TRENDS IN REGULATORY CONVERGENCE/HARMONIZATION IN WEST AFRICA

Mr. ERIC KARIKARI BOATENG
HEAD OF DEPARTMENT
FDA, GHANA.
OUTLINE

- Brief Introduction –FDA GHANA
- Biologics Product Department-Procedures
- Updates on the WA-MRH
- Conclusion
The Food and Drugs Authority is an Agency under the Ministry of Health.

The Agency was established in 1992 as the Food and Drugs Board (FDB) on the basis of the 1992 Food and Drug Law (PNDCL 305B).

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.

**REGULATED PRODUCTS**

1. Drugs and Biologics
2. Food
3. Medical Devices
4. Cosmetic
5. Household Chemicals
6. Tobacco & Substance of Abuse
Biologics Product Department

- **Number of Reviewers- Seven(7)**
  - 4 Quality or CMC Reviewers
  - 3 Clinical & Non-Clinical Reviewers

- An acknowledgement letter is issued to the applicant upon receipt of application.

- **Dossier Evaluation Meetings.**
  - Meetings are held at least once every month depending on the number of applications received.
  - Quality Reviewers evaluate the quality sections (module 3) of the CTD dossier.
  - Clinical Reviewers evaluate the Clinical & Non-Clinical sections of the CTD dossier.
  - List of Questions are combined and presented for Drug Registration Committee to review.

- **Drug/Biologics Registration Meeting**
  - The List of Questions are reviewed and changes made if necessary.
  - Final list of Questions are established and communicated to the applicant by the Department.
  - In the absence of any outstanding queries approval is given and letter is communicated to Applicant.

- Post Approval Changes are regulated under FDA Ghana’s guideline for variation of biologics.

- Priority is on Biosimilars and Major Challenge is limited number of Competent Reviewers.
West Africa Medicines Regulatory Harmonization Project (WA-MRH) - Overview

2. Coordinated by WAHO.
3. 15 ECOWAS Countries involved.
4. Goal is to improve access to safe, quality and efficacious medicines in ECOWAS region.

Expert Working Groups (7)
1. Product Evaluation and Registration
2. GMPs Inspections
3. Clinical Trial & Safety
4. Quality Control Lab.
5. Quality Mgt. System
6. Information Mgt. System
7. Policy and Legislation

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
WA-MRH Governance Structure

Steering Committee Members
1. Heads of NMRAs
2. Director General of WAHO
3. Chairpersons of EWG
4. Technical Partners

NMRAs of 15 Countries

WAHO (coordinator)
FDA GHANA is acting as the lead coordinating NMRA. The Joint Medicinal Product Dossier Evaluation & Registration Expert Working Group (MPDER-EWG) and Technical Partners are responsible for the Assessment.

Expression of Interest (EOI) is published on WAHO platform. Applicant submit application to FDA Ghana.

Screening of application for eligibility and issue certificate of eligibility or non-eligibility to applicant -15 days

FDA Ghana notifies the WAHO Secretariat and post screened dossiers on the MRH platform for assessment to begin.

Assessment is done and list of questions are sent to applicant. Assessment is done by MPDER- EWG and technical partners WHO, EMA & SWISSMEDIC.
The joint assessment of dossier is to be completed within 3 months from the date of acceptance of application.

MRH secretariat will organize joint GMP inspection and QC testing if necessary.

Final notification letter (acceptance or rejection) is communicated to Applicant by WAHO based on decision of the Steering committee.

When additional information is required, Applicant has 60 days to respond beyond which application is deemed withdrawn. The additional information shall be assessed within a period of 2 months from the date of submission.

Applicant obtains product registration from each NMRA based on a positive Joint Assessment Notification letter.
Basket of Medicines in WA-MRH Joint Assessment Procedure

❖ Programme Medicines (HIV/AIDS, Malaria, Tuberculosis, Reproductives Health, Neglected Tropical Diseases, Vaccines).

❖ Medicines used in public health emergencies.

❖ Products registered by Stringent Regulatory Authorities, prequalified by WHO, registered under SwissMedic MAGHP Procedure or EMA Article 58 (Positive Scientific opinion).

❖ Biotechnology Products
Opportunities for Accelerated Approval in WA-MRH

❖ Assessment time of dossier is reduced.

❖ Registration/Market Authorization of product can be achieved in 15 different countries based on one assessment report reducing cumulative time when done individually.

❖ Abbreviated assessment of Products approved by Stringent Regulatory Authority, WHO prequalified products and SwissMedic MAGHP.
CONCLUSION

The Joint Assessment of Dossiers in the West Africa Medicines Regulatory Harmonization programme has commenced and there are opportunities that sponsors can take advantage of to reduce time for Market Authorization in the entire region.
FDA GHANA-OFFICE COMPLEX
THANK YOU

MEDAASE

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