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ELECTRONIC PHARMACY REGULATIONS, 2024

PHARMACY COUNCIL OF NIGERIA (ESTABLISHMENT) ACT, 2022

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Contents

Commented [TI1]: Patient/Client Authentication can be matched with Users Information which was later seen after going through the body of the Regulations. However, there might be a need for expansion of the information thereunder.

Commented [TI2]: The use of electronic as against online pharmacy or pharmaceutical services is necessary to ensure consistency and alignment with the name of the Regulation. In view of the foregoing, anywhere "online" is used as an adjective in the Regulation should be replaced with "electronic" where found necessary. This surfices to say that it is not all "online" that would be replaced with "electronic" but only the "online" used to qualify any other word as an adjective and only where necessary. This rider became necessary to avoid the use of a command such as "replace all online with electronic", while editing the document (Regulation).

Commented [TI3]: Record keeping and documentation are very crucial and should be intentional in pharmacy practice, as such the elements of record keeping and documentation should clearly defined and provided for in the document

Commented [TI4]: There are needs for patient counselling and authentication of patient to project and fulfil the requirements of professional practice rather than mere trade. The document should provide for comprehensive information for authentication of patient and key elements of patient counselling that are especially incidental to e-pharmacy services

Recognizing the rapid growth of electronic pharmaceutical services and to uphold the safety, quality, and equitable access to pharmaceuticals in the digital era, the Pharmacy Council of Nigeria, as empowered by Sections 4, 4(1) (p), and 64 of the Pharmacy Council of Nigeria (Establishment) Act with all other powers enabling it in that behalf, with the approval of the Coordinating Minister of Health and Social Welfare, hereby makes these Regulations:

PART I – OBJECTIVES AND SCOPE OF THE REGULATIONS

1. **Objectives**

The purpose of these Regulations shall be to:

(a) Establish a regulatory framework that aligns with international best practices, protecting consumers while fostering innovation in the healthcare sector,

(b) Regulate electronic pharmacy services and operations in Nigeria,

(c) Certify and licence electronic pharmacies and provide a platform for verification of electronic pharmacies,

(d) Safeguard public by ensuring that person with requisite knowledge and qualifications are involved in online practice;

(e) Establish a National Electronic Pharmacy Platform (NEPP) to serve as the nodal platform for facilitating, transacting, and monitoring electronic pharmacy services in Nigeria,

(f) Facilitate filling of e-prescriptions from telemedicine or telehealthcare services,

Commented [TI5]: One of the major objectives of establishing a national electronic pharmacy platform aside facilitation of wider visibility of electronic pharmacy supply chain for better and easier regulation to ascertain patients or clients' safety, is to operationalise an holistic telehealthcare services such as e-prescription (based on a validated list of authorized prescribers and a comprehensive database of uniquely identified producers, providers, payers and patients/users) and telemedicine. As such, establishment of a national electronic pharmacy platform is a sine qua non for filling of e-prescriptions, and once it is in place the objective of filling of prescription is necessary for digital health enabling innovation governance.

(g) Safeguard public health by ensuring that pharmaceutical products dispensed through electronic pharmacies meet high standards of quality, safety, and authenticity as specified by the relevant regulatory agency,

(h) Facilitate the accessibility and affordability of pharmaceutical products and services while maintaining effective regulatory oversight,

(i) Promote transparency, ethical practices, and users' safety in the electronic pharmacy industry,

(j) Facilitate the verification of authentic electronic pharmaceutical service providers in Nigeria using the Registered Electronic Pharmacy Sites Emblem (REPSE),

(k) Provide penalties for defaulters to these Regulations, and

(l) Provide for other relevant matters.

2. **Scope of the Regulations**

These Regulations shall apply to electronic pharmacy services and operations in Nigeria as defined under section 49 of these Regulations.

PART II – REGISTRATION AND LICENSING

3. **Registration Authority**

(i) Electronic pharmacies in Nigeria shall be registered with the Pharmacy Council of Nigeria.

(ii) Electronic pharmacies shall be categorized into two namely:

(a) Electronic pharmaceutical services providers as defined in Section 49 of this regulation.

(b) Electronic pharmacy aggregators as defined in Section 49 of these Regulation.

4. **Application for Registration as an Online Pharmaceutical Service Provider**

(1) Application for registration as an electronic pharmaceutical service provider shall be made to the Registrar by the Superintendent Pharmacist specifically designated to oversee the pharmaceutical service delivery and operations of the electronic pharmacy. The applications shall include the following documents:

(a) Application letter for registration of the electronic pharmaceutical service provider Company's Certificate of Incorporation (evidence of registration of business name is acceptable for pharmacist-owned retail premises)

(b) Certified True Copies of Articles and Memorandum of Association

(c) Certified True Copies of documents showing names and particulars of Directors

(d) Standard operating procedures and/ or policy documents which shall include procedures and processes for all operations of the electronic pharmacy ensuring clarity and consistency in how the electronic pharmacy is managed and utilized

(e) Evidence of payment of prescribed fee to the Council

(f) Letter of appointment of the Superintendent Pharmacist who shall be responsible for overseeing the pharmaceutical service delivery and operations of the electronic pharmacy

(g) Legal agreement between the Superintendent Pharmacist and the owner of the pharmaceutical premises where applicable

(h) Current annual license of the Superintendent Pharmacist, where applicable

(i) Letter of resignation from previous employment, where applicable

(j) NYSC Discharge or Exemption Certificate

(k) Copy of the current premises registration licence or evidence of current registration of the premises where applicable

(l) In the case of an application for registration by an electronic pharmaceutical service provider without a physical premises, evidence of a partnership agreement detailing the roles and responsibilities of the parties between the electronic pharmaceutical service provider and a licensed physical retail pharmacy, wholesaler, or distributor; which will also incorporate a copy of the current premises registration licence or evidence of current registration of partners' pharmaceutical premises as an annexure

(m) Service level agreement between the electronic pharmaceutical service provider and electronic pharmacy aggregator(s) showing the responsibility of each party, where applicable

(n) An undertaking by the Managing Director of the electronic pharmacy to the effect that electronic pharmaceutical service delivery shall be under the direct control and management of the Superintendent Pharmacist, where applicable

(o) An undertaking by the Superintendent Pharmacist of the electronic pharmaceutical service provider to be held accountable for the pharmaceutical service delivery and operations provided by the electronic pharmacy, or provided through the pharmaceutical premises that the electronic pharmaceutical service provider is in partnership with, or through an electronic pharmacy aggregator's platform

(p) Any other requirement which the Council may determine from time to time.

Commented [TI6]: Correction of syntax errror

(2) 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. No electronic pharmaceutical service provider shall be registered under section 4 (1) except it has a Superintendent Pharmacist to oversee service delivery as required by the Pharmacy Council of Nigeria (Establishment) Act, 2022 and other Regulations made thereunder.

Commented [TI7]: Complete citation of the legislation

(3) For contract entered under Section 4(1)(m), the partners shall comply with all requirements set out by the Council as it relates to pharmaceutical premises including but not limited to the Pharmaceutical Premises Location, Inspection, Structure, Monitoring and Enforcement Regulation, 2021 or any subsequent Regulations.

(4) A copy of any revision, amendment or alteration made to the contract entered under Section 4 (1)(n) shall be forwarded to the Council within 30 days.

Commented [TI8]: Better use of English language

(5) Within six (6) months from the commencement of these Regulations, all previously registered electronic pharmaceutical service providers, as defined under these Regulations, shall submit any additional registration documents specified in section 4 (1).

(6) All electronic pharmaceutical service providers as defined under these Regulations, shall comply with the provisions of these Regulations.

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

5. **Licensing of the** electronic **Pharmacy**

(1) The Council is empowered to issue an electronic pharmacy licence to all electronic pharmaceutical service providers based in Nigeria upon meeting the registration requirements.

(2) To be eligible to obtain an electronic pharmacy licence, an electronic pharmaceutical services provider shall:

(a) Register with the Council in accordance with Section 4 of these Regulations,

(b) Have a registered and licensed pharmaceutical premises in Nigeria, or a partnership agreement as stipulated under Section 4(1) (m) which shall comply with all relevant laws and regulations,

(c) Demonstrate compliance with good pharmacy practices (GPP),

(d) Maintain appropriate storage conditions for pharmaceutical products in accordance with established standards,

(e) Adhere 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

(d) Any other requirement which the Council may determine from time to time.

(3) The Council may conduct, from time to timet a review of the licensing requirement stated under Section 5(2) of these Regulations.

(4) The Council shall issue or grant electronic pharmacy licence to registered electronic pharmaceutical service providers in Nigeria in line with Good Pharmacy Practices (GPP).

(5) Upon the issuance of an electronic pharmacy licence, the electronic pharmacy shall be eligible to use the Council's Registered electronic Pharmacy Sites Emblem (REPSE).

Commented [TI9]: Remote prescribing is not a subset of e-pharmacy or what was rendered as telepharmacy. In addition, e-pharmacy was preferred over telepharmacy for consistency.

Commented [TI10]: Syntax error was corrected for better use of English language

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

6. **Renewal of Electronic Pharmacy Licence**

(1) An electronic pharmaceutical service provider's 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 renewal shall be as prescribed in the Guidelines made pursuant to the provisions of these Regulations.

7. **Electronic Pharmacy Aggregators**

(1) All electronic pharmacy aggregators as defined under these Regulations shall be required to register with and be licensed by the Pharmacy Council of Nigeria as set out in these Regulations.

(2) Failure to obtain an operating licence as required by this section shall be an offence under these Regulations.

8. **Application for Registration as an Electronic Pharmacy Aggregator**

(1) Application for registration as an electronic pharmacy aggregator shall be made to the Registrar by the superintendent Pharmacist specifically designated to oversee the pharmaceutical service delivery and operations of the aggregator platform. The application shall include the following documents:

(a) Company's Certificate of Incorporation,

(b) Certified True Copies of Articles and Memorandum of Association,

(c) Certified True Copies of documents showing names and particulars of Directors as contained in the Corporate Affairs Commission incorporation documents,

(d) Board Resolution to commence an electronic pharmacy aggregator's operation,

(e) Policy documents which shall include procedures and processes for all operations of the technological infrastructure such as websites or applications (mobile or desktop),

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

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

(h) Certificate of registration with the Nigeria Data Protection Commission (NDPC), and

(i) Any other requirement which the Council may determine from time to time.

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

Commented [TI11]: Syntax error was corrected for better use of English language

9. **Licensing of an Electronic Pharmacy Aggregator**

(1) The Council is empowered to issue licence to all registered electronic pharmacy aggregators based in Nigeria upon meeting the registration requirements.

(2) To be eligible to obtain an electronic pharmacy aggregators licence, an electronic pharmacy aggregator shall provide the following:

(a) Evidence of registration with the Council in accordance with Section 8 of these Regulations,

(b) Evidence of payment of prescribed licensing fee to the Council,

(c) Curriculum Vitae (CV) including the current practice license 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 but is not limited to the framework covering authentication of products and users, platform failure, and processes or tools to detect contraventions of these Regulations by electronic pharmaceutical service providers as described under Section 10,

(h) An agreement to link the electronic pharmacy aggregator's platform legally and technically to the Council's National Electronic Pharmacy Platform,

(i) Any other requirement which the Council may determine from time to time.

(3) The Council may conduct from time to time, a review of the licensing requirements stated under section 9(2) of these Regulations.

(4) An electronic pharmacy aggregator's 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.

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

10. **Suspension of Services by the Electronic Pharmacy Aggregator**

Where the electronic pharmacy aggregator, while carrying out the management and maintenance of a platform, discovers an electronic pharmaceutical service provider committing any of the following acts:

(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 from time to time, it shall promptly report to the Council and suspend the provision of technological infrastructure such as websites or applications (mobile or desktop) to the electronic pharmaceutical service provider and ultimately cease the display of relevant drug information.

11. **Obligation of the Electronic Pharmacy Aggregator to cooperate with the Council**

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

(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 contemplated under Section 17(1).

(3) If 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, upon 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.

Commented [TI12]: Complete citation of the legislation

12. **Requirements to be displayed on the Electronic Pharmacy Site**

The following shall be made available on the electronic pharmacy site by the electronic pharmaceutical services providers:

(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(es) of the pharmaceutical premises with which the electronic pharmacy is licensed, and the designated address of the electronic pharmaceutical service provider, if different from the registered address(es) of the pharmaceutical premises,

(c) The electronic pharmacy's telephone number and email address,

(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 licensed health care professional (authorized prescriber), having a physical address and contact details in Nigeria, and so defined under these Regulations",

Commented [TI13]: It is not all authorised prescribers who are healthcare professionals in Nigeria. Many healthcare workers are authorised prescribers, using standing order approved for their practice.

(e) The registration number of the pharmaceutical premises with which the electronic pharmacy is licensed, on its home page,

(f) 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 Registered Electronic Pharmacy Sites Emblem of the Council,

(i) Contact information of the Council, and

(j) Any other requirement which the Council may determine, from time to time.

Commented [TI14]: As previously corrected

13. Change or Variation of Licence

An electronic 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 a Superintendent Pharmacist, sites, platform, scope and areas of practice or any other change or variation in a licence.

14. **Suspension, Revocation, and Withdrawal of Licence**

(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.

(2) If the Registrar is satisfied by the reasons so given, such licence shall not be suspended, revoked, withdrawn, or cancelled.

(3) If no reason is provided, or the Registrar determines that the reason given is not satisfactory, the Registrar shall notify the electronic pharmaceutical service provider of the decision to suspend, revoke, modify, withdraw or cancel the licence.

(4) An electronic pharmaceutical service provider whose licence is suspended, revoked, withdrawn, or cancelled may appeal to the Council within 14 days of receiving such notification.

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

15. **Closure of Facility**

(1) Where an electronic pharmaceutical service provider intends to close its operations, it shall notify the Council of this intention 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 of licence may not be granted.

16. **Compliance with the Nigeria Data Protection Act 2023**

Every electronic pharmaceutical service provider shall comply with the Nigeria Data Protection Act 2023, and other relevant laws governing data protection and privacy in Nigeria.

PART III – INSPECTION, MONITORING AND ENFORCEMENT

17. **Inspection and Monitoring of Electronic Pharmacy**

(1) Upon submission of registration documents, the Council shall carry out inspection of the electronic pharmaceutical service providers and shall from time to time carry out follow up inspections, as required, throughout the electronic pharmacy's supply chain.

(2) The Council may appoint one or more of its inspectors or suitably qualified persons as accredited external inspectors to undertake inspection of the website or platform, records, and documents.

(3) The internal inspectors or accredited external inspectors appointed by the Council under this section, shall have the powers while carrying out their duties, at reasonable times and upon production of their identity cards to:

(a) Enter any premises, whether constituting a pharmaceutical premises or not, which hosts the electronic pharmaceutical service provider or access the backend of the website or platform, using available technological mechanisms, if there are reasonable grounds to believe or suspect that an article to which these Regulations apply is stored, sold, offered for sale, dispensed in contravention of these regulations

(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 believed or suspected to be a breach of these Regulations

(c) Examine any article or records in the premises or electronic pharmaceutical service provider's website or platform 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

(d) Examine 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 and make copies

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

(f) Take down the v pharmacy website or platform or seal the premises of any electronic pharmaceutical service provider if the online pharmaceutical service provider is found to be unregistered or unlicensed, or if 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 including making available all such information as they may require for the purpose of enforcing these Regulations.

(5) Records retrieved from the premises or the 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. Such 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 in force.

(6) The Council shall ensure that the retrieval and processing of all personal data from the backend of the electronic pharmaceutical service provider under this section are:

(a) processed in a fair, lawful and transparent manner, and

(b) processed 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

18. Operations

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

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

(3) Websites or platforms shall provide clear and accurate information about pharmaceutical products, including names, prices, indications, contraindications, side effects and any other information stipulated in the NAFDAC Advertisement Regulation 2021 or any other applicable law in force.

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

(5) electronic pharmaceutical service providers shall establish secure and user-friendly systems for users and healthcare professional to submit prescriptions electronically.

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

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

19. **Communications**

(1) Every electronic pharmaceutical service provider shall make the website or platform user friendly and interactive to ensure the mechanisms for:

(a) Consultation services to users or clients whether in proximity or remote

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

(c) Educating users on their rights to seek clarification and consultation with authorised prescribers and pharmacists

(d) Educating users on their rights as set out in the Patients' Bill of Rights

(e) Issuing educational materials when dispensing family planning drugs authorised for self-administration

(f) Contacting users regarding delays in delivering prescriptions, feedback and recalls, reporting adverse drug reactions and medication errors

(g) Providing guidance to users on protecting their personal and health-related data when using electronic pharmacy services

(h) Contacting pharmacists or healthcare providers for inquiries and clarifications,

(i) Making complaints and receiving feedback

(j) E-prescriptions as defined in these Regulations

(k) Medication reminder, where possible, and

(l) Any other mechanism which the Council may determine, from time to time

(2) Electronic pharmaceutical service providers shall establish clear protocols for the submission, verification, and record-keeping of prescriptions received electronically.

(3) Electronic pharmaceutical service providers shall guide users and healthcare professionals on how to submit prescriptions securely through online platforms.

(4) The electronic based pharmaceutical service provider shall ensure that appropriate mechanisms are in place for identifying requests for medicines that are inappropriate, including but not limited to multiple orders to the same individual, to the same address, or multiple orders using the same payment details.

20. **Dispensing Prescription Only Medicines**

(1) Electronic pharmaceutical service providers shall ensure implementation of Good Pharmacy Practice on their websites or platforms regarding dispensing of Prescription-Only-Medicines amongst 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 (authorised prescriber) before dispensing same

(c) Policy (Nigeria National Prescription and Dispensing Policy) on the dispensing of approved medicines classified as Over the Counter, Pharmacist Initiated Medicines or Prescription Only Medicines (POM) with Over-the Counter waiver**,** or any other classification that may be decided by the relevant authority from time to time

(d) Systems to ensure restriction on the quantity of prescribed medicines that can be ordered or sold electronic based on guidelines to be set out by the appropriate authority, and

(e) A secure portal for the uploading of prescriptions including for prescription-only-medicines

(2) Electronic pharmaceutical service providers may display Prescription-Only Medicines electronic in accordance with NAFDAC Advertisement Regulation 2021 or any other applicable law in force provided that such medicines shall not be dispensed without a valid prescription

(3) Electronic pharmaceutical service providers shall ensure that the electronic pharmacy meets the following requirements:

(a) Electronic systems shall incorporate robust security measures to prevent unauthorized access, tampering, or interception of prescriptions

(b) Systems shall facilitate accurate and error-free prescription transmission, minimizing the risk of incorrect medication dispensing

(c) Electronic pharmaceutical service providers shall establish mechanisms for verifying the authenticity of electronic prescriptions and the identity of prescribing healthcare providers (authorised prescribers)

(d) Electronic pharmaceutical service providers shall ensure the secure transmission of prescriptions between users, healthcare providers, and the electronic pharmacy. Secure communication channels and encryption shall be employed to protect prescription data during transmission

(4) A valid prescription shall contain the following requirements:

(a) Users' details

(b) Medication information

(c) Duration of prescription

(d) Prescription refill information if applicable

(e) The date of the prescription

(f) The health care professional's name and signature

(g) Prescriber's Registration number

(h) Prescriber/hospital Telephone number

(i) Physical address of clinic or hospital in Nigeria, and

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

Commented [TI15]: This provision is necessary to allow a handshake with extant policy on the subject matter

An electronic pharmaceutical service provider shall not dispense any Prescription Only Medicines if a prescription fails to meet the requirements provided.

(5) 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.

(6) 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.

(7) All prescription-only-medicines sold on the online platform shall be appropriately labelled before dispatch.

(8) electronic pharmaceutical service providers shall dispense medicines only when on prescription issued by authorised and licensed medical practitioner, dentist or veterinary practitioner or other authorised prescriber having a physical address and contact details in Nigeria.

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

21. Patient Counselling

A pharmacist shall be available online at all times (through appropriate arrangement) to provide counseling to clients accessing medicines electronically. There should be a user-friendly interface for interaction with the client to provide counseling on the electronic platform.This is to ensure patients use their medications more safely and effectively and also improve patient satisfaction and health-related outcomes.

22. Authentication of Patient

An electronic pharmaceutical service provide shall have a process in place for verifying a client's identity before allowing them to purchase medications. This should include but not limited to requesting for a valid prescription, personal information verification (name, address, date of birth), national ID upload, phone number verification to ensure the person is who they claim to be and is eligible to receive the medication.

21. **Restriction on Quantity of Prescribed Medicines Purchased Online**

(1) An electronic pharmaceutical service provider shall dispense Prescription Only Medicines directly to a user in the amount not exceeding the duration stated in the prescription unless otherwise provided.

(2) The supply restriction under section 21(1) may be increased either within the duration stated in the prescription or after, if the prescribing health care professional (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

(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 OTC 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.

22. **Dispensing Over the Counter Medicines (OTC)**

(1) Sales of OTC medicines shall, in addition to these Regulations, comply with relevant laws regarding the sales and dispensing of the medicines.

(2) Dangerous drugs as contained in the Dangerous Drugs Act D1, LFN, 2004 shall not be sold online.

23. **Advertisement**

(1) Only OTC medicines, as approved by the National Agency for Food and Drug Administration and Control, and family planning products authorised for self-administration shall be advertised by an electronic pharmacy**.**

(2) The advertisment of family planning products authorised for self administration shall adhere to the guidelines of the most current edition of the National Family Planning Communication Plan or any other applicable law or policy document in force.

24. **Compliance with Relevant Regulations**

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

25. **User Information**

(1) Electronic pharmaceutical service providers shall institute:

(a) Policies, procedures, and technology to protect users' 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 section 25 (1)(a) shall ensure encryption of user's data for the purpose of preventing unauthorised access.

(3) For the purpose of section 25(1) (b), presentation of any government approved identification documents shall be an appropriate mechanism.

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

26. **Storage, Delivery, Distribution and Quality of Drugs**

(1) Electronic pharmaceutical service providers 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 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 providers or by other entities including but not limited to on-demand courier/logistics companies or online delivery platforms. The 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.

(3) Users who obtain medication from an electronic pharmaceutical service provider shall be entitled to return medicines within a reasonable time:

(a) Where the package appears to have been tampered with or mishandled, and

(b) Where the drugs have expired.

(4) An expired drug so returned shall not be re-entered into the inventory; but shall be destroyed in accordance with the Guidelines for Handling and Disposal of Unwholesome Medicines and NAFDAC Regulated Products (Food, Medicines, Medical Devices, and Cosmetics etc) or any other applicable law in force.

(5) Electronic pharmaceutical service providers shall strictly adhere to quality control standards for pharmaceutical products when sourcing, storing, or dispensing drugs which include but are not limited to:

(a) Ensuring that drugs are sourced from licensed 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, from time to time.

27. **Record** Keeping and Documentation

(1) An electronic pharmaceutical service provider shall maintain records of:

(a) The identity of customers (that is, name and address) who have been supplied with medicines via the electronic pharmacy website or platform,

(b) Details of the medicines requested and supplied including but not limited to the name, quantity, 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 extanct 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 prescriber, and

(g) (g) Any other relevant information.

(2) All relevant records must be maintained for a period of not less than 5 years.

28. **Data Protection and Privacy**

(1) Electronic pharmaceutical services providers shall establish and adhere to robust regulations governing the collection, storage, and handling of users' data, ensuring strict compliance with data protection laws, including but not limited to the Nigerian Data Protection Act, 2023 and extant regulations.

(2) Electronic pharmaceutical services providers shall be guided by the following data protection and privacy requirements:

(a) Electronic pharmaceutical services providers shall collect only the minimum amount of users' data necessary for the provision of pharmaceutical and telemedicine services; and to ensure cooperation with the Council,

(b) Electronic pharmaceutical services providers shall implement adequate safeguards, including encryption and secure storage, to protect users' data from unauthorized access, disclosure, alteration, or loss,

(c) Access to users' data shall be restricted to authorised personnel only, with access logs and audit trails maintained for accountability,

(d) Users' data shall be retained for 5 years, after which it shall be securely deleted or anonymized,

(e) Electronic pharmaceutical service providers engaging in telemedicine consultations shall obtain informed and voluntary consent from users for the use of their data during telehealth interactions,

(f) Users consent shall 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) Users shall have the right to withdraw their consent at any time, and their data shall not be used for telemedicine or any other purposes thereafter,

(h) Electronic pharmaceutical service providers shall maintain records of user consent for data use and provide users with access to their data upon request,

(i) Electronic pharmaceutical service providers shall establish procedures for responding to data breaches, including the notification of affected individuals and regulatory authorities in accordance with data protection laws,

(j) Timely and comprehensive reporting of data breaches shall be a priority to minimise potential harm to users and ensure regulatory compliance.

PART V – GENERAL PROVISIONS

29. **Registered Electronic Pharmaceutical Service Providers**

(1) Registered electronic pharmaceutical service providers and electronic pharmacy aggregators shall display the Pharmacy Council of Nigeria (PCN) Prescribed Emblem.

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

(3) A request for temporary closure of the 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 any electronic pharmaceutical service provider shall be as prescribed by the Council.

30. **Payment of Inspection Fees**

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

31. **The PCN Emblem**

(1) The Council shall prescribe distinct Pharmacy emblem for the usage of electronic pharmacies and electronic pharmacy aggregators.

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

(3) A person shall not display any PCN emblem or 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 be Investigating Panel; and,

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

32. **Prohibition of Cross-Border Sale of Drugs Online**

(1) Subject to the provision of Section 32 (2) of these Regulations, 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 in breach of the provisions of these Regulations or guidelines made therefrom is prohibited.

Commented [TI16]: Since it is not all Guidelines that can be made thereunder immediately or now and other Guidelines could be made later without necessarily in these Regulations, it is better to say "therefrom" to capture both the Guidelines made thereunder or therefrom as both categories are derivatives of these Regulations.

(2) Exceptions for cross border online sale of medicine:

(a) Where the medicine is life saving

(b) The sale/purchase shall be conducted by a registered and currently licensed pharmacist

(c) The source of the products shall be specified and ascertainable and properly documented.

(d) The 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 but not limited to 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 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.

33. **Creation of a National Electronic Pharmacy Platform (NEPP)**

(1) There is hereby established a National Electronic Pharmacy Platform (NEPP), hereafter referred to as The Platform which shall require all online drug orders to be placed through it with independent platforms of all electronic pharmaceutical services providers (including aggregators) legally and

technically linked to it, to ensure a synchronous recording and storage of transaction.

(2) In addition to the annual licensing fee, electronic pharmaceutical service providers shall be required to pay an annual subscription fee to the Council for utilizing The Platform. The annual subscription fee and the date for which it becomes payable shall be determined by the Council.

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

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

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

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

(7) 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.

(8) 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 these Regulations or the Act or any guidelines made by the Council to ensure the efficient running of The Platform.

(9) The electronic pharmaceutical service provider shall implement mechanisms to ensure that its service is provided to only adults, including through identity verification.

(10) The Council shall ensure that processing of personal data on The Platform complies with the Nigeria Data Protection Act, 2023, and any other relevant laws governing data protection and privacy in Nigeria.

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

34. **Consumer Education**

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

35. **Reporting Mechanisms**

(1) The Council shall establish mechanisms for the reporting of noncompliance by whistle-blowers, consumers, or other stakeholders. These mechanisms shall include secure and confidential reporting channels.

(2) The Council shall investigate reports of non-compliance and take appropriate action in accordance with these Regulations or guidelines made hereunder..

PART VI – OFFENCES AND PENALTY

36. **Making of False Statement or Misrepresentation of Facts**

Commented [TI17]: There is a need to expand this section to include patient counselling services or create another section for patient counselling as observed under the table of contents. Patient counselling is a professional pharmaceutical service that goes with dispensing of drugs/medicines to clients or patients, and it is necessary to bear this in mind before some people misunderstand e-pharmacy platform as a mere electronic commerce or trade platform for which its regulation and control can be undertaken by IT, trade, or any other presumed or mischief-informed body or agency.

A person who knowingly or negligently makes a false statement or misrepresents information for the purpose of obtaining registration and/or licensing shall be required to pay a remedial fee or penalty in the sum of N500, 000.00.

37. **Display of fake licence, registration, certificate, or emblem**

A person or a corporate body which displays, produces, or uses a fake licence or registration certificate or emblem, or displays the Council's Emblem without registration shall be required to pay a remedial fee or penalty in the sum of N2, 000,000.00 or imprisonment for a term of two (2) years or both in addition to closure of the platform.

38. **Late Payment of Renewal Fees for Licensing of an Electronic Pharmacy**

Any 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% of the applicable fee as late payment fees.

39. **Failure to Register and be Licensed as an Electronic Pharmaceutical Service Provider**

Any person or corporate body that operates, establishes, maintains, or owns an electronic pharmacy, or provides services as an electronic pharmaceutical services provider without registering with and obtaining necessary licence from the Council commits an offence and is liable on conviction to a fine of

N2,500,000.00 or imprisonment for a term of two years or both. Such unregistered platform shall also be sealed and/or closed.

40. **Failure to Register and be Licensed as an Electronic Pharmacy Aggregator**

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 N3,000,000.00 or imprisonment for a term of two years or both.

41. **Failure to Provide Access to Backend for Inspection or Monitoring**

Any electronic pharmaceutical service provider who fails to provide access to the backend of its operations for the purposes 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 a fine of N2,000,000.00 or imprisonment for a term of two years or both.

42. **Obstruction of the Council's Inspectors**

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 therefrom,

(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,

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

Commented [TI18]: It is better to clearly specify who is/are to be imprisoned as the corporate body is not a human person but a legal person, is it the CEO, any of the Directors, the Superintendent Pharmacist? The same query applies to any section where the offence is committed by either the Online Pharmacy or Online Pharmacy Aggregator

Commented [TI19]: Since it is not all Guidelines that can be made thereunder immediately or now and other Guidelines could be made later without necessarily in these Regulations, it is better to say "therefrom" to capture both the Guidelines made thereunder or therefrom as both categories are derivatives of these Regulations. This explanation applies to earlier corrections in this regard.

Commits an offence and is liable on conviction to a fine of N2,000, 000.00 or imprisonment for a term of two years or both.

43. **Dispensing Without a Valid Prescription**

A person or a corporate body who dispenses Prescription-Only Medicines without a valid prescription as provided for under these Regulations or carries out any other unauthorised online disposal of drugs commits an offence and is liable on conviction to a fine of N2, 000,000.00 or imprisonment for a term of two years or both.

44. **Dispensing of Dangerous drugs**

A person or a corporate body who dispenses 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 a fine of N2,500,000.00 or imprisonment for a term of two years or both.

45. **Cross-border Sale of Drugs Online**

Any person or corporate body which 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 hereunder commits an offence and is liable on conviction to a fine of N2, 500,000.00 or imprisonment for a term of two years or both.

46. **Cross-border Purchase of Drugs Online**

Any 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

therefrom commits an offence and is liable on conviction to a fine of N2,500,000.00 or imprisonment for a term of two years or both.

47. **Joint and Vicarious Liability**

(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 or 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 capacity, the officer and the corporate body commit an offence and are liable to be proceeded against and punished accordingly.

(2) In relation to a corporate body carrying on an electronic pharmaceutical service, section 47 (1) 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:

(a) Is the Superintendent Pharmacist,

(b) At any premises where the business is carried on, is 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 preceding subsection.

(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.

48. **General Penalties**

(1) A person who commits an offence under these Regulations for which no specific penalty is provided is liable on conviction to a fine of at least N500,000.00 or imprisonment for a term of two years or both.

Commented [TI20]: Since it is not all Guidelines that can be made thereunder immediately or now and other Guidelines could be made later without necessarily in these Regulations, it is better to say "therefrom" to capture both the Guidelines made thereunder or therefrom as both categories are derivatives of these Regulations. It is obvious that there are no Guidelines made thereunder here, so "therefrom" should apply.

Commented [TI21]: I think this paragraph has put to rest my worry and concern with regard to human person to be sanctioned or punished in the case of a corporate body that is in breach of the Regulations, so much as the following paragraphs have done too.

(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 at least N2,000,000.00.

PART VII – MISCELLANEOUS PROVISIONS

49. Interpretation

In these Regulations, unless the context otherwise requires:

(1) "**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 function.

(2) "**Consumer application**" means a software application or online platform designed to accommodate users' 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.

(3) "**Data protection**" means the measures and safeguards in place to secure and protect users' data from unauthorised access, disclosure, alteration, or loss, in accordance with applicable data protection laws and regulations.

(4) **Disciplinary Tribunal**" means the Disciplinary Tribunal of the Pharmacy Council of Nigeria established in accordance with the provision of Section 46 (1) of the Pharmacy Council of Nigeria (Establishment) Act, 2022.

(5) **E-prescription" means** prescriptions transmitted electronically to pharmacist as opposed to written prescriptions. Electronic prescription becomes valid for the purpose of these Regulations if the prescription is:

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

(b) Signed with an electronic signature, or directly on the written prescription before scanning,

(c) Sent through the National e-pharmacy platform to be created by the Council, or

(d) Transferred to the electronic pharmaceutical service provider as an electronic communication through telephonic or online medical consultation.

(6) **"Health care professional"** means a licensed medical practitioner, dentist, or veterinary practitioner, pharmacist, nurse and other designated healthcare personnel so licensed to practice in Nigeria and having a physical address and contact details in Nigeria.

(7) **"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 nonprescription medications to users at their homes.

(8) **"Home page"** means a page designated to 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.

(9) **"Internet"** The term '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/ Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.

(10) **"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.

(11) "**The Council"** means the Pharmacy Council of Nigeria.

(12) **"The Platform"** means the National Electronic Pharmacy Platform.

(13) **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.

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

(15) **"Electronic pharmacy"** is an internet-based service owned and operated by an electronic pharmaceutical service provider and / or 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.

(16) **"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.

(17) **"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.

(18) **"Electronic pharmaceutical service provider"** means:

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

(b) 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 licensed as an electronic pharmaceutical service provider under these Regulations.

(c) A pharmacist who in the absence of a pharmaceutical premises is in partnership with a registered and licensed pharmaceutical premises and registered and licensed as an electronic pharmaceutical service provider under these Regulations.

(d) Corporate entities exclusively operating through an online platform primarily focusing on the delivery of health and pharmaceutical products and registered and licensed as an electronic pharmaceutical service provider under these Regulations.

(e) E-commerce entities with retail pharmacy sections dedicated for health and pharmaceutical items; and registered and licensed as an electronic pharmaceutical service provider under these Regulations.

(f) 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 licensed as an electronic pharmaceutical service provider under these Regulations.

(g) 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 marginalized communities, or to address specific health challenges, and registered and licensed as an electronic pharmaceutical service provider under these Regulations duly authorised by the Council to sell, supply, dispense, pharmaceutical products and/or provide other pharmaceutical professional services directly to consumers over the internet, either independently or in conjunction with an electronic pharmacy aggregator.

(19) Person means a natural person or a body corporate

(20) Pharmacy Council of Nigeria Emblem" means the symbol as prescribed by the Council and patented by the Registrar of Patents and Trademarks.

(21) "Pharmaceutical premises" means as defined under the Pharmaceutical, Premises Location, Inspection, Structure, Monitoring and Enforcement Regulation, 2022 or any subsequent Regulations.

(22) "**Prescribed fees**" means such fees as approved by the Council.

(23) "**Prescribed emblems**" means such emblems produced and approved by the Council and which is required to be displayed by all electronic pharmaceutical service providers as mandated by the Council.

(24) "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.

(25) "**Superintendent pharmacist**" means a registered and licensed 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.

(26) **"Users"** means Clients who drugs are dispensed to, and who receive electronic pharmaceutical services rendered by the electronic pharmaceutical service provider.

(27) "**Users data**" includes any information related to an individual user, including but not limited to their personal and medical information, health history, prescription records, and other data collected during the provision of pharmaceutical and healthcare services.

(28) **'Valid means of identification" include international passport, National identification Card, National driver's licence**

(29) **"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 if 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 pieces of information as may be required by the Nigeria National Prescription and Dispensing Policy or other extant legislations or policy in Nigeria;

(30) "PCN Act or the Act" means Pharmacy Council of Nigeria (Establishment) Act 2022.

(31) "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.

50. **Citation**

These Regulations may be cited as the Electronic Pharmacy Regulations, 2024.

Commented [TI22]: This is a provision to accommodate any contemplation of the country's Prescription and Dispensing Policy that is currently being developed and any other extant legislations and policies.