MEDICAL DEVICES REGISTRATION DEPARTMENT

(REGULATION OF MEDICAL DEVICES)

Presented by

Mr. Emmanuel Nkrumah

(DIRECTOR, MEDICAL DEVICES, COSMETICS AND HOUSEHOLD CHEMICALS)

FOOD AND DRUGS LAW

- **The Food and Drugs Board was established by the Food and Drugs Law 1992 (PNDCL 305B).**
- **The Law was amended by the Food and Drugs Amendment Act, Act 523.**
- **Public Health Act, 2012 (Act 851) Food And Drugs Law**

STRUCTURE OF PUBLIC HEALTH ACT 851

PART ONE	-	COMMUNICABLE DISEASES
PART TWO	-	VACCINATION
PART THREE	-	QUARANTINE
PART FOUR	-	VECTOR CONTROL
PART FIVE	-	ENVIRONMENTAL SANITATION
PART SIX	-	TOBACCO CONTROL MEASURES
PART SEVEN	-	FOOD AND DRUGS (FDA)
PART EIGHT	-	CLINICAL TRIALS
PART NINE	-	MISCELLANEOUS
SCHEDULES		

OVERVIEW OF THE PUBLIC HEALTH ACT

- **70 Sections**
- **14 Sections on Food**
- **19 Sections on Drugs, Cosmetics, Medical Devices, Household Chemicals**
- **17 Sections on Administration**
- **20 Sections on General Provisions**
- **Schedules**

✓ **FOURTH SCHEDULE**
List of publication for standards for drugs

✓ **FIFTH SCHEDULE**
Diseases for which advertisement for treatment, prevention or cure are prohibited

SECTIONS OF THE PUBLIC HEALTH ACT

Section 80(1) establishes the FDA

Section 81 Object of the Authority: to provide and enforce standards for the sale of food, herbal medicinal products, cosmetics, drugs, medical devices and household chemical substances.

Section 82 Functions: The Authority shall

- ***(a) ensure adequate and effective standards for the regulation of food, herbal medicinal products, cosmetics, household chemicals, drugs, and*** **medical devices.**
- ***(b) monitor through the District Assemblies and any other*** **agency of State compliance with the provisions of this Part;**
- ***(c) advise the Minister on measures for the protection of the*** **health of consumers;**
- ***(d) advise the Minister on the preparation of effective Regulations*** **for the implementation of this Part; and**
- ***(f) Perform any other functions that are ancillary to attaining*** **the objects of the Authority**

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DEFINITION OF MEDICAL DEVICE

Refers to an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is:

(a) Recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;

(b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals; or

(c) Intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

PRINCIPLES UNDERPINNING REGULATION OF MEDICAL DEVICES

- **Quality**
  - Must meet all internationally accepted standards
- **Safety**
  - All devices must be safe to the user, the patient, the environment and any other person
- **Good performance**
  - The performance of medical devices must be as specified and not be compromised by virtue of the country of origin or the particular manufacturer involved or the country in which the device will be used.

REGULATING MEDICAL DEVICES

Critical elements :

- **Regulatory System**
  - Functional
  - Dynamic
- **Import Controls**
  - Robust
  - Responsive
- **Distribution Channel Control**
  - Effective
  - Integrative

CLASSIFICATION OF MEDICAL DEVICES

- Medical devices are classified into four groups, based on a risk assessment.
- Class I represents the group with the lowest risk and Class IV represents the group with the highest risk.
- Under this classification process, all devices fit into one of the four categories
- When a medical device is classified into more than one class, the class representing the higher risk applies (syringe and needle)

CLASSES OF MEDICAL DEVICE

CLASS	RISK LEVEL	EXAMPLES
I	Low	Cotton Wool, Gauze Roll, Plaster, Bandages, Baby Diapers, Sanitary Pads, Examination Gloves. etc
II	Low - Moderate	Syringe and needle, Catheters, Surgical Gloves, Infusion Set, IV Cannula, Blood Bags, Pregnancy Test Kit, Malaria Test Kits. etc
III	Moderate - High	Condoms, Xray Machine, MRI Machines, Syphillis Test Kit. etc
IV	High	Pacemaker, Hip Implants, Stents, Heart valve, Mesh, HIV test kit, Covid-19 kit, Absorbable Sutures etc

Per the FDA classification rules (Appendix IV- Classification Rules for MD, Part 2, Rule 2a) in the use of a test kit for life threatening diseases, if an erroneous result can lead to the propagation of the disease in the Ghanaian population, the device is placed in the Class IV category.

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CLASSIFICATION OF MEDICAL DEVICES

- **Determination of the risk**
  - risk associated with the device to the human body usually during proper use (indication for which it is registered).
  - the risk to the safety of patients or
  - the safety and health of users or
  - the safety and health of other person or the environment.

- **Control/Regulation of MD's is based on the level of potential Hazard to the body.**
  - the higher the risk, the greater the regulatory oversight
  - low risk class has minimum regulatory control

CLASSIFICATION OF MEDICAL DEVICES

- **The level of risk is influenced by**
  - Degree of invasiveness
  - Mode of action - whether active or passive device
  - The duration of contact with the patient - the 30-day mark
  - Impact on the body - local vs. Systemic effect

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REGULATORY REQUIREMENTS

- **Dossier/Document evaluation**
  - To evaluate documentary evidence relating to the development and manufacture of the medical device, as well as issues on the safety, quality and performance. It also includes Pre-clinical information and Clinical data

- **GMP/QMS Audit of manufacturing facility**
  - Provides information on ability to consistently produce quality/safe products

- **Quality Evaluation of samples**
  - To evaluate the representative samples on the stated specifications
  - On-site verification and validation of bulky devices.

- **Import and Export Control**
  - Monitors to ensure that only registered products enter the country legally

- **Post Market Surveillance (PMS)**
  - Ensure that continuous monitoring of the safety, quality and good performance of registered medical devices on the market

THE REGISTRATION/APPROVAL PROCESS

- **Submission of the application**
  - The applicant submits the completed application form.
  - Samples
  - Fees

- **Evaluation of the Application**
  - Dossier evaluation Committee Meeting
  - Laboratory Evaluation of Samples
  - GMP/QMS Audit of facility

- **Product Registration Committee Meeting**
  - Recommendation for Approval
  - Recommendation for Deferral
  - Recommendation for Rejection

- **Final Decision**
  - The CEO takes the final decision which is communicated to the client

- **Appeal**
  - Applicant can appeal against the decision

APPLICATION TIMELINES

- Processing of applications – within six (6) months
- **Applicant may be required to provide additional data within 12 months of the first submission**
- **In case additional time is required, a formal request for extension must be submitted**
- Product Registration validity - three (3) years
- Importer license validity - one (1) year

GUIDELINES FOR MEDICAL DEVICES

- Guideline For Donation Of Medical Devices
- Guideline For Importation Of Medical Devices
- Guideline For Registration Of Software As Medical Device
- Guidelines For Registration Of Homemade Facemasks
- Guidelines For The Registration Of Medical Devices

NEW GUIDELINES

- Guidelines For Naming Medical Devices
- Guidelines For Authorization For Emergency Use RDTs For SARS-CoV-2 Virus

GUIDELINES UNDER REVIEW

- Guidelines For The Registration of Used and Refurbished Medical Devices

FEE SCHEDULE

PRODUCT CLASS	REGISTRATION FEE FOR 3 YEARS
I	$180 (per product)
II	$300 (per product)
III	$480 (per product)
IV	$480 (per product)
Locally Produced (I-IV)	750 GHC (per product)
On-site Testing Fees For Bulky Devices	1,200 GHC (per site)
QMS/GMP Audit For Foreign Facilities (Within Africa)	$4,000 (5 years)
QMS/GMP Audit For Foreign Facilities (Outside Africa)	$7,500 (5 years)

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THANK YOU

ANY QUESTIONS PLEASE?

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