REPUBLIC OF GHANA

# 20 15
# ANNUAL REPORT

## FOOD AND DRUGS BOARD

*.....Working for your safety*

**FIGURES**

**TABLES**

**ACRONYMS AND ABBREVIATIONS**

| | | |
|---|---|---|
| ADRs | - | Adverse Drug Reactions |
| BPU | - | Biological Products Unit |
| BBBPERU | - | Biologics, Blood and Blood Products Evaluation and Regulation Unit |
| BNARI | - | Bio-Technology and Nuclear Agriculture Research Institute |

| | | |
|---|---|---|
| CEPS | - | Customs Excise and Preventive Service |
| CID | - | Criminal Investigation Department |
| CMS | - | Central Medical Stores |
| CT | - | Clinical Trials |
| CTAs | - | Clinical Trials Applications |
| EMEA | - | European Medicine Agency |
| FDA | - | Food and Drugs Authority |
| FDL | - | Food and Drugs Law |
| FSMU | - | Food Safety Management Unit |
| FPMSU | - | Food Post Market Surveillance Unit |
| FPIU | - | Food Premises Inspection Unit |
| GAIN | - | Global Alliance for Improved Nutrition |
| GAP | - | Good Agricultural Practice |
| GCMS | - | Ghana Customs Management System |
| GCNet | - | Ghana Community Network Limited |
| GCP | - | Good Cold Store Practices |
| GCP | - | Good Clinical Practice |
| GDP | - | Good Distribution Practice |

GHP - Good Hygiene Practice

GM - Genetically Modified

GMP - Good Manufacturing Practices

GWP - Good Warehouse Practice

LMWH - Low Molecular Weight Healing

HACCP - Hazard Analysis and Critical Control Point

IECD - Import and Export Control Department

ICT - International Competitive Tender

ISO - International Standard Organization

ISOP - International Society of Pharmacovigilance

INFOSAN - International Food Safety Authorities Network KNUST - Kwame Nkrumah University of Science and Technology

NCB - National Competitive Bidding

NFFA - National Food Fortification Alliance

NMCP - National Malarial Control Programme

NRAs - National Regulatory Authorities

PNDC - Provisional National Defence Council

PNDCL - Provisional National Defence Council Law

PRMISD - Projects, Research and Management Information System Department

| | | |
|---|---|---|
| QAMSA | - | Quality of Anti-malarial Survey Assessment |
| SAEs | - | Serious Adverse Events |
| TAC | - | Technical Advisory Committee |
| TACSM | - | Technical Advisory Committee for Safety Monitoring |
| MOFA | - | Ministry of Food and Agriculture |
| U.K | - | United Kingdom |
| USI | - | Universal Salt Iodation |
| USP | - | United State Pharmacopeia |
| WHO | - | World Health Organization |
| WAHO | - | West Africa Health Organization |

**EXECUTIVE SUMMARY**

In accordance with the Public Health Act 851, 2012, this Report covers activities of the Food and Drugs Authority over the period 1st January 2015 to 31st December, 2015.

The Food and Drugs Authority achieved a momentous feat in the year 2015 and there was a continuation of work to consolidate the instituitional framework for the establishment of the Food and Drugs Authority (FDA) as a Government regulatory body responsible for the control of the manufacture, importation, exportation, distribution, use and advertisement of food, drugs, cosmetics, medical devices and household chemical substances, under the Public Health Act 851, 2012. The Tobacco Control Bill, which forms part of the Public Health Act, 2012 is under the control of the FDA, Ghana. Other policies and guidelines aimed at strengthening the FDA to deliver on its mandate were put in place. These included the guidelines and documents for food and drugs activities and the mandated fee schedule. An inventory of other policies and guidelines

already developed, which have implications for the operations of the FDA, were initiated and steps were taken to review them.

During the year, a range of activities including consumer and public education programmes, regulatory enforcement functions and Good Manufacturing Practices (GMP) training programmes were outlined to support industry and to protect public health and safety.

Applications for the registration of drugs, food, cosmetics, household chemical substances, and Medical devices as well as premises inspections increased by 45% during the year as compared to 40% in 2014. Medicines post market surveillance functions and Food Market Surveillance activities increased by 65% especially on Herbal Medicinal and imported food products, respectively, which have grave consequences on public health and its implications for healthcare delivery. There was an improvement in the operations of the Regional Offices especially during post market surveillance activities over the previous years, which recorded 15,350 in 2015 as compared to 13,253 in 2014; 9,500 in 2013 and 9,200 in 2012. The FDA continued its regulatory control of the exportation of palm oil to the European Union. However, permits issued through the GcNet were nineteen thousand two hundred and forty-two (19,242) as compared to twenty one thousand, three hundred and forty-five (21, 345) in 2014 and eighteen thousand and seventy-one (18,071) in 2013.

## 1.0 THE AUTHORITY

### 1.1 INTRODUCTION

The Food and Drugs Authority (FDA) as a national regulatory body that has the responsibility for the regulatory control of the manufacturing, importation, exportation, distribution, sale and advertisement of food, drugs, cosmetics, medical devices and household chemical substances as enshrined in the Public Health Act, 2012 (ACT 851). This is a very critical role, as misbranding, substandard and/or counterfeit, as well as unsubstantiated product information has very grave consequences on public health and serious implications for healthcare delivery. The FDA, since August 1997, has been pursuing various specific objectives to address issues on regulatory control of products as stated in our mandate.

The following sections deal with the summaries of achievements in 2014.

#### 1.1.0 Governing Board

The Governing Board of the Food and Drugs Authority consists of twelve (12) members appointed by the President of Ghana acting in consultation with the Council of State of the Republic. In

making the appointment, the President takes into consideration the knowledge, expertise and experience of the persons so appointed and in particular, their knowledge in matters relevant to the functions of the Authority.

The Chief Exective Officer is responsible for the day-to-day administration of the Food and Drugs Authority and is required to ensure the implementation of the decisions of the Board.

The current composition of the Board is as follows:

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

12. Ms Cynthia Adwoa Dapaah Food and Drugs Authority.

### 1.1.2 Objectives

The objectives of the Authority is to provide and enforce standards for the sale of food, herbal medicinal products, cosmetics, drugs, medical devices and household chemical substances. The critical statutory mandate of the FDA as spelt out by the Public Health Act, 2012 (ACT 851) includes the following:

- *Ensure adequate and effective standards for food, drugs, cosmetics, household chemicals and medical devices;*
- *Monitor through the District Assemblies and any other agency of State compliance with the provisions of this Part;*
- *Advise the Minister on measures for the protection of the health of consumers;*
- *Advise the Minister on the preparation of effective Regulations for the implementation of this Part;*
- *Approve the initiation and conduct of clinical trials in the country; and*
- *Perform any other functions that are ancillary to attaining the objects of the Authority.*

### 1.1.3 STRUCTURE

The Authority's operations are structured under six (6) Divisions as follows:

1. **Drugs Evaluation and Inspectorate Division**. five (5) specialised Departments make up the Division:
    a. Tobacco and Substances of Abuse Department;
    b. Drugs Enforcement Department;
    c. Drugs Registration Department;
    d. Herbal Medicine Department; and
    e. Drugs Industrial Support Department;

The Drugs Evaluation and Inspectorate Division is responsible for the safeguarding of public health by ensuring that all medicines on the market meet appropriate standards of safety, efficacy, and quality. These functions are carried out by regulating all medicines submitted in the registration dossiers, pre-registration inspection, drug quality analysis reports, licensing of manufacturing plants, warehouses and inspections. The Division also controls tobacco, licit narcotic drugs, psychotropic substances and chemical precursors in Ghana.

2. **Medical Device, Cosmetics and Household Chemicals Division**. The Division is made up of three (3) Departments:

    **a.** Medical Devices Department;

    **b.** Cosmetics and Household Chemical Substance Department and;

    **c.** Medical Devices, Cosmetics and Household Chemical Substance Enforcement Department.

    The Division is responsible for the regulation of all classes of medical devices, cosmetics and household chemicals in Ghana.

3. **Safety Monitoring and Clincial Trials Division**. The following Departments and unit constitute the Division:

    **a.** Safety Monitoring Department;

    **b.** Clinical Trial Department and ;

    **c.** Blood and Blood Product Unit.

    The Division derived its mandate from the Public Health Act, 2012, Act 851, Part 7 and 8, Section 125 and 150-166 respectively. As part of its mandate, the Division monitors the safety of the medicines analysis of the adverse effect or event reports and by any other means and takes appropriate regulatory action when necessary.

4. **Food Inspectorate Division**. The Division achieved its mandate through the following three (3) Departments:

    **a.** Food Enforcement Department;

    **b.** Food Registration Department and;

**c.** Food Industrial Support Department.

This Division contributes to the achievement of the goals of the Food and Drugs Authority for safeguarding public health by ensuring that all food products on the market meet appropriate standards of safety and quality through pre-marketing assessment of food safety and quality. This is achieved by evaluating all samples submitted in the registration process, premises inspection, and meeting labelling requirements. The Division is also mandated to undertake inspection of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify compliance to Good Manufacturing Practices. In addition, the Division ensures that all imported and locally manufactured food products are of good quality and wholesome.

5. **Food Safety Division**. This Division is made up two (2) departments:

    **a.** Food Safety Management Department and;

    **b.** Animal Product and Biosafety Department.

    And it's mandated to safeguard public health by ensuring that all restaurants and cold storage facilities are licenced. It also conducts public education to sensitise the public on food safety issues such as Genetically Modified Organisim (GMO).

6. **Regional Monitoring and Evaluation Division**. The following regions make up the Division:

    **a.** Upper West Regional Office;

    **b.** Upper East Regional Ofice;

    **c.** Northern Regional Office

    **d.** Brong Ahafo Regional Office;

    **e.** Ashanti Regional Office;

    **f.** Volta Regional Office;

    **g.** Eastern Regional Office;

    **h.** Central Regional Office and;

    **i.** Western Regional Office.

The Division supervises all the nine (9) regions by preparing indicative plans and making recommendations which would ensure that all demands for activities in the regions are met in an efficient and sustainable manner.

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

**j. <u>The finance, Administration, Human Resource, Communication and Public Education and PRMIS</u>**

They are charged with ensuring that the Authority continuously possesses the needed capacity and the financial, human and technological resources required to effectively and efficiently play its role as Technical regulator within the health sector. The specific tasks of these departments and unit include developing and implementing systems and procedures for the efficient and effective delivery of general administrative services of the Authority, coordinating the preparation of annual budgets of the Authority, developing a human resource plan to provide the requisite skill levels to meet the Authority's mission and objectives; coordinating the procurement of contracted general services for the Authority; developing and implementing staff performance appraisal and incentive systems; providing stable internet and security; and ensuring that the Food and Drugs Authority is constantly in touch with the public by maintaining healthy relations with the Ghanaian Media and the general Public.

**k. <u>Legal Department</u>**

As a state institution established by an Act of Parliament, the entire mandate of the Food and Drugs Authority is founded on legal provisions and regulatory boundaries which have to be followed to the letter. The Authority's legal Department is required to make appropriate recommendations relating to the efficiency and effectiveness of established regulatory frameworks and strategies; to serve as the Board Secretariat and in that regards to advise members of the Board on all legal matters, and to represent the Authority on all legal matters.

**l. <u>Internal Audit Department</u>**

In keeping with the good governance principles of transparency and accountability, the Authority's internal Audit Department is charged with planning, managing,

organising and controlling its audit functions as well as ensuring that proper books of accounts are maintained in line with current trends and international best practices. The Department also ensures that standard accounting practices, policies and procedures are adhered to and that adequate producedures have been instituted for the detection of risk and for the prevention or elimination of such risk.

**m. Import and Export Control Department (IECD).**

The Department is mandated to regulate the importation and exportation of food, drugs, cosmetics, household chemical substances, and medical devices in accordance with the Public Health Act, 2012, (ACT851). The activities of the Department are concentrated at the various entry routes to the Country. The activities of the Department cover the Tema Port, Kotoka International Airport (KIA), and the Head Office as well as having oversight responsibilities of the all land boarders in the country, for the issuance of electronic permits through the GCNet System. The operational areas of the Department include various freight stations and carrier terminals at the KIA as well as container terminals, freight stations, sheds and wharf sites at the Tema Port.

**n. Laboratory Services Department**

The Quality Control Laboratory provides laboratory services in the form of quality evaluation of food, drugs, cosmetics and household chemical substances. The Laboratory plays the role of determining the quality of these products, thereby enabling the Authority to take regulatory decisions. The laboratory performs chemical, physical and microbiological analysis of chemical and herbal drugs. The quality parameters employed are as established in standard compendia indicated in schedule IV of the Public Health Act, 2012 (ACT 851). The Department also supports both internal and external clients by providing reliable analytical and advisory services.

## 1.2 ORGANOGRAM OF THE FOOD AND DRUGS AUTHORITY

The current organogram of the FDA is indicated on page 15.