



WELCOME TO

SAMED-SALDA Regulatory Forum

2 February 2022

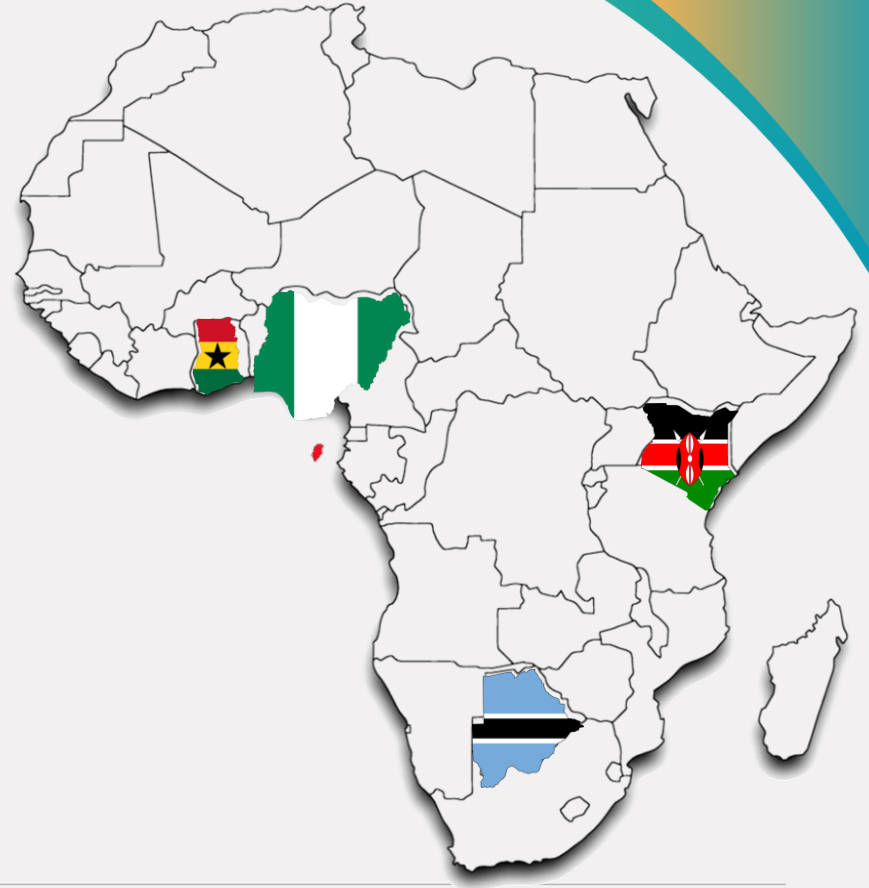
Facilitator: Frangie Letsoalo

AFRICAN MEDICAL DEVICE REGULATORY LANDSCAPE

1. Kenya : Frangie Letsoalo
2. Nigeria : Frangie Letsoalo
3. Ghana : Michelle Bronze
4. Botswana : Athene Saul & Karabo Tlhapane

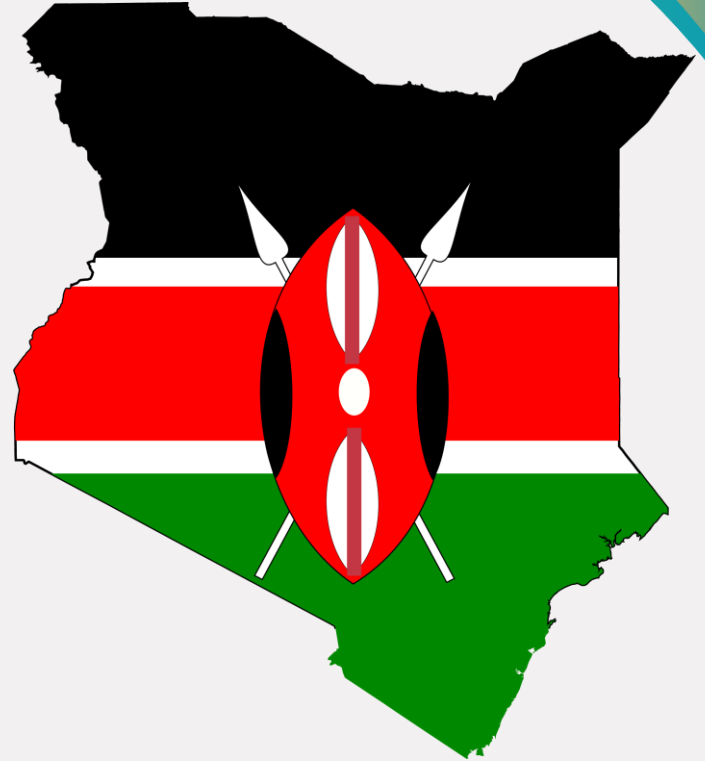


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KENYA MEDICAL DEVICE REGULATORY LANDSCAPE

- Ranked as among the fastest growing markets
- The market is set will record high single-digit growth
- Limited medical device production, and the market is largely dependent on imports



KENYA MEDICAL DEVICE REGULATORY LANDSCAPE

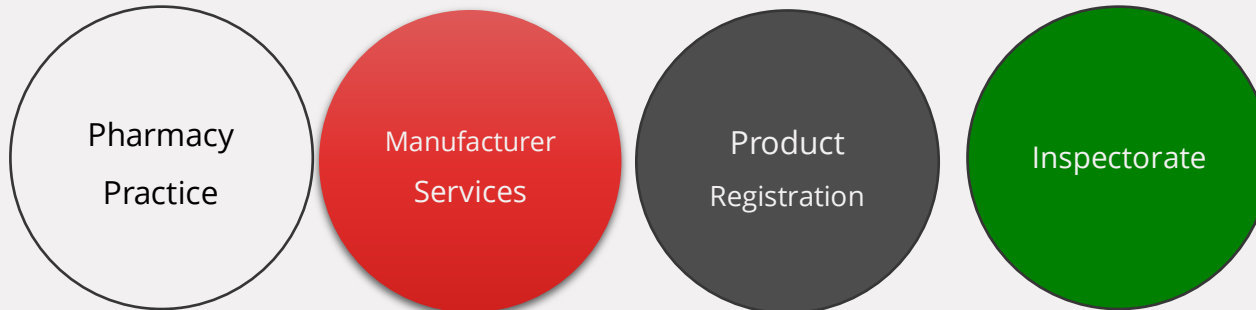


Pharmacy and
Poisons Board

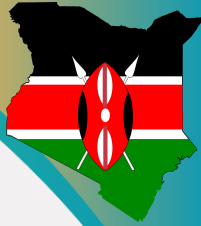
MANDATE

Regulate Practice of Pharmacy and the Manufacture and Trade in drugs and poisons.

CORE FUNCTIONS

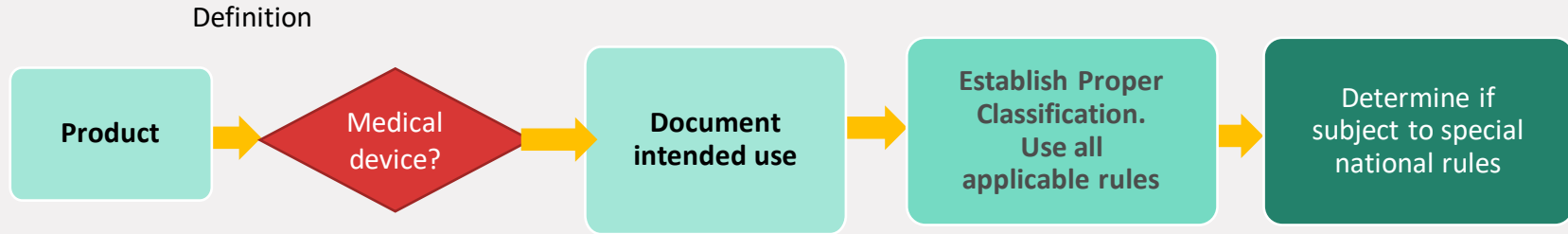
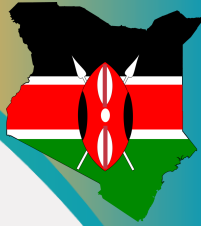


MEDICAL DEVICE REGISTRATION REQUIREMENTS



- Appointment of a Local Technical Representative (LTR)
 - ✓ Not an individual but a Company
 - ✓ LAR/LTR to provide written evidence
 - ✓ Only 1 Local Representative Person
 - ✓ Register on PPB Portal Platform
 - ✓ serve as the central communication pathway with the PPB
- PVOC or Certificates of Conformity (CoC)
- Guidelines for Medical Device & IVD

MEDICAL DEVICE REGISTRATION PROCESS

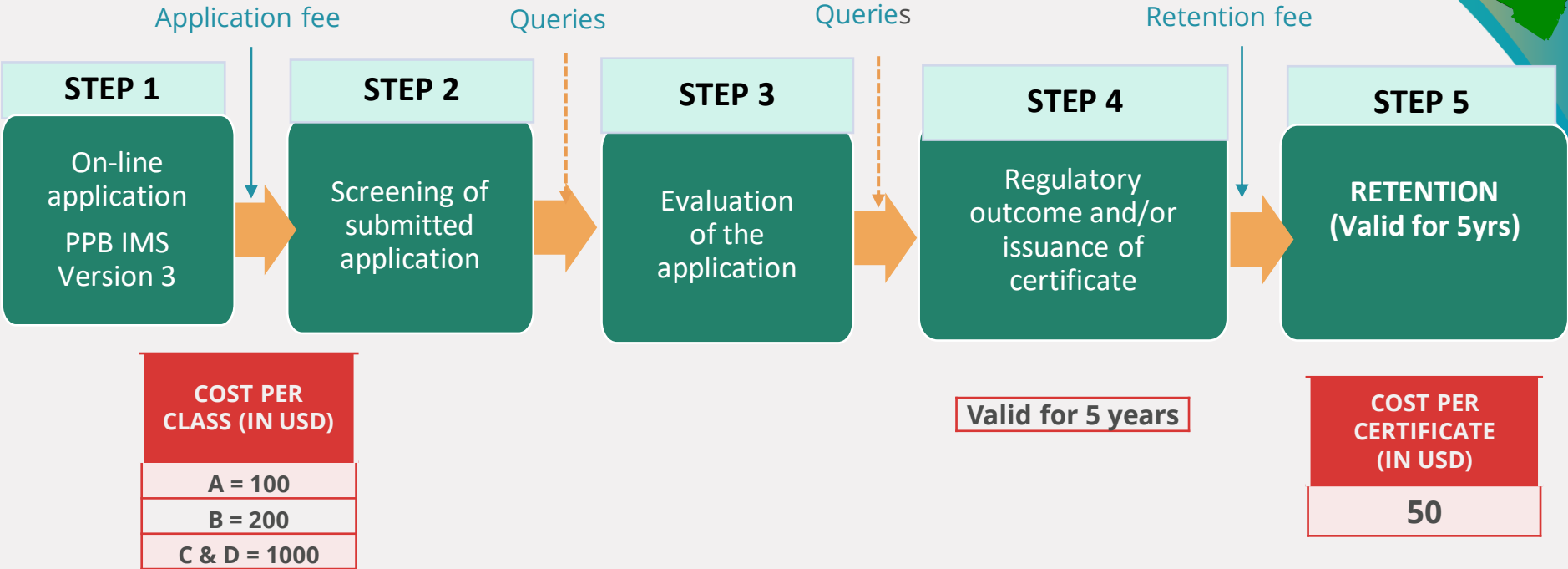
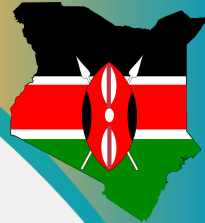


Medical Device Definition aligned with GHTF/IMDRF

Classification System: A; B; C; D

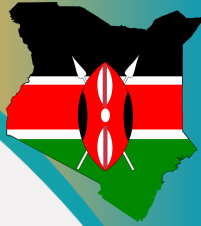
<https://www.pharmacyboardkenya.org/>

MEDICAL DEVICE REGISTRATION PROCESS



<https://prims.pharmacyboardkenya.org/home>

APPLICATION FOR MARKETING AUTHORISATION



Class A : REQUIREMENTS

1. Letter of authorization

2. Proposed Primary pack Label Artwork

3. Pre-Verification Certificate or Certificate of Conformity

4. Instructions for Use

5. Certificate of Analysis

6. Sterilization method & Validation Standard (where applicable)

7. Regulatory approval from Country of origin

8. Proof of QMS e.g., ISO 13485, FDA QMS, CE Cert, Japan MHLW

APPLICATION FOR MARKETING AUTHORISATION

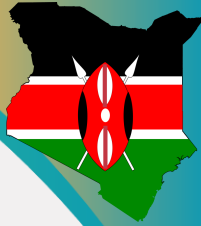
CLASS B : PRODUCT EVALUATION PATHWAYS

Full Evaluation Route

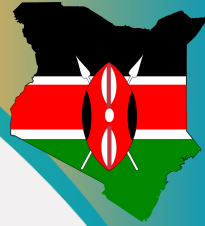
**Not obtained any
prior approval**

Abridged Evaluation Route

A medical device that has obtained at least two reference regulatory agency approval for a labelled use identical to that intended for marketing in Kenya at the time of submission will qualify for the abridged evaluation route



CLASS B : FULL EVALUATION ROUTE



ELIGIBILITY CRITERIA

Not obtained any prior approval

Requirements

1. Letter of authorization

3. Common Submission Dossier Template (CSDT)

5 Essential Principles Checklist and Declaration of Conformity

7. Design Verification and Validation Documents

9. Clinical Evidence

11. Manufacturer Information

13. Manufacturing Process Flow

2. List of Configurations

4. Executive Summary

6 Device description

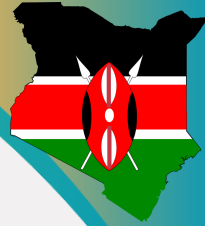
8. Preclinical Studies including the detailed sterilization Validation (if applicable)

10. Risk analysis

12. Name & address of manufacturing sites

14. Proof of QMS e.g., ISO 13485

APPLICATION FOR MARKETING AUTHORISATION



CLASS B : PRODUCT EVALUATION PATHWAYS

Expedited Class B Registration (EBR)

- Approvals by 3 MD IRRA
- Marketed **for ≥4yrs** in 2 RRA with
- no Safety issues/deaths
- No open field safety corrective actions/recalls
- No Rejection/withdrawal by any RRA or PPB

or

Obtained approvals from at least 3 of PPB's independent reference regulatory agencies for a labelled use identical to that intended for marketing in Kenya

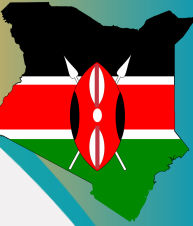
Immediate Class B Registration (IBR)

- Approvals by 3 MD IRRA
- Marketed **for ≥ 5yrs** in 2 IRRA with
- no Safety issues.
- No open field safety corrective actions or recalls.
- No Rejection or withdrawal by any RRA or PPB

or

Obtained approvals from at least 5 of PPB's independent reference regulatory agencies for a labelled use identical to that intended for marketing in Kenya.

APPLICATION FOR MARKETING AUTHORISATION



EXPEDITED REGISTRATION REQUIREMENTS

1. Letter of authorization

2. List of Configurations

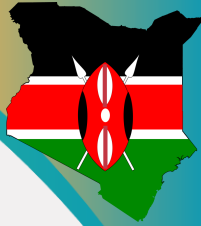
3. Proof of marketing history in the same independent reference regulatory agency's jurisdictions i.e., Invoice with date, proof of sale or a declaration on marketing history)

4. Declaration of safety issues globally

5. Common Submission Dossier Template (CSDT) dossier approvals from the independent reference regulatory agencies

VITAL ELEMENTS AND CHALLENGES

- Appointment of a suitable Local Technical Representative
- Classification and grouping of medical devices
- Management of Variations
- Change of a Local Technical Representative
 - the option not in the version 3 of the Portal .
 - Must have “**No objection Letter**” from current LTR.
 - **Current LTR not cooperating**
- **Inconsistent responses** – document evidence



Thank you for listening

Questions or Comments?

KENYA MEDICAL DEVICE DEFINITION

Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- a. diagnosis, prevention, monitoring, treatment or alleviation of disease,
- b. diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- c. investigation, replacement, modification, or support of the anatomy or of a physiological process,
- d. supporting or sustaining life,
- e. control of conception,
- f. disinfection of medical devices,
- g. providing information by means of in vitro examination of specimens derived from the human body;
- h. disinfection substances,
- i. aids for persons with disabilities,
- j. devices incorporating animal and/or human tissues,
- k. Devices for in-vitro fertilization or assisted reproduction technologies. and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.