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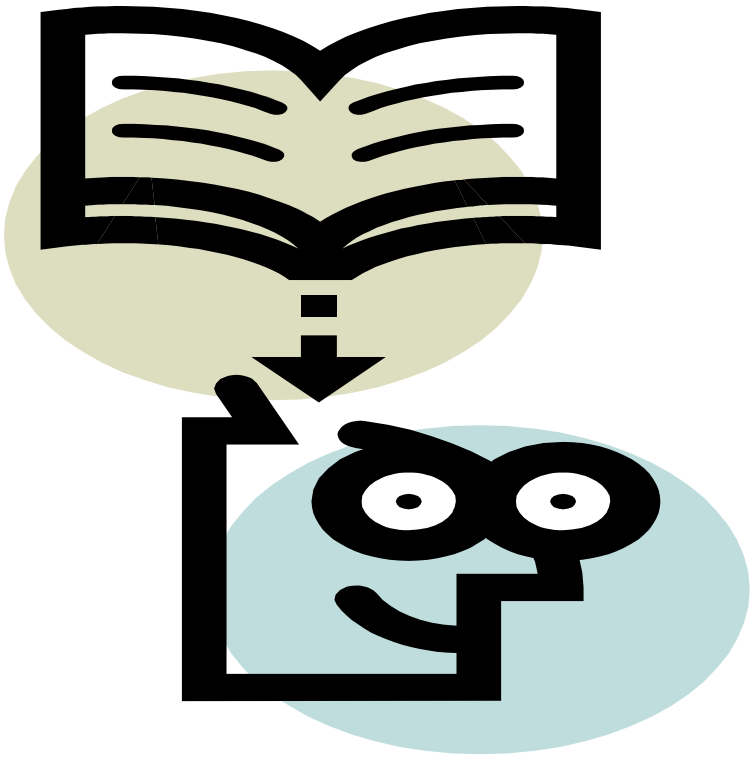
POST MARKETING SURVEILLANCE

Agnes Sitta Kijo
Manager, Medical Devices Assessment and Enforcement
Tanzania Food and Drugs Authority
P.O. Box 77150, Dar es Salaam, Tanzania
agnes.kijo@tfda.or.tz or agneskijo@yahoo.com

Talking points



- Introduction
- Key elements of Quality & safety of MD
- PMS
- PMS key elements

Quality and safety of Medical devices in Tanzania

Three elements :

- Pre- market authorization (Registration)
- Import and export Control
- Post Marketing Surveillance

Pre –Market authorization (Registration)

- Registration system has taken into consideration risk of the device (GHTF model).
- Some Class A Devices are exempted from registration (adhesives, bandage, clip e.t.c)
- Any other class A device not in exempted list has to be registered
- All Devices in Class B, C and D needs to be registered

Import and export control

- Approval of importation documents

- Inspection of products at the POE including collection of samples (suspicious).

Post Marketing Surveillance

- Activities conducted to monitor the quality, safety and performance of registered devices that are on the market.

- It's a risk based surveillance- it is not possible to test everything that's on the market.

- Devices that present higher risks merit higher priority for surveillance.

Why is PMS conducted?

- To test registered products sampled from the market against product quality standards.

- To investigate complaints received pertaining to a registered product.

- To examine product labels and inserts to ensure compliance to approved indications and labeling requirements.

Why?.....

- To monitor device safety profiles through the adverse events programme (vigilance) and compare the incidences of AEs in humans treated and not treated with the device.

- To identify risk factors responsible for an increased frequency or severity of AEs.

- To conduct literature reviews and gather information about PMS obtained through networking with other NRAs, harmonization initiatives and the WHO

PMS Key elements:

Sampling plan: prepared and approved

- For systematic collection of samples
- PMS team (consists Laboratory staff) has the responsibility to prepare the SP
- Sample size is pre determined (depending on available resources)

PMS Key elements……SP

SP must indicate products to be sampled.

Main criteria for selection of products

- The product has to be registered
- Capacity to analyze
- Availability of resources (number of products and types)
- Risk associated with their use
- Reports of poor quality

PMS key elements……SP

- ✓Sample size and number of batches

  Should be enough//adequate for laboratory testing as determined in the SP

- ✓Sampling areas: SP should specify areas esp. those that borders other countries, big business cities and distribution chain (wholesalers, retailers, health facilities)

PMS Key elements……

- **Packaging, labeling and storage of samples**: sample collection bags should be sealed and tamper proof, properly labeled and contain information as provided on the label.

  Samples should be stored according to the manufacturer's recommendations in a manner that prevents deterioration, contamination or adulteration.

PMS Key elements……

- Transportation of samples: Adherence to storage condition (temperature monitoring devices) and adequate protection during transportation to avoid damaging the samples.

- Sampling records: Collected samples must be recorded in sample collection forms and in the sample register

PMS Key elements……

- Sample testing

✓ Visual and physical inspection

All samples must be subjected to visual and physical verification before testing (Verify manufacturing source, Sample integrity, Identification of substandard and suspicious samples.

✓ Laboratory testing

PMS Key elements…….

- Data Evaluation and Dissemination

✓involves collection of a mass of information

✓Information will be evaluated by the PMS team plus risk assessors and epidemiologists

✓Statistical treatment of data, graphical presentations, trend analysis

✓Information will be made public.

PMS Key elements…….

- Enforcement

✓Recall

✓Suspension

✓Quarantine

✓Withdraw

✓Inspection to the manufacturing site to verify implementation of QMS requirements

PMS Key elements…….

- Vigilance (Safety):
- Why?
- evaluate reported AEs,
- disseminate information to minimize or prevent the consequences of AEs,
- modifying the medical device (manufacturer) and
- removing the product from the market.

Vigilance

TFDA has developed the following tools:

- ✓SOPs for receiving and processing of AEs.
- ✓Three (3) AEs reporting forms for manufacturers, suppliers/importers and consumers.
- ✓AEs Register at TFDA.
- ✓AEs assessment template.
- ✓ Conceptual framework for vigilance.

TFDA

Tanzania Food & Drugs Authority

Thank you for your attention