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**ACRONYMS AND ABBREVIATIONS**

| | | |
|---|---|---|
| ADRs | - | Adverse Drug Reactions |
| CEPS | - | Customs Excise and Preventive Service |
| CID | - | Criminal Investigation Department |
| CMS | - | Central Medical Stores |
| EMEA | - | European Medicine Agency |
| FDB | - | Food and Drugs Board |
| 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 |
| GHP | - | Good Hygiene Practice |
| GM | - | Genetically Modified |
| GMP | - | Good Manufacturing Practices |
| GWP | - | Good Warehouse Practice |
| 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 |

| | | |
|---|---|---|
| KNUST | - | Kwame Nkrumah University of Science and Technology |
| NCB | - | National Competitive Bidding |
| NFFA | - | National Food Fortification Alliance |
| NMCP | - | National Malarial Control Programme |
| PNDC | - | Provisional National Defence Council |
| PNDCL | - | Provisional National Defence Council Law |
| PRMIS | - | Projects, Research and Management Information System |
| QAMSA | - | Quality of Anti-malarial Survey Assessment |
| 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 2012 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 substance, and Medical devices as well as premises inspections increased significantly during the year. Medicines post market surveillance functions and Food Market Surveillance activities increased significantly 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 over the previous year. The FDA continued its regulatory control of the exportation of palm oil to the European Union. Destination inspections surpassed the previous year at the various ports of entry especially Tema Port. One new Unit, Biological, Blood and Blood Product Evaluation and Registration, was created to enhance the regulatory function of the FDA, Ghana.

## INTRODUCTION

This report covers the activities of the Food and Drugs Authority performed during the year 2012.

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 851, 2012.

### 1.1 Background of Food and Drugs Authority

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 law (PNDCL 305B) are as follows:

*The Authority shall advise the Minister of Health on all matters relating to the administration and implementation of the Law.*

*Without prejudice to the above, the Authority shall*

- *advise the Minister on measures for the protection of the health of consumers;*
- *in co-operation with the Ghana Standards Board, ensure adequate and effective standards for food and drugs;*
- *monitor through the District Assemblies and other agencies of state compliance with this Law;*
- *advise the Minister on the preparation of effective regulation for the full implementation of the provisions of the Law;*
- *perform the functions assigned to it under this law*

### 1.3 Mandate

The Food and Drugs Law of 1992 (PNDCL 305B), which established the Food and Drugs Authority and further amended by the Public Health Act 2012 (Act 851), put the control, the manufacture, importation, exportation, distribution, use and advertisements of food, drugs, cosmetics, medical devices and household chemicals under the purview of the FDA with respect to ensuring their safety, quality and efficacy.

### 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 and Goals

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.

To realize this mission, the Food and Drugs Authority has set for itself the following goals:

*The FDA shall:*

- *Advise the Minister of Health on measures to protect the health of the consumer.*
- *Recruit qualified staff and ensure their training, development and maintenance for optimal productivity and quality service delivery.*

- *Ensure that Legislative Instruments are passed for the laws and guidance of its clients.*
- *Develop and implement a well-researched communications strategy to promote the functions of the Food and Drugs Board and matters relating to the health of the consumer under the Food and Drugs Board's contributions to safety and efficacy.*
- *Ensure that product information and advertisement are not misleading or deceptive nor contain references to diseases for which advertisement is prohibited.*
- *Ensure that all local manufacturers of products are licensed and that their operations conform to current codes of Good Manufacturing Practices (GMP).*
- *Ensure that all products locally manufactured, imported, and/or exported are registered to assure their safety, quality and efficacy.*
- *Collaborate with other governmental and non-governmental bodies, the district and municipal assemblies to enable optimal performance of its functions.*
- *Undertake research and analysis to enable the fulfilment of its obligations to the nation.*
- *Develop an organizational structure with financial, information technology and human resource facilities that encourage self-development, responsibility and empowerment of staff to meet the functions of the Food and Drugs Board.*
- *Have well branded, comprehensive, distinctive and high quality operations throughout the nation.*
- *Establish, maintain, monitor and update standards of products.*

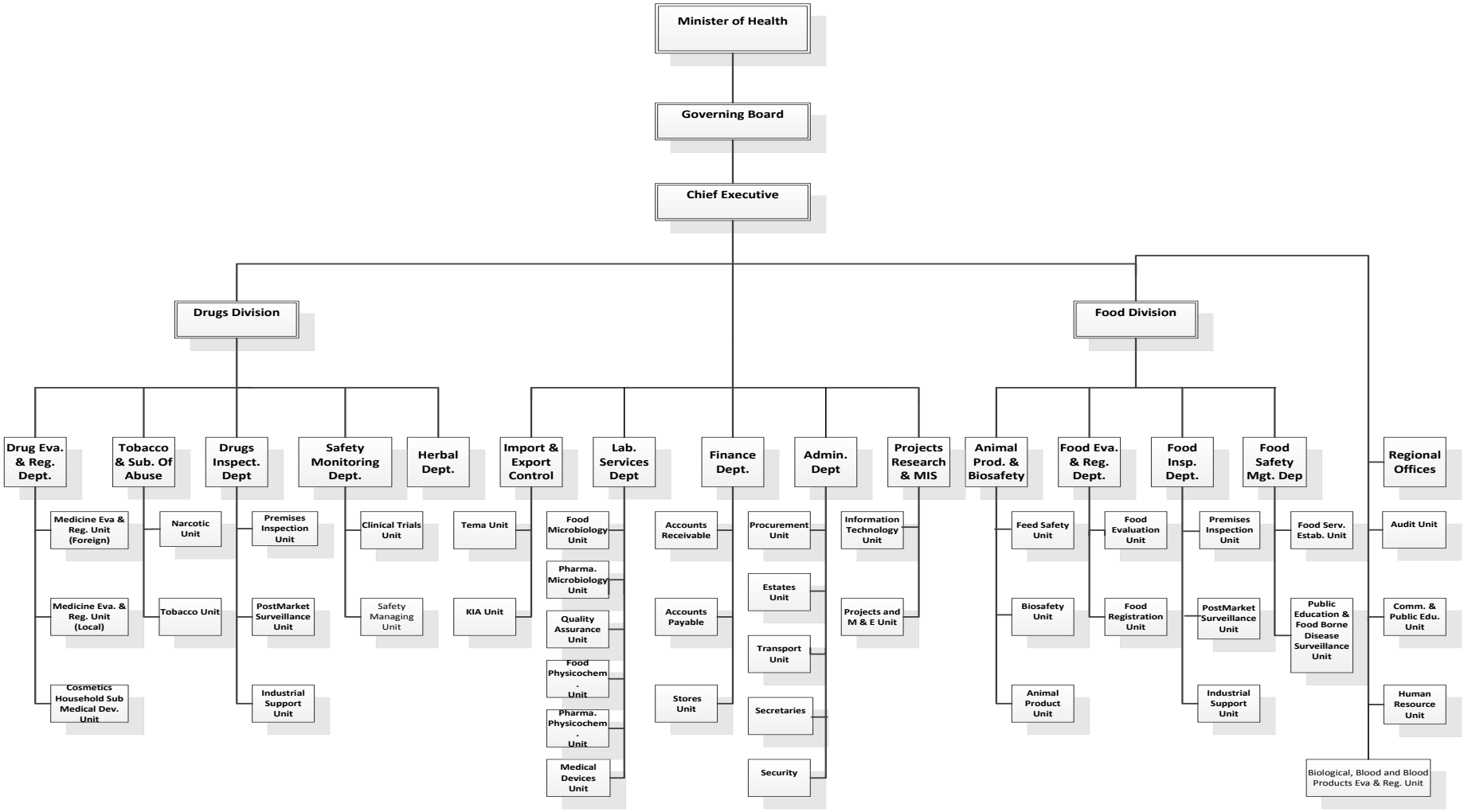
### 1.6 The Governing Board

The Food and Drugs Law 1992 (PNDCL 305B) and Food and Drugs Amendment Act 523, 1996 provide for a management structure spear-headed by a Governing Board appointed by the President of the Republic of Ghana. The Chief Executive of the FDA is Dr Stephen Kwabena Opuni and the current Governing Board members are;

| | | |
|---|---|---|
| 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. | To be nominated | Crop Services, MOFA |
| 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.


Minister of Health
Governing Board
Chief Executive
Drugs Division
Food Division
Drug Eva. & Reg. Dept.
Tobacco & Sub. Of Abuse
Drugs Inspect. Dept
Safety Monitoring Dept.
Herbal Dept.
Import & Export Control
Lab. Services Dept
Finance Dept.
Admin. Dept
Projects Research & MIS
Animal Prod. & Biosafety
Food Eva. & Reg. Dept.
Food Insp. Dept.
Food Safety Mgt. Dep
Regional Offices
Medicine Eva & Reg. Unit (Foreign)
Medicine Eva. & Reg. Unit (Local)
Cosmetics Household Sub Medical Dev. Unit
Narcotic Unit
Tobacco Unit
Premises Inspection Unit
PostMarket Surveillance Unit
Industrial Support Unit
Clinical Trials Unit
Safety Managing Unit
Tema Unit
KIA Unit
Food Microbiology Unit
Pharma. Microbiology Unit
Quality Assurance Unit
Food Physicochem. Unit
Pharma. Physicochem. Unit
Medical Devices Unit
Accounts Receivable
Accounts Payable
Stores Unit
Procurement Unit
Estates Unit
Transport Unit
Secretaries
Security
Information Technology Unit
Projects and M & E Unit
Feed Safety Unit
Biosafety Unit
Animal Product Unit
Food Evaluation Unit
Food Registration Unit
Premises Inspection Unit
PostMarket Surveillance Unit
Industrial Support Unit
Food Serv. Estab. Unit
Public Education & Food Borne Disease Surveillance Unit
Audit Unit
Comm. & Public Edu. Unit
Human Resource Unit
Biological, Blood and Blood Products Eva & Reg. Unit

In summary, the FDA as a national regulatory body has the responsibility for the regulatory control of manufacture, import, export, distribution, advertisement and product information for food, drugs, cosmetics, medical devices and household chemical Substances. 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 above.

The ensuing sections deal with the summaries of achievements in 2012.

## 2.0 DRUGS DIVISION

The Drug 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 evaluating all information submitted in the registration dossiers, pre-registration inspection, and drug quality analysis reports.

The Division also evaluates and registers veterinary medicines to promote and protect animal health and to ensure safe animal products for human consumption.

### 2.1 Drug Evaluation and Registration Department

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

- Medicine and Vaccines Evaluation and Registration Unit
- Cosmetic, Household Chemicals and Medical Devices Unit

#### 2.1.1 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 and vaccines products 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 are 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, 471 product applications were submitted to the Medicines Evaluation and Registration Unit. This total number was made up of 437 allopathic drugs (human), 43 allopathic drugs for veterinary use. 399 allopathic drug applications were submitted

for product re-registration. This figure was made up of 389 allopathic drugs for humans and 10 allopathic drug for veterinary use applications.

The difference between the registered veterinary and the received applications is due to the registration approval of applications submitted during the previous year.

Table 1 and 2 give the summaries of applications received for registration and re-registration, respectively, during the year under review.

**Table 1: Summary of applications received and registered**

| **Product Type** | **Applications Received** | **Number Registered** |
|---|---|---|
| Allopathic Drugs (Human) | 437 | 301 |
| Veterinary Drugs | 34 | 43 |
| Vaccines | - | - |
| **Total** | **471** | **344** |

Source: Medicine Evaluation and Registration Unit, 2012

**Table 2: Summary of applications received for re-registration**

| **Product Type** | **Applications Received** | **Number Re-registered** |
|---|---|---|
| Allopathic Drugs (Human) | 389 | 362 |
| Veterinary Drugs | 10 | 11 |
| Vaccines | - | - |
| **Total** | **399** | **373** |

Source: Medicines Evaluation and Registration Unit, 2012.

#### 2.1.1.1 Product Registration and Document Reviews

In 2012, twenty-two dossier evaluation retreats and four (4) product registration meetings were held. The following are the details of the documentation, which were evaluated at the dossier evaluation meetings**.**

**Table 3: Product Registration and Document reviews**

| **TYPE OF DOCUMENT** | **NUMBER EVALUATED** |
|---|---|
| New Applications | 469 |
| Additional Documentation | 495 |
| Variation documentation | 106 |
| **Total** | **1070** |

Source: Medicine Evaluation and Registration Unit, 2012

### 2.1.2 Cosmetics, Medical Devices and Household Chemical Substance Unit

The principal functions of the Unit are:

- Evaluation of documents related to all cosmetics, medical devices and household chemicals substances.

- Registration of cosmetic products, medical devices and household chemical substances.

During the year under review, a total number of Six Hundred and fifty-One (651) applications were submitted for registration. Out of the total number of applications received, two hundred and forty-three (243) applications were for cosmetics, eighty-one (81) were for household chemical substances and One hundred and four (104) applications for medical devices, respectively. The Unit was able to approve three hundred and thirty-four (334) cosmetics products, ninety-one (91) from the previous year, whilst ninety-six (96) household Chemicals were given approval with fifteen (15) of the approvals from the previous year. In the case of medical devices one hundred and twenty (120) were approved. The difference between the approved applications and the one Hundred and four (104) applications received is due to the approval of sixteen applications from the previous year.

Table 4, shows the number of products received and registered during the year under review.

**Table 4: Summary of types of products received and registered**

| **Product Type** | **Applications Received** | **Number Registered** |
|---|---|---|
| Cosmetics | 243 | 334 |
| Household Chemicals | 81 | 96 |
| Medical Devices | 104 | 120 |
| Cosmetics-Registered | 83 | 169 |
| Household Chemicals-re-registered | 32 | 82 |
| Medical Devices-re-registered | 108 | 43 |
| **Total** | **651** | **844** |

Source: Cosmetics, Medical Device and Household Chemical Substance Unit, 2012.

## 2.2 Herbal Medicine Department

The Herbal Medicine Unit was elevated to the status of a Department in April 2010.

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, Mampong-Akuapim, 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 thirty-eight (338) herbal medicine applications were received including re-registration applications and two hundred and forty-three )243) were approved.

A total number of three hundred and fifty (350) food supplement applications were received, three hundred and seventy-nine (379) food supplements approved including 29 applications from the previous year.

**Table 5: Summary of herbal products received and registered**

| | **Applications Received** | | **Number Registered** | |
|---|---|---|---|---|
| | Foreign | Local | Foreign | Local |
| Herbal Products for Registration | 20 | 212 | 27 | 141 |
| Herbal Products for Re-registration | 10 | 96 | 9 | 66 |
| Food Supplement | 350 | - | 379 | - |
| Food Supplement for Re-registration | 142 | | 129 | |
| Homeopathic Medicine for Re-registration | 5 | | 5 | |
| **Total** | **527** | **308** | **549** | **207** |

Registration Activities, 2012

### 2.3 Safety Monitoring Department

The Safety Monitoring Unit was upgraded to the status of a Department in April 2010 with the following objectives:

- Strengthen the science that supports safety and monitoring of products as used in everyday practice to identify previously unrecognized or changes in the patterns of the risk profile.
- Assess regulatory information relating to product safety in order to determine what action, if necessary, to improve safe use of products and make recommendations on product label amendments, product withdrawals and change in the category of distribution of medicines.
- Provide healthcare professionals and the general public with access to clear and timely risk-benefit information for products.
- Maintain contact with international regulatory bodies working in pharmacovigilance and exchange information on drug safety.
- Ensure that all clinical trials conducted in Ghana are in accordance to the Good Clinical Practice and the Helsinki Declaration to ensure the protection and right of human subjects.

The functions of the Department are supported by three (3) specialized Units, namely: Signal Management and Communication Unit, Clinical Trials Assessment Unit and Research and Risk Management Unit.

#### 2.3.1 Signal Management and Communication Unit

**Functions:**

- Maintain national Drug Safety Database
- Commit reports to the WHO vigiflow database
- Acknowledge receipt of Adverse drug reaction (ADR) reports/ Adverse Events following Immunisation ( AEFI) reports and provide feedback to reporters
- Communicate safety information to healthcare professionals through Dear Doctor / Healthcare professional letters
- Communicate safety information to healthcare professionals and the general public through publications (safety newsletter, website information, media articles, e-mails etc.)
- Coordinate Technical Advisory Committee for safety monitoring (TACSM) meetings

- Identify areas for training and provide training for healthcare professionals and public awareness

### 2.3.2 Clinical Trials Assessment Unit

- Evaluation of Clinical Trials Applications (CTAs)
- Evaluation of clinical trials reports and updates
- Processing of import permits for investigational products and/or placebo
- Correspondence with PIs, Sponsors, etc.
- Collate and categorize serious adverse events (SAEs) from clinical trials
- Maintain clinical trials database
- Maintain Database of Serious Adverse Events
- Conduct Good Clinical Practice Inspections
- Coordinate TAC clinical trial meetings

### 2.3.3 Research and Risk Management Unit

- Collaborate with the pharmaceutical industry regarding safety related to marketed products
- Evaluate pharmacovigilance plans and periodic safety update reports submitted by pharmaceutical industry.
- Conduct pharmacovigilance inspections
- Develop proposals for activities and projects
- Carry out impact analysis of the Safety Monitoring activities.

During the year under review, four (4) Technical Advisory Committee for clinical trials meetings were held and Serious Adverse Events (SAEs) and progress reports reviewed from 7 ongoing clinical trials.

There were also four (4) meetings of the TACSM at which 312 adverse drug reaction reports received from the spontaneous reposting system were reviewed.

The Department also had four National Expert Committees to review reports received from the following safety monitoring activities, namely; two new vaccines (Rotavirus and Pneumococcal vaccines), Yellow Fever Phase II vaccination campaign, MenAfriVac vaccination campaign, Cohort Event Monitoring of Artemisinin Combination Therapies (ACTs).

The summaries of activities conducted in 2012 are summarized in table 6.

**Table 6: Summary of activities conducted by Safety Monitoring Department**

| Activities | Number |
|---|---|
| Spontaneous ADR Reports Received | 312 |
| Number of spontaneous AEFI reports received | 14 |
| Number of AEFI reports received from active monitoring campaigns | 1,679 |
| Number of reports committed into vigiflow | 289 |
| Number of institutions trained | 40 |
| Number of SAE reports received from on-going clinical trials | 1,351 |
| Number of permits processed for investigational products and placebo | 14 |

Source: Safety Monitoring Activities, 2012

### 2.3.5 Training/Workshop

The Department provided training in forty (40) institutions involving one hundred and eighty nine healthcare professionals.

### 2.3.6 Conferences and Meeting

The Department organised and participated in the following conferences and meetings:

- Third African Regulatory Conference, Accra
- A three day workshop on Effective Communication and Crisis Management in Pharmacovigilance organised by WAHO and WHO in collaboration with Uppsala Monitoring Centre in Accra.
- The third African Pharmacovigilance meeting in Nairobi, Kenya
- A two day workshop on the Introduction of Biological Medicinal Products and Biosimilars, Nigeria.
- Legislation for Clinical Trials of Vaccines, Kenya
- Health Products and Food Branch (HPFB), Health Canada International Regulatory Forum, Canada
- European Medicines Agency GCP Working Group Workshop, United Kingdom

- International Conference of Drug Regulatory Authority (ICDRA) (Ghana presentation paediatric medicines), Estonia.

**Other Achievements**

Development of the first Edition of the Safety News Letter (Drug Lens)-to be distributed twice a year, this is expected to create awareness for the National Centre and improve reporting.

Requests made by other Public Health Programmes to incorporate Pharmacovigilance.

- National AIDS Control Programme
- National TB Control Programme
- Neglected Tropical Diseases Programme
- Maternal and Child Health

### 2.4 Drug Inspectorate Department

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

- Premises Inspection Unit
- Post-Market Surveillance Unit/Task Force
- Industrial Support Service/Operational Research

The Department's main activities include pre-licensing and post licensing inspections of pharmaceutical, herbal, cosmetic 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).

#### 2.4.1 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.

**Table 7: Summary of activities conducted by Drugs Premises Inspection Unit**

| Program of Activities | Outcome |
|---|---|
| Foreign GMP Audit | 20 |
| Routine Audit of local Pharmaceutical Plants | 31 |
| Routine Audit of local Herbal Manufacturing Plants | 29 |
| Routine Audit of local Cosmetics, H.C and M.D Manufacturing Plant | 15 |
| Pre-Licence Inspection of Local Pharmaceutical Manufacturing Plants | 5 |
| Pre-License Inspection of Local Herbal medicines Manufacturing Plants | 14 |
| Pre-License Inspection of Cosmetics, H.C and M.D | 2 |
| UNIDO | 8 |

Source: Drugs Inspectorate Activities, 2012

### 2.4.2 Industrial Support Services Unit

The Unit supports the activities of the Premises Inspection Unit and the Post Market Surveillance Unit of the Drug Inspectorate Department. The Unit supports these Units by capturing and managing qualitative and quantitative data together with operational guidelines of the Department.

**Table 8: Summary of activities conducted by Industrial Support Services Unit**

| Program of Activities | Outcome |
|---|---|
| Vetting and approval of submitted adverts | 295 |
| Training Program on Dealing with Counterfeit Medicines conducted for newly recruited staff of Bureau of National Investigation | 1 |

Source: Drugs Inspectorate Activities, 2012

### 2.4.3 Drug Post Market Surveillance Unit

The Unit monitors registered drugs, cosmetics, household chemical and medical substances that have been given marketing authorisation or otherwise that is in distribution on the Ghanaian market and is 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 Pharmacy Council 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.

**Table 9: Activities of Drugs Post Market Surveillance Unit**

| Program of Activities | Outcome |
|---|---|
| Warehouse Inspection | 70 |
| Product Quality Monitoring | 33 |
| Safe Disposal | 44 |
| Complaints & Investigations | 40 |
| Destination Inspection | 24 |
| Product recall | 15 |
| Public Education | 81 |

| | |
|---|---|
| Training on GDP | 1 |
| Administrative charge | 11 |

**Source: Drugs Inspectorate Activities, 2012**

## 2.5 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 2012, the Department vetted and issued 85 import permits for controlled substances, 27 import permits for tobacco. 73 advice of receipt were received. 85 returns on utilised controlled substances were monitored. 56 export authorisations endorsed and confirmed. Export authorisation was received before consignments reached the country. Multilateral Chemical Reporting Notification endorsed in 2012 was 30.

During the year under review thirteen (13) quarterly and annual reports were submitted to International Narcotics Control Board (INCB) on the imports and exports of psychotropic narcotics and precursor chemicals.

The total number of permit received for narcotic was ninety-four (94), however, fourteen (14) permits were returned due to the validity date of the permit. The importers were not able to meet the deadline.

# 3 FOOD DIVISION

The Food 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 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 Food Division are carried out by four (4) Department namely; Food Evaluation and Registration Department, Food Safety Management Department, Food Inspectorate Department and Animal Products and Biosafety Department. The four (4) Departments are supported by nine (9) operational units.

## 3.1 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 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 2012, a total number 2,209 applications were considered for registration including previous year. Out of this number, 1,254 representing 56.77% were registered.

**Table 10: Summary of food products submitted and registered**

| ACTIVITY | Outcome |
|---|---|
| Applications | 1531 |
| Product registration | 1254 |
| Registration meetings | 23 |
| Client service enquiries | 2,284 |
| General enquiries | 667 |
| Submission of Application | 1,617 |
| Group Registration | 4 |

Source: Food Registration Activities, 2012.

### 3.2 Food Inspectorate Department

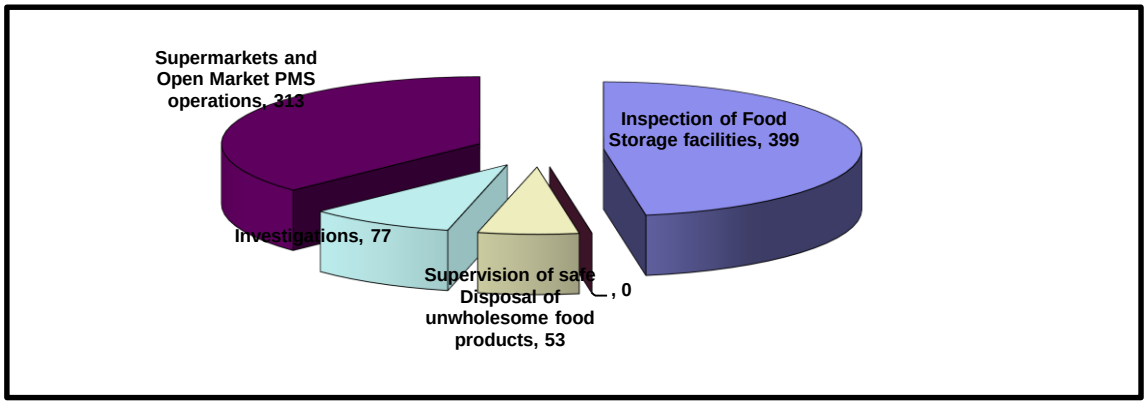
The Food Inspectorate Department is one of the four Departments making up the Food Division of the FDA. The responsibilities of the Department are performed by three Units, namely Food Post-Market Surveillance Unit (FPMSU), Food Premises Inspection Unit (FPIU) and Industrial Support Services Unit (ISSU).

#### 3.2.1 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 the 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.

**Figure1: Food Post-Market Surveillance conducted**




Source: 2012 Food Post Market-Surveillance Activities

In the course of 2012, the Department processed 273 advertisement Applications, 253 applications approved, 17 script approvals, 18 applications deferred and one (1) application pending still meeting. Eleven (11) Advertisement vetting committee meetings were held.

### 3.2.1.1 Supervision on safe Disposal at Unwholesome Food

In 2012, 55 applications were received, ten (10) mandatory and 45 voluntary, fifty-four (54) destruction supervised, one (1) awaiting confirmation destruction date from applicant.

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

During the year under review, four (4) companies requested for supervised re-packaging of grains on seven (7) occasions for a total of ninety (90) days.

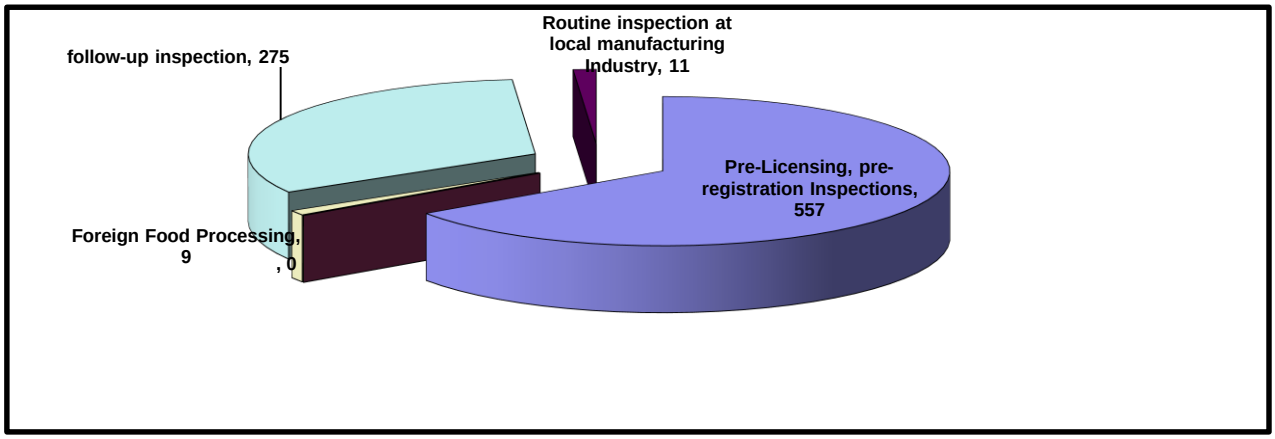
### 3.2.2 Food Premises Inspection Unit

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, 852 types of inspections were conducted covering 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 2012 at the various food plants.

**Figure 2: Premises Inspections Conducted**




Source: 2012 Food Premises Inspection Activities

Based on the outcome of the inspections and other non-compliances noted, the Unit included a training activity in its programme. In consequence, the Unit organised training in GMP and Food Safety management system based on the Principles of Hazard Analysis and Critical Control Point (HACCP) for quality assurance officers of local alcoholic beverage producing companies.

### 3.2.3 Industrial Support Services Unit

The Unit provides the following functions to support the Food Division:

- Provision of technical support to the food industry through training and implementation of food safety and quality management systems.
- Control of export of palm oil to the European Union.
- Implementation of GAIN project on fortification of wheat flour and vegetable oil with micronutrients.
- Training of stakeholders in relevant areas of the Food Law.
- Implementation of Universal Salt Iodation (USI) programme

#### 3.2.3.1 Food Industry Audit

To assess adherence to GMP and other food safety management systems, the Unit conducted twenty (20) GMP audits, eight (8) palm oil pack-house audits, thirteen (13) Needs assessments and one (1) HACCP audits were conducted throughout the year.

#### 3.2.3.2 Sampling and Screening of all palm oil samples intended for export

Curbing the adulteration of palm oil with Sudan dyes to facilitate export and for consumer protection, the unit was able to screen palm oil as and when application is received. Seventy seven (77) samples of palm oil intended for export were screened for Sudan dye, seventy-six samples were found to be free of the adulterant and one (1) consignment suspected to contain the dye was diverted for soap production.

#### 3.2.3.4 Universal Salt Iodation Programme (USI)

The objective of the programme is to achieve 90% household consumption of iodated salt in Ghana. To monitor each of the three police checks points monthly and monitor salt sold on the markets and issue permits for the transport of raw salt. During the period under review, the Unit made visited 24 checkpoints, 26 markets in Greater Accra and Tema to monitor the iodation

status of salt sold, five (5) mining sites were visited and twenty-two (22) permits were issued for non-iodated salt within the country and one thousand two hundred and eighty five (1,285) Certificates of Manufacture and free sale were issued for the transport of salt outside the country. Forty two (42) Radio/TV talk shows were carried out as part of public education outreach programme on USI (UNICEF and WFP sponsored).

#### 3.2.3.5 National Food Fortification Alliance (NFFA)

The Ghana National Fortification Programme aims at reducing the prevalence of micronutrient deficiencies among vulnerable and at risk populations. The principal activity is to monitor and sample producers of wheat flour and vegetable oil for quantitative laboratory analysis of vitamin A and iron. In 2012, thirteen (13) (16 planned) assessment visits were made to the participating industries.

## 3.3 Food Safety Management Department

The Food Safety Management Department (FSMD) is under the Food 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 INFOSAN for exchange of Food Safety alert notification.

### 3.3.1 The registration and inspection of Food Service Establishment

1. One hundred and thirteen (**113**) new Food Service Establishments introduced to the Food Hygiene Permit
2. One hundred and thirty two (132) Food Service Establishments were inspected and Technical Assistance offered
3. 347 food handlers from 30 FSE were trained in Basic Food Safety and Hygiene
4. Three (3) Food Service Establishment were introduced to HACCP System
5. Seventy Six (76) Food Service Establishments were issued with Food Hygiene Permit.

### 3.3.2 STREET FOOD VENDORS

#### 1. PUBLIC EDUCATION PROGRAMME

a) 115 Campaigns in 10 markets and 8 Lorry Stations

b) Developed Handbook for Lower Primary School Pupils on Basic Education in Food Safety

c) Held 38 Radio Talk Shows, 14 Television Show and 1 Print interview held

d) Door –to- Door educational campaign in Nima, Maamobi and Kotobabi during the cholera outbreak (2000 copies of educational materials distributed)

e) Collaborated with Disease Control Unit of Ghana Health Service to curb cholera outbreak (500 copies of educational materials distributed)

#### 2. SPECIAL PROGRAMMES

a) Dansoman market is now a model clean market and awaiting inauguration

b) Participated in Farmer's Day celebration as an exhibitor

c) Participated in the development of FAO Ghana Country Programming Framework

### 3.4 Animal Products and Biosafety Department

The Department was created in August 2007 to ensure 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.

**Table 11: The types of inspections the Department conducted.**

| **inspection** | **Actual** |
|---|---|
| Inspection conducted for the year (Routine, Follow-up, Pre-Christmas) | 487 |
| Supervision of safe disposal, relabeling and investigation | 52 |
| **Total** | **539** |

Source: 2012 Inspections of Animal and Biosafety Activities.

The main non-conformances observed during these inspections included:

- Non- calibration of weighing scales
- Lack of pest control programmes
- Lack of proper documentation
- Poorly maintained ancillary facilities
- Lack/expired medical certificates

Steps were taken to help the companies to address all the non-compliances observed.

### 3.3.1 Biosafety Unit

Two members of staff of the Department attended the second GenØk sub-regional Biosafety course- Hazard Identification and Risk Assessment in Norway. Since their return a series of in-house presentations on the knowledge acquired at the program has been going on.

During the period of review, 15 training programmes were conducted for the Food Division with the aim of deepening awareness on Biosafety within the Division, which covered major topics in Genetically Modified Foods. In addition to the in-house training programmes, other staff members like National Service personnel and attachment staff also benefited from the topics the Unit treated.

**Table 12: Capacity Building Programmes Attended by APBD Staff**

| Programme | Organizer | Participants |
|---|---|---|
| Workshop on biosafety communication strategy | ABNE | 2 |
| training workshop on risk assessment conduct for the following applications:<br>Protein enriched sweet potato<br>Maruca resistant cowpea<br>Drought tolerant salt and Nitrogen utilization efficiency rice | ABNE | 1 |
| Holistic foundation for assessment and regulation of Genetically modified organisms | Genok- centre for biosafety, univeristy of tromso, norway | 1 |
| ECOWAS regional workshop on harmonization of Food Hygiene | Better training for safer food | 1 |

**Source: 2012 Animal product and Biosafety Activities**

## 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 PNDC Law 305B. 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 Zonal office and Aflao duty post, under the Ho Regional Office.

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.

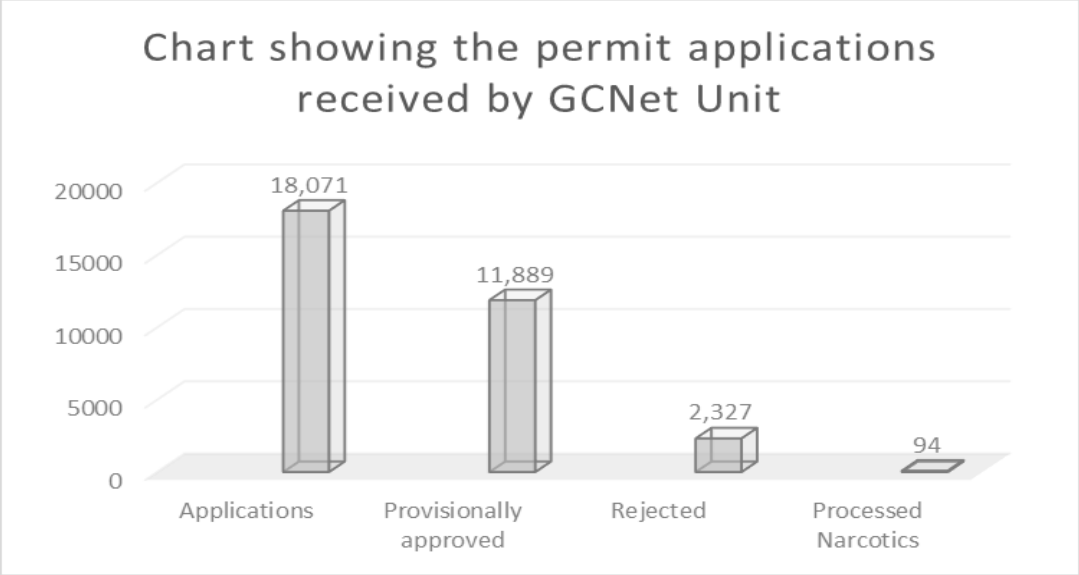
- Verification of international documents accompanying regulated products of imports and exports.
- Compilation of Data on regulated imports and exports at the various entry points.
- Gather intelligence on smugglers and investigate sources of fake regulated products.
- Education of stakeholders (importers and exporters) of regulated products on the FDB's requirements for importation and exportation of the regulated products.

### 4.1 Issuance of Permits

**PERMIT ISSUANCE**

- The Permit (GCNet) unit of the department received 18,071 permit applications in 2012. The details are indicated below:

**Figure 3: Permit Applications received by the (GCNet)**



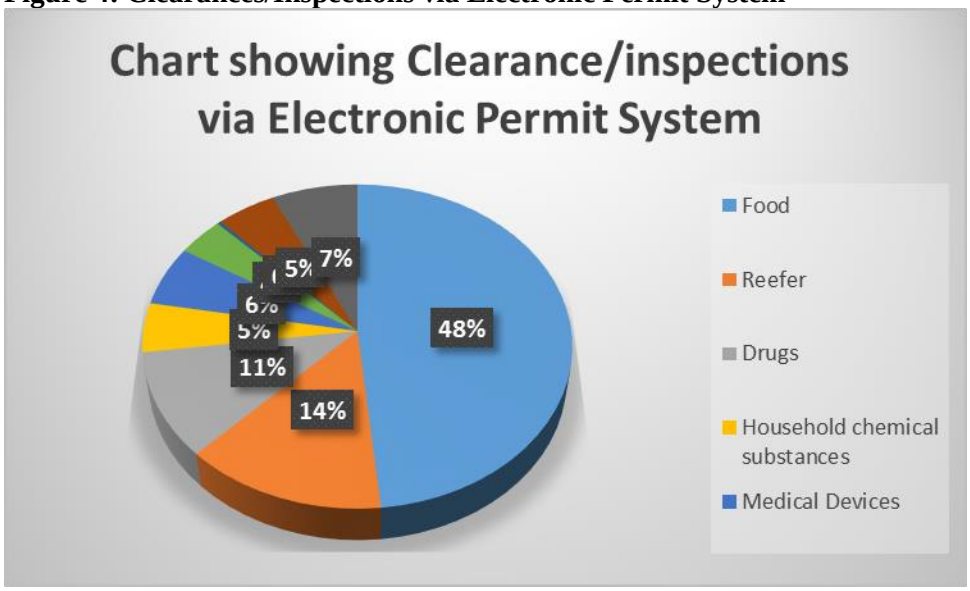

**Source: 2012 Import and Export Department Activities**

### 4.2 Inspections/Clearances

**INSPECTIONS/CLEARANCES**

Inspections/clearances of imported food and drug products carried out by the Department at Tema Port and KIA during the period under review as indicated in table 13.

**Figure 4: Clearances/Inspections via Electronic Permit System**

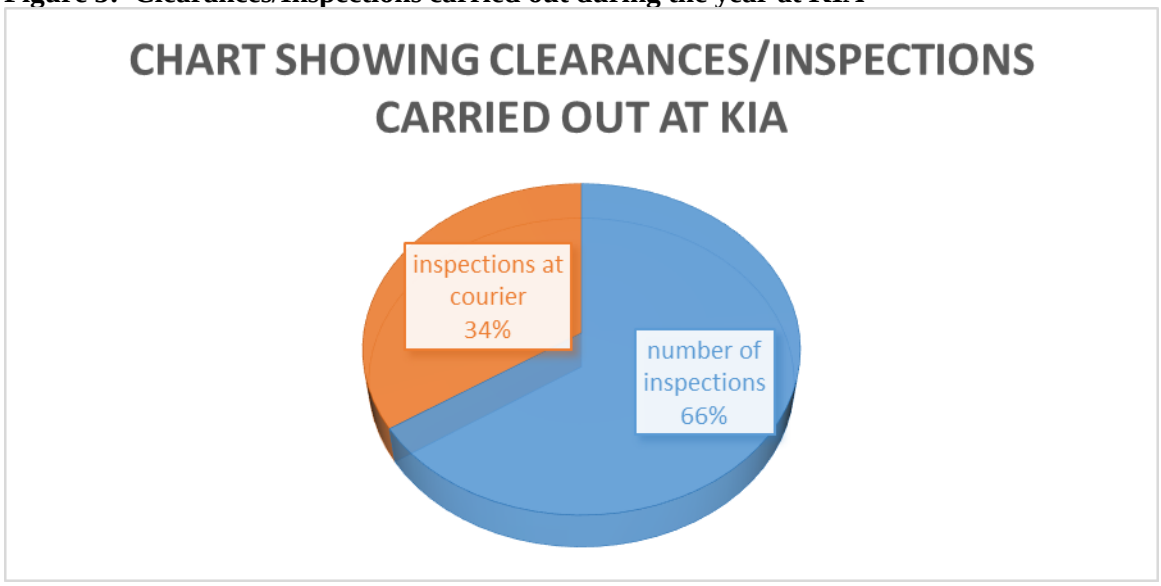



Source: 2012 Import and Export Control Activities

### 4.3 KIA Unit Operations

A total of 3,002 inspections were conducted at the KIA for the period under review. Inspections of samples of products brought into the country via courier were also conducted within the period under review. The monthly breakdowns of the inspections conducted are shown in table 14.

**Figure 5: Clearances/Inspections carried out during the year at KIA**




Source: 2012 Import and Export Control Department.

### 4.4 Cargo Tracking

The Pre-inspection Monitoring Unit of the Department were stalled for a period as a result of the malfunction of the GCNet system at the Tema Office.

### 4.5 Patrols at the Terminals

The Tema Office of the Department patrols the port daily to identify reefer vessels that have berthed at the wharf sites. Information gathered during the patrol is passed on to the team that inspects the reefer vessels. The various container terminals are also patrolled to identify specific containers for inspection.

### 4.6 Inspection of Reefer Containers and Vessels

During the period under review, a total of nine hundred and sixty one (961) reefer containers inspected. A total of one hundred and fifty-seven (157) reefer vessel inspections were carried out at the Tema port. The products were mainly frozen fish, chicken and fish meal. All consignments inspected were wholesome expect fish that was carried by M/V Sally Reefer part of which had gone bad due to leakage of water into one of the lower hatches. The receiver declined to receive it. It was thus re-exported. This took place in the first quarter.

### 4.7 Detention Unwholesome Food Destructions

During the 2012 operational year, the Department supervised destruction of several products including;

- 306 consignments/products were detained. 188 were food consignments/products whilst 124 were drugs, cosmetics, medical devices, household chemical substances.
- Most of the products were detained pending completion of registration/renewal of registration whilst others were detained pending correction of labelling.
- Others were detained for thorough inspection and sorting.
- All detentions were referred to the appropriate departments/regional offices.

## 5.0 Quality Control Laboratory Department

The Quality Control Laboratory provides laboratory services in the form of quality evaluation of Food, Drugs, Cosmetics and 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 microbial analysis of chemical and herbal drugs. The quality parameters employed are as established in standard compendia indicated in schedule IV of the Food and Drugs Law (PNDCL 305B). 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 three main Units namely:

- Physicochemical Unit
- Microbiological Unit and
- Medical Devices Unit

### 5.1 Physicochemical Unit

The Physicochemical Unit undertakes quality investigation by considering physical and chemical properties of the products. The products the Unit handles are mainly food and food related products, drugs (allopathic, herbal and veterinary), cosmetics and household chemical substances.

The Unit accepts samples from Drug Registration Department, Food Safety and Nutrition Department, Inspectorate Departments, Post-Market Surveillance Units, Port Offices and Zonal Offices. The Unit also receives samples from external organisations for analysis, such as Criminal Investigation Department (CID) of the Ghana Police Service, Custom Excise and Preventive Service (CEPS), Central Medical Stores (CMS) of Ghana Health Services, and the Pharmacy Board of Sierra Leone.

### 5.2 Microbiology Unit

The Microbiological Unit undertakes microbiological testing of samples including food and food products, water, non-alcoholic beverages, drugs, cosmetics, and herbal preparations.

The analytical tests include the determination of aerobic plate count, yeast, mould count, and coliform count. The determination of faecal streptococcus, pseudomonas as well as the detection and enumeration of pathogenic and toxigenic microbes such as Salmonella, Staphylococcus aureus, Escherichia coli, Clostridium perfringens, and Bacillus cereus in food, water, drug and cosmetic samples are some of the functions the Unit perform.

### 5.3 Medical Devices Unit

The Medical Devices Unit of the Quality Control Laboratory started operation in June 2004 following successful installation of the following equipment from Valendor, Sweden:

- Four Station Air Inflation Tester
- Electric Hole Tester
- Water Leakage Tester
- Tensile Testing Machine and Cutting Press
- Water Vacuum Bowl and Vacuum Bowl for package seal
- Aging Oven
- Mandrel and Digital Gauge and others

### 5.4 Extent of Performance and Achievements in Product Testing

The Department received a total of two thousand, four hundred and sixteen (2,416) samples for quality evaluation for the year under review. This represents a decrease of three hundred and ninety-nine (399) in comparison with the number of samples received in the previous year 2011 (2,815). These were made up of allopathic drugs (35.3%), cosmetics (9.5%), household chemical substances (5.3%), food (26.3%), herbal drugs (13.9%), medical devices (9.1%) and veterinary drugs (0.6%). Table 17 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 | 854 | 483 | 371 | 432 | 51 |
| Herbal Drugs | 335 | 91 | 244 | 39 | 52 |
| Veterinary Drugs | 15 | 15 | - | 15 | - |
| Food | 635 | 573 | 62 | 497 | 76 |
| Cosmetics | 229 | 208 | 21 | 187 | 21 |
| Household Chemical Substance | 128 | 118 | 10 | 101 | 17 |
| Medical Devices | 220 | 218 | 2 | 210 | 8 |
| **Total** | **2,416** | **1706** | **710** | **1481** | **225** |

Source: 2012 Laboratory Analysis

### 5.5 Projects Executed

In 2012, the fourth round of the United State Pharmacopeia quality Monitoring (USP/FDA PQM) Anti-Malaria project was completed in the third quarter of the year. Three hundred and seventy samples of antimalarial preparations on the market were sampled and screened with Minilabs. One hundred and sixty-five (165) of these samples were subjected to full monograph analysis. The observed failure rate of antimalarial preparations was 6.3%.

The first phase (round one) of testing of Analgesics commonly prescribed during malaria was also carried out-one hundred and eleven (111) samples were analysed out of which twenty-two (22)-(19.8%) failed.

The year also saw the first round of Quality Surveillance of Uterotonic preparations namely Oxytocin Injections and Ergometrine Maleate Preparations (Injections and Tablets). Out of the two hundred and seventy-Nine (279) analysed, one hundred and seventy-Eight (178) representing 63.7% failed.

The final reports of all the three (3) studies have been forwarded to Management for the necessary regulatory actions to be taken, and that has been carried out.

### 5.6 Chemical, and other laboratory Consumables

The Department received all the Chemicals it requested for the year 2012, however that of glassware, consumables and microbiology media were not delivered due to technicalities in the bidding (procurement) process.

### 5.7 Equipment

All the new equipment which was ordered for the Microbiology and Physicochemical Units was delivered in the month of December, 2011 and it was installed and qualified in the first quarter of 2012.

### 5.8 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

- A two (2) week training programme in Good Documentation Practices (GDP), UV, HPLC and Karl Fischer analysis, ISO 17025 requirements and Laboratory Safety from the 9$^{th}$-20$^{th}$ of January, 2012, organised by United States Pharmacopeia.

- A member attended training in compendia of Pharmaceutical Microbiological Testing at the United States Pharmacopeia (USP) Laboratories. Hyderabad, India from the 25th February-10th March, 2012
- A member also attended a workshop organised by UNFPA/WHO/FAMILY HEALTH 360 on Laboratory Quality Control for reproductive health products (28th February -2nd March, 2012).
- Workshop on Biosimilars: Science and Regulations organised by the ERA Consultancy (Europe)-Lagoes Nigeria 12th-13th March, 2012.
- West Africa Health Organisation (WHO)-Conference on Document Review as per ISO 17025 requirements, 16th-17th February, 2012 Ouagadougou-Burkina Faso.
- Workshop on Analytical Method Validation and Measurement of Uncertainty-organised by CDM Training solutions, South Africa from 26th to 29th March 2012, Accra.
- Up gradation of Food Testing Skills Food Processing Professionals-organised by Shriram Institute for Industrial Research India, from 1st-15th February, 2012, India.
- The Quality Assurance Unit conducted an In-House training in FT-IR analysis of Medicines for Twenty Three (23) Analysts in the Physico-Chemical Unit (Food and Drugs).
- The Head of Unit of the Quality Assurance Unit was sponsored by the Food and Drugs Authority to attend a two (2) week training course in Laboratory Management at the North West University in the Republic of South Africa.
- A member from Physico-Chemical Unit (Medicines) and a member from Quality Assurance Unit attended a two (2) day training workshop in ISO 17025 requirements in Laboratory Quality Management System at the Ghana Standards Authority.

**6. Regional Operations**

The FDA operates Regional Offices as part of its decentralization programme. This is to fulfil its mandate of regulating food, drugs, cosmetics, household chemical substances and medical devices to ensure its quality, safety and efficacy. In 2012, the FDA operated 9 Regional Offices that are 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
- 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 Volta regions.

Generally, the activities of the Regional Offices which are mainly operational cover the following areas:

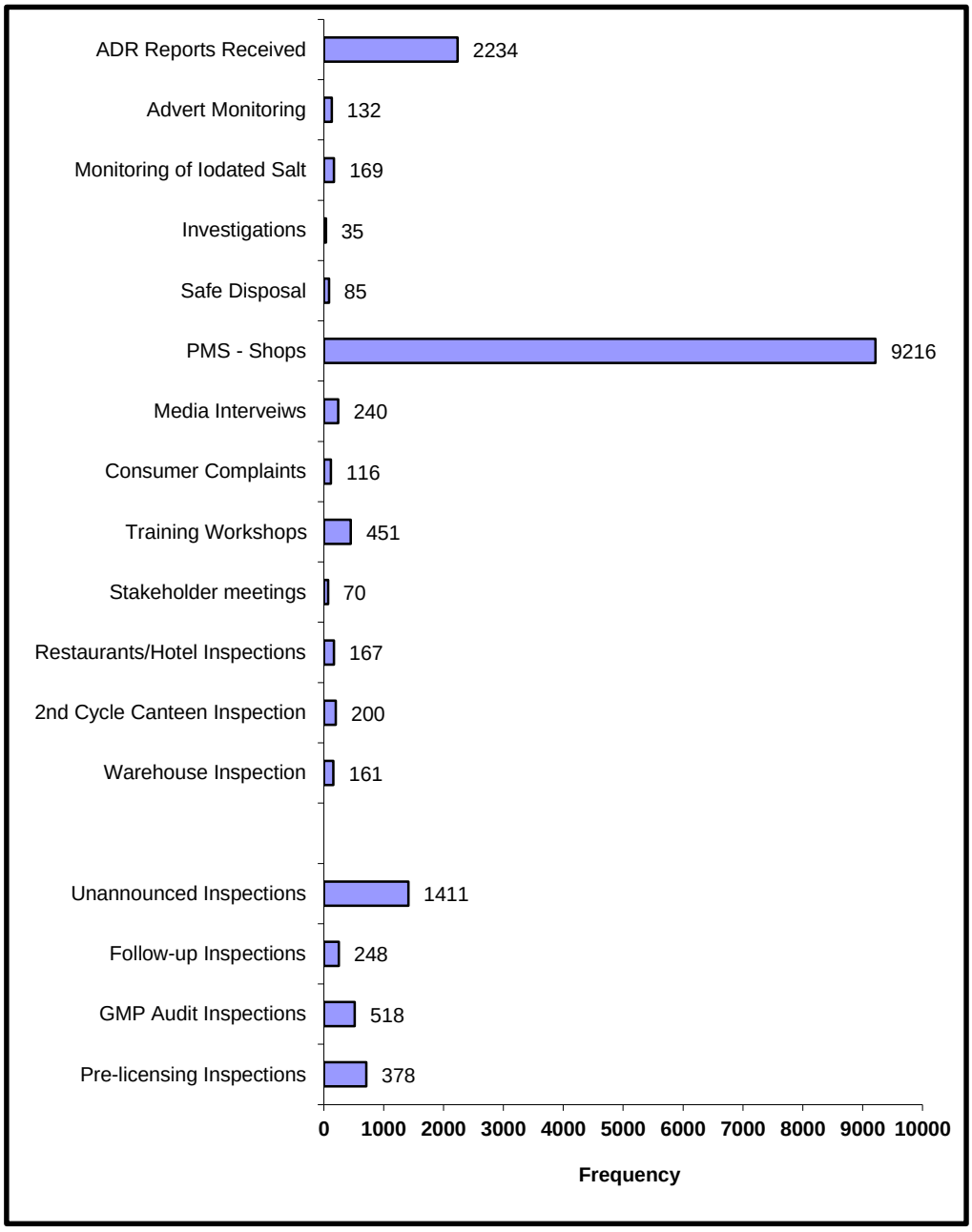
- Premises inspections.
- Carry out post-market surveillance exercise.
- Advert monitoring function
- Embark on consumer awareness and education programmes.
- Organise stakeholders meeting.
- Organise sensitization programmes, seminars, workshops, and training for all stakeholders in the food and drug 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 12 shows the combined summary of activities performed by the Regional Offices.

**Figure 6: Extent of Performance of Regional Operations.**




Source: 2012 Regional Operations

## 7. 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 management and administration (which includes administrative support to all Divisions and Departments), transport management, estates management and security, and procurement management.

The department generally facilitated the rigorous recruitment drive leading to an increase in staff numbers by 155 personnel.

### 7.1 Transport

Transportation plays a pivotal role in the running of any organisation. The Transport Unit was established in April 2009 and was headed by a Transport Officer.

The activities for the period are as follows:

- Implementation of transport management system.
- Improved the use of forms and logbooks by vehicles operators and users for better data collection.
- Assessment of vehicles performance using key performance indicators (KPI's).
- Record keeping and data collection has improved through the use of logbooks and other forms including computer software.
- Improved fuel consumption.
- Organization of training for Transport Management Unit staff.
- Improve the use of transport management tools such as the use of Vehicle log books, trip authority forms, planned preventive maintenance (PPM) etc.
- Routine Vehicle checks.
- Assessment of vehicle performance using the key performance indicators.
- Periodic TMU meetings.
- Insurance and renewal of Road-worthiness of all vehicles.
- Accident-free year due to improved supervision and training on road safety.

### 7.2. Estates

Within 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,

- Coordinated and facilitated the completion and occupation of the Head Office Building.
- Modern laboratory equipment procured to boost the capacity of the quality control laboratory in accordance with ISO 17025 requirements.
- Coordinated and facilitated the procurement of a new office accommodation for the Ashanti Regional Office.
- The construction of a befitting residential accommodation for the Chief Executive of the Food and Drugs Authority has commenced.

### 7.3 Procurement Unit

The Procurement Unit was established to ensure that internationally accepted standard procedures are followed in all the FDA procurement activities. This was done within the context of a national procurement code, Public Procurement Act 663 enacted in 2003. The main objective of the FDA procurement processes was to establish a system of procurement that is transparent, competitive, accountability and fairness.

The act sets out the legislative framework for public procurement in Ghana and defines official rules for the acquisition of Goods, Works and Services.

**Activities carried out in the year 2012**

- Completion and occupation of the Head Office Building.
- A new office accommodation was procured for the Ashanti Regional Office.
- Eleven (11) operational pick-ups were procured to boost operational activities
- Four (4) small capacity engine vehicles were procured for port operational activities
- Two (2) 30-Seater capacity buses were procured for the transportation of staff to and from work.

- 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.

**9. Projects, Research and Management Information System (PRMIS) Department**

The Projects, Research and Management Information System Unit (PRMIS) was set-up in November 2003 with limited scope to deal with the increasing Food and Drugs Authority (FDA) functions and work programmes including its decentralisation programmes with a few human resources. The scope and the capabilities of PRMIS Unit have grown apart from core information technology functions to include monitoring and evaluation functions to effectively manage the growing information needs of the FDA, which necessitated the change in status from a Unit level to a Departmental level in April 2010. This is to ensure an effective management of information and its technologies to maximise improvements in the FDA mission performance.

The mandate of the Department is 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.

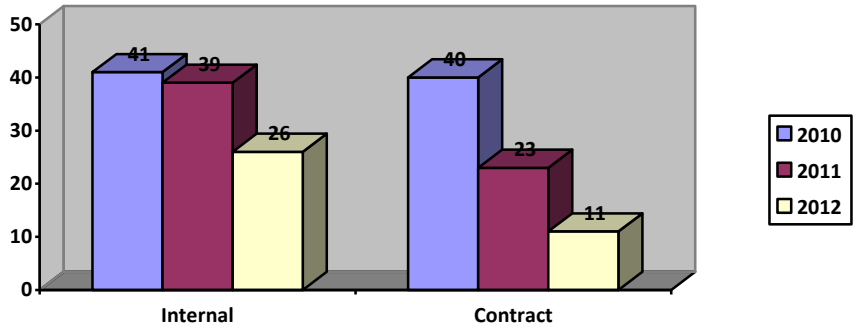
The overall performance of PRMIS Department was more than 92% of its programme of work to support regulation. The Department continued hosting the FDA website and deployed the corporate e-mail system across the FDA. The local area networks were enhanced to enable management of groups, network resources and users. There was the installation of a dedicated fibre optic connectivity of the internet access and connectivity to enhance fast information search and download. The Untangle software ver. 8.1 was updated to ver.9.3 to enable internet connectivity for over 184 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 was upgraded to accommodate FDA corporate e-mail service to the Regional Offices. The web server (DNS) was also updated from ver. 5.0 to ver. 6.0

The web portal was re-designed to accommodate new developments in regulation and to allow mobile, tablets internet access with the corporate e-mail.

During the year under review, the Department also developed two comprehensive software in-house to support Dispatch and Stores Unit, respectively. The Department also facilitated the installation of GCNet at the Takoradi and Elubo port Office respectively in collaboration with Ghana Community Network Limited (GCNet). The FDA, Ghana acquired new computer hardware systems, which are 140 desktop computers, 13 laptops, one (1) server, one (1) scanner and 50 printers for distribution to enhance the regulatory functions. The Department also facilitated the procuring of data capturing software for the Safety Monitoring Department (Pharmacovigilance system) which is yet to be installed.

**Computer Repairs**

**Figure 7: Total Number of IT Equipment (computer Hardware)**




## 10. Support Units under the Chief Executive Office

The Communication Unit, which report directly to the Chief Executive Officer (CEO) of the FDA, also perform duties that significantly support the functional activities of the FDA.

### 10.1 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 activities performed under the Communication Unit are as shown in table 18.

**Table 14: Activities conducted by the Communication and Public Education Unit**

| Area of Activity | 2012 | 2011 |
|---|---|---|
| Media Coverage | 5 | 30 |
| Media Interviews | 311 | 135 |
| Press Releases, Disclaimers, Notices | 23 | 40 |
| Visas Acquired (India, USA, Canada, South Africa, China, Netherlands, Germany, Morocco, Brazil, Norway | 84 | 84 |
| Tickets Purchased (India, USA, Canada, Switzerland, Lagos, Italy, Hungary, Singapore, Kenya, Norway) | 137 | 114 |
| Travel Insurance | 14 | 24 |
| Sponsored travels | 18 | 15 |
| **Total** | **592** | **442** |

Source: 2012 Communication Activities

### 10.1.0 Collaborative Functions with other Departments.

The Unit played a major role in the successful implementation of the following programmes:

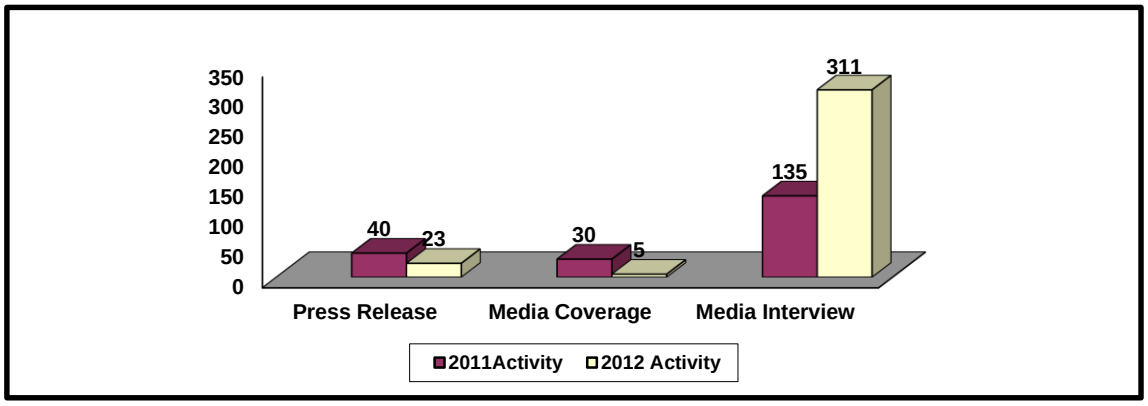
- Stakeholders Validation Workshop to discuss the Situational Analysis Report for Food Safety in the country.
- The World Food Day organized under the theme '**Safe and Adequate Food, Our Quality Responsibility'.**
- Police swoop on producers of wele at the Mallam market production site under unhygienic conditions**.**
- Police raid on unregistered Yafo Yafo and Kingdom Herbal products**.**
- Police swoop at Makola market to arrest sellers of fake rice branded products.
- Training for Sachet water producers.
- Destruction of seized expired, unregistered and unwholesome products.
- Food sensitization Programme for travelers within the country.

- Inspection of Street Food Vendors within the Accra Metropolis
- Destruction of seized turkey tail.

**10.1.1 Some of the major press releases that were issued also include the following;**

- Fraudulent Health Claims by some Health Facilities/Clinics in the Brong Ahafo and Ashanti Regions
- 780 Cartons of unwholesome fish being sold by WE2 Sea Company Ltd.
- Unregistered food supplements and medical devices being sold for the treatment of life threatening diseases by Jimon Company Ltd.
- Unwholesome chicken parts being sold by Sucatrade Company Ltd.
- Unregistered food supplements and medical devices being sold for the treatment of life threatening diseases by Jimon Company Ltd.
- Circulation of fake Hords Brown cocoa Powder.

**Figure 8: Comparison of Communication Activities 2011 & 2012**




Source: 2011&2012 communication data

**10.1.2 Human Resource Unit**

During the year under review, the FDA got financial clearance from the Ministry of Finance and Economic Planning to recruit personnel to fill existing vacancies. Fifty-five (55) Regulatory Officers II, five (5) Regulatory Officers I, two (2) Senior Regulatory Officers, one (1) Principal Regulatory Officer, two (2) Administrative Officers I, four (4) Administrative Officers II, ten

(10) Administrative Assistant, ten (10) drivers, twenty (20) Security officers, four (4) Artisans totalling 113. Nine (9) resignations with one (1) termination of appointment were recorded.

The FDA was migrated unto the SSSS and was successful despite the initial challenges encountered, and have duly paid the 2010 and 2011 SSSS salary arrears.

**Table 14: Summary of permanent staff**

| **Employee Categories** | **Total Staff Strength** |
|---|---|
| Permanent | 491 |
| Temporary | 24 |
| National Service Personnel | 65 |
| Seconded Staff | 13 |
| **Total** | **593** |

Source: 2012 Human Resource Data

**Future Direction**

The Food and Drugs Authority will continue to confront the challenges presented by the implementation of the Food and Drugs law, 1992 (PNDCL 305B) and its Amendment Act, 1996 (Act 523) as well as the Public Health Act 2012 Act 857. In particular, steps will be taken to reinforce the corporate identity of the FDA and reposition management for increased commitment to the mandate of the FDA.

With the promulgation of the Public Health Act 851 and the increased mandate and responsibilities, the FDA finds it strategic to restructure its operational divisions and upgrade key Departments and Units. This has being approved by the Governing Board and the following are;

Drugs Division is to be restructured into three new divisions:

- Drug Registration and Inspectorate Division
- Cosmetics, Medical Devises and Household Chemicals Division
- Safety Monitoring and Clinical Trials Division.

Food Division will also be restructured into:

- Food Inspectorate Division
- Food Safety Division

In this regard, the FDA's operational direction for 2013 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 Tema Port Office Complex
- Increase presence at the Border Posts.
- Increase fleet of operational vehicles to enhance 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.
- Construction of a permanent CEO's residence.
- Procurement of computers and IT accessories both hard and software.
- Procurement of Laboratory chemicals, glassware, microbiology media and equipment.
- The FDA's condition of service is in its final draft stage.
- Developing 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 the Accreditation as per ISO 17025 requirements.
- Constructing of a four-storey Office/Laboratory Building

**ANNEX A.1**

**FOOD AND DRUGS BOARD MANAGEMENT TEAM AND REGIONAL OFFICES**

**Strategic Management Team**

| | |
|---|---|
| **Chief Executive** | Dr Stephen Kwabena Opuni |
| **Head of Drug Division** | Mrs Akua Amartey (Acting) |
| **Head of Food Division** | Mr J. Odame Darkwah |
| **Head of Administration** | Mr Jones Ofosu |
| **Head of Finance** | Mrs Perpetual Tawiah |
| **Head of Quality Control Laboratory** | Mr Karikari Boateng |
| **Head of Project Research Management** | Mr Andrews Boadi |
| **Information Systems** | |

**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 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