 Unannounced -13 Inability -12	53 inspections were not conducted due to: ▪ Inspection called off by clients on the day of inspection. ▪ Facility not operating ▪ Inadequate staff ▪ Unavailability of vehicle ▪ Unforeseen emergency and multi-jobs assigned to staff. 49 inspections were not fully conducted.
Training	• GMP training for workers in the	0	No application received

	feed processing and warehousing facilities. • Strengthening the capacity of FDA staff to handle issues of GM food/ feed	2	A National survey on perceived harms associated with GM foods was completed; information derived was used for the hazard identification. Hazard Identification & Characterization section drafted for corn and soybean. The other sections, Risk hypothesis; Exposure assessment; and Risk characterization are pending.
Research and Reviews	36	36	
Public Education	118	68	
Consumer Complaints	4	4	All consumer complaints were investigated.

Source: 2016 Inspections of Animal and Biosafety Department.

6.3 Animal Product Department

In 2016, the Department achieved the following as indicated in tables 12

ACTIVITY	TARGET	ACTUAL	REMARKS
Inspections Conducted • Pre-license • Pre-approvals • Follow-ups • Routine • Unannounced	404	465	+61 Target for total achieved through the dedication of my colleagues

Pre-Christmas inspections	70 Cold Storage Facilities - 60 Meat Shops-10	52 Cold Storage Facilities - 47 Meat Shops -5	-18 Activity undertaken in only 8 days
Post Market Surveillance	10	4	-6 Unavailability of vehicles
Supervision of the process of safe disposal	14	10	Exercises carried out to completion
Supervision of sorting, re-labeling and re-packaging exercises	18	6	Exercises carried out to completion
Investigation of complaints received	11	9	All complaints were investigated fully
Identifying non-conformances at the proposed facilities	2	2	Carried out successfully
Inspection of the facilities	170 Facilities	159 facilities comprising: Meat/Fish Processing-51 Cold Storage-81 Meat Shops- 15 Honey- 12	10 - facilities were yet to address their non-compliances 18 - new applications received in December carried forward
SOPs were developed for routine activities	All relevant activities	SOPs have been finalized	
Developed Regulations for the Animal Products Industry	To finalize the document for onward submission to AG's office	Final Draft to be reviewed with VSD	
Designed flyers on Safe Meat Handling Practices for Consumers and Meat Handlers	To have it uploaded on the website and distributed	Flyer designed, but yet to be finalized	
Meeting with officers of the Municipal Assemblies	3	3	
Meeting with some of the Executive Members of the Association	1	1	
Sampled sausages (local, imported) for analyses at the Department of Food Science, UG	20	20	10 of the samples exceeded the limit of 125mg/kg
Market Survey	10 Markets	Visited 9 Markets	Survey revealed the use of Dainess Bright Red Powder in colouring the meat
Visits to spots along the Sakumono beach road			None of the women admitted the offence but they embraced the message
Market Survey	10 Markets	9 Markets	The use of Noprest is not known at the retail level

Training Programme for workers of Cold Storage facilities	12 Companies	10 companies were trained	Training carried out on request
Training for honey processors	1	1	Training carried out on request

Source: 2016 Animal Product Department Activities

7.0 **Import and Export Control Activities**

7.1 Issuance of Permits

In 2016, the Department with the support from the GcNet Unit, issued twenty thousand, five hundred and twenty-one (20,521) permits. The department also inspected eleven thousand one hundred and eighty-three (11,183) dry containerized cargos at the Tema Port and three thousand six hundred and twenty-one (3,621) at the KIA.

The department also inspected three hundred and sixty-seven imported fresh package fruits and vegetables.

7.2 Detention

During the period under review, one thousand two hundred and sixty-three (1,263) consignments were detained by the department. All detentions were referred to the appropriate divisions/regional offices for further action.

7.3 Safe Disposal

The department supervised eleven (11) safe disposal of several products and consignments which were unwholesome.

7.4 Licensing of Bonded Warehouse

fourteen (14) 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 2016.

7.5 Export

During the period under review, one hundred and eighty-seven (187) 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 seven hundred and forty-one (2741). Out of the above figure two thousand two hundred and twenty (2,220) samples were analysed; of which one thousand six hundred and fifty-seven (1,657) passed whilst five hundred and sixty-three (563) failed, with five hundred and twenty-one (521) samples still pending analysis.

Table 13 gives a summary of product categories received for various analytical tests.

Table 13: Summary of product categories received and analysed

SAMPLE	RECEIVED	ANALYZED	PENDING	PASSED	FAILED
ALLOPATHIC MEDICINES	554	318	236	241	77
HERBAL MEDICINES	568	463	105	201	262
COSMETICS	129	113	16	106	7
HOUSEHOLD CHEMICAL SUBSTANCES	71	57	14	41	16
MEDICAL DEVICES	427	313	114	301	12
FOOD	992	956	36	767	189
TOTAL	**2,741**	**2,220**	**521**	**1,657**	**563**

Source: 2016 Laboratory Services Department

8.1 Accreditation

Successful maintenance of the ANAB ISO 17025 status by the Drug Physico-chemical with ANAB of the United States of American with the expansion of its scope fHPLC

- Titrimetry (Manual and Automated)
- Polarimetry
- Thin Layer Chromatography (TLC**)**

Medical Devices gained accreditation by ANAB for the following underlisted tests.

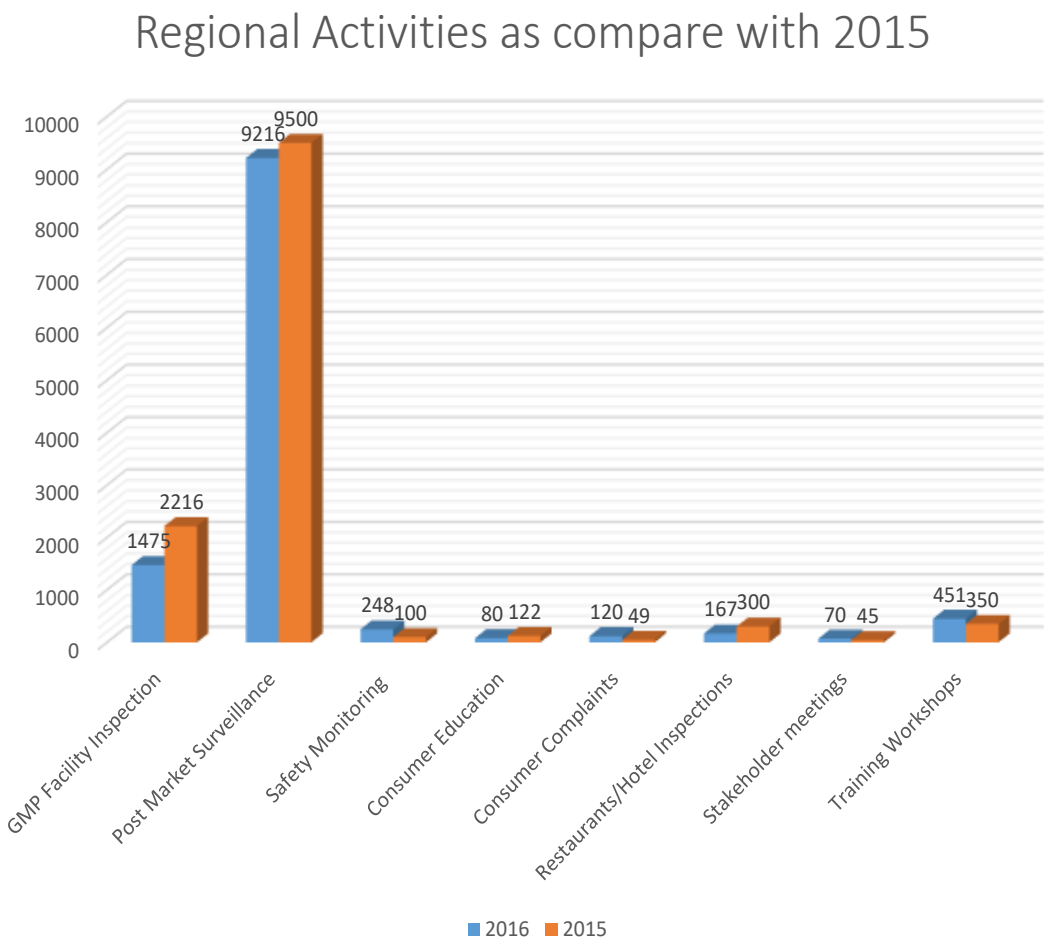
- Determination of length
- Determination of width
- Determination of thickness
- Determination of bursting volume and presence
- Testing of holes
- Testing for packaging integrity
- Determination of total lubricants for condom in individuals container

- Sampling by attributes

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: 2016 Regional Operational data

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

10.1 **Administration**

The department in 2016 the following:

1. Procurement of Ten Units double cabin pickups for operational use.
2. Provision of stationery and other consumable for operational purposes.
3. Acquisition of two new HPLCs for QCL.
4. Procurement of laboratory chemicals, reference standards, microbiology media and consumables.
5. Automatic Transfer Changeover Switch was acquired to enhance the Power Alternating System of FDA at the Head Office.
6. Gas pipelining installed as scheduled. All cylinders fully fixed, manifold yet to be installed at the Laboratory Service Department Annex Project
7. Contractor is currently on site and works are ongoing at the Tema Office Complex Project,
8. Update of the FDA Asset register is fully completed.
9. Servicing of machines/equipment carried out on schedule (Air conditioners, Firefighting equipment, Generator sets etc.) at the Head office, KIA and Tema offices
10. Participation in ISO implementation through training and development of SOPs for Administrative and transport operations.
11. Vehicular Record keeping and general data collection has improved.
12. Vehicle control has been also being enhanced by ensuring that vehicles are parked after work.
13. Sensitization of Drivers to uphold safety and Improved interpersonal relation among the vehicles users and TMU staff.
14. Majority of vehicle request for both official activities and personal trips eg. for funerals, weddings and conveying personal effects were honored.
15. The continuous creation and improvement of the electronic filing system for both in-coming and out-going mails has been very effective for the tracking and retrieval of all documents that pass through the Dispatch office.

16. The immediate E-mail and one (1) hour phone calls to client for the collection of outgoing mails from the unit is now very effective
17. The Dispatch Unit continues to improve upon its activities by ensuring all documents are treated with the urgency they deserve.
18. The sustenance of a positive client relationship over the period under review is aiding the efforts of a good image creating for the Authority with our stake holders.
19. The constant updating of database which enables the Dispatch Unit to contact clients promptly.

As at 2016, the summary of Vehicles of the FDA is indicated in table 14.

Table 14: **Inventory of FDA Vehicles**

NO.	**MAKE/TYPE of VEHICLE**	**NUMBER**
1.	SALOON	18
2.	PICK UP	70
3.	STATION WAGON	5
4.	MOTORCYCLE	3
5.	BUS	3
	TOTAL	99

Sources: Transport Unit, 2016

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

In 2016, the Department continued maintaining the Food and Drugs Authority's website and deployed the corporate email system across the FDA. The local area netowrks were enhanced to enable management of groups, network resource and users. The dedicated fibre optic bandwidth was expanded to enable fast information search and downloads. The Untangle software version 10.1 was udpdated to ver. 11.8 to enable internet connectivity for over 200 computers and laptop computres and to reduce the incidence of accessing and downloading inappropriate materials, blocking of social networking sites, hackers, etc. that reduce productivity. The web portal was upgraded to accommodate new developments in food and drugs regulation.

The department also customised food information system to cater for medicines, medical devices, and cosmetics registration processes. The Authority was put on the National Single Window platform to facilitate trade related proceses. The programme is on-going.

In 2015, the installation of Ghana Integrated Financial Management Information System (GIFMIS) started, which was to impvoe budgetary, financial management (record keeping) and reporting in the public sector. Even though the installation compleleted in 2016, its full implementation was not achieved.

10.3 Communications and Public Education Unit

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.

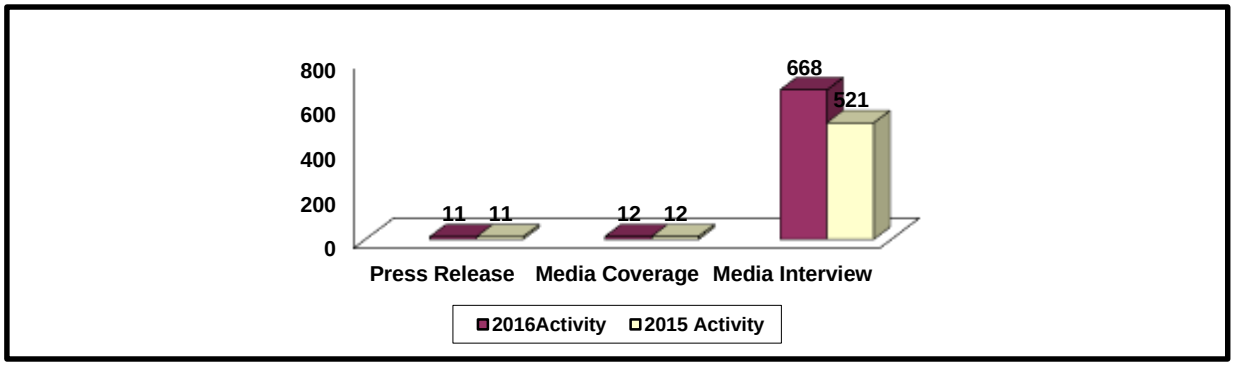
Table 13: Activities conducted by the Communication and Public Education Unit

Planned Activity	Actual Performance	Comments
Advise Management on media/communication strategies.	• Plastic rice • Awareness creation	
Promotion of interagency collaboration	• Advertising Association of Ghana • Ghana Police Service • Bureau of National Investigations • Consumer Protection Agency	Readiness to assist the FDA in dealing with unapproved products and advertisements. Pledge to assist FDA to create consumer awareness
To facilitate and coordinate effective public education through the media in schools, churches, mosques and other social functions.	• 668 media interviews conducted • Media coverage provided for 12 activities	Unable to coordinate public education at mosques, churches, schools and other social functions.
Development of Information, Educative and Communication materials	❑ 2017 calendar • Patient reporting • Laboratory accreditation • Food safety • Skin bleaching • Newsletter ❑ Developed a schedule and coordinated the airing of Patient reporting on Adverse Drug Reactions ❑ Developed some educative pamphlets	Developed and printed One edition successfully published, next edition is being worked on. Feedback indicated a positive impact during the airing, impact however reduced when the airing ended. Yet to be approved for printing

	-Guide for clients and Consumers - Complaints Policy and Procedures - Regulation on Product registration, importation and exportation	
Assist in monitoring and management of airing of advertisement	Adverts monitored are communicated to the various Division/Departments	Feedback challenges
Swoops with Police	Assisted in the organization of swoops with the Police and the various Divisions/Departments	In some instances, culprits were arrested and products seized.
Consumer complaints/enquiry	A number of calls were received	Assistance were given to clients who called and those that needed further action were forwarded to the appropriate Divisions/Departments

Source: 2016 Communication and Public Education Unit

Figure 10: Comparison of Communication Activities 2015 & 2016



Source: 2016 communication data.

11.0 Human Resource Unit

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 seventy (70) staff on temporary to augment its manpower capacity in 2016.

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 2016. 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 2016 is indicated in table 14.

Table 14: Summary of permanent staff

BROAD OPERATION/PROJECT	STATUS OF IMPLEMENTATION AS AT DECEMBER, 2016	KEY ISSUE/CHALLENGES/COMMENTS
To be a strategic Partner to management	HR policies (manual) and other related documents have been submitted to Management for approval.	The FDA needs HR Operational documents for effective and efficient service delivery and customer satisfaction
Staff Establishment	Difficult getting financial clearance for recruitment. Efforts made proved futile.	• Difficult getting financial clearance to replace those who left the FDA from 2014 to 2016. • Temporal frozen of employment by the government.
Employee Performance Management System (appraisal)	151 staff out of 445 available staff participated in the appraisal exercise representing 34%	▪ Most of the immediate supervisors do not attach the necessary attention and seriousness to the PMS exercise ▪ 249 staff did not submit their completed appraisal forms representing 66%
Training and Development	HR applied for JDS training Program and French Embassy	A lot of staff showed interest in the programme but could not meet the

	Programme. • Out of six (6) staff presented for consideration • None was successful	application requirement.
Training on Advanced Human Resource Management (Performance Management, Policy & Strategy	Two staff from HRD undertook the program	HRD has develop policy on Key HR issues.
Study leave with pay / without pay	As at December Nine staff were granted study leave to build their capacity.	• Self -development is encourage by the FDA • The number of staff sponsored by FDA was extremely lower as compared to staff sponsored in 2015
Orientation	New employees, staff on transfers within the Authority and interns were introduced to the mission, vision, values and culture of the Authority	Orientation was successfully carried out.
FDA Provident Fund SSNIT Contribution 2nd Tier Contribution	CDH has been give a notification of award letter The HRD received 20 complaint on non-payment of SSNIT contribution A number of companies have applied to manage our tier 2	Head of Legal Department has initiated the process of approving the contract terms Letters were sent to SSNIT and those non-payments have been collected The report has been submitted to the management – awaiting feedback on the recommendations made
Occupational Health and Safety	• The staff of Laboratory Service department were screened on health implication • About 90% of the drivers had their eyes screened by Amasha Optical Center. • The sensitization program was well attended by staff	• Some of the staff at the Laboratory services dept were recommended for further investigations • To ensure accident free for drivers • Feedback from staff indicated that the one day program was not enough.

		• They suggested that more days should be allocated for the programme
Promotion	No promotions were effected in 2016.	Completed staff appraisal were not submitted on schedule and this disrupted the promotion process.
Trade Union	the Trade Union has issued a collective bargaining certificate FDA TUC	• Staff expressed interest in joining the Union • Executives have been duly elected
Disciplinary issue	No staff was invited to appear before the disciplinary committee in the year under review	• Most of the disciplinary issues were put on counseling section
Regional Tour	Unable to carry out activity	Financial constraints
2015/16 National Service intake	• 98 NSP were distributed to various Division and Department • 29 NSP were posted to the various Regional Offices	• The number of Service Personnel received exceeded the request from the various dept. • The 127 NSP were given farewell package at the end of their Service Year
Loans from Banks	It has increased tremendously as compare to 2015	Management has to consider giving loans to staff
Validation of the Electronic Payment Voucher	All Electronic Salary Payment Vouchers for the year 2016 were validated and approved by FDA with the exception of June which was not made available by Controller and Accountant General Department.	Salaries for the year 2016 were paid accordingly.

Source: 2016 Human Resource Unit

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 2016 will focus on the following:

Infrastructure Development

1. Completion of the Tema Office Complex
2. Commencement of the construction of the Head Office Annex

Regulation

3. Intensify Post-market surveillance activities to rid the market of fake, substandard and unwholesome regulated products.
4. Increase FDA presence at the Border Posts.
5. Increase collaboration with stakeholders.
6. Intensive public education to create consumer awareness for continued protection of public health and safety.
7. Continuing dissemination of Public Health Act.
8. Effective monitoring of unapproved advertisement in the media.
9. Procurement of Laboratory chemicals, glassware, microbiology media and equipment, as well as the installation of registration information system for the Registration Departments

Administration and Management

10. Implementation of Structural Changes approved by the Board.
11. Increase staff strength.
12. Implementation of condition of Service for Staff.
13. Training of staff in requisite areas of regulation to enhance their output.
14. Development of Human Resource policy manual.

ANNEX A.1

FOOD AND DRUGS BOARD MANAGEMENT TEAM AND REGIONAL OFFICES

Strategic Management Team

Chief Executive	Mr Hudu Mogtari
DCE Food Safety Division	Mr J. Odame Darkwah
Head, Medical Device, Cosmetics and Household Chemicals Division	Mr**s** Akua Amartey (Acting)
Head, Drugs Inspectorate Division	Mr Seth Seaneke (Acting)
Head, Safety Monitoring Division	Mrs Delese Mimi Darko (Acting)
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 Information Systems	Mr Andrews Boadi
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