*Extraordinary*


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# PHARMACY COUNCIL OF NIGERIA (ESTABLISHMENT) ACT, 2022

## ELECTRONIC PHARMACY REGULATIONS, 2026

ARRANGEMENT OF REGULATIONS

*Regulation* :

# PHARMACY COUNCIL OF NIGERIA (ESTABLISHMENT) ACT, 2022

## ELECTRONIC PHARMACY REGULATIONS, 2026

ARRANGEMENT OF REGULATIONS

*Regulation* :

Application

**2.** These Regulations shall apply to all electronic pharmacy services and operations in Nigeria.

PART II — REGISTRATION AND LICENSING

Registration authority

**3.**—(1) An electronic pharmacy in Nigeria shall be registered with the Pharmacy Council of Nigeria.

(2) Electronic pharmacy includes —

(*a*) electronic pharmaceutical service providers; and

(*b*) electronic pharmacy aggregators.

Application for registration as an electronic pharmaceutical service provider

**4.**—(1) An application for registration as an electronic pharmaceutical service provider shall be made to the Registrar of the Council by the Superintendent Pharmacist specifically designated to oversee the pharmaceutical service delivery and operations of the electronic pharmacy.

(2) The application for registration as an electronic pharmaceutical service provider shall include —

(*a*) application letter for registration of the electronic pharmaceutical service provider;

(*b*) company certificate of incorporation with the Corporate Affairs Commission or evidence of registration of business name, for pharmacist-owned retail premises engaging in online pharmacy practice;

(*c*) Certified True Copy of the articles and memorandum of association in the case of a company;

(*d*) Certified True Copy of any documents showing the names and particulars of Directors of the company;

(*e*) Standard Operating Procedure or policy documents which shall include the procedures and processes for all operations of the electronic pharmacy to ensure clarity and consistency in how the electronic pharmacy is managed and utilised;

(*f*) evidence of payment of the prescribed fee to the Council;

(*g*) letter of appointment of the Superintendent Pharmacist who shall be responsible for overseeing the pharmaceutical service delivery and operations of the electronic pharmacy;

(*h*) legal agreement between the Superintendent Pharmacist and the owner of the pharmaceutical premises where applicable;

(*i*) current annual Licence of the Superintendent Pharmacist, where applicable;

(*j*) letter of resignation and acceptance from previous employment, where applicable;

(*k*) Certificate of National Youth Service Corps (NYSC) or Certificate of Exemption;

(*l*) copy of the current premises registration certificate or evidence of current registration of the premises where applicable;

(*m*) in the case of an application for registration by an electronic pharmaceutical service provider without a physical premises, evidence of a partnership agreement between the electronic pharmaceutical service provider and a licenced physical retail pharmacy, wholesaler, or distributor, detailing the roles and responsibilities of parties with a copy of the current premises registration certificate or evidence of current registration of partners' pharmaceutical premises;

(*n*) service level agreement between the electronic pharmaceutical service provider and electronic pharmacy aggregator showing the responsibility of each party, where applicable;

(*o*) an undertaking by the Managing Director of the electronic pharmacy that the electronic pharmaceutical service delivery shall be under the direct control and management of the Superintendent Pharmacist, where applicable;

(*p*) an undertaking by the Superintendent Pharmacist of the electronic pharmaceutical service provider, to be held accountable for the pharmaceutical service delivery and operations provided —

(*i*) by the electronic pharmacy,

(*ii*) through the pharmaceutical premises that the electronic pharmaceutical service provider is in partnership with, or

(*iii*) through an electronic pharmacy aggregator's platform; and

(*q*) any other requirement which the Council may determine.

(3) The registration of an electronic pharmaceutical service provider shall be subject to the appointment of a Superintendent Pharmacist who shall oversee the professional service delivery and operations of the electronic pharmacy as required by the Pharmacy Council of Nigeria (Establishment) Act, 2022 and other Regulations made thereunder.

(4) In the case of a partnership agreement as provided under paragraph (*m*) of subregulation (2) of this regulation, the partners shall comply with all requirements set out by the Council as it relates to pharmaceutical premises including the Pharmaceutical Premises Location, Inspection, Structure, Monitoring and Enforcement Regulation, 2021 and any relevant Regulations.

(5) A copy of any revision, amendment or alteration made to the service level agreement entered under paragraph (*n*) of subregulation (2) of this regulation shall be forwarded to the Council within 30 days.

(6) Within six months from the commencement of these Regulations, all previously registered electronic pharmaceutical service providers, shall submit any additional registration documents specified in subregulation (2) of this regulation.

(7) The Council shall digitalise the registration process, to enhance the efficiency and seamlessness of the registration procedure.

Licensing of Electronic Pharmacy

**5.**—(1) The Council shall issue or grant an electronic pharmacy licence to electronic pharmaceutical service providers in Nigeria —

(*a*) on meeting the registration requirements; and

(*b*) in line with Good Pharmacy Practices (GPP).

(2) An electronic pharmaceutical services provider is eligible to obtain an electronic pharmacy licence, where the electronic pharmaceutical service provider —

(*a*) registers with the Council in accordance with regulation 4 of these Regulations;

(*b*) has a registered and licenced pharmaceutical premises in Nigeria, or a partnership agreement as stipulated under subregulation (2) of regulation 4 of these Regulations which shall comply with all relevant laws and regulations;

(*c*) demonstrates compliance with Good Pharmacy Practices (GPP);

(*d*) maintains appropriate storage conditions for pharmaceutical products in accordance with established standards;

(*e*) adheres to telemedicine guidelines and protocols, ensuring that e-pharmacy services, as well as remote prescribing, are conducted ethically and in compliance with applicable laws; and

(*f*) fulfils any other requirement which the Council may determine.

(3) The Council may conduct, a periodic review of the licensing requirements provided in subregulation (2) of this regulation.

(4) An electronic pharmacy with an electronic pharmacy licence, shall utilise the nodal platform of the Council as a gateway.

(5) The Council may grant the public access to relevant information of registered electronic pharmaceutical service providers.

Renewal of Electronic Pharmacy Licence

**6.**—(1) The Licence of an electronic pharmaceutical service provider 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 renewal shall be as prescribed in the guidelines made pursuant to these Regulations.

Electronic pharmacy aggregators

**7.**—(1) An electronic pharmacy aggregator shall be required to register with and be licenced by the Council as set out in these Regulations.

(2) The failure of an electronic pharmacy aggregator to obtain an operating licence as required by this regulation is an offence under these Regulations.

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Application for registration as an electronic pharmacy aggregator

**8.**—(1) Application for registration as an electronic pharmacy aggregator shall be made to the Registrar of the Council by the Superintendent Pharmacist specifically designated to oversee the pharmaceutical service delivery and operations of the aggregator platform.

(2) An application for registration as an electronic pharmacy aggregator shall include —

(*a*) company Certificate of Incorporation with the Corporate Affairs Commission;

(*b*) Certified True Copy of Articles and Memorandum of Association of the company;

(*c*) Certified True Copy of any documents showing the names and particulars of directors of the company as contained in the incorporation documents;

(*d*) board resolution to commence an electronic pharmacy aggregator operation;

(*e*) policy documents including procedures and processes for all operations of the technological infrastructure such as websites or applications;

(*f*) service level agreement between the electronic pharmacy aggregator and potential electronic pharmaceutical service provider showing the responsibility of each party;

(*g*) Certificate of registration with the Nigeria Information Technology Development Agency, or such other agency charged with the statutory responsibility to regulate information technology development in Nigeria;

(*h*) Certificate of registration with the Nigeria Data Protection Commission ; and

(*i*) any other requirement which the Council may determine.

(3) An electronic pharmacy aggregator shall display its registered address and the telephone number of the Superintendent Pharmacist on its platform.

Licensing of an electronic pharmacy aggregator

**9.**—(1) The Council shall issue licence to all registered electronic pharmacy aggregators in Nigeria on meeting the registration requirements.

(2) An electronic pharmacy aggregator is eligible to obtain an electronic pharmacy aggregator Licence where the electronic pharmacy aggregator provides —

(*a*) evidence of registration with the Council in accordance with regulation 8 of these Regulations;

(*b*) evidence of payment of prescribed licensing fee to the Council;

(*c*) Curriculum Vitae including the current practice Licence of the Superintendent Pharmacist;

(*d*) evidence of the principal place of business of the electronic pharmacy aggregator and confirmation of place of hosting the technological infrastructure;

(*e*) final prototype showing contents of the platform or proposed platform;

(*f*) details of the technological infrastructure underpinning the platform;

(*g*) a copy of the Risk Management Framework which shall include authentication of products and users, platform failure, and processes or tools to detect contraventions of these Regulations by electronic pharmaceutical service providers as provided under regulation 10 of these Regulations;

(*h*) an agreement to link the electronic pharmacy aggregator platform legally and technically to the National Electronic Pharmacy Platform of the Council; and

(*i*) any other requirement which the Council may determine.

(3) The Council may conduct a periodic review of the licensing requirements provided under subregulation (2) of this regulation.

(4) The Licence of an electronic pharmacy aggregator 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.

(5) The procedure for renewal shall be as prescribed in the Guidelines made pursuant to these Regulations.

Suspension of Services by the electronic pharmacy aggregator

**10.** The electronic pharmacy aggregator, in carrying out the management and maintenance of a platform shall promptly report to the Council and suspend the provision of technological infrastructure such as websites or applications to the electronic pharmaceutical service provider and ultimately cease the display of relevant drug information, in the case of —

(*a*) sale of medicines without the requisite registration with the Council;

(*b*) sale of medicines without a prescription where required;

(*c*) sale of prescription drugs beyond the limit contemplated by these Regulations;

(*d*) operating despite revocation, suspension, or withdrawal of the Licence of an electronic pharmaceutical service provider by the Council; or

(*e*) any other act which the Council may determine.

Obligation of the electronic pharmacy aggregator to cooperate with the Council

**11.**—(1) An electronic pharmacy aggregator shall comply with such directives issued by the Council as it relates to hosting the operations of an electronic pharmaceutical service provider.

(2) The electronic pharmacy aggregator shall cooperate with the Council when the Council carries out necessary inspection and monitoring of electronic pharmaceutical service providers as provided under these Regulations.

(3) Where the Council finds that the electronic pharmaceutical service provider has conducted acts not in conformity with requirements under these Regulations or the Pharmacy Council of Nigeria (Establishment) Act, 2022 through the platform or website, the electronic pharmacy aggregator, on being notified by the Council shall immediately cease the display of the electronic pharmacy on its platform and carry out such acts as may be required by the Council.

Requirements to be displayed on the electronic pharmacy site

**12.** The electronic pharmaceutical services provider shall make available on the electronic pharmacy site —

(*a*) the name, full registration number, and licensing status of the Superintendent Pharmacist and all other professionals involved in the operation of the online pharmacy platform on its home page;

(*b*) the registered address of the pharmaceutical premises with which the electronic pharmacy is licenced, and the designated address of the electronic pharmaceutical service provider, where it is different from the registered address of the pharmaceutical premises;

(*c*) the telephone number and email address of the electronic pharmacy;

(*d*) unless revised by the Council, a declaration to the effect that "the electronic pharmaceutical service provider will only dispense Prescription Only Medicines to a person who has a valid prescription issued by a licenced health care professional or authorised prescriber, having a physical address and contact details in Nigeria";

(*e*) the registration number of the pharmaceutical premises with which the electronic pharmacy is licenced, on its home page;

(*f*) the Licence number of the online pharmacy on its home page;

(*g*) details of how to make a complaint about the electronic pharmaceutical service provided;

(*h*) the authorised PCN logo;

(*i*) contact information of the Council; and

(*j*) any other requirement which the Council may determine.

Change or variation of Licence

**13.** An electronic pharmaceutical service provider shall make application to the Registrar of the Council within 30 days of the change or variation, for approval of change, variation or modification in a Licence in respect of a Superintendent Pharmacist, sites, platform, scope and areas of practice or any other change or variation in a Licence.

Suspension, revocation, and withdrawal of Licence

**14.**—(1) Where there is a breach of the provisions of these Regulations or the Act by the holder of a Licence, or where the electronic pharmaceutical service provider has provided false information or misrepresented information for the purpose of obtaining registration and licensing, the Registrar shall issue a notice of breach to the electronic pharmaceutical service provider requiring it to give reasons within 14 days of receipt of such notice why the Licence should not be suspended, revoked, modified, withdrawn or cancelled.

(*b*) compel the electronic pharmaceutical service provider to provide access to the backend of the website or platform and examine records of activities relating to the online pharmacy that are reasonably suspected to be in breach of these Regulations;

(*c*) examine any article or records in the premises, website or platform of an electronic pharmaceutical service provider to which these Regulations apply, where it is 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;

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

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

(*f*) take down the e-pharmacy website or platform or seal the premises of any electronic pharmaceutical service provider where the electronic pharmaceutical service provider is found to be unregistered or unlicenced, or where access to records, documents or articles is not granted by electronic pharmaceutical service provider when requested by the Council's appointed inspectors.

(4) The Chief Executive Officer, the Superintendent Pharmacist or representative of the electronic pharmaceutical service provider or other entities rendering services to it, including an electronic pharmacy aggregator, shall give all necessary assistance to the appointed inspectors of the Council including making available all such information as they may require for the purpose of enforcing these Regulations.

(5) Records retrieved from the premises, website or platform of an electronic pharmaceutical services provider pursuant to these Regulations may be submitted to any certified analyst for examination, after which the analyst shall issue a report.

(6) An analyst to be appointed by the Council for the purpose of certification shall be certified as a data protection officer by the Nigeria Data Protection Commission and shall be placed under a data protection obligation as provided for under the Nigeria Data Protection Act 2023 and any other applicable law.

(7) The Council shall ensure that the retrieval and processing of all personal data from the backend of the electronic pharmaceutical service provider under these Regulations are processed —

(*a*) in a fair, lawful and transparent manner; and

(*b*) only for the purpose of investigating the breach of these Regulations by an electronic pharmaceutical service provider and not further processed in any way incompatible with that purpose.

PART IV — OPERATIONS OF ELECTRONIC PHARMACY

Operations

**18.**—(1) An electronic pharmaceutical service provider shall operate in line with Good Pharmacy Practices and other relevant regulations.

(2) An electronic pharmaceutical services provider website and platform shall comply with established standards for user-friendliness, security, and data privacy and any guidance established by the Council.

(3) A website or platform shall provide clear and accurate information about pharmaceutical products, including names, prices, indications, contraindications, side effects and any other information stipulated in the National Agency for Food and Drug Administration and Control (NAFDAC) Advertisement Regulations or any other applicable law.

(4) Product descriptions and labelling shall adhere to applicable regulations.

(5) An electronic pharmaceutical service provider shall establish a secure and user-friendly system for users and healthcare professionals to submit prescriptions electronically.

(6) Prescription submission processes shall include safeguards to verify prescription authenticity and users' identity.

(7) An electronic pharmaceutical service provider shall implement mechanisms to ensure that prescriptions are only filled once on the electronic pharmacy.

Communications

**19.**—(1) An electronic pharmaceutical service provider shall make the website or platform user friendly and interactive to ensure the mechanism for —

(*a*) consultation services to users physically or remotely;

(*b*) education of users regarding the medication and disease state, responsible use of medicines, effects of medicines and the importance of adherence to dosage instructions;

(*c*) education of users on the rights to seek clarification and consultation with authorised prescribers and pharmacists;

(*d*) education of users on the user rights as set out in the Patients' Bill of Rights;

(*e*) issuing of educational materials when dispensing family planning drugs authorised for self-administration;

(*f*) contacting of users regarding delays in delivering prescriptions, feedback and recalls, reporting adverse drug reactions and medication errors;

(*g*) provision of guidance to users on the protection of personal and health-related data when using electronic pharmacy services;

(*h*) contacting of pharmacists or healthcare providers for inquiries and clarifications;

(*i*) ease of making complaints and receiving feedback;

(*j*) e-prescriptions as defined in these Regulations;

(*k*) medication reminders, where possible; and

(*l*) any other mechanism which the Council may determine.

(2) An electronic pharmaceutical service provider shall —

(*a*) establish clear protocols for the submission, verification, and record-keeping of prescriptions received electronically;

(*b*) guide users and healthcare professionals on how to submit prescriptions securely through online platforms;

(*c*) ensure that appropriate mechanisms are in place for identifying requests for medicines that are inappropriate, including multiple orders to the same individual, to the same address, or multiple orders using the same payment details.

Dispensing Prescription Only Medicines

**20.**—(1) An electronic pharmaceutical service provider shall ensure implementation of Good Pharmacy Practice on its website or platform regarding dispensing of Prescription-Only-Medicines (POM) by providing —

(*a*) a system to ensure the integrity and legitimacy of prescription drug orders;

(*b*) processes and procedures to authenticate the validity of a prescription and confirm that it is from a licenced health professional or authorised prescriber before dispensing same;

(*c*) Pharmacist Initiated Medicines or Prescription-Only-Medicines with Over-The-Counter waiver or any other classification that may be decided by the Council, in compliance with, the Nigeria National Prescription and Dispensing Policy on the dispensing of approved medicines classified as Over-The-Counter;

(*d*) systems to ensure restriction on the quantity of prescribed medicines that can be ordered or sold electronically based on guidelines to be set out by the Council; and

(*e*) a secure portal for the uploading of prescriptions including for Prescription-Only-Medicines.

(2) An electronic pharmaceutical service provider may display Prescription-Only-Medicines electronically in accordance with NAFDAC Advertisement Regulations or other applicable laws provided that such medicines shall not be dispensed without a valid prescription.

(3) The systems of electronic pharmaceutical service providers shall —

(*a*) incorporate robust security measures to prevent unauthorised access, tampering or interception of prescriptions;

(*b*) facilitate accurate and error-free prescription transmission, minimising the risk of incorrect medication dispensing;

(*c*) establish mechanisms for verifying the authenticity of electronic prescriptions and the identity of prescribing healthcare providers or authorised prescribers;

(*d*) ensure the secure transmission of prescriptions between users, healthcare providers and the electronic pharmacy; and

(*e*) ensure secure communication channels and encryption are employed to protect prescription data during transmission.

(4) A valid prescription shall contain —

(*a*) user details;

(*b*) medication information;

(*c*) duration of prescription;

(*d*) prescription refill information, where applicable;

(*e*) date of the prescription;

(*f*) name and signature of the health care professional;

(*g*) registration number of the prescriber;

(*h*) telephone number of prescriber or hospital;

(*i*) physical address of clinic or hospital in Nigeria; and

(*j*) any other requirement specified by the Nigeria National Prescription and Dispensing Policy.

(5) An electronic pharmaceutical service provider shall not dispense any Prescription-Only-Medicines where a prescription fails to meet the requirements provided in subregulation (4) of this regulation.

(6) A scanned copy of a written prescription can be transmitted by a user to the electronic pharmacy and shall for the purpose of these Regulations serve as a valid means of e-prescription.

(7) A prescription issued shall be valid for 6 months from the date of the issuance or as may be determined by the Nigeria National Prescription and Dispensing Policy.

(8) All Prescription-Only-Medicine sold on the online platform shall be appropriately labelled before dispatch.

(9) An electronic pharmaceutical service provider shall dispense Prescription Only Medicines, only on prescription issued by authorised and licenced medical practitioner, dentist or veterinary practitioner or other authorised prescriber having a physical address and contact details in Nigeria.

(10) Notwithstanding any provision under these Regulations, electronic pharmaceutical service providers shall verify the authenticity of prescriptions through mechanisms established by the Council.

Patient counselling

**21.**—(1) A pharmacist shall be available online at all times to provide counseling to clients accessing medicines electronically.

(2) An electronic pharmacy platform shall ensure a user-friendly interface for interaction of pharmacist with the client to provide counseling on the electronic platform.

(3) The interaction of pharmacist with the client shall ensure patients use medications safely and effectively, and also improve patient satisfaction and health-related outcomes.

Authentication of patient

**22.**—(1) An electronic pharmaceutical service provider shall have a process in place for verifying client identity before purchase of medications.

(2) The process for verifying client identity shall include —

(*a*) requesting for a valid prescription;
(*b*) personal information verification;
(*c*) national identification upload; and
(*d*) phone number verification.

Restriction on quantity of prescribed medicines purchased online

**23.**—(1) An electronic pharmaceutical service provider shall dispense Prescription-Only-Medicines in the amount not exceeding the duration stated in the prescription, unless otherwise provided.

(2) The supply restriction under subregulation (1) of this regulation may be increased either within the duration stated in the prescription or after, where the prescribing health care professional or authorised prescriber so directs through the issuance of a subsequent prescription which shall provide the medical reasons for requiring the larger supply and set out the duration for the subsequent prescription.

(3) Prescription-Only-Medicines which require refills shall be dispensed in accordance with the refill times set out by the health care professional or authorised prescriber in the prescription and shall not exceed the quantity required for each refill as provided for in the prescription.

(4) Refill requests may be sent to the electronic pharmaceutical service provider that immediately dispensed the prior medication to confirm its availability for a refill and the electronic pharmaceutical service provider shall

respond within a reasonable time, failing which the user may present the refill prescription to any other electronic pharmaceutical service provider.

(5) Prescription-Only-Medications with Over-The-Counter waivers, such as family planning drugs authorised for self-administration and oral contraceptives shall be subject to the standard course of treatment supply.

(6) The Council may set out guidelines for restrictions on dispensing of drugs.

Sale of controlled medicines and dangerous drugs

**24.** Controlled Medicines and Dangerous Drugs as contained in the Dangerous Drugs Act Cap. D1, LFN, 2004 shall not be sold online.

Dispensing Over-The-Counter medicines (OTC)

**25.** An electronic pharmaceutical service provider involved in sale of Over-The-Counter medicines shall, in addition to these Regulations, comply with relevant laws regarding the sale and dispensing of the medicines.

Advertisement

**26.**—(1) The advertisement of OTC medicines and family planning products authorised for self-administration by an electronic pharmacy shall be as approved by the National Agency for Food and Drug Administration and Control.

Compliance with relevant regulations

**27.** An electronic pharmaceutical service provider shall comply with all relevant regulations made by the appropriate authority relating to the advertisement, pricing and discounting of drugs.

User information

**28.**—(1) An electronic pharmaceutical service provider shall institute —

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

(*b*) procedures to ensure reasonable verification of the identity of the user and prescriber by employing appropriate mechanisms to verify identity taking into consideration available technology; and

(*c*) maintenance of user medication profiles, where possible.

(2) Procedures and technology envisaged under subregulation (1) of this regulation shall ensure encryption of user data for the purpose of preventing unauthorised access.

(3) Presentation of any government approved identification documents shall be an appropriate mechanism for the purpose of subregulation (1)(*b*) of this regulation.

(4) An electronic pharmaceutical service provider shall adhere to the Patients' Bill of Rights.

Storage, delivery, distribution and quality of drugs

**29.**—(1) An electronic pharmaceutical service provider shall —

(*a*) ensure that the right temperature for storage of drugs is maintained during mailing and delivery;

(*b*) provide a system for safe and secure delivery of all medications;

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

(*d*) develop full audit trail from the initial request for a medicine through to its delivery, which should include signature on delivery;

(*e*) ensure the inclusion of dispensing labels that provide instructions for use;

(*f*) ensure that all medications including thermolabile products are transported in line with Good Distribution Practices; and

(*g*) ensure that all delivery mechanisms, including delivery entities, comply with Good Distribution Practices and all relevant regulations.

(2) The delivery and distribution of drugs may be undertaken by an electronic pharmaceutical service provider or by other entities including on-demand courier, logistics companies or online delivery platforms.

(3) An electronic pharmaceutical service provider shall ensure that delivery and distribution undertaken by on-demand courier, logistics companies, online delivery platforms or other entities are done in accordance with Good Distribution Practices and these Regulations.

(4) A user who obtains medication from an electronic pharmaceutical service provider shall be entitled to return medicines within a reasonable time where the —

(*a*) package appears to have been tampered with or mishandled; and

(*b*) drugs have expired.

(5) An expired drug so returned shall not be re-entered into the inventory and shall be destroyed in accordance with the Guidelines for Handling and Disposal of Unwholesome Medicines and NAFDAC regulated products, including food, medicines, medical devices and cosmetics or other applicable law.

(6) An electronic pharmaceutical service provider shall strictly adhere to quality control standards for pharmaceutical products when sourcing, storing, or dispensing drugs which include —

(*a*) ensuring that drugs are sourced from licenced and reputable suppliers, manufacturers, or wholesalers who meet the highest quality and safety standards;

(*b*) implementing guidelines to ensure authenticity and quality of medicines sold online;

(*c*) verifying the authenticity and legality of the source for pharmaceutical products; and

(*d*) any other standard which the Council may determine.

Record keeping and documentation

**30.**—(1) An electronic pharmaceutical service provider shall maintain records of —

(*a*) the identity of customers who have been supplied with medicines via the electronic pharmacy website or platform;

(*b*) details of the medicines requested and supplied, the name, quantity and expiry date;

(*c*) the purpose for which the drug was stated to be required and in case of a prescription, a copy of the prescription in line with extant legislations, regulations and policy requirements;

(*d*) the basic information upon which decisions to supply were made and any other information required by guidelines set out by the Council;

(*e*) details of any consultation between the user and the electronic pharmaceutical service provider;

(*f*) details of any consultation between the electronic pharmaceutical service provider and the authorised prescriber; and

(*g*) any other relevant information.

(2) An electronic pharmaceutical service provider shall maintain all relevant records for a period of not less than 5 years.

Data protection and privacy

**31.**—(1) An electronic pharmaceutical service provider shall adhere strictly to relevant regulations governing the collection, storage and handling of users' data, ensuring strict compliance with data protection laws, including the Nigerian Data Protection Act and extant regulations.

(2) In ensuring data protection and privacy of users, electronic pharmaceutical service providers shall —

(*a*) ensure cooperation with the Council and collect only the minimum amount of user data necessary for the provision of pharmaceutical and telemedicine services;

(*b*) implement adequate safeguards, including encryption and secure storage, to protect user data from unauthorised access, disclosure, alteration or loss;

(*c*) ensure access to user data is restricted to authorised personnel only, with access logs and audit trails maintained for accountability;

(*d*) ensure user data is retained for 5 years, after which it shall be securely deleted or anonymised;

(*e*) ensure that for use of user data during telehealth interactions, informed and voluntary consent of the user is obtained in telemedicine consultations;

(*f*) ensure that user consent include clear information about the purpose of data collection and use, data security measures, and the potential disclosure of data to healthcare providers involved in the telemedicine consultation;

(*g*) ensure the right of a user to withdraw consent at any time, and that user data shall not be used for telemedicine or any other purpose after the withdrawal of consent;

(*h*) maintain records of user consent for data use and provide users with access to their data upon request;

(*i*) establish procedures for responding to data breaches, including the notification of affected individuals and regulatory authorities in accordance with data protection laws; and

(*j*) ensure the priority of timely and comprehensive reporting of data breaches, to minimise potential harm to users and ensure regulatory compliance.

PART V — GENERAL PROVISIONS

Registered electronic pharmaceutical service providers

**32.**—(1) A registered electronic pharmaceutical service provider and electronic pharmacy aggregator shall utilise the nodal platform of the PCN as a gateway.

(2) There shall be a licenced pharmacist at all times to ensure pharmaceutical service delivery.

(3) A request for temporary closure of an electronic pharmacy 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 of licence may not be granted.

(4) The fees payable in respect of registration of an electronic pharmaceutical service provider shall be as prescribed by the Council.

Payment of inspection fees

**33.** Inspection of any sector of the pharmaceutical industry shall attract a fee as prescribed by the Council.

The PCN logo

**34.**—(1) The Council shall use its official logo on the nodal platform hosting electronic pharmacies and electronic pharmacy aggregators.

(2) Where a logo of the Council is found on an unauthorised internet website or platform, such website or platform shall be sanctioned appropriately.

(3) A person shall not display the PCN logo or any licence not approved by the Council.

(4) A Superintendent Pharmacist shall be eligible to register only one electronic pharmacy, any Superintendent Pharmacist who registers or attempts to register more than one electronic pharmacy commits an offence and shall —

(*a*) have the electronic pharmacy website or platform closed;

(*b*) be referred to the Investigating Panel; and

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

Prohibition of cross-corder sale of drugs online

**35.**—(1) Subject to subsregulation (2) of this regulation, the cross-border sale of drugs online, whether originating from Nigeria to persons outside Nigeria or from any other location outside Nigeria to individuals within Nigeria, is prohibited.

(2) Cross border online sale of medicine is permissible, where the —

(*a*) medicine is life saving;

(*b*) sale or purchase shall be conducted by a registered and currently licenced pharmacist;

(*c*) source of the products shall be specified, ascertainable and properly documented; and

(*d*) transaction shall be in accordance with the laws of the Federal Republic of Nigeria and the laws of the country of origin.

(3) The Council shall collaborate with other relevant agencies responsible for regulating the importation of goods including, the Nigeria Police Force, National Agency for Food and Drug Administration and Control, Nigeria Customs Service, Nigeria Drug Law Enforcement Agency, and the Central Bank of Nigeria for the enforcement of the provisions of these Regulations.

(4) Nothing in these Regulations shall preclude the application of the provisions of the Pharmacy Council of Nigeria (Establishment) Act, No. 31 2022, the Poisons and Pharmacy Act, Cap 535, LFN 1990 or any other applicable law in force with respect to the establishment of pharmacies in Nigeria, and the requirements for such registration and operation.

Establishment of a National Electronic Pharmacy Platform (NEPP)

**36.**—(1) There is established a national electronic pharmacy platform ("the Platform").

(2) The Platform shall —

(*a*) require all online drug orders to be placed through it;

(*b*) require independent platforms of electronic pharmaceutical service providers and electronic pharmacy aggregators to be legally and technically linked to it; and

(*c*) ensure a synchronous recording and storage of transaction.

(3) An electronic pharmaceutical service provider shall be required to pay an annual subscription fee in addition to the annual licensing fee, as the Council may determine, for utilising the Platform.

(4) A user shall be required to register with an acceptable valid means of identification and a unique identification number shall be generated for the user which shall be accessible to all electronic pharmaceutical service providers.

(5) The unique identification number shall contain user medication history, accessible to an electronic pharmaceutical service provider only upon obtaining explicit consent from a user.

(6) The Council shall ensure that the Platform incorporates technology mechanisms that grant electronic pharmaceutical service providers access to user electronic health records upon obtaining explicit consent from a user.

(7) Health care professionals shall also be required to register on the Platform with a valid, acceptable means of identification and, with the unique registration number issued to them by the relevant regulatory body for the purpose of verifying the prescriber.

(8) Nothing contained in this section shall prevent a registered user or health care professional from declining participation or disenrolling from the Platform at any time, provided that all outstanding obligations are discharged.

(9) The Council shall have the right to decline participation, disenroll a user or any health care professional at any time if such person is found to have provided false information, misrepresented information and identity, or is in breach of the Act, these Regulations or any guidelines made by the Council to ensure the efficient running of the Platform.

(10) An electronic pharmaceutical service provider shall implement mechanisms, such as identity verification to ensure that its service is provided to adults only.

(11) The Council shall ensure that processing of personal data on the Platform complies with the Nigeria Data Protection Act and any other relevant laws governing data protection and privacy in Nigeria.

(12) The Council shall develop necessary guidelines to ensure the seamless operation of the National Electronic Pharmacy Platform.

Consumer education

**37.** The Council shall educate users and the public on the provisions of these Regulations, employing multiple communication platforms, including online channels.

Reporting mechanisms

**38.**—(1) The Council shall —

(*a*) establish secure and confidential reporting channels and other mechanisms for the reporting of noncompliance by whistle-blowers, consumers, or other stakeholders; and

(*b*) investigate reports of non-compliance and take appropriate action in accordance with these Regulations or guidelines made pursuant to these Regulations.

## Part VI — Offences and Penalty

Making of false statement or misrepresentation of facts

**39.** Any person who knowingly or negligently makes a false statement or misrepresents information for the purpose of obtaining registration or licensing shall be liable to an administrative fine of ₦500,000.00.

Display of fake licence, registration certificate, or logo

**40.** A person or corporate body which displays, produces, or uses a fake licence or registration certificate or logo, or displays the logo of the Council without registration, commits an offence and is liable on conviction to imprisonment for a term of two years or a fine of ₦2,000,000.00 in addition to closure of the platform.

Late payment of renewal fees for licensing of an electronic pharmacy

**41.** A registered electronic pharmaceutical service provider or electronic pharmacy aggregator that fails, refuses or neglects to renew its electronic pharmacy Licence by the 31st day of January of every year, shall, in addition to paying the prescribed renewable fee, pay 50 percent of the applicable fee as late payment fees.

Failure to register and be licenced as an electronic pharmaceutical service provider

**42.** Any person or corporate body that operates, establishes, maintains, or owns an electronic pharmacy, or provides services as an electronic pharmaceutical service provider without registering with and obtaining necessary licence from the Council commits an offence and is liable on conviction to imprisonment for a term of two years or a fine of ₦2,500,000.00 or to both in addition to closure of such unregistered platform.

Failure to register and be licenced as an electronic pharmacy aggregator

**43.** A corporate body that operates, establishes, maintains, or owns a third-party platform offering services as an electronic pharmacy aggregator without registering with and obtaining necessary licence from the Council commits an offence and is liable on conviction to a fine of ₦3,000,000.00 or imprisonment for a term of two years or both.

Failure to provide access to backend for inspection or monitoring

**44.** An electronic pharmaceutical service provider who fails to provide access to the backend of its operations for the purpose of carrying out an inspection as required under these Regulations or guidelines made pursuant to these Regulations commits an offence and is liable on conviction to imprisonment for a term of two years or a fine of ₦2,000,000.00 or both.

Obstruction of the council's inspectors

**45.** A person who —

(*a*) obstructs, resists, or attempts to obstruct or resist an inspector in the execution of his duty under these Regulations or guidelines made pursuant to these Regulations;

(*b*) makes any statement to an inspector in the course of his duties which the person knows is, or has reasonable cause to believe to be false or misleading; or

(*c*) without the authority of the inspector removes, alters, or interferes in anyway with any restriction placed by the Council under these Regulations,

commits an offence and is liable on conviction to imprisonment for a term of two years or a fine of ₦2,000,000.00 or both.

Dispensing without a valid prescription

**46.** A person or corporate body who —

(*a*) dispenses Prescription-Only-Medicines without a valid prescription as provided for under these Regulations; or

(*b*) carries out any other unauthorised online disposal of drugs,

commits an offence and is liable on conviction to imprisonment for a term of two years or a fine of ₦2,000,000.00 or both.

Dispensing of controlled medicines and dangerous drugs

**47.** A person or corporate body who dispenses controlled medicines and dangerous drugs prohibited by the law or these Regulations from being sold online with or without a valid prescription commits an offence and is liable on conviction to imprisonment for a term of two years or a fine of ₦2,500,000.00 or both.

Cross-border sale of drugs online

**48.** A person or corporate body that engages in cross border sale of drugs online, whether originating from Nigeria or any other location outside Nigeria in breach of the provisions of these Regulations or guidelines made pursuant to these Regulations commits an offence and is liable on conviction to imprisonment for a term of two years or a fine of ₦2,500,000.00 or both.

Cross-border purchase of drugs online

**49.** A person or corporate body who carries out cross-border purchase of drugs online from persons or entities located outside Nigeria in breach of the provisions of these Regulations or guidelines made pursuant to these Regulations commits an offence and is liable on conviction to imprisonment for a term of two years or a fine of ₦2,500,000.00 or both.

Joint and vicarious liability

**50.**—(1) Where an offence under these Regulations which has been committed by a corporate body is proved to have been committed with the consent, connivance, collusion of or attributable to any neglect on the part of a director, manager, secretary or any other similar officer of the corporate body or any person who was purporting to act in any such capacity, the officer and the corporate body are liable to be proceeded against and punished accordingly.

(2) In relation to a corporate body carrying on an electronic pharmaceutical service, subregulation (1) of this regulation shall have effect as to a person who, not being an officer of the corporate body at the time of the commission of the offence is —

(*a*) the Superintendent Pharmacist; or

(*b*) at any premises where the business is carried on, the pharmacist who acts under the directions of the Superintendent Pharmacist, or as if he were such an officer of the corporate body as mentioned in the subregulation (1) of this regulation.

(3) An electronic pharmaceutical service provider shall be vicariously liable for the acts or omissions of its agents or employees, in so far as the acts or omissions relate to the provision of electronic pharmaceutical service.

General penalties

**51.**—(1) A person who commits an offence under these Regulations for which no specific penalty is provided is liable on conviction to imprisonment for a term of six months or a fine of not less than ₦500,000.00 or both.

(2) A corporate body that commits an offence under these Regulations for which no specific penalty is provided is liable on conviction to a fine of not less than ₦2,000,000.00.

PART VII — MISCELLANEOUS PROVISIONS

Interpretation

**52.** In these Regulations —

"*Act*" means the Pharmacy Council of Nigeria (Establishment) Act, No. 31, 2022;

"*Backend*" means a part of a computer system or application that cannot be directly accessed by the user but is responsible for the server-side operation and functionality and includes the server, database and application logic that work together for the purpose of processing requests, managing data, and ensuring the proper functioning of the website or platform;

"*Consumer application*" means a software application or online platform designed to accommodate user needs and wants, allowing users to seamlessly interact with the application or platform, and usually offered by electronic pharmaceutical service providers, couriers, and on-delivery platforms;

"*Data protection*" means the measures and safeguards in place to secure and protect user data from unauthorised access, disclosure, alteration, or loss, in accordance with applicable data protection laws and regulations;

"*Disciplinary Tribunal*" means the Disciplinary Tribunal of the Pharmacy Council of Nigeria established in under section 46(1) of the Pharmacy Council of Nigeria (Establishment) Act, No. 31, 2022;

"*E-prescription*" means prescriptions transmitted electronically to pharmacist as opposed to written prescriptions, electronic prescription becomes valid for the purpose of these Regulations where the prescription is —

(*i*) created in an electronic form by scanning a prescription written and signed by an authorised prescriber,

(*ii*) signed with an electronic signature, or directly on the written prescription before scanning,

(*iii*) sent through the National e-pharmacy platform created by the Council, or

(*iv*) transferred to the electronic pharmaceutical service provider as an electronic communication through telephonic or online medical consultation;

"*Electronic pharmacy*" is an internet-based service owned and operated by an electronic pharmaceutical service provider or an electronic pharmacy aggregator as defined under these Regulations, based in, and operating within Nigeria, that facilitates the sale, consultation, dispensing and delivery of pharmaceutical and health-related products directly to consumers, by means of the internet or any other electronic mode;

"*Electronic pharmacy aggregator*" means a third-party platform approved by the Council, owned by a corporate body, that offers technological infrastructure such as websites or applications (mobile or desktop) to connect multiple electronic pharmaceutical service providers with consumers, which does not own the products being offered for sale on the electronic pharmacy aggregator platform, and whose activity is restricted to the management and maintenance of the electronic pharmacy aggregator platform;

"*Electronic pharmacy aggregator's platform*" means any hardware or software used to host an application or service and serves as an online marketplace to do pharmacy business;

"*Electronic pharmaceutical service provider*" means —

(*i*) a person or a corporate body operating either a retail or community, wholesale and importation pharmacy, registered and licenced as an electronic pharmaceutical service provider under these Regulations,

(*ii*) a chain retail or community pharmacy having a Nigerian pharmacist or pharmacists on its board of directors, owning either solely or jointly not less than 40% of the shares of the company, combined with an online platform, to provide a wide range of health, wellness, and pharmaceutical products to consumers and registered and licenced as an electronic pharmaceutical service provider under these Regulations,

(*iii*) a pharmacist who in the absence of a pharmaceutical premises is in partnership with a registered and licenced pharmaceutical premises and registered and licenced as an electronic pharmaceutical service provider under these Regulations,

(*iv*) corporate entities exclusively operating through an online platform primarily focusing on the delivery of health and pharmaceutical products and registered and licenced as an electronic pharmaceutical service provider under these Regulations,

(*v*) E-commerce entities with retail pharmacy sections dedicated for health and pharmaceutical items and registered and licenced as an electronic pharmaceutical service provider under these Regulations,

(*vi*) telehealth entities that offer health-related services via telecommunication technologies which often range from consultations with healthcare providers to prescription services and might include partnerships or integrated features for delivery of medications and registered and licenced as an electronic pharmaceutical service provider under these Regulations, and

(*vii*) Non-profit Organizations that provide health and pharmaceutical services either directly or through partnerships with online platforms that facilitate healthcare delivery, especially to underserved or marginalised communities, or to address specific health challenges, and registered and licenced as an electronic pharmaceutical service provider under these Regulations duly authorised by the Council to sell, supply, and dispense, pharmaceutical products or provide other pharmaceutical professional services directly to consumers over the internet, either independently or in conjunction with an electronic pharmacy aggregator;

"*Health care professional*" includes an authorised prescriber and means a licenced medical practitioner, dentist, or veterinary practitioner, pharmacist, nurse and other designated healthcare personnel so licenced to practice in Nigeria and having a physical address and contact details in Nigeria;

"*Home delivery*" means service provided by electronic pharmaceutical service providers and other drug distribution channels such as courier, logistics or online delivery platforms to deliver prescription and non-prescription medications to users at home;

"*Home page*" means a page designated as the main entry point to a website or platform of an electronic pharmacy serving as a default or entry point of a website or platform and often provides links to various sections on the website or platform and information or services available on the website or platform;

"*Internet*" means collectively the myriads of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol or Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio;

"*Medication reminder*" means a timely reminder given to a user to take prescribed medication but does not include medication assistance, prescription reminders can be offered by electronic pharmaceutical service providers;

"*NAFDAC*" means the National Agency for Food and Drug Administration and Control.

"*National Electronic Pharmacy Platform*" means the technical platform authorised by the Council to facilitate and regulate access to medicines and pharmaceutical services remotely whilst protecting the safety and promoting high accountability and responsibility for such medicines, it is a centralised, integrated platform for regulating electronic pharmaceutical service providers;

"*Nodal platform*" means National Electronic Pharmacy Platform;

"*On-demand courier, logistics companies or online delivery platforms*" means corporate entities collaborating with electronic pharmaceutical service providers to facilitate the purchase and rapid delivery of pharmaceutical products to consumers in line with good distribution practices;

"*Online consultation*" means virtual health care service between health care professionals and users over the internet or through a digital platform;

"*Person*" means a natural person or a body corporate;

"*Pharmacy Council of Nigeria authorised logo*" means the symbol as prescribed by the Council and patented by the Registrar of Patents and Trademarks;

"*Pharmaceutical premises*" means the definition prescribed under the Pharmaceutical Premises Location, Inspection, Structure, Monitoring and Enforcement Regulation, 2022 or any subsequent Regulations;

"*Prescribed fees*" means such fees as approved by the Council;

"*Prescribed logo*" means such logo produced and approved by the Council and which is required to be displayed by an electronic pharmaceutical service provider as mandated by the Council;

"*Reasonable time*" means the appropriate time frame ascribed by the Council in the relevant policy document of an electronic pharmaceutical service provider or an online pharmacy aggregator;

"*Superintendent Pharmacist*" means a registered and licenced pharmacist who applied for, and through whom the registration of the electronic pharmacy was procured and who is specifically designated to oversee the professional service delivery of the electronic pharmacy;

"*The Council*" means the Pharmacy Council of Nigeria;

"*The Platform*" means the National Electronic Pharmacy Platform;

"*User*" means a client to whom drugs are dispensed to, and who receives electronic pharmaceutical services rendered by the electronic pharmaceutical service provider;

"*User data*" includes any information related to an individual user, including their personal and medical information, health history, prescription records, and other data collected during the provision of pharmaceutical and healthcare services;

"*Valid means of identification*" includes international passport, National identification card, and National driver's licence, Voter's card or any other means of identification considered and recognised as being valid by the Pharmacy Council of Nigeria;

"*Valid prescription*" means a written or electronically transmitted order that is issued for a legitimate medical purpose in the usual course of professional practise by a health care professional who has conducted a medical evaluation of the user and containing essential information including

the users details, medication information, duration of prescription, prescription refill information where applicable, the date of the prescription, the health care professional's name and signature, registration number, telephone number, physical address of clinic or hospital in Nigeria for the purpose of ensuring its legality and legitimacy and other information as may be required by the Nigeria National Prescription and Dispensing Policy or other extant legislations or policy in Nigeria; and

"*Quality control*" involves the establishment of standards and processes to ensure the authenticity, safety, and efficacy of pharmaceutical products dispensed through electronic pharmacies, including sourcing, storage, and distribution practices.

Citation

**53.** These Regulations may be cited as the Electronic Pharmacy Regulations, 2026.

MADE at Abuja this 9th day of February, 2026.

PROF. MUHAMMAD ALI PATE, CON
*Coordinating Minister of Health and Social Welfare*