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**GROWTH OF HEALTHTECH IN
NIGERIA – ANALYSING THE
ONLINE PHARMACEUTICAL
REGULATIONS 2021**

ARTICLE SERIES

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INTRODUCTION

With the pandemic and its associated developments, the ability to timeously and efficiently place orders for drugs and medicine to meet the needs of patients and consumers has become crucial and online-based pharmaceutical service providers have created a niche for themselves by filling this yearning gap.

However, with the proliferation of these internet-based pharmaceutical service providers, it has become necessary to regulate their activities. In exercise of its powers, the Pharmacists Council of Nigeria (“PCN”) released the Online Pharmacy Regulations (“the Regulations”), 2021.

In this article, we review the Regulations and consider its impact on the healthtech sector in Nigeria.

APPLICATION OF THE REGULATIONS

‘Online Pharmacy’ is defined in the Regulations as an internet dependent pharmaceutical service. The inference from this definition is that [1] The PCN is empowered by the Regulations to issue licence to all Internet based Pharmaceutical Services Providers (“the Providers”) based in Nigeria

The Regulations specify lawful activities to be carried out by the Providers, the powers of the PCN over the Providers and penalties for breach of the Regulations.

Registration

The Regulations provide that Internet based pharmaceutical service providers (“the Providers) in Nigeria shall be registered with the PCN.[2] They also provide that a Pharmacist can only register one internet-based platform. [3]

[1] Reg 23, The Online Pharmacy Regulations, 2021.

[2] Reg. 1, The Online Pharmacy Regulations, 2021.

[3] Reg. (5), The Online Pharmacy Regulations, 2021.



A Superintendent Pharmacist shall be designated by the Internet pharmaceutical service who would complete the application form accompanied by necessary documents on behalf of the Provider. The application shall be made to the PCN. [4] The name and credentials of the Superintendent Pharmacist and other professionals involved in the online pharmacy shall be displayed online. [5]

Upon submission of the documents, the PCN shall carry out an inspection of the Providers and shall from time to time carry out follow up inspections throughout the supply chain. The accredited supervisors shall carry out their duties, at reasonable times and upon production of their identity cards. [6]

The accredited supervisors shall have the powers to do the following:

- Enter any premises that hosts the Provider or visit the online platform of such Provider through the use of such force or technology necessary.
- Examine any article or records in the premises or on the site to which the Regulations apply.
- Access the backend of the site or platform to examine the records of activities of the Provider where it suspects a breach of the Regulations.
- Examine books, records, or documents found on the premises, sites or platforms that is reasonably believed or suspected to contain information relevant to the enforcement of these Regulations and to make copies of those books, records or documents.
- Retrieve and process information from the site that is reasonably believed or suspected to have violated the Regulations.
- Seal any unregistered or unlicensed Provider's premises or site, where access to records, documents or articles is not granted by the operator.

The provider or his/her representative shall give all necessary assistance to the inspectors and make available all information necessary for the purpose of enforcing the Regulations. [7]

[4] Reg. 2, The Online Pharmacy Regulations, 2021.

[5] Reg. 3, The Online Pharmacy Regulations, 2021.

[6] Reg. 10 (1), The Online Pharmacy Regulations, 2021.

[7] Reg. 10(2), The Online Pharmacy Regulations, 2021.

[8] Reg. 11, The Online Pharmacy Regulations, 2021.

[9] Reg. 12, The Online Pharmacy Regulations, 2021.

The PCN shall also prescribe a pharmacy emblem for the usage of the Providers and only the prescribed emblem shall be displayed by the Providers.

Operation of the platform

Every internet service provider shall operate in line with best practices and within relevant Regulations as issued by the Nigerian Communications Commission. [8] The sites of Providers shall be user friendly and interactive. [9] The Providers shall ensure the implementation of Good Pharmacy Practice on their sites with regard to dispensing of Prescription-Only-Medicines and shall set up the following:

- A system to ensure the integrity and legitimacy of prescription drug orders;
- Process and procedure to authenticate the validity of a prescription and confirm that it is from a licensed health professional before dispensing same;
- Policy to prevent medications from being prescribed or dispensed based on telephonic or online medical consultation; and
- Systems to ensure restriction on the quantity of prescribed medicines that can be ordered or sold online. [10]

Over-the-Counter drugs shall be sold in compliance with relevant laws and only such drugs may be advertised on the sites. [11]

The Providers shall among other things, provide systems for safe and secure delivery of all medications, ensure that the right temperature for storage of drug is maintained during mailing and delivery, ensure that the medication remains in a tamper-evident container until it is delivered.

The sites of the Providers are required to be user friendly as to ensure mechanisms for consultancy, educating patients, contacting patients and reporting adverse drug reactions and medication errors. [12]

[10] Reg. 13, The Online Pharmacy Regulations, 2021.

[11] Reg. 14, 15(1), The Online Pharmacy Regulations, 2021.

[12] Reg. 12, The Online Pharmacy Regulations, 2021.

Data protection

The Regulations also places data protection obligations on the Providers. The Regulations provide that the Providers shall institute policies and procedures to protect patient information and confidentiality. [13]

Penalties

The PCN sets out penalties for non-compliance with the provisions of the Regulations which include the following:

- A registered provider that fails, refuses or neglects to renew its license by the 31st of January every year shall pay 50% of the applicable fee as late payment fees. [14]
- An unregistered Provider premises or site shall be closed by the PCN. [15]
- Where an emblem of the PCN is found on an unauthorized internet site or platform, such site shall be closed down. [16]
- A person who displays an emblem or licence not prescribed by the PCN commits an offence and is liable to pay the PCN a penalty of not less than N250,000 (two hundred and fifty thousand Naira)in addition to the closure of the site or platform. [17]
- Any Pharmacist who registers or attempts to register more than one online site or premises commits an offence and shall have the site closed down, be referred to the Investigating Panel and be referred to the Disciplinary Tribunal of the PCN for appropriate action. [18]
- A person who fails to comply with the provisions of the Regulations shall be guilty of an offence and liable on conviction to a term of imprisonment of not less than 6 months or fine of not less than N250,000 (two hundred and fifty thousand Naira)or both. [19]

CONCLUSION

Technology has transformed several industries in recent times. The advent of innovative and modern technological advancements has made a notable difference in the medical field. The Regulations are a welcome development as they will serve as a check to the budding market of Providers.

However, it is pertinent to note that the Regulations provide that the provider's site shall be user friendly and interactive to allow mechanisms for a number of things but notably, **consultancy services to patients and clients** [20]. Nevertheless, in another breath, the Regulations mandates the providers to implement policies to prevent medication from being dispensed or prescribed based on telephonic or online consultation. [21]

While one might immediately recognize the mischief that the latter provision seeks to curb, it seems inefficacious that a pharmacist may provide consultancy services to a client but be unable to prescribe medication based on the diagnosis made because the provider has a policy in place preventing him from making the prescription. It also works hardship on a patient who is in need of quick delivery of medication based on an online consultation.

One importance of the providers is their ability to timeously provide medication to customers. The above provision makes them unable to do so unless the customer obtains a physical prescription, which may not always be possible.

It is therefore our recommendation that the PCN examines this provision with a view to revising it so it serves as an enabler rather than an inhibitor.

[13] Reg. 16, The Online Pharmacy Regulations, 2021.

[14] Reg. 19(1), The Online Pharmacy Regulations, 2021.

[15] Reg. 19(2), The Online Pharmacy Regulations, 2021.

[16] Reg. 20(2), The Online Pharmacy Regulations, 2021.

[17] Reg. 20(4), The Online Pharmacy Regulations, 2021.

[18] Reg. 20(5), The Online Pharmacy Regulations, 2021.

[19] Reg. 22(3), The Online Pharmacy Regulations, 2021.

[20] Regulation 12(a), The Online Pharmacy Regulations, 2021.

[21] Regulation 13(c), The Online Pharmacy Regulations, 2021.



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