# FOOD AND DRUGS BOARD

# ANNUAL REPORT

# JANUARY – DECEMBER 2003

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## EXECUTIVE SUMMARY

The global movement of goods and services have placed a greater sense of responsibility on regulatory bodies to ensure that regulated products moving in trade and commerce are safe, efficacious and of good quality. The Food and Drugs Board, cognizance of these facts put in place a five-year strategic plan beginning 2002 which includes among others,

- Decentralization of the Board's activities nation-wide,
- Capacity building in human resource mobilization,
- Infrastructural development, strengthening of laboratory testing and,
- Review of legislation mandating the Board to regulate food, drugs, cosmetics, household chemicals and medical devices.

The year 2003 therefore saw a substantial increase in the staff strength of the Board; in all 50 more staff were employed to fill various vacancies within departments of the Board. Seventeen members of staff attended and pursued various degree courses, short-term courses, workshops and conferences overseas in diverse fields of food safety and quality, drug quality assurance and registration, adverse drug monitoring, counterfeiting of pharmaceuticals and product stability testing. In-house training and training in local institutions in the areas of management, HACCP, HACCP Audit, Defensive Driving and computer applications were organized for staff.

In order to respond to legal matters including effective interpretation of its mandate and the review of the law, PNDC Law 305B which set up the Board, a State Attorney was seconded from the Attorney General's and Ministry of Justice to the Board.

As part of the Board's decentralization programme to expand regulatory jurisdiction nationwide, the Board opened two Zonal Offices in Takoradi and Bolgatanga; it expanded its fleet of operational vehicles, and enhanced the testing capacities of the Quality Control Laboratory with the building of a microbiology laboratory.

During the period under review, the bulk of the Board's revenue was internally generated through product registration fees, import permit fees, manufacturing licensing fees, product advertisement fees, sale of registration forms, variation fees, destination inspection fees, expired/unwholesome products destruction fees and drug analysis fees. These internally generated funds (IGF) have been the mainstay of support for the Board's decentralization and regulatory programmes.

It is expected that the Food and Drugs Board's strategic direction for 2004 will focus on the following:

- Continue decentralization programme for effective implementation and enforcement of the regulatory laws.
- Expansion of Human Resource base with relevant skills, knowledge and abilities.
- Manpower training and development.
- Review of PNDCL 305B to make it more effective and relevant to the needs of the country and its obligations to the international community
- Intensify consumer awareness programmes to ensure public health and safety and consumer confidence.
- Become ISO 9000:2000 Quality Management System compliance.
- Install efficient MIS to capture important Data.
- Quality and safety management of programme drugs.

# 1.0 INTRODUCTION

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, 1996, Act 523 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 Setting up and History

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, chemicals substances and medical devices. The Pharmacy Act 1994 (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 Board

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

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

Without prejudice to (1.2.1) 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

In summary, the Board is therefore to have the responsibility for the regulatory control of manufacture, import, export, distribution, advertisement and product information for food, drugs, cosmetics, medical devices and household chemicals. This is a very critical role, as misbranding, substandard and/or counterfeit, as well as unsubstantiated product information, have very grave consequences on public health and serious implications for healthcare delivery.

The Board, since August 1997, has been pursuing various specific objectives to address issues on regulatory control of products as stated above.

## 1.3 Mission Statement and Goals

The 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 Board has set for itself the following goals:

The Board 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.

The Law and its Amendment Act, provides for a management structure spear-headed by a Governing Board appointed by the President as follows:

- *A Chairman*
- *A representative of the Ghana Standard Board*
- *A representative of the Food Research Institute*
- *The Director of Fisheries*
- *A representative of the Ghana Medical Association*
- *The Registrar of the Pharmacy Council*
- *The Head of Nutrition and Food Science Department of the University of Ghana*
- *A Veterinary Surgeon nominated by the Minster for Agriculture*
- *The Director of Crop Services Department*

- *A representative of the Environmental Protection Agency*
- *A representative of herbal medicine practitioners*
- *The Chief Executive of the Food and Drugs Board*
- *A representative of the Attorney General or a lawyer of not less than ten years standing*
- *Two other persons including at least one woman, representing consumer interest.*

In 2003, the governing Board of Directors had not been re-constituted since its dissolution in January, 2002.

### 1.4 Our 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 Board with respect to ensuring their safety, quality and efficacy.

### 1.5 The 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.

## 2.0 HIGHLIGHTS OF THE YEAR

The Board, in 2003, continued to consolidate the already initiated regulatory schemes. The major stated outputs during the year under review were:

- All manufacturing facilities inspected and monitored for compliance with Good Manufacturing Practice (GMP).
- Database of all registered products updated.

- Products registered prior to release unto the market to assure safety, efficacy and quality.
- Permits issued prior to importation of drugs into the market.
- Drugs prescribed and dispensed according to classification list ensured.
- Adverse effects of drugs and safety of food products monitored.
- Increased in consumer awareness in the use of regulated products.
- Products advertised in accordance with the law ensured.
- Office equipment, including IT infrastructure, installed to improve service delivery, and access to data and information.
- Legislative instruments reviewed and/or amended.
- Manpower developed to be well-versed in regulatory functions.
- Two more Zonal Offices in Takoradi and Bolgatanga opened.
- Additional operational vehicles acquired.

The summaries of activities achieved during 2003 are as detailed below:

# 3.0 ACHIEVEMENTS

## 3.1 FINANCE AND ADMINISTRATION

### 3.1.1 Personnel and Administration Unit

Globalization and its attendant free movement of goods and services have placed a greater sense of responsibility on regulatory bodies to ensure that regulated products moving in trade and commerce are safe, efficacious and of good quality. The Food and Drugs Board, cognizance of these facts, put in place a five-year strategic plan beginning 2002, which includes, among others:

- Decentralization of the Board's activities nation-wide.
- Capacity building in human resource mobilization.

- Infrastructural development, strengthening of laboratory testing, and
- Review of legislation mandating the Board to regulate foods, drugs, cosmetics, household chemicals and medical devices.

The year 2003, therefore, saw a substantial increase in the staff strength of the Board; in all 50 more staff were employed to fill various vacancies within departments of the Board. A summary of staff complement as at the end of December 2003 stood as shown below:

| | |
|---|---|
| Pharmacists | 27 |
| Biochemists | 14 |
| Food Scientists | 6 |
| Chemists | 6 |
| Biologists | 2 |
| Botanists | 1 |
| Veterinary Surgeons | 1 |
| Operations Research Scientists | 1 |
| Agricultural Scientists | 3 |
| Laboratory Technologists | 6 |
| Laboratory Technicians | 2 |
| Secretaries | 12 |
| Accountants | 3 |
| Clerks | 3 |
| Administrative Assistants | 2 |
| Administrative Officers | 2 |
| Store Managers | 1 |
| Drivers | 11 |
| Communications and PR personnel | 3 |
| Lawyers | 1 |
| Security Guards | 11 |
| **Total** | **118** |

The Board secured the services of a Human Resource Consulting Firm to develop an organizational structure, job design and job specification for HR requirements of the Food and Drugs Board.

### 3.1.2 Capacity Building

The attainment of any organizational goal cannot be accomplished without the deployment of a human resource base with the right mix of skills, knowledge and abilities. During the year under review, management applied the necessary effort to improve the quality and motivation of staff in a number of ways. For instance, three employees in the Food Division successfully completed a three-year Sandwich Training Programme in HACCP with the Natural Resources Institute of Greenwich University of UK leading to their certification as Food Safety Auditors. Two staff were sponsored to attend one year postgraduate programmes in Food Legislation and Communication Studies. Twelve members of staff attended various short-term courses, workshops and conferences overseas in diverse fields of food safety and quality, drug quality assurance and registration, adverse drug monitoring, counterfeiting of pharmaceuticals and product stability testing.

In order to respond to legal matters, including effective interpretation of its mandate and the review of the law, PNDC Law 305B which set up the Board, a State Attorney was seconded from the Attorney General's and Ministry of Justice to the Board.

In-house training and training in local institutions in the areas of management, HACCP, HACCP Audit, Defensive Driving and computer applications were organized for staff.

As part of the Board's decentralization programme to expand its regulatory jurisdiction nationwide, the Board opened two Zonal Offices in Takoradi and Bolgatanga, expanded its fleet of operational vehicles, and enhanced the testing capacities of the Quality Control Laboratory with the building of a microbiology laboratory.

### 3.1.3 Finance and Accounts Unit

The main sources of external funds for the Board are government subvention and grants provided through donor-pooled funds from the nation's development partners. The bulk of the Board's revenue is internally generated through product registration fees, import permit fees, manufacturing licensing fees, product advertisement fees, sale of registration forms, variation fees, destination inspection fees, expired/unwholesome products destruction fees and drug analysis fees. These internally generated funds (IGF) have been the mainstay of support for the Board's decentralization and regulatory programmes.

With the approval of the Ministry of Health, the management of the Board, in the absence of a governing Board of Directors, utilized needed amounts of the IGF to purchase two Mercedes Benz buses, two Nissan 4-wheel drive pick ups, and three saloon cars. Two regional offices were opened in Takoradi and Bolgatanga in the Western and Upper East regions, respectively. A Microbiology Laboratory was built to expand the testing capacities of the Quality Control Laboratory of the Board. The IGF also provided the source of funding for the purchase of laboratory reagents, glassware, primary chemical reference standards and reference textbooks and journals. Some of the overseas training workshops and conferences were financed from the IGF. Accounts of the Board are audited annually by the Auditor General's Department.

Tabulated below is a summary of IGF for the year 2003.

| **Activity** | **Cedi( ¢) Component** | **US $ Component** |
|---|---|---|
| Registration Fees | 834,012,865.00 | 388,650.00 |
| Re-Registration Fees | - | 255,300.00 |
| Permit Fees | 106,360,000.00 | 4,750.00 |
| Tender Fees | - | 2,600.00 |
| Destination Inspection Fees | 62,223,135.00 | 15,100.00 |
| Sale of Forms | 19,470,000.00 | - |
| Processing Fees | 106,250,000.00 | - |
| Advertising Fees | 112,900,000.00 | - |
| Manufacturing Licence Fees | 117,050,000.00 | - |
| Establishment of Industries Fees | 5,000,000.00 | - |

| | | |
|---|---|---|
| Registration as Importer | 84,400,000 | - |
| Destruction Fees | 10,900,000.00 | - |
| **Total** | **1,458,566,000.00** | **666,400.00** |

### 3.1.4 Legal Unit

A Legal Unit was set up within the organizational structure of the Board to oversee the legal issues of the Board's activities. The Unit provided the needed guidance for the contract of a consultant to review the Food and Drugs Law, PNDC Law 305B. The Unit also succeeded in securing an out of court settlement of a long standing case between the Board and a food processing company.

### 3.1.5 Communications Unit

The Unit, which served as an interface between the Board and its stakeholders comprising the media, the business community, industry and consumers, arranged for various media programmes particularly with respect to consumer education, media coverage of the Board's activities and publication of health alerts and press releases for the information of the general public and the international community at large. During the year under review, the following press releases and health warnings were issued through the coordinated activities of the Unit:

| **Area of Activity** | **Frequency** | **%** |
|---|---|---|
| Press Release | 15 | 44.1 |
| Media Coverage | 6 | 17.6 |
| Media Interviews and Programs | 13 | 38.2 |
| **Total** | **34** | **100** |

### 3.1.6 Projects, Research &MIS Unit

This Unit was set up in the year under review, to play the roles of a co-ordinating centre for projects, research activities within the Board, and the development, administration

and maintenance of the Board's management information systems (MIS). The Unit is also responsible for compiling and producing the final draft of annual reports and programmes, as well as research reports from all departments and units of the Board. The Unit also advises management in all matters related to Information Technology (IT).

## 3.2 DRUG DIVISION

Drugs play an important role in improving and protecting public health. Drugs should be safe, effective, of good quality, and used rationally to produce desired effects.
The Drug Division contributes to the achievement of goals 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 through pre-marketing assessment of safety, quality, and efficacy of medicines 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.

The activities of the Division are carried out by two specialized departments, supported by seven operational units.

### 3.2.1 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 Evaluation and Registration Unit
- Pharmacovigilance Unit
- Herbal Medicine Unit
- Cosmetic, Chemicals and Medical Devices Unit

#### 3.2.1.1 Medicine Evaluation and Registration Unit

The Medicine Evaluation and Registration Unit registers drug products and issues certificates for a period of three years after which re-registration is required.

Assessment of applications for the registration of products involves the following:

- Evaluation of dossiers submitted for registration to ensure that application forms are properly completed and the requisite information duly submitted.
- Ensuring a current Good Manufacturing Practice Certificate/Certificate of Pharmaceutical Product is provided.
- Ensuring information provided in dossiers and on packages is correct and adequate to enable the Board take the appropriate decision.
- Ensuring Laboratory analysis to ascertain safety, quality and efficacy.

Product registration meetings are held on monthly basis to review applications for product registration.

During the period under review, 1,635 applications were received and 1,363 were registered, which included applications brought forward from December 2002. Table 1 below gives a summary of the breakdown of applications processed and registered by the Unit in 2003.

**Table 1: Breakdown of Applications Processed and Registered**

| **Product Type** | **Applications Received** | | **Number Registered** | |
|---|---|---|---|---|
| | Foreign | Local | Foreign | Local |
| Allopathic (orthodox) Drugs | 653 | 148 | 547 | 231 |
| Veterinary Drugs | - | - | - | - |
| Herbal Drugs | 82 | 130 | 82 | 83 |
| Cosmetics | 194 | 48 | 65 | 40 |
| Chemicals | 84 | 10 | 44 | 8 |
| Medical Devices | 109 | - | 92 | - |
| Food Supplements | 173 | - | 167 | - |
| Vaccines | 4 | - | 4 | - |
| **Total** | **1299** | **336** | **1001** | **362** |

- The Board also registered 32 drugs for procurement by the Ministry of Health.

During the year under review it was recommended that:

- Local manufacturing companies should start stability testing programmes for all products. Shelf-life of locally produced allopathic drugs should be two years and may be extended based on completion of stability studies.
- All guidelines, application forms and certificates should be reviewed
- Suspension of registration of Nimesulide, Cox-2 Inhibitors, and Phenylpropanolamine should be revoked because of the favourable data on the safety profiles. Circulars in this regard were issued to all stakeholders.
- Classification of plain Cyproheptadine and Cyproheptadine in combination with vitamins, minerals and/or amino acids should be reviewed. This was communicated to all stakeholders.

#### 3.2.1.1.1 Product Advertisement

Assessment of applications for advertisement of products involves the following:

- Evaluation of scripts submitted for advertisement to ensure that content is acceptable to the Board.
- Evaluation of audio and video cassettes to ensure conformance to vetted scripts.

In 2003, the Unit vetted 192 advertisement applications in various categories and approved 105. Table 2 gives the summary of advertisements processed in 2003, and Fig. 1 gives the distribution of product advertisement among media houses.

**Table 2: Advertisements Received and Processed**

| Area of Advert | No. of Applications | Number Approved |
|---|---|---|
| Allopathic (orthodox) Drugs | 77 | 41 |
| Herbal Drugs | 73 | 30 |
| Cosmetics | 15 | 14 |

| | | |
|---|---|---|
| Household Chemical | 5 | 5 |
| Food Supplements | 9 | 7 |
| Medical Devices | 13 | 8 |
| **Total** | **192** | **105** |

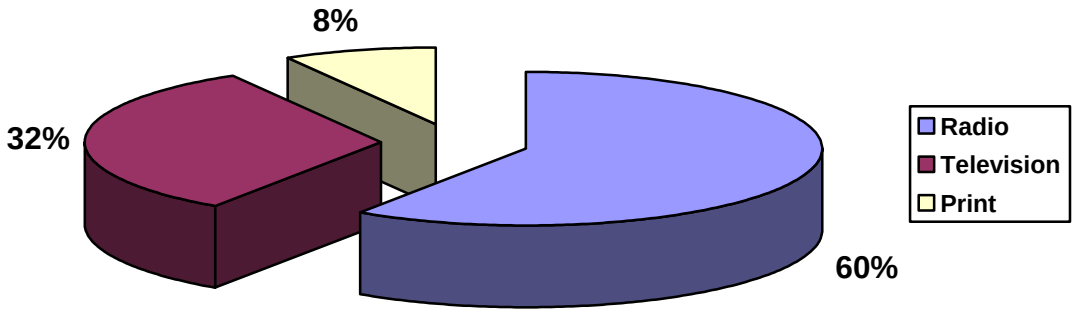


**Fig. 1: Distribution of Product Advertisement among Media Houses**

### 3.2.1.1.2 Import Permits

The Unit also undertakes the assessment of applications for import permit, which involves the following:

- Ensuring that products to be imported have valid registration numbers.
- Names of products and their respective quantities stated in invoices tally with information provided in application forms.
- Ensuring that application submitted is acceptable to the Board

In 2003, the Unit processed a total number of 2,924 import permits covering the following products: finished products, pharmaceutical raw materials, hospital supplies, donations and prescriptions for personal use. Table 3 shows the summary of import permits processed from January to December, 2003.

**Table 3: Summary of Import Permits Processed**

| Month | Finished Products | Raw Materials | Hospitals | Donations | Personal Use | Total |
|---|---|---|---|---|---|---|
| JAN | 324 | 81 | 10 | 1 | 1 | **417** |
| FEB | 129 | 58 | 7 | 3 | - | **197** |
| MAR | 161 | 93 | 23 | 1 | - | **278** |
| APR | 142 | 48 | 3 | - | - | **193** |
| MAY | 149 | 43 | 7 | - | - | **199** |
| JUNE | 82 | 39 | 6 | - | - | **127** |
| JULY | 154 | 65 | 5 | - | - | **224** |
| AUG | 191 | 78 | - | - | - | **269** |
| SEP | 157 | 82 | - | - | - | **239** |
| OCT | 207 | 68 | 14 | 1 | - | **290** |
| NOV | 142 | 94 | 2 | 2 | - | **240** |
| DEC | 160 | 76 | 13 | 1 | 1 | **251** |
| **Total** | **1998** | **225** | **90** | **9** | **2** | **2924** |

Fig. 2 shows the monthly total number of import permits processed from January to December, 2003.

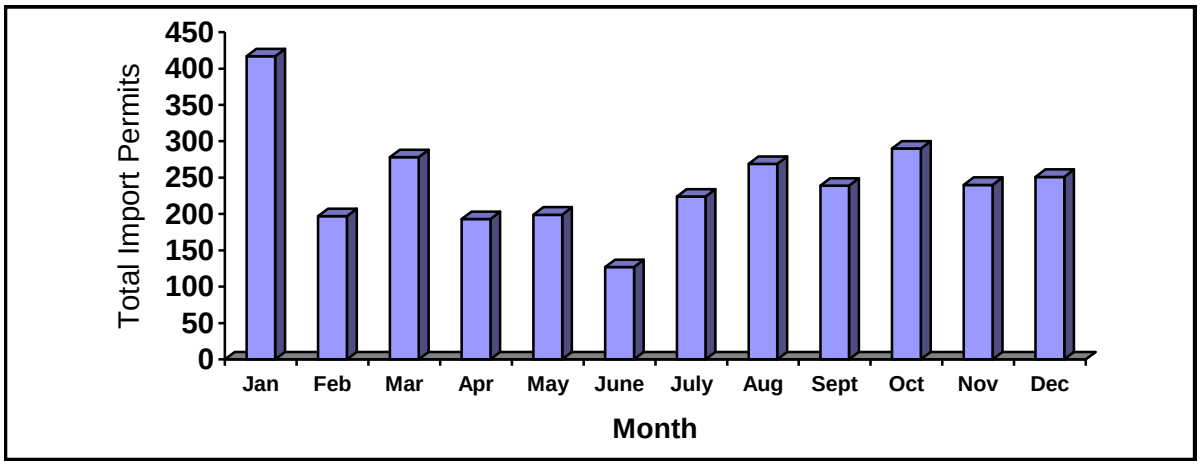


**Fig. 2: Monthly Total Import Permits issued from January – December, 2003.**

### 3.2.1.2 Pharmacovigilance Unit

The Pharmacovigilance Unit of the Board started operation in January, 2003 as Risk Management Unit. The main function of this Unit is to co-ordinate the activities of the Post-Market Surveillance, Narcotic and Psychotropic Unit. The Unit is on the verge of building a database of all healthcare professionals practicing in Ghana so as to readily access them and provide information on drug safety.

The National Centre for Pharmacovigilance (NCPv) continues to be a collaborative link between the Food and Drugs Board (FDB) and the Centre for Tropical and Clinical Pharmacology & Therapeutics (CTCPT), University of Ghana Medical School.
During the year under review, the Unit investigated 13 complaints on products, and received 918 Adverse Drug Reactions (ADRs) reports. The Unit also participated in local and international meetings, held 4 training workshops for healthcare professionals and played host to dignitaries from the world of Pharmacovigilance.

Out of 918 ADRs reports received, 908 of these reports were received form the Director of the Onchocerciasis Chemotherapry Research Center (OCRC) in Hohoe. The OCRC reports covered a study conducted using Mectizan (Ivermectin). Mectizan is a drug indicated for onchocerciasis. A total of 68 of these reports were sent to the Uppsala Monitoring Centre (UMC) in Sweden between January and December 2003.

During the year under review, the Unit also supported the Drug Evaluation and Registration Department by seeking information on the licensing and safety profile status of several drugs in different countries. This was to enable the Board take a decision for Ghana. Some of the products considered were Cyproheptadine, Nimesulide and Phenylpropanolamine. The Unit also responded to requests on issues concerning the safety of *Ginseng* and the antimalarial properties of *Cassia siamea*.

In 2003, Ghana was nominated as one of three (3) countries tasked to report ADRs on-line using the newly developed Vigibase-on-line software.

Fig. 3 shows the major activities conducted by the Pharmacovigilance Unit.

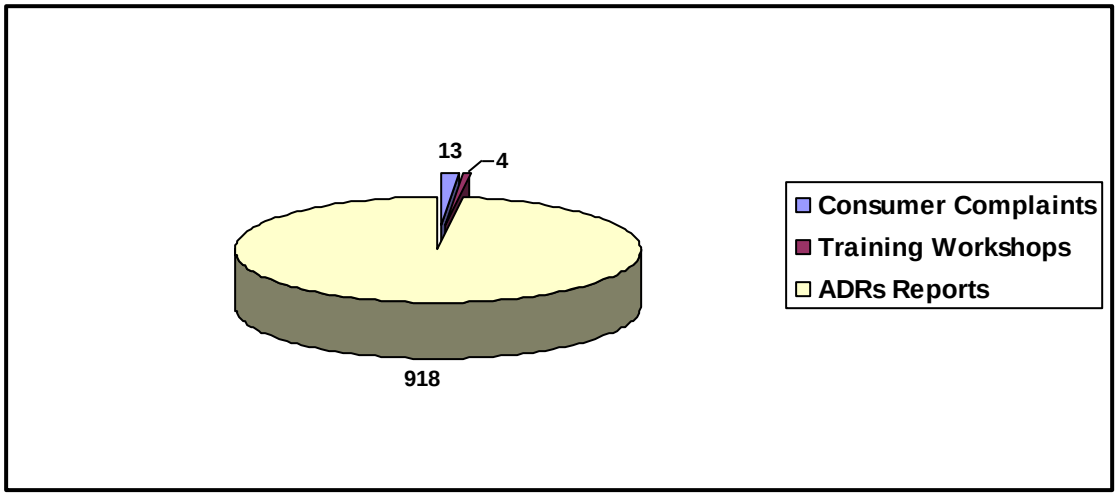


**Fig. 3: Pharmacovigilance Major Activities**

### 3.2.2 Drugs 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, Narcotics and Psychotropics Unit

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

#### 3.2.2.1 Drug Premises Inspection Unit

During the period under review, 24 out the 31 companies licensed by the FDB renewed their manufacturing licenses. The Unit was able to conduct routine audit inspections of almost all the pharmaceutical manufacturing companies that were registered with the Board. Generally, the findings of the inspections indicated improvement in Good Manufacturing Practice. .

Although the local pharmaceutical manufacturing companies were requested to submit annual returns of their production to enable the Unit compile and assess the total national production and sale of locally manufactured products, only few of the companies did so.

The department conducted routine inspection of herbal manufacturing companies whose products were already registered with the Board. During the period under review, there were regional inspections of these facilities in the Central, Eastern and Western Regions of the country.

In 2003, the Board in conjunction with the Ghana National Drugs Programme (GNDP) embarked upon a regional medical stores inspection to verify the state of these stores as far as good storage practices (GSP) were concerned. In all, 9 regional medical stores were inspected. The need for direct contacts with these stores to improve drug regulation was also highlighted.

#### 3.2.2.1.1 External Good Manufacturing Practice (GMP) Audit Inspections

Overseas GMP inspections of Indian Pharmaceutical Companies doing business in Ghana were carried out during the period under review.

In March 2003, the first phase of inspections of Indian Pharmaceutical Manufacturing Industries doing business in Ghana was brought to a close. In all, 49 pharmaceutical manufacturing facilities were inspected, out of which 42 were found to be Good Manufacturing Practice (GMP) compliant while 7 companies were found to be GMP non-compliant.

Fig. 4 shows Good Manufacturing Practice (GMP) compliant companies of the 49 Indian companies the team inspected in 2003. The second phase of the exercise is expected to end in March 2004.

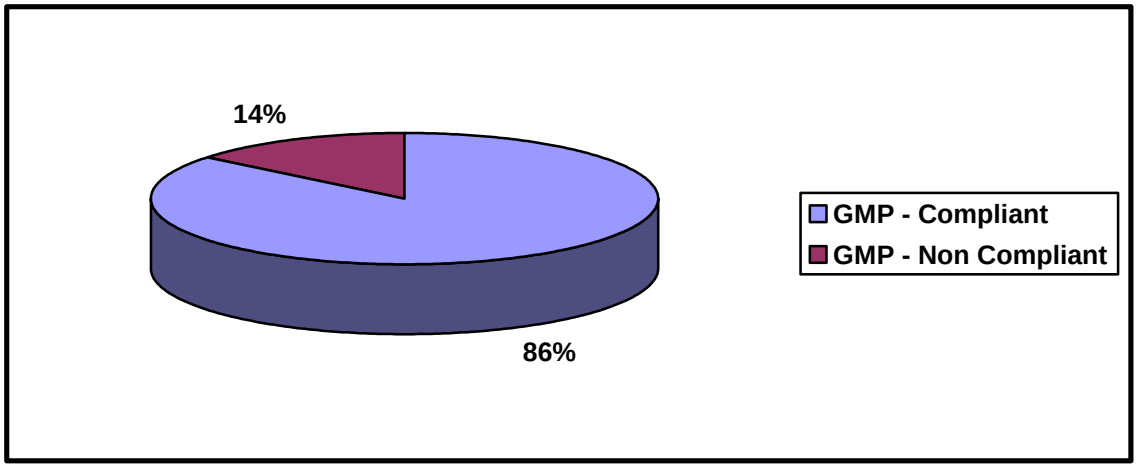


**Fig. 4: GMP–Compliant Indian Companies**

#### 3.2.2.1.2 Inspections of Local Cosmetic and Household Chemicals Manufacturing Industries

Local companies manufacturing cosmetics and household chemicals were inspected as a pre-requisite to the listing of their products. During the period under review, only 2 medium-size companies were licensed by the Board for meeting of the pre-licensing requirements.

#### 3.2.2.1.3 Destination Inspections

Destination inspections were conducted on consignment of drugs imported with invalid import permits, whenever referrals to this effect were received from the Customs, Excise and Preventive Service (CEPS). In 2003, four such investigations were conducted at the Aflao Border Post, three at the Central Post Office, Accra and four at Customs Excise and Preventive Service (CEPS) Head Office to assess the quality of these products. As a result, large consignments of products were destroyed, including vaccines flouting stipulated good storage conditions.

### 3.2.2.2 Drug Post-Market Surveillance, Narcotics and Psychotropics Unit

The Unit monitors drugs, cosmetics, medical devices and household chemicals for the purpose of ensuring public health and safety and consumer confidence. The activities of the Unit start when market authorization has been granted to the importer.

The functions of the Unit include to:

- Collaborate with Pharmacy Council to continuously monitor quality of products on the Ghanaian market.
- Conduct operational research on products registered by the Board on the Ghanaian market.
- Monitor products on the Ghanaian market for registration, expiry date, and labelling conformance.
- Liaise with Port Offices to monitor drug and other product donations.
- Reconcile inventory and perform destruction of expired products.
- Monitor and review drug promotion and advertising
- Monitor storage facilities of clinics, hospitals, central medical stores and regional medical stores.
- Investigate issues on consumer complaints and counterfeiting.

During the year, a proposal to seek the joint collaborative functions of the Pharmacy Council and the Board in the area of product quality monitoring and the development of a system of reporting on defective, spurious, substandard and counterfeit drugs was made. The proposal is under consideration stage. In 2003, analytical work started on the quality of Antimicrobials, Anti-malarials, Anti-retrovirals, Anti-tubercular drugs and Toothpastes to ensure their effectiveness in Ghana. Work on these products is still at the developmental stage.

Table 4 indicates the major activities carried out by the Unit in 2003.

**Table 4: Summary of DPMS Activities**

| Area of Activity | Frequency | % |
|---|---|---|
| Product Disposal and Destruction | 4 | 26.7 |
| Adverse Monitoring for Drugs | 1 | 6.6 |
| Consumer Complaints and Counterfeiting | 10 | 66.7 |
| **Total** | **15** | **100** |

## 3.3 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 by evaluating all samples submitted in the registration process, 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 conformance to Good Manufacturing Practices. Moreover, the Division ensures that all imported and locally produced food products are of good quality and wholesome.

The activities of the Division are carried out by 2 specialized departments and supported by 6 operational units.

### 3.3.1 Food Safety and Nutrition Department

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

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

#### 3.3.1.1 Food Product Evaluation and Registration Unit

In 2003, a total number of 755 products were submitted to the Board, out of which 602 were imported (foreign) and 153 locally manufactured. Of the 755 products submitted, a total of 365 products were registered, out of which 211 were imported and 154 locally manufactured, 16 of which were brought forward from December, 2002 applications. Table 5 gives the summary of food products submitted and registered by the Unit.

**Table 5: Summary of Food Products Submitted and Registered**

| Product Category | Imported (Foreign) | Registered (Foreign) | Manufactured Locally | Registered (Locally) |
|---|---|---|---|---|
| Drinks | 171 | 54 | 48 | 40 |
| Fats and Oils | 63 | 43 | 1 | 1 |
| Confectionery | 92 | 26 | 3 | 3 (8)* |
| Packaged Water | 1 | - | 69 | 69(4)* |
| Fish/ Fish Products | 28 | 9 | 3 | 2 |
| Diary Products | 50 | 20 | 1 | 1 (2)* |
| Additives | 75 | 12 | 8 | 6 |
| Meat and Meat Products | 9 | 5 | - | - |
| Roots and Tubers | 4 | 1 | - | - |
| Fruits | 11 | 3 | - | - |
| Cereals | 51 | 20 | 10 | 10(2)* |
| Vegetables | 47 | 18 | 10 | 6 |
| **Total** | **602** | **211** | **153** | **138(16)*** |

During the year under review, a total of 160 food products were deferred for reasons ranging from improper labelling, unsatisfactory premises, poor packaging, suspected fake product, No accredited regulatory body registration number (Nigerian products), and presence of particles.

Fig. 5 shows the number of food products submitted, registered and rejected in 2003.

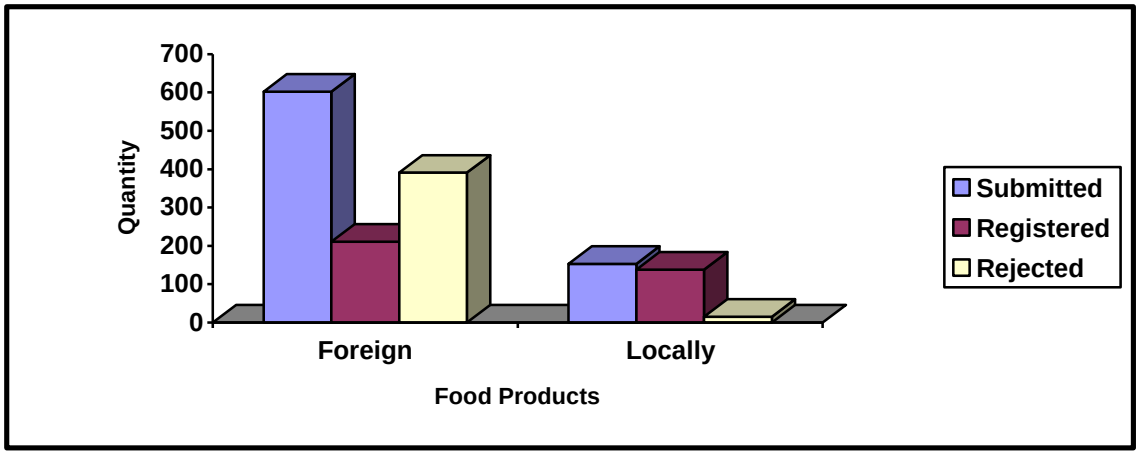


**Fig. 5: Food Products Processed, Registered and Rejected**

To stimulate local food manufacturing industries and dealers in food products to register with the Board, the Unit intends to increase awareness on the importance of registering food products through sensitization seminars and workshops and instituting compliance to the importation requirements by allowing only food products that have registered with the Board.

#### 3.3.1.2 Food Standards Unit

The Unit was set up in the last quarter of 2003. The principal objective of the Unit is to make available the appropriate food standards to augment the work of the Food Division.

### 3.3.2 Food Inspectorate Department

The Food Inspectorate Department under the Food Division is 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 that they conform to current Good Manufacturing Practices. The department undertakes three types of inspections, namely, Premises inspections, Destination inspections, and Audit inspections.

The functions of the Department are carried out by the following operational Units:

- Veterinary Unit

- Premises Inspection Unit
- Post-Market Surveillance Unit

#### 3.3.2.1 Veterinary Unit

The Veterinary Unit began operations in June, 2003. During the period under review, the following activities were initiated:

- Proposed Regulatory Activities
- Inspection of the Accra Abattoir
- Inspection of slaughter facilities in the Upper East Region
- Inspection of veterinary drugs importing companies in Accra

##### 3.3.2.1.1 Proposed Regulatory Activities

The following regulatory functions were proposed in line with the mandate of the Board.

- **Feed Mills**
  1. Compile a list of all feed mills.
  2. License feed mills.
  3. Routinely inspect feed mills' warehouses to ensure good warehouse practices (GWP), and good manufacturing practices (GMP).
  4. Regularly educate feed mills operators about the law on animal feed and the requirements for approval of feed additives and the registration procedure.
- **Abattoirs**
  1. Compile a list of abattoirs, and other slaughter facilities.
  2. Register all slaughter facilities.
  3. Routinely inspect slaughter facilities to ensure good slaughtering and processing practices (GSPP).
  4. Regularly educate workers of slaughter facilities on the proper handling of meat.
- **Veterinary Drugs**

1. Compile a list of veterinary drug manufacturers and importers
2. Register all veterinary drugs on the market.
3. Inspect veterinary drugs warehouses to ensure good warehouse practices (GWP).
4. Educate drug importers on the law and the requirements for veterinary drugs registration

#### 3.3.2.1.2 Specific Activities Undertaken

**Inspection of Accra Abattoir**

Staff of the Veterinary Unit visited the Accra Abattoir to acquaint themselves with operations there and to explain to the management of the company what is expected of them and to discuss areas of collaboration. The visit was also to gather baseline data on the activities which can help in regulating similar facilities in the country.
The abattoir has the capacity for handling

- 240 cattle per shift per day
- 240 sheep/goats per shift per day
- 120 pigs per shift per day.

The team inspected the holding area for animals received, the place for disposal of excreta, the stunning area, the de-skinning facility, and the place for conducting post-mortem examination on the slaughtered animals.
The team was taken through the normal process of receiving animals at the facility and the slaughter process they go through before the meat is delivered to the market. Also inspected were the drainage system, the treatment plant for faecal matter, as well as the condensed chillier for storage.

Documentations on company activities such as destruction of unwholesome carcasses, sanitary procedures, and records of medical status of the workers were also inspected.

**Level of compliance:**

1. Anti-mortem and post-mortem examination on animals are strictly carried out by qualified veterinary officers.
2. Documentation covering the medical status of the workers was available.
3. The drainage system was well structured and maintained.
4. Faecal matter and other forms of waste were properly collected and disposed of.
5. Proper disposal of unwholesome carcasses could not be substantiated as documentation could not be provided
6. The chillier was non-functional
7. Toilet and washing facilities were non-functional. As a result people defecate close to the fencing of the facility posing serious environmental and food safety problems.
8. The meat transport van was in a state of disrepair.
9. Not all workers were properly dressed, as many of them were found working in casual attire.

After the visit, the company was requested to inform the Board of any future destruction of unwholesome carcasses to enable the proper supervision to be carried out on the next visit.

**Inspection of slaughter facilities in the Upper East Region**

During the period under review, 4 slaughter facilities in Bolga, Bawku, Navrongo and Paga were inspected. The inspections were carried out together with the Head of the Zonal Officer in Bolga and representatives from the local authorities of the respective towns for compliance with the Food and Drugs Law, PNDC Law 305

**Inspection of veterinary drug importing companies**

During the year 17 companies were inspected to ascertain their compliance level with Food and Drugs Law, PNDC Law 305. All the companies were found to be involved in active importation of veterinary drugs. During interactions with management of the various companies, it became clear that the companies not complying PNDC Law 305, with regards to the registration of veterinary drugs was due to two factors:

- The registration fee which they consider to be unfavourably high.
- Insufficient pressure from the FDB on these companies to register their drugs.

The intention as to carry out much more on compliance, for example, registration and inspection of feed mills could not be fulfilled due largely to transportation constraint. It is, therefore, important that a vehicle be made available to the Unit to enable it perform its duties creditably.

#### 3.3.2.2 Food Premises Inspection Unit

The Food Premises Inspection Unit (FPIU) carries out its functions based on product classification adapted by the Board, namely:

- Water
- Drinks
- Confectionary
- Additives (pepper sauce, sugar, salt, white and black pepper, chili, etc.)
- Milk and other Dairy Products
- Vegetables

During the period under review, a total number of 197 companies or institutions were visited for inspections, ranging from pre-registration, routine, consumer complaints, and destination (import control). Generally, most of the local companies did not conform to the required level of current good manufacturing practices (cGMP).

Table 6 indicates the summary of activities conducted by the Unit in 2003.

**Table 6: Summary of Activities Conducted by FPIU**

| Category of Inspection | Number of Inspection | % |
|---|---|---|
| Destination Inspection | 9 | 4.6 |
| Water | 114 | 57.9 |
| Diary | 4 | 2.0 |

| | | |
|---|---|---|
| Vegetables | 11 | 5.6 |
| Drinks | 27 | 13.7 |
| Confectionery | 5 | 2.5 |
| Additives | 17 | 8.6 |
| Consumer Complaints | 10 | 5.1 |
| **Total** | **197** | **100** |

#### 3.3.2.3 Food Post-Market Surveillance Unit

The Unit undertakes the following functions to contribute to the achievements of the Food Inspectorate Department:

1. Inspect food storage facilities to ensure their operations conform to Good Warehouse/Cold store Practices (GWP / GCP).
2. Inspect retail outlets and their storage accessories to ensure their operations conform to Good Retail Practices (GRP).
3. Monitor and regulate advertisements of food products
4. Destroy unwholesome food products
5. Investigate consumer complaints and any other relevant query regarding food products
6. Monitor food product registration and quality status on the Ghanaian market.

In 2003, the Unit inspected 54 food storage facilities and 27 cold store facilities to ensure Good Warehouse Practices (GWP) and Good Coldstore Practices (GCP), respectively. It was observed that almost all the companies did not conform to GWP and GCP requirements. As a step to overcome these deficiencies, the Unit intends to embark on the following in the first quarter of 2004:

- A sensitization program in Good Storage Practices for importers and warehouse operators.
- A training program in Good Warehouse Management for warehouse managers and supervisors.

- Institute sanctions against any Warehouse/Coldstore operator who fails to implement any recommendations given by the Board.

In 2003, not much was achieved in the Retail Outlets (Supermarkets) inspections due to limited staff. However, a pilot survey conducted by the Unit in the area of product monitoring activities revealed that 15 different locally manufactured and 2 imported products sold on the open market had not been registered with the Board and the labelling did not conform to the General Labeling Rules (LI 1541) 1996.

## 3.4 QUALITY CONTROL LABORATORY

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 Board to take regulatory steps. The laboratory performs chemical, physical and microbial analysis of chemical and herbal drugs. It also supports both internal and external clients by providing reliable analytical and advisory services. Internally, samples come from the Product Registration Department, Post-Market Surveillance activities, Food Safety and Nutrition Department, Inspectorate Departments, Ports Operations, and Consumer Complaints. External clients include CEPS, POLICE CID, Central Medical Stores and the Pharmacy Board of Sierra Leone.

In 2003, a total of 2091 samples were received and 2015 were analyzed. All the samples received were assessed for quality, efficacy and safety. The details are provided below (Table 7).

### 3.4.1 Source of Samples Received

During the year under review, a total of 2091samples were received. The sources of these samples were Drug Evaluation and Registration Department, Inspectorate Departments, Post Market Surveillance activities, Port Operations, Customs Excise and Preventive Service (CEPS), Ghana Health Service/Central Medical Stores, Police Service

CID, Sierra Leone Pharmacy Board, Veterinary Council, Consumer Complaints, and Requests.

Table 7 shows the summary of source of samples received in 2003.

**Table 7: Distribution of Source of Samples**

| **Source** | **Allopathic Drugs** | **Herbal** | **Cosmetics** | **Food** | **Sachet Water** |
|---|---|---|---|---|---|
| Drug Evaluation & Registration | 750 | 148 | 163 | - | - |
| Inspectorate/PMS/Port Offices | 28 | 9 | 8 | 18 | 73 |
| Food Safety & Nutrition | - | - | - | 549 | 92 |
| CEPS | 21 | 2 | 2 | 3 | - |
| M.O.H/GHS | 109 | - | - | - | - |
| Central Medical Stores | 47 | - | - | - | - |
| Police CID | 17 | - | - | - | - |
| Sierra Leone Pharmacy Board | 5 | - | - | - | - |
| Veterinary | 12 | - | - | - | - |
| Consumer Complaints | 1 | - | 1 | - | 3 |
| Request | 30 | - | - | - | - |
| **Total** | **1020** | **159** | **174** | **570** | **168** |

Table 8 gives the summary of samples received for various analytical tests.

**Table 8: Summary of Samples Received**

| **Sample Category** | **Number Received** | **%** |
|---|---|---|
| Allopathic Drugs | 1020 | 49 |
| Food | 570 | 27 |
| Cosmetics | 174 | 8.3 |
| Herbal | 159 | 7.6 |
| Sachet Water | 168 | 8.0 |

| | | |
|---|---|---|
| **Total** | **2091** | **100** |

### 3.4.2 Sample Analysis

Out of the total samples received, 1713 samples (81.9%) passed and 302 samples (14.4%) failed the analytical tests. 76 samples, representing 3.6% were not analyzed due to lack of equipment or full compliment of reagents and reference standards. The details are shown in Table 9. Fig. 6 shows the status of sample analysis.

**Table 9: Summary of Sample Analysis**

| Sample Category | Total Received | Analyzed | Passed | Failed | Not Analyzed |
|---|---|---|---|---|---|
| Drugs | 1,020 | 945 | 843 | 102 | 75 |
| Food | 570 | 569 | 528 | 41 | 1 |
| Cosmetics | 174 | 174 | 162 | 12 | - |
| Herbal | 159 | 159 | 102 | 57 | - |
| Sachet Water | 168 | 168 | 78 | 90 | - |
| TOTAL | 2,091 | 2,015 | 1,713 | 302 | 76 |

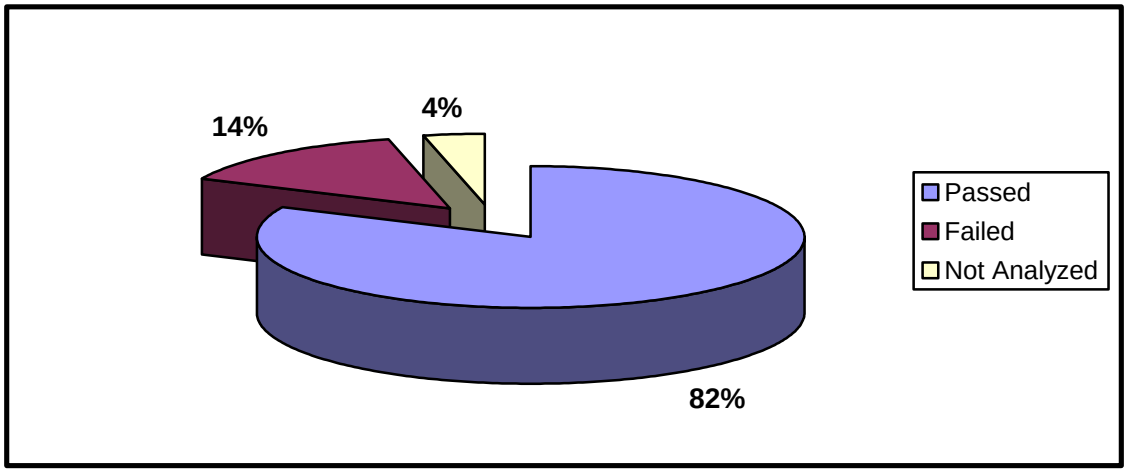


**Fig 6: Status of sample analysis**

### 3.4.3 Equipment

In order to increase the analytical capacity of the Laboratory, high precision instruments were acquired and installed during the year under review. The instruments installed included a High Performance Liquid Chromatography (HPLC) series 200 by Perkin Elmer and Fourier Transform Infra-red Spectrophotometer (FTIR) by Perkin Elmer.

The following instruments are already installed and functional:

- UV/VIS spectrophotometer (Perkin Elmer)- Lambda 35
- Dissolution Tester (six station) (Erweka)
- Disintegration Tester (four station) (Pharma Test)
- Suppository Disintegration Tester
- Suppository Hardness Tester
- Suppository Melting Point Apparatus
- Viscometer
- Distilled Water Generating Plant
- De-ionized water plant
- Digital Polarimeter
- Digital Abbe Refractometer
- Protein / Fat / Moisture Analyzer.

An Atomic Absorption Spectrophotometer (AAS) and a Gas Chromatograph (GC) have been acquired and awaiting installation by the end of June 2004. It is hoped that after the installation of the AAS and the GC, the Laboratory will be in a position to analyze almost all classes of compounds and products.

Medical devices, including condom testing machines, have also been ordered and will be delivered by the end of March, 2004.

## 3.5 PORT OPERATIONS

To strengthen its mandate in regulatory affairs, the Board extended its operations to major ports of entry in the country. In 2003, the Board had two operational port offices located at Kotoka International Airport (KIA) and Tema Sea Port.

The principal function of these offices is to conduct destination inspection of imported products that fall within the purview of the Food and Drugs Law, PNDCL 305 (B). Other duties performed by the port offices include supervision of destruction of expired or unwholesome products and to a limited extent, post-marketing surveillance.

The inspection covers the expiry dates, manufacturing dates, batch/lot numbers, packaging, storage, physical condition of the goods, quantities, number of different items imported, the registration status of the products, etc. A report on the inspection is issued to the Head Office which issues permits through the port offices to the importer for the goods to be released.

During the year under review, 1,393 destination inspections were conducted by the Tema Port Office whilst 1,531 were conducted by the KIA Office. Table 10 indicates the summary of destination inspections conducted from January – December, 2003 by the two offices.

**Table 10: Summary of Destination Inspections Conducted in 2003**

| Month | Tema Port Office | KIA Office |
|---|---|---|
| JANUARY | 132 | 285 |
| FEBRARY | 129 | 68 |
| MARCH | 184 | 94 |
| APRIL | 123 | 70 |
| MAY | 127 | 72 |
| JUNE | 115 | 12 |
| JULY | 84 | 140 |
| AUGUST | 86 | 183 |
| SEPTEMBER | 109 | 130 |
| OCTOBER | 96 | 194 |
| NOVEMBER | 105 | 135 |

| | | |
|---|---|---|
| DECEMBER | 103 | 148 |
| **Total** | **1,393** | **1,531** |

Some importers or their clearing agents tried to circumvent the process by avoiding the destination inspection of their products. To address this problem, CEPS attention was drawn to the need to ensure that all food and drug imports be inspected by Regulatory Officers of the Board and approval given prior to the release of the products.

## 3.6 ZONAL OFFICES

The Food and Drugs Board, in line with its decentralization policy and desirous to uphold its mission statement, extended its services to the regions.

Before 2003, the Board had only one Zonal/Regional Office located at Kumasi to carry out its mandate in Brong Ahafo and Ashanti regions. In 2003, additional 2 Zonal Offices were opened to augment the number to three. The Zonal Offices are:

- Bolgatanga Zonal Office, responsible for Northern, Upper East and Upper West regions.
- Kumasi Zonal Office, responsible for Ashanti and Brong Ahafo regions.
- Takoradi Zonal Office, responsible for Central and Western Regions.

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

- Vetting and approval of advertisement scripts and jingles
- Monitoring of advertisements on the electronic media
- Embark on consumer awareness programmes such as radio talk shows, seminars, lectures, and press release etc.
- Organized stakeholders meeting
- Inspections including post-market surveillance
- Consumer complaints protocol to deal with consumer issues

- Sale and processing of application/permit for premises, product registration and renewals
- Registration of importers of food, drugs, cosmetics, household chemicals, and medical devices.

The internal generated funds of the Zonal Offices come from the activities of sale of registration forms, advertisement forms, advertising right fees, destination inspection fees, destruction fees, and product registration fees.

### 3.6.1 Zonal Activities Conducted in 2003.

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 was 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.
Table 11 shows the summary of activities performed by the various Zonal Offices.

**Table 11: Summary of Activities by Zonal Offices**

| **Activity** | **Bolga Zonal Office** | **Kumasi Zonal Office** | **Takoradi Zonal Office** |
|---|---|---|---|
| Pre-licensing Inspection | 17 | 201 | 88 |
| PMS (Seizures)<br>Food<br>Drugs | 684 Cola Flavour Drinks<br>10,760 Tablets of Super Apetit | -<br>- | 1 Crispy Cracker<br>150 Veterinary Products |
| Meeting with Stakeholders | 5 | 8 | Nil |
| Seminar/workshop | Nil | 3 | Nil |
| Consumer | | | |

| | | | |
|---|---|---|---|
| Complaints | Nil | Nil | 1 |
| Media Interview and Programmes | 1 | 19 | 1 |
| Total Amount Generate | Not Available | ¢165,910,000.00 and $6,200.00 | ¢18,790,000.00 |

As part of its decentralization programme, the Board plans to open additional offices at Aflao and Elubo border posts and four more Zonal offices in Brong Ahafo, Eastern, Northern and Volta regions, respectively, by December 2004. Preparations began in the fourth quarter of 2003 to open a Zonal Office in Ho in the Volta region, which is hoped to become operational by May 2004.

## 4.0 FUTURE DIRECTION

It is expected that the Food and Drugs Board's strategic direction for 2004 will focus on the following:

- Continue decentralization programme for effective implementation and enforcement of the regulatory laws.
- Expansion of Human Resource base with relevant skills, knowledge and abilities. In all, the Board would need additional staff strength of 50 made up of 35 core staff and 15 support staff.
- Manpower training and development.
- Review of PNDCL 305B to make it more effective and relevant to the needs of the country and its obligations to the international community
- Intensify consumer awareness programmes to ensure public health and safety and consumer confidence.
- Become ISO 9000:2000 Quality Management System compliance.
- Install efficient MIS to capture important data.