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PREFACE

In view of the present re-positioning of the Registry of the Pharmacy 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. This informed the update and presentation of these "Guidelines for Registration of Pharmacists and Pharmaceutical Premises".


The Council is responsible for inspection, approval and licensing of premises where pharmaceutical activities take place, among other functions. The Registry has the responsibility of ensuring that stakeholders are properly guided in accordance with Pharmacy Council of Nigeria (Establishment) Act, 2022.

These "Guidelines for Registration of Pharmacists and Pharmaceutical Premises" is such an attempt to guide Pharmacists and other stakeholders involved with registration of premises on the requirements and steps. These guidelines are primarily intended to guide the following: -

- (i) Fresh graduates seeking Provisional Registration.
- (ii) Provisionally registered pharmacists wishing to go for Internship Training;
- (iii) Pharmacists seeking full registration;
- (iv) Pharmacists and Companies wishing to establish Pharmaceutical Premises (Community, wholesale, distribution, importation and manufacturing)

All pharmacists and stakeholders should avail themselves of these guidelines to be conversant with the basic requirements and steps for registration with Pharmacy Council of Nigeria.

Pharm. Ibrahim Babashehu Ahmed, B.Pharm, MBA, FPCPharm, FPSN, FNAPharm, FCAI
 Registrar and CEO

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1.0 **Introduction**

The Pharmacy Council of Nigeria is established by the Pharmacy Council of Nigeria (Establishment) Act, 2022 and charged with the following responsibilities among others:

- i) Setting standards of education for those seeking to become pharmacists;
- ii) Laying down the code of conduct for the practice of pharmacy profession;
- iii) Monitoring the practice of pharmacy through Pharmaceutical inspectorate activities;
- iv) Discipline of erring pharmacists.

In carrying out these responsibilities, the Council:

- (a) Determines what standard of knowledge and skill are to be attained by persons seeking to become pharmacists in Nigeria;
- (b) Gives approval (if its standard are met) to any course of training which is intended for persons seeking to become or are already pharmacists;
- (c) Approves institutions in Nigeria and recognizes others elsewhere, for the training of pharmacists;
- (d) Approves any qualification, which is granted to candidates who have met the standards of the training institutions in line with PCN requirements on training;
- (e) Keeps itself informed of the nature of instructions given at approved institutions and examinations taken by persons attending such institutions;
- (f) Arranges for the orientation courses and examination for Foreign-trained candidates and prescribes fees for such courses and examinations;
- (g) Establishes and maintains registers of pharmacists and pharmaceutical premises and secures the publications from time to time of the list of those names as entered in the registers;
- (h) Maintains discipline among pharmacists;
- (i) Appoints Pharmaceutical Inspection Officers to ensure the enforcement of the provisions of the Pharmacy Council of Nigeria (Establishment) Act, 2022, Poisons and Pharmacy Act Cap 535 LFN 1990 and other drug Laws and Regulations;

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- (j) Maintains a register of **Patent and Proprietary Medicine License Holders** throughout the Federation;
- (k) Sets standards for training and maintains a register of Pharmacy Technicians throughout the Federation.

2.0 Registration as a Pharmacist in Nigeria


2.1 Provisional Registration of Pharmacists (Pharmacist Trained in Nigeria)

- i) To be considered for Provisional Registration, the following documents shall be submitted to the Registrar at least 24 hours before the induction ceremony:
 - (a) A completed **Form F** duly endorsed by the Dean of School/Faculty of Pharmacy attended by the applicant;
 - (b) Statement of Result/Testimonial;
 - (c) Two passport size photographs of the applicant authenticated by the Dean;
 - (f) The prescribed fee payable to the Pharmacy Council of Nigeria; and
 - (e) Birth Certificate or sworn affidavit of age declaration.
- ii) At such induction ceremony, which is organized by the Dean of Faculty or School of Pharmacy, the Registrar of the Council shall be invited to administer the Pharmacist's oath on the graduating pharmacists;
- (iii) A fresh pharmacy graduate from institution approved by the PCN, after the oath taking, shall be issued with certificate of provisional registration by the Registrar.
- (iv) Photocopies of the Pharmacist's oath (signed by the Pharmacist and the Registrar), and certificate of provisional registration shall be submitted to PCN staff.

2.2 Registration of a Foreign Trained Pharmacy Graduate

2.2.1 Definition

A "Foreign Trained Pharmacy Graduate" is a graduate of pharmacy whose undergraduate pharmacy degree was conferred by a recognized school of pharmacy outside Nigeria. Foreign nationals who graduated from schools in Nigeria are not included in this programme.

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2.2.2 General Information

- (i) To be registered in Nigeria, a Foreign Pharmacy Graduate is expected to forward first, a written application for participation in the Foreign Pharmacy Graduate Orientation Programme (FPGOP) and thereafter, a completed application form with relevant documents.

NOTE: Applicants are advised to obtain a copy of the Foreign Pharmacy Graduate Orientation Programme (FPGOP) manual from the nearest PCN office for further details.

- (ii) It is the applicant's responsibility to make sure that all the required supporting documents are submitted and received before the deadline published by the Council.

2.2.3 Application for Foreign Pharmacy Graduate


Orientation Programme (FPGOP)

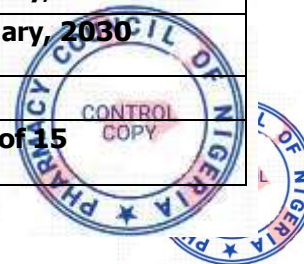
- (i) An applicant must complete and submit a current form each time he/she applies for the FPGOP, regardless of whether applications have been submitted in the past.
- (ii) The Registry will notify each candidate directly in writing, regarding the status of his or her application including any deficiency(ies).
- (iii) Applicant's name, as it appears on the application form must be used in all communications with PCN.
- (iv) If all requirements are satisfactorily met, the candidate will receive letter of acceptance for FPGOP.

2.2.4 Time, Duration, Cost and Venue:

- (i) The Programme shall normally hold in two (2) cycles annually, April/May and August/September, or otherwise the Council may decide.
- (ii) The **duration** of the FPGOP will be six weeks. There are two (2) categories, Regular Programme (4 weeks of lectures, practicals and field trips, 1 week revision, and 1 week examination) and the online programme (3 weeks of online lectures, 1 week practicals and field trips, 1 week revision, and 1 week examination).

NB: The regular programme is for pharmacy graduates with less than five (5) years post qualification experience, while the online programme is for pharmacy graduates with five (5) years and above post qualification practical experience and current annual licence in their country of training or residence

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- (iii) The prescribed fee shall be as decided by the Council.
- (iv) The **venue** is usually rotated among the **accredited Faculties of Pharmacy in Nigerian Universities and National Institute of Pharmaceutical Research and Development (NIPRD)**.

2.2.5 Candidate should Note

- (i) Success in FPGOP examination is not a license to practice pharmacy
- (ii) Those who pass the examination will proceed for the twelve-month continuous internship programme after which they will be eligible for registration. However, those who have evidence of registration in their country of training may be granted full registration in line with laid down procedures.

2.3 Registration of Non-Nigerian Pharmacist


A person who is not a citizen of Nigeria may be registered as a pharmacist under the PCN (*Establishment*) Act 2022 if the country of which he is a citizen or national, as the case may be, grants reciprocal registration facilities to Nigerian Citizens.

- (a) He holds a qualification approved by the Council;
- (b) He has passed the Council's examination in law and ethics governing the practice of pharmacy in Nigeria and such other examinations as the Council may prescribe;
- (c) He has acquired the requisite experience in accordance with section 35 (3) (b) of the PCN (Establishment) Act, 2022;
- (d) He has been resident in Nigeria for not less than twelve (12) calendar months immediately preceding the date of his application for registration;
- (e) He has met all other requirements for registration as may be prescribed by the Council.

2.4 Pharmacists Internship Training Programme

After provisional registration, a pharmacist wishing to be fully registered, shall undergo a compulsory twelve months Internship Programme in an institution approved by the Council for that purpose. This is in compliance with the provisions of the Pharmacy Council of Nigeria (*Establishment*) Act, 2022.

The following conditions shall be met for Internship Training Programme:

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(i) The internee shall at point of induction (oath-taking) obtain a copy of the internship training manual and logbook.

(ii) Application shall be made in Form F/2 **in triplicate** before the commencement of the internship programme.

One copy for the designated official in the State, one for the Preceptor and the third copy to be forwarded to PCN within 6 weeks of commencement of internship.

(iii) The applicant must ensure that the institution where he wishes to undergo the Internship Training is approved by the Council for that purpose;

(iv) Every institution approved for Internship Training shall:


(a) be inspected by the Council from time to time to ensure compliance with laid down standards and;

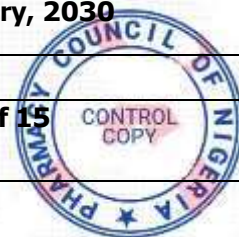
(b) furnish such information as may be required by the Council on the personnel, facilities and adequacy of the approved premises for the purpose of pre-registration training (internship).

2.4.1 Scope of Training: General

The internee is expected to undertake practical training in the following areas during the programme:

- Manipulation of pharmaceutical equipment in common use;
- Recognition by characters of crude drugs and chemical substances used in medicines;
- Manufacture of galenicals and preparation/manufacture of medical products;
- Reading, translation and copying of prescriptions including the checking of prescribed doses (evaluation of prescription);
- Dispensing (Filling of prescription);
- Proper storage of drugs and medical products;
- Drug store management;
- The use of common reference books in the practice of pharmacy;
- Pharmacy management;

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- j. Any other duties that may be assigned by the supervising pharmacist including rural **posting** of not more than three months where necessary;
- k. A knowledge of keeping of records required by the Poison and Pharmacy Act, Dangerous Drugs Act and the Food and Drugs Act Cap. F. 32 LFN 2004 and any other relevant Legislations in respect of pharmacy practice;
- l. Patient medication profile and patient counseling;

2.4.2 Record of Training

- a. The internee shall use the log book for keeping record of his work and such record shall be regularly inspected and signed by the Supervising Registered Pharmacist and the Director of Pharmaceutical Services, or any designated official in the State is to complete the DPS comment form.
- b. A representative of the Council shall have the right to inspect the record at any reasonable time, and at the end of the training, the **detachable DPS comment form** shall be submitted to the Council as evidence of successful completion of the programme.

2.4.3 Certificate of Experience

On completion of the practical training, a **Certificate of Experience** (Form D) shall be signed by the Council's recognized Intern Preceptor who shall be in good standing with the Council and possess a minimum of 5-year post NYSC working experience.


2.5 Guidelines for Registration of Pharmacists and Pharmaceutical Premises

2.5.1 Full Registration as a Pharmacist

On completion of the Internship Training, the pharmacist seeking full registration shall forward the following documents to the Registrar of Pharmacy Council of Nigeria.

- i) Duly completed Form D (Certificate of Experience);
- ii) Duly completed Form C (Application for Registration as a Pharmacist);
- iii) Duly completed Form J (Application for Retention of Name in the Register);
- iv) Receipt of payment of prescribed fees.

After the processing, the applicant shall be considered for full registration if found fit and proper and shall be sent the following:

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- a) Certificate of Registration as a Pharmacist - Form E - which is to be issued within twelve (12) months after first Annual Licence.
- b) First Annual Licence to practice as a Registered Pharmacist - Form H; to be issued fifteen (15) working days after approval of the results of Pre-Registration Examination for Pharmacists (PEP) by the Governing Council.

2.6 Renewal of Annual Licence

2.6.1 **Online Renewal:** The Superintendent Pharmacist shall pay the prescribed fee and obtain scratch card for renewal of the licence and follow the instruction on the back of the scratch card to submit the application. The application is to be recommended for Registrar's approval within three working days. Following the Registrar's approval, the electronic copy of the licence will be automatically sent to the Pharmacist's email. Thereafter there will be a surface dispatch of the duly stamped hard copy of the licence to the Pharmacist within seven working days.

2.6.2 In respect to post-licensure changes in name on annual licence, the Pharmacist will apply using Form J, enclosing the following documents:

- A formal letter of application to the Registrar for change of name;
- A signed affidavit
- Newspaper publication of change of name
- Photocopy of Marriage Certificate where applicable


The above-listed documents are to be submitted to the PCN State Office where the applicant is domiciled and licence will be processed within 14 working days.

3.0 Registration and Licensing of Pharmaceutical Premises

3.1 Registration and Licensing of a new Pharmaceutical Premises


A new pharmaceutical premises shall be registered after all necessary inspections have been carried out in accordance with the Guidelines for Location, Structure and Inspection of Pharmaceutical Premises.

A fully registered pharmacist is eligible to apply for registration of a pharmaceutical premises (Community, wholesale, distribution, or importation pharmacy) provided he has completed his National Youth Service Corps (NYSC) and presents a Certificate of National Service (NYSC) or Certificate of Exemption. The Pharmacist is expected to be up-to-date with Mandatory Continuing Professional Development (MCPD) programme of Pharmacy Council of Nigeria (PCN) (if eligible).

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For the registration of a new pharmaceutical premises (Community, wholesale, distribution or importation pharmacy), the superintendent pharmacist obtains Form B (Application for registration of premises) from the Zonal/ State offices and fills the Form B, which shall be submitted with the following documents to the Registrar, Pharmacy Council of Nigeria through the PCN Zonal/State Offices where the premises is to be located and operated:

- i) Application letter to register the premises;
- ii) Duly completed Form B
- iii) Photocopy of current Annual Licence to practice as a pharmacist or application for retention of name on the Register (Form J)
- iv) Receipt of payment of prescribed inspection and registration fees
- v) Letter of resignation from previous employment (if applicable);
- vi) Letter of acceptance of resignation (if applicable);
- vii) Letter of appointment in the new premises where applicable;
- viii) Legal agreement between the Superintendent Pharmacist and the employer where applicable;
- ix) Company's Certificate of Incorporation (Evidence of registration of business name is acceptable for pharmacist- owned Community premises);
- x) Articles and Memorandum of Association (certified copy);
- xi) Certified true copies of Particulars of Directors as issued by Corporate Affairs Commission (CAC);
- xii) Photocopy of Certificate of National Service (NYSC)/Certificate of Exemption
- xiii) Letter of undertaking by the Superintendent Pharmacist to the effect that he has only one full time job;
- xiv) 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;

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- xv) Pharmacist's inter-state movement form (where applicable);
- xvi) There must be at least one Pharmacist on the Board of Directors;
- xvii) Such application shall be accompanied with the Current Annual Licence of the Pharmacist Director.

3.2 **Renewal of Certificate of Registration of Premises**

A registered pharmaceutical premises shall be due for renewal of its certificate from the first of January every year.

3.2.1 **Online Renewal:** The superintendent pharmacist shall pay the prescribed fee and obtain scratch card for renewal of the premises and follow the instruction on the back of the scratch card to submit the application. The application is to be recommended for Registrar's approval within three working days. Following the Registrar's approval, the electronic copy of the premises certificate will be automatically sent to the Pharmacist's email. Thereafter there will be a surface dispatch of the duly stamped hard copy of the certificate to the Pharmacist within seven working days.


3.2.2 **Change or variation of certificate:** A registered pharmaceutical premises shall make application to the Registrar, via Form B, for approval of change, variation or modification in the certificate in respect of Superintendent Pharmacist name or title, name of premises, structure of premises, location of premises, scope/areas of practice, and additional line for manufacturing or any other change or variation that may affect the licence. Documents to accompany Form B include:

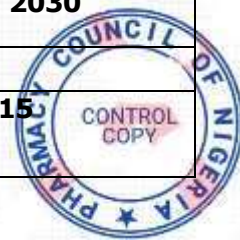
- Letter to the Registrar specifying the type and reason for change
- Evidence of change
- Any legal document that may be required.

The above-listed documents are to be submitted to the PCN State Office where the applicant is domiciled and licence will be processed within 14 working days.

3.3 **Registration and Renewal of Certificate of Pharmaceutical Manufacturing Premises**

The documents required for registration of Pharmaceutical Manufacturing premises are the same as stated in 3.1 above for other pharmaceutical premises. However, in addition, the following shall be submitted:

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- (i) List of products to be manufactured;
- (ii) Organogram;
- (iii) List of staff, qualifications and duties;
- (iv) Factory layout;
- (v) Production flow chart;
- (vi) List of equipment in production and quality control department;
- (vii) State source of water and treatment facilities available;
- (viii) Water analysis report of raw and treated water;
- (ix) List and sources of suppliers of raw materials and packaging materials;
- (x) Standard Operating Procedures (SOPs);
- (xi) Standard Cleaning Procedures;
- (xii) Receipt of payment of prescribed inspection fees.

Note: All correspondence with the Council must be on the company's letterhead.

On receipt of the above documents, inspection of the premises shall be carried out within one (1) month.


3.4 Registration and Licensing of Hospital Pharmacies

1. Submission of application letter to register the Pharmacy;
2. Submission of application form duly completed;
3. Photocopy of current Annual Licence to practice or Application for Retention of Name on the Register (Form J);
4. Prescribed inspection and registration fees payable to the Council;
5. Photocopy of resignation/acceptance letter from previous employment (if applicable);

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6. Letter of appointment of Superintendent Pharmacist in the new premises (where applicable);
7. Legal agreement between the Superintendent Pharmacist and the employer (where applicable);
8. Company's Certificate of Incorporation (where applicable);
9. Certified True Copies (CTC) of Articles and Memorandum of Association (where applicable);
10. Particulars of Directors as issued by Corporate Affairs Commission (C.A.C.) (Where applicable);
11. Photocopy of Certificate of National Service (NYSC)/Certificate of Exemption;
12. Letter of undertaking by Superintendent Pharmacist to the effect that he only has one full time job.
13. Letter of undertaking by Managing Director of the Hospital to the effect that all pharmaceutical businesses shall be left under the direct personal control and supervision of the superintendent pharmacist.
14. Pharmacist's inter-state movement form (where applicable)
15. List of staff in the hospital pharmacy showing qualification and assigned duties.
16. Design layout of pharmacy
17. Compilation of Standard Operating Procedures (SOPs)
18. List of equipment in Production and Quality Control Unit (where applicable)
19. List of products being produced by the hospital compounding or manufacturing unit (where applicable)
20. Organogram

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3.5 Registration of Patent and Proprietary Medicine Vendor's (PPMV) Shops

On the above, refer to the Guidelines on the Issuance of Patent and Proprietary Medicine Vendors' Licence (PPMVL).

3.6 Suspension, Revocation, Withdrawal or Cancellation of Licence

1. When there is a breach of any of the provisions of the Regulations or the Act by the holder of a licence, the Pharmacy Council of Nigeria, a is empowered to suspend, revoke, recall, withdraw or cancel the licence.
2. Where the Registrar is of the view that a licence should be suspended, revoked, recalled, withdrawn, canceled or restored, the holder of such licence shall, by notice, be required to give reasons within 14 days of receipt of such notice why the licence should not be suspended, revoked, recalled, withdrawn or cancelled and if the:
 - a) Registrar is satisfied by the reasons so given such licence shall not be suspended, revoked, recall, withdrawn or cancelled; or
 - b) Reason given is not satisfactory, the Registrar shall notify the holder of the decision to suspend, revoke, recall, withdraw or cancel same and in such case, the holder of the licence shall appeal to the Council within 14 days.

3.7 Time Frame

The following shall be the time frame for registration and licensure of pharmaceutical premises.

- (i) On receipt of application for registration of premises at State/Zonal offices, inspection shall be carried out within one month, provided all necessary documents and evidence of prescribed fees are submitted.
- (ii) The report of the above inspection shall, together with all the relevant documents submitted, be forwarded by the State /Zonal offices within ten (10) working days after recommendation by the Pharmaceutical Inspection Committee (PIC) to the Registrar, Pharmacy Council of Nigeria (PCN).
- (iii) Upon receipt of the documents at Registry, the premises shall be issued with a licence within twenty-one (21) working days provided all documents submitted complied with the requirements for the registration of such premises.