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PHARMACISTS COUNCIL OF NIGERIA ACT (CAP. P17 LFN), 2004

PHARMACEUTICAL PREMISES LOCATION, INSPECTION, STRUCTURE, MONITORING AND ENFORCEMENT REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :

S. I. No. 87 of 2021

PHARMACISTS COUNCIL OF NIGERIA ACT (CAP. P17 LFN), 2004

PHARMACEUTICAL PREMISES LOCATION, INSPECTION, STRUCTURE, MONITORING AND ENFORCEMENT REGULATIONS, 2021

[19*th Day of July*, 2021] Commencement.

In exercise of the powers conferred upon the Pharmacists Council of Nigeria by Sections 1 and 24 of the Pharmacists Council of Nigeria Act and all other powers enabling the Council in that behalf, the Council with the approval of the Honourable Minister of Health hereby makes the following Regulations—

PART I—GENERAL PROVISION

Pharmaceutical Inspectors.

1. The Pharmaceutical Inspection, Monitoring Department and Enforcement Department shall consist of registered pharmacists designated as pharmaceutical inspectors and shall be appointed by the Council.

PART II—INSPECTION AND MONITORING

Inspection of premises and powers of Pharmaceutical Inspectors.

2.—(1) The Pharmacists Council of Nigeria shall carry out regular inspection of pharmaceutical premises throughout the supply chain.

(2) Pharmaceutical Inspectors appointed by the Council shall have powers in the course of carrying out their duties, at reasonable time and on the production of their identity card, when required to—

(*a*) enter any premises by the use of such reasonable force as may be necessarily required on the believe or suspicion that an article to which these Regulations apply is manufactured, prepared, packaged, warehoused, distributed, stored, sold or dispensed in such premises ;

(*b*) examine any article or records in the premises to which these Regulations apply, which they reasonably believe or suspected to be used or is capable of being used for the manufacture, preparation, preservation, packaging, storage or sale of any such article ;

(*c*) take sample or specimen of any article to which these Regulations applies ;

(*d*) open and examine while in the premises any container or package, which they reasonably believe or is suspected to have any articles to which these Regulations applies and help in their investigations ;

(*e*) examine any book, document or other record found in the premises, which they reasonably believe or suspects to contain information that is relevant to the enforcement of these Regulations and may make copies of it ; and

(*f*) seize and detain, as may be necessary, any article, which is reasonably believed or suspected to have contravened any provisions of these Regulations.

Siting of pharmaceutical premises.

3.—(1) Pharmaceutical premises shall not be located in—

(*a*) motor parks or petrol stations ;
(*b*) clustered environments ;
(*c*) around open market places ; and
(*d*) kiosks, containers or stalls.

(2) Where a pharmaceutical premises has become clustered, surrounded or covered by a growing market or close to it, it shall be moved to another location within two years after due notice of the Council.

(3) Pharmaceutical premises shall be sited in not less than 200 metres from each other.

(4) Patent and Proprietary Medicine Vendor's (PPMV) shop shall be sited in not less than 400 metres from a pharmacy.

(5) PPMV shops shall be sited in not less than 200 metres from each other.

(6) Pharmaceutical premises within a shopping centre shall not be more than three and they shall be well spaced out.

(7) The distance between registered pharmaceutical premises in a shopping centre to a new pharmaceutical premise in another shopping centre shall not be less than 200 metres.

(8) The distance between a registered pharmaceutical premise, which is not in a shopping complex and another one in a shopping Centre shall not be less than 200 metres from each other.

(9) Pharmaceutical premises shall be situated in a good sanitary environment.

Structure of Pharmaceutical Premises.

4.—(1) The pharmaceutical premises shall not be less than—

(*a*) 30square metres for retail ;

(*b*) 70square metres for wholesale ;

(*c*) 70square meters for Distributors or Importers ;

(*d*) 1,000square meters for Mega Wholesale Centres (MWC) or Public Wholesale Centres (PWC) ;

(*e*) 300square metres for Zonal Public Wholesale Centres (ZPWC) ;

(*f*) 70square metres per subsidiary space within Co-ordinated Wholesale Centres (CWC) of not less than 100 facility space ; and

(*g*) not more than 15 square metres for PPMV.

(2) Other requirements in respect of the structure and layout of facilities to be used as pharmaceutical premises shall be as contained in the Second and Fifth Schedules to these Regulations.

Monitoring of Pharmaceutical Premises.

5.—(1) The Council shall carry out regular evaluation and monitoring of Pharmaceutical premises to ensure that standards are maintained and sustained in line with best practices.

(2) Guidelines on monitoring of pharmaceutical premises and contravention of these Regulations are contained in the First Schedule to these Regulations.

PART III—ENFORCEMENT

Enforcement on Pharmaceutical Premises.

6. The Council is empowered to carry out enforcement activities on Pharmaceutical premises throughout the supply chain.

Pharmaceutical Inspectors power to seal.

7.—(1) Pharmaceutical Inspectors shall have the power to seal up any pharmaceutical premises for—

(*a*) non-registration and not having a valid licence ;

(*b*) stocking medicines that are not authorized ;

(*c*) unethical practices or engaging in illegal act ;

(*d*) refusal to grant Inspectors access to premises, books, document, record, material or article to be inspected ;

(*e*) reasonably believing or suspecting that the provisions of the Act, these Regulations or the Council's Guidelines have been contravened ; and

(*f*) obstructing the Pharmaceutical Inspector from the performance of its duties.

(2) Pharmaceutical Inspector shall have power to seize any drug, poison or article in any unregistered premises or from any premises reasonably suspected to have in such premises such an item within the scope of operation of the Inspector.

Duty of the owners of Pharmaceutical Premises.

8. The owner or person in charge of a pharmaceutical premises or person found in pharmaceutical premises shall give necessary assistance to any Pharmaceutical Inspector including, making available to the Inspector all such information as may be necessary for the purpose of carrying out investigation or inspection under these Regulations.

Seizure of articles.

9. Any article seized pursuant to the provisions of these Regulations shall be kept or stored in such a place as the Registrar may direct.

Forfeiture.

10.—(1) Any article seized pursuant to the provisions of thes Regulations shall be forfeited to the Federal Government of Nigeria.

(2) Where a person is convicted of an offence under these Regulation the Court may make an order that the article by means of, or in respect o which an offence was committed or anything of a similar nature belonging t or in the possession of the person convicted, be forfeited to the Federa Government of Nigeria and such an article shall be free of all encumbrances

Special powers of the Council.

11.—(1) The Council shall have the power to—

(*a*) cause an investigation to be conducted on certain person involved in commission of an offence under these Regulations ;

(*b*) determine whether a person has committed an offence under these Regulations ; or

(*c*) prosecute offender in a Court of competent jurisdiction.

PART IV—MISCELLANEOUS

Offences and Penalties.

12. Any person who—

(*a*) obstructs or resists a Pharmaceutical Inspector or such other designated officers of the Council in the execution of its duties under these regulations ;

(*b*) makes a false statement reasonably believe to be false or misleading to a Pharmaceutical Inspector or such other designated officer in the course of carrying out its duties ;

(*c*) without the authority of a Pharmaceutical Inspector or any other designated officer, removes, alters or interferes in any way with the article seized under these Regulations ;

(*d*) breaks the seal or padlock placed by the PCN in accordance with the provisions of these Regulations ; or

(*e*) contravenes any of the provisions of these Regulations,

commits an offence and is liable on conviction to imprisonment for a term of not less than 6 months or fine of not less than ₦250,000.00 or to both.

Revocation.

13. The Inspection, Location and Structure of Pharmaceutical Premises Regulations, 2005 is revoked.

Interpretation.

14. In these Regulations—

"*Act*" means The Pharmacists Council of Nigeria Act, Cap. P17 LFN 2004 ; and the Poisons and Pharmacy Act, Cap 535 1990 ;

"*Approved*" means approved by the Council ;

"*Article*" includes any drug, poison, device, medicine including that for animal use, record or book required to be kept under these Regulations ; or electronic record, receipt, invoice or other relevant document or thing ;

"*Authorized or Registered Premises*" means Premises registered by the Pharmacists Council of Nigeria with valid licence to operate a specific category of pharmacy practice ;

"*Council*" means the Pharmacists Council of Nigeria established under the Pharmacists Council of Nigeria Act, Cap. P17 LFN 2004 ;

"*Direct Personal Control*" means to be in charge or taking decisions on all aspects of pharmaceutical activities of the premises ;

"*Dispensing*" means to prepare, to count out, measure or transfer from a bulk supply, or mix, or dissolve, or disperse, and dispose the drug, for gain or otherwise for the treatment of a particular person or animal, but does not include the actual administration of the drug ;

"*Distribution Centres*" include premises involved in different categories of drug distribution such as Co-ordinated Wholesale Centres (CWCs), Mega Wholesale Centres (MWCs), Public Wholesale Centres (PWCs), Wholesale Centres (WCs) and Scientific offices involved in drug distribution ;

"*Enforcement*" means use of lawful means, which may include force to ensure compliance with the law, Regulations, Guidelines or Standards ;

"*Ethical Drugs*" means prescription drugs or medicines dispensed under the direct supervision of a licensed Pharmacist ;

"*GPP*" means Good Pharmacy Practice in accordance with best global practices ;

"*GXP*" means G-Good; X-Pharmacy, Distribution, Warehousing, Manufacturing, Dispensing or Storage; P- Practice ;

"*Hospital Pharmacy*" is the department, section or unit of the hospital or clinic that manages the procurement, storage, preservation, packaging, sterilization, compounding, preparation, dispensing, counselling or distribution of medicines in the hospital or clinics ;

"*Inspection*" means checking, scrutinizing, or examining a pharmaceutical premise or an intending pharmaceutical premises for assessment for compliance with the Council's prescribed standards in line with GXP ;

"*Licence*" means an authority to practice as a Pharmacist issued by the Council to a practitioner which is renewable annually and expires on the 31st day of December of the given year ;

"*Minister*" means the Minister charged with responsibility for Health ;

"*Monitoring*" means the process of regular or routine observation, checking, correcting and guiding to ensure compliance with the regulation, recording of activities taking place in registered Pharmaceutical premises ;

"*PCN*" means Pharmacists Council of Nigeria ;

"*Pharmaceutical activities*" include procurement, dispensing, counselling, selling, distribution, storage, stocking, wholesaling or manufacturing of drugs and poisons, therapeutic drug monitoring and such other activities ;

"*Pharmaceutical Inspector or Pharmaceutical Inspection Officer*" means a Pharmacist duly registered and appointed by the Council under these Regulations or any other person that assist in enforcing the law ;

"*Pharmaceutical Premises*" refers to a place approved and registered by the Council for any of the following purposes of dispensing, selling, distribution centre, storage, stocking, retailing, wholesale, manufacturing, warehousing, importation, exportation of drugs and poisons, herbal and dietary supplements, scientific offices or any other form of pharmaceutical activities ;

"*Pharmacy Practice*" include giving of patient-centred care, provision of drug information, monitoring of drug therapy, discovery and evaluation of drugs, clinical interventions and provision of technical aspects of pharmaceutical services or business such as importation, exportation, mixing, compounding, preparing, dispensing, selling and distribution of drugs and poisons and such other related functions ;

"*Poison*" includes substances whether natural or synthetic, mixed with other ingredients or not, and whatever restrictions under the provisions of these Regulations are placed on any particular poison, shall apply to it, whether it is unmixed or is contained as an ingredient in some preparation, unless it is contained in one of the preparations specifically exempted from such provisions ;

"*PPMV*" means Patent and Proprietary Medicine Vendor ;

"*PPMVL*" means Patent and Proprietary Medicine Vendor Licence ;

"*Premises Certificate*" means authority conferred on premises to carry on pharmacy practice and business in a particular location issued by the Pharmacists Council of Nigeria ;

"*Registrar*" means the Registrar of the Pharmacists Council of Nigeria ; and

"*Superintendent Pharmacist*" means a registered and licenced pharmacist who applied for and through whom the registration of the pharmaceutical premises was procured and he exercises direct personal control and management of pharmaceutical activities carried on in the premises.

Citation.

15. These Regulations shall be cited as Pharmaceutical Premises Location, Inspection, Structure, Monitoring and Enforcement Regulations, 2021.

FIRST SCHEDULE *Regulation* 5[2]

SUPPLEMENTARY PROVISIONS RELATING TO OPERATIONAL FEES FOR MONITORING OF PHARMACEUTICAL PREMISES

S/N	*Infringement/Default(s)*	*Administrative Charges*
1.	Absence of Superintendent Pharmacist on 3 consecutive visits without making adequate provision for a locum pharmacist to render pharmaceutical care, and on every occasion where the Superintendent Pharmacist will be away, shall write a letter to the PCN.	1st Inspection Visit – compliance directive. 2nd Inspection Visit – compliance directive. 3rd Inspection Visit – ₦20,000.00.
2.	Non-Pharmacists or sale attendants having access to controlled drugs and poison register.	₦20,000.00
3.	Non-use of poison register or failure to make entries of poisons disposed off.	₦10,000.00
4.	Inadequate current reference books relevant to area of practice, soft or hard copies.	1st Inspection Visit – compliance directive. 2nd Inspection Visit – ₦5,000
5.	Failure to conspicuously display current premises and pharmacist's license to practice and PPMVL for vendors.	1st Inspection Visit – compliance directive. 2nd Inspection Visit– ₦5,000 (Pharmacy and Pharmacist) 2nd Inspection Visit– ₦2,500 (PPMVs).
6.	Improper storage of drugs as a result of inadequate temperature or humidity control or absence of pallets or poor housekeeping.	Manufacturers - ₦100,000.00 Distributors - ₦50,000.00 PWCs - ₦30,000.00 CWCs - ₦200,000.00 MWCs - ₦100,000.00 NGO-owned Warehouses - ₦50,000.00 Importers – ₦100,000.00 Wholesalers – ₦20,000.00 Retail – ₦5,000.00 PPMV – ₦2,500.00
7.	Unregistered warehouses.	Seal and Pharmaceutical Premises to pay ₦500,000.00 Administrative Charges for unsealing.
8.	Sales to unregistered Pharmaceutical Premises by Manufacturers, Importers, Distributors and Wholesalers.	₦100,000.00

S/N	Infringement/Default(s)	Administrative Charges
9.	Poor sanitary condition of the Pharmaceutical Premises or PMS.	1st Inspection Visit – compliance directive 2nd Inspection Visit – ₦5,000 for Pharmaceutical Premises and ₦2,500.00 for PMS to be sealed if the unhygienic practices persists. However such Pharmaceutical Premises shall be unsealed upon payment of ₦30,000.
10.	Distribution or Wholesale Pharmaceutical Premises involved in retail activities.	1st Inspection Visit – ₦50,000 2ndInspection Visit – ₦100,000.00. If Pharmaceutical Premises persists it should be sealed.
11.	PPMV stocking and selling beyond approved list for PPMV shop.	1st Inspection Visit – Sample of drugs outside the approved list shall be taken as exhibits; supervise evacuation of the ethical to registered premises, where appropriate. 2nd Inspection Visit – the shop shall be sealed and Vendor prosecuted.
12.	PMS engaging in activities outside scope of practice other than selling beyond approved list.	Take pictorial or video evidence and then SEAL the shop. Offender to depose to an affidavit or make an undertaking not to repeat such and pay Administrative charge of ₦30,000.00.
13.	Training apprentices in Pharmaceutical Premises or PPMV Shops.	₦10,000 – ₦100,000 depending on the number of apprentices. The offender shall make an undertaking not to continue this malpractice. However, if the offender continues in this malpractice, the Pharmaceutical premises/PMS shall be sealed and the offender prosecuted.
14.	A different person other than the licensee operating a PPMV Shop.	Take photographs or videos as proof and SEAL the shop. To pay Administrative charge of ₦30,000.00 for unsealing if need be, after the guideline for issuance of PPMVL has been complied with.
15.	Improper or incomplete documentation.	1st Inspection Visit – compliance directive Subsequent Violation – PPMV – ₦2,500 Pharmacy – ₦10,000
16.	Use or possession of false documents.	1st Inspection Visit – compliance directive. Subsequent Violation – PPMV – ₦20,000 Pharmacy – ₦20,000

SECOND SCHEDULE *Regulation* 4(2)

SUPPLEMENTARY PROVISIONS RELATING TO THE STRUCTURE, LOCATION, OFFICE OF THE SUPERINTENDENT PHARMACIST AND FACILITIES TO BE PROVIDED FOR IN PHARMACEUTICAL PREMISES.

Structure of Pharmaceutical Premises.

1.—(1) Pharmaceutical premises shall be made of concrete walls and not in the form of kiosk or container and have a ceiling height of at least 3.05 metres.

(2) The floor of a pharmaceutical premises shall be made of concrete, tiles or terrazzo or epoxy.

(3) A pharmaceutical premises or shop shall—

(*a*) be well painted ;

(*b*) have shelves, which are well arranged and painted ; and

(*c*) have a proper ceiling.

(4) A pharmaceutical premise shall—

(*a*) have a well demarcated area for filling prescriptions, counseling and providing pharmaceutical care to patients, client waiting area, storage and dispensing areas ; and

(*b*) contain in the dispensing area, scheduled prescription drugs which shall be locked in the absence of the Superintendent Pharmacist, where applicable.

Office of Superintendent Pharmacist.

2.—(1) There shall be provided in pharmaceutical premises an office for the Superintendent Pharmacist.

(2) The name of the Superintendent Pharmacist shall be properly and conspicuously displayed.

(3) The Superintendent Pharmacist and other pharmacists on duty shall be in white overalls with proper name tags.

Facilities to be provided in pharmaceutical premises.

3. There shall be provided in pharmaceutical premises—

(*a*) air-conditioners and fans to ensure proper ventilation ;

(*b*) metric balances, weight and measures in the compounding room, where applicable ;

(*c*) refrigerator for thermolabile preparations ;

(*d*) adequate pallets or shelves for storage ;

(*e*) good water supply ;

(*f*) facilities for filtration to achieve the desired quality, where water is required for the compounding of drugs ;

(*g*) proper records of the purchases and sales made ;

(*h*) disposal of poisons book, which shall be properly kept ; and

(*i*) copies of recent editions of reference books including—

(*i*) Standard Treatment Guidelines (STG), Nigeria ;

(*ii*) National Drug Policy ;

(*iii*) 4 Part Compendium of Minimum Standards of Assurance of Pharmaceutical Care ;

(*iv*) Extra Pharmacopoeia ;

(*v*) International Pharmacopoeia (IP) ;

(*vi*) British National Formulary (BNF) ;

(*vii*) National Formulary and Essential Drugs List ;

(*viii*) A Compilation of Pharmacy, Drugs and Related Laws and Rules in Nigeria, 1935-2000 ; and

(*ix*) Current list produced by PCN of Registered Pharmacists and Pharmacies.

Manufacturing premises.

4. For manufacturing premises, other facilities to be provided include—

(*a*) offices for Production Pharmacist, Quality Control manager, Quality Assurance manager and other key personnel ;

(*b*) dispensing area with appropriate equipment ;

(*c*) production room with appropriate or adequate machines properly fitted to ensure easy movement ; and

(*d*) packaging room, Warehouse or stores and various components or departments of the premises to ensure a unidirectional flow.

Display of registration Certificate.

5. There shall be conspicuously displayed in pharmaceutical premises the premises current registration Certificate and the Superintendent Pharmacist's Annual licence to practice.

THIRD SCHEDULE

SUPPLEMENTARY PROVISIONS RELATING TO CONFIDENTIALITY AND NON-DISCLOSURE AGREEMENT FOR PHARMACEUTICAL INSPECTORS

PHARMACISTS COUNCIL OF NIGERIA
CONFIDENTIALITY AND NON-DISCLOSURE AGREEMENT

This confidentiality Agreement (hereinafter referred to as this Agreement) is made effective ..... 2020 between the Pharmacists Council of Nigeria (PCN) of plot 7/9 Idu Industrial Layout, Idu Abuja Nigeria and Pharm. of.....

.....

WHEREAS ..... has been appointed as a Pharmaceutical Inspector in accordance with the provisions of the Poisons and Pharmacy Act and the Pharmacists Council of Nigeria Act.

AND WHEREAS in recognizing the importance of confidentiality in addressing regulatory infringements and the protection of official data and the fact that the position of a Pharmaceutical Inspector makes such an Inspector possess certain proprietary or confidential information.

NOW THEREFORE, the Pharmaceutical Inspector agrees as follows—

(*a*) to treat every information received or obtained pursuant to engagement as a Pharmacist as strictly confidential and not to divulge such information to an unauthorized third party ;

(*b*) not to make use of such information, or any part thereof without prior written consent from the Council ;

(*c*) not to communicate, share or divulge any of such information to any unauthorized third party except with the express written authorization of the party who originated and provided such information ; and

(*d*) to protect confidential information and uphold the principles of equity and fair play at all times and to abide by the laws of the Federal Republic of Nigeria.

CONFLICT OF INTEREST

I, ... have undertaken that I shall disclose any interest that may impair my judgment in relation to any premises while carrying out my duties as a Pharmaceutical Inspector.

....

Registrar *Pharmaceutical Inspector*

FOURTH SCHEDULE

GUIDELINES FOR MONITORING OF PHARMACEUTICAL PREMISES

Meaning of monitoring inspection.

(1) Monitoring inspection is an on-spot check carried out on pharmaceutical premises to ensure maintenance of pharmaceutical standards in line with global best practices.

Pharmaceutical inspectors.

(2) Pharmaceutical Inspectors shall without prior notice to carry out monitoring activities enter into any premises.

Monitoring activities.

(3) Monitoring activities involve checking for the following—

(*a*) layout and neatness of premises and personnel, including—

(*i*) premises layout to conform with the practice area,

(*ii*) neatness and hygiene of the premises and surroundings, and

(*iii*) overall dressing and appearance of the pharmacists, pharmacy technicians, PPMVs and other sales attendants ;

(*b*) professional practice, including—

(*i*) presence of pharmacist in the premises or vendor in case of PPMV shop,

(*ii*) good arrangement and easy flow within the premises,

(*iii*) arrangement of drugs within the premises,

(*iv*) documentation of poisons and dispensed prescriptions for pharmacies,

(*v*) check for expired drugs and drugs without NAFDAC registration number,

(*vi*) check purchase receipts to ensure drugs are purchased in registered premises,

(*vii*) good professional outlook of the premises, and

(*viii*) check for pharmaceutical care activities carried out for pharmacies ;

(*c*) facilities, includes—

(*i*) functional refrigerators for thermo labile products,

(*ii*) functional air conditioning units or fans,

(*iii*) functional weight balances,

(*iv*) thermometer for pharmaceutical care,

(*v*) neat, well-arranged and kept shelves,

(*vi*) good water supply and washing hand facilities,

(*vii*) serviceable fire extinguisher,

(*viii*) storage area and pallets,

(*ix*) thermometer and hygrometer for charting temperature and humidity, and

(*x*) any other such facilities required to ensure good pharmacy practice ;

(d) records. which includes—

(*i*) record of sales and receipt of purchases,

(*ii*) record of patient medication profiles, for retailers or community pharmacies,

(*iii*) list of distributors for importation or manufacturing premises,

(*iv*) record of poison disposal,

(*v*) records of expired or damaged drugs,

(*vi*) any other record required to be kept to ensure good pharmacy practice ; and

(*vii*) check for other activities within the premises, fill the monitoring form and compliance report.

Offences and administrative penalty relating to monitoring activities.

4. The following acts constitute an offence and penalty is recommended as tabularized in the table as follows—

S/N	*Offence*	*Administrative Charges*
1.	Where there is absence of Superintendent Pharmacist for three consecutive visits without making adequate provision for a locum pharmacist to render pharmaceutical care, on every occasion the Superintendent Pharmacist is going to be absent, shall write a letter to the PCN ;	1st Inspection Visit – compliance directive. 2nd Inspection Visit – compliance directive. 3rd Inspection Visit – ₦20,000.00
2.	Allowing non-Pharmacist's sale attendants to have access to controlled drugs and poison register.	₦20,000.00
3.	Failure to make entries into the poison register or to make entries of poisons disposed off into the poison register.	₦10,000.00
4.	Lack of inadequate current reference books relevant to area of practice (soft or hard copies).	1st Inspection Visit – compliance directive. 2nd Inspection Visit – ₦5,000
5.	Failure to conspicuously display current premises and pharmacist's license to practice and PPMVL for vendors.	1st Inspection Visit – compliance directive 2nd Inspection Visit– ₦5,000 (Pharmacy and Pharmacist) 2nd Inspection Visit - ₦2,500 (PPMVs)
6.	Improper storage of drugs as a result of inadequate temperature or humidity control or absence of pallets or poor housekeeping.	Manufacturers - ₦100,000.00 Distributors - ₦50,000.00 PWCs - ₦30,000.00 CWCs - ₦200,000.00 MWCs - ₦100,000.00 NGO owned Warehouses - ₦50,000.00 Importers – ₦100,000.00 Wholesalers – ₦20,000.00 Retail – ₦5,000.00 PPMV – ₦2,500.00.
7.	Operating unregistered warehouse.	SEAL and Pharmaceutical Premises to pay ₦500,000.00 as administrative charges for unsealing.
8.	Sales to unregistered Pharmaceutical Premises by Manufacturers, Importers, Distributors and Wholesalers.	₦100,000.00

S/N	*Infringement/Default(s)*	*Administrative Charges*
9.	Poor sanitary condition of the Pharmaceutical Premises or PMS.	1st Inspection Visit – compliance directive. 2nd Inspection Visit – ₦5,000 for Pharmaceutical Premises and ₦2,500.00 for PMS to be sealed if the unhygienic practices persists. However such Pharmaceutical Premises shall be unsealed upon payment of ₦30,000.
10.	Distribution or Wholesale Pharmaceutical Premises involved in retail activities	1st Inspection Visit – ₦50,000 2ndInspection Visit – ₦100,000.00. If Pharmaceutical Premises persists it should be sealed.
11.	PPMV stocking and selling beyond approved list for PPMV shop.	1st Inspection Visit – Sample of drugs outside the approved list shall be taken as exhibits; supervise evacuation of the ethical to registered premises, where appropriate. 2nd Inspection Visit – the shop shall be sealed and Vendor prosecuted.
12.	PMS engaging in activities outside scope of practice other than selling beyond approved list.	Take pictorial or video evidence and then SEAL the shop. Offender to swear to an affidavit or undertaking not to repeat such and pay Administrative charge of ₦30,000.00.
13.	Training apprentices in Pharmaceutical Premises and PPMV Shops.	₦10,000 – ₦100,000 depending on the number of apprentice. The offender shall make an undertaking not to continue this malpractice. However, if the offender continues in this malpractice, the Pharmaceutical premises or PMS shall be sealed and the offender prosecuted.
14.	A different person other than the licensee operating a PPMV Shop.	Take photographs or videos as proof and SEAL the shop. Shall pay Administrative charge of ₦30,000.00 for unsealing, if need be, after the guideline for issuance of PPMVL has been complied with.
15.	Improper or incomplete documentation.	1st Inspection Visit – compliance directive Subsequent Violation – PPMV – ₦2,500 Pharmacy – ₦10,000
16.	Use or possession of false documents.	1st Inspection Visit – compliance directive Subsequent Violation – PPMV – ₦20,000 Pharmacy – ₦20,000.

S/N	*Infringement/Default(s)*	*Administrative Charges*
17.	Pharmaceutical Premises engaging in activities outside scope of practice.	Take pictorial or video evidence and then SEAL the premises. Offender to submit an affidavit or undertaking not to repeat such and pay administrative charge of₦30,000.00.

Submission of report to the head office

5. The State officer shall compile list of premises monitored, attach the completed monitoring form and forward to head office.

FIFTH SCHEDULE

GUIDELINES FOR LOCATION, STRUCTURE AND INSPECTION OF PHARMACEUTICAL PREMISES

PREAMBLE

The Council has the responsibility of ensuring that stakeholders are properly guided in accordance with Pharmacists Council of Nigeria Act Cap. P.17 LFN, 2004 and Poisons and Pharmacy Act, Cap. 535 LFN 1990 and Regulations made under it.

WHEREAS, pursuant to the responsibility of the Council to inspect, approve and license premises, where pharmaceutical activities take place and among other functions that these Guidelines are made.

WHEREAS, in view of the need to re-position the Registry of the Pharmacists Council of Nigeria (PCN) for more effective regulation and control of the practice of Pharmacy, it is only proper that various components of the Council's activities are clearly explained in perspective for easy understanding and compliance by the stakeholders.

WHEREAS, before any premises can be said to be registered or licensed by the Council to operate as pharmaceutical premises, the said premises must have undergo inspection by the Council to determine its suitability in terms of location, structure and facilities to be provided, hence the "Guidelines for Location, Structure and Inspection of Pharmaceutical Premises" is such an attempt to provide procedure for Pharmacists and other stakeholders.

NOW THEREFORE, these Guidelines provides guide as follows—

Citing of Pharmaceutical Premises.

1.—(1) Pharmaceutical premises shall not be located in the following areas—

(*a*) motor park or petrol stations ;

(*b*) clustered environment ;

(*c*) a market place ; and

(*d*) kiosk, container or a stall.

(2) Pharmaceutical premises shall be relocated within 2 years after due notice is given by the Council, where It has become—

(*a*) clustered or surrounded ; or

(*b*) covered by a growing market close to it.

(3) Pharmaceutical premises shall be sited from each other in not less than 200metres.

(4) Patent and Proprietary Medicine Vendor's (PPMV) shop shall be sited in not less than 400 metres from another pharmacy.

(5) PPMV shops shall be sited not less than 200 metres from each other.

(6) Pharmaceutical premises within a shopping centre shall not be more than three and they shall be well spaced out from each other.

(7) The distance from registered Pharmaceutical premises in a Shopping Centre to new pharmaceutical premises in another Shopping Centre shall not be less than 200 metres.

(8) The distance between registered pharmaceutical premises and another one in a shopping centre shall not be less than 200 metres from each other.

(9) Pharmaceutical premises shall be situated in a good sanitary environment.

Measurement between pharmaceutical premises.

2. The distance between pharmaceutical premises shall be measured from the main front doors through the shortest accessible route.

Structure of pharmaceutical premises.

3.—(1) Pharmaceutical premises shall not be less than—

(*a*) 30square metres for retail ;

(*b*) 70square metres for wholesale ;

(*c*) 70square meters for Distributors or Importers ;

(*d*) 1,000square meters for Mega Wholesale Centres (MWC)/ Public Wholesale Centres (PWC) ;

(*e*) 300 square metres for Zonal Public Wholesale Centres (ZPWC) ;

(*f*) 70square meters per shop space within Co-ordinated Wholesale Centres (CWC) of not less than 100 shop space ; and

(*g*) not more than 15 square metres for PPMV shop.

(2) Pharmaceutical premises shall be made of concrete walls and not in the form of kiosk or container and have a ceiling height of at least 3.05 metres and in the case of manufacturing, the ceiling shall not be made of asbestos.

(3) The floor of a pharmaceutical premises shall be made of concrete, tiles, terrazzo or epoxy (for manufacturing).

(4) Pharmaceutical premises or shop shall—

(*a*) be well painted in white colour ;

(*b*) have painted and well-arranged shelves ;

(*c*) have a ceiling with a height of not less than 3.05meters ;

(*d*) maintain adequate lighting and ventilation ;

(*e*) have functional air conditioning system and fans while PPMV shops shall install and use at least fans ;

(*f*) maintain adequate safety measures such as providing fire extinguishers, sand bucket, emergency exits, Personal Protection Equipment (PPEs), where applicable ; and

(*g*) maintain neatness of premises and surroundings and shall not allow bush to grow within the premises or for the surrounding to be littered.

(5) Pharmaceutical premises shall—

(*a*) have a well demarcated area for filling prescriptions, dispensing areas, counseling and providing pharmaceutical care to patients, client waiting area and storage ;

(*b*) contain in the dispensing area, scheduled prescription drugs, which shall be locked in the absence of the Superintendent Pharmacist ; and

(*c*) have design and flow which facilitate efficient pharmaceutical service delivery.

Superintendent Pharmacist.

4.—(1) There shall be provided in pharmaceutical premises an adequately furnished office for the Superintendent Pharmacist.

(2) The name of the Superintendent Pharmacist shall be properly and conspicuously displayed.

(3) The Superintendent Pharmacist and other pharmacists on duty shall be in white overalls with proper name tags.

(4) The Superintendent pharmacist shall ensure that the Pharmacy Technician assisting the pharmacists on duty are properly dressed in a blue overall with a name tag.

Facilities to be provided in pharmaceutical premises

5. There shall be provided in pharmaceutical premises—

(*a*) air-conditioners and fans to ensure proper ventilation ;

(*b*) metric balances, weight and measures in the compounding room, where applicable ;

(*c*) thermometers and hygrometers for temperature and relative humidity measurements ;

(*d*) functional refrigerator to be used solely for thermo labile preparations ;

(*e*) adequate pallets and or shelves for storage of pharmaceutical products ;

(*f*) warehouse for pharmaceutical companies involved in manufacturing, distribution and or importation of drugs ;

(*g*) good water supply ;

(*h*) wash hand basin or sink ;

(*i*) equipment for water treatment to achieve quality ;

(*j*) proper records of the purchases and sales made therein ;

(*k*) record for patient medication profile ; and

(*l*) copies of recent editions of reference books including—

(*i*) Standard Treatment Guidelines (STG), Nigeria,

(*ii*) British Pharmacopeia (BPC),

(*iii*) Extra Pharmacopoeia,

(*iv*) International Pharmacopoeia (IP),

(*v*) British National Formulary (BNF),

(*vi*) National Formulary and Essential Drugs List,

(*vii*) a Compilation of pharmacy, drugs and related Laws and Rules in Nigeria, 1935-2000,

(*viii*) current Gazettes of list of registered pharmacists and pharmacies,

(*ix*) PCN four-part compendium, and

(*x*) PCN Procedure for Registration and Copies of PCN Regulations.

Handling of Controlled substances or Poisons.

6.—(1) There shall be provided in every pharmaceutical premises—

(*a*) a disposal of poisons book, where all records of controlled substances received and dispensed are entered by the pharmacist on duty ;

(*b*) in the case of manufacturing, entries shall be made by the designated pharmacist ; and

(*c*) a dedicated and secured storage area (poisons cupboard).

(2) Handling of Controlled substances or Poisons shall exclusively be by a licensed pharmacist.

(3) For manufacturing premises, other facilities to be provided include—

(*a*) offices for production pharmacist, Quality Control Manager, Quality Assurance Manager and other key personnel ;

(*b*) dispensing area with appropriate equipment ;

(*c*) production rooms with appropriate and adequate machines and properly fitted to ensure easy movement ; and

(*d*) packaging rooms, warehouse or stores and other various components or departments of the premises to ensure a unidirectional flow.

(4) There shall be conspicuously displayed in pharmaceutical premises the premises current registration certificate and the Superintendent Pharmacist's annual licence to practice.

Inspection of Pharmaceutical Premises.

7. Pharmaceutical Inspectors appointed by the Council shall carry out inspection and monitoring of pharmaceutical premises for registration purposes and continuous licensure of such premises.

Location, inspection and approval for retail, wholesale, distribution centres, importation and manufacturing premises.

8.—(1) A pharmacist shall apply for the location, inspection and obtain approval for proposed pharmaceutical premises.

(2) For the location, inspection and approval of the above mentioned proposed pharmaceutical premises, the superintendent pharmacist shall submit the following documents to the Registrar of the Council through the zonal or state office, where the premises is located—

(*a*) application letter for location, inspection and approval shall be addressed to the Registrar of the Council ;

(*b*) photocopy of current annual Licence to practice or application for annual license renewal ;

(*c*) evidence for payment of prescribed fees, payable to the Council ;

(*d*) letter of appointment of the Superintendent Pharmacist with the company intending to open new premises, where applicable ;

(*e*) certified true copy of the Company's certificate of incorporation or evidence of registration of business name, for Pharmacist-owned retail premises ;

(*f*) Certified True Copy of Articles and Memorandum of Association ;

(*g*) Certified True Copy of Particulars of Directors ;

(*h*) the particulars of Directors shall indicate that there is at least one Pharmacist on the Board of Directors ;

(*i*) current annual licence of the Pharmacist Director ; and

(*j*) completed disclaimer of liability form over processing of application for Location Approval Inspection.

(3) Location Approval Inspection shall be carried out by Pharmaceutical Inspectors appointed by the Council in line with PCN prescribed practice category checklists and Standard Operating Procedures (SOPs) to ensure that the siting of the proposed premises and the size meets the requirement of the PCN.

(4) The Time frame for carrying out location inspection and approval for—

(*a*) retail, wholesale or distribution and importation premises, shall be within 2 weeks on the receipt of the application from inspection at Zonal or State offices, where all conditions precedent are met ; and

(*b*) manufacturing premises and distribution centres shall be conducted within 4 weeks on the receipt of the application by the PCN registry.

Pre-Registration Inspection for Retail, Wholesale or Distribution and Importation.

9.—(1) Pharmaceutical Inspectors at the Zonal or State offices shall carry out pre-registration inspection on the proposed premises after the location has been approved and the Superintendent pharmacist submits the following documents—

(*a*) documents listed in paragraph (*c*) of subregulation (1) of Regulation 9 ;

(*b*) application for pre-registration inspection of the premises addressed to the Registrar of PCN ;

(*c*) duly filled Form B (PCN application form for registration of premises) ;

(*d*) evidence of payment of prescribed pre-registration inspection and registration fees payable to the Council ;

(*e*) photocopy of letter of resignation from previous employment (if applicable) ;

(*f*) letter of acceptance of resignation (if applicable) ;

(*g*) agreement between the Superintendent Pharmacist and his employer, where applicable ;

(*h*) photocopy of NYSC Discharge or Exemption Certificate, where applicable ;

(*i*) letter of undertaking by the Superintendent Pharmacist not to be to the effect that he has only one full time job ;

(*j*) letter of undertaking by the Managing Director of the Company to the effect that pharmaceutical business of the Company shall be left under the direct, control and supervision of the superintendent Pharmacist ; and

(*k*) pharmacists' inter-state movement Form (where applicable).

(2) Pre-registration inspection shall be carried out in line with the Council's prescribed practice category checklists and Standard Operating Procedures (SOPs), to ensure that structures with adequate facilities are in place in accordance with PCN requirements.

(3) Time frame for pre-registration inspection shall be conducted within 2 weeks after the Superintendent Pharmacist indicated his readiness to go for inspection and have met all the requirements.

Pre-Registration Inspection for Manufacturing and Distribution Centres (MDDC, SDDC and CWC).

10.—(1) A proposed premises seeking to be registered as a manufacturing or distribution centre, the requirements in regulation 9(1) shall be submitted in addition to the following—

(*a*) list of products to be manufactured or distributed ;

(*b*) organogram ;

(*c*) list of staff, qualifications and duties ;

(*d*) factory or premises layout ;

(*e*) quality control documents–list of equipment, procedures, processes;

(*f*) Standard Operating Procedures (SOPs) ;

(*g*) Standard Cleaning Procedures ;

(*h*) list of suppliers of drugs and medical consumables for distribution centre.

(2) The following shall be included for manufacturing premises—

(*a*) production flow chart ;

(*b*) list of equipment in production ;

(*c*) water analysis report of raw and treated water ;

(*d*) List and source of suppliers of raw materials and packaging materials ; and

(*e*) source of water and water treatment facilities.

(3) Pre-registration inspection shall be carried out in line with Council's prescribed practice category checklists and Standard Operating Procedures (SOPs) to ensure that structures with adequate facilities are in place in accordance with PCN requirements.

(4) Time frame for Pre-registration inspection shall be conducted within 6 weeks after the owner of the pharmaceutical premises has indicated their readiness for the inspection and have met all the requirements for the inspection.

Patent and Proprietary Medicine Vendors (PPMVs) registration inspection.

11.—(1) An intending PPMV shall submit application for inspection, evidence of payment of prescribed inspection fees and other prescribed documents as stated in the PCN's Guidelines for issuance of Patent and Proprietary Medicines Vendor's Licence (PPMVL).

(2) Every inspection for PPMVs shall be conducted in line with the PCN's Guidelines for the issuance of PPMVL, PCN and prescribed SOPs for the various inspections, location approval and pre-registration inspection.

(3) The time frame to carry out location inspection shall be within 2 weeks after the intending vendor has successfully passed the screening exercise conducted by PPMVL committee and met the requirements as stated in the Guidelines for Issuance of PPMV Licence.

(4) Pre-registration inspection shall be carried out 2 weeks after PPMVL committee has conducted orientation programme for the successful intending vendor.

Routine inspection.

12.—(1) Routine inspection shall be carried out in all PCN registered pharmaceutical premises and PPMV shops to ensure that standards are maintained for continuous licensure of the said premises and such inspections shall be carried out using PCN prescribed category of practice checklists and SOPs for routine inspections.

(2) Time frame for all pharmaceutical premises including PPMV shops shall be due for re-inspection or routine inspection after 2 years interval.

Investigative inspection.

13.—(1) Pharmaceutical Inspectors shall carry out investigative inspections on any pharmaceutical premises on—

(*a*) suspicion of impropriety ;

(*b*) receipt of allegation or petition against it ;

(*c*) premises not conforming to good pharmacy practice ; or

(*d*) for any other sufficient reason.

(2) The investigative inspection shall be conducted in line with PCN prescribed SOPs.

(3) Time frame for action shall be determined as soon as petition is received and resolution time may vary depending on the nature of the petition.

MADE at Abuja this 19th day of July, 2021.

DR OSAGIE E. EHANIRE, MD, FWACS
Honourable Minister of Health