HARMONIZATION OF REGULATION OF MEDICAL PRODUCTS:
TRANSFORMATION OF NIGERIA’S REGULATORY DYNAMICS AND
OPTIMIZING RELIANCE

PRESENTATION BY

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NAFDAC MANDATE

The National Agency for Food and Drug Administration and Control (NAFDAC), was established by decree 15 of 1993 as amended by decree 19 of 1999 and now the National Agency for Food and Drug administration and Control (NAFDAC)

The Act Mandates the Agency to regulate and control the manufacturer, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, chemicals, detergents, medical devices and packaged water
PURPOSE

- Improves efficiency of medicine registration process
- Increase availability of life saving medicines
- Increase product safety and promote trade
- Improve access to knowledge and skills
METHODS ADOPTED

_approach to regulatory process optimization:

- Regional approach
- Global approach
- Capacity building
METHODS

REGIONAL APPROACH

• Regional Harmonization (ECOWAS MRH)
  ✓ Establishment of Steering Committee
  ✓ Participation in all 7 EWG’s
  ✓ Participation in Joint assessments
  ✓ Harmonization of guidelines and procedures

• Regional deployment of QMS
METHODS CONTD

ECOWAS MRH Technical Session
METHODS

GLOBAL APPROACH

• WHO Global benchmarking
• Maturity level identification
• Identifying gaps
• Development of IDP’s
• Regulatory Reliance
METHODS

CAPACITY BUILDING

• WHO trained assessors
• In-house capacity building
• In-house Faculty of WHO trained assessors
• Development of training modules for assessors
• Conducted ten (10) in-house training sessions for assessors
• Collaboration with development partners
METHODS

Registration through Harmonization and Reliance mechanism:

- WHO Collaborative Procedures (Drugs, Vaccines and IVD’s)
- Regionally approved pharmaceutical products (ECOWAS MRH)
- SwissMedic MAGHP Procedure
- WHO/EMA Article 58 Procedure
- Risk categorization of manufacturing facilities
RESULTS
# RESULTS

Registrations through reliance mechanisms

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RESULTS

CATEGORIES OF APPLICATION RECEIVED

- HIV/AIDS
- MALARIA
- TUBERCULOSIS
- NTD
- REPRODUCTIVE

NAFDAC
NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL

...safeguarding the health of the nation
CONCLUSION

After 10 years of AMRH goals achieved, the Agency is poised for the next steps:

• Sustaining successes/results achieved

• Building on existing regulatory framework
Thank You!