NAFDAC EXECUTIVE SUMMARY FOR INTERNATIONAL COUNCIL FOR HARMONIZATION (ICH) M13A(R3) GUIDELINES ON BIOEQUIVALENCE (APRIL 9-11)

Overview:

The National Agency for Food and Drug Administration and Control (NAFDAC) organized a training on **International Council for Harmonisation (ICH) M13A guidelines on Bioequivalence for immediate-release solid oral dosage forms** , conducted from April 9 to 11, 2025, was a strategic initiative aimed at building national and regional capacity in understanding and implementing bioequivalence standards, as defined by the (ICH) M13A guideline. This training is part of broader efforts to ensure the quality, safety, and efficacy of generic medicines within Nigeria and the West African region.

Objectives

- To enhance understanding of the ICH M13A/B guidelines and their application in BE studies.
- To provide comprehensive training on study design, bioanalytical methods, and regulatory requirements.
- To foster regional regulatory capacity in evaluating BE data.
- Clinical, analytical, and ethical aspects of conducting BE studies.
- To promote collaboration between regulatory authorities and pharmaceutical stakeholders.

Key features of the training included:

- **Expert-led Sessions:** Delivered by experienced international and local facilitators, including key contributors to ICH guideline development.
- **Practical Case Studies:** Real-world scenarios to contextualize the concept
- **Interactive Discussions:** Facilitated exchange of ideas on study design, pK parameters, and data integrity.
- **Stakeholder Engagement:** Fostered collaboration among regulators, sponsors, industry representatives, and research institutions to ensure harmonized implementation.

Participants:

The training had a total of 255 participants, with 120 attending in person. It brought together a diverse mix of participants, including regulators, clinical researchers, and representatives from the pharmaceutical and contract research sectors across Nigeria and the West African sub-region.

Participants feedback:

The training assessment record showed an improvement in the knowledge gained from 49% to 78.6%. Feedback reports highlighted the following.

- **Knowledge gained**: 95% of respondent reported significant improvement in their understanding of the ICH M13a.
- **Practical Application**: 97% of respondents felt confident in applying the knowledge gained.
- **Quality of training**: 95% of respondents valued the content and delivery of the presentations. They were satisfied with the expertise of the facilitators.

Impact:

The training has enhanced understanding of the scientific and regulatory basis for BE studies. It has strengthened the readiness of regulators and industry players to apply ICH M13A principles. It has also set the stage for improved oversight of generic drug development and approvals in Nigeria.

Next Steps:

- Continued capacity-building activities targeting CROs, reviewers, and sponsors.
- Implementation of guidance documents and tools aligned with ICH M13A.
- Implementation of a regulatory roadmap for bioequivalence enforcement by NAFDAC.
- Strengthening of inter-agency and regional collaboration on generic medicine regulation.

Implementation:

The implementation of the ICH M13a is shown in the documents below.

- Guideline for Investigation of Bioequivalence
- Note to industry on Bioequivalence
- Road Map: Strategic Plan for Managing the Implementation of Bioequivalence (BE) Regulatory Requirement

Conclusion

The ICH M13A training successfully met its objectives. This training reflects NAFDAC's commitment to improving public health outcomes through science-based regulation and advancing Nigeria's role in global harmonization efforts and ultimately supporting faster patient access to safe and effective generics.