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OVERVIEW OF REGULATION OF MEDICAL DEVICES AND IVDS

DR PAULYNE WAIRIMU

Head, Health Technologies Evaluation and Registration
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PPB-MDRC WORKSHOP
Four Points Sheraton

Presentation Outline

- History/Background
- Legal Framework
- Organization chart
- Management infrastructure
- Human resource(MA)
- QMS
- Communication with other institutions
- Market Information
- Collaborations with other Agencies
- MA Function
- Scope of MA Activities
- Good Review Practices
- Review Timelines
- Achievements
- Future Plan
- Constraints/Challenges

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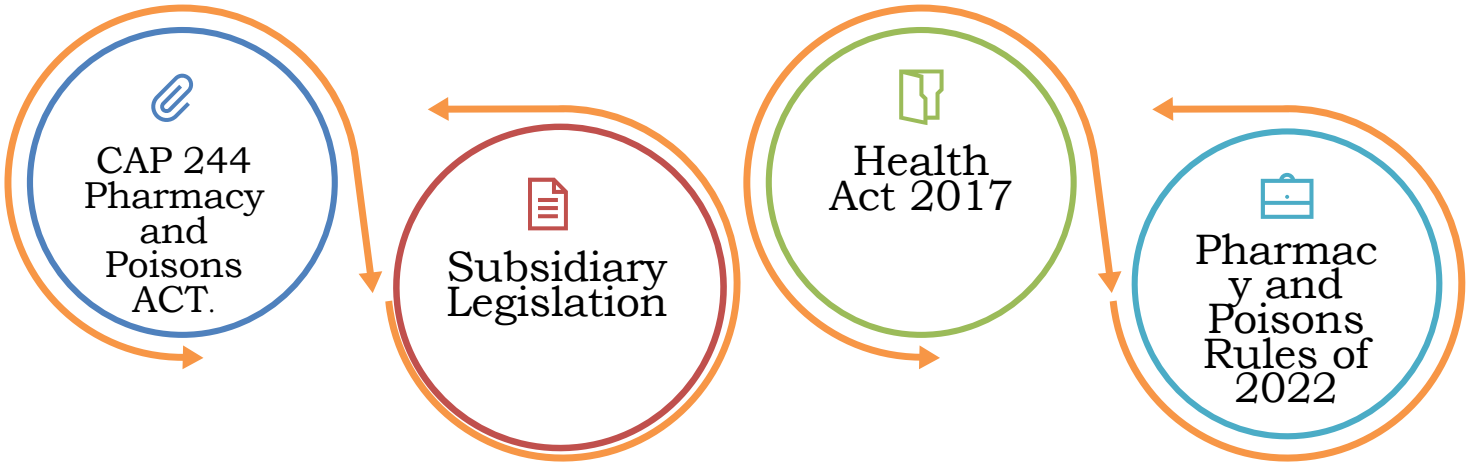
Legal Framework For Medical Devices and In-Vitro Diagnostics



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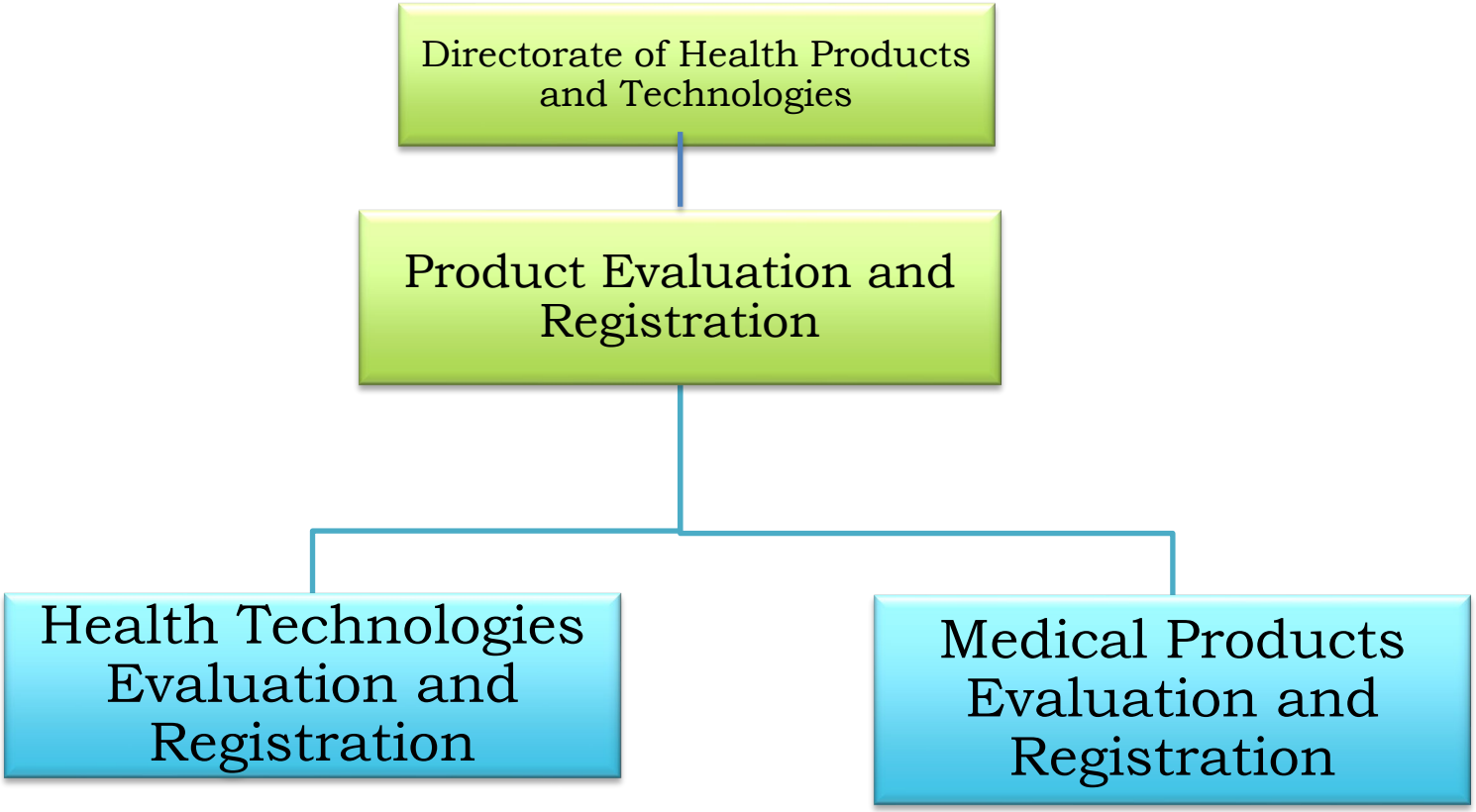
Health Technologies Evaluation and Registration



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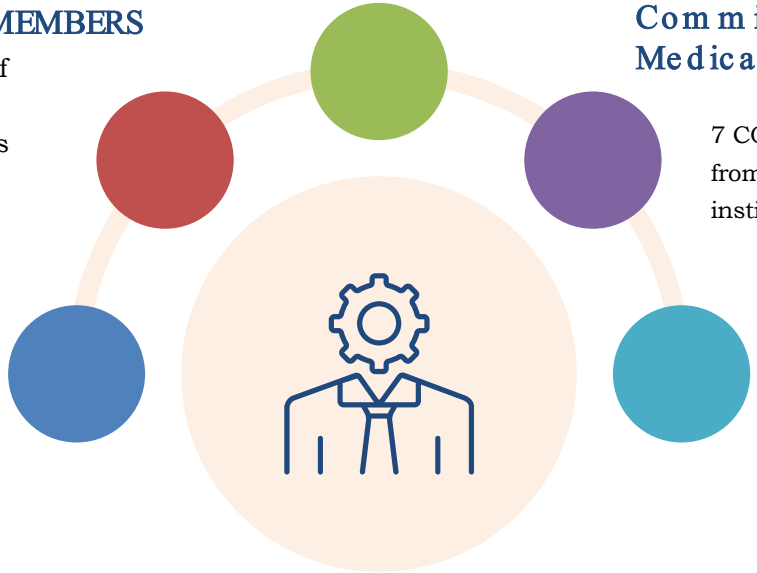
HUMAN RESOURCE FOR MEDICAL DEVICES AND IVDs

CORE STAFF MEMBERS

3 Core staff running the activities of the Evaluation and Registration – 12 Years of Experience and 4 Years respectively .

Technical Staff

-10 Technical Staff support the Medical Devices and IVDs activities such as reviewing of Technical files and assessments



Committee of Experts Medical Devices

7 COE Members with backgrounds from various backgrounds and other institutions

Committee of Experts in-Vitro Diagnostics

7 Experts with Diagnostics background including Laboratory Background, Research

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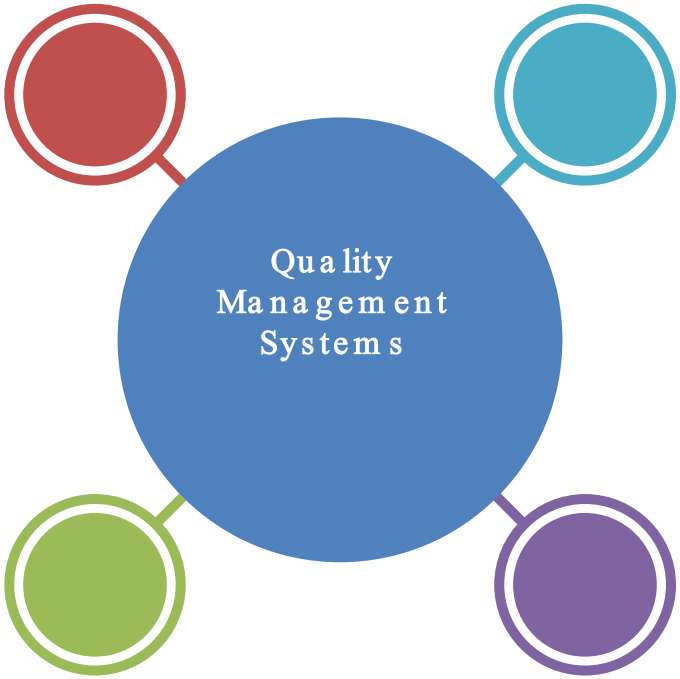
Quality Management System For Medical Devices

Documents

-Quality Manual
- Quality Objectives
-Guidelines across different functions
-Internal audits, external audit manuals
-QMS related trainings and workshops



Processes

-SOPs (Screening, Procedure for Evaluation of MDs and IVDs)
-Form 1(Listing of Medical Devices)
-Forms for receipt of Samples for IVDs
-Assessment templates
*Register of Reports from Laboratory *Assessment for Performance and Validation

Records

-Certificates of Registration
-Laboratory report for performance and validation of IVDs
-Minutes of meetings attended
-List of Products registered
-Automated Product Submission system (PRIMS V.3)

Records

-List of Medical devices Change notifications
-Committee of experts Reports

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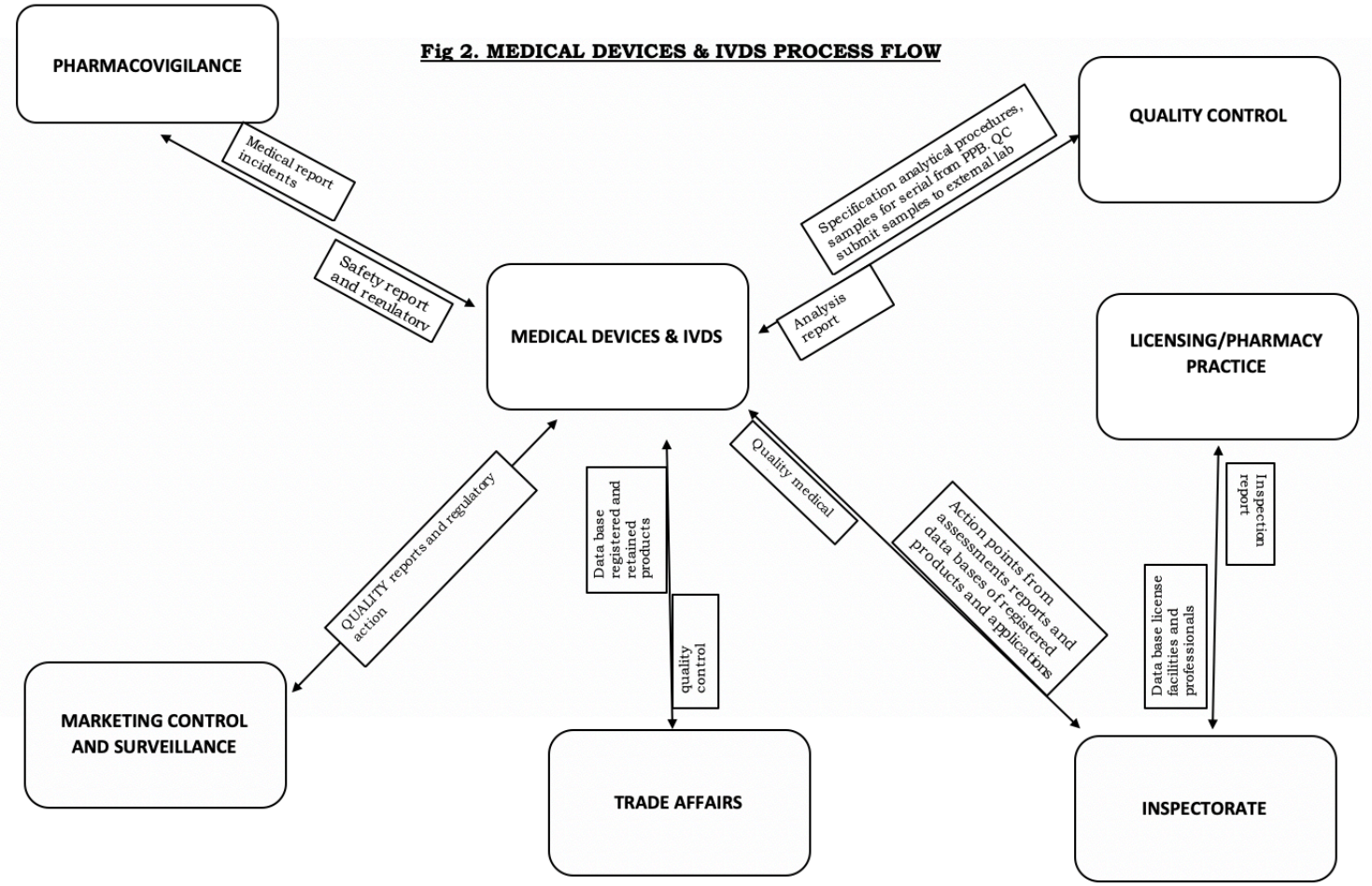
Inter Departmental Relation and Communication



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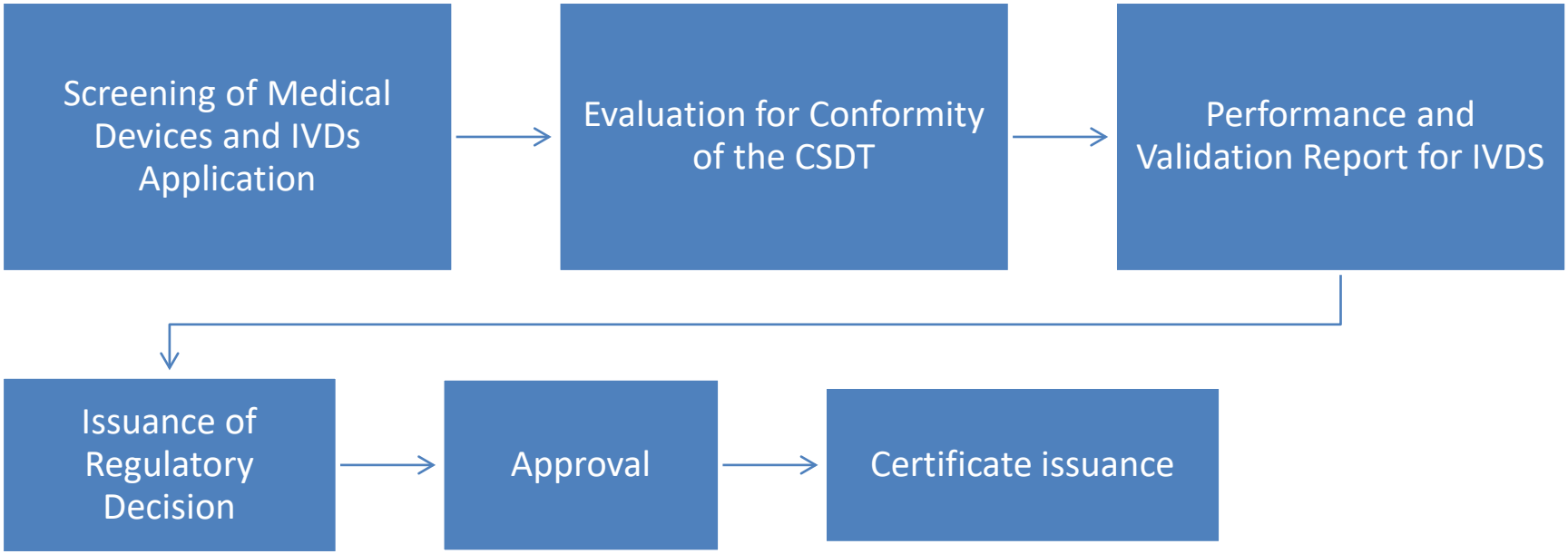
MA-Medical devices communication with external Entities

Overview of the Market Market Authorization Function

Scope of Activities



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Key Function

- Marketing Authorization of Medical Devices and IVDs
- Retention of Medical Devices and IVDs
- Change Notification of Medical Devices and IVDs

Department Functions

- Formulate, review and implement policies, rules, regulations and corporate strategies for the testing of of Medical Devices and IVDs
- Formulate, review and implement guidelines, standards, infrastructure, procedures and tools for the testing of of Medical Devices and IVDs
- Formulate, review and implement quality and risk management systems in regards to testing the quality of Medical Devices and IVDs
- Ensure that the laboratories develop and use quality system approach to laboratory testing that provide accurate test results;
- Oversee sampling and testing of Medical Devices and In-Vitro Diagnostics

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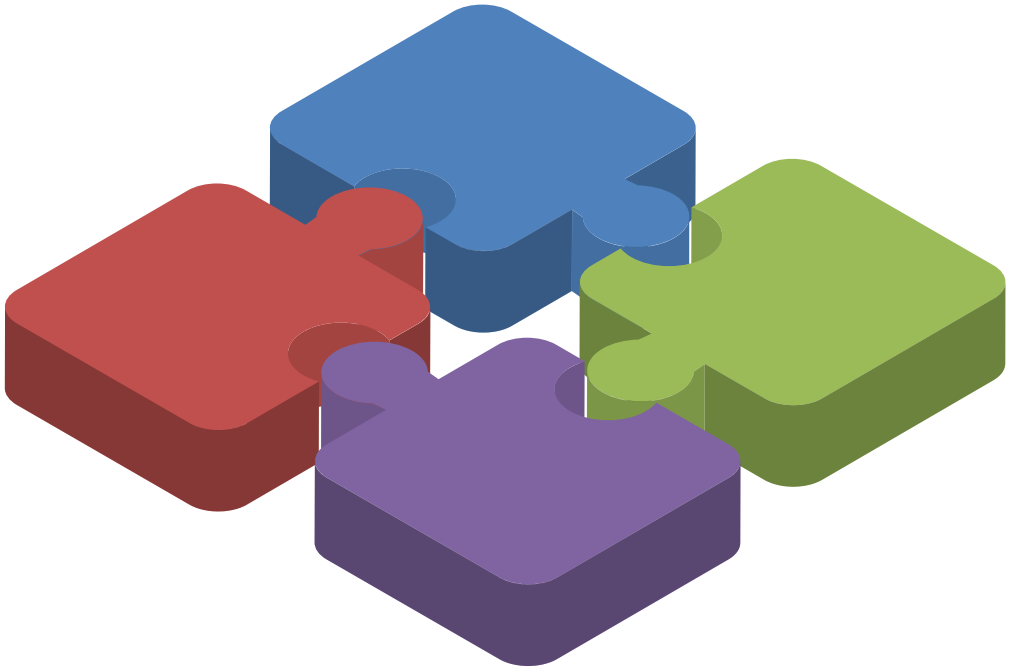
QUALITY OBJECTIVES

Objective 01

100% compliance to registration standards for all regulated health products and technologies

Objective 02

enhance compliance to timelines in regulatory decision-making.



WORKPLAN OUTPUTS

Activities

Evaluate class C and D Medical Devices & Invitro Diagnostics with regard to safety.

Activities

Priority review of applications made through the Reliance Pathways

Activities

Approval of Emergency use Authorization application with stated timelines.

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Regulatory Processes

	Timelines
Screening • -New applications are screened for completeness of documentations	Within 90 working days
Evaluation • Using the conformity assessment template, review of submitted information by technical experts • Performance and Validation of In-Vitro Diagnostics Reports from the Laboratory	Within 24 Months
Query Responses • -Communication to the applicant if there are queries that have been raised	Depending on applicant response time
Approval • Satisfactory applicants receive approvals	Within 24 Months
Issuance of certificates • Certificates are released to the applicant	Within 7 days of approval decision
Change notifications • Notifications are reviewed and approved	Depending on the type of notification (within 7days to 60 days)

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SUBMITTED APPLICATIONS FOR MEDICAL DEVICES 2019-2022

Using PRIMS Automated System

No of MDs

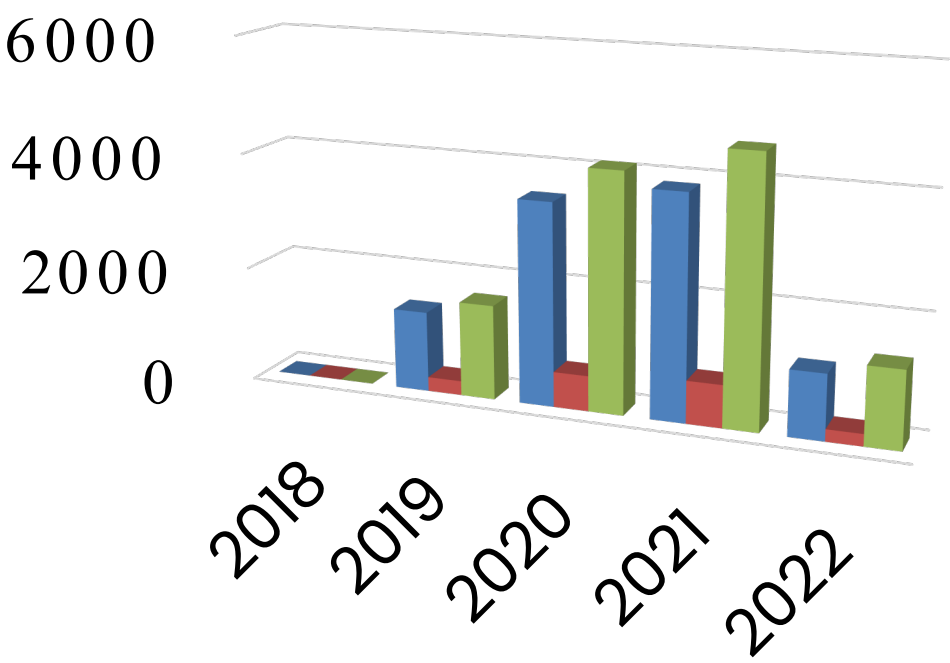
Received applications for Medical Devices

No of IVD

Received applications for IVDs

Total No MD+IVDs

Combined no of applications



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REGULATORY DECISIONS FOR MEDICAL DEVICES

Using PRIMS Automated System for Receiving of Applications

Successfully Evaluated

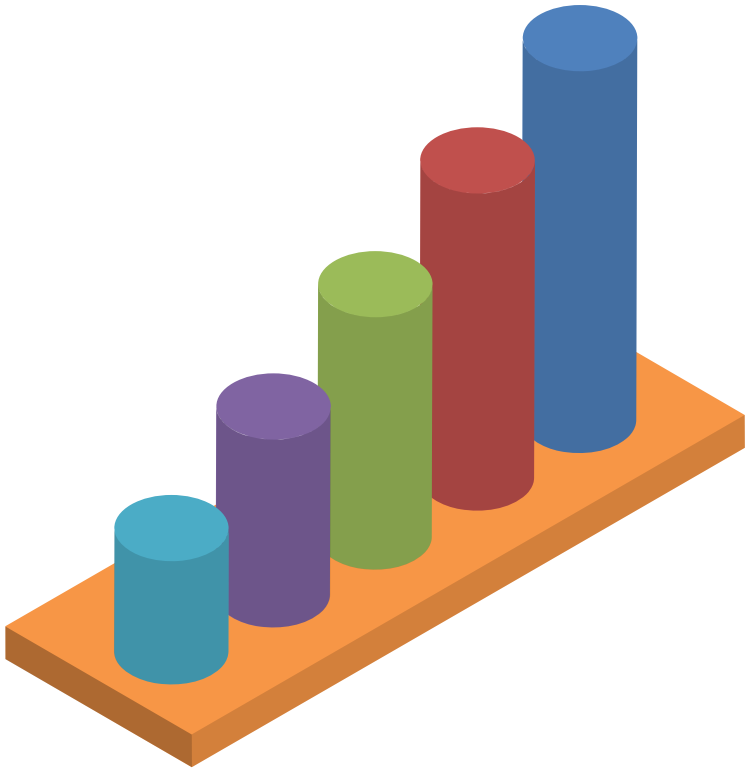
Applications that have all the documentation and have been screen, have undergone first review by an assessor.

Successfully screened

Applications have the requisite documentations and screening is approved.

Approved applications

Applications have been approved for registration



Queried applications

Additional information has been requested by the assessor

Rejected Applications

There is sufficient reason to reject the application.

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Good Review Practices

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Overview of the Market Surveillance and Control (MC) and Vigilance (VL)

Pharmacy and Poisons Board
Ensuring the provision of safe, quality and efficacious pharmaceutical products and services

Post-market surveillance (PMS)

PMS is the monitoring of the quality (and safety & efficacy) of medical product after it has been released in the market (and made available to the public)

- **Primary objective** = to develop information about HPTs quality and effects under usual conditions of use

- Facilitates evidence-based decision making on **Substandard and Falsified (SF)** medical products

Market Surveillance

Two approaches

Active Surveillance

Reactive Surveillance

Active Surveillance

- PMS quality surveys
- Batchwise testing and release- based on risk
- Male latex condoms, syringes, surgical face masks, COVID 19 RDTs

Market Surveillance (2)

RRI PMS- male latex condoms (85.7%)

Syringes (100%)

PoCTs- Only nine (50%) tests had sensitivities ≥ 40% (range: 40% –60%)

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Compliance level

3.4.2 Medical Devices

Table 12 and Figure 10 below summarize the compliance status of the analyzed medical devices

Table 12: Compliance status of medical devices

	Analytical Tests Performed									
	Dimensions		Burst Volume & Pressure		Freedom from Holes		Force to Operate Piston		pH	
	Compliant	Non-Compliant	Compliant	Non-Compliant	Compliant	Non-Compliant	Compliant	Non-Compliant	Compliant	Non-Compliant
Condoms	12	2	14	0	12	2	-	-	-	-
5 mL Syringes	-	-	-	-	-	-	15	0	15	0
10 mL Syringes	-	-	-	-	-	-	11	0	11	0
Total	**12**	**2**	**14**	**0**	**12**	**2**	**26**	**0**	**26**	**0**
% Compliance	85.7%	14.3%	100%	0%	85.7%	14.3%	100%	0%	100%	0%

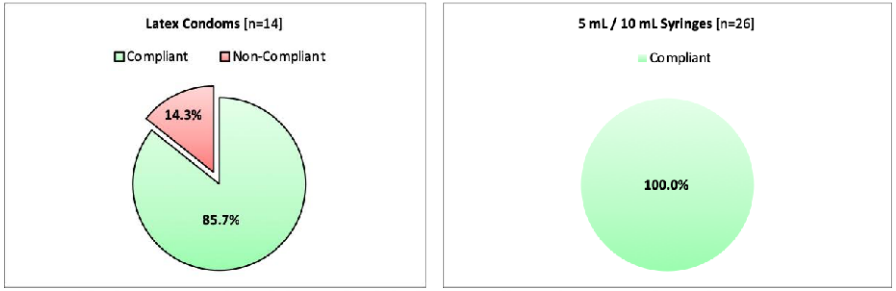

Figure 10: Graphical representation of the medical devices compliance by test performed

30

Reactive Surveillance

Pharmacovigilance Electronic Reporting System (PvERS)

- provides for public reporting

-USSD code and Mobile application (work in progress)

-Receive hard copy FSCA, FSNs

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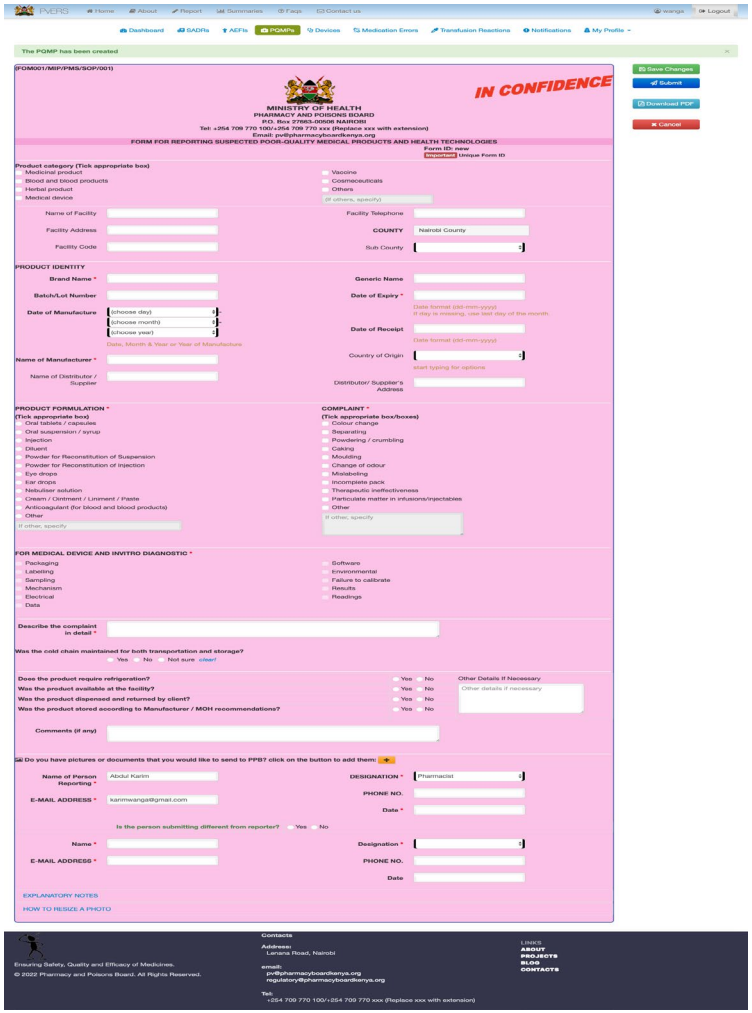
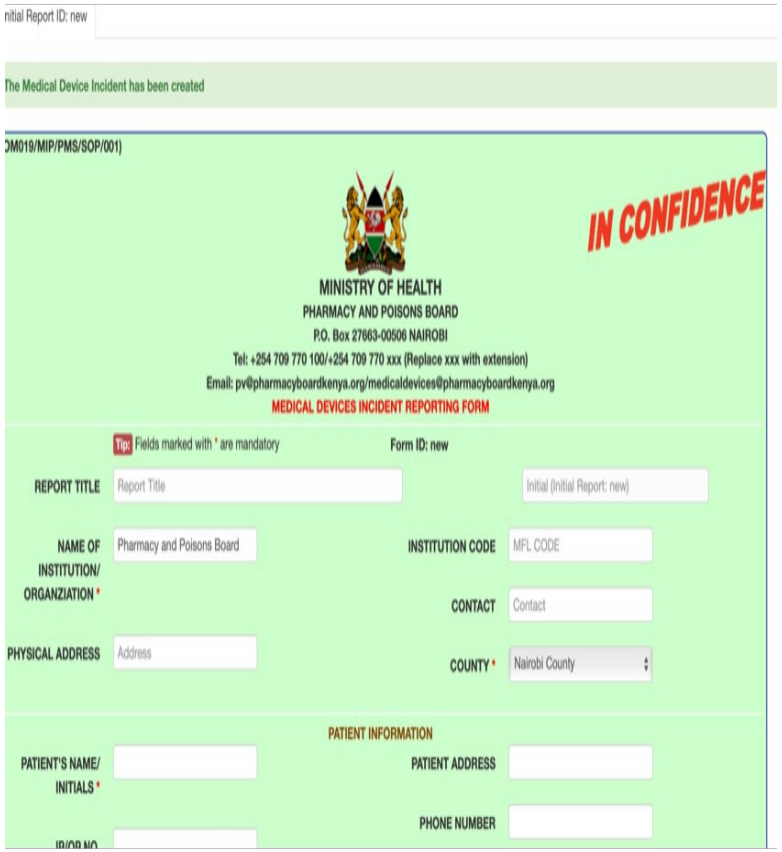
Incident reporting forms





Product Related Investigations

SOP for handling product related market complaints

SOP for receiving, reviewing and investigations of reports on incidents and FSCA of MDs including IVDs

Part of investigations- requesting additional information from the reporter

Additional information from MAH, LAR, Manufacturer

Review of root cause investigation report

Testing

Quality audits (done for male latex condoms)

Feedback Mechanisms

Feedback given to

- Market Authorization Holders,
- Local Authorized Representatives,
- Health Care Professionals,
- Manufacturers,
- Reporters
- Letters, Emails, e shot, website

Regulatory Actions

- Regulatory Guidance to Industry
- Quarantine
- Recalls
- suspension of MA
- withdrawals

Collaborations and partnerships and Reliance

Collaboration with KEMRI-validation of COVID 19 test kits (PoCTs)

https://ajlmonline.org/index.php/ajlm/article/view/1317#.YUhNWj4Itv4

MOU with KEBS-Pre-Export verification of conformity (PVoC)

Reliance and convergence mechanism – WHO,

NPHL-Donors funded programs for HIV,TB,STDs

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Case Study

S/N	Description of the case / market complaint/ Market feedback	Nature of investigation carried out	Final conclusion of the investigation	Regulatory actions implemented
1	2018- Suspected Falsified male latex condoms	Collaboration with MAH to gather intelligence on the product-source, distribution chain and individuals involved Distinguishing features from genuine product	Product was found to be falsified, *February 2018*	Guidance issued to public and HCPs
2	March 2020- Kenya Received notification from WHO on suspected HIV test kits	Collaboration with DCI, and Tanzanian Authorities	Products were found to be falsified	Suspects arrested , The case is on-going

Some photos of suspected falsified products

Consumer Pack

Counterfeit pack | **Current Trust pack**

Counterfeit	Genuine pack
Has the triple tested mark on the **left** of the pack	Has the triple tested mark on the **right** of the pack
Has **NO c**lear definer at the center of the pack highlighting "Studded"	Has **a** clear definer at the center of the pack highlighting "Studded"
Studs on the right front face of the pack are white in color	Studs on the right front face of the pack are a different shade of orange
Has no white stripe at the base of the pack begins- **Studded------ "3 quality condoms"**	Has a white stripe at the base of the pack with the definition – **3 quality studded condoms**

- Counterfeited product has an old Trust studded artwork- these packs were discontinued in 2015.
- The box is quite smaller than PS Kenya box by 1mm- both length and width

Some photos of suspected falsified products (2)

Foil

- The foil colour and font differ between PS KENYA pack and counterfeit pack
- Counterfeit pack has a white foil while PS KENYA pack has a grey one

Some photos of suspected falsified products (3)

Dispenser Pack

- Counterfeit pack is smaller than PS KENYA pack
- Counterfeit- 18cm(H) by 12cm (W)
- PS KENYA- 19cm(H) by 12.5cm (W)

- Counterfeit product has a deeper dark orange color
- Overall font slightly differs between original and counterfeit pack
- Colors also differ between the two packs

page 6

Counterfeit pack **PS KENYA pack**

Some photos of suspected falsified products (4)

Figure: test kit with falsified label with incorrect expiry date format = D MMM YYYY

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Overview of the LICENSING ESTABLISHMENTS (LI)

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Guidelines on Establishments

-Establishments of Medical Devices registration guideline -2022

-Licensing-Premises

-Licencing of operators and contractors of MDs*-

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Overview of the REGULATORY INSPECTION (RI)

Manufacturers of MDs

-List of Manufacturers of MDs established

-Quality audits using ISO 13485- not conducted.

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Overview of the LABORATORY TESTING (LT)

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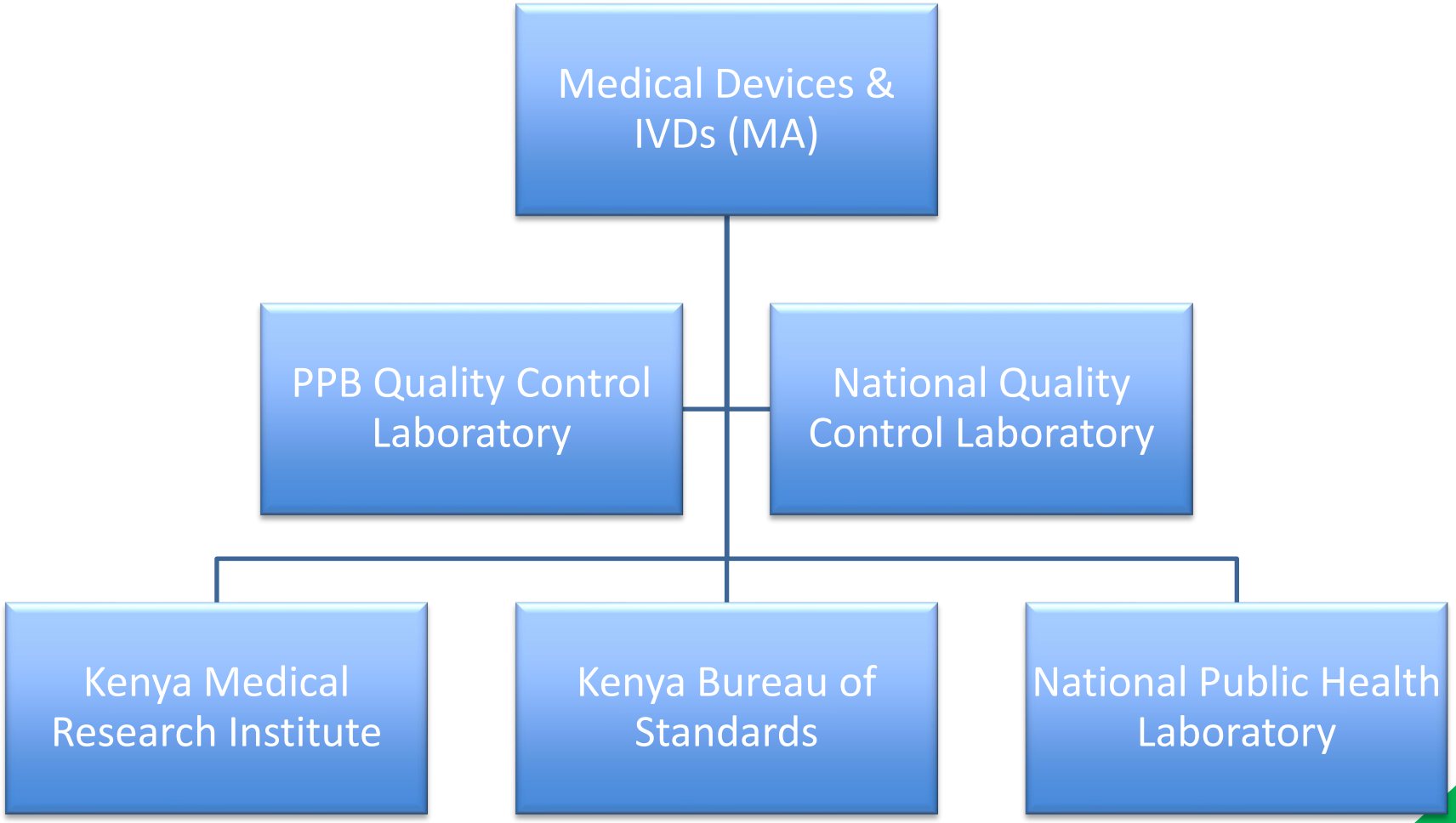
MA-Medical devices communication with external Entities



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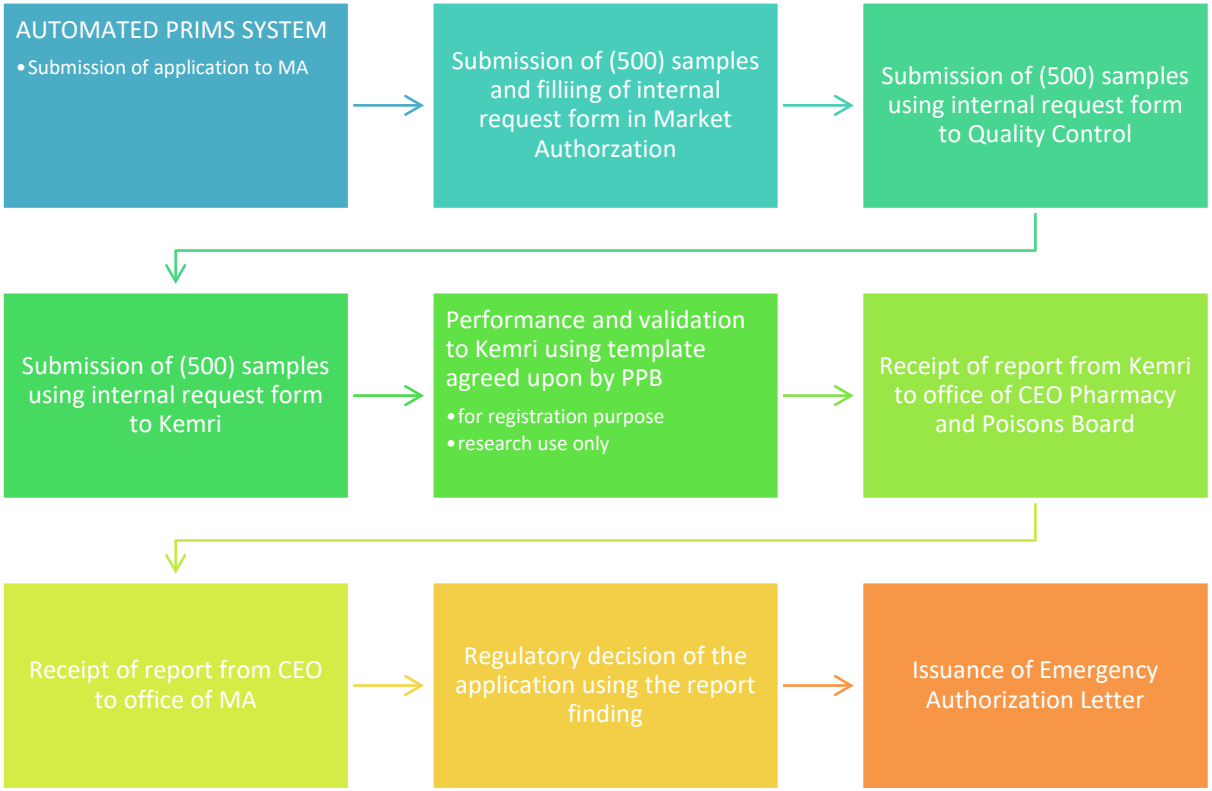
Process Flow with KEMRI



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Overview of the
CLINICAL TRIALS OVERSIGHT (CT)

Medical Devices Oversight

-Established guidelines

-Legal framework

-Applications for MD CTs submitted and reviewed

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MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS

Road Map on Regulatory decision from listing to registration requirements

Listing of Medical Devices and IVDs

2011- Manual applications received
Import control and issuance of Trade Permit

Listing of Medical Devices and IVDs

Gazettement of Notice no CXVI no 37 of 2014 for Form 1.
Annex 1- Application form for registration of Medical Device on PPB Portal

Mandatory Migration to Prims Class C&D

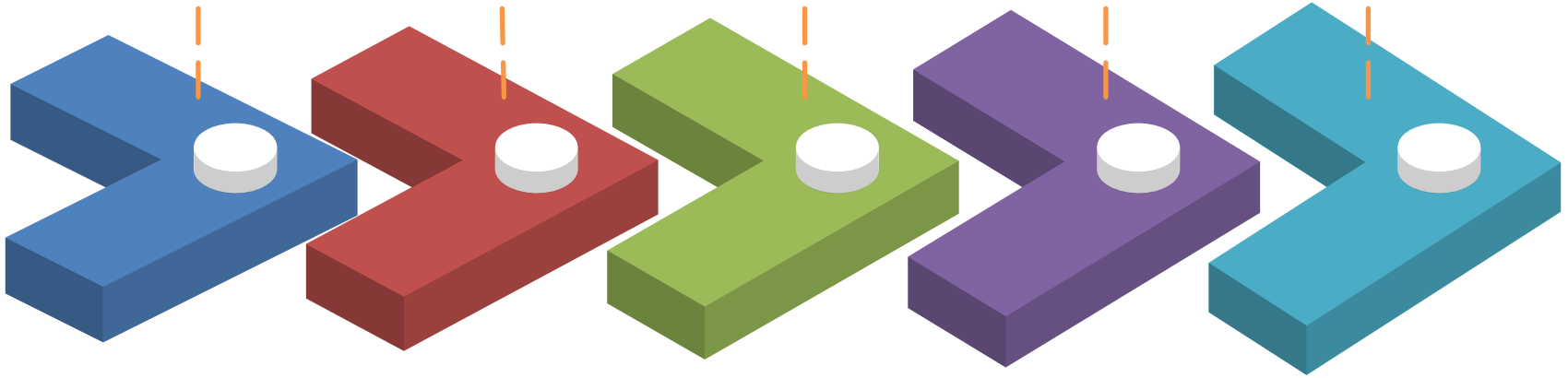
Using Risk Approach, finalization of Guidelines for Medical Devices 2017-2018.

Mandatory Registration of MD for all Classes

2018 all MD and IVDs require registration on Prims System.

In-Vitro Diagnostics in country assessment; Testing of MDs

Response to Emergencies COVID-19 Pandemic use of in-country assessment as part of Registration process



Achievements-Phased Implementation

Future Plans

-Quality audits for Medical Devices

-Quality audits for IVDs

-Clinical investigations controls for MDs and IVDs

--Capacity building of Expertise in Medical Devices and Diagnostics

-Laboratory strengthening in Testing of Medical Devices and IVDs

Challenges

HUMAN RESOURCE

Develop a large workforce to focus on Medical Devices activities.

Expertise and Capacity Building

Need to build capacity within the NRAs for Medical Devices and IVDs with specializations

Institutional Frameworks

Medical Devices and IVDs activities centered in larger Pharma units

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THANK YOU

P.O. Box 27663 – 00506

Nairobi, Kenya

Telephone: 0709 770 100

Email: info@pharmacyboardkenya.org

Website: web.pharmacyboardkenya.org