



For A Healthier Africa
AFRiSUMMIT

2nd - 5th November 2025

Hilton Grand Nile Hotel, Cairo - Egypt

REGULATORY UPDATES- KENYA

BRAYHAN KARIUKI IRERI & SHELLAN OMONDI



Introduction

- PPB as the National Medicines Regulatory Authority under Cap 244.
- Mandate expanded to include Medical Devices & In Vitro Diagnostics (IVDs).
- Growing focus on strengthening oversight, harmonization, and reliance practices.

Institutional strengthening

- Establishment of Medical Devices & IVDs Unit.
- Formation of External Medical Devices Expert Committee (9 members):
 - ✓ Technical file assessment
 - ✓ Guideline review and standard-setting
 - ✓ Field safety corrective action support
 - ✓ Clinical trial evaluation.

Reliance and Harmonization Updates

- Adoption of WHO Good Reliance Practices.
- Reliance pathways in Kenya:
 - Abridged
 - Expedited
 - Immediate recognition
- Reference Authorities: US FDA, EU NB, TGA, HC, PMDA, WHO.
- Kenya as an affiliate of MDSAP and contributor to continental reliance (AMA).

Opportunities and Ongoing Reforms

- Strengthening of QMS auditing capacity.
- Enhancement of digital platforms, eg reliance, AI in screening, renewals
- Stakeholder engagements
- Continental reliance models
- Ongoing training of assessors and auditors
- Emerging trends- AI,ML, SaMD

THANK YOU

P.O. Box 27663 – 00506

Nairobi, Kenya

Telephone: 0709 770 100

Email: info@pharmacyboardkenya.org

Website: web.pharmacyboardkenya.org