INVESTING IN VACCINE LIFE CYCLE MANAGEMENT IN AFRICA

TOWARDS EQUAL ACCESS TO VACCINES AND BEYOND

VACCINE REGULATION IN GHANA NOW AND FUTURE.

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OUTLINE

- Introduction
- Regulation of vaccines in Ghana
- Legal basis for vaccines regulation in Ghana
- Regulatory required documents for the registration/licensing of vaccines
- Timelines for registration/licensing of vaccines
- Establishment of a Lot release system for future vaccines to be manufactured in Ghana
- Way Forward

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 2012 ACT851** and with the name Food and Drugs Authority.

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

OUR REGULATORY ACTIVITIES

Regulated Products

Allopathic medicines

Herbal medicines

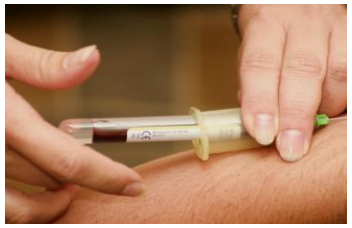
Food

Medical devices

Household chemicals

Cosmetics

Tobacco & Tobacco products



Blood & blood products

Vaccines

Some key Regulatory Functions:

- **Registration** of food and medical products.
- **License** manufacturing, storage, and distribution facilities.
- **Market surveillance** and **Control** of regulated products.
- **Authorisation** and **inspection** of Clinical Trials.
- **Safety monitoring** of regulated products.
- Enforce **tobacco control** regulations.
- **Advertisement** approval and monitoring
- **Quality Control Testing** of regulated products

REGULATION OF VACCINES

Section 118 of the Public Health Act 2012, Act 851, mandates the FDA to register/license vaccines intended to be marketed in Ghana.

Vaccines can be registered/license via two pathways:

- Routine
  - Full evaluation (Module 1-5)
- Non-routine
  - Abridged evaluation (Reliance pathway) - (e.g., WHO PQ, well-resourced NRA (SRA), etc)

LEGAL BASIS FOR VACCINE REGULATION

- Legal provisions for vaccine regulation found in Parts Seven (7) and Eight (8) of PHA 2012 Act 851
- Applicable Sections of the PHA 2012 Act851:
  - Clinical Trials Oversight – Section 150 to 166
  - Registration of drugs, including vaccines – Section 118-124
  - Safety Monitoring – Section 125
  - Laboratory Testing – Section 127
  - Penalties – Section 129
  - Registration of premises – Section 130
  - Licenses and Permits – Section 131
  - Guidelines Section – 149

REQUIRED DOCUMENTS FOR AUTHORIZING VACCINES CLINICAL TRIALS

- Administrative requirements
- Clinical trial protocol
- CMC (Information of the drug substance and drug product in CTD format)
- Investigators Brochure (IB)

REQUIRED DOCUMENTS FOR LICENSING VACCINES_MARKETING AUTHORIZATION

- Administrative requirements
- Complete product application dossier in CTD format
- Risk Management Plan (RMP)

TIMELINES FOR AUTHORIZING VACCINES CLINICAL TRIALS

- Routine application – 60 days
- Reliance pathway – 30 days
- Emergency Use Authorization (EUA) – 21 days
  - Reduced to 15 days by AVAREF

TIMELINES FOR LICENSING VACCINES_MARKETING AUTHORIZATION

- Routine application – 240 days
- Reliance pathway – 90 days
- Emergency Use Authorization (EUA) – 15 days

LESSONS LEARNT FROM COVID-19 PANDEMIC

- Wide acceptance of Adaptive design in CT
- Emergency review timelines reduced from 21 days to 15 days
- EUA based on WHO EUL – 4 days
- Acceptance of rolling submission data. Data is submitted when it becomes available
- Joint review by an all-inclusive assessment team comprising of quality, non-clinical and clinical assessors.

Establishment of a Lot Release System

- Lot release system is mandatory for NRAs of vaccine producing countries in accordance with WHO TRS 978 Annex 2
- FDA Ghana has started preparations to put in place a system that will ensure the release of vaccines that would be manufactured locally in the future in accordance with TRS 978 Annex 2.
- Development of SOPs for vaccine lot release
- Training of more staff in

vaccine manufacture cGMP (Upstream and Downstream) and formulation of finished vaccine products

Non clinical and clinical evaluation of vaccine dossiers

Laboratory staff in vaccine testing (NAATs,ELISA, Neutralization Assays ,flow cytometry etc)

WAY FORWARD

- Locate resources to build the necessary capacity to establish an efficient vaccine lot release system in Ghana to ensure the Quality,Safety and Efficacy of all vaccines (imported and locally manufactured) in Ghana.

QUESTIONS

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