Preamble:

The Council has the responsibility of ensuring that stakeholders are properly guided in accordance with Pharmacy Council of Nigeria (Establishment) Act 2022 and Poisons and Pharmacy Act, CAP 535 LFN 1990 and Regulations made thereunder. Pursuant to the responsibility of the Council for the inspection, approval and licensing of premises where pharmaceutical activities take place, among other functions, these Guidelines are hereby made.

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

Before any premises can be registered/ licensed by the Council to operate as a pharmaceutical premises, the said premises shall 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 provide guide as follows:

1.0 Siting of Pharmaceutical Premises

i. Pharmaceutical premises shall not be located in the following areas:

(a) motor parks, Petrol Stations;

(b) clustered environment;

(c) in and around market places; and

(d) kiosks, containers and other stalls.

ii. Any pharmaceutical premises shall be relocated within two years after due notice is given by the Council where it has become:

(a) Clustered or surrounded

(b) Covered by a growing market or close to it.

iii. Pharmaceutical premises shall be sited not less than two hundred metres (200m) from each other.

iv. Patent Medicine Shop (PMS) shall be sited not less than four hundred meters (400m) from a pharmacy.

v. PPMV shops shall be sited not less than two hundred metres (200m) from each other.

vi. Pharmaceutical premises within a shopping centre shall not be more than three. The premises shall not be located door to door and the spacing of the premises shall not be less than five shops in between.

vii. The distance from the pharmaceutical premises in a Shopping Centre to a new pharmaceutical premises in another Shopping Centre shall not be less than 200 metres.

viii. The distance between a stand-alone pharmaceutical premises and a pharmaceutical premises located in a shopping Centre shall not be less than 200 metres from each other.

ix. A pharmaceutical premises shall be situated in a good sanitary environment.

x. **Wherever distances between any premises are to be measured, it shall be from front main doors of the premises through shortest accessible route.**

2.0 Structure of Pharmaceutical Premises:

i. A pharmaceutical premises shall not be less than:

- 30 square metres for retail;
- 70 square metres for wholesale;
- 70 square metres for Distributors/Importers;

- 1,000 square metres for Mega Wholesale Centres (MWC)/ Public Wholesale Centres (PWC);
- 300 square metres for Zonal Public Wholesale Centres (ZPWC);
- 70 square metres per shop space within Coordinated Wholesale Centres (CWC) of not less than 200 shop spaces; and
- Not more than 15 square metres for patent medicines shop.

ii. A pharmaceutical premises shall be made of concrete walls and not in a kiosk or container. In the case of manufacturing the ceiling should not be made of asbestos.

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

iv. A pharmaceutical premises/shop shall:

(a) be well painted;

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

(c) have a proper ceiling with a height of not less than 3.05m;

(d) maintain adequate lighting, temperature and ventilation. Pharmacies shall have functional air conditioning system and fans. PPMV's shops shall have at least fans;

(e) maintain adequate safety measures by providing fire extinguishers, sand bucket, emergency exits, Personal Protection Equipment (PPEs) (where applicable);

(f) maintain neatness of premises and surroundings and shall not allow bushes to grow within it or for the surroundings to be littered.

v. A community pharmacy shall:

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

(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.

vi. Office of Superintendent Pharmacist:

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

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

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

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

vii. Facilities to be provided in Pharmaceutical Premises

There shall be provided in a 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 /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/ sink;

(i) equipment for water treatment to achieve the desired quality;

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

(k) record for patient medication profile (where applicable);

(l) copies of recent editions of reference books including:

- Standard Treatment Guidelines (STG), Nigeria
- British Pharmacopeia (B.P.C.)
- Extra Pharmacopoeia
- International Pharmacopoeia (I.P.)
- British National Formulary (B.N.F.)
- National Formulary and Essential Drugs List
- A Compilation of Pharmacy, Drugs and Related Laws and Rules in Nigeria
- Current Gazettes of list of registered pharmacists and pharmacies
- Compendium of Minimum Standards of Pharmacy Practice in Nigeria

viii. Handling of Controlled Substances/ Poisons

There shall be provided in every pharmaceutical premises –

(a) A disposal of poisons book appropriate for the category of practice wherein all records of controlled substances received and dispensed

are entered by the pharmacist on duty. In case of manufacturing, the entries must be made by the designated pharmacist;

(b) A dedicated and secured storage area (poisons cupboard);

(c) Handling of controlled substances or poisons shall exclusively be by a licensed pharmacist.

ix. For manufacturing premises, other facilities to be provided are listed in the Compendium of Minimum Standards of Pharmacy Practice in Nigeria

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

3.0 Inspection of Pharmaceutical Premises:

Pharmaceutical Inspection Officers appointed by the Council shall carry out inspection and monitoring on pharmaceutical premises for registration and continuous licensure of such premises.

The following are the different types of inspection and procedures to be followed:

3.1 Location Approval Inspection for Retail, Wholesale, Distribution Centres, Importation and Manufacturing Premises

(i) A pharmacist shall apply to the Registrar, Pharmacy Council of Nigeria, for the location approval inspection of a proposed pharmaceutical premises. The application which shall include the address of the proposed location, scope and area of practice shall be submitted at the zonal/state offices where the proposed premises is located.

The application shall be accompanied with the following documents:

- Photocopy of current Annual Licence to practice /application for Annual Licence renewal
- Evidence for payment of prescribed Location approval inspection fees payable to the Council;
- Letter of appointment of the Superintendent Pharmacist with the company intending to open new premises (where applicable);
- Certified true copy of the Company's Certificate of Incorporation (Evidence of registration of business name is acceptable from Pharmacist-owned retail premises);
- Certified true copy of Articles and Memorandum of Association;
- Certified true copy of Particulars of Directors. The Particulars of Directors shall indicate that there is at least one Pharmacist on the Board of Directors (who shall be a shareholder in the company), if the premises is not for retail practice;
- Current Annual Licence of the Pharmacist Director and
- Duly signed Disclaimer of Liability Form

(ii) Location approval inspection shall be carried out by Pharmaceutical inspection officers appointed by the Council in line with PCN prescribed scope and area of practice checklists and Standard Operating Procedures (SOPs) to ensure that the siting of the proposed premises and the size meet the requirements.

(iii) Time Frame:

a. For retail, wholesale/distribution and importation premises, location approval inspection shall be

conducted within two (2) weeks on receipt of the application for inspection at Zonal/State offices if all conditions precedent are met.

b. For manufacturing premises and distribution centres (MWC, PWC, CWC), the location approval inspection shall be conducted within two (2) weeks on receipt of the application by the PCN registry.

3.2 Pre-Registration Inspection

(i) Pre-Registration Inspection for Retail, Wholesale/ Distribution and Importation

(a) Pharmaceutical Inspection Officers at the Zonal/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:

- Documents listed in 3.1
- Application for pre-registration inspection of the premises addressed to the Registrar, PCN
- Duly completed Form B (Application for registration of premises)
- Evidence for payment of prescribed pre-registration inspection and registration fees payable to the Council;
- Photocopy of letter of resignation from previous employment (if applicable);
- Letter of acceptance of resignation (if applicable);

- Legal agreement between the Superintendent Pharmacist and his employer (where applicable);
- Photocopy of Certificate of National Service or Certificate of Exemption;
- Letter of undertaking by the Superintendent Pharmacist to the effect that he has only one full time job;
- Letter of undertaking by the Managing Director of the Company to the effect that all pharmaceutical business shall be left under the direct, personal control and supervision of the Superintendent Pharmacist;
- Pharmacist's Inter-State Movement Form (where applicable);

(b) The Pre-registration inspection shall be carried out in line with PCN prescribed scope and areas of practice checklists and Standard Operating Procedures (SOPs) to ensure that structures with adequate facilities are in place in accordance with PCN requirements.

(c) Time Frame:

i. Pre-registration inspection shall be conducted within two (2) weeks after the Superintendent Pharmacist has indicated the facility's readiness for the inspection.

ii. Report of inspection and recommendations shall be forwarded to the Registrar within two (2) weeks after the inspection.

(ii) **Pre-Registration Inspection for Manufacturing and Distribution Centres (MWC, PWC and CWC)**

(a) Where the proposed premises is applying to be registered as manufacturing or distribution centre, the following documents shall be submitted in addition to the requirements for retail, wholesale and importation outfits listed in 3.2 (i) (a)

- List of products to be manufactured or distributed;
- Organogram;
- List of staff, qualifications and duties;
- Factory /premises layout;
- Quality control documents – list of equipment and, processes;
- Standard Operating Procedures (SOPs);
- List of suppliers of drugs and medical consumables for distribution centres;

(b) The under listed shall be included for manufacturing premises:

- Production flow chart;
- List of equipment in production;
- Water analysis report of raw and treated water;
- List and source of suppliers of raw materials and packaging materials;
- Source of water and water treatment facilities.

(c) The Pre-registration inspection shall be carried out in line with PCN prescribed scope and areas of practice checklists and Standard Operating Procedures (SOPs) to ensure that structures with adequate facilities are in place in

accordance with PCN requirements.

(d) Time Frame:

Pre-registration inspection shall be conducted within four (4) weeks after the premises has indicated their readiness for the inspection and have met all the requirements for the inspection.

3.3 Patent and Proprietary Medicine Vendors (PPMVs) Registration Inspection

(i) An intending Patent and Proprietary Medicine Vendor (PPMV) shall submit application for inspection, evidence of payment of prescribed inspection fees, and other required documents as stated in the PCN's Regulations for Issuance of Patent and Proprietary Medicines Vendor's Licence 2022.

(ii) All inspections for PPMVs shall be conducted in line with the PCN's Regulations for the Issuance of Patent and Proprietary Medicines Vendor's Licence 2022 and PCN prescribed Standard Operating Procedures (SOPs) for the various inspections (location approval and pre-registration inspection).

(iii) Time Frame:

(a) Location approval inspection shall be carried out within two (2) weeks after the intending vendor has successfully passed the screening exercise by PPMVL committee and met the requirements.

(b) Pre-registration inspection shall be carried within twenty-one (21) working days after PPMVL committee has conducted orientation programme for the successful intending vendor.

3.4 Routine inspection of community, wholesale, distribution and importation premises and PPMV's shops and re-granting of license inspection for manufacturing premises

(i) Routine inspections shall be carried out in all PCN registered community, wholesale, distribution and importation premises and PPMV's shops and re-granting of license inspection for manufacturing premises based on the risk rating of the premises to ensure that standards are maintained for continuous licensure of the said premises. Such inspections shall be carried out using PCN prescribed scope and areas of practice checklists and SOPs for routine inspections.

(ii) Time Frame:

The time frame for routine inspection shall be based on the risk rating of the premises as determined during the previous inspection.

3.5 Investigative Inspection

(i) Pharmaceutical inspection officers shall carry out investigative inspections on any pharmaceutical premises on:

- suspicion of impropriety;
- receipt of allegation or petition against it;
- premises not conforming to good pharmacy practice or for any other sufficient reason.

(ii) The investigative inspection shall be conducted in line with PCN prescribed Standard Operating Procedures.

(iii) Time Frame: Action shall be taken as soon as the petition is received. However, resolution time varies depending on the nature of the petition.

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Registrar/CEO