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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 2010 saw the continuation of work to consolidate the institutional framework for the establishment of the Food and Drugs Board (FDB) 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 Food and Drugs Law 1992 (PNDCL 305B) and its amendment Act 523, 1996. The passage of Tobacco Control Bill and the revision of the Food and Drugs Law are still pending at the Parliament. Other policies and guidelines aimed at strengthening the FDB 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 FDB were initiated and steps were taken to review them.

During the year, a range of activities including consumer awareness programmes, 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, medical devices and premises inspections increased significantly during the year. Post market functions increased significantly especially on Herbal Medicinal products, which have grave consequences on public health and its implications for healthcare delivery. There was an improvement in the operations of the Zonal Offices over the previous year. The FDB continued its regulatory control of the exportation of palm oil to the European Union. Three Units of the FDB was upgraded to the Departmental level to enhance the regulatory functions of the FDB. The Units are Projects, Research and Management Information System Unit, Herbal Medicine Unit and Safety Monitoring Unit, respectively.

1. INTRODUCTION

This report covers the activities of the Food and Drugs Board performed during the year 2010.

The Food and Drugs Board was established by the Food and Drugs Law, 1992 (PNDCL 305B). This law has since been 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.

1.1 Background of Food and Drugs Board

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 Board is under the control and supervision of the Minister responsible for Health.

1.2 Functions of the Food and Drugs Board

The functions of the FDB as spelt out by law (PNDCL 305B) are as follows:

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

Without prejudice to the above, the Board 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 Board, 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 FDB with respect to ensuring their safety, quality and efficacy.

1.4 Vision

The vision of the Food and Drugs Board 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 Board 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 Board has set for itself the following goals:

The FDB 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.*

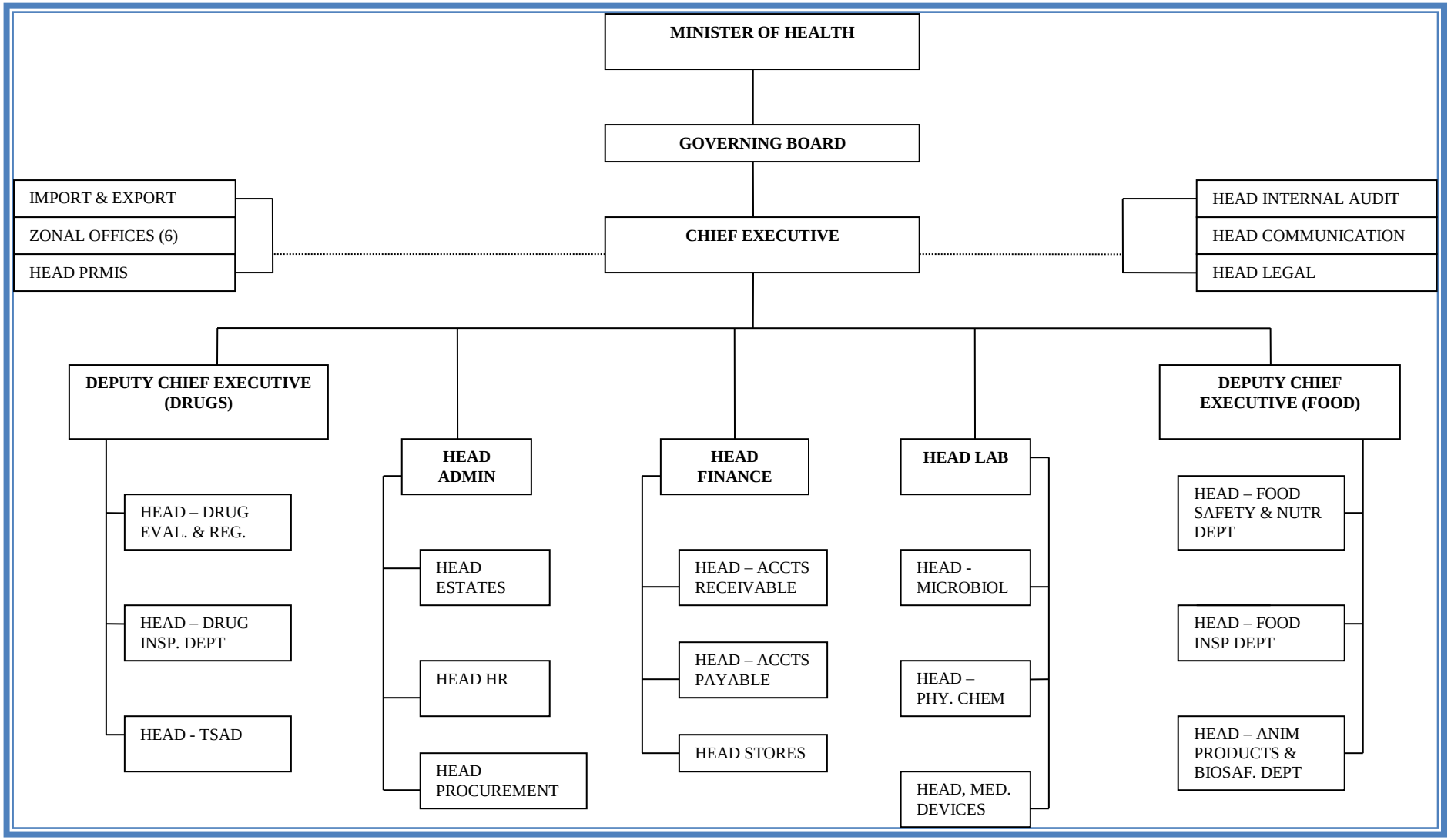
1.6 The Governing Board

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 FDB 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 Board
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.	To be nominated	Veterinary Services
8.	To be nominated	Crop Services, MOFA
9.	Dr George Ben Crentsil	Executive Director, Ghana Standards Board.
10.	Dr Kwaku Tano-Debrah	Dept. of Nutrition & food Science University of Ghana
11.	Ms Grace Issahaque.	Attorney General's Department.
12.	Dr Poku Adusei	Medical and Dental Council
13.	Mrs C. Ribeiro	Consumer Representative
14.	To be nominated	Consumer Representative
15.	Mr Kenneth Danso	Ghana Association of Traditional Healers

1.7 The Organisational Structure

The current organogram of the FDB is indicated on page 5.


MINISTER OF HEALTH
GOVERNING BOARD
CHIEF EXECUTIVE
IMPORT & EXPORT
ZONAL OFFICES (6)
HEAD PRMIS
HEAD INTERNAL AUDIT
HEAD COMMUNICATION
HEAD LEGAL
DEPUTY CHIEF EXECUTIVE (DRUGS)
HEAD – DRUG EVAL. & REG.
HEAD – DRUG INSP. DEPT
HEAD - TSAD
HEAD ADMIN
HEAD ESTATES
HEAD HR
HEAD PROCUREMENT
HEAD FINANCE
HEAD – ACCTS RECEIVABLE
HEAD – ACCTS PAYABLE
HEAD STORES
HEAD LAB
HEAD - MICROBIOL
HEAD – PHY. CHEM
HEAD, MED. DEVICES
DEPUTY CHIEF EXECUTIVE (FOOD)
HEAD – FOOD SAFETY & NUTR DEPT
HEAD – FOOD INSP DEPT
HEAD – ANIM PRODUCTS & BIOSAF. DEPT

In summary, the FDB 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 FDB, 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 2010.

2.0 DRUGS DIVISION

The Drug Division contributes to the attainment of the functions of the Food and Drugs Board for safeguarding public health by ensuring that all medicines on the market meet appropriate standards of safety, efficacy, and quality. These functions are carry 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.

In April 2010, two Units under the Drugs Division were upgraded to the departmental level to make the number of specialised Departments under the Division to five. The two operational Units that were upgraded to the departmental status were Herbal Medicine Unit and Safety Monitoring Unit, respectively.

2.1 Drug Evaluation and Registration Department

The Drug Evaluation and Registration Department of the Food and Drugs Board 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 FDB take the appropriate decision.

- Maintenance of SIAMED database (WHO application software for medicines registration).
- To conduct product application reviews.

During the year under review, 624 product applications were submitted to the Medicines Evaluation and Registration Unit. This total number was made up of 494 imported allopathic drugs (human), 117 locally manufactured allopathic drugs (humans) and 13 imported allopathic drugs for veterinary use. 495 applications were submitted for product re-registration. This figure was made up of 390 imported allopathic drugs for humans, 1 veterinary application, and 104 locally manufactured allopathic drugs (humans). 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**	
	Foreign	Local	Foreign	Local
Allopathic Drugs (Human)	494	117	402	84
Veterinary Drugs	13	-	8	-
Vaccines	-	-	-	-
Total	**507**	**117**	**410**	**84**

Source: Medicine Evaluation and Registration Unit, 2010

Table 2: Summary of applications received for re-registration

Product Type	**Applications Received**		**Number Re-registered**	
	Foreign	Local	Foreign	Local
Allopathic Drugs (Human)	390	104	270	55
Veterinary Drugs	1	-	5	-
Vaccines	-	-	-	-
Total	**391**	**104**	**275**	**55**

Source: Medicines Evaluation and Registration Unit, 2010.

2.1.1.1 Product Registration and Document Reviews

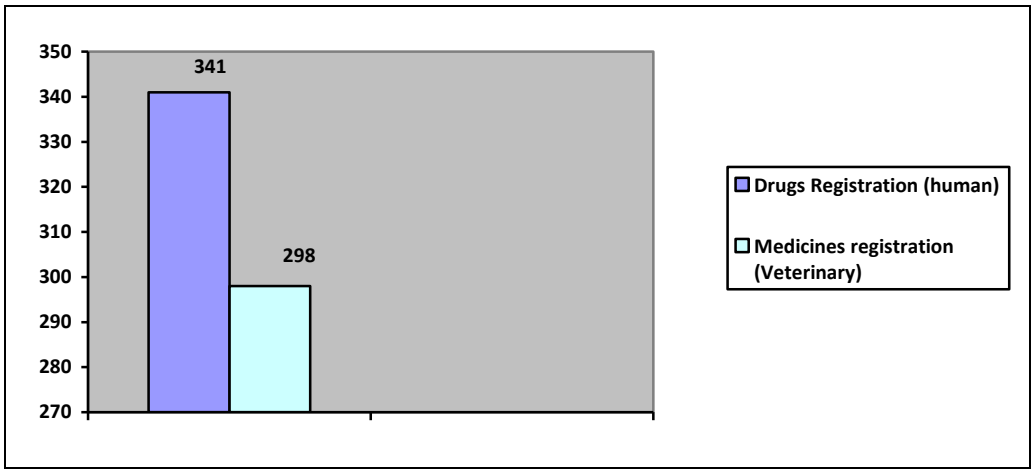
In 2010, eight (8) dossier evaluations and four (4) product registration meetings were held. The following are the details of the documentation, which were evaluated at the dossier evaluation meetings**.**

Table 3: Product Registration and Document reviews

TYPE OF DOCUMENT	NUMBER EVALUATED
Imported and local Allopathic Drug Registration (for Human)	341
Allopathic drugs additional documentation	298
Imported allopathic medicines registration (veterinary)	-
Total	**639**

Source: Medicine Evaluation and Registration Unit, 2010

Figure: 1 **Type of Dossiers Evaluated and Processed**



Source: Medicine Evaluation and Registration Unit, 2010

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 five hundred and eighty-eight (588) applications were submitted for registration. Out of the total number of applications received, two hundred and sixty eight (268) applications were for cosmetics, two hundred and seventeen (217) were for household chemical substances and One hundred and three (103) applications for medical devices, respectively. The Unit was able to approve two hundred and twenty-eight (228) cosmetics products and deferred forty (40), due to unavailability of laboratory results, whilst one hundred and eighty-five (185) household Chemicals were given approval and thirty-two (32) were deferred. Two hundred and

thirty one (231) Medical Devices were approved including approval from the previous year.

Table 4 and Figure 2 respectively, show the number of products received and registered during the year under review.

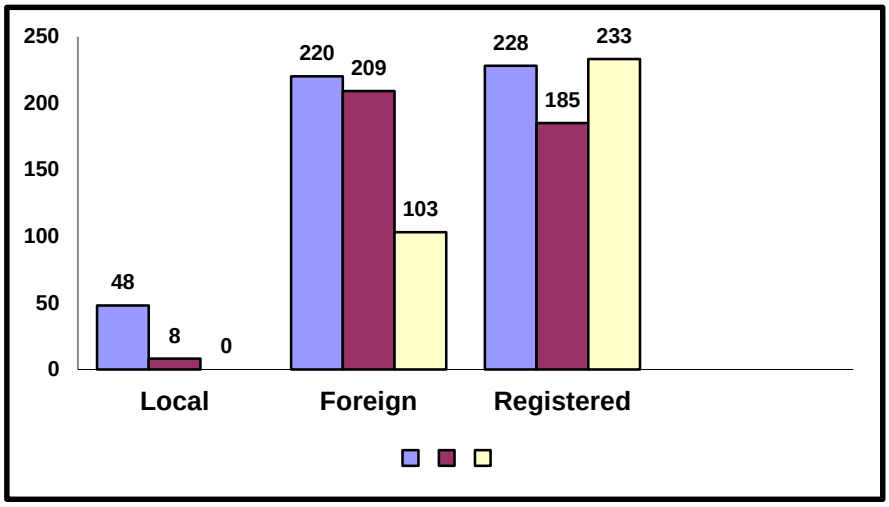
Table 4: Summary of types of products received and registered

Product Type	**Applications Received**		**Number Registered**	
	Foreign	Local	Foreign	Local
Cosmetics	220	48	215	13
Household Chemicals	209	8	54	131
Medical Devices	103	-	231*(130)	2
Total	**532**	**56**	**500**	**146**

* 130 products from the previous year were approved in addition to the total received and approved in 2010

Source: Cosmetics, Medical Device and Household Chemical Substance Unit, 2010.

Figure 2: Product Types Received and registered.



Source: Cosmetics, Medical Device and Household Chemical Substance Unit, 2010

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 two hundred and thirty-six (236) herbal medicine applications were received including re-registration applications and one hundred and fifty-eight (158) were approved.

A total number of eighty-seven (87) food supplement applications were received and one hundred and sixty-three (163) food supplements approved including 76 applications from the previous year.

The FDB participated in the 4th Annual meeting of the International Regulatory Cooperation for Herbal Medicines (IRCH) of the World Health Organization (WHO) in Dubai, UAE from 8th-10th June 2010. The FDB also participated in the 14th International Conference of Drug Regulatory Authorities (ICDRA) at Singapore from 29 Nov-3rd - December 2010. In 2010, the summary of activities conducted are summarized in table 5

Table 5: Summary of herbal products received and registered

	Applications Received		**Number Registered**	
	Foreign	Local	Foreign	Local
Herbal Products for Registration	9	117	33	69
Herbal Products for Re-registration	26	84	20	36
Food Supplement	87	-	163*(76)	-
Total	**122**	**201**	**216**	**105**

*76 from 2009 were approved in addition to the products received and approved in 2010. Source Herbal Medicine Registration Activities, 2010

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 report (ADR) / 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 (TAC) for safety monitoring meetings
- Identify areas for training and provide training for healthcare professionals and public awareness

2.3.2 Clinical Trials Assessment Unit

The Unit evaluates clinical trial applications with support from the Drug Evaluation and Registration Department with the following functions:

- 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
- Liaise with Drugs Inspectorate Department to conduct Good Clinical Practice Inspections
- Coordinate TAC clinical trial meetings

2.3.3 Research and Risk Management Unit

The Unit collaborates with public health programmes with the following functions:

- 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 meeting were held and fourteen (14) sensitization lectures were conducted.

The summaries of activities conducted in 2010 are summarized in table 6.

Table 6: Summary of activities conducted by Safety Monitoring Department

Activities	Number
ADR Reports Received	257
Suspected Product Quality Reports	1
AEFI Reports Received	1094
Reports forwarded to TAC	171
Reports completely assessed by TAC	253
Reports committed by the FDB to W.H.O Pharmacovigilance (Vigiflow)	326

Source: Safety Monitoring Activities, 2010

2.3.5 Training/Workshop

Sensitization workshop was conducted for Six hundred (600) health professionals about optimizing efficacy of therapeutic interventions and ensuring patient safety.

The Department provided training for two hundred (200) Licensed Chemical Sellers and Community Pharmacists in the Central, Western and Greater Accra Regions on Drug Safety awareness.

2.3.6 Conferences and Meeting

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

- Hosted the 33rd Annual meeting of National Centres Participating in the WHO Programme for International Drug Monitoring Meeting from 31st October to 3rd November 2010.
- Participated in the 10th International Society of Pharmacovigilance (ISoP) meeting held from the 3rd to 6th November 2010
- A member of staff participated in the Good Clinical Practice (GCP) inspectors training course in London.
- A member of staff participated in the training on Practical Guide for Pharmacovigilance: Clinical Trials and Post marketing in South Africa held from the 11th-13th August 2010.
- 2 members of staff participated in the West Africa Health Organisation (WAHO) workshop to review and strengthen the implementation of National

Pharmacovigilance systems in Economic Community of West Africa States (ECOWAS).

2.3.6 Safety Communications

During the year under review, the Department dealt with the following Safety Communications:

1. An alert relating to the sale and distribution of unregistered Vit. K3 Injection, which was distributed to healthcare institutions. Healthcare professionals nationwide were informed about the risks associated with the use of Vit. K3 and to avoid the use of the product.
2. Recalled and withdrew some batches of Tylenol Arthritis Tablets by the manufacturer, McNeil Consumer Healthcare.
3. Review of the safety of Metamizole sodium: communication of the Technical Advisory Committee (TAC) of Safety Monitoring recommendation on the use of metamizole sodium.
4. Restrictions on the use of over-the-counter cold and cough preparations in children: follow-up to an earlier communication and the recommendation that these products should not be used in children less than 5 years of age.
5. Suspension of Marketing Authorisation of Rosiglitazone containing Anti-diabetes medicines: issued to all healthcare professionals.
6. Safety information on sibutramine: recommendation by European Medicine Agency (EMEA) to suspend this product and United State, Food and Drugs Administration's (FDA) recommendation to amend the label to include the risk associated with the use of the product in patients with cardiovascular events.

2.4 Drug Inspectorate Department

The Drug Inspectorate Department of the Food and Drugs Board 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).

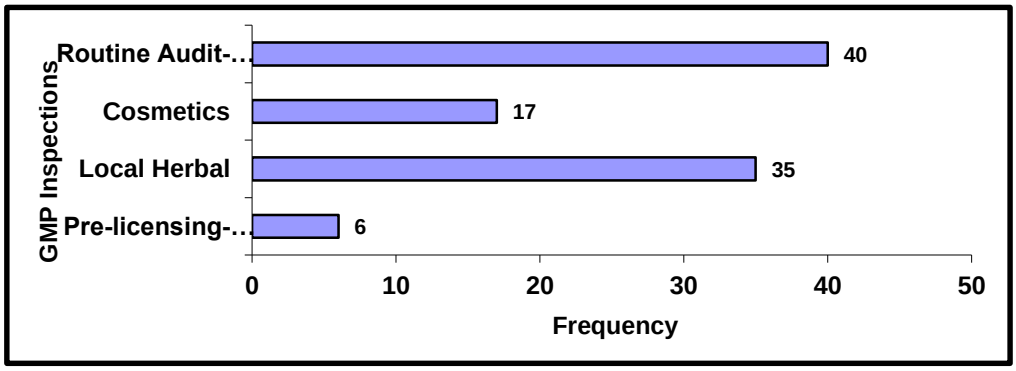
2.4.1 Drug Premises Inspection Unit

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.

The Unit was able to conduct routine audit inspections in 49 manufacturing companies that were registered and generally, the findings of the inspections indicated improvement in Good Manufacturing Practice. Figure 3 shows the routine inspections conducted in local allopathic, herbal, and cosmetics manufacturing plants.

Figure 3: Summary of local GMP inspections conducted



Source: 2010 Drug Inspectorate activities

2.4.1.1 External GMP Audit Inspections

Overseas GMP audit inspections of Pharmaceutical Companies carrying out business in Ghana were carried out during the period under review. In all, 40 pharmaceutical manufacturing facilities were inspected and all were found to be GMP compliant.

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. The Unit also monitors medicine adverts. A total of 238 applications were vetted within the year 2010, 181 were approved, 5 were rejected, 17 were deferred and 3 are pending.

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 are 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.

2.4.4 Enforcement Activities of the Department

In 2010, the task force of the FDB embarked on various swoops to check on non-compliant medicinal products from the Ghanaian Market. The outcome of the operation was that many medicinal products were found to contain no active pharmaceutical ingredients whiles others were found to contain either wrong active ingredients that are harmful to human health or were not registered at all with the FDB and that their quality, safety and efficacy could not be ascertained.

The following regulatory actions were taken against the perpetrators, an administrative fine was imposed, products were seized and destroyed and the company's facility closed down.

Table 7: Summary of task force activities

Origin of Drug Sample / Name of Facility	Medicine Name	Name of Manufacturer	Country of Origin	Activity	Overall Conclusion/outcome
Darose Pharmacy Royal Pharmacy Adepa Pharmacy Sarkuff Pharmacy Biakoye Pharmacy	Ventolin Evohaler and Syrup (Allen & Handburys)	Allen & Hanburys	UK	Products seized from identified shops dealing in the suspected article. Product being distributed by Ernest Chemist, Royal Dach Pharmacy and Inter Pharmacy	Seized products disposed off safely.
VicDoris Pharm.	CIPRO-DOR 500mg	Shijazhuang Pharm group.	China	Product not registered with FDB Company tasked to recall the products from the market and recalled products were safely disposed off.	Company initiate steps to register product. Seized products disposed off safely Administrative fine imposed on company.
	CLAVU-DOR 625mg TABS	Shandong Reyoung Pharms.	China		
Okaishie Market	Ghandour Cosmetics-elitis, lune d'ete, lomani and cigar natural spray	Source of beauty cosmetics co. ltd.		Products seized from identified shops dealing in the suspected article.	Seized products disposed off safely.
Kintampo Municipal Hospital	Artine (Artemether Lumefantrine tablets)	Ambica Pharma sale, Mumbai	India	Products seized and samples submitted for laboratory analysis	Product is not registered, seized product disposed off safely.
Vitamin K^3 injection-kemin 3				Product not registered with the FDB. Product seized and disposed off safely.	Administrative charge imposed.
Meilun Company Limited Ghana	Hou Ji Ling capsules, Su Gang Ning capsules Tummycare capsules wet tissue (men) wet tissue (women) Aloe Sanitary Napkin refreshing wet wipe	Meilun Company	China	Products disposed off safely after establishing that the products were not registered. Samples submitted for complete laboratory analysis Closure of facility.	Opening of Facility after company furnished the FDB with supporting document to prove separation of residence from the operating facility and also taken steps to bring the facility into compliance. Company initiate moves to register products administrative fine.
Accra Metropolis	Sex Enhancing Drugs (Aphrodisiacs) 1. Black superman 2. Beautiful penis augments	Unknown	China	Series of swoop conducted to cause seizure and apprehension of dealers where applicable. Arrested dealers were arraigned before the court, samples submitted to the FDB laboratory for	Seized products disposed off safely. Arrested dealers arraigned before court. Public education exercise via press release by FDB Investigation on-going.

	3. Big penis 4. African iron rod 5. Great penis 6. Black butterfly-1200mg 7. Lonely Girl 8. Max-Hero 9. Sex Lovewarrior 10. Good Man 11. Bed War 12. Magic Man 13. Aphrodisiac Milk 14. Jaguar Power 15. Gerrmany Kim fox 16. Playboy Bunny girl			analysis. Result indicated that the products contains lead, etc.	

Source: Task force activities, 2010

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 FDB with advice of receipt, annual returns, and the requisitions for the ensuing year. The FDB also receives multilateral chemical reporting notification forms for endorsement in connection with the importation and control of precursors. The FDB 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 2010, the Department vetted and issued 62 import permits for controlled substances. 58 advice of receipt were received. 78 returns on utilised controlled substances were monitored. 33 export authorisations endorsed and confirmed. Export authorisation was received before consignments reached the country.

Tobacco products permit granted in 2010 were 32.

3 FOOD DIVISION

The Food Division contributes to the achievement of the goals of the Food and Drugs Board 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 produced food products are of good quality and wholesome.

The activities of the Food Division are carried out by Food Safety and Nutrition Department, Food Inspectorate Department and Animal Products and Biosafety Department and these are supported by eight (8) operational units.

3.1 Food Safety and Nutrition Department

The Food Safety and Nutrition Department is made up of the following operational Units:

- Food Evaluation and Registration Unit
- Food Safety and Management Unit

3.1.1 Food Evaluation and Registration Unit

The principal functions of the Unit include:

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

In 2010, a total number of 888 applications were considered for registration. Out of this number, 366 representing 41.2% were locally manufactured whilst 522 representing 58.8% were imported (foreign). Table 8 gives the summary of food products submitted and registered by the Unit.

Table 8: Summary of food products submitted and registered

Product Category	Imported (Foreign)	Registered (Foreign)	Locally Manufactured	Registered (Locally)
Drinks	188	103	90	60
Bakery Products	64	18	9	11
Fats and Oils and Emulsion	40	40	0	0
Condiments and Spices	10	5	4	4
Soups and Sauces	3	1	9	5
Confectionery	35	2	16	10
Packaged Water	0	0	198	249
Diary and Diary Products	34	10	11	5
Sugar and Sugar Products	1	2	2	5
Additives	7	22	2	0
Roots and Tubers	2	5	1	0
Fruits	6	0	0	0
Cereals	65	30	17	19
Vegetables	38	6	5	2
Animal Feed	10	11	1	0
Fish/Fish Product	12	10	1	1
Meat and Meat Products	7	1	0	1
Total	**522**	**266**	**366**	**372**

Source: Food Registration Activities, 2010. *Including 2009 approvals

During the year under review, 250 products were deferred for the following reasons:

- Incomplete address of manufacture/agent
- Absence of name & address of Manufacturer/agent
- No Country of origin
- No date of manufacture/ minimum durability
- No batch number
- Misleading labelling/claims
- No net weight
- Ingredients not specified
- Failed laboratory results

- Unsubstantiated claims on labels
- Labelling ink not indelible
- Inadequate Certificates of Analyses.

3.1.1.1 Group Registration

An evaluation was carried out from Evergreen Supermarket, Great wall Ventures and Imexco Ghana Limited under the Group Registration exercise at the premises of the companies.

3.1.1.2 Training on Food labeling

Two Staff members of the Department and the Unit Head attended a training programme on food labelling at the Food and Drugs Administration (FDA) in the United State of America. This was to understudy the FDA's food regulation with emphasis on Food labelling in order to help upgrade food labelling evaluation in the Unit.

3.1.1.3 Training on Evaluation of Labels and Certificates of Analysis

During the first quarter, all the members of the Registration Unit attended a training Programme, which sought to enhance the knowledge on the evaluation of labels and certificates of Analyses.

3.1.1.4 Site Verification

The following companies, namely United Africa Company (UAC) in Nigeria, Wyeth Nutritionals in Ireland, and Tianjin Hongbao in China, were respectively, audited in accordance with Good Manufacturing Practices. They were all GMP compliant.

3.1.2 Food Safety Management Unit

The Food Safety Management Unit (FSMU) has been actively involved in the execution of the following functions:

- Organisation of in-house training for staff.

- Inspection of Food Safety Management Systems in the Food Service Industry.
- Assisting the Food Service Industry to implement Food Safety Management Systems.
- Public Education on Food safety Issues.
- Cooperative programs with state and local governments.
- Regulatory and research programs to address health risks associated with food borne chemical and biological contamination.
- International Food Standard and Safety harmonisation efforts.

In 2010, the Unit conducted Food Audit in a number of restaurants and hotels in Accra – Tema Metropolis. Out of 284 facilities audited, 163 were recommended, 121 were not recommended. On food hygiene permits, 59 facilities were issued with food hygiene permits. 154 street food vendors were also trained, in the Ashiaman Municipality and the Tema Metropolis, respectively. This exercise will be intensified in 2011 for nationwide training for street vendors. 22 food safety and hygiene awareness programme for private basic schools in the Greater Accra Region were organised.

3.1.2.1 Courses/Seminars/ Conferences Attended

As part of building capacity, some staff members of the Unit attended series of seminars and conferences as follows:

- Six newly recruited members of the Unit attended a training programme on (HACCP) and auditing at T.C. Corquaye Conference Room at the Head office.
- One member of the Unit attended a Food Safety Management Training Seminar in China.
- The Unit Head attended the World Food Day weekly planning committee meetings at the Ministry of Food and Agriculture.
- Two members of the Unit attended the inauguration of the National Fruit Fly committee at Alisa Hotel, Accra. A member of staff also attended a National Food Safety Policy Technical Task Team meeting at T.C. Corquaye Conference Room at the Head office.

- The Unit Head attend the 32nd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses. The venue was Santiago, Chile.

3.2 Food Inspectorate Department

The Food Inspectorate Department is one of the three Departments making up the Food Division of the FDB. 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.
- Training of stakeholders in relevant areas of the Food Law.
- Enforce compliance to Breast Feeding Code.

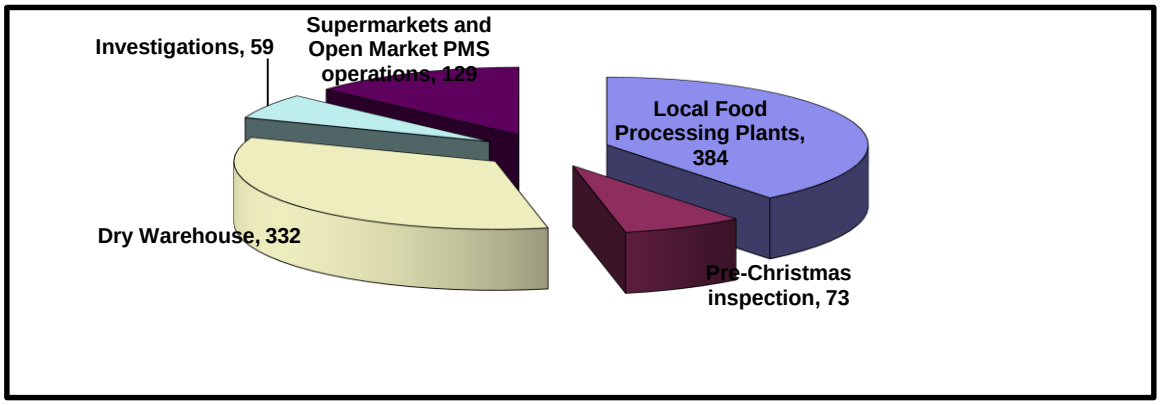
3.2.2 Food Premises Inspection Unit

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, 977 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 7 indicates the summary of frequency of inspections conducted in 2010 at the various food plants.

Figure4: Premises Inspections Conducted



Source: 2010 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.

In the course of 2010, the Department embarked on three swoops on Bells Olive Oil, Star Kist Tuna in Vegetable and Sam's Ice Cream Lollipop. All the products were seized and destroyed.

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.
- 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 audited 22 companies.

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. One hundred and three (103) samples of palm oil intended for export were screened and found to be free of Sudan dye.

3.2.3.3 Management of Food Alert

During the year under review, 3 alerts on Sudan-dye adulterated palm oil were received. The adulterated samples did not pass through the Food and Drugs Board for clearance before export.

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 95 checkpoints, 22 markets in Greater Accra to monitor the iodation status of salt sold and 113 permits were issued for non-iodated salt within the country and 683 certificates of Manufacture and Free Sale were issued for the transport of salt outside the country.

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 2010, thirty four (34) factory visits were made and seventy (70) samples were taken from the factories for analysis.

3.2.3.6 Nationwide Post-Market Surveillance/Sampling of wheat flour and vegetable oil.

Four hundred (400) samples of flour and vegetable oil were collected for laboratory analysis from retail outlets and markets nationwide for Vitamin A and Iron analysis. Out of the total collected, two hundred and eighty were analysed. 28.6% of the samples analysed did not meet the prescribed standard whilst 71.4% were satisfactory. The objective of the sampling was to provide accurate figures on the availability of fortified products on the Ghanaian Market.

3.2.3.7 Supervision on unwholesome Food Destructions Operations

In 2010, 39 applications were received, four (4) mandatory and 35 voluntary, thirty six (36) destruction supervised, three (3) awaiting confirmation destruction date from applicants.

3.3 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;

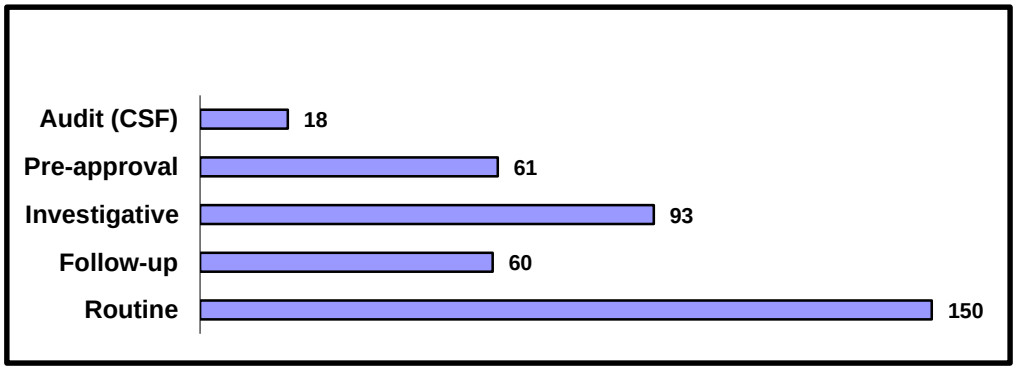
- Animal Products Unit (APU)
- Feed Safety Unit (FSU), and
- Biosafety Unit (BU)

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.

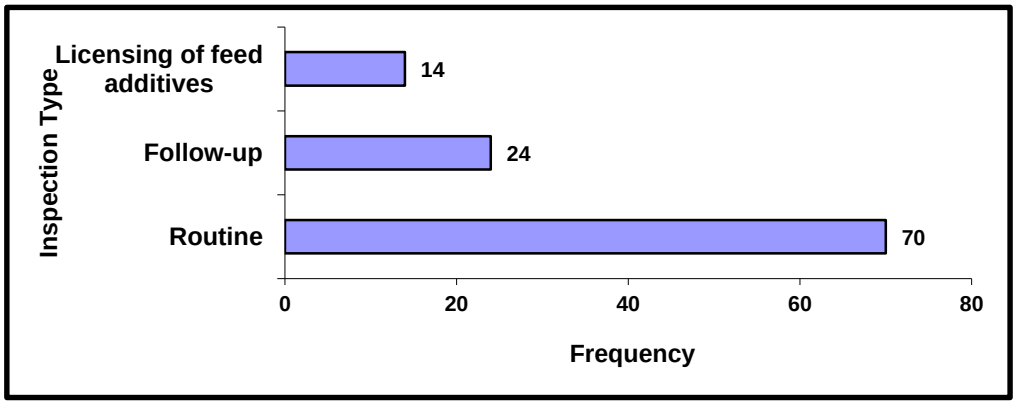
In 2010, the types of inspections the Department conducted are shown in figure 5 and figure 6, respectively.

Figure5: Summary of type and frequency of inspections conducted



Source: 2010 Inspections of Animal and Biosafety Activities.

Figure6: Summary of Feed Mills Premises Inspections conducted



Source: 2010 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.

3.3.1.1 Capacity Building

During the year under review,

- Two members of the Department attended a Stewardship Awareness Creation workshop organised by Africa Biosafety Network of Expertise (ABNE) with support from Syngenta foundation and FARA (Forum for Agriculture Research in Africa). Three officers also attended a training program on Confined Field Trails (CFTs) for Genetically Modified Crops: A Theoretical and Practical Course for Regulators, Applicants, Reviewers and Inspectors of CFTs.
- Two officers received training; one on Environmental Biosafety, and the second on the safety of Foods including Genetically Modified Food.
- One Officer went on a Regulatory Study Tour to South Africa on Biosafety.
- One officer had a Biosafety Internship Program with the South Africa regulatory authority.
- One member of the Department attended a one-month course in China on Feed Safety

3.3.1.2 Articles for Public Education

The Department was able to published one article on “fresh meat handling in Ghana”.

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 Zonal 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

The Permit (GCNet) Unit of the Department received a total of 9,924 permit applications in 2010. The details are indicated below;

Table 9: Permit Applications received by the Permit (GCNet) Unit

PERMIT CATEGORY	NUMBER OF PERMITS	REMARKS
Applications	9,924	From Agents/importers
Provisionally approved	7,546	Products duly registered and valid
Rejected	2,011	Mostly unregistered products, others to be sent to different MDAs
Processed narcotics	72	

4.2 Inspections/Clearances

Inspections/clearances of imported food and drugs products carried out by the Department, at both the Tema Port and the KIA during the year is indicated in table 10.

Table 10: Clearances/Inspections via Electronic Permit System

Month	Clearances/Inspections Made						
	Food	Drugs	Household chemical substances	Cosmetics	Medical Device	Tobacco	Total
January	371	356	50	15	7	3	**802**
February	317	300	33	17	9	2	**678**
March	402	314	56	13	11	-	**796**
April	394	330	43	29	18	2	**816**
May	400	370	59	20	17	-	**866**
June	456	320	49	31	12	2	**870**
July	501	351	58	30	24	1	**965**
August	377	363	62	41	19	1	**863**
September	338	351	47	29	15	-	**780**
October	420	150	31	43	43	2	**689**
November	470	140	19	43	50	1	**723**
December	515	180	35	45	53	3	**831**
Total	**4,961**	**3,525**	**542**	**356**	**278**	**17**	**9,679**

Source: 2010 Import and Export Control Activities

4.3 KIA Unit Operations

A total of 2,720 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 11.

Table 11: Clearances/Inspections carried out during the year at KIA

MONTH	NUMBER OF INSPECTIONS	INSPECTIONS AT COURIER
January	118	44
February	121	41
March	153	46
April	177	55
May	168	56
June	183	62
July	185	64
August	184	56
September	196	50
October	232	36
November	203	45
December	212	33
Total	**2,132**	**588**

Source: 2010 KIA Unit Operations

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 Frozen Animal Products

During the period under review, a total of one hundred and four (104) reefer vessel inspections were carried out at the Tema port. The products were mainly frozen fish, chicken and fish meal. All the inspections conducted indicated that the cold chain of the products had not been compromised and the products were in good condition for human consumption.

4.7 Unwholesome Food Destructions

During the 2010 operational year, the Department supervised destruction of several products including;

- Three (3) containers of frozen turkey tails imported by Binamy Ltd.
- Two thousand five hundred cartons of unwholesome chicken thighs and wings belonging to Cocas Impex Ghana Ltd and Five hundred cartons of unwholesome chicken gizzard belonging to Servister Ltd.
- Four tonnes of tomato pastes concentrate belonging to Trusty Foods Ghana Limited.

4.8 Coordination of Other Points of Entry/Exit

The Head of Department went on a three-day working visit to the Takoradi Zonal office and Elubo post to assess the level of importation/exportation made through those routes as well as the support that the Takoradi office will require to adequately control imports

and exports. The Takoradi office has since had quite a significant increase in revenue generated from control of imports and exports. As a follow-up, the Department in conjunction with PRMIS Department will hold a training program for the Takoradi office in 2011.

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 FDB 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 three thousand two hundred nineteen (3,219) samples for quality evaluation for the year under review. This represents an increase of four hundred and fifty-two (452), representing (16.34%) in comparison with the number of samples received in the previous year 2009 (2,767). These were made up of allopathic drugs (55.4%), cosmetics (89.2%), household chemical substances (69.0%), food (88.5%), herbal drugs (76.3%), medical devices (99.5%) and veterinary drugs (100%).

Table 12 gives the summary of product categories received for the various analytical tests.

Table 12: Summary of product categories received and analysed

Sample Category	Received	Analysed	Not Analysed	Passed	Failed
Allopathic Drugs	1378	763	615	691	72
Herbal Drugs	371	211	160	161	50
Veterinary Drugs	11	11	-	11	-
Food	505	505	-	447	58
Cosmetics	204	182	22	178	4
Household Chemical Substance	126	89	37	81	8
Medical Devices	624	621	3	481	140
Total	**3,219**	**2,382**	**837**	**2050**	**332**

Source: 2010 Laboratory Analysis

5.5 Projects Executed

In 2010, the second round of the United State Pharmacopeia quality Monitoring (USP/FDB PQM) Anti-Malaria project was completed. The results of the study lead to the recall of some products on the Ghanaian market and the detection of some counterfeits on the Ghanaian Market.

5.6 Chemicals, Reagents and other Laboratory Consumables

The Department's requisition for the year was received during the last quarter of the year. This is the main reason why the percentage of pending samples shot up from 14.7% in 2009 to 26.0% of total samples received.

5.7 Equipment

The Department requested had the following equipment to support its activities that will be installed in first quarter of 2011:

- Turbovap Evaporator

- Nitrogen Gas Generator
- 4Cyberscan 6500 pH Meters
- 4Vacuum Pneumatic Pumps
- ADP 440 Digital LCD Polarimeter

5.8 Training/Workshop Activities

The Department benefited from the following training and workshops;

- Best Microbiological Practices course organised by CDM Training Solution of South Africa at La Palm Hotel-Accra on 24th and 25th May 2010.
- Workshop in Analytical Method Validation organised by CDM Training Solution of South Africa on 24th to 25th May 2010.
- Inter-Regional Seminar for Quality Control Laboratories involved the World Health Organisation Pre-qualification Programme (PQP) at North Western University, Potchefstroom, Republic of South Africa on 16th-19th November 2010.
- Sanitary and Phytosanity workshop (SPS) for third countries organised by the European Union (EU) from 22nd November to 3rd December 2010 in Copenhagen Denmark.
- A training course on the Role of Quality Managers in the implementation of ISO 17025 Quality Management System in Sri Lanka 11th-24th September 2010. Course sponsored by UNIDO/MOTI
- Inter-regional Seminar for Quality Control Laboratories involved on the World Health Organisation Pre-qualification Programme (PQP) 16th-19th November 2010, North western University, Potchefstroom, Republic of South Africa.

6. Zonal Operations

The FDB operates Regional and Zonal 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 2010, the FDB operated 3 Regional Offices and 3 Zonal 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 Zonal Office, responsible for Upper East and Upper West regions.
- Takoradi Zonal Office, responsible for Central and Western Regions.
- Ho Zonal Office, responsible for Eastern and Volta regions.

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

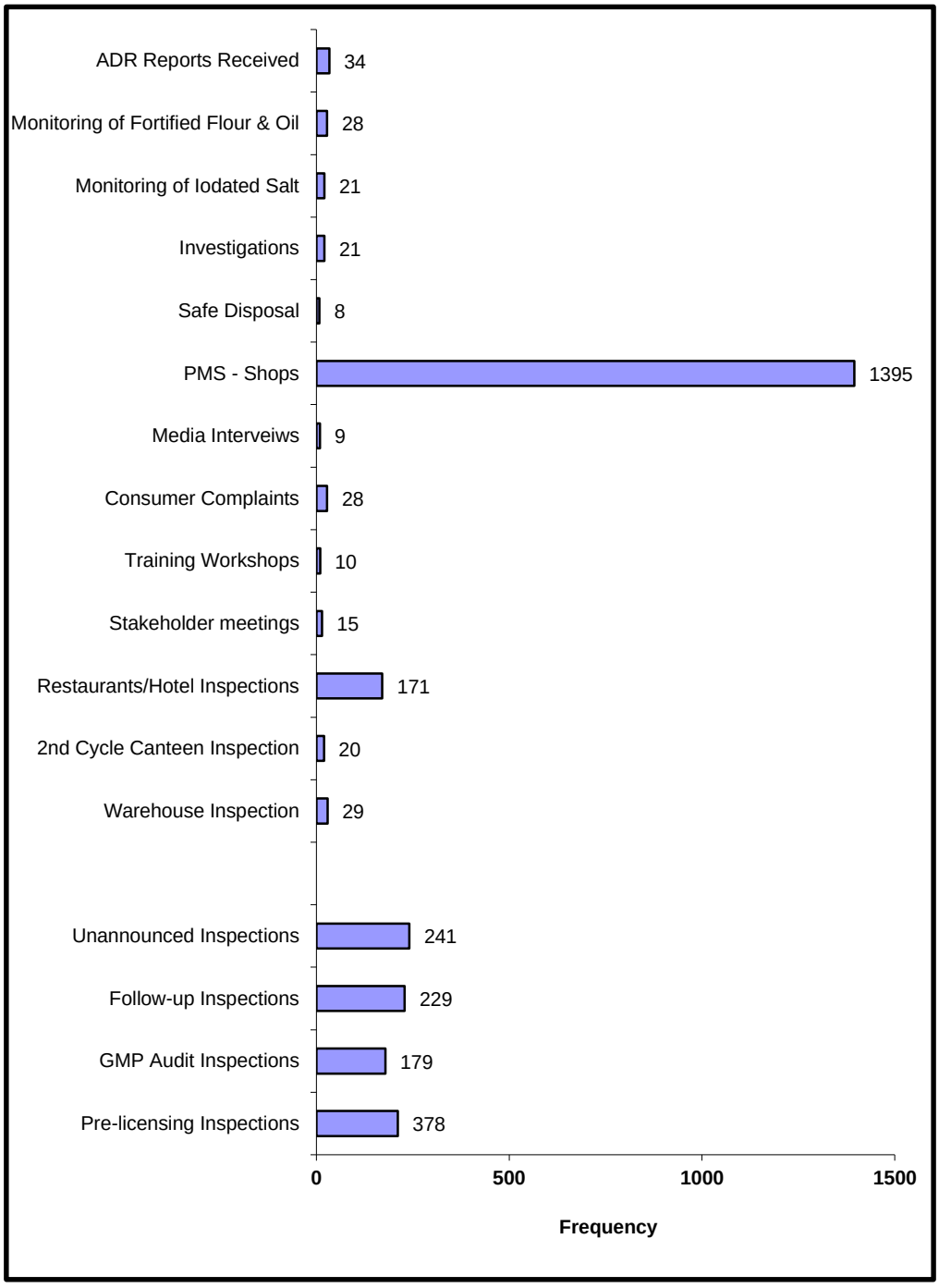
- Premises inspections.
- Carry out post-market surveillance exercise.
- Advert monitoring function
- Embark on consumer awareness and education programmes.
- Organise stakeholders meeting.
- Organise sensitization programmes, seminars, workshops, and training for all stakeholders in the food and drug 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 Zonal 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 Zonal/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 Zonal/Regional Offices.

Figure 7: Extent of Performance of Zonal/Regional Operations.



Source: 2010 Zonal/Regional Operations

7. Administration

The Administration Department of the Food and Drugs Board supports the services of the various technical Departments of the FDB. 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, human resource management and procurement management.

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:

- 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.
- The implementation of the transport management system has ensured that the vehicles were well-maintained and were under control after close of work. At the same time record keeping and data collection has improved through the use of logbooks.
- There was a reduction in driver indiscipline; hence no major accident occurred in the course of the year.

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 Board. However,

- The Food and Drugs Board office complex located at Okponglo has been re-awarded to a contractor for completion. The intended purpose of the office complex is to house the head office of the Food and Drugs Board and the Laboratory Services Department.
- The Sunyani Zonal Officer's residential bungalow has also been renovated by a contractor and has since been handed over to the Food and Drugs Board by the contractor and AESL the supervising body that supervised the execution of the renovated bungalow.
- General repairs and maintenance of the Food and Drugs Board Estates has improved throughout all our locations in the country.
- One other major development is, a new pump has been fixed to the underground tank at the Head Office to enable gradual flow of water.
- To reduce energy consumption, a new capacitor was installed by energy commission at the Head Office to reduce our energy consumptions.
- Seven (7) air conditioners were also replaced. – Five (5) at the Head Office, One (1) at the Laboratory Services Department and One (1) at the Airport Office.
- Plans are also far ahead for the renovation of the office accommodation for the Tamale Zonal Officer.
- Most tenancy agreement with Landlords of buildings we are renting have been redefined and signed between the various Landlords and the Food and Drugs Board.

7.3 Human Resource Unit

During the year under review, the FDB got financial clearance from the Ministry of Finance and Economic Planning to recruit personnel to fill existing vacancies. Thirty-six (36) Regulatory Officers comprising of thirty (30) scientific officers and six (6) administrative Officers. Ten (10) resignations with one (1) retiree were recorded.

Table 13: Summary of permanent staff

Employee Categories	Total Staff Strength
Permanent	316
Temporary	56
National Service Personnel	49
Total	**421**

Source: 2010 Human Resource Data

The year also saw the Food and Drugs Board migrating to controller and Accountant General's Department (CAGD) payroll. The role of Human Resource has slightly improved but can be further developed.

7.4 Procurement Unit

The Procurement Unit was established to ensure that internationally accepted standard procedures are followed in all the FDB 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 FDB 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 2010

- Construction of the new Head Office complex was handed over to Maripoma Enterprise for work to begin. Work started in June 2010 and it expected to be completed in May 2011.
- The FDB acquired Microbiological chemicals and replacement of five old equipment at the Laboratory, through the procurement process.
- 15 vehicles, 58 desktop computers, 4 laptops, 8 scanners, 23 printers, 8 palm tops and one 1 server, office stationery and other office consumables were procured

8. 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 Board (FDB) 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 FDB, 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 FDB 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 Board.

In 2010, the PRMIS Department was able to execute about 90% of its programme of work to support regulation. The Department continued hosting the FDB website and deployed the corporate e-mail system across the FDB. The local area networks were enhanced to enable management of groups, network resources and users. The bandwidth of the internet access and connectivity was upgraded from 2mb/256k to 4mb/1mb to enhance fast information search and download. The internet access was also extended to KIA and Tema Offices, respectively, to support import and export control functions under the Ghana TradeNet system. This was to support information search for food and medicines regulation and permit control of the regulated products. A new Untangle software ver. 8.0 was acquired and installed to enable internet connectivity for over 117 computers and to reduce the incidence of accessing and downloading inappropriate

materials, blocking of social networking sites, etc., which reduce productivity. The Zimbra software for corporate e-mailing was upgraded from 32 bit to 64 bit to accommodate FDB corporate e-mail services to the Zonal/Regional Offices. The web portal was re-designed to accommodate new developments in regulation and to allow mobile internet access with the corporate e-mail.

During the year under review, the Department also developed two comprehensive software in-house to support pharmacovigillance activities and Stores Unit, respectively. The FDB acquired new computer hardware systems for distribution to enhance the regulatory functions. The computer hardware systems are as follows: desktop computers – 58, laptops – 4, servers – 1, palm tops – 8, scanners – 23, printers – 10 (ordinary) and – 27 (network).

The year saw the development and installation of knowledge base management system to enable staff to have ready access to FDB's documented base of facts, regulatory information, and operational processes electronically.

9. Support Units under the Chief Executive Office

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

9.1 Communications Unit

The Unit serves as an interface between the FDB 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 FDB'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 15.

Table 14: Activities conducted by the Communication Unit

Area of Activity	**Frequency**	**%**
Media Coverage	32	0.02
Media Interviews	75	20.66
Press Releases, Disclaimers, Notices	29	7.99
Visas Acquired (India, USA, Canada, South Africa, China, Netherlands, Germany, Morocco, Brazil, Norway	90	24.79
Tickets Purchased (India, USA, Canada, Switzerland, Lagos, Italy, Hungary, Singapore, Kenya, Norway)	121	33.33
Travel Insurance	16	4.07
Total	**363**	**100**

Source: 2010 Communication Activities

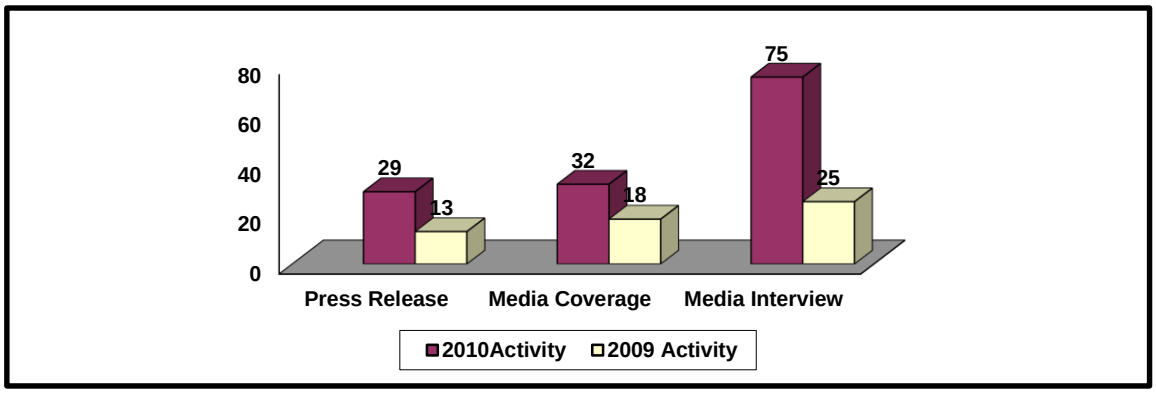
9.1.1 Collaborative Functions with other Departments.

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

- The 33rd Annual Meeting of Representatives of National Centers participating in the W.H.O. Programme for International Drugs Monitoring Conference sponsored by the W.H.O.
- Destruction of seized Turkey Tails at various dumping sites.
- Media visits to some Herbal Facilities in Tema and Accra Metropolis.
- Seizure of dangerous medical devices including :
- Detoxification Machines,
  - *(I)* Blood Circulation and
  - *(II)* Life Prolongation Machines
- The FDB organized a Stakeholders Meeting to discuss a Situational Analysis Report for the Development of a National Food Safety Policy on the 17th of March, 2010

- A National Food Day was organized in collaboration with the Ministry of Food and Agriculture and the World Food Programme.
- Seizure and Destruction of the following items:
  (I) Various types of unregistered Drugs
  (II) 6,000 bags of unwholesome Rice,
  (III) 3,000 cartons of turkey tails.
- The FDB organized a stakeholders meeting between members of the FDB and the Environmental Health Officers of the Metropolitan Assemblies.
- The FDB organized numerous Police swoops on illegal sellers of unregistered products such as manufacturers of Biscuits, toothpastes, etc.

Figure8: Comparison of Communication Activities 2009 & 2010



Source: 2009&2010 communication data

Future Direction

The Food and Drugs Board 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). In particular, steps will be taken to reinforce the corporate identity of the FDB and reposition management for increased commitment to the mandate of the FDB.

In this regard, the FDB's operational direction for 2011 will focus on the following:

- The decentralization programme for effective implementation and enforcement of the regulatory laws will continue with new offices being opened at Cape Coast, Koforidua and Wa.
- The review of the Tobacco Bill will be completed.
- The human resource situation will be critically examined and recruit qualified staff. Staff motivation will also receive increased attention.
- Staff will receive adequate training and development.
- The review of the Food and Drugs law 1996 (PNDCL 305B) to make it more effective and relevant to the needs of the country and its obligations to the international community will be completed.
- Strengthen consumer awareness programmes to ensure public health and safety and consumer confidence.
- The Laboratory Services will be accredited.
- To put in place a viable Human Resource policy, that will enable the FDB meet its mission.

ANNEX A.1

FOOD AND DRUGS BOARD MANAGEMENT TEAM AND ZONAL 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 **(**Acting)
Head of Administration	Mr Jones Ofosu
Head of Finance	Mr Kwasi Agyei
Head of Quality Control Laboratory	Mr Karikari Boateng

Office Addresses

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P O Box CT 2783
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Telephone: +233-0302-235100/233200/225502
Fax: +233-0302-229794
URL: http://www.fdbghana.gov.gh
E-mail: fdb@fdbghana.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/Zonal Offices:

Kumasi
Address: The Regional Officer
Food and Drugs Board
P O Box ST 402, Kumasi.

Location: SIC Building 2nd Floor, Bompata, Kumasi
Tel/Fax: 03220-36070

Takoradi
Address: The Zonal Officer
Food and Drugs Board
P O Box MC 2129, Takoradi.
Location: SSNIT Regional Offices, (near central Police Station)
Tel/fax: 0303-27558

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

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

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

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