FOOD AND DRUGS AUTHORITY

Presented by

COMMUNICATIONS & PUBLIC EDUC. DEPT

OUTLINE

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Introduction to the Food and Drugs Authority

The FDA was established in **August 1997** as the Food and Drugs Board (FDB) under the Food and Drugs Law, 1992 (PNDCL 305B).

PNDCL 305B in 2012 was integrated into the **Public Health ACT 851, 2012 and** with the name Food and Drugs Authority.

The Food and Drugs Authority is mandated by Parts 6, 7, 8 & 9 of the Public Health Act 2012, Act 851 to *protect public health and safety*.

Strategic focus…

Vision

Our Vision is to protect the health and safety of people in Ghana and be a global Centre of Excellence for food and medical products regulation.

Mission

The FDA exists to ensure the **safety**, **quality** and **efficacy** of human and veterinary drugs, food, biological products, cosmetics, medical devices, household chemical substances and clinical trials, and the control of tobacco products through the enforcement of relevant standards to protect public health.

Our core values

Integrity

Accountability

Teamwork

How we are funded…

We are funded both by Government of Ghana and internally generated funds (IGF).

IGF is generated via

- Fees for regulatory services such as products registration, licensing of facilities etc.
- Administrative fines for non-compliance to regulations.
- Percentage of free on board (FOB) cost of imported products.

Our regulatory activities…

The products we regulate:

Allopathic medicines

Herbal medicines

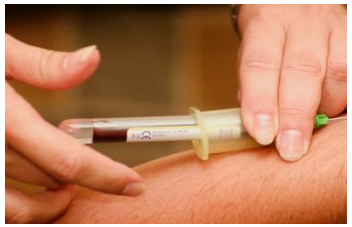
Food

Medical devices

Household chemicals

Cosmetics

Tobacco & Tobacco products



Blood & blood products

Vaccines

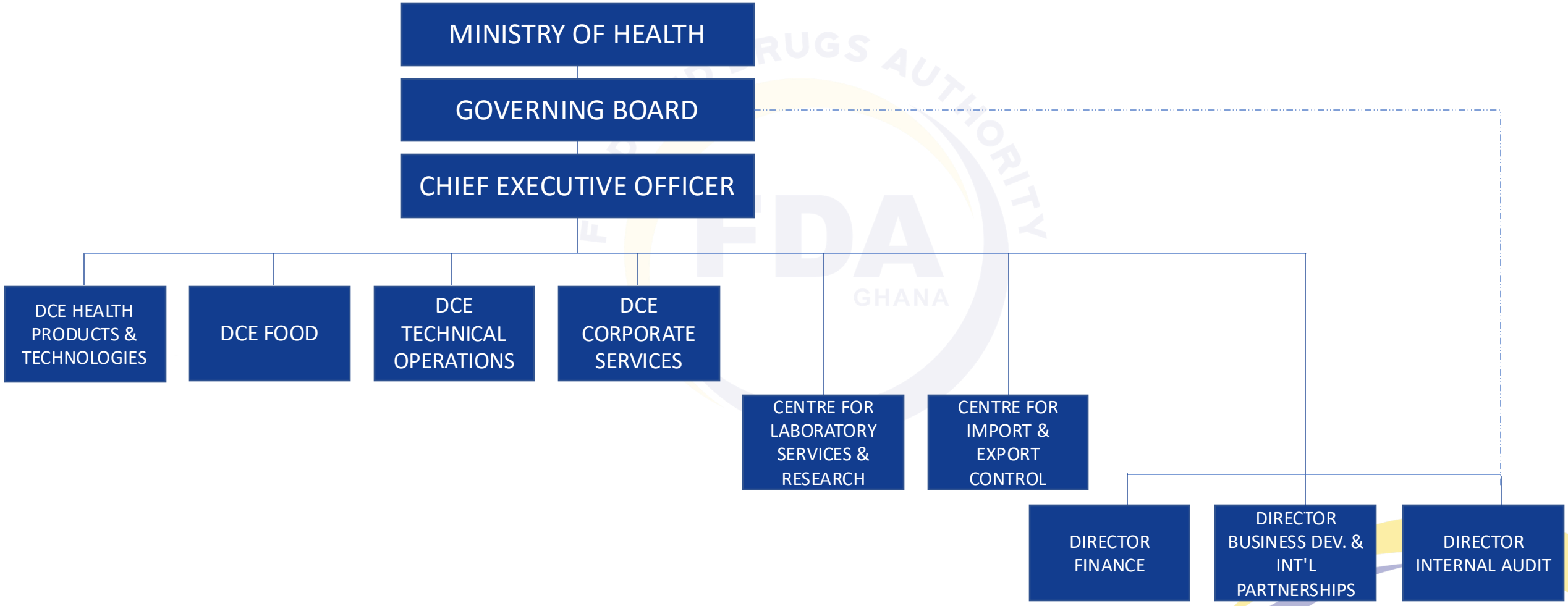
Some of our key activities include:

- **Registration** of FDA-regulated products.
- **License** manufacturing, storage, and distribution facilities.
- **Market surveillance** of FDA-regulated products**.**
- Authorisation and monitoring **clinical trials**.
- **Safety monitoring** of FDA-regulated products.
- Provide **industrial support** to *local manufacturers*.
- **Enforce standards** for FDA-regulated products as well as **tobacco control** regulations.
- **Advertisement** approval and monitoring

Operational Offices…

FDA has offices in 12 Regions in the country

Our organogram…



Centre for Laboratory Services & Research

Our state of the art laboratory ascertains the safety, quality and efficacy of regulated products.

OVERVIEW OF THE FDA LAB:

The Centre has **6 testing Laboratories and a Quality Assurance Office.** The testing laboratories include:

- Drug Physiochemical
- Food Physiochemical
- Pharmaceutical Microbiology
- Food Microbiology
- Cosmetic/ Household Chemical Substances
- Medical Devices

We offer commercial testing services

Centre for Import and Export Control

The Centre for Import and Export Control (CIEC) comprises **1 airport (KIA)**, **2 seaports**, and **12 border posts**.

CORE ACTIVITIES:

- Issuance of permits
- Inspection and clearance of imported products
- Import data analytics
- Sampling and testing of high-risk products
- Inspection of export cargo
- Inspection of customs bonded warehouses

No Registration
No Importation

ISO Accreditation …

Our administrative, operational and quality control lab are accredited to ISO standards.

- Our administrative and operational procedures for FDA offices in Greater Accra, Volta, and Ashanti Regions are certified to **ISO 9001:2015** since 2017.
- Our Quality Assurance function maintains ISO/IEC 17025:2017 for testing and calibration laboratories and ISO 9001:2015 for quality management systems. Our drug laboratory is WHO-prequalified.
- We have the largest scope of accredited tests under a single roof in Africa.

Regional Centre of Regulatory Excellence (RCORE)

The FDA has been designated by AUDA-NEPAD and AMRH as RCORE since 2014 for Clinical Trials, Medicine Evaluation and Registration and Medicines Safety

RCORE ACTIVITIES :

- Annual 30-day fellowship course
  - Clinical trial authorisation
  - GCP inspections
  - Adverse events and safety monitoring
  - Regulatory attachment
- Capacity building in medicines dossier assessment

More than 60 regulators in Sub-Saharan Africa trained

International Collaborations & Affiliations

The FDA has been actively involved in regulatory activities on the Continent and beyond.

COLLABORATIONS & AFFILIATIONS

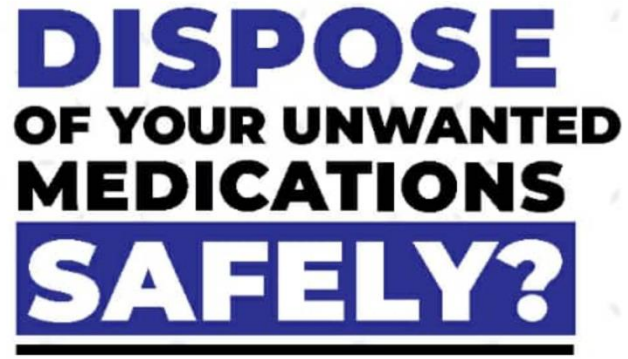
- Member of African Vaccine Regulatory Forum (AVAREF)
- Non-EU member of European Medicines Agency (EMA) Good Clinical Practice (GCP) Inspectors' Working Group.
- Lead coordinating country for West Africa Medicines Regulatory Harmonization (WA-MRH) Project.
- Participate in the WAHO Joint Medicine Evaluation Harmonization Process
- Africa Medicines Regulation Harmonisation
- Member of the WHO Programme for International Drug Monitoring
- WHO/ CIOMS Committee on Vaccine Safety
- UK MHRA
- Paul Ehrlich Institute

Initiatives…

1. **Take Back Unwanted Medicines (TBUM)** is an FDA project to promote safe disposal of unused and expired medical products.

2. **Progressive License Scheme (PLS)** this aims to support small business units to improve on the safety, quality and wholesomeness of their products.

3. **Promotion of Made-In-Ghana goods** in large supermarket chains to boost their patronage.



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ABARAKA

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