For A Healthier Africa
AFRiSUMMIT
2nd - 5th November 2025
Hilton Grand Nile Hotel, Cairo - Egypt

ENHANCING POST MARKET SURVEILLANCE

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Agenda

- Introduction
- Falsified/Substandard Medical Products
- Post-Market Surveillance System in Kenya
- Post-market surveillance by manufacturers
- Enhanaching Traceability
- Roles and resoensibilities for various stakeholders

Introduction

Post-market surveillance refers to all the, processes that are carried out to continuously track/ monitor quality, safety and efficacy of medical products in the market **(after registration)**

Brainstorm

- What are falsified/substandard medical product?
- What are poor quality medical products ?
- What are Unregistered/Unlicensed medical products ?

Falsified/Substandard Medical Products

i. Substandard HPTs

Also called ‘out of specification,’ these are authorized medical products that fail to meet their quality standards, their specifications or both, e.g., manufacturing error, expired or degraded products.

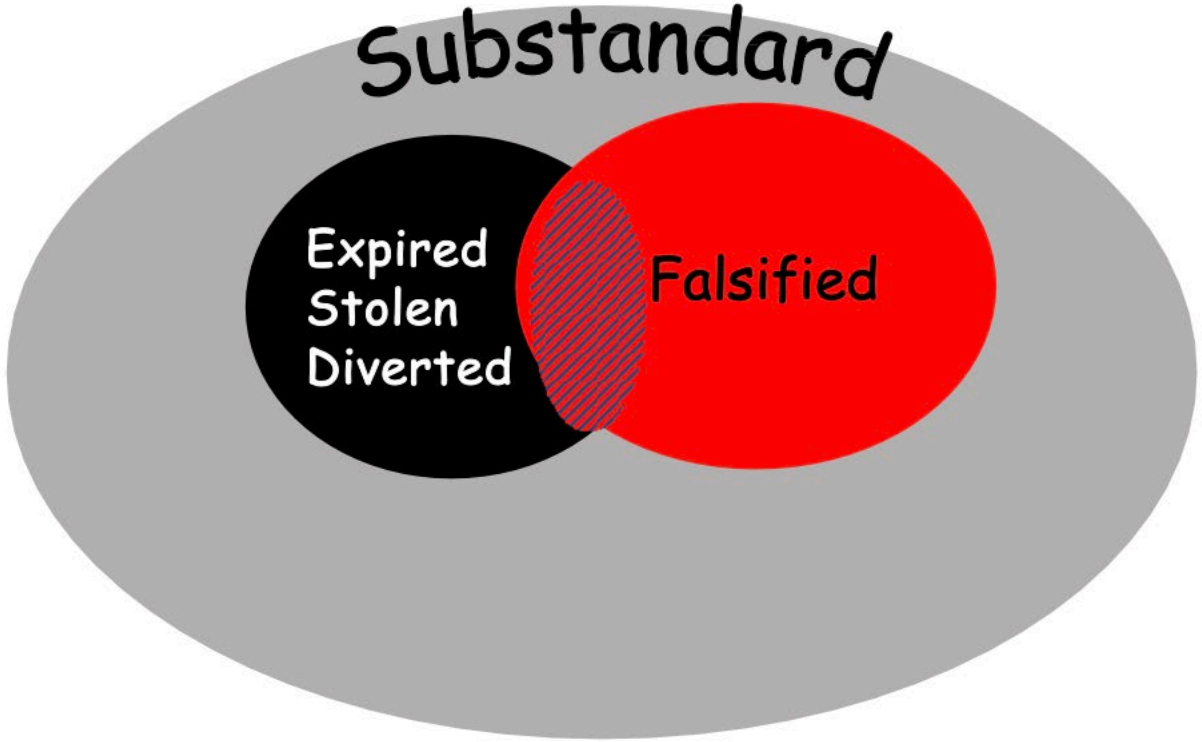
ii. Falsified HPTs

WHO defines a falsified pharmaceutical product as…
“a product that is deliberately and fraudulently mislabeled with respect to identity and / or source”.

iii. Unregistered/Unlicensed medical products

Medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed, distributed or used, subject to conditions under national or regional regulation and legislation

All falsified products are substandard…But Not all Substandard products are falsified



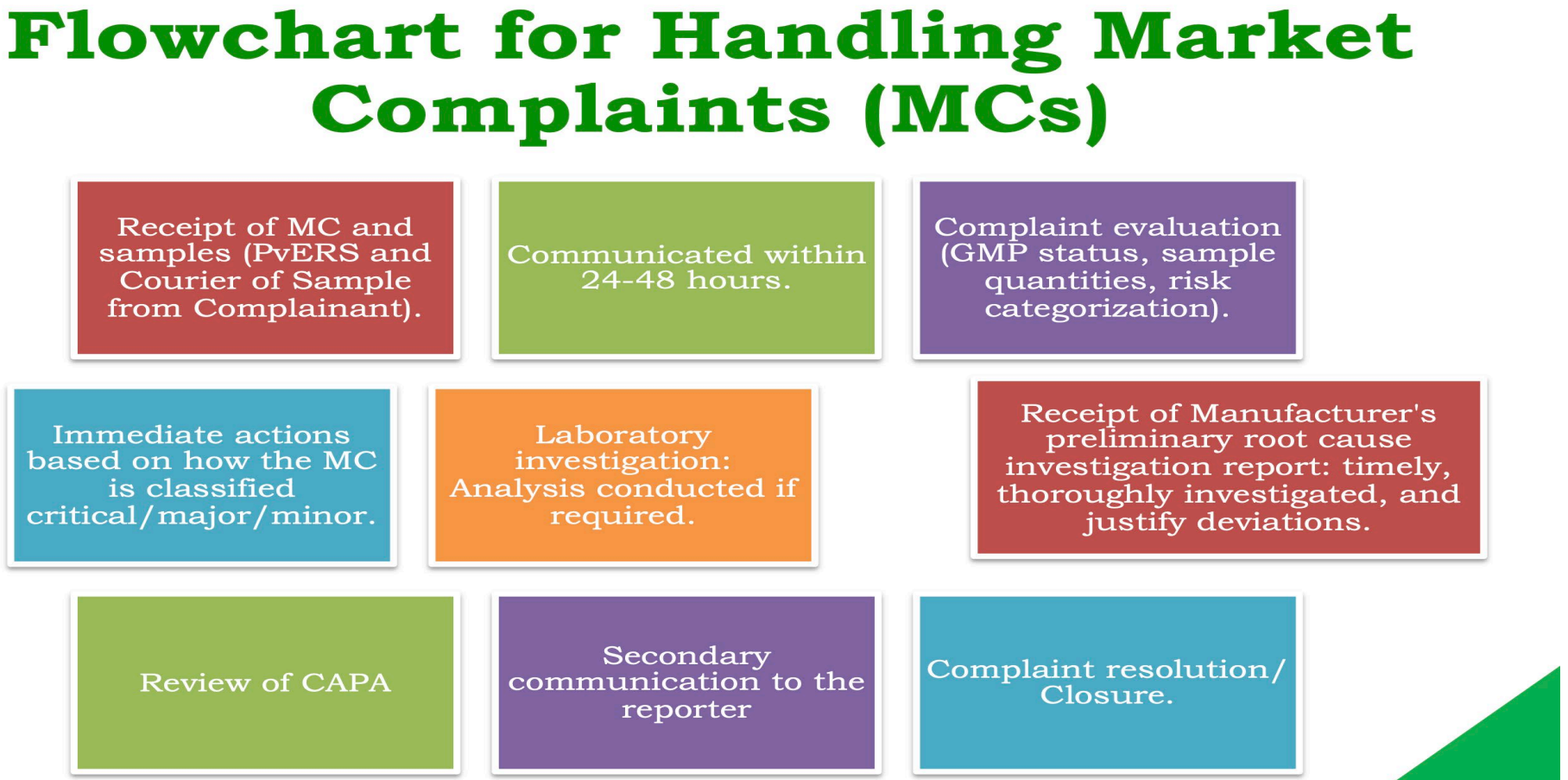
Post-Market Surveillance System in Kenya

- Proactive post-market surveillance involves systematic, scientific, and structured quality surveys based on a study protocol.

- Reactive post-marketing surveillance - conducted through evaluation of feedback from stakeholders, investigation of product-related market complaints and reports of poor-quality
medical products, and implementation of regulatory actions

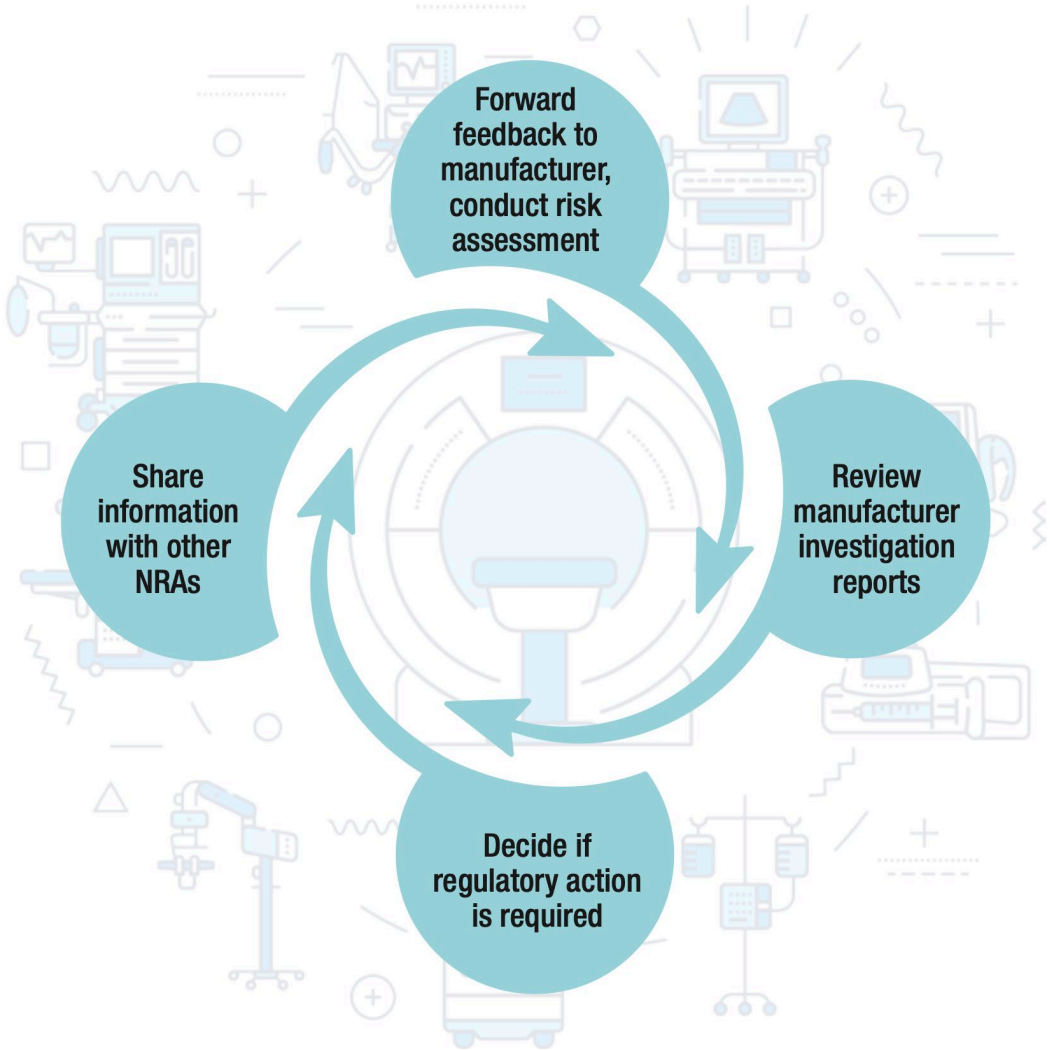
Flowchart for Handling Market Complaints (MCs)

Republic of Kenya
Ministry of Health



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

Potential actions to oversee manufacturer investigation of feedback



Possible regulatory actions

Depending on the risk/benefit posed by an incident reported in the post-market phase and/or potential for future harm, NRAs should consider the following possibilities:1

- No action.
- Perform additional surveillance of the medical device concerned in use.
- Issue a safety alert giving advice to users.
- Require the manufacturer to make appropriate changes in the design, manufacturing process or information/labelling supplied with the medical device.
- Mandate (enforce and monitor) and field safety corrective action (FSCA) (e.g. a medical device return/disposal or withdrawal from the market).
- Send the data acquired to the manufacturer and store them in a database to help identify trends that require action.

Post-market surveillance by manufacturers

Actions for manufacturers to undertake include;

- Collect feedback
- Classify feedback and determine reportability to NRA
- Undertake root cause analysis
- Decide if correction is required
- Implement corrective/ preventive action

Enhanaching Traceability

Unique device identification

- Implementation of IMDRF's UDI systems for medical devices is intended to "facilitate unambiguous identification of the medical device through distribution and use by providing a single global identifier that can be used to link and integrate existing government, clinical, hospital, and industry databases"
- Unique device identification will allow manufacturers and their economic operators, as well as NRAs to more rapidly identify medical devices implicated by user feedback.
- The UDI may be added to manufacturer reports, and to registries.
- The UDI device identifier (UDI- DI) and UDI production identifier (UDI-PI) allow for traceability of the medical device throughout distribution and use

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Roles and resoensibilities for various stakeholders

Stakeholder	Key Activities
I. Users and Clients/Patients	• Observe/detect issues • Document feedback • Provide feedback
II. Manufacturers and Economic Operators	• Follow manufacturer's instructions • Implement a PMS system • Classify and escalate feedback • Report to NRA if required • Conduct root cause analysis • Implement corrections and CAPA
III. National Regulatory Authority (NRA)	• Ensure feedback is forwarded to manufacturers • Conduct risk assessments • Collect and review reports • Coordinate testing (risk-based) • Gather market intelligence • Take regulatory action if needed • Share information with other NRAs/WHO

Way forward

- Continued strengthening of national regulatory systems
- Enhanced international cooperation and timely information-sharing;
- Better coordination among regulators, law enforcement and customs authorities;
- Increased public awareness of the risks of SF medical products;
- Strengthened national and international recording systems
- Increased use of technology for product authentication or tracking

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THANK YOU