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REPUBLIC OF KENYA
Pharmacy and Poisons Board

Medical Device Regulatory Convergence Project (MDRC)

Overview

- Nations have scrambled to increase production, improve supply chains, and improve access to medical devices.
- Countries cannot safely deploy these products without a strong medical device regulatory framework and knowledge of emergency use authorization (EUA) procedures and rules.
- No nation has sufficient resources to develop agency and all required country-unique technical regulations.
- Public health systems and the medical technology industry spend $4 billion per year . . . most of which occurs in developing countries.
- **MDRC** increases the transparency and predictability of partner governments' regulatory ecosystems for medical devices, aligning them with international standards.

MDRC Purpose and Partnerships

Purpose

- ✓ To advance regulatory convergence in partnership with standards developing organizations as well as national and regional health/regulatory and trade authorities.

A public-private partnership between:

United States Agency for International Development (USAID)

USAID leads international development and humanitarian efforts to save lives, reduce poverty, strengthen democratic governance and help people progress beyond assistance.

American National Standards Institute (ANSI)

A private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system

Advanced Medical Technology Association (AdvaMed) AdvaMed

A trade association of over 400 member companies, ranging from the largest to the smallest medical technology innovators and enterprises that produce medical devices, diagnostic products and digital health technologies

What MDRC does

- Build capacity of partner countries for standards and conformity assessment procedures related to medical devices;
  - Remove countries' technical barriers to trade for medical devices;
    - Increase patients' access to needed high-quality PPE and other medical technologies to respond to and recover from COVID-19 and future global health crises; and,
      - Foster private sector engagement in the (medtech) regulatory space.

What MDRC does (cont'd)

- Delivers tailored training to:
  - Central regulatory coordination bodies on cross-sectoral good regulatory practices (GRPs) and international standardization that is required for regulatory convergence in the medical device sector; and
  - National Regulatory Authorities and relevant stakeholders that directly facilitates regulatory convergence in the medical device sector
- Advises on the adoption of international benchmarks for EUAs and related emergency regulatory frameworks and approval processes.
- Builds transparent, convergent, predictable, and agile regulatory frameworks so medical devices are received across and within borders at points of care in times of health crises and beyond.
- Assists customs authorities in following the import criteria and policies set by the health authorities.
- Established an Resource Center for Emergency Regulatory Response in collaboration with the Global Medical Technology Alliance.

Global Collaborations

1. Global Medical Technology Alliance (GMTA)

2. Global Diagnostics Alliance (GDA)

3. GMTA Africa Working Group and the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector

4. International Medical Device Regulators Forum (IMDRF)

ROLE OF THE MDRC AFRICA LIAISON

- **Kenya National Focus:** Support to MDRC partners in Kenya, principally with PPB, focused on national MEL plan implementation.
- **PPB Strategic Plan:**
  - **Vision, Mission and Values**
  - **Environmental Scan (Internal and External)**
    - Overview of the existing regulatory framework and regulations in place for the medical devices
    - Run a gap assessment leveraging on existing documents.
  - **Strategic Themes**
  - **Strategic Goals and Objectives**
  - **Draft Strategy**
  - **Draft Implementation plan (**remediation / enhancement plan)
  - **Public Participation & Capacity Building on Strategy**
- **Africa Continental Focus:** Support to MDRC partners in the AMDF, focused on continental plan implementation.

Thank You

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