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PHARMACISTS' COUNCIL OF NIGERIA ACT
CAP. C17 L. 10
ONLINE PHARMACY REGULATIONS, 2021



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

ONLINE PHARMACY REGULATIONS, 2021



(19th Day of July, 2021)

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PHARMACY ACT, 1967
ONLINE PHARMACY REGULATION, 2021



GOVERNMENT OF INDIA

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S. L. No. 58 of 2021

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

ONLINE PHARMACY REGULATIONS, 2021

[19th Day of July, 2021]

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 Poisons and Pharmacy Act, (Cap. 535 LFN) 2004 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 AND LICENSING

1. Internet based Pharmaceutical Service providers in Nigeria shall be registered with the Pharmacists Council of Nigeria.

2. Application for registration of online pharmaceutical services shall be made to the Registrar, Pharmacists Council of Nigeria by the Superintendent pharmacist specifically designated for the online pharmaceutical service, who shall complete the application form, accompanied with the following documents—

- (a) application letter for registration of online pharmaceutical services ;
- (b) current annual licence of the Superintendent Pharmacist ;
- (c) photocopy of the current premises registration licence or evidence of current registration of the premises, as applicable to existing pharmacies ;
- (d) evidence of payment of prescribed fees to the Council ;
- (e) letter of resignation from previous employment, where applicable ;
- (f) letter of acceptance of resignation, where applicable ;
- (g) letter of appointment as the Superintendent Pharmacist in the new premises, where applicable ;
- (h) legal agreement between the Superintendent Pharmacist in the new premises and the owner of the pharmaceutical premises, where applicable ;
- (i) Company's Certificate of Incorporation (evidence of registration of business name is acceptable for pharmacist-owned retail premises) ;
- (j) Articles and Memorandum of Association ;
- (k) certified true copies of CAC documents showing names and particulars of Directors ;

Commence-
ment.Registration
Authority.Application
for
registration
of online
Pharmacy.

(l) NYSC Discharge or Exemption Certificate ;

(m) an undertaking by the Superintendent Pharmacist to be held accountable for the services provided on the online pharmacy platform ;

(n) an undertaking by the Managing Director of the online Company to the effect that online pharmaceutical services shall be under the direct control and management of the Superintendent Pharmacist, where applicable ; and

(o) policy documents, which shall include procedures and processes for all operations of the internet services.

Names and qualifications of Superintendent Pharmacists and other professionals.

3.—(1) The name and qualification of Superintendent Pharmacist and all other professionals involved in the operation of the online pharmacy shall be made available online.

(2) The address where the online pharmacy is located physically shall be visible online.

Licensing of Online Pharmacy.

4.—(1) The Council is empowered to issue licence to all registered internet based pharmaceutical service providers based in Nigeria.

(2) The Council shall issue or grant licence to registered internet based Pharmaceutical Services Providers in Nigeria in line with Good Pharmacy Practice (GPP).

(3) Upon registration and licensing of an online site, the site shall be eligible to the Council Registered Online Pharmacy Sites Emblem (ROPSE).

Renewal of premises licence.

5.—(1) Online Pharmacy licence shall expire on the 31st day of December of every year and be due for renewal on the 1st day of January of the following year.

(2) The procedure for licensing and renewal shall be as prescribed in the Registration Guidelines made pursuant to the provisions of these Regulations.

Change or variation of licence.

6. An internet based licensed Pharmaceutical Service Provider shall make application to the Registrar of the Council within 30 days for approval of change, variation or modification in a licence in respect of Superintendent Pharmacist, sites, platform, scope and areas of practice or any other change or variation in a licence.

Suspension, Revocation, Withdrawal or Cancellation of licence.

7. —(1) Where there is a breach of the provisions of these Regulations or the Act by the Holder of a Licence, the Council may suspend or revoke or withdraw or cancel the licence.

(2) The Council shall update and keep records of alteration made to an existing licence issued.

8.—(1) Where an Internet Based Pharmaceutical Service Provider intends to close down its operations, shall notify the Council of this intention not later than 14 days to the date of cessation of operations.

Closure of facility.

(2) Where the closure is intended to be temporary, the period of closure shall not exceed 12 months and the renewal fees shall be paid for the period of the closure after which further request for renewal may not be granted.

9. Every Internet Based Pharmaceutical Service provider shall comply with relevant laws relating to Information and Communication Technology in Nigeria.

Compliance with Information and Communication Technology laws.

PART II—INSPECTION, MONITORING AND ENFORCEMENT

10.—(1) Upon submission of registration documents, the Council shall carry out inspection of the Internet Based Pharmaceutical Service providers and shall from time to time carry out follow up inspections throughout the supply chain and accredited inspectors appointed by the Council shall have the powers in the course of carrying out their duties, at reasonable times and upon production of their identity cards, to—

Inspection, Monitoring and Enforcement of Online Pharmacy.

(a) enter any premises, which hosts the internet-based pharmaceutical service provider or visit the online platform or site through the use of such force and technology as is necessary, reasonably believed or suspected that an article to which these Regulations apply is stored, sold or dispensed ;

(b) examine any article or records in the premises or internet based-pharmaceutical service provider's site to which these Regulations apply, reasonably believed or suspected to be used or is capable of being used for the manufacture, preparation, preservation, storage or sale of items covered by the Act ;

(c) access the backend of the site or platform and examine records of activities relating to the internet-based services that is reasonably believed or suspected to be a breach of these Regulations ;

(d) examine books, documents or records found on the premises or sites or platforms that is reasonably believed or suspected to contain information relevant to the enforcement of these Regulations and make copies ;

(e) retrieve and process information from the internet site that is reasonably believed or suspected to have violated the provisions of these Regulations ; and

(f) seal any unregistered or unlicensed internet-based pharmaceutical service provider's premises or a site, where access to records and documents or articles is not granted by the operator.

(2) The owner or person in charge of the internet pharmaceutical services or anybody found representing the company online shall give all necessary assistance to the pharmaceutical inspectors including making available all such information as they may require for the purpose of enforcing these Regulations.

(3) Record retrieved from the premises or internet site of a pharmaceutical services provider pursuant to these Regulations may be submitted to any certified analyst for examination, after which the analyst shall issue a report.

PART III—OPERATION OF ONLINE PHARMACY

Operations.

11. Every internet-based pharmaceutical service provider shall operate in line with best practices and within relevant Regulations in the telecommunication Industry.

Communication.

12. Every internet-based pharmaceutical service provider shall make the site user friendly and interactive so as to ensure the mechanisms for—

- (a) consultancy services to patients or clients ;
- (b) educating patients regarding the medications and disease states ;
- (c) contacting patients regarding delays in delivering prescriptions as well as feedback and recalls ; and
- (d) reporting adverse drug reactions and medication errors.

Dispensing Prescription-Only-Medicines.

13. Internet based pharmaceutical service providers shall ensure implementation of Good Pharmacy Practice on their sites with regard to dispensing of Prescription-Only-Medicines among others as follows—

- (a) a system to ensure the integrity and legitimacy of prescription drug orders ;
- (b) process and procedure to authenticate the validity of a prescription and confirm that it is from a licensed health professional before dispensing same ;
- (c) policy to prevent medication from being prescribed or dispensed based on telephonic or online medical consultation ; and
- (d) systems to ensure restriction on the quantity of prescribed medicines that can be ordered or sold online.

Dispensing Over-the-Counter Drugs (OTC).

14.—(1) Sales of OTC drugs shall comply with relevant laws regarding the sales and dispensing of the drugs.

(2) Dangerous drugs as contained in the Dangerous Drugs Act (CAP. 9, 1935) shall not to be sold online.

Advertisement.

15.—(1) Only OTC medications shall be advertised publicly.

(2) Classes of drugs available can be made public.

16. Internet-Based Pharmaceutical Service Providers shall institute—

(a) policies, procedures and technology to protect patient information and confidentiality when such information is transmitted over the internet ;

(b) procedures to ensure reasonable verification of the identity of the patient and prescriber ; and

(c) maintenance of patient medication profiles, where possible.

Patient
Information.

17. Internet-Based Pharmaceutical Service Providers shall—

(a) provide systems for safe and secure delivery of all medications ;

(b) ensure that the right temperature for storage of drug is maintained during mailing and delivery ;

(c) ensure that the medication remains in a tamper-evident containers until it is delivered ;

(d) ensure that right medication is mailed to patient with appropriate labels ;

(e) develop full audit trail for delivery of medication, which should include signature on delivery ; and

(f) ensure that all medicines including thermolabile products are transported in line with Good Distribution Practice.

Storage and
Delivery of
Drugs.

PART IV—GENERAL PROVISIONS

18.—(1) Registered internet based pharmaceutical service providers shall display only the Pharmacists Council of Nigeria (PCN) Prescribed Emblem.

Registered
Internet
Pharmaceu-
tical Service
Providers.

(2) Where there is no online Superintendent Pharmacist, there shall be a resident or locum pharmacist to take charge of the internet services.

(3) A request for temporary closure of internet sites shall be for a maximum period of 12 months and the renewal fees shall be paid for the period of the closure after which further request for renewal during the closure may not be granted.

(4) The fees payable in respect of registration of any Internet Based Pharmaceutical Service Provider shall be as prescribed by the Council.

19.—(1) A Registered sites that fails, refused or neglect 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 fees.

Penalties for
late payment
of practicing
fees and fees
for
registration
of online
pharmacy.

(2) An unregistered Online Internet Pharmaceutical Service Providers premises and sites shall be closed by the Council.

Payment of inspection fee.

20. Inspection of any sector of the Pharmaceutical Industry for registration shall attract a fee as prescribed by the Council

The PCN emblem.

21.—(1) The Council may prescribe a Pharmacy emblem for the usage of its members.

(2) Where an emblem of the Council is found in an unauthorized internet site or platform such site or platform shall be closed down.

(3) A person shall not display any emblem or licence not prescribed by the Council.

(4) A person who display an emblem or licence not prescribed by the Council commits an offence and shall be liable to pay to the Council a penalty of not less than N250,000.00 in addition to closure of the site or platform.

(5) A pharmacist shall only register one internet-based platform, any pharmacist who registers or attempt to register more than one premises, commits an offence and shall—

(a) have the online site closed down in line with prescribed PCN Inspection of Pharmaceutical Premises Guidelines or Regulations ;

(b) be referred to the Investigating Panel ; and

(c) be referred to the Disciplinary Tribunal of the Council for appropriate action as may be determined by the Investigating Panel.

Offences and Penalties.

22.—(1) A person who carries out unauthorized internet-based disposal of drugs shall be penalized in accordance with these Regulations.

(2) A person who displays, produces or uses fake pharmaceutical licences or online registration certificate or emblem shall be guilty of an offence.

(3) A person who contravenes or fails to comply with the provision of these Regulations shall be guilty of an offence and shall be liable on conviction to an imprisonment for a term of not less than 6 months or fine of not less than N250,000 or to both.

Interpretation.

23. In these Regulations,—

“the Council “ means Pharmaceutical Council of Nigeria (PCN) ;

“Disciplinary Tribunal” means the Tribunal established in accordance with the provision of Section 17 (1) of the PCN Act ;

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

“Online Pharmacy” means an internet dependent Pharmaceutical Services ;

“PCN Act or the Act” means Pharmacists Council of Nigeria Act Cap P17 LFN 2004 ;

"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 ;

"Prescribed fees" means such fees as approved by the Council; and
ICT means Information and Communication Technology.

24. These Regulations shall be cited as the Online Pharmacy Regulations, 2021. Citation.

Processing Fee (Non-Refundable)

CATEGORY	Application Fee	Registration Fee	Renewal Fee	Annual Fee
Manufacturing (Pharmaceuticals)	₦10,000	₦50,000	₦20,000	₦10,000
DISTRIBUTION (Wholesale)	₦5,000	₦25,000	₦10,000	₦5,000
Dispensing (Retail)	₦2,000	₦10,000	₦4,000	₦2,000

B 2978

FIRST SCHEDULE

PHARMACIST COUNCIL OF NIGERIA

APPLICATION FOR REGISTRATION OF PREMISES ONLINE



**Coloured
Passport
Size
Photograph**

Name and Address of Premises :

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

**Name of Registered Pharmacist
Having control of the Business**

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

Telephone :

E-mail :

I apply for registration and enclose :

(State all documents enclosed)

Signature :

Date :

Please complete the form appropriately

SECOND SCHEDULE

PHARMACISTS COUNCIL OF NIGERIA

APPLICATION FOR REGISTRATION OF NEW PREMISES OR SITE
AND RETENTION OF OLD PREMISES OR SITE

FORM B

This application shall 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

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

Processing Fee (Non Refundable)

Class	New	Renewal	Inspection Fees Location	Approval
MANUFACTURERS				
CATEGORY A - Manufacturing (3 or more Product lines)	N300,000.00	N200,000.00	N250,000.00	
CATEGORY B - Manufacturing (2 Product line)	N200,000.00	N150,000.00	N200,000.00	
CATEGORY C - Manufacturing (1 Product line)	N100,000.00	N100,000.00	N100,000.00	

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 Facility Unit	N500,000.00	N350,000.00	N500,000.00	N20,000.00
B2 Mega Drugs Distribution Centre	N500,000.00	N350,000.00	N100,000.00	N20,000.00
B3 State Drugs 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: Retails	N15,000.00	N7,500.00		

Every retention fee must be paid before 31st January each 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 make a claim and recover all costs of litigations incurred to defend any court action instituted against it at the instance of any registered Pharmacist or registered Pharmaceutical Premises and where 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 forwarded ?.....

(iii) Is the premises or site recommended ? Yes or No

(iv) Name of the designated official in the State :.....

Signature :.....

Stamp of 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

Is the application approved ?

Signature :

Stamp of Office :

Date :

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

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

