STAKEHOLDERS ENGAGEMENT ON IMPLEMENTATION OF PHARMACEUTICAL TRACEABILITY

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introduction

What is GDP?

- GDP is that part of quality assurance which ensures that the quality of a pharmaceutical product is maintained by means of adequate **control** of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and or misbranded pharmaceutical products.

Why GDP?

- The reason for having GDP is to ensure that desired products are procured, imported, exported, stored, transported and distributed so that they maintain the quality, identity, purity, strength, safety, and efficacy, which they claim to have.

- As a Stakeholder, you should be concerned whether a product has been handled under the required conditions or not. If the conditions of handling deviate from GDP then you might be distributing a potentially ineffective, unsafe or dangerous product for yourself or your family members.

INTRODUCTION CON'T

- As a stakeholder, your facility must be operating in compliance with GDP otherwise your products that is beeing packed or distributed from your facility could be considered "sub-standard" and you may likely loose public trust.

Imortance of GDP:

- Good Distribution Practice (GDP) is very key to ensuring that good quality, safe and efficacious pharmaceutical products, vaccines, Biologics etc reach the targeted consumers in very good condition.

- It helps practitioners and regulators to identify substandard and falsified products which may enter into the distribution/supply chain.

- It creats a level play groung for both Regulator and Stake holder to collaborate and ensure quality medicines and sold and distributed to the public.

What Happen during GDP

- GDP inspection is a "verification" exercise,the NAFDAC Inspector is the "verifier".
- The inspector is expected to carefully verify that products are being packed, held and distributed under GDP conditions.
- Inspector is to enforce NAFDAC GDP for Pharmaceutical Products by evaluating compliance through on-site inspections of distribution and holding facilities.
- The insector review documents and sometimes by sampling of drug (regulated) products and related materials for laboratory testing where necessary.

EXPECTATION FROM STAKEHOLDER

- The professional licenses must be valid SOP requirements relevant to the products and processes at the targetfacility.
- All GDP inspection related **current** SOPs should be made available at all time.
- All submitted documents from the company (e.g. list of products distributed by company, list of companies having distribution contract with company.
- Keep the lists of all products marketed or distributed in your facility

AREAS OF INTEREST DURING GDP

☐During the inspection, you are to note the following areas of interest.

- Company's organizational structure and general information about the Distributor/wholesaler/importer/warehouse/exporter /outlets
- Facility (**facilities and equipment must have suitable layout and design for the intended operation.** Equipments
  - Personnel (There must be sufficient number of qualified personnel,**personnel records including training records must always be updated.**Responsibilities must be clearly defined and understood by personnel using Job descriptions as stated in the SOP and documented. Every personnel must receive initial and continuing training, on their specific job, GDP, sanitation and hygiene.Every personnel must be appropriately clothed/kitted for their tasks.
- Products (**the procurement/supply process of relevant dosage forms, check how these steps are controlled, monitored and recorded,** Distribution of drug products and related products in consonance with GDP requirements and possessing the requisite quality assurance systems ultimately rely upon having qualified people.
- D

AREAS OF INTEREST DURING GDP .....

Inspector in the facility:

- TRAININGS:

•We review training records of your personnel qualification and experience to verify initial and continual training on GDP, hygiene and sanitation and specific job functions. We could further Interview trained staff on trainings.Examine consultant records for proof of experience/qualification

- Vehicle and EquiptmentsDocumentaion (**documents, e.g. procedures, records, raw data and personnel training records.)**

- QMS Compliance

GDP INSPECTION

- **Buildings:**

Premises and facilities must be adequately designed, located, constructed, and maintained to suit the operations to be carried out .Layout and design must aim to minimize risk of errors, facilitate cleaning and maintenance to avoid cross-contamination, build-up of dust, dirt and other adverse effects on the quality of products.

- **Facility:**

- ✓ We check that there are clear restrictions signs on doors to restricted areas .
- ✓ We Verify whether there is orderly placement of products
- ✓ Defined areas of adequate size for receipt of products,
- ✓ Quarantine of products,
- ✓ Prescription medicines, cold storage, narcotics and other dangerous pharmaceutical products, medical gases,
- ✓ Rejected products, Expired products,
- ✓ Quality control (where applicable)
- ✓ Highly active and radioactive materials and hazardous products presenting special risks such as fire or explosion, which shall be subject to appropriate additional safety and security measures

- WareHouse, Premise and Storage

GDP INSPECTION.....

- **We Confirm visible, clear, and logical provisions for storage, designed to provide , temperature, sanitation, humidity, space, equipment and security conditions**
- **Verify smooth, cleanable floors, walls, seamless corners, ceiling and fittings that prevent buildup of dust.**
- **Are lighting, ventilation, cooling/freezing systems adequate for operations?Review schedule for lighting maintenance e.g. changing bulbs.**
- **Check air pressure differential gauges and flow directions as you cross to different levels or areas**

SOP REVIEW

Do you carry Traceability of calibration standards?

- **Hygiene/Sanitation**
- Building Maintenance
- **Equiptment Callibration:**
- Expired and damaged products should be handed over to NAFDAC I&E Directorate while packaging wastes should be disposed of by the company.
- **Pest control, Disposal of expired/damaged products& Waste disposal.**
- **Equiptment Callibration:**
- Cleaning:
- **Storage and transportation of samples**

Samples should be kept in their original packaging and stored under the conditions specified on theIir package/label;

i. All samples should be packaged adequately and transported in such a way as to avoid breakage and contamination. Any residual space in the container should be filled with a suitable material.

ii. For temperature-sensitive medicines, temperature data loggers may be included within shipments to document maintenance of an appropriate temperature during prolonged transit.

SOP FOR STORAGE TRANSPORTATION.....

- **Warehousing and distribution :**

The drug product shall be established and followed SOP which shall include:

- ✓ Store under appropriate conditions of temperature, light and humidity to maintain quality, identity, purity and strength of drug product
- ✓ The personnel on recall may be interview including other relevant warehousing, distribution procedures.
- ✓ A Visit wto Warehouse will be made, confirm records of temperature, Light and humidity .
- ✓ Confirm if SOP exists to manage stock to ensure that oldest approved stock of drug product is distributed first.
- ✓ Is there a documented system for traceability of distribution of each batch of drug and related product to facilitate recall.

SUMMARY OF DOCUMENTS TO BE REVIEWED

The GDP inspection avail the opportunity to Assess the company's overall documentation management system, including its change control practices,evaluate the role of the person who is responsible for this duty.

In addition to SOP's,below are the list of documents which may be reviewed:

- **Handling Consumer Complaints;**
- **Incident reports;**
- **Relevant standard operating procedures and records, e.g., recall procedure;**
- **Relevant contracts;**
- **Job descriptions and training records**
- **Validation information;**
- **Self-inspection programme. Self-inspection reports may be reviewed (if available).**
- Documentation/ Record keeping
- Corrective action and preventive action (CAPA)

WAY FORWARD AFTER GDP (PMS)

The Agency carry out the following:

- Communicate with Head of PMS, State coordinator
- Send Reports within 3 working days unless otherwise directed, to PV/PMS Headquarters on return from Inspection.
- Send written communication to inspected facility within 14 calendar days of return to your office
- Address next steps to achieve closure on any issues requiring further action by Team.
- Are there any issues?If yes, what are the plans to address and close open issues?
- Defer to next inspection? Conduct special Follow-up Inspection?
- All Documentation completed and filed

WHAT IS PMS

- Post Marketing Surveillance (PMS): is a regulatory function of National Medicines Regulatory that involves the assessment of safety and quality of pharmaceutical products throughout their shelf life at all levels of the supply chain.

- PMS is meant to continuously monitor the quality, safety and efficacy of pharmaceutical products on the market at all levels of the supply chain,the quality of any medicine are safety, potency efficacy, stability and compliance with regulatory requirements such as labeling and product information leaflet.

- PMS ensures the quality medicines from manufacturer to the end user is maiintained.

- Surveillance is sustained through out their shelf life

RESPONSIBILITY OF PMS

- Monitoring of authorized/registered/licensed medicines within the supply chain to ensure quality and efficacious of medicines gets to the end user.
- Carry ing out regular surveillance of manufacturers, wholesalers/distributors/retailers and quality control.
- The PMS conduct survey based on high-risk medicinal products to accertain quality and efficacy and send to the lab for analysis.▪
- The PMS monitors advertising and product on promotion to ensure mis-lead to the public.
- PMS collaborate with stakeholders to carry out recall of defected/substandard products and send for destruction
- PMS is meant to continuously monitor the quality, safety of medicine within the supply chain
- Handling of consumer Complaints.

ESTABLISHMENT OF PMS

- Management of PMS process
- Execution of PMS Process:
- Training of personnel on requirements of PMS
- Performing a surveillance study
- Protocol for surveillance
- Methodology
- Selection of sites for PMS study
- Sentinel site monitoring
- Types of Sampling
- Storage and transportation of samples

ESTABLISHMENT OF PMS....

- It is a regulatory function of ALL relevant stakeholder including National Medicines Regulatory Authorities.
- It involves the assessment of safety and quality of pharmaceutical products throughout their shelf life and at all levels of the supply chain. PMS is meant to continuously monitor the quality, safety and efficacy of pharmaceutical products in the market at all levels of the supply chain.
- It helps regulatory authorities in a country in assessing products quality and safety to generate reliable scientific evidence required to take regulatory action to protect public health.
- It continuously monitors the efficacy, quality and safety of marketed products throughout their shelf life and at all levels of the supply chain.

ESTABLISHMENT OF PMS....

- The dependency of regulatory systems on adverse event reporting alone may not capture all risks related to medicines and the use of medical devices.
- The quality of medicine is its level of suitability for intended use by the end user. It also means its ability to maintain its quality throughout the distribution chain.
- To ensure that quality of medicines are is maintained/monitored while being distributed.There has been different platforms NAFDAC and relevant stakeholders to discuss and emphasize the need for a best practices

IMPORTANCE OF PMS

- it ensures that only quality and safe medicines and other regulated products are distributed throughout the country.
- Effective implementation of PMS will enable NAFDAC and stakeholders to generate scientific evidence on the quality and safety of medicines .
- It is important that we sustains a high quality and scientifically credible safety and efficacy data for on these vital health commodities to enhance evidence base decision making that impacts public health.
- PMS of pharmaceuticals products will enhance evidence based regulatory decision to improve health outcomes.
- It provides an important source of information on the quality of Pharmaceutical product available in the market.

IMPORTANCE OF PMS……

- The PMS program is designed to respond to health priorities and challenges. It is impossible to test the quality of ALL registered products in the country hence the need to prioritize Pharmaceutical products based on the perceived risk to the consumer.

- The information obtained from PMS activities is vital to enhance and maintain the quality assurance system in Nigeria.

- Data collection on the quality of medicines, if properly executed, interpreted and used, are vital for the planning of effective interventions that will improve the quality of medicines. The accuracy, reliability and interpretation of the data obtained will also depend on the PMS plan, method of sample collection,

- Conducting survey

IMPORTANCE OF PMS.....

- The Post marketing surveillance study on the quality of medicines may be costly, and available resources may restrict the number of samples to be collected, tested but worth it.

- In order to sustain regular PMS activities, we must established a suitable and practical organizational structure that ensure execution of effective surveillance activities all year round.
- Every facility must establish PMS (you must own your process) while NAFDAC monitors compliance.
- The existing PMS division in NAFDAC is solely dedicated to carry out PMS activities and will continue to execute of PMS program.

REFERENCES

- Nafdac Good Distribution practice Guideline 2016
- National Quality Assurance Policy (NQAP) 2015
- Guidelines on Quality Control Testing of Antimalarial Medicines at NAFDAC ISO 17025 Accredited Laboratories
- NAFDAC Act Cap NL LFN 2004
- WHO guidelines for sampling of pharmaceutical products and related materials. (TRS No. 929, 2005)
- NAFDAC GDP guidelines 2016
- WHO Good practices for pharmaceutical quality control laboratories (WHO TRS No. 957, 2010. Annex 1

Thank You.