REPUBLIC OF GHANA

2013
ANNUAL REPORT

FOOD AND DRUGS BOARD

.....Working for your safety

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 Heparins
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

The year 2013 saw the continuation of work to consolidate the institutional 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 advertisements 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 40% during the year. Medicines post market surveillance functions and Food Market Surveillance activities increased by 55% 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 year, which recorded 9,500 as compare to 9,200 recorded in 2012. The FDA continued its regulatory control of the exportation of palm oil to the European Union. Destination inspections conducted by Drug Enforcement Department surpassed the previous year of twenty-four (24) to forty-nine (49) at the various ports of entry especially Tema Port. However, permits issued through the GcNet were twenty one thousand, three hundred and fortyfive (21, 345) as compared to eighteen thousand and seventy-one (18,071). The various Divisions were restructured from the existing two (2) Divisions to Six (6) Divisions with exception of one Division, the rest are headed by an acting Deputy Chief Executives. The new Divisions were: Drug Registration and Inspectorate Division, Cosmetics, Medical Devices and Household Chemicals Division, Safety Monitoring and Clinical Trials Division, Food Inspectorate Division, Food Safety Division and Regional Monitoring and Evaluation Division to enhance the regulatory function of the FDA, Ghana.

On the 1st of December 2013, the Chief Executive of the Authority, Dr Stephen K. Opuni was appointed as Chief Executive Officer for Ghana Cocoa Board. He was replaced by Mr Hudu Magtari a Pharmacist by profession.

1.0 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 ensuing sections deal with the summaries of achievements in 2013.

1.1 Background of Food and Drugs Authority

The Food and Drugs Board that was established by the Food and Drugs Law, PNDCL 305B, 1992 and was amended by the Food and Drugs Amendment Act 523, 1996 to provide for the fortification of salt to alleviate nutritional deficiencies, and to bring the provision of the law in conformity with the 1992 constitution of the Republic of Ghana is now known as the Food and Drugs Authority (FDA) under the Public Health Act, 2012 (ACT 851).

Before 1990, the control of drugs and the practice of pharmacy profession were under the Pharmacy and Drugs Act (Act 64), 1961. In 1990, the Provisional National Defence Council (PNDC) passed the Narcotics Drugs Control, Enforcement and Sanctions Law (PNDCL 236). This law established the Narcotics Control Board to deal with the rising incidence of drug abuse in the country and threatening dimensions that illicit drug dealing had taken internationally.

In 1992, the PNDC separated the control of drugs other than narcotics from the practice of Pharmacy.

The Food and Drugs Law, 1992 (PNDCL 305B) was then enacted to control the manufacture, importation, exportation, distribution, use and advertisements of food, drugs, cosmetics, medical devices and household chemical substances. The Pharmacy Act 489 was subsequently passed in 1994 to establish the Pharmacy Council to control the practice of the Pharmacy profession and the registration of Pharmacists. Although the Food and Drugs Law was passed as far back as 1992, it was not until 26th August 1997 that the first Board was inaugurated.

The Food and Drugs Authority is under the control and supervision of the Minister responsible for Health.

1.2 Functions of the Food and Drugs Authority

The functions of the FDA as spelt out by the Public Health Act, 2012 (ACT 851) are as follows:

- *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.*

1.3 The Object of the Authority

The object 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

1.4 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.

1.5 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.

1.6 The Governing Board of the Authority

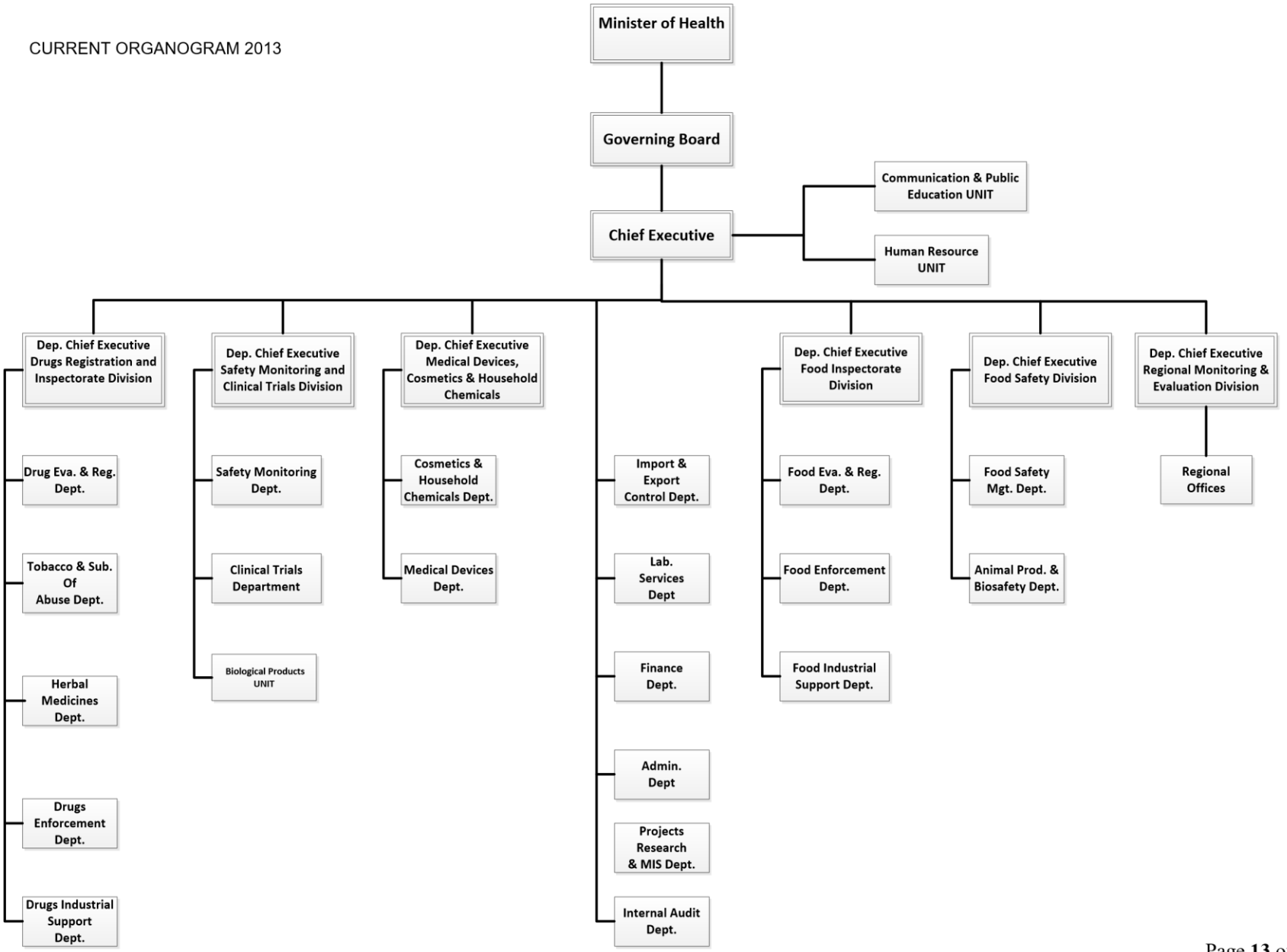
The Governing Board for the period under review, were as indicated below:

1. Mr T.C Corquaye — Chairman, Government Representative.
2. Dr Stephen K. Opuni — Chief Executive, Food and Drugs Authority
3. Mr J.A. Pwanmang — Environmental Protection Agency
4. Mr Joseph Nyoagbe — Registrar, Pharmacy Council
5. Dr Paa Nii Johnson — Director, Food Research Institute
6. Mr Alfred Yeboa Tetebo — Fisheries Dept., Ministry of Food and Agriculture
7. Dr. Bashiru Boi Kikimoto — Veterinary Services
8. NIL — Crop Services, MOFA (Representative)
9. Dr George Ben Crentsil — Executive Director, Ghana Standards Authority.
10. Prof. Kwaku Tano-Debrah — Dept. of Nutrition & food Science University of Ghana
11. Ms Grace Issahaque. — Representative, Attorney General's Department.
12. Dr Poku Adusei — Representative, Medical and Dental Council
13. Mrs C. Ribeiro — Consumer Representative
14. Mr Kenneth Danso — Ghana Association of Traditional Healers

1.7 The Organisational Structure

The current organogram of the FDA is indicated on page 13.

CURRENT ORGANOGRAM 2013



2.0 DRUGS DIVISIONS

2.1 DRUGS EVALUATION AND INSPECTORATE DIVISION

The Drugs Evaluation and Inspectorate Division contributes to the attainment of the functions of the Food and Drugs Authority for safeguarding 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, and drug quality analysis reports.

2.1.1 Medicines Evaluation and Registration Department

The Drug Evaluation and Registration Department is responsible for the evaluation of medicines and applications leading to the registration of medicinal products. Some of the achievements of the Department are as indicated below:

1. A system of registration of medicinal products has been established over the past 16 years and is well controlled to ensure consistency of activities and regulatory decisions on all medicine registration applications.
2. The Department has competent dossier evaluation committee that reviews all parts of dossiers submitted for registration. Two of the assessors are currently members of the World Health Organisation (WHO) Prequalification Assessment Team. The Department is currently contributing to the West Africa Health Organisation (WAHO) harmonization process.
3. The Department has a detailed guideline to control the names of products, information on product characteristics and patient information leaflet. This is strictly controlled to ensure that information on product to health professionals and patients is not deceptive. Product brand names and colour schemes are also controlled to avoid prescription and medication errors.
4. The Department has a system to ensure the monitoring of applications after registrations, including tracking of variations to registration applications.

2.1.1.1 Medicine Evaluation and Registration Unit

The main functions of Medicine Evaluation and Registration Unit are:

- Registration of Medicinal products and issuance of certificates:
  The Assessment of applications for the registration of medicines involves the following:

- Evaluation of dossiers submitted for registration to ensure that application forms are properly completed and the requisite information and certificates are duly submitted.
- Ensuring that information provided on packages and package inserts is correct and adequate to enable the FDA take the appropriate decision.
- Maintenance of SIAMED database (WHO application software for medicines registration).
- To conduct product application reviews.

During the year under review, one thousand four hundred and fifty (1450) product applications were submitted to the Drugs Evaluation and Registration Department for registration. These applications were made up of one thousand (1000) imported allopathic drugs (human), two hundred (200) allopathic drugs for veterinary use and two hundred and fifty (250) for local manufactured drugs allopathic. Eight hundred and eighty-four (884) were registered in the year 2013 as compared to seven hundred and seventeen (717) registered products in 2012.

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 2013	Received 2012	Registered 2013	Registered 2012
Allopathic Drugs (Human)	1000	826	695	663
Veterinary Drugs	200	44	33	54
Local Allopathic	250	-	156	-
Total	**1450**	**870**	**884**	**717**

Source: Drug Evaluation and Registration Department.

Product Registration and Document Reviews

In 2013, twenty-two (22) dossier evaluation meetings and five (5) product registration meetings were held. Details of the documentation, which were evaluated at the dossier evaluation meetings are presented in table 2**.**

Table 2: Product Registration Document reviews

TYPE OF DOCUMENT	NUMBER EVALUATED
New Applications	580
Additional Documentation	690
Variation documentation	751
Total	**2021**

Source: Drug Evaluation and Registration Department.

2.1.2 Herbal Medicine Department

The main functions of the Herbal Medicine Department are:

- Registration, processing and evaluation of all herbal medicine applications and food supplements.
- Evaluation of toxicological and clinical information as well as therapeutic data submitted from Centre for Scientific Research into Plant Medicine, MampongAkuapim, Noguchi Memorial Institute for Medical Research, Legon-Accra, Faculty of Pharmacy, Kwame Nkrumah University of Science and Technology (KNUST) Kumasi, and Department of Pharmacology, Korle-Bu Teaching Hospital
- Issuance of product registration number, which is valid for one (1) year in case of locally manufactured products and three (3) years for imported herbal drugs. During the year under review, a total number of three hundred and forty (340) herbal applications were received as compare to 2012, which were three hundred and eight (308) including reregistration applications. Two hundred and two (202) were approved in 2012 as against two hundred and four (204) in 2013. This represent a decrease of 16.04%.

A total number of forty hundred and ninety-two (492) food supplement applications were received in 2012, whilst two hundred and thirty-eight (238) applications were received in 2013. Out of which two hundred twenty-nine (229) including re-registration approved for 2013 representing a decrease of 42.48%. The total approved food supplements applications in 2012 were five hundred and eight (508).

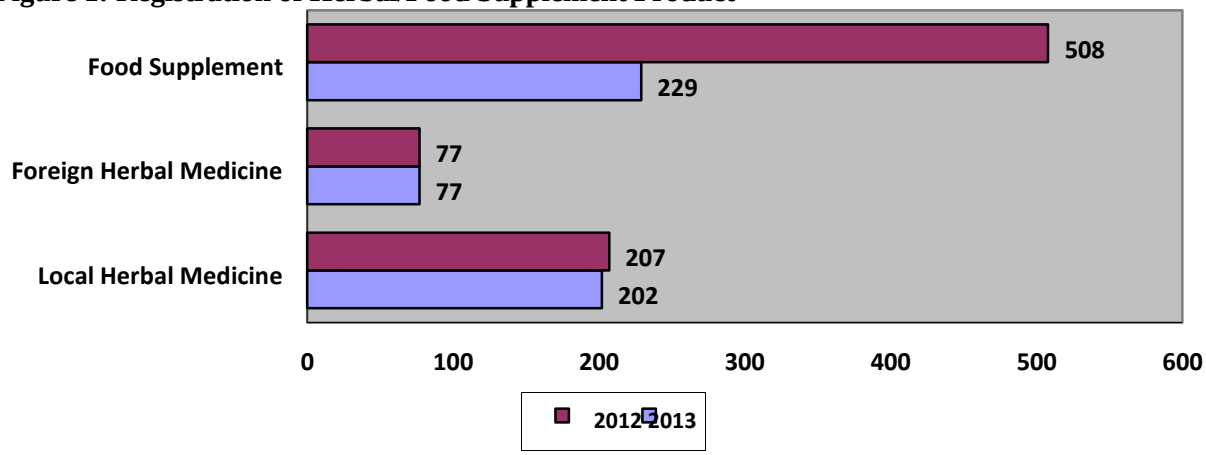
The summary of applications received and registered by the Department in 2013 as indicated in table 3 and figure 1 below.

Table 3: Summary of applications received and registered.

Product	Application Submitted		Applications Approved	
	2012	2013	2012	2013
Local Herbal Medicines	308	340	207	202
Foreign Herbal Medicines		77		77
Food supplement	492	238	508	229

Source: herbal Medicine Department

Figure 1: Registration of Herbal/Food Supplement Product



Source: Herbal Medicine Department.

2.1.3 Tobacco and Substance of Abuse Department

The Tobacco and Substance of Abuse Department has the mandate to control tobacco, licit narcotic drugs, psychotropic substances and chemical precursors in Ghana. Under its mandate, the Department regulates the importation and use of these substances by means of a permit system and other regulatory functions. The importing companies have to furnish the FDA with advice of receipt, annual returns, and the requisitions for the ensuing year. The FDA also receives multilateral chemical reporting notification forms for endorsement in connection with the importation and control of precursors. The FDA also sends quarterly and annual returns on the use and importation of narcotics and psychotropic substances to the International Narcotics Control Board (INCB) in Vienna.

In 2013, the Department vetted and issued 68 import permits for controlled substances, 33 import permits for tobacco. Received 54 advice of receipts. 93 returns on utilised controlled substances were monitored. 32 export authorisations endorsed and confirmed. Export authorisation was received before consignments reached the country. The Department as part of its mandate also endorse thirtyone (31) multilateral chemical reporting notification to INCB. In addition, thirteen (13) reports on imports and exports of psychotropic narcotic and precursor chemicals were submitted to International Narcotics Control Board (INCB).

2.1.4 Drug Enforcement Department

The Drug Enforcement Department of the Food and Drugs Authority is made up of the following operational units:

- Premises Inspection Unit
- Post-Market Surveillance Unit/Task Force

The Department's main activities include pre-licensing and post-licensing inspections of pharmaceutical, herbal, cosmetic, medical devices and household chemical substances manufacturing industries. The Department also conducts inspection of local and overseas drug manufacturing facilities to verify compliance to Good Manufacturing Practice (GMP).

2.1.4.1 Drug Premises Inspection Unit

The principal functions of Drug Premises Inspection Unit are:

- To conduct routine, announced, unannounced Good Manufacturing Practice (GMP) audit inspections in all local licensed pharmaceutical manufacturing facilities for the production of allopathic and herbal drugs, cosmetics and household chemical substances.
- To conduct pre-licensing inspections for new applicants and evaluation of block plans of new manufacturing facilities.
- To conduct site verification inspections in foreign pharmaceutical manufacturing plants in line with GMP Audit inspections for pharmaceutical companies that carry out business in Ghana.
- To conduct industry production capacity monitoring and control of extemporaneous preparations.

The summary of activities conducted by the Unit in 2013 are indicated in tables 4 and 5

Table 4: Summary of activities conducted by Drugs Premises Inspection Unit

Program of Activities	2013	2012
Foreign GMP Audit of Pharmaceutical Plants	25	20
Routine Audit of local Pharmaceutical Plants	29	31
Routine Audit of local Herbal Manufacturing Plants	38	29
Routine Audit of local Cosmetics, H.C and M.D Manufacturing Plant	16	15
Pre-License Inspection of Local Pharmaceutical Manufacturing Plants	3	5
Pre-License Inspection of Local Herbal medicines Manufacturing Plants	26	14
Pre-License Inspection of Cosmetics, H.C and M.D	3	2

Block Plan Evaluation	2	-

Source: Drugs Enforcement Department

Table 5: Summary of advert monitored by Drugs Enforcement Departments

Activity	Submitted	Deferred	Rejected	Approved	Pending
New Applications	476	98	12	353	13
Renewals	94	-	-	94	-
Total	570	98	12	447	13

Source: Drugs Enforcement Department.

In 2013, five hundred and seventy (570) adverts for herbal medicines, medical devices, cosmetics and household chemical substance were received and four hundred and forty-seven (447) were approved.

2.1.4.2 Drug Post Market Surveillance Unit

The Unit monitors registered drugs, cosmetics, household chemical substances and medical devices that have been given marketing authorisation or otherwise that is in distribution on the Ghanaian market to ensure that they are of right quality, safe and efficacious. The Unit therefore undertakes the following activities:

- Inspection of storage facilities.
- General and targeted market surveillance (conduction of product quality monitoring).
- Collaboration with stakeholders to monitor quality of products on the Ghanaian market.

- Supervision of safe disposal of expired, unwholesome and confiscated products.
- Destination inspection in liaison with the Import and Export Control Department.
- Undertake investigations into consumer and other complaints.
- Undertake random sample products for analysis.
- Public Education
- Training of stakeholders

Table 6 shows the activities conducted during the period under review.

Table 6: Activities of Drugs Post Market Surveillance Unit

Program of Activities	2013	2012
Warehouse Inspection	44	70
Product Quality Monitoring	-	33
Safe Disposal	31	44
Complaints & Investigations	40	40
Destination Inspection	49	24
Product recall	67	15
Public Education	640	81
Training on GDP	1	1
Administrative charge	19	11
GDP Inspection	64	-

Source: Drugs Enforcement Department.

2.1.5 Drugs Industrial Support Services Department

The Drugs Industrial Support Department (DISD) is a department under the Drug Registration and Inspectorate Division of the Food and Drugs Authority. The Department was established in fulfilment of the Authority's commitment to offer technical assistance to the pharmaceutical, herbal, medical devices, cosmetics and Household chemical manufacturing industries in Ghana. The responsibilities of the department are as follows:

2.1.5.1 Warehousing Inspection and Licensing

- Inspection and Licensing of storage facilities
- Licensing of importers of pharmaceuticals, cosmetics, household chemicals, medical devices, food supplements and herbal products.
- Data capture of volumes of pharmaceuticals, cosmetics, household chemicals, medical devices, food supplements and herbal products imported into the country by the respective companies.

2.1.5.2 Capacity Building and Monitoring

- Provide industrial support/technical assistance for the manufacturing industry (pharmaceuticals, cosmetics, household chemicals, medical devices, food supplements and herbal products) to ensure conformance to Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) and Good Distribution Practices (GDP).
- Perform gap analysis of the manufacturing industry to identify GMP deficiencies for immediate attention.
- Ensure the adherence to GMP and GLP by plant managers as per requirements of the FDA/international best practices.
- Capture data on manufacturing activities of all manufacturing industries in terms of raw materials utilization, installed and production capacities etc.
- Evaluate for approval, the architectural design/block plan of all new manufacturing concerns before construction to ensure conformance to GMP.
- Develop and implement training programs to ensure that technical officers at the FDA and personnel at the industry are abreast with current trends in industrial practices/pharmaceutical technology.
- Provide technical assistance in the development of documentation (Dossier, Site Master File, Validation Protocols, and Analytical Method Validation etc.)

2.2 MEDICAL DEVICE, COSMETICS AND HOUSEHOLD CHEMICALS DIVISION

The Division is one of the new Divisions created to ensure improved efficiency in the work of the Food and Drugs Authority. The Division has two Departments, namely the Medical Devices Department and the Cosmetics and Household Chemical Substances Department.

2.2.1 Medical Devices Department

The Medical Devices Department is responsible for the regulation of all classes of medical devices in Ghana. To achieve their function, the Department undertakes the evaluation of applications and registration of medical devices both foreign and locally manufactured.

2.2.1.1 Scope of Work

The activities perform by the Department include:

- The development of guidelines and requirements for the registration of all classes of medical devices.
- Evaluation of all documentation for the registration and re-registration of medical devices
- Development of the appropriate administrative and evaluation tools to ensure that all medical devices are appropriately labelled and pose minimal risks to both users and operators.
- Monitoring the safety of all medical devices for the purposes of effective classification.
- Ensuring that all manufacturers and importers of medical devices in Ghana are licensed.
- Dissemination of current product information on medical devices.
- Monitoring international regulations and assess the impact of any changes and their impact on the regulation of medical devices in Ghana.

- Liaising with other Departments to undertake the inspection of manufacturing facilities for medical devices.

- Liaising with other Departments for the post-market monitoring of medical devices.

2.2.1.2 Structure of the Department

The Medical Devices Department is made-up of two Units based on the classification of the risk factors associated with the devices.

2.2.1.3 Unit for Class I Medical Devices

This Unit is responsible for the regulation of all medical devices in Class I. Activities include:

- Receipt of all applications for the registration and re-registration of medical devices in Class I.
- Evaluation and processing of all applications received.
- Management of the relevant data on clients and products.
- Initiating, coordinating and carrying out appropriate research for the enhancement of regulation of medical devices in Classes I.
- Initiate and coordinate meetings with stakeholders.
- Initiate and coordinate training programmes for stakeholders.

2.2.1.4 Unit for Class II, III and IV Medical Devices

This Unit is responsible for the regulation of all medical devices in Classes II, III and IV. The activities of the Unit include:

- Receipt of all applications for the registration and re-registration of medical devices in Classes II, III and IV.
- Evaluation and processing of all applications received.
- Management of the relevant data on clients and products.
- Initiating, coordinating and carrying out appropriate research for the enhancement of regulation of medical devices in Classes II, III and IV.
- Initiate and coordinate meetings with stakeholders.

- Initiate and coordinate training programmes for stakeholders.

During the year under review, a total number of two hundred and sixty-four (264) applications were submitted for registration. Out of the total number of applications received, one hundred and seventynine (179) applications were fresh foreign applications which were approved, and two hundred and thirty-one (231) were re-registration applications and were also approved.
The Department vetted all permits submitted via the GcNet and even exceeded the target of 548 to 929.

2.2.2 Cosmetics and Household Chemical Substance Department

The core mandate of the Cosmetics and Household Chemical Substances Department is to evaluate applications submitted for the registration of all cosmetics and household chemical substances both imported and locally manufactured.

The Cosmetics and Household Chemical Substances Department has two units namely:

- The Cosmetics Unit
- The Household Chemical Substances Unit

3.2.1 Functions of the Department

The functions of the Department are as follows:

- Inform and update clients on the registrations requirements for cosmetics and household chemical substances
- Develop guidelines and registration requirements in line with international regulation
- Evaluate product label and documentation to ensure unsubstantiated label claims and banned substances are not passed on to the consumer Organise and coordinate training programmes aimed at capacity building for stakeholders in the cosmetics and household chemical substances industry

- Organise consumer education on cosmetics and household chemical substances Correspond with the Ports of entry and process import permit applications for the release of registered cosmetics and household chemical substances.
- Ensure effective data management aimed at obtaining data and information to guide and inform policy formulation for the effective regulation of imported and locally manufactured products.

During the year under review, a total of one thousand two hundred eighty-four (1,284) cosmetics and Household Chemical products were registered as compare to six hundred and eighty-one (681) registered in 2012.

Importation Control

The Department vetted all permit submitted via the GcNet. In all, nine hundred and seventy (970) were approved for household Chemicals substances whilst one thousand and eighty-five (1,085) were approved for Cosmetics products.

Table 7 shows the number of products received and registered during the year under review.

Table 7: Summary of types of Cosmetics products received and registered

Product Type	Received		Registered	
	2012	**2013**	**2012**	**2013**
Cosmetics	243	559	334	801*
Household Chemicals	81	130	96	164
Cosmetics-Re-registered	83	210	169	260
Household Chemicals-re-registered	32	60	82	59
Total	**439**	**959**	**681**	**1,284**

Source: Cosmetics and Household Chemical Substance Department. *The excess registered products were the previous pending applications

2.3.0 SAFETY MONITORING AND CLINICAL TRIALS DIVISION

The Safety Monitoring and Clinical Trials Department was upgraded to the status of a Division in March 2013. The Division has two (2) Departments and one unit under it namely;

1. Safety Monitoring Department
2. Clinical trials Department
3. Biological Products Unit

Mandate

The Safety Monitoring and Clinical Trials 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 take appropriate regulatory action when necessary.

2.3.1 Safety Monitoring Department

The Safety Monitoring Department has two Units, the Risk Management and Vigilance Unit. The major objectives of the Department are monitoring of product safety, creation of awareness amongst the general public and healthcare professionals about the need to report adverse events.

(a) Risk Management Unit

The Unit is responsible for ensuring compliance by industry of the requirements in the Public Health Act, 851. This is done through the activities including; conducting of Pharmacovigilance Inspections and review of safety information submitted e.g. Risk Management Plans for new products. The Unit is also responsible for ensuring incorporation of Pharmacovigilance into Public Health Programmes (PHPs) and ensuring the successful implementation of safety monitoring activities undertaken in collaboration with the PHPs.

(b) Vigilance Unit

The Unit is responsible for the management and maintenance of the database of safety information. This includes ensuring availability and accessibility of reporting forms (Adverse Drug Reaction

(ADR) and Adverse Events Following Immunization (AEFI))
Pharmacovigilance promotion activities in healthcare facilities and to the general public are undertaken by the unit. This is done through sensitization activities organized for these stakeholders and the generation of Information Education and Communication (IEC) materials for them.

During the year under review, six (6) Technical Advisory Committee for safety monitoring meetings were held to review three hundred twelve (312) adverse drug reaction reports that were received from the spontaneous reposting system.

The Department also had five National Expert Committees to review reports received from the following safety monitoring activities, namely; two new vaccines (Rotavirus and Pneumococcal vaccines), Measles-Rubella, final Yellow Fever meeting for classification of serious AEFI reports and Gardasil National Expert Committee Meeting.

The summaries of activities conducted in 2013 are summarized in table 8.

Table 8: Summary of activities conducted by Safety Monitoring Department

Activities	**2012**	**2013**
Spontaneous ADR Reports Received	312	308
Number of spontaneous AEFI reports received	14	5
Number of AEFI reports received on Gardasil	-	8
Number of AEFI reports received on New Vaccines		22
Number of reports committed into vigiflow	289	205

Source: Safety Monitoring and Clinical Trials Division.

Training/Workshop

The Department provided training of focal persons in fifteen (15) selected districts in the Central and Northern Regions and two (2) districts in the Greater Accra Region for the Gardasil Vaccination Campaign.

Some members of the department also attended under listed training and workshops:

- 15th International Training Course on Pharmacovigilance and Study of Adverse Drug Reactions
- CDER International Forum for Drug Regulators
- Training Workshop on Data Analysis and CEMFlow

- 36th Annual Meeting of Representatives of the National Centres
- International Society of Pharmacovigilance Meeting
- Made an oral presentation and publication on MenAfriVac AEFI Monitoring in GHANA, 2012
- Training of Pharmacy Auxiliary Staff on Pharmacovigilance of Zinc in the management of Diarrhoea in children
- (USAID SHOPS Programme) in the Greater Accra and Central Regions
- Training of Trainers Programme on the Introduction of Pharmacovigilance into the National TB Programme
- Healthcare Professionals involved in the management of TB
- TB Specific adverse reaction reporting form developed
- Sixth WHO African Pharmacovigilance Consultants (PVSF) Meeting.
- Training workshop on Data Management for Clinical and Regulatory Affairs.
- AEFI Causality Assessment Training by WHO for the TAC and NEC members and Staff of SMD

2.3.2 Clinical Trials Department

The Department aims to implement the appropriate and modern regulatory measures to achieve the highest standard for design, conduct, recording and reporting of clinical trials in Ghana such that data and results from these trials are credible and accurate to support the safety and efficacy for all drugs, cosmetics, household chemical substances and medical devices that are locally manufactured, imported, exported, distributed, sold, or used.

This will ensure the protection of the consumer as envisaged by the laws regulating food and drugs in force in Ghana.

Also, a Technical Advisory Committee on Clinical Trials (TAC-CT), a committee of experts has been set up to provide the Department with ongoing and timely medical and scientific advice on current and emerging issues related to clinical trials.

Objectives

1. Authorization of clinical trials
2. Monitoring of clinical trials

The Department regularly collaborates with other stakeholders to deliberate on current trends, challenges and the way forward for regulating Clinical Trials worldwide.
The detailed functions of the two (2) units under this Department are:

1. Clinical Trials Authorization Unit
2. Clinical Trial Monitoring Unit

The details on performance and figures are captured in table 9.

Table9: Summaries activities of Clinical Trials Department

PLANNED ACTIVITIES	TARGETS	ACHIEVEMENTS
Good Clinical Practice (GCP) Inspections of approved on-going clinical trials	14	12 GCP inspections were conducted
Coordinate all Technical Advisory Committee (TAC) meetings for the year	4 TAC Meetings.	4 Meetings held on March, July, and October & December 2013.
Process Clinical Trial Applications received		4 out of the 8 new applications received; 4 pending.
Process Clinical Trial Amendments received		All 8 amendments received evaluated: i. 7 amendment approvals given ii. 1 pending due to unresolved issues
Evaluation of progress reports, safety & final reports from approved ongoing clinical trial sites	• 44 Progress reports expected from ongoing trials • Evaluate all safety (4) and final (8) reports submitted	• 38 Progress reports submitted, evaluated and records updated • 4 safety reports • 4 final reports were submitted, evaluated and records updated

Management of SAE reports received from on-going clinical trial sites	To process all SAE reports received for TAC meetings and update database	Received 256 SAE reports • 126 initial SAE reports forwarded for TAC meetings • 130 follow-up reports were reviewed in-house and database updated.
Processing of Permits		7 permits processed / approved
Good Clinical Practice (GCP) Trainings	1. Training of Regional officers on GCP Inspections 2. Annual GCP Training for 40 Investigators	45-minute power point presentation on Basic GCP Principles was prepared and presented, to refresh old staff and train new employees. This was followed by a discussion A 3-day GCP Training workshop was organized at the Head office for all interested stakeholders of clinical trials. 53 participants
Good Clinical Practice (GCP) Trainings	GCP Trainings on request - to train all who request for GCP training • Observational Study — Eurartesim • Rifampin / Isoniazid	2 requests were received: -Training for Eurartesim study team was done on 28th April 2013 at the Dodowa Health Research Centre. -Training for Rifampin/Isoniazid study could not be done, even though the cost of the training was forwarded to the PI & Sponsor
Capacity building for Departmental staff	4 External training courses targeted	Attended Data Management Course & GCP Inspection Training.
Capacity building for Departmental staff	Four In-house training sessions on various topics in Clinical Trials.	Departmental staff were trained.

Source: Safety Monitoring and Clinical Trials Division

2.3.3 **Biological Products Unit**

The National Regulatory Authorities (NRAs) have the added duty to ensure that biological products; including biologics and biopharmaceuticals, whether imported or manufactured locally, are of adequate quality, safety and efficacy. This requires diverse and specialized regulatory focus by NRAs.

As a result, the Food and Drugs Authority, created a unit dedicated to the evaluation and registration of all biological products submitted for marketing authorization.

Biological Products Unit (BPU), formerly Biologics, Blood and Blood Products Evaluation and Registration Unit (BBBPER), was formed in November, 2012. The mandate of the unit is to protect and enhance public health by assuring the quality, safety and efficacy of biopharmaceuticals, biologics, whole blood and blood components intended to be use. In ensuring that biological products used in Ghana are of adequate standards of quality, safety and efficacy, BPU manage the regulatory evaluation processes that precede the issuance of marketing authorization in four distinct phases (*i.e.* Registration application acceptance phase, registration application documentation evaluation phase, registration committee phase, and decision phase).

In addition to its conventional mandate, the BPU is actively developing regulatory guidance documents that will be used to support the implementation of quality and safety systems for the extraction, production and control of whole blood and blood components. The initiative would equip the Authority with the competence to regulate blood establishments and hospital blood banks by setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. Thus, the overall goal of the Unit is to ensure that only biological products of demonstrated quality, safety and efficacy are retailed and used in Ghana.

The mandate of the Unit is performed by two (2) desks:

- Biopharmaceuticals/biologics.
- Whole blood and blood products.

These desks review and evaluate registration applications of biological products submitted for marketing authorization. Products regulated by the Unit include, but are not limited to the following:

- Vaccines and vaccine-related products.

- Biotechnology-derived therapeutic proteins. Biosimilars (copy versions of the innovator products) Plasma-derived medicinal products.
- Cell therapy products.
- Urine- or tissue-derived medicinal products.
- Gene therapy products.
- Low Molecular Weight Heparins (LMWH).
- Blood products.

Achievements

Since its inception, BPU has developed registration guidance documents, and registration application forms specific to biological products, including biosimilar products and has modelled regulation of these biosimilar products along that of biologics. Batch release templates for nine (9) different vaccines have also been developed.

The Unit has developed twelve (12) guidance documents and four (4) registration application forms to support its operations.

In 2013 the Unit conducted eleven (11) in-house training programmes designed to impact the fundamental principles of biotechnology and to improve regulators understanding of the key techniques used by biotechnologist.

The details on performance and figures are captured in table 10.

Table 10: Summary of BPU activities and its achievements

ACTIVITIES	TARGET	ACTUAL
Development of guidelines	14	14
Development of application forms	4	4
Reviewing and documenting existing administrative and technical activities in the Unit-Development of SOPs	15	13
Registration application documents reviewed	15	15
Registration renewal application documents reviewed	22	22 evaluated and subjected to full dossier and label evaluation

Review and receive variations / notifications into appropriate excel spread sheets in accordance with SOP	75	75
processed import permits through the GcNet		• 45 approved • 8 rejected
Organize in-house trainings for staff to develop their expertise	7	7

Source: Biological Unit

3.0 FOOD DIVISIONS

3.1.0 Food Inspectorate Division

The Food Inspectorate 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 Food Inspectorate 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.

The activities of the Division are carried out by two (2) Departments namely, Food Evaluation and Registration Department and Food Enforcement Department and are supported by five (5) operational units.

3.1.1 Food Evaluation and Registration Department

The Food Evaluation and Registration Department is made up of the following operational Units:

Food Evaluation and Registration Unit

3.1.1.1 Food Evaluation and Registration Unit

The principal functions of the Unit include:

- Vetting of food product applications and samples for evaluation.
- Evaluation of food products.
- Registration of food products.
- Maintenance of food product register
- Verification/vetting of permit applications.
- Shelf life monitoring of food products.
- Review of labelling and promotional materials.
- Processing of permits.
- Client Services support.

In 2013, a total number of 1,731 applications were considered for registration. Out of this number, 1502 representing 86.77% were registered. The Department attended to three thousand, one hundred and five (3,105) clients, out of the total figure two thousand, four hundred and seventy-two (2,472) clients submitted applications whilst six hundred and thirty-three (633) of the client sort for information pertaining to registration. In total the Department held twelve-three (23) registration meetings.

Table 10 shows the activities of the Department under the period under review **Table 10: Summary of food products submitted and registered**

Activity	Submitted	Deferred	Registered	Pending
New Applications for food products	1731	229	1502	-

Source: Food Registration and Evaluation Department.

3.1.2 Food Enforcement Department

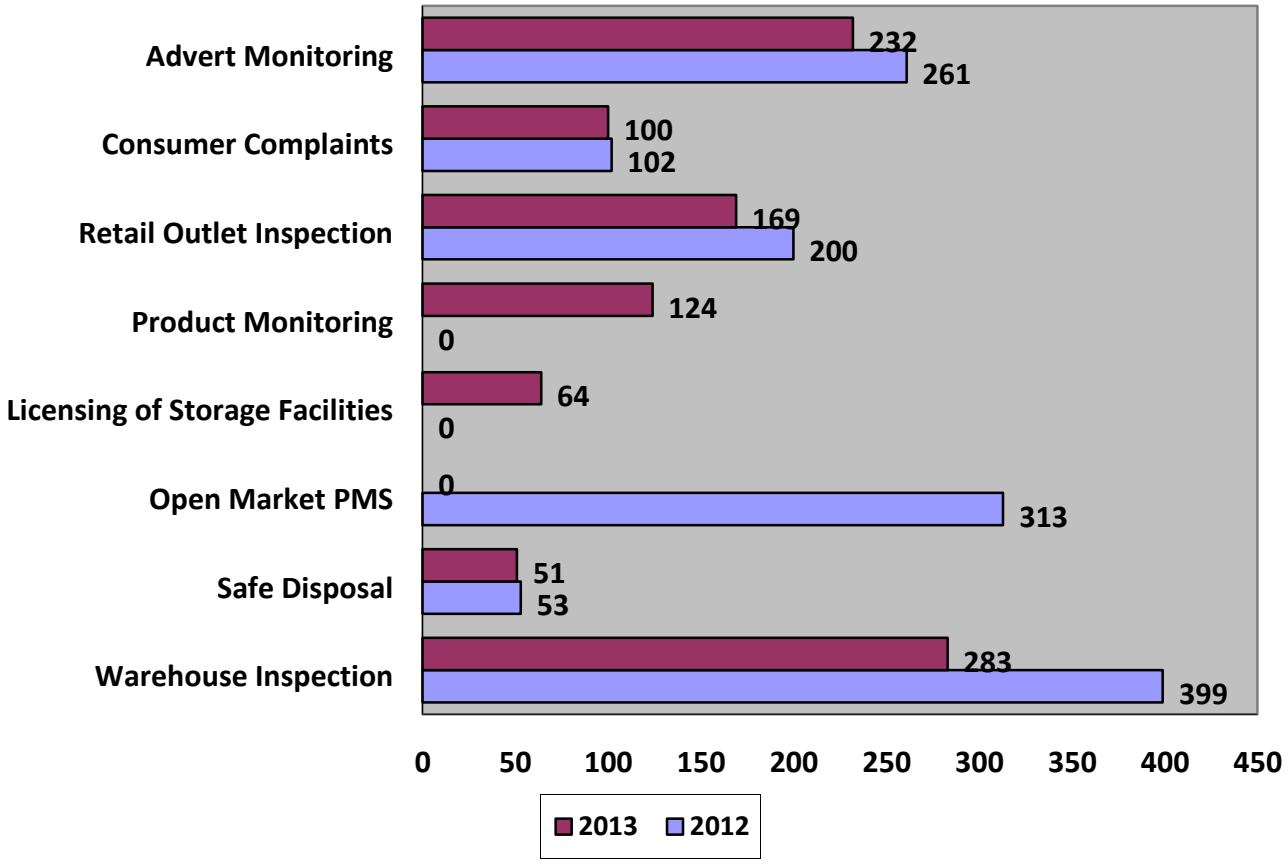
The Food Enforcement Department is one of the three Departments making up the Food Inspectorate Division of the FDA. The responsibilities of the Department are performed by two Units, namely Food Post-Market Surveillance Unit (FPMSU) and Food Premises Inspection Unit (FPIU).

3.1.2.1 Food Post-Market Surveillance Unit

The major functions of the Unit are:

- Inspection of dry food storage facilities (Food Warehouse) to ensure their compliance to Good Warehouse Practice (GWP) as a guarantee for safe storage of food products.
- Investigate into consumer complaints and related issues.
- Monitoring of practices employed in the retail of pre-packaged food to safeguard public health and safety.
- Vetting and approval of food product advertisement applications.
- Enforce compliance to Breast Feeding Code.

Figure 2: Food Post-Market Surveillance conducted



Source: 2013 Food Post Market-Surveillance Activities

In the course of 2013, the Department processed 261 advertisement Applications, 232 applications were approved and 29 applications were deferred. Seventeen (17) Advertisement vetting committee meetings were held.

Supervision on safe Disposal of Unwholesome Food

In 2013, 54 applications were received, nine (9) mandatory and 45 voluntary. Fifty-one (51) destruction were supervised.

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

During the year under review, fourteen (14) companies requested for supervised pre-packaging and all were approved.

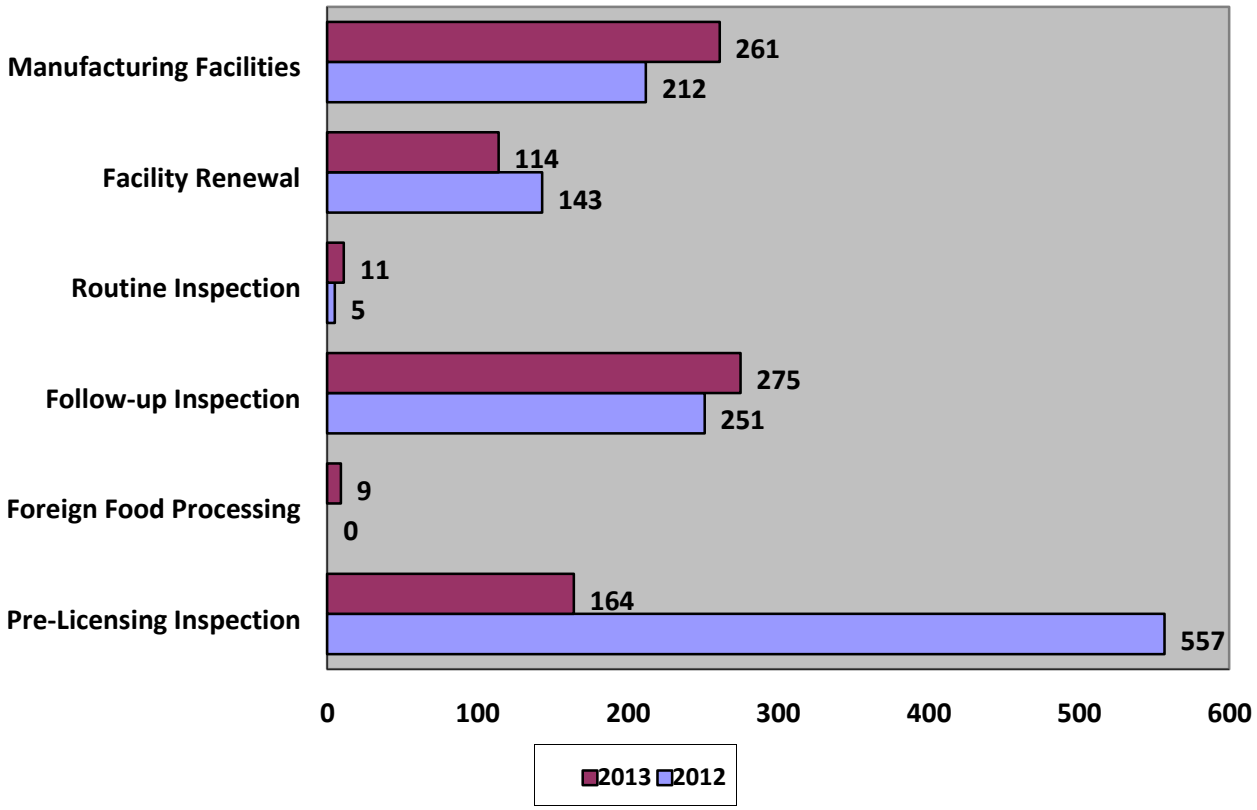
3.1.2.2 Food Premises Inspection Unit

The Food Premises Inspection Unit (FPIU) carries out the following functions to support the activities of the Food Division:

- Inspection of food processing facilities to assess compliance to current codes of GMP, Good Hygiene Practice (GHP), and other food safety management systems as a guarantee for the production of safe and quality food products.
- Conduct investigation into consumer complaints.

During the year under review, 563 types of inspections were conducted as compare to 852 in 2012 that covers local food processing plants, investigation into consumer complaints, dry warehouse, annual pre-christmas inspections, and supermarkets and retail outlets. Figure 2 indicates the summary of frequency of inspections conducted in 2013 compared with 2012 at the various food plants.

Figure 3: Premises Inspections Conducted



Source: 2013 Food Premises Inspection Unit

3.2 Food Safety Division

3.2.1 Food Safety Management Department

The Food Safety Management Department (FSMD) is under the Food Safety Division which has two units namely;

- Food Service Establishment Inspection Unit (FSEIU)
- Public Education and Food Borne Disease Surveillance Unit (PEFDSU) **Functions of the Department include:**
- The Registration and Inspection of Restaurants, Food Joints, Street-Vended Food, Catering Facilities and Caterers.
- Maintenance of liaison with the Ministry of Local Government and Rural Development (MLGRD) to ensure dissemination of Food Safety at the District Level and the Safety of the School Feeding Programme Menu.
- Development of Food Safety Guidelines to guide the Out-of –Home Service Operators.

- Collection and maintenance of data on foodborne related illnesses for consideration in Public Health Strategic Plan.
- Plan and conduct Consumer Awareness Campaign and Education Programmes on Food Safety Issues.
- Introduction of Hazard Analysis and Critical Control Points (HACCP) Food Safety Management System in the Hospitality Industry.
- Management of the Food Alert System International Food Safety Authorities Network (INFOSAN) for exchange of Food Safety alert notification.

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

- Twenty one (21) Institutional Catering Facilities (Senior High Schools) were inspected.
- Three hundred and six (306) Food Service Establishments were inspected and Technical Assistance offered as compare with one hundred and thirty two (132) in 2012.
- In 2012, three hundred and forty-seven (347) food handlers from 30 Food Service Establishment were trained in Basic Food Safety and Hygiene, the figure decrease to 316 food Handlers from 20 Food services Establishments in 2013.
- One hundred and twenty two (122) Food Service Establishments were issued with Food Hygiene Permit in 2013, whilst seventy six (76) were recorded in 2012.

The Department also undertakes Public Education and the following were the programme that were carried out in 2013

1. 63 Campaigns in 42 markets and 21 Lorry Stations
2. Eighteen (18) training sessions were held to educate street food vendors on Food safety and Hygiene for two thousand, eight hundred and fifty-seven (2,857) traditional caterers.
3. One hundred and five (105) talk shows held in 2013, which comprised seventy-eight (78) Radio Talk shows and twenty-seven (27) Television Shows.
4. One hundred and fifteen (115) educational sessions were held in 49 different Public Basic Schools. In all 17,117 pupils were educated on basic Food Safety Principles.

3.2.2 Animal Products and Biosafety Department

The Department ensures the safety of foods of animal origin (meat, poultry, fish, milk and honey), animal feed and to regulate genetically modified (GM) foods/feeds imported into Ghana. The Department comprises three units;

- Animal Products Unit (APU)
- Feed Safety Unit (FSU), and
- Biosafety Unit (BU)

The functions of the Department include:

- Inspection of cold storage facilities to ensure Good Cold Storage Practices (GCSPs).
- Inspection of Feed mills to ensure Good Manufacturing Practices (GMPs).
- Technical Evaluation of Genetically Modified (GM) Foods/Feed
- Inspection of feed establishments (feed/fish milling, facilities/drying platforms) to ensure Good Feed Handling and Manufacturing Practices (GFHMPs)
- Organisation of training workshops on GCSPs and GMPs for meat and feed industries.
- Consumer education on safety of products of animal origin.

In 2013, the Department achieved the following as indicated in tables 11 and 12, respectively.

Table 11: The types of inspections the Department conducted.

Inspection	**2013**	**2012**
Inspection conducted for the year (Routine, Follow-up, Pre-Christmas)	524	487
Pre-Christmas inspections	82	-
Supervision of safe disposal, relabeling and investigation	10	52
Consumer Complaints received and investigated	19	
Total	**635**	**539**

Source: 2013 Inspections of Animal and Biosafety Department.

The main non-conformances that were observed and solved during these inspections were:

- Non- calibration of weighing scales
- Lack of pest control programmes
- Lack of proper documentation

- Poorly maintained ancillary facilities
- Lack/expired medical certificates

Table 12: Capacity Building Programmes Attended by APBD Staff

Programme	Organizer	Participants
Presentations on Agricultural Biotechnology and Biosafety.	FDA	44
Workshop on Cartagena protocol on Biosafety and related obligations held on 18th November 2013	BNARI	-
Presentation on Good Cold Storage Practices	FDA	10
Stakeholders meeting with managers of meat processing facilities	FDA	27

Source: 2013 Animal product and Biosafety Department

3.2.3 Food Industrial Support Services Department (FISSD)

The Food Industrial Support Services Department (FISSD) was established in 2013 to provide technical support to the food industry through training of industry players in best practices that will ensure and promote the production of safe and quality food products throughout the food supply chain. This is envisaged to reduce the incidence of the production of unsafe and poor quality food with its attending socio-economic burden on consumers, the food industry and international trade.

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.

4.0 Import and Export Control Department

The Import and Export Control Department (IECD) 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, 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. The details are listed below: **Head Office**

1. Electronic Permit System-Office

Tema

2. Main Port (Wharf Sites and Sheds)
3. Tema Container Terminal (TCT)
4. Maersk Container Terminal (MCT)
5. Africa Coastal Services (ACS) Terminal
6. Tema Bonded Terminal (TBT)
7. Golden Jubilee Terminal (GJT)
8. Container Freight Station (SDV, DHL,CONSHIP, Maersk)
9. SCAN Station

KIA Office

1. DHL warehouse
2. Courier Dome
3. Aviance warehouse

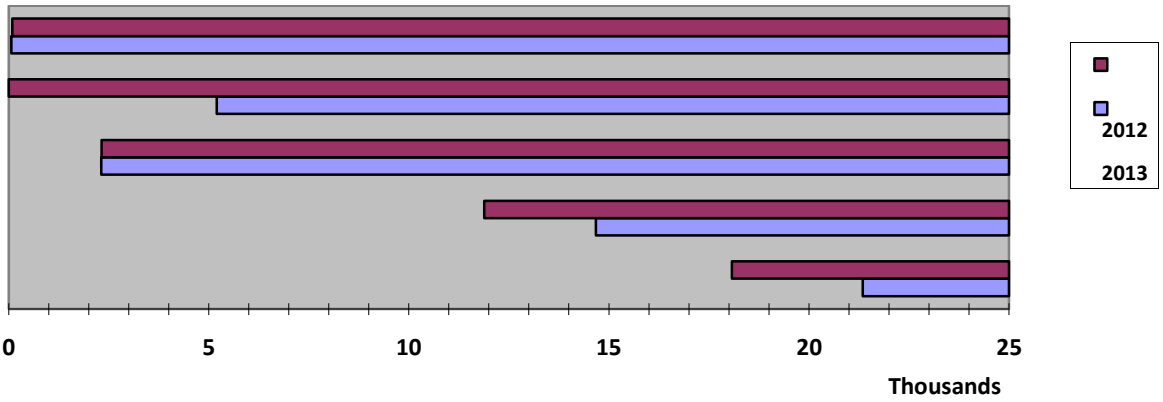
The Department also perform an oversight responsibility over the Takoradi Harbour and Elubo duty post under Takoradi Regional Office and Aflao duty post, under the Ho Regional Office, respectively. The main functions of the Department are:

- Receiving and processing import permits electronically.
- Inspection of regulated products at the ports and duty posts
- Identification and streamlining of all permits and registration issues before regulated products are released to importers.
- Verification of international documents accompanying regulated products of imports and exports.
- Compilation of Data on regulated imports and exports at the various entry points.
- Gather intelligence on smugglers and investigate sources of fake regulated products.
- Education of stakeholders (importers and exporters) of regulated products on the FDA's requirements for importation and exportation of the regulated products.

4.1 Issuance of Permits

- The Permit (GcNet) Unit of the Department received 21,345 permit applications in 2013 as compare to 2012 figure of 18,071. The details are indicated below:

Figure 4: Permit Applications received by the (GcNet)



Source: 2013 Import and Export Department

4.2 Destination Inspections

Inspections of imported food and drug products carried out by the Department at Tema Port during the period under review are indicated in figure 5.

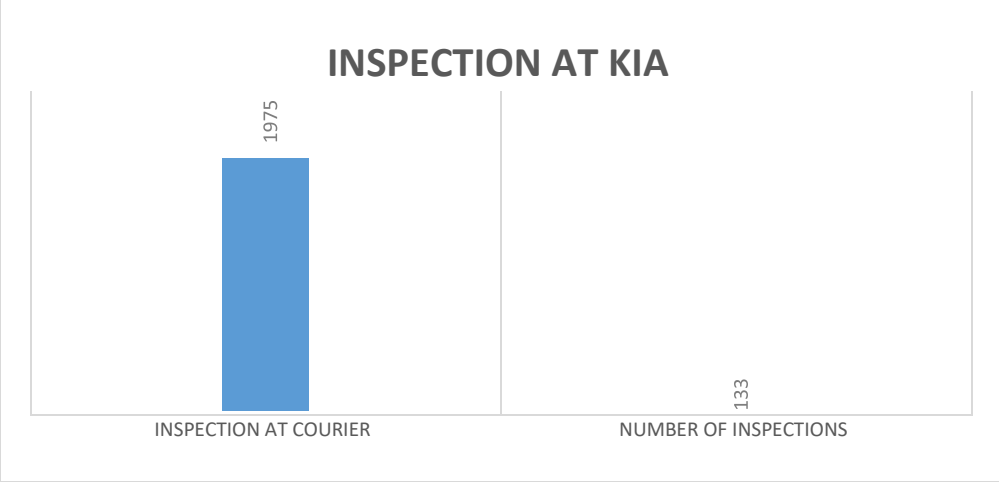
Figure 5: Destinations Inspections

Source: 2013 Import and Export Control Department

4.3 KIA Unit Operations

A total of 2,108 inspections were conducted at the KIA for the period under review as compare to 3,002 inspections conducted in 2012. This indicates a decrease of 15% over 2012. Inspections of samples of products brought into the country via courier were also conducted within the period under review.

Figure 6: Clearances/Inspections carried out at KIA



Source: 2013 Import and Export Control Department.

4.4 Cargo Tracking

The Pre-inspection Monitoring Unit of the Department continues to track the cargo manifests of all ships that dock at the Tema harbour as well as Final Classification and Valuation Report (FCVR) of all imports in its bid to prevent freight forwarders/importers from circumventing the FDA's clearance procedure. The Department also visits Agencies that have maneuvered to clear products that the FDA should have inspected and such culprits brought to book. This has contributed to the increased revenue observed over the period.

4.5 Licensing of Bonded Warehouse

Forty (40) custom bonded warehouses were inspected in 2013 and as a result fifteen (15) of them were issued with license after successful implementation of the recommendations, and the remaining twenty-five (25) were scheduled for re-evaluation and licensing in 2014.

4.6 Detention of Unwholesome Food and Medicinal products and Destructions

During the year, five hundred and fifty (550) consignments of food and medicinal products were detained. The detention is made up of four hundred and nineteen (419) food products and one hundred and thirty-one (131) medicinal, cosmetics, medical devices and household chemical substances products. The reasons of the detained products were:

- Pending completion of registration
- Renewal of registration Correction of labels.

The Department supervised destruction of sixteen (16) different types of food and medicinal products which were unwholesome and counterfeit.

5.0 Quality Control Laboratory 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 FDA 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. The functions of the Quality Control laboratory are carried out by four main Units namely:

- Physicochemical Unit
- Microbiological Unit and
- Medical Devices Unit
- Quality Assurance Unit

5.1 Extent of Performance and Achievements in Product Testing

The Department received a total of two thousand, one hundred and four (2,104) samples for quality evaluation for the year under review. This represents a decrease of three hundred and twelve (312) in comparison with the number of samples received in the previous year 2012 that was 2,416. This excludes the three hundred and forty-five (345) samples which were analysed under the Food and Drugs

Authority/United State Pharmacopeia-Promoting the Quality of Medicine (FDA/USP-PQM) Antimalarial/Analgesics in 2013.

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

Table 13: Summary of product categories received and analysed

Sample Category	Received	Analysed	Pending	Passed	Failed
Allopathic Drugs	597	220	377	209	11
Herbal Drugs	236	129	107	76	53
Veterinary Drugs	4	4	-	4	-
Food	738	642	96	443	199
Cosmetics	234	229	5	203	26
Household Chemical Substance	57	55	2	52	3
Medical Devices	238	213	25	205	8
Total	**2,104**	**1,492**	**612**	**1,192**	**300**

Source: 2013 Laboratory Services Department

5.2 Projects Executed

In 2013, the fifth round of the FDA/USP-PQM Quality Surveillance Project on the quality of Antimalarial Products on the Ghanaian Market and the second round of Analgesic preparations commonly prescribed during malaria fever, which started in the month of May 2013 was completed in December 2013.

The overall failure rate for Antimalarial was 3.8% compared to 7.7% obtained in 2012. For Analgesics the failure rate dropped from 19.8% in 2012 to 7.3% in 2013.

5.3 Training/Workshop Activities

The Department continued with its in-house training programmes as part of its preparation towards ISO 17025 accreditation, the Department also benefited from the following training programmes:

- A week training programme in Qualification and Validation of Analytical Methods at the Faculty of Pharmacy, KNUST in Kumasi from the 12th-16th of March 2013. The course was organised by Action Medeor e.v of Germany in collaboration with KNUST and attended by a staff.

- A trainer from USP-PQM organised a workshop for all analysts in the Department on Good Documentation practices in accordance with ISO 17025 requirements and determination of water content in Pharmaceutical Substances and preparation using the karl Ficher Method. This was organised from 11th and 21st November 2013.
- Four (4) analysts from the Drug Physico-Chemical Unit were trained at Centre for Pharmaceutical Advancement of the USP for two (2) weeks in Good Laboratory Practice in the month of November.

6. REGIONAL OPERATIONS

The FDA operates Regional Offices as part of its decentralization programme. This is to fulfil its mandate as contained in the Public Health ACT, 2012 (ACT 851). There are nine (9) Regional Offices that support the Head Office to achieve the overall mandate of the FDA. The Regional Offices are as indicated below.

- Kumasi Regional Office, responsible for Ashanti Region.
- Tamale Regional Office, responsible for Northern Region.
- Sunyani Regional Office, responsible for Brong Ahafo Region.
- Bolgatanga Regional Office, responsible for Upper East Region.
- Wa Regional Office, responsible for Upper West Regions.
- Takoradi Regional Office, responsible for Western Region
- Cape Coast Regional Office, responsible for Central Region.
- Koforidua Regional Office, responsible for Eastern Region.
- Ho Regional Office, responsible for Volta Region.

The activities performed by the Regional Offices are mainly operational, which cover the following areas:

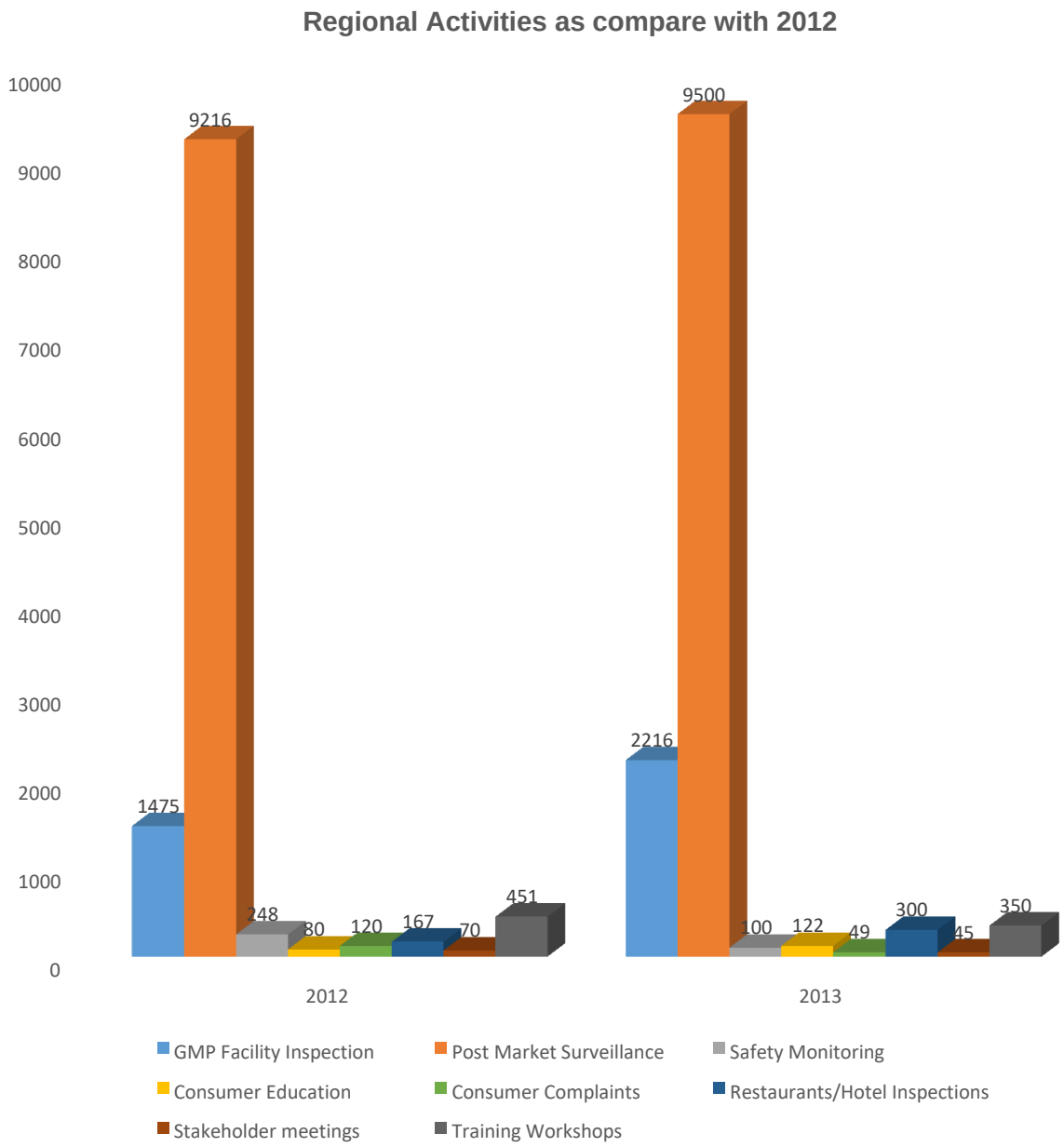
- Premises inspections.
- Post-market surveillance exercise.
- Advert monitoring function
- Consumer awareness and education programmes.
- Stakeholders meeting.
- Sensitization programmes, seminars, workshops, and training for all stakeholders in the food and drug industry.
- Investigate consumer complaint protocols to deal with consumer issues.
- Sale and assisting manufacturers, producers and importers in the registration of regulated products.

Most of the internally generated funds of the Regional Offices come from the activities of sale of registration forms, advertisement forms, advertising fees, destination inspection fees, destruction fees, and product registration fees.

6.1 Extent of Performance and Achievements of Regional Operations

Most of the activities during the year under review centred on pre-licensing inspection 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 7 shows the combined summary of activities performed by the Regional Offices.

Figure 7: Extent of Performance of Regional Operations.



Source: 2013 Regional Operational data

7.0 Administration

The Administration Department of the Food and Drugs Authority supports the services of the various technical Departments of the FDA. The Department provides services in the areas of general administration across the functional areas of the FDA. The Services include; transport management, estates management, security, secretarial and procurement management.

7.1 Transport Unit

Transportation plays a pivotal role in most of the activities performed by the Authority. The Unit is headed by a Transport Officer with forty-seven (47) permanent drivers all told.

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

- Seventy-five (75) vehicle documentation renewed.
- Improved the use of forms and logbooks by vehicles operators and users for better data collection.
- Routine maintenance and repairs were carried out successfully on seventy-five (75) vehicles.
- Eight (8) insurance claim settlements were processed, which six (6) were received and two (2) still pending due to the delay in the process of documents.
- Fourteen aged vehicles and two (2) motorbikes were successfully disposed through auction. However, report submitted for eighteen (18) vehicles valued for disposal is still pending for consideration for approval.

As at 2013, the summary of Vehicles of the FDA are indicated in table 14.

Table 14: **Inventory of FDA Vehicles**

Department	Total number	Number on road	Number off road
Head office	35	35	
Regional Offices	27	27	-
Import/Export Depts.	6	6	-
Project Vehicles	7	7	-

Sources: Transport Unit, 2013

7.2. Estate unit

During the year under review, a number of activities were conducted, especially in the maintenance of estates due to the increasing numbers of staff, both permanent and National Service persons. 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:

- Supervised the construction of five (5) bedroom house with boy's quarters for the Chief Executive which is expected to be completed by the end of February 2014.
- The laboratory equipment have been moved from the old office to the new head office whiles Epoxy flooring of the Laboratory has been completed.
- Compiled data on FDA Inventory Register, Asset Register is yet to be completed.
- Organised an in-house training on safety and fire fighting for staff of the FDA Head office.

7.3 Procurement Unit

The Procurement Unit was established to ensure that the procurement process of the FDA adhered to the procurement law as enshrined in Ghana Procurement ACT, 2003 (ACT 663). The main objective of the Procurement Unit is to establish a system of procurement that is transparent, competitive, accountable and fairness.

During the year under review, the following activities were carried out.

- Seven (7) official saloon vehicles were procured for management at the Head Office.
- Procurement of Pharmacovigilance software and installation.
- Developing and Printing of educational materials for Public Education.
- Laboratory chemicals, reagents, microbiology media and glassware's were procured to ensure the smooth running of the quality control laboratory.
- Modern laboratory equipment were procured to boost the capacity of the quality control laboratory in accordance with ISO 17025 requirement.

8.0 Projects, Research and Management Information System Department (PRMISD)

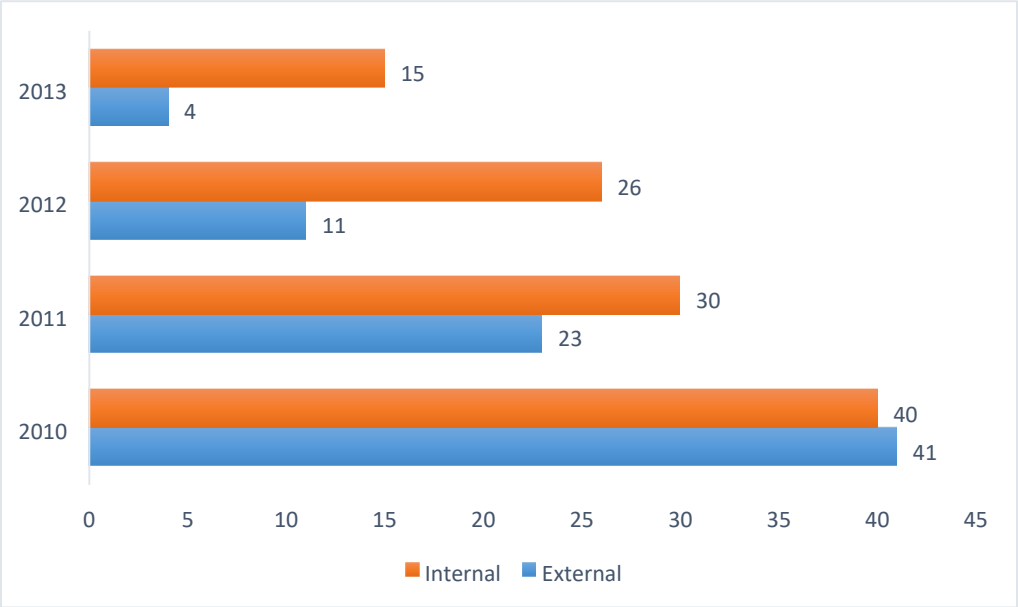
The Projects, Research and Management Information System Department (PRMISD) was set-up in November 2003 to provide service and support for all aspects of computerisation including: determination of information technology (IT) policies, information and information management systems, information system environment, and management of hardware and software; to monitor and evaluate programme of work and to generate quarterly performance and annual reports to Management and the Health Ministry; and finally to coordinate and collate project and research reports of the Food and Drugs Authority.

During the year under review, the department continued maintaining the FDA 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 of 4mb was increased to 6mb to enhance fast information search and downloads. The Untangle software ver 9.3 was updated to ver 10.1 to enable internet connectivity for over 194 computers and to reduce the incidence of accessing and downloading inappropriate materials, blocking of social networking sites, etc. which reduce productivity. The Zimbra/VMware (software) for corporate e-mailing and the web server (DNS) were upgraded from static pages to dynamic pages to accommodate new developments in regulation. The Department also facilitated the procuring of data capturing software for the Safety Monitoring Department (Pharmacovigilance system) which was installed and configured for trial basis. The final roll-out will be 2014.

8.1 Computer Repairs

The number of both external and internal repairs of computer hardware systems have reduced drastically after installation of appropriate software and the Department instituting 'green' environment practices on its IT equipment. Figure 8 below shows the trend of the repairs**.**

Figure 8: Number of Repaired IT Equipment from 2010-2013



9.0 SUPPORT UNITS UNDER THE CHIEF EXECUTIVE OFFICE

The Communication and Public Education and Human Resource Units, which report directly to the Chief Executive Officer (CEO) of the FDA, also perform duties that significantly support the functional activities of the FDA.

9.1 Communications and Public Education Unit

The Unit serves as an interface between the FDA and its stakeholders, which includes the media, the business community, industry and consumers. The Unit arranges for foreign travels, various media programmes particularly with respect to consumer education, and media coverage of the FDA's activities. The Unit also ensures the publication of health alerts and press releases for the information of the public and the international community at large. Assisting in the organisation of swoops with the police and the media is another function of the Unit.

During the year under review, the key objective was to increase public education to safeguard public health and safety through media interviews and other available avenues. The Unit performance increased significantly over the previous year as indicated in table 15.

Table 15: Activities conducted by the Communication and Public Education Unit

Area of Activity	**Frequency**	
	2013	**2012**
Media Coverage	5	5
Media Interviews	1,014	311
Press Releases, Disclaimers, Notices	20	23
Total	**1039**	**339**

Source: 2013 Communication and Public Education Unit

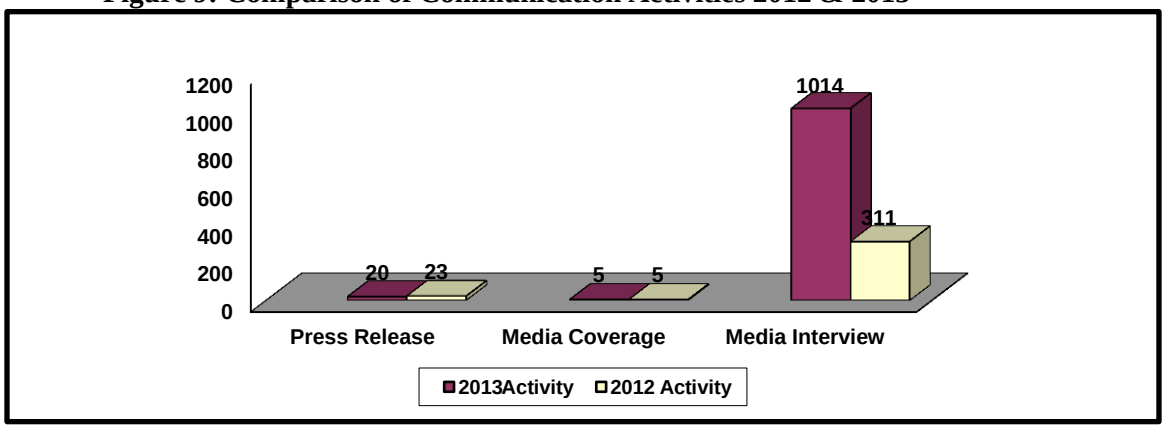
9.1.1 Press Releases

Some of the major press releases issued also include the following:

- Fake medicines peddlers arrested for the distribution and sale of fake Postinor 2 and Vermox tablets.

- Ban of smoking in public places.
- Tobinco Pharmaceuticals Ltd floods the Ghanaian market with fake condoms.
- Fake importer of Tres Orix arrested.
- Producer of fake Unilever products busted by FDA/Security Agency.
- Blacklisting of Bliss GVS Pharma Ltd, India from manufacturing medicinal products for Ghanaian market.
- Public health warning to avoid patronizing GSUNATE plus Suppository.
- Do not patronize products from Bliss GVS Pharma Ltd, a partner of Tobinco Pharmaceuticals Ltd.

Figure 9: Comparison of Communication Activities 2012 & 2013



Source: 2012&2013 communication data.

9.2 Human Resource Unit

In 2013, the FDA had a permanent staff strength of four hundred and eighty-nine (489) permanent staff. This figure represents 42.7% female and 57.3% male.

The summary of staff strength of the FDA in 2013 is indicated in table 16.

Table 16: Summary of permanent staff

Employee Categories	Total Staff Strength
Permanent	489
Temporary	36

National Service Personnel	87
Seconded Staff	15
Total	**627**

Source: 2013 Human Resource Unit

9.2.1 Transfers

As part of staff rationalisation, forty-five (45) employees were posted within the various Departments and Regional Offices**.**

9.2.2 Dismissal and Employee Labour Turnover

In 2013, five (5) staff of the Authority were dismissed for gross misconduct whiles two (2) other staff were issued with caution letters. Three (3) employees resigned from the Authority.

9.2.3 Training

Eleven (11) employees of the FDA were sponsored to further their education.
The Unit also collaborated with Administration and PRMISD respectively to organise an inhouse training for Regional Heads, Regional Administrators, Regional Accountants, Divisional, Departmental and Unit Heads of the FDA-Ghana. Seven (7) Senior Officers were sponsored to undergo a training programme in Management in the United Kingdom.

Table 17: Summary of study leave and scholarship granted in 2013.

Department/Division	Quantity	Programme of study
Administration	1	MBA Business Administration
Drugs	4	MSc. Pharmaceutical Quality and design MSc. Pharmaceutical Biotechnical. MSc. Pharmaceutical Designs. (Distance Learning)
Laboratory Services	2	MSc. Food Science and Technology
PRMIS	1	MSc. Information Technology

Source: Human Resource Unit 2013

9.2.4 Promotion

Sixty-Eight (68) members of staff were promoted in the year 2013. Table 18 gives the breakdown.

Table 18: Internal Training

Current Grade	New Grade	Number of staff Promoted
Senior Regulatory Officer	Principal Regulatory Officer	16
Regulatory Officer I	Senior Regulatory Officer	26
Regulatory Officer II	Regulatory Officer I	1
Driver Grade I	Senior Driver	10
Driver Grade II	Driver Grade I	3
Chief Driver	Yard Foreman	1
Stenographer Secretary I	Stenographer Secretary	6
Stenographer Secretary II	Stenographer Secretary I	3
Stenographer Secretary I	Senior Stenographer Secretary I	1

Source: Human Resource Unit 2013

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 the mandate of the FDA.

In this regard, the FDA's operational direction for 2014 will focus on the following:

- Intensified Post-market surveillance activities to rid the market of fake, substandard and unwholesome regulated products.
- Commencement of 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.
- Increase staff strength.
- Appointment of legal Officer for FDA.
- Complete the review 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.
- 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.
- Dissemination of new Public Health Act.
- Completion and furnishing of the chemical laboratory for Accreditation as per ISO 17025 requirements.

ANNEX A.1

FOOD AND DRUGS BOARD MANAGEMENT TEAM AND REGIONAL OFFICES

Strategic Management Team

Chief Executive	Dr Stephen K Opuni
DEC, Food Safety Division	Mr. John Odame-Darkwah
Head, Medical Device, Cosmetics and Household Chemicals Division	Mrs 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, Import and Export Control	Mr. Solomon Agampim
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
Fax: +233-0302-229794/225502
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 Officer

Food and Drugs Authority
P O Box ST 402, Kumasi.

Location: Regional Coordinating Council, Denyame- Kumasi
Tel/Fax: 03220-36070

Western

Address: The Regional Officer

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

Volta Region

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

Northern Region

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

Brong Ahafo Region

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

Central Region

Address: The Regional Officer
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 Officer
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 Officer
Food and Drugs Authority
Box, 291,
Upper West Region

Location: Controller Block, Ministries

Tel: 0392020111 Telefax: 0392020001