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PHARMACISTS COUNCIL OF NIGERIA ACT
(CAP. P17 LFN), 2004
REGISTRATION AND LICENSING OF PHARMACEUTICAL
PREMISES REGULATIONS, 2021.



ARRANGEMENT OF REGULATIONS

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3. Application for registration of a premises to manufacture.
4. Wholesale, Distribution and Importation centres, etc.
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SCHEDULE.

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

**REGISTRATION AND LICENSING OF PHARMACEUTICAL
PREMISES REGULATIONS, 2021.**

[19th Day of July, 2021]

Commence-
ment.

In exercise of the powers conferred by sections 1, 13, 14, 21 and 24 of the Pharmacists Council of Nigeria Act (Cap P17, LFN) 2004 and and Poisons and Pharmacy Act, (Cap. 535 LFN) 1990 and Regulations made thereunder with all powers enabling it in that behalf, the Council of the Pharmacists Council of Nigeria with the approval of the Honourable Minister of Health, hereby makes these Regulations—

PART I—REGISTRATION

1. Pharmaceutical premises in Nigeria shall be registered with the Pharmacists Council of Nigeria.

Registration
Authority.

2.—(1) Application for registration of pharmaceutical premises shall be made to the Registrar, Pharmacists Council of Nigeria.

Application
for
registration
of
pharmaceu-
tical
premises.

(2) The applicant shall complete an application form, which shall be accompanied with the following documents—

- (a) application letter to register the premises ;
- (b) current annual licence to practice pharmacy ;
- (c) evidence of payment of prescribed fees to the Council ;
- (d) letter of resignation from previous employment, where applicable ;
- (e) letter of acceptance of resignation, where applicable ;
- (f) letter of appointment as the superintendent pharmacist in the new premises, where applicable ;
- (g) legal agreement between the superintendent pharmacist in the new premises and the owner of the pharmaceutical premises where applicable ;
- (h) company's Certificate of Incorporation or evidence of registration of business name is acceptable for pharmacist owned retail premises ;
- (i) a copy of Articles and Memorandum of Association of the company ;
- (j) a certified true copies of CAC documents showing names and particulars of Directors ;
- (k) current Annual Licence to practice of the Pharmacist Director ;
- (l) NYSC Discharge or Exemption Certificate ;

(m) letter of undertaking by the Superintendent Pharmacist having only one full time job ;

(n) letter of undertaking by the managing Director of the Company to the effect that all pharmaceutical business shall be under the direct, personal control and management of the Superintendent Pharmacist, (where applicable); and

(o) Pharmacists Inter-state movement form (where applicable).

Application
for
registration
of a
premises to
manufacture.

3.—(1) Where the pharmaceutical premises sought to be registered is for manufacturing, in addition to the documents listed in regulation 2 of these Regulations, the application shall be accompanied with the following documents—

(a) list of products to be manufactured ;

(b) list of equipment acquired for Production and Quality Control Departments ;

(c) list and sources of suppliers of raw and packaging materials ;

(d) standard operating procedures (SOPs) ;

(e) factory layout ;

(f) environmental impact assessment report (EIA) ;

(g) production flow chart ;

(h) water source and treatment facilities ;

(i) water analysis report (raw and treated water) ;

(j) list of qualified staff engaged, showing their qualifications and job descriptions ;

(k) organogram ; and

(l) disposal of poisons records.

(2) Each production line shall be supervised by a Production Pharmacist.

(3) The over-all quality assurance of the establishment shall be the responsibility of the Superintendent Pharmacist.

(4) The Production and Quality Control Managers shall report to the Superintendent Pharmacist.

Wholesale,
Distribution
and
Importation
centres, etc.

4.—(1) For pharmaceutical premises involved in Wholesale, Distribution, Importation, Exportation, Scientific Offices, Warehousing and Storage of drugs, poisons and devices, there shall be at least one registered pharmacist on the Board of Directors of the Company.

(2) The business shall be carried out under the direct personal control and management of the Superintendent Pharmacist.

(m) letter of undertaking by the Superintendent Pharmacist having only one full time job ;

(n) letter of undertaking by the managing Director of the Company to the effect that all pharmaceutical business shall be under the direct, personal control and management of the Superintendent Pharmacist, (where applicable); and

(o) Pharmacists Inter-state movement form (where applicable).

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(2) The business shall be carried out under the direct personal control and management of the Superintendent Pharmacist.

Hospital
Pharmacy.

5.—(1) Every hospital shall cause its pharmacy to be registered with the Pharmacists Council of Nigeria in accordance with the Guidelines regulating the operations of hospital pharmacy prescribed by Council.

(2) Hospitals shall make their pharmacies available for inspection as at when due.

(3) The fees payable for registration of hospital pharmacies shall be as prescribed by Council.

(4) All existing hospital pharmacies in Nigeria not registered with the Council before the coming into force of these Regulations shall be inspected and registered.

(5) Hospitals shall employ and maintain required number of registered pharmacists as prescribed by the Council.

6. Where the premises sought to be registered is a Retail Pharmacy, the company shall be wholly owned by a registered pharmacist or in partnership with other registered pharmacists.

Retail
Pharmacy.

7. Where the premises sought to be registered is a Patent and Proprietary Medicine Vendors' shop, the vendor shall be registered in accordance with the Guidelines for Issuance of Patent and Proprietary Medicines Vendors' Licence.

Patent and
proprietary
medicine
vendors'
shop.

8.—(1) Manufacturers, Importers, Exporters, Warehouses, Stores, Distribution Centers, Scientific Offices, Wholesalers and Retailers of drugs, poisons and devices shall keep proper records of the receipts and disposal of drugs and poisons.

Proper
record
keeping.

(2) Retail outlets of drugs, poisons and devices shall keep proper records of the following—

- (a) receipts of purchases made ;
- (b) disposal of poisons ;
- (c) ledgers, bin cards, electronic inventory record ; and
- (d) prescription order of dispensed control drugs.

(3) Distribution Centres, Wholesalers of drugs, poisons and devices shall keep records as provided under sub-regulation (2) of this regulation.

(4) Importers of drugs, poisons and devices shall keep proper records of the following—

- (a) all relevant import documents ; and
- (b) documents provided under sub-regulation (2) of this regulation.

(5) Manufacturers of drugs, poisons and devices shall at all times keep proper records of all documents and information relating to—

- (a) the purchases of raw materials ;
- (b) production and quality control activities ; and
- (c) distribution and sales of finished products.

(6) Only registered pharmacists shall be in possession of market ethical products.

(7) Patent and Proprietary Medicine Vendors are required to maintain proper records of all receipts of purchases and sales.

PART II—LICENSING

Licensing of pharmaceutical premises.

9.—(1) The Pharmacists Council of Nigeria shall be the licensing authority for all Pharmaceutical premises involved in the drug distribution throughout the supply chain.

(2) The Pharmacists Council of Nigeria may issue or grant licences to registered pharmaceutical premises in Nigeria in line with Good Pharmacy Practice (GPP) and in accordance with the Guidelines for Registration.

Renewal of pharmaceutical premises licence.

10. All licenses shall expire on the 31st day of December every year and shall be due for renewal on the 1st day of January of the following year and the procedure for renewal of licences shall be in accordance with the Guidelines made pursuant to the provisions of these Regulations.

Change or variation of licence

11. A licensed Pharmaceutical premise shall make application to the Registrar for approval for change, variation or modification in a licence in respect of Superintendent Pharmacist, structure of premises, location of premises, scope and areas of practice or any other change or variation that may affect the licence.

Suspension, revocation, withdrawal

12.—(1) When there is a breach of any of the provisions of these Regulations or the Act by the holder of a licence, the Pharmacists Council of Nigeria shall suspend, revoke, withdraw or cancel the licence.

Cancellation of licence.

(2) The Council is empowered to make and keep an update of any alteration to any licence issued.

PART III—MISCELLANEOUS PROVISIONS

General provisions.

13.—(1) A Pharmacists shall not use any other names other than that registered with the Pharmacists Council of Nigeria on the sign post of his pharmacy.

(2) Registered pharmaceutical premises shall display the Pharmacists Council of Nigeria (PCN) prescribed emblem in the premises.

(3) Where there is no Superintendent Pharmacist, there shall be a resident locum pharmacist, who shall temporarily take charge of the pharmacy.

(4) It shall be a professional misconduct for any registered pharmacist to hold more than one full time job at a time.

(5) A request for temporary closure of a premises shall be for a maximum period of 2 years and the renewal fees shall be paid for the period of the closure after which further request for renewal may not be granted.

(6) Failure, refusal or negligence to renew premises licence for a maximum period of 2 years is deemed to be notice to the Pharmacists Council of Nigeria (PCN) of permanent closure of Pharmaceutical business.

(7) The fees payable in respect of registration of a set of premises shall be as prescribed or reviewed by the Council.

14. Where the owner of a retail pharmacy shop dies before the expiration of his licence for the year, there shall be a moratorium of two (2) years for the successors-in-title to either close the pharmacy or apply for variation in the category of practice premise licence.

Death of the owner of a retail Pharmacy.

15.—(1) Any registered pharmacist who failed, refused or neglected to pay the prescribed practicing fees by the 31st day of January of every year shall, in addition to the prescribed fees payable, pay 50% (fifty per cent) of the applicable fee as late payment penalty.

Penalty for late payment of practicing fees and registration of pharmaceutical premises.

(2) Any pharmaceutical premises that failed, refused or neglected to renew its licence by the 31st day of January of every year shall, in addition to paying the prescribed renewal fee, pay 50% of the applicable fee as late payment.

(3) Any Pharmaceutical premises owner that failed to renew their premises licence by 31st day of March of each year, shall be sealed.

(4) All unregistered pharmaceutical premises shall be closed.

(5) Any pharmacist found guilty of a criminal offence of immorality by a Court of competent jurisdiction or tribunal shall not be registered or licensed until the Pharmacists Council of Nigeria Tribunal decides otherwise.

16. Inspection of any sector of the Pharmaceutical Industry for registration shall attract a fee as prescribed by the Council in First Schedule to these Regulations.

Payment of inspection fee.

17.—(1) The Council shall prescribe a Pharmacy emblem.

(2) Where an emblem prescribed by the Council is found in an unauthorized premise, such shall be forfeited to the Council.

The Pharmaceutical Council of Nig. 'a emblem.

(3) Any Pharmacist that display pharmacy emblem or licence that is not prescribed by the Council commits an offence and shall be liable to administrative fine of not less than ₦100,000.00 and shall in addition forfeit the emblem or licence to the Council.

(4) A pharmacist shall not register more than one premises at a time and any pharmacist who registers or attempts to register more than one premises, commits an offence and shall—

(a) have his premises closed down in line with prescribed Pharmaceutical Premises Guidelines ;

(b) be recommended for investigation by the Investigating Panel (where applicable) ; and

(c) be referred to the Disciplinary Tribunal of the Council for appropriate action.

Offences and Penalties.

18.—(1) A person who carries out unauthorized disposal of drugs commits an offence and shall be penalised in accordance with these Regulations.

(2) Any person that displays, produces or uses fake pharmaceutical licence or premises registration certificate is guilty of an offence.

(3) Any person that contravenes or fails to comply with the provision of these Regulations shall be guilty of an offence and is liable on conviction to an imprisonment for a term of not less than 6 months or fine of not less than ₦250,000 or to both.

Revocation.

19. The Registration of Pharmaceutical Premises Regulations , 2005 is revoked.

Interpretation.

20. In these Regulations,—

“Act” means Pharmacists Council of Nigeria Act (Cap. P17 LFN 2004) ;

“CAC” means Corporate Affairs Commission ;

“Council” means Pharmacist Council of Nigeria ;

“Disciplinary Tribunal” means the Tribunal established in accordance with section 17 of the Act ;

“Ethical Products” means products that are prescription-only ;

“PCN” means Pharmacists Council of Nigeria ;

“Pharmacists Council of Nigeria Emblem” means the symbol as prescribed by the Council and patented by the Registrar of Patents and Trade Marks ;

“Prescribed Emblems” means such emblems produced and approved by the Council ; and

“Prescribed fees” means such fees as approved by the Council ;

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B 2992

Production Pharmacist means the Pharmacist-in-Charge of the Production Unit or his or her duly authorised representative.

FIRST SCHEDULE
PHARMACIST COUNCIL OF NIGERIA
APPLICATION FOR REGISTRATION OF PREMISES



Recent coloured
Passport
Size
Photograph

Name of Premises (*In Block Letters*)
.....

Name of Registered Pharmacist
Having control of the Business

Address of Premises
.....
.....

.....
(*Surname*) (*Other Names in Full*)

Full Reg. No. of the Pharmacist :

Telephone :

E-mail :

I apply for registration and enclose :

(State all documents enclosed)

Signature :

Date :

Please complete the form appropriately

SECOND SCHEDULE

FORM B

PHARMACISTS COUNCIL OF NIGERIA

APPLICATION FOR REGISTRATION OF NEW PREMISES AND
RETENTION OF OLD PREMISES

This application should be completed in duplicate and sent through the designated official in the State who will keep the duplicate and after necessary endorsement, forward the original together with the applicant's passport photograph to:

The Registrar,
Pharmacists Council of Nigeria
Plot 7/9, Idu Industrial Layout, Idu
P.M.B. 415, Garki, Abuja
E-mail: pcnig@yahoo.ca

I enclose herewith Remital Number : for the
sum of (N.....)
Amount in words) (Amount in Figure)

Processing Fee (Non Refundable)

Class	New	Renewal	Inspection Fees	Location Approval
MANUFACTURERS				
Multinational CATERGORYA- Manufacturing (3 or more Product lines)	N750,000.00	N500,000.00	N250,000.00	
CATERGORYB- Manufacturing (2 Product line)	N200,000.00	N150,000.00	N200,000.00	
CATERGORYC- Manufacturing (1 Product line)	N100,000.00	N100,000.00	N100,000.00	

(Other Names in Full)

(Signature)

(Date of Qualification)

(Current Residential Address)

DISTRIBUTORS				
CATEGORY A- (Importation)				
A1 (20 or more products)	N350,000.00	N200,000.00	N300,000.00	N20,000.00
A2 (10-19 Products)	N200,000.00	N150,000.00	N150,000.00	N20,000.00
A3 (less than 10 products including scientific office)	N150,000.00	N100,000.00	N100,000.00	N20,000.00
CATEGORY B:				
B1 (a) Co-ordinated Wholesales Centre Facility	N1,000,000.00	N500,000.00	N1,000,000.00	N200,000.00
B1 (b) Co-ordinated Wholesales Centre Facility Unit	N500,000.00	N350,000.00	N500,000.00	N20,000.00
B2 Mega Wholesale Centre	N500,000.00	N350,000.00	N100,000.00	N20,000.00
B3 Public Wholesale Distribution Centre	N200,000.00	N100,000.00	N50,000.00	N20,000.00
CATEGORY C: Wholesales Distribution	N150,000.00	N100,000.00	N15,000.00	N15,000.00
CATEGORY D: Community Pharmacy (Retail)	N15,000.00	N7,500.00		

Retention fee shall be paid before 31st January of every year.

2.—(a) Name and Address of Pharmaceutical Premises :

.....

(b) State the category of practice :

- (i) Manufacturing
- (ii) Importation
- (iii) Distribution
- (iv) Wholesale
- (v) Retail and Dispensing

(Mark Yes or No)

(c) If is an old premises, state the last premise certificate number issued with date.

3. Full Name :

(Surname)

(Other Names in Full)

(a) Date of Qualification :

(b) Current Residential Address :

.....

(c) Last Annual Licence No :

(d) Were you the Superintendent Pharmacist Last Year ?
..... Yes No

(e) If answer to 3(d) No, where were you working in full time employment :
.....

4. Full Name(s) of Director(s) and their profession as in Form C.O.7 :

Full Reg. No. and current Annual
Licence of Pharmacist Directors.

.....
.....
.....

Other Director(s)

.....
.....
.....

5.—(a) The Registrar shall be notified immediately of any change of address of premises or any change of Pharmacist in personal control of the business.

(b) TAKE NOTICE that the Pharmacists Council of Nigeria (PCN) shall claim and recover all costs of litigation incurred by it in defence of any court action instituted against it at the instance of a registered Pharmacist or registered Pharmaceutical Premises, whereby the suit is struck out, withdrawn or the Pharmacist or the Pharmaceutical Premises loses the case.



.....
Signature of Pharmacist-in-Charge

.....
Date

FOR OFFICIAL USE ONLY

- A. FOR THE DESIGNATED OFFICIAL IN THE STATE
- (i) has the premises been duly inspected?
 - (ii) is the inspection report been forwarded?
 - (iii) is the premises or site recommended? Yes or No
 - (iv) Name of the designated official in the State :
 - Signature :
 - Stamp of the Office :
 - Date :

- B. FOR THE COUNCIL SECRETARIAT
- (i) Is the application recommended or rejected?
 - (ii) If rejected, state the reason(s)

Name :

Signature:

Date :

- C. FOR THE REGISTRAR
- (i) the application approved?
 - Signature :
 - Stamp of Office :
 - Date :

.....
 Signature of Registrar



THIRD SCHEDULE

PROCEDURE FOR REGISTRATION OF PHARMACISTS AND PHARMACEUTICAL PREMISES

PREAMBLE

In view of the present re-positioning of the Registry of the Pharmacists Council of Nigeria (PCN) to effectively regulate and control the practice of Pharmacy, it is only proper that various components of the Council's activities are clearly explained in perspective. This informed the presentation of this "procedure for Registration of Pharmacists and Pharmaceutical Premises".

The Council among other functions, is responsible for inspection, approval and licensing of premises where pharmaceutical activities are conducted and among other functions, it is therefore obligatory on the Council to ensure that applicant and stakeholders are properly guided and in accordance with the Act.

This "Procedure for Registration of Pharmacists and Pharmaceutical Premises" is a deliberate attempt to guide Pharmacists and other stakeholders involved in the registration of Pharmaceutical premises on the requirements and steps to be followed.

It is therefore imperative for Pharmacists to avail themselves of this manual, so as to be conversant with the basic procedures for registration with the Council by the following categories of applicants,—

- (a) fresh graduates seeking Provisional Registration ;
- (b) provisionally registered pharmacists wishing to go for Internship Training ;
- (c) Pharmacists seeking full registration ;
- (d) Pharmacists and companies wishing to establish pharmaceutical premises retail, distribution centres or importation ; and
- (e) companies wishing to establish drug manufacturing outlets.

1.0. REGISTRATION AS A PHARMACIST IN NIGERIA

1. 1. *Provisional Registration of Pharmacists Trained in Nigeria :*

(1) A fresh pharmacy graduate from approved institution by the Pharmacists Council of Nigeria shall be inducted and apply to the Registrar of the Council for provisional registration.

(2) Induction ceremony shall be organized by the Dean of Faculty or School of Pharmacy, the Registrar of the Council shall administer the Pharmacist's oath on the graduating pharmacists.

(3) Applicant for provisional registration shall submit to the Registrar the following documents—

- (a) a completed "Form F" duly endorsed by the Dean of School or Faculty of Pharmacy attended by the applicant ;
- (b) Pharmacist's Oath form, duly signed by the applicant and the Registrar,
- (c) statement of result or testimonial ;
- (d) two passport size photographs of the applicant authenticated by the Dean ;
- (d) evidence of payment of fee prescribed by the; and
- (e) birth certificate or sworn affidavit of age declaration.

1.2. PROVISIONAL REGISTRATION OF FOREIGN TRAINED PHARMACISTS GRADUATE

1.2.1. *Definition :*

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

1.2.2. *General Information :*

(1) A foreign pharmacy graduate intending to register in Nigeria shall submit the following documents to the Registrar of the Council—

- (a) a written application for participation in the Foreign Pharmacy Graduate Orientation Programme (FPGOP) ;
- (b) a completed application form with relevant documents ; and
- (c) applicant shall ensure that all relevant supporting documents are submitted and received before the Council published dead line.

Note : Applicants are advised to obtain a copy of the Foreign Pharmacy Graduate Orientation Programme (FPGOP) manual for further details.

1.2.3. *Application for Foreign Pharmacy Graduate Orientation Programme (FPGOP) :*

- (1) Applicant shall complete and submit a current form each time an application is made for FPGOP, regardless of whether applications have been submitted in the past or not.
- (2) The Registry shall notify applicant directly in writing, regarding the status of every application including any deficiency.
- (3) Applicant's name, as it appears on the application form shall be used in all communications with the PCN.

(3) Where an applicant meet all requirements for registration, the candidate will receive letter of acceptance for the FPGOP registration.

1.2.4. Time, Duration, Cost and Venue :

(1) The Programme shall hold twice every year.

(2) The duration of the FPGOP will be 5 weeks comprising of 4 weeks of lectures, practicals, hospital and field visitations and one week of examinations.

(3) The cost of the programme is \$900.00 or its Naira equivalent.

(4) The fees are subject to review without notice.

(5) The venue is usually rotated among the accredited Faculties of Pharmacy in Nigerian Universities and National Institute of Pharmaceutical Research and Development (NIPRID).

1.2.5. Candidates Notice :

(1) Success at the FPGOP examination is not a license to practice pharmacy.

(2) Those who pass the examination may initiate their provisional registration and proceed for the 12 months continuous internship programme after which they will be eligible for registration.

(3) Notwithstanding the provisions of paragraph 1.2.5 (2), those who have evidence of registration in their country of training may be granted registration in line with laid down procedures.

2.1. REGISTRATION FOR NON-NIGERIAN PHARMACIST

A person who is not a citizen of Nigeria may be registered as a pharmacist, where the country of such citizen or such national grants reciprocal registration facilities to Nigeria and the person—

(a) holds a qualification approved by the Council ;

(b) passed the Council's examination in Law and Ethics governing the practice of pharmacy in Nigeria and such other examinations as may be prescribed by the Council before being registered and have acquired the required experience in accordance with section 11 (i) (a) of the Act ; and

(c) has been resident in Nigeria for not less than 12 months immediately preceding the date of his application for registration.

2.2. PHARMACISTS INTERNSHIP TRAINING PROGRAMME

2.2.1. After provisional registration, a pharmacist wishing to be fully registered, shall undergo a mandatory 12 months Internship Programme in an institution approved by the Council for that purpose in compliance with section 11 (i) (b) (iii) of the Act.

2.2.2. The following conditions shall be met for internship training programme by applicant—

- (a) The internee shall at point of induction (oath taking), obtain a copy of the internship training manual and logbook for detailed guidelines ;
- (b) Application shall be made in Form F2 in triplicate, one copy shall be forwarded to the Registrar of the Council within six weeks of the commencement of internship through the PCN State Officer, one copy shall be kept by the Director of Pharmaceutical Services (DPS) and one copy shall be kept with the internship centre ;
- (c) the applicant shall ensure that the institution under which is to undergo the Internship Training is approved by the Council ;
- (d) every institution approved for internship training shall—
 - (i) be inspected by the Council from time to time to ensure compliance with laid down standards ; and
 - (ii) furnish such information as may be required by the Council for the purpose of the pre-registration of internship training.

2.2.3. GENERAL SCOPE OF TRAINING

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

- (a) manipulation of pharmaceutical equipment in common use ;
- (b) recognition by characters of crude drugs and chemical substances used in medicines ;
- (c) manufacture of galenicals and preparation or manufacture of medical products ;
- (d) reading, translation and copying of prescriptions including the checking of prescribed doses (evaluation of prescription) ;
- (e) dispensing (filling of prescription) ;
- (f) proper storage of drugs and medical products ;
- (g) drug storage management ;
- (h) the use of common reference books in the practice of pharmacy ;
- (i) pharmacy management ;
- (j) any other duties that may be assigned by the supervising pharmacist, including rural posting of not more than three months, where necessary ; and
- (k) record keeping under the Poison and Pharmacy Act, Dangerous Drugs Act and the Food and Drugs Act and any other relevant legislations in respect of pharmacy practice ; and
- (l) patient medication profile and patient counseling.

2.2.4. RECORD OF TRAINING

(1) The internee shall use the log book for record keeping of his work and such record shall be regularly inspected and signed by the Supervising Registered Pharmacist and the Director of Pharmaceutical Services of the State is to complete the DPS comment form.

(2) 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.

2.2.3. CERTIFICATE OF EXPERIENCE

On the 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.

2.3. FULL REGISTRATION AS A PHARMACIST

After the completion of the Internship Training, pharmacist seeking full registration shall forward the following documents to the Registrar of the Council—

- (a) duly filled Form D (Certificate of Experience) ;
- (b) Form C (application for registration as a pharmacist) ;
- (c) Form J (application for retention of name in the Register) ; and
- (d) prescribed fees payable to the Council.

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

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

3.0. REGISTRATION AND LICENSING OF PHARMACEUTICAL PREMISES

3.1. *Registration and Licensing of Pharmaceutical Premises*

(1) A registered pharmacist is eligible to apply for the registration of a retail or distribution or importation pharmacy; provided the pharmacist completed his National Youth Service Corps (NYSC) and presents an NYSC Discharge or Exemption Certificate.

(2) The Pharmacist is expected to be up to date with Mandatory Continuing Professional Development (MCPD) programme of Pharmacists Council of Nigeria, if eligible.

(3) For the registration of a pharmaceutical premises, the following documents shall be submitted to the Registrar, Pharmacists Council of Nigeria through the PCN State Officer where the premises is to be located and operated—

- (a) application letter to register the premises ;
- (b) duly filled Form B (PCN Application form for registration of premises) ;
- (c) photocopy of Annual Licence to practice and application for retention of name on the Pharmaceutical Register (Form J) ;
- (d) prescribed inspection and registration fees payable to the Council ;
- (e) letter of resignation from previous employment, if applicable ;
- (f) letter of acceptance of resignation, if applicable ;
- (g) letter of appointment in the new premises, where applicable ;
- (h) legal agreement between the Superintendent Pharmacist and his employer, where applicable ;
- (i) company's Certificate of Incorporation (Evidence of registration of business name is acceptable from Pharmacist-owned retail premises) ;
- (j) Articles and Memorandum of Association (certified copy) ;
- (k) certified true copies of Particulars of Directors as issued by Corporate Affairs Commission (CAC) ;
- (l) photocopy of NYSC Discharge or Exemption Certificate ;
- (m) letter of undertaking by the Superintendent Pharmacist to having only one full time job ;
- (n) 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 ;
- (o) pharmacist's inter-state movement Form (where applicable) ;
- (p) evidence of having at least a Pharmacist on the Board of Directors ; and
- (q) the application shall be accompanied with the Current Annual Licence of the Pharmacist Director.

3.2. REGISTRATION AND LICENSING OF PHARMACEUTICAL MANUFACTURING PREMISES

Same as registration requirement for pharmaceutical premises, however there shall be in addition—

- (a) list of products to be manufactured ;
- (b) organogram ;
- (c) list of staff, qualifications and duties ;
- (d) factory layout ;

- (e) production flow chart ;
- (f) list of equipment in production and quality control department ;
- (g) source and water treatment facilities ;
- (h) water analysis report of raw and treated water ;
- (i) list and sources of suppliers of raw materials and packaging materials ;
- (j) Standard Operating Procedures (SOPs) ;
- (k) Standard Cleaning Procedures ; and
- (l) evidence of payment of inspection fees payable to the Council.

Note : All Correspondences with the Council must be on the Company's letter head paper and on receipt of the above-named documents, inspection of the premises shall be carried out.

3.3. REGISTRATION AND LICENSING OF HOSPITAL PHARMACIES

The following conditions shall be met by applicant seeking for Registration and licensing of hospital pharmacies—

- (a) application letter to register the Pharmacy and form duly completed ;
- (b) photocopy of Annual Licence to practice and application for retention of name of the Superintendent Pharmacist ;
- (c) evidence of payment of prescribed inspection and registration fees to the Council ;
- (d) photocopy of resignation or acceptance letter from previous employment, where applicable ;
- (e) letter of appointment of Superintendent Pharmacist in the new premises, where applicable ;
- (f) agreement between the Superintendent Pharmacist and the employer, where applicable ;
- (g) Company's certificate of incorporation; where applicable ;
- (h) Certified True Copies of Articles and memorandum of association, where applicable ;
- (i) particulars of Directors as issued by Companies and Allied Matters Commission, where applicable ;
- (j) photocopy of NYSC discharge certificate, where applicable ;
- (k) letter of undertaking by the Superintendent Pharmacist to having only one full time job ;
- (l) letter of undertaking by the Managing Director of the Hospital that all pharmaceutical businesses shall be left under the direct, personal control and supervision of the superintendent pharmacist ;
- (m) pharmacist's inter-state movement form, where applicable ;

- (n) list of staff in the hospital pharmacy showing qualification and assigned duties ;
- (o) design layout of the pharmacy ;
- (p) Compilation of Standard Operating Procedures (SOPs) ;
- (r) list of equipment in production and quality control unit, where applicable ;
- (s) list of products being produced by the hospital, compounding or manufacturing unit, where applicable ; and
- (t) the organogram of the hospital.

3.4. REGISTRATION OF PATENT AND PROPRIETARY MEDICINE VENDORS (PPMV) SHOPS

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

3.5. TIME FRAME

(1) The following shall be the time frame for registration and licensing of pharmaceutical premises—

(a) pharmaceutical premises inspected by Pharmaceutical Inspection Committee (PIC) for Importation outlets, Wholesale or distribution premises, retail premises, and PPMV shops ;

(b) on the receipt of an application for registration of premises at State or zonal office, inspections shall be carried out within one month provided necessary documents and evidence of prescribed fees have been paid and evidence of payment submitted ;

(c) the report of the above inspection shall, together with all the relevant documents submitted, be forwarded by the state or zonal office within 10 working days with the recommendation of the Pharmaceutical Inspection Committee (PIC) to the Registrar of the Council ;

(d) upon receipt of the documents by the Registrar, the premises shall be issued with a licence within 21 working days; provided all documents submitted complied with the requirements for the registration of such premises.

(2) Registration of manufacturing premises shall be 2 weeks after the inspection report has been forwarded to the Registrar of the Council with necessary documents and submission of evidence of payment of the prescribed fees.

(3) Registration of hospital pharmacy shall be 2 weeks after the inspection report has been forwarded to the Registrar of the Council with necessary documents and submission of evidence of payment of the prescribed fees.

B 3005

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

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