OUTLINE

- ESTABLISHMENT & LEGAL MANDATE OF FDA GHANA
- FDA-GHANA GUIDANCE DOCUMENTS
- THE HIGHEST PRIORITIES OF FDA GHANA
- TRENDS IN THE DEVELOPMENT OF BIOSIMILARS
- TRENDS IN REGULATORY CONVERGENCE AND/OR HARMONIZATION IN ECOWAS REGION
ESTABLISHMENT & LEGAL MANDATE

- The FDA was established in 1992 as the Food and Drugs Board (FDB) on the basis of the 1992 Food and Drug Law (PNDCL 305B),
- Later amended by the Food and Drugs ACT of 1996.

- The Food and Drugs legislation was revised in 2012 and integrated into a new Public Health ACT 581, 2012 that gave birth to the Food and Drugs Authority.

- The FDA's legal mandate is found in part 6 (Tobacco Control Measures), part 7 (organisation and responsibilities of the FDA), and part 8 (Clinical trials) of the Public Health Act, 2012 Act 851.
REGULATORY RESPONSIBILITY

- The FDA exists to protect public health by assuring the quality, safety, and efficacy of the following:
  - Human and veterinary drugs,
  - Food,
  - Biological products,
  - Cosmetics & Household Chemical Substances
  - Medical Devices,
  - Tobacco and Substances of Abuse
  - The conduct of clinical trials in the Ghana.
TECHNICAL ADVISORY COMMITTEES (TAC)

TAC for Clinical Trials and Pharmacovigilance of vaccines and biological products

TAC for Pharmacovigilance of Allopathic and Herbal Medicines

TAC for Pharmacovigilance of Cosmetics and Household chemicals

14/06/2018
FDA-GUIDANCE DOCUMENTS: BIOLOGICAL PRODUCT

- GUIDELINES FOR REGISTRATION OF BIOLOGICAL PRODUCTS
- GUIDELINES FOR REGISTRATION OF BIOSIMILAR PRODUCTS
- GUIDELINES FOR REGISTRATION OF WORLD HEALTH ORGANISATION (WHO) PRE-QUALIFIED BIOLOGICAL PRODUCTS
- GUIDELINES FOR APPLICATION TO IMPORT UNREGISTERED BIOLOGICAL PRODUCT FOR A NAMED PATIENT
- GUIDELINES FOR REPORTING VARIATIONS TO BIOLOGICAL PRODUCTS
- GUIDELINES FOR THE IMPORT AND EXPORT OF PATHOLOGICAL MATERIALS TO AND FROM GHANA
- GUIDELINES FOR THE REGISTRATION OF VACCINES AND OTHER BIOLOGICAL PRODUCTS IN GHANA_CTD
- GUIDANCE DOCUMENT FOR BLOOD FACILITY LICENSURE APPLICATION FORM
- GUIDELINES FOR LICENSING BLOOD FACILITIES AND BLOOD PRODUCTS LISTING
GUIDELINES FOR ADVERSE REACTION REPORTING
GUIDELINES FOR CONDUCTING PHARMACOVIGILANCE INSPECTIONS
GUIDELINES FOR QUALIFIED PERSON FOR PHARMACOVIGILANCE
SURVEILLANCE OF ADVERSE EVENTS FOLLOWING IMMUNIZATION IN GHANA
GUIDELINES FOR SAFETY MONITORING OF MEDICINAL PRODUCTS
GUIDELINES FOR REGISTRATION OF ALLOPATHIC DRUGS
GUIDELINES FOR THE FAST TRACK REGISTRATION OF WHO PREQUALIFIED MEDICINAL PRODUCTS
REGISTRATION PROCESS OF BIOLOGICAL PRODUCTS

**PRE-ASSESSMENT**

- Application received at client service. Client service perform pre-evaluation assessment. If satisfied, application fee is paid.
- Documentation directed to the appropriate division.

**Application acceptance phase**

- Acknowledgement letter sent to applicant
- Registration samples, method of analysis and AMV sent to the FDA Quality Control Laboratory

**Evaluation phase**

- Evaluation of registration application documents commences-quality, safety and efficacy data critically evaluated against regulatory requirements. Following evaluation, applicant may be advice to submit additional documents
- Review of evaluation report by a peer reviewer

14/06/2018
Registration committee phase
- Committee members review evaluation report and make recommendation to the CEO.
- Additional review of Analytical report from FDA Quality Control Laboratory and GMP audit report

Decision phase
- The CEO reviews recommendations of the product registration committee and a final decision is made on the application

OUTCOME
- Registration application APPROVED (3 years validity period).
- Registration application NOT APPROVED.
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<tr>
<th>BRAND NAME</th>
<th>INN</th>
<th>MANUFACTURER</th>
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<tr>
<td>Avastin</td>
<td>Bevacizumab</td>
<td>F. Hoffman La Roche Switzerland</td>
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<td>Remicaide</td>
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<td>Mircera</td>
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<td>Peg Interferon Alpha2b</td>
<td>Schering Plough Ireland</td>
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<td>Osteotide</td>
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# Approved Insulin and Its Analogues

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<tr>
<th>Brand Name</th>
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<td>Humulin R (Regular)</td>
<td>Insulin</td>
<td>Lily Egypt SAE</td>
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<td>Humalog mix 25</td>
<td>Insulin Lispro/Protamine</td>
<td>Lily France SAS</td>
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<td>Humalin N</td>
<td>Insulin</td>
<td>Lily Fertigung GmbH &amp; Co</td>
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<td>Mixtard 30 Penfil</td>
<td>InsulinIso</td>
<td>Lily Egypt SAE</td>
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<td>Actrapid Penfill</td>
<td>InsulinBiphasic Isophane 30/70</td>
<td>Novo Nordisk Denmark</td>
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<td>InsulinNeutral</td>
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14/06/2018
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<tr>
<td>SII RABIVAX</td>
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<td>PREVENAR 13</td>
<td>WYETH PHARMACEUTICAL</td>
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<td>SANOFI PASTEUR SA</td>
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<td>VEROAB VACCINE</td>
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<td>QUNVAXEM INJ</td>
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<td>TYPHIM VI</td>
<td>BERNA BIOTECH KOREA CORP</td>
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<td>ROTATEQ</td>
<td>SANOFI PASTEUR SA</td>
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<td>HEPATITIS B VACCINE (rDNA) (PAEDIATRIC)</td>
<td>MERCK SHARP &amp; DOHME CORP.</td>
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DOSSIER REQUIREMENTS

FDA GHANA CTD GUIDELINE

Dossier submissions are required in two electronic copies as per the FDA-Ghana CTD guideline.

Highlights of FDA CTD Guideline was adopted from ICH M4

- Module 1
- Module 2
- Module 3 (BMR of one executed production batch of FPP)
- Module 4
- Module 5 (Risk Management Plan RMP)
FAST TRACK PRODUCT APPROVALS

The FDA-Ghana has made provision for an accelerated procedure for granting marketing authorizations to all WHO PREQUALIFIED BIOLOGICAL PRODUCTS.

- Clock starts
- 15 Days
- 25 Days
- 30 Days

14/06/2018
THE HIGHEST PRIORITIES OF FDA GHANA

BIOSIMILARS
The FDA - Ghana Biosimilar guideline: adopted guidelines of the EMA and WHO

DEFINITION:
A Biosimilar product is a new biological product claimed to be ‘similar’ to an already approved reference product, which is marketed by an independent applicant, subject to all applicable data protection periods and/or intellectual property rights in the originator product.
APPLICANT must demonstrate biosimilarity to an FDA Ghana approved or a Stringent Regulatory Authority (SRA) approved Reference Biological Product in all three areas through comparability exercise:

- Quality (Head to Head comparison with reference product)
- Non-Clinical (Abridged)
- Clinical (Abridged)
CASE STUDY
PHARMACOVIGILANCE SYSTEM IN GHANA

PATIENTS/GENERAL PUBLIC

PRIMARY REPORTERS
- Doctors, Pharmacist, Nurses, etc

ICPs

RPOs

SMD of FDA

FDA SAFETY DATABASE (SWS)

WHO DATABASE

SIGNAL GENERATION

POSSIBLE REGULATORY ACTION

• ICPs-Institutional Contact Person
• RPOs-Regional PV Officers
• SWS-SafetyWatch System
• SMD-Safety Monitoring Department

14/06/2018
REGULATORY UPDATES:
MEDICINES REGULATION HARMONIZATION (MRH) IN THE ECOWAS REGION

GOAL: To have a harmonized and functioning medicines regulatory systems within the region in accordance with national and international policies and standards.

- ECOWAS: Economic Community of West African states
- Consist of fifteen (15) member states within the region:

1. BENIN
2. BURKINA FASO
3. CAPE VERDE
4. COTE D’IVOIRE
5. GAMBIA
6. GHANA
7. GUINEA
8. GUINEA BISSAU
9. LIBERIA
10. MALI
11. NIGER
12. NIGERIA
13. SENEGAL
14. SIERRA LEONE
15. TOGO
MRH ACTIVITIES

- Harmonization programme has been lunched since February 2015 in Accra-Ghana
- A Joint Steering Committee on Harmonization programme has been formed
- Expert Work Groups have been constituted by members drawn from all the 15 Member States.
- Draft guidelines for MRH in on-going
- Terms of reference for all committees and EWGs have been defined
EXPERT WORKING GROUPS

- PRODUCT EVALUATION AND REGISTRATION
- GOOD MANUFACTURING PRACTICES INSPECTIONS
- CLINICAL TRIALS, PHARMACOVIGILANCE & MEDICINES SAFETY
- QUALITY CONTROL LABORATORY
- QUALITY MANAGEMENT SYSTEM
- INFORMATION MANAGEMENT SYSTEM
- POLICY AND LEGISLATION
GOVERNANCE STRUCTURE

The governance structure is organized on the basis of the following:

- A steering committee (SC)
- Expert Working Groups (EWGs)
- A secretariat
- Project Management Unit (PMU)
- NMRA experts and representatives
- National Medicines Regulatory Officers (NMRO)
CHALLENGES - REGIONAL HARMONIZATION PROCESS

- Inadequate Assessors with the requisite technical capacity.
- Differences in laws and guidelines for regulation of medicines in member countries.
- Language barrier.
FDA GHANA QUALITY CONTROL LABORATORY-ISO 17025 ACCREDITED BY ANAB(ANSI/ASQ)

ACCREDITATION SCOPE: 39 tests in Physico-chemical, Microbiology and Medical Devices.
GHANA FDA-OFFICE COMPLEX
THANK YOU

MEDAASE

www.fdaghana.gov.gh