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The following is published as Supplement to this Gazette:

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Pharmacists Council of Nigeria Online Pharmacy Regulations, 2020

S.1.14 of 2020

PHARMACISTS COUNCIL OF NIGERIA
(CAP. P17 L.F.N. 2004)
PHARMACISTS COUNCIL OF NIGERIA ONLINE PHARMACY REGULATIONS, 2020
Commencement: July, 2020

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

PART A: REGISTRATION AND LICENSING

Registration
Authority

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

Application for
registration of
online
Pharmacy

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 which shall be accompanied by 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 (in the case of existing pharmacies)
- (d) Evidence of payment of prescribed fees to the Council;
- (e) Letter of resignation from previous employment (if applicable);
- (f) Letter of acceptance of resignation (if applicable);
- (g) Letter of appointment as the Superintendent Pharmacist in the new premises (if applicable);
- (h) Legal agreement between the Superintendent Pharmacist in the new premises and the owner of the pharmaceutical premises (if 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;

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- (k) Certified true copies of CAC documents showing names and particulars of Directors;
- (l) NYSC Discharge or Exemption Certificate;
- (m) An undertaking by the Superintendent Pharmacist to the effect that he is to be held accountable for the services provided on the online pharmacy platform(s);
- (n) An undertaking by the Managing Director of the online Company to the effect that online pharmaceutical services shall be under the direct, personal 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. The names and qualifications of superintendent pharmacist and all other professionals involved in the operation of the online pharmacy must be made available online.

4. The address where the online pharmacy is located physically must be visible online.

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

Licensing of online Pharmacy

(2) The Council may issue/grant licences to all registered internet base Pharmaceutical services providers in Nigeria in line with Good Pharmacy Practice (GPP).

(3) Upon registration and licensing the online site must have the prescribed PCN Registered Online Pharmacy Sites Emblem (ROPSE).

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

Renewal of premises licence

(5) A licensed internet based 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 that may affect the licence.

Change or variation of licence

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Suspension,
Revocation,
Withdrawal or
Cancellation of
licence

- (5) Where there is a breach of any of the provisions of these Regulations or the Act by the holder of a licence, the Council is empowered to suspend, revoke, withdraw or cancel the licence.
- (6) The Council is empowered to make and keep an update of any alteration to the issued licence.

Closure of
facility

6. (1) Every internet based pharmaceutical service provider shall notify the Council of his intention to close down operations not later than 14 days to the date of cessation of operations.
- (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

Compliance
with ICT laws

7. Every internet based pharmaceutical service provider shall comply with the provisions of the laws relating to Information and Communication Technology in Nigeria

PART B: INSPECTION, MONITORING AND ENFORCEMENT

Inspection,
Monitoring and
Enforcement of
Online
Pharmacy

8. (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. 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 if so required to:
 - (a) enter any premises which hosts the internet-based pharmaceutical service provider or visit the online platform/site through the use of such force and technology as is necessary when they reasonably believe or suspect that an article to which these Regulations apply is stored, sold, or dispensed therein;
 - (b) examine any article or records in the premises/internet based-pharmaceutical service provider's site to which these Regulations apply which they reasonably believe or suspect is 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 to examine records of activities relating to the internet-based services where they reasonably believe or suspect a breach of these Regulations;

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- (d) examine any books, documents or other records found on the premises/sites or platforms which they reasonably believe or suspect may contain information relevant to the enforcement of these Regulations and make copies thereof;
 - (e) retrieve and process any information from the internet site when they reasonably believe or suspect that any provisions of these Regulations have been contravened;
 - (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 this Regulations.
- (3) Any record retrieved from the premises or internet site pursuant to this Regulation may be submitted to any certified analyst for examination. The analyst on making such examination shall issue a report setting out the result of such examination.

PART C. OPERATION OF ONLINE PHARMACY

- Operations **9.** Every internet-based pharmaceutical service provider shall operate in line with global best practices.
- Communication **10.** Every internet-based pharmaceutical service provider shall make the site user friendly and interactive so as to ensure the following mechanisms for:
- a. contacting patients regarding delays in delivering prescriptions as well as feedback and recalls.
 - b. educating patients regarding the medications and disease states.
 - c. consultant services to patients/clients
 - d. reporting adverse drug reactions and medication errors.
- Dispensing Prescription Only Medicines **11.** 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:

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- a. a system shall be in place to ensure the integrity and legitimacy of prescription drug orders.
- b. processes and procedures shall be in place to authenticate the validity of a prescription and confirm that it is from a licensed health professional before dispensing.
- c. policy must prevent medication from being prescribed or dispensed based on telephonic or online medical consultation.
- d. systems shall be in place to ensure restriction on the quantity of Prescribed of Medicines that can be ordered or sold online.

Dispensing
Over the
Counter
Drugs

12. Sales of OTC drugs must comply with all Federal Government laws regarding sales and dispensing of OTC drugs.

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

Advertisement

14

- a. Only OTC medications shall be advertised publicly.
- b. Classes of drugs available can be made public.

Patient
Information

15. Internet-based pharmaceutical service providers shall institute the following:

- 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.
- c. maintenance of patient medication profiles where possible.

Storage and
Delivery of
Drugs

16. 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 is maintained during mailing and delivery.
- c. ensure that the medication remains in a tamper-evident containers until it is delivered.
- d. ensure that the right medication is mailed to patient with appropriate labels.
- e. develop a full audit trail for delivery of medication which should include signature on delivery.
- f. Ensure that all medicines including thermolabile products are transported in line with GDP.

PART D: GENERAL PROVISIONS

General
provisions

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17. (1) Registered internet based pharmaceutical service providers shall display only the Pharmacists Council of Nigeria (PCN) Prescribed Emblem.
- (2) In the absence of the online Superintendent Pharmacist, there shall be a resident/ locum pharmacist to take charge of the internet services.
- (3) Any 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 the registration of any internet based pharmaceutical service provider shall be as prescribed or reviewed by Council.

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

18. (1) Any Registered sites 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% (fifty per cent) of the applicable fee as late payment fees.
- (2) All unregistered online internet pharmaceutical service providers premises and sites shall be closed.

Closure

Payment of Inspection fee

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

The PCN emblem

20. (1) The Council may prescribe a Pharmacy emblem.
- (2) Where a Council prescribed emblem is found in an unauthorized internet site / platform such site / platform shall be closed down.
- (3) The display of any emblem or licence not prescribed by the Council is an offence and shall attract a charge of not less than N250,000.00 (Two Hundred and Fifty Thousand Naira) in addition to closure of the site or platform.
- (4) A pharmacist shall register only one internet based platform. Any pharmacist who registers or attempt to register more than one premises, commits an offence and shall:
 - (a) have his online site closed ~~down~~ in line with prescribed PCN Inspection of Pharmaceutical Premises Guidelines;
 - (b) be referred to the Investigating Panel and;
 - (c) be referred to the Disciplinary Tribunal of the Council for appropriate action as determined by the Investigating Panel.

Offences and penalties

21. (1) Any person who carries out unauthorized internet based disposal of

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drugs shall be penalized in accordance with these Regulations.

- (2) Any person who displays, produces or uses fake pharmaceutical licences or online registration certificate / emblem is guilty of an offence.
- (3) Any person who contravenes or fails to comply with any 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 (Two Hundred and Fifty Thousand Naira) or both.

22. In these Regulations, unless the context otherwise requires:

- (a) "Online Pharmacy" is any internet dependent Pharmaceutical Services
- (b) "Pharmacists Council of Nigeria Emblem" means the symbol as prescribed by the Council and patented by the Registrar of Patents and Trade Marks.
- (c) Ethical Products means products that are obtained on prescription-only
- (d) "Prescribed fees" means such fees as approved by the Council
- (e) "Prescribed Emblems" means such emblems produced and approved by the Council
- (f) "Disciplinary Tribunal" means the Tribunal established in accordance with the provision of Section 17 (1) of the PCN Act.
- (g) "PCN Act or the Act" means Pharmacists Council of Nigeria Act Cap P17 LFN 2004

Interpretation

23. These Regulations may be cited as the Registration of internet based Pharmaceutical services provider Regulations, 2020.

Citation

Dr. E. Osagie Ehanire, MD, FWACS.

*The Honourable Minister
Federal Ministry of Health
Federal Secretariat Complex
Phase III
P.M.B. 083, Garki
Abuja*

Schedule A

Pharmacists Council of Nigeria Online Pharmacy Regulations, 2020



PHARMACISTS COUNCIL OF NIGERIA
APPLICATION FOR REGISTRATION OF PREMISES/SITE



Recent
Coloured Passport
Size Photograph

Name of Premises
(Block Letters)

.....
.....

Name of Registered Pharmacist
having control of the Business

Address of Premises

(Surname) (Other Names in Full)

Full Reg. No. of Pharmacists

Telephone: _____

.....

E-mail: _____

I apply for registration and enclose: _____
(State all documents enclosed)

Signature: _____

Date: _____

Please complete the form appropriately

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PHARMACISTS COUNCIL OF NIGERIA APPLICATION FOR REGISTRATION OF NEW PREMISES/SITE AND RETENTION OF OLD PREMISES/SITE

FORM B

(Under the Pharmacists Council of Nigeria Act Cap P17 LFN 2004)

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

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				
CATERGORY A: Manufacturing (3 or more Product lines)	N300,000.00	N200,000.00	N250,000.00	
CATERGORY B: Manufacturing (2 Product line)	N200,000.00	N150,000.00	N200,000.00	
CATERGORY C: Manufacturing (1 Product line)	N100,000.00	N100,000.00	N100,000.00	
DISTRIBUTORS				
CATERGORY 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
CATERGORY B:				
B1 (a) Coordinated Wholesales	N1,000,000.00	N500,000.00	N1,000,000.00	N200,000.00

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Centre Facility B1 (b) Coordinated Wholesales Centre Facility Unit	N500,000.00	N350,000.00		
	N500,000.00	N350,000.00	N500,000.00	N20,000.00
B2 Mega Drugs Distribution Centre	N200,000.00	N100,000.00	N100,000.00	N20,000.00
B3 State Drugs Distribution Centre	N150,000.00	N100,000.00	N50,000.00	N20,000.00
CATEGORY C: Wholesales/ Distribution	N15,000.00	N7,500.00	N15,000.00	N15,000.00
CATEGORY D: Retails				

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 _____
(Mark Yes or No)

(ii) Importation _____

(iii) Distribution _____

(iv) Wholesaling _____

(v) Retail and Dispensing _____

(c) If 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 No to 3(d) where were you working in full time employment:

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

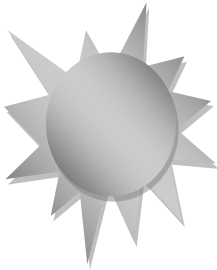
Full Reg. No and current Annual
Licence of Pharmacist Director(s)

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 by it in defence of any court action instituted against it at the instance of any registered Pharmacist and/or registered Pharmaceutical Premises and 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/site been duly inspected?

(ii) Is the inspection report forwarded _____

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

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: _____

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Stamp of Office: _____

Date: _____

Dr. E. Osagie Ehanire, MD, FWACS.

*The Honourable Minister
Federal Ministry of Health
Federal Secretariat Complex
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Abuja*