PHARMACOVIGILANCE/POST MARKETING SURVEILLANCE NEWSLETTER

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Recent Developments in Nigerian Implementation of Good Distribution Practices of Pharmaceutical Products.

Content

All MAH's are requested to submit to the Agency a documented evidence of the establishment of **Department of Pharmacovigilance and post marketing surveillance** to properly relate and share intelligence on happenings in the market with respect to their products.

HAVE YOU SUBMITTED?

EDITOR'S NOTE...

We wish to thank all our numerous stakeholders who have been working tirelessly with the National Pharmacovigilance Centre (NPC) to ensure the safe use of medicines in Nigeria. The NPC is committed to sending out the quarterly newsletter to its stakeholders. The objectives of the Newsletter are to disseminate information on Pharmacovigilance activities nationally and globally, to educate stakeholders on medicine safety issues, to promote rational use of drugs and to promote reporting of Adverse Drugs Reactions (ADRs). This edition of the newsletter focuses on **Recent Developments in Nigerian Implementation of Good Distribution Practices of Pharmaceutical Products.**

We encourage Health care Professionals and other stakeholders to continue to report all adverse drug reactions. Your valued comments and acknowledgement of receipt of this issue through our email addresses (nafdac_npc@yahoo.com; pharmacovigilance@nafdac.gov.ng, fdic@nafdac.gov.ng) would be most appreciated.

You may also send us an email if there are any areas of interest that you would want addressed in subsequent issues of the newsletter

Thank you for your relentless efforts in strengthening Pharmacovigilance System in Nigeria.

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Text any DRUG RELATED PROBLEM to the SHORT CODE 20543 (For free on MTN, Glo, Etisalat and Airtel) for action by the Pharmacovigilance Centre

Introduction

The reviewed NAFDAC Good Distribution Practices (GDP) Guidelines for Pharmaceutical Products (2021) is accessible on the NAFDAC website (https://www.nafdac.gov.ng/). These guidelines provide adequate advice on the various components of GDP. Good Distribution Practice is that part of quality assurance that 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. The distribution of pharmaceutical products is an important activity in the Supply chain and involves several players. It consists of **procuring, holding, supplying, importing** and **exporting of pharmaceutical products**. Distribution activities are carried out by manufacturers, importers, wholesalers/distributors, retailers and other persons authorized to supply pharmaceutical products in the public and private sectors. The Good Distribution Practice (GDP) guidelines are intended to help players in the supply chain of pharmaceutical products comply with NAFDAC Good Distribution Practice Regulations; it provides appropriate tools to assist all categories of distributors in conducting their activities in order to maintain the quality of pharmaceutical Products and prevent counterfeits from entering the legal supply chain. They are intended to help in minimizing the inherent risks in distribution such as mix-ups, adulteration, contamination, cross contamination and diversions.

Some injections like Oxytocin and Tetanus toxoid must be stored in a dedicated refrigerator for drugs to prevent losses in potency and denaturation respectively.

General Principles of GDP

The General principles of GDP include the following:

- All parties involved in the distribution of pharmaceutical products have a responsibility to ensure that the quality of pharmaceutical products and the integrity of the distribution chain are maintained throughout the distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient.
- The principles of good distribution practice (GDP) are applicable both to pharmaceutical products moving forward in the distribution chain from the manufacturer to the entity responsible for dispensing or providing the product to the end user; and to products which are moving backwards in the chain such as it obtains in return and recall
- The principles of GDP are also applicable to donated pharmaceutical products.
- All distributors should apply due diligence with adherence to the principles of GDP, for example, in procedures relating to traceability and in recognition of security risks.
- All distributors should comply with the extant national legislations on pharmaceutical products.
- All distributors should be appropriately authorized and can be held accountable for all the activities that relate to the distribution of pharmaceutical products.
- Only entities which have marketing authorization for pharmaceutical products or their agents are entitled to import or export pharmaceutical products.

- Pharmaceutical products may be distributed within or to a country or territory if a marketing authorization or similar authorization has been granted, which allows the use of that pharmaceutical product in that country or territory.
- Holders of an authorization to distribute pharmaceutical products should obtain their supplies only from persons or entities which are in possession of the applicable authorization to sell or supply such products.
- Distributors or their agents should supply pharmaceutical products only to persons or entities which are themselves authorized to acquire such products either in terms of an authorization to act as a distributor or to sell or supply products directly to a patient.
- Some duties and responsibilities may be delegated or contracted out to suitably designated persons or entities as authorized and as necessary. Duties and responsibilities may only be delegated to entities which are suitably authorized. There should be no gaps or unexplained overlaps with regard to the application of GDP. These delegated and contracted activities should be documented in agreements or contracts. There should be a periodic audit of such activities with regard to application of GDP.
- A system should be put in place to monitor transactions and investigate any irregularity in the sales patterns of narcotics, psychotropic substances or other controlled substances. Unusual sales patterns that may constitute diversion or misuse of pharmaceutical product should be investigated and reported to the Agency where necessary. Steps should be taken to ensure fulfilment of regulatory requirements of the Agency.

Components of GDP

The components of GDP as elaborated in NAFDAC Good Distribution Practices Guidelines for Pharmaceutical Products are as follows:

- **Organization and Personnel**- The correct distribution of pharmaceutical products relies upon people. For this reason, there must be sufficient number of competent personnel to carry out all tasks for which the distributor is responsible. Individual responsibilities should be clearly understood by employee and be recorded.
- **Quality Management System**- Distributors of Pharmaceutical products should maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities. All distribution activities should be clearly defined in procedures and systematically reviewed and significant changes should be justified and where relevant, validated. The quality system is the responsibility of the organizations management and requires their leadership and active participation and should be supported by staff commitment
- **Premises, warehousing and storage facilities**- Distributors must have suitable and adequate premises to ensure proper storage, distribution of pharmaceutical products and adequate space in warehouses for movement of personnel & efficient cleaning. In particular, the premises should be clean, dry and maintained within acceptable temperature limits
- **Vehicles and equipment**- It is the responsibility of the distributor of pharmaceutical products to ensure that

vehicles and equipment used to distribute, store or handle pharmaceutical products are suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their quality and integrity

- **Operations management**- All actions taken by distributors should ensure that the identity of the pharmaceutical product is not lost, and that the distribution of pharmaceutical products is performed according to the information on the outer packaging. The distributor should use all means available to minimize the risk of falsified pharmaceutical products entering the legal supply chain. All pharmaceutical products distributed in the intended market by a distributor must be appropriately authorized.
- **Qualification of suppliers and customers-** There must be a system to ensure that suppliers and customers are duly qualified and authorized to supply or receive pharmaceutical products and comply with the principles and guidelines of good distribution practices. They must be assessed against a set of standard requirements and records should be available to show this.
- **Donated pharmaceutical products**- Donations of pharmaceutical products should benefit the recipient in Nigeria to the maximum extent possible. All donations should be based on an expressed need as unsolicited pharmaceutical product donations are prohibited. Donations should conform with regulations of the Agency. There should be effective coordination and collaboration between the donor and the recipient, with all donations made according to a plan formulated by both parties. All pharmaceutical product donations should be relevant to the disease pattern in Nigeria, and quantities should be agreed between donor and the recipient. All donated pharmaceutical products or their generic equivalents should be approved for use in Nigeria unless specifically requested and provided with a justification by the recipient.
- **Self-inspection**- Self-inspections should be conducted in order to monitor implementation and compliance with GDP principles and to propose necessary corrective measures.
- **Training-** Training of personnel is key to entrenching GDP in facilities.

It is noteworthy that Records of temperature monitoring data should be available for review in the premises. There should be defined intervals for checking temperature. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained. All monitoring records should be kept for at least the shelf-life of the stored pharmaceutical product plus one year.

Temperature mapping should show uniformity of the temperature across the storage facility and at different seasons (dry and rainy). It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.

Equipment used for monitoring of storage conditions should also be calibrated at defined intervals.

The storage conditions for products should follow the required storage specification of the product (this is a very important labelling requirement by the Agency). Where the temperature is not stated (in terms of range) on the label of the products, the following definitions should be used as seen below:

Freezer	The temperature is thermostatically controlled between – 25°C and –10°C
Refrigerator	The temperature is thermostatically controlled between 2°C and 8°C
Cold place	the temperature does not exceed 8°C
Cool place	The temperature is between 8°C and 15°C
Room temperature	The temperature is between 22°C and 25°C
Ambient temperature	The required storage temperature of nonrefrigerated pharmaceutical product; usually stated on the product label as 'store below 25 °C' or 'store below 30 °C'.
Warm	The temperature is between 30°C and 40°C
Excessive heat	The temperature is above 40°C

Do not store over 30°c	The temperature is between 2°C and 30°c
Do not store over 25°c	The temperature is between 2°C and 25°C
Do not store over 8°c	The temperature is between 2°C and 8°C
Do not store below 8°c	The temperature is between 2°C and 8°C
Protect from moisture	The temperature is between 8°C and 25°C. **Not more than 60% relative humidity in normal Storage conditions to be provided to a patient in a Moisture resistant container**
Protect from light	To be provided to the user in a light resistant container

Nationwide GDP Inspections, the journey so far

Good Distributions Practices Inspections are conducted by NAFDAC to ensure that the integrity and quality of NAFDAC regulated products are maintained across the supply chain ecosystem. It is a specialized inspection targeted at Wholesale, Distribution and Importation outlets in Nigeria. The Agency has adopted a phased approach, starting with the pharmaceuticals and expanding to other regulated products sectors.

The Agency commenced formal GDP inspections across the country in May, 2021. NAFDAC has 41 designated GDP inspectors and more than 50 support inspectors nationwide. As at February, 2022, a record of 609 baseline GDP inspections have been carried out. These baseline inspections, according to an approved plan were rounded up in April, 2022. NAFDAC has done an initial risk categorization of the inspected facilities based on their compliance to the Agency's requirements and global best practices. The facility managers were requested to provide a Corrective and Preventive Action Plan (CAPA) to resolve non-conformances observed in their facilities; CAPA efficiency verification inspections for closing the non-conformances in facilities have been scheduled and are in progress. Deficiencies are classified as **Critical, Major** or **others**.

So far, the stakeholders are glad that NAFDAC is implementing these GDP inspections, most of them now have come to understand the necessity of these requirements and are putting measures in place to comply as much as possible. Conducting GDP inspections in Nigeria will further challenge the pharmaceutical sector into entrenching appropriate best practices on storage and distribution including thermolabile drugs and performing better in safe-guarding the health of the nation.

A CALL FOR MAHs TO ESTABLISH PHARMACOVIGILANCE & POST MARKETING SURVEILLANCE DEPARTMENT:

The need to control Substandard and Falsified medical products (SFs) has become increasingly very important in Nigeria and one critical point that must be emphasized here is collaboration and information sharing among the entities involved in the distribution chain. The MAHs should as part of their statutory functions know what is happening in the market in respect to their brands. This function should be uncoupled from Regulatory Affairs function.

The establishment of the pharmacovigilance & post marketing surveillance department is to strengthen the prevention, detection and reporting of SFs to NAFDAC. Adequate personnel should be engaged to handle this required function effectively.

NAFDAC has given the deadline of **December 2021** for the establishment of the department by MAHs and enforcement activities will commence in due course.

Conclusion

GDP is that part of quality assurance that 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. Entrenching GDP in Nigerian drug facilities will prevent counterfeits from

entering the distribution chain and minimize risks in distribution such as adulteration, mix-ups, contamination and cross- contamination. Appropriate temperature storage and environmental monitoring will prevent alterations in drug potency, denaturation of vaccines, insulin and other causes of therapeutic failure.

References

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