



Health Ethics & Law
CONSULTING



A REVIEW OF THE ELECTRONIC PHARMACY REGULATIONS 2026

Introduction

The rapid growth of digital health and telemedicine practice has led to a significant shift in the approach to healthcare. Increasingly, consultations in physical clinics are now conducted online, allowing patients to report symptoms, receive diagnoses, and obtain prescriptions within minutes from the comfort of their homes. In the same way, the dispensing and distribution of medicines are increasingly moving into the digital space, giving rise to a structured global online pharmaceutical services industry.

Nigeria is currently experiencing a similar shift as healthcare providers explore innovative ways to expand access to medicines and pharmaceutical services. In 2021, the Online Pharmacy Regulations were introduced by the Pharmacy Council of Nigeria (PCN) to regulate the online sale of drugs. As time progressed, it became clear that the 2021 Regulations had some gaps such as the non-regulation of online pharmacy aggregators and other players in online drug sales, registration of online pharmacies without physical premises, the notorious Regulation 13(c) which prevented online pharmacies from dispensing prescriptions arising from online consultations, the requirement to display only Over-the-Counter (OTC) drugs without reference to drugs which have been granted OTC waiver status, and Regulation 13(d) which required electronic pharmaceutical service providers to implement systems to ensure restriction on the quantity of prescribed medicines that can be ordered and sold online, without specifying the exact restrictions. The Electronic Pharmacy Regulations 2026 replaced the 2021 Regulations, addressing these and other emergent issues.

It is essential for digital health startups, hospitals, e-pharmacies, telehealth organisations, and investors to understand the key provisions of these Regulations and their implications for business operations before entering the online pharmacy market.

This article provides an overview of the Regulations, including the categories of entities regulated, licensing and registration pathways, key compliance obligations, and sanctions for non-compliance. HELC was privileged to have supported the regulatory development process.

Below are the key highlights from the 2026 Regulations.

Who Can Register as an Electronic Pharmaceutical Service Provider?

Under the replaced Online Pharmacy Regulations 2021, Part 1, Regulation 2(c) required an application to include photocopies of the current premises registration licence, or evidence of current registration of premises, this added a layer of difficulty for pharmacists and non-pharmacists intending to own online pharmacies without a registered physical premises.

The Electronic Pharmacy Regulations remove the physical premises barrier. Accordingly, four (4) pathways exist to register.

- An individual or entity seeking to operate as an Electronic Pharmaceutical Service Provider may register with the PCN where it has both existing physical premises and the requisite online infrastructure, upon submission of the required application.[1]
- Where an individual or entity has an existing physical premises but lacks the online infrastructure to operate an electronic pharmacy, it may register by entering into a service-level agreement with an Electronic Pharmacy Aggregator, and submitting evidence of that agreement alongside other required documents to the PCN.
- An individual or entity without physical premises but with an online infrastructure may apply for registration, provided evidence of a partnership agreement with a licensed physical retail pharmacy, wholesaler, or distributor is submitted.[2]
- Finally, an individual or entity with neither physical premises nor online infrastructure may apply by providing evidence of a partnership with a licensed physical retail pharmacy, wholesaler, or distributor, as well as a service-level agreement with an electronic pharmacy aggregator, together with other required documentation to the PCN.

This provision introduces flexible pathways for registration, enabling individuals and entities to apply even where they lack physical premises or the online infrastructure required to host an electronic pharmacy.

It should, however, be noted that although non-pharmacists are permitted to own online pharmacies, the Regulations require that registration be undertaken by an in-house Superintendent Pharmacist, who will be responsible for overseeing and accountable for the delivery and operations of pharmaceutical services.[3]

Furthermore, following the enactment of the PCN Act, non-pharmacists may own chain retail or community pharmacies, provided that a pharmacist (or pharmacists) holds at least 40% equity in the company, whether solely or jointly. [4] In the same vein, such chain retail or community pharmacies may only establish an online pharmacy where this 40% ownership threshold is satisfied.

Registration Requirements

To register an electronic pharmacy in Nigeria, the applicant must submit a number of documents to the Registrar of the Pharmacy Council of Nigeria through the Superintendent Pharmacist. An important point to note is that mere registration does not confer the right to commence operations. The Regulations require an Electronic Pharmaceutical Service Provider to obtain an Electronic Pharmacy Licence upon fulfilling certain requirements provided under the Regulations, which must be renewed annually. [5] Such a licence runs from 1 January to 31 December of each year. [6]

Registration of Electronic Pharmacy Aggregators

The Regulations now cover Electronic Pharmacy Aggregators, given the vital role they play in access to medicines. Regulation 3 requires an Aggregator to be registered as an electronic pharmacy. Electronic Pharmacy Aggregators are defined as third-party platforms offering technology infrastructure to connect multiple Electronic Pharmaceutical Service Providers with consumers, who do not own the products being offered for sale on the platform, and whose activities are restricted to the management and maintenance of the platform. [7]

An Aggregator is required to have a Superintendent Pharmacist specifically designated to oversee the pharmaceutical service delivery, and also to be registered by a Superintendent Pharmacist. [8] Some of the registration requirements include: evidence of payment of prescribed fees, CV of the Superintendent Pharmacist, final prototype showing contents of the proposed platform, details of the technological infrastructure underpinning the platform, among others. [9]

Mere registration does not confer the right to commence operations. An Aggregator must obtain an aggregator licence upon fulfilling certain requirements provided under the Regulations. This licence runs from 1 January to 31 December and must be renewed annually. [10]

Though there is a clear difference between Electronic Pharmaceutical Service Providers and Aggregators, those interested in registering as either, may need more clarity on how to proceed.

The Regulations require Aggregators to also appoint a Superintendent Pharmacist responsible for pharmaceutical service delivery and oversight of the aggregator platform, notwithstanding that they are primarily defined as entities engaged in the management and maintenance of platforms for online pharmacies. While this reflects an underlying regulatory position on the role of aggregators within pharmaceutical service delivery, this may also create a grey area. It is also important to note that, in certain circumstances, an entity may be able to operate under both licensing regimes. However, the implications of such dual operation fall outside the scope of this article. Electronic Pharmaceutical Service Providers and Aggregators are advised to engage with legal advisors to ensure compliance and avoid liability.

Requirements to be Displayed Online by an EPSP

The Regulations retain certain requirements from the previous regime, while introducing additional obligations. These include, among others, the display of the authorised PCN logo and the licensing number of the online pharmacy on its homepage; the display of the Electronic Pharmaceutical Service Provider registration number on its homepage; and a declaration that the Electronic Pharmaceutical Service Provider will dispense prescription-only medicines solely upon presentation of a valid prescription issued by a licensed healthcare provider. [11]

Data Protection

The Regulations introduce detailed provisions on data protection. The previous regulations required Electronic Pharmaceutical Service Providers to comply with relevant laws relating to Information and Communication Technology, which was too broad. The 2026 Regulations now adopt a more precise approach by requiring compliance with the Nigeria Data Protection Act and other applicable data protection laws. In addition, aggregators are required to submit evidence of registration with the Nigeria Data Protection Commission as a condition for licensing.

Internal Compliance Requirements

Electronic Pharmaceutical Service Providers are required to have in place several internal compliance mechanisms and due diligence protocols to ensure compliance. Some of these include the requirement to ensure prescriptions are only filled once, to make the website user-friendly, to ensure education of users regarding the medication and disease state, to educate users on their rights to seek clarification and consultation, to educate users on the Patients' Bill of Rights, to contact users regarding delay in delivering medications, and to ensure that appropriate mechanisms are in place for identify-

ing inappropriate requests including multiple orders by the same individual, to the same address or using the same payment details.^[12]

Electronic Pharmaceutical Service Providers are also required to put in place mechanisms for verifying the user's or prescriber's identity before the purchase of drugs. This could be through personal information verification, or other means of identification e.g., national identification.^[13]

The Regulations further require Electronic Pharmaceutical Service Providers to implement appropriate storage, delivery, and distribution practices. In relation to storage, Electronic Pharmaceutical Service Providers are required to ensure, among other things, that medicinal products are maintained under suitable temperature conditions throughout the course of storage, transit, and delivery.

Recognising that delivery and distribution may be undertaken either directly by Electronic Pharmaceutical Service Providers or through contracted third-party courier and logistics providers, the Regulations place a continuing obligation on them to ensure that all such activities are carried out in accordance with applicable Good Distribution Practices.^[14] The Regulations further require Electronic Pharmaceutical Service Providers to maintain an exhaustive list of records (i.e., the identity of customers and the details of medicine requests) and maintain such records for a period of 5 years.^[15]

Dispensing of Drugs Online Through Consultations

Prior to the 2026 Regulations, Regulation 13(c) of the former framework required Electronic Pharmaceutical Service Providers to implement policies preventing the prescription or dispensation of medicines based on telephonic or online medical consultations. This provision has now been removed under the 2026 Regulations, thereby permitting prescriptions and dispensing based on online consultations, provided that a valid prescription is issued.

Notably, the Regulations go further by expressly defining what constitutes a valid prescription—an area that was not addressed under the former regulations. Under the current framework, a valid prescription must be issued by a licensed healthcare practitioner in Nigeria and must include, among other things, the practitioner's physical address and contact details in Nigeria, patient details, relevant medical information, duration and date of the prescription, the prescriber's registration number, as well as the name and signature of the healthcare professional.^[16]

This list remains open for the Nigeria National Prescription and Dispensing Policy to provide more requirements. Such prescriptions, once issued, remain valid for only 6 months. Electronic Pharmaceutical Service Providers are prohibited from dispensing drugs unless the prescription requirements under the Regulations are met.

By implication, prescriptions issued by healthcare professionals not licensed in Nigeria may not constitute a valid prescription under the Regulations.

Sliding Scale Restriction on the Online Sale of Drugs

Regulation 13(d) of the former framework required Electronic Pharmaceutical Service Providers to implement systems to enforce limits on the quantity of prescribed medicines that could be sold online. The updated Regulations go beyond this by expressly stipulating those limits, rather than merely requiring Electronic Pharmaceutical Service Providers to establish internal controls.

Under the Regulations, Electronic Pharmaceutical Service Providers are required to dispense medicines strictly in quantities that do not exceed those specified in a valid prescription. However, such quantities may be increased within the treatment duration indicated by the healthcare professional, provided that a clear medical justification is given and the additional quantities are expressly stated.^[17]

Prescription-only medicines that require refills may be dispensed in accordance with the refill intervals specified by the prescribing healthcare provider. In contrast, prescription-only medicines with an OTC waiver (such as family planning drugs authorised for self-administration and oral contraceptives) are subject to the standard course-of-treatment supply.

Prohibition of Cross-Border Sale of Drugs

While the former regulations were silent on cross-border sales of drugs into and out of Nigeria, the 2026 Regulations expressly prohibit such sales except in narrowly regulated circumstances, where the medicine is lifesaving, the sale or purchase is carried out by a duly registered and currently licensed pharmacist operating under a PCN-registered pharmaceutical premises, done according to Nigerian law and the foreign law, among other requirements. It remains to be seen how this would be implemented; however, Electronic Pharmaceutical Service Providers and Aggregators are advised to engage with legal advisors to ensure compliance and avoid liability.

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Cap on Electronic Pharmacies to be Registered by a Superintendent Pharmacist

Under the previous regulations,^[18] a Superintendent Pharmacist was permitted to register only one internet platform linked to a single premises. The Regulations refine this position by removing the express reference to a single premises, as this requirement is already provided for under the enabling Act. Accordingly, a Superintendent Pharmacist remains restricted to registering only one electronic pharmacy. ^[19]

Integration on the National Electronic Pharmacy Platform (NEPP)

Although the Regulations require Electronic Pharmaceutical Service Providers to implement mechanisms for verifying the authenticity of prescriptions, Regulation 20(10) goes further by mandating that such verification be carried out through mechanisms prescribed by the Council.

The National Electronic Pharmacy Platform serves as this mechanism, functioning as the central (nodal) platform for facilitating, transacting, and monitoring electronic pharmacy services in Nigeria. Accordingly, all online drug orders must be processed through the Platform, and all independent platforms operated by Electronic Pharmaceutical Service Providers and Aggregators must be both legally and technically integrated into it.

In addition, all healthcare professionals, including licensed medical practitioners, dentists, veterinary practitioners, pharmacists, nurses, and other designated personnel, must register on the Platform using valid identification and their unique registration numbers issued by their respective licensing bodies. This framework enables the verification of prescribers and, in turn, may give effect to Regulation 20(10).^[20]

Electronic Pharmaceutical Service Providers are also required to pay an annual subscription fee to utilise this Platform.^[21] While the Platform may take some time to become fully operational, Electronic Pharmaceutical Service Providers should, in the interim, engage their legal and technical teams to ensure seamless readiness for integration.

Access to Essential Reproductive Health Services

As earlier noted, the Regulations were introduced to enhance access to essential medicines, particularly family planning products approved for self-administration following the grant of over-the-counter (OTC) waiver status (e.g., DMPA-SC).

This focus is reflected throughout the Regulations, which make specific reference to such products. Regulation 19(1)(e) requires Electronic Pharmaceutical Service Providers to ensure that their platforms are user-friendly and interactive, including the incorporation of mechanisms for providing educational materials when dispensing family planning drugs authorised for self-administration. In addition, Regulation 20(1) mandates Electronic Pharmaceutical Service Providers to adhere to Good Pharmacy Practices in the dispensing of Prescription-Only Medicines that have obtained OTC waiver status.

Furthermore, Regulation 26 permits the advertisement of family planning drugs authorised for self-administration, subject to compliance with prescribed modalities governing such advertisements.

Patients' Rights

The Regulations introduce more robust protections for patients' rights; a theme reflected throughout the Regulations. Key provisions require Electronic Pharmaceutical Service Providers to strictly adhere to the Patients' Bill of Rights,^[22] educate users on these rights—including the right to seek clarification and consultations,^[23] and uphold patients' entitlement to return medicines where the packaging appears to have been tampered with, or the drug has expired.^[24]

Consequences for Non-Compliance

Failure to comply with the provisions of the Regulations and other relevant laws exposes operators to possible sanctions. Depending on the nature and severity of the breach, the PCN may suspend, revoke, modify, withdraw, or cancel the licence issued. Sanctions may also extend to imprisonment or the payment of fines, as prescribed under the Regulations.^[25] Electronic Pharmaceutical Service Providers, Aggregators, and other stakeholders are advised to seek legal support to ensure operations are aligned with compliance requirements.

Conclusion

As Nigeria's digital health sector evolves, compliance with the Electronic Pharmacy Regulations 2026 and other applicable laws remains critical for Electronic Pharmaceutical Service Providers and E-Pharmacy Aggregators. Stakeholders must ensure their platforms, operations and partnerships align with regulatory requirements to mitigate risk and avoid sanctions for non-compliance. Engaging legal advisors is essential to navigate these requirements and maximise the opportunities in this growing sector.

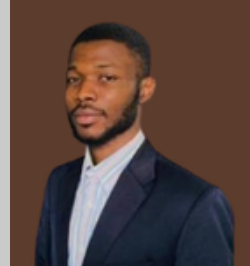
References

- [1] Electronic Pharmacy Regulations 2026, Regulation 4(1) (m)
- [2] Ibid, Regulation 4(1) (n)
- [3] Ibid, Regulation 4(1) (p)
- [4] Pharmacy Council of Nigeria (Establishment) Act 2022, Section 27(3)
- [5] Ibid, Regulation 5
- [6] Ibid, Regulation 6
- [7] Ibid, Regulation 52
- [8] Ibid, Regulation 8(1)
- [9] Ibid, Regulation 9
- [10] Ibid, Regulations 9(4)
- [11] Ibid, Regulation 12
- [12] Ibid, Regulation 19
- [13] Ibid, Regulation 22(2) and 28
- [14] Ibid, Regulation 29
- [15] Ibid, Regulation 30
- [16] Ibid, Regulation 20(4)
- [17] Ibid, Regulation 23(1)
- [18] Online Pharmacy Regulations 2021, Regulation 20(5)
- [19] Electronic Pharmacy Regulations, Regulation 34(4)
- [20] Ibid, Regulation 36(7)
- [21] Ibid, Regulation 36(3)
- [22] Ibid, Regulation 28(4)
- [23] Ibid, Regulation 19(1)
- [24] Ibid, Regulation 29(4)
- [25] Ibid, Part VI

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