

# Regulating Digital Health

**Review of Online Pharmacy Regulations 2021**



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## Executive Summary

The Online Pharmacy Regulations 2021 seeks to provide a regulatory regime regarding the activities of internet-based pharmaceutical service providers in Nigeria. This review focuses on salient provisions of the Regulations and compares them with similar laws in other climes like the US, the UK, and the EU. The comparable legislation in this respect are:

- Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet 2019 (UK)
- Conditions of use for the GPhC voluntary internet pharmacy logo (UK)
- Inspection Decision Framework 2019 (UK)
- Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (USA)
- Falsified Medicines Directive 2011 (EU)

There are similarities between the Nigerian position on certain issues, the UK/US position, and their diverging points. Nigeria and the USA agree that controlled substances should not be prescribed over the internet, whereas the UK permits it, subject to certain requirements. Nigeria and the UK agree that the regulatory body should be notified when an online pharmacy is shut down.

Nigeria's proposed approach to inspection of online pharmacies leaves much to be desired as it gives too many reserve powers to regulators, making them judges and executors. It also fails to consider the possibility of privacy infringements in enforcement. It also does not consider items that affect the patient's wellbeing and focuses on more punitive sanctions.

On the other hand, the UK's approach provides an avenue for self-regulation and self-review, empowers staff of online pharmacies to become enforcement partners, and prioritises ventilation and storage. But unfortunately, all of these are absent in Nigeria's Online Pharmacy Regulations.

The Online Pharmacy Regulations also seek to extend the scope of telecoms regulations to online pharmacies. However, considering the disconnect between healthcare and telecoms, this provision seems misplaced. The Regulation also fails to specify what telecoms regulations online pharmacies should comply with. A review of some telecoms regulations showed that they were only applicable to licensees of the telecoms regulator and organisations that offer communication services.

This review also shows that there is the possibility of dark patterns in the design of online pharmacies. None of the legislation for Nigeria's review for banning the manifestations of dark patterns, the country will be in the small club of nations that have commenced legislation concerning dark patterns. Dark patterns pose a higher risk in the healthcare sector.

Online pharmacies in Nigeria are required to audit their delivery processes. In contrast, their counterparts in the UK are required to conduct business-wide audits covering their staffing, communication methods, and records of decisions. They are also required to track and monitor packages.

Online pharmacies registered with the Pharmaceutical Council of Nigeria (PCN) will be entitled to use an emblem displayed on their website. However, the Regulation is poorly worded in this section as it suggests that an applicant can register one internet-based platform or only one physical premise. This review recommends that this provision be improved, alongside other recommendations to enhance the Regulations.

Some highlights from this review are as follows:

- Under EU legislation, member states are required to set up a website that links to all approved online pharmacies, a requirement absent under the Nigerian Regulations
- UK legislation allows applicants to register multiple websites in one application, unlike what Rule 21 of the Regulations implies.
- The Online Pharmacy Regulations fail to define what it means to depend on the internet, leaving it to conjecture and debate.
- The Regulations seek to capture manufacturers, wholesalers, distributors, importers, retailers and dispensers as potential online pharmacies, unlike in the US, where only retailers and dispensers are captured.
- The definition of internet dependency under US legislation is tied to the transaction in question, not the pharmaceutical service provider.



## Introduction

The Online Pharmacy Regulations 2021 is Nigeria's first attempt at directly legislating telemedicine, focusing on pharmaceutical service providers who leverage the internet to deliver their services. This review seeks to analyse the regulations' general state and juxtapose them with similar legislation in advanced climes, focusing on the USA, UK, and the EU. This review aims to point out areas where improvements can be made and show where Nigeria meets the global standards of telemedicine legislation.

## Application for registration of online pharmacy

Registration of an online pharmacy can only be done by its Superintendent Pharmacist, who may not necessarily be the owner.<sup>1</sup> This Superintendent Pharmacist will be responsible for the services provided by the online pharmacy.<sup>2</sup> In line with the UK position that online pharmacies must be transparent by showing who the responsible pharmacist is regarding the supply of medicines and medical supplies.<sup>3</sup>

## Closure of facility

Rule 8 provides that where an internet-based pharmaceutical service provider intends to close down its operations, the Council should be notified of this no later than 14 days to closure. The General Pharmaceutical Council (GPhC) of the UK similarly requires that it be informed if an online pharmacy is to be shut down.<sup>4</sup> It, however, fails to state a timeline for notifying the Council, unlike the Regulations.

The Regulations fail to consider that an online pharmacy may wish to change its URL or add additional URLs. For instance, if the company started a business with a .ng domain and, in the course of expansion, seeks to register a .com domain for greater visibility, the company may run afoul of Rule 21(5), which seems to limit pharmacists to just one internet-based platform. This Rule is poorly written and gives room for confusion. It is discussed in greater detail under 'The PCN Emblem' heading of this review.

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<sup>1</sup> Online Pharmacy Regulations 2021, Rule 2

<sup>2</sup> Ibid, Rule 2(m)

<sup>3</sup> Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet, April 2019, General Pharmaceutical Council, Principle 4.2, p. 16

<sup>4</sup> Conditions of use for the GPhC voluntary internet pharmacy logo, General Pharmaceutical Council, para. 10

The UK's position concerning new URLs is simply that the GPhC be notified.<sup>5</sup>

Going back to Rule 8 of the Regulations, where the closure is only temporary, it must not exceed 12 months. Renewal fees will still have to be paid, which is unfair because an online pharmacy will not be making any income during the closure period.

## Inspection, Monitoring and Enforcement

There is a wide gulf between the inspection framework under the Nigerian Online Pharmacy Regulations and the UK's *Inspection Decision Framework 2019*, also issued by the General Pharmaceutical Council (GPhC). The UK's approach is to provide a checklist, cutting across several principles and standards, thus tilting towards soft law and providing more detail to aid understanding and ease of compliance. The Nigerian approach is more punitive and emphasises seeking out breaches of the Regulations rather than encouraging good practices.

Some of the key differences will be presented in tabular form below:

Nigerian Online Pharmacy Regulations 2021, Rule 10	UK's Inspection Decision Framework 2019
<p><b>a.</b> Empowers inspectors to enter premises hosting online pharmacy or visit the website using force and technology as is necessary</p>	<p>There are governance frameworks safeguarding the health, safety and wellbeing of patients and the public, such as data standard operating procedures (SOPs), which are signed off by the superintendent pharmacist (Principle 1, Standard 1.1)</p>
<p><b>b.</b> Examine any article or record on the premises or website relevant to the manufacture, preparation, preservation, storage, or sale of items covered.</p>	<p>Reviews are carried out on the entire range of services provided, not just for supplying and dispensing, and to ensure the safety of services and detect room for improvement (Principle 1, Standard 1.2)</p>
<p><b>c.</b> Access to the backend of the site to examine records relating to the online pharmacy where there is suspicion of breach of Regulations</p>	<p>Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public. For instance, knowing who is locally accountable and reporting mechanisms regarding controlled drugs. (Principle 2, Standard 2.3)</p>
<p><b>d.</b> Examine books, documents, or records found on-premises or online that are believed to contain information relevant to the enforcement of Regulations and make copies.,</p>	<p>Staff are empowered to provide feedback and raise concerns about meeting the standards and other aspects of pharmacy services, for instance, by way of a whistleblowing policy that is regularly reviewed (Principle 2, Standard 2.5)</p>

<sup>5</sup> ibid

<p>e. Retrieving and processing information from the internet site that is reasonably believed or suspected to have violated the Regulations</p>	<p>All medicines are obtained from licensed wholesalers or suppliers, and the pharmacy complies with the <i>Falsified Medicines Directive</i> (Principle 4, Standard 4.3)</p>
<p>f. Sealing unregistered or unlicensed online pharmacy premises or sites where the operator does not grant access to records, documents, or articles.</p>	<p>Equipment and facilities are used to protect the privacy and dignity of the patients and the public who receive pharmacy services. For instance, access to patient medication records (PMR) is controlled through passwords that are secure and frequently changed (Principle 5, Standard 5.3)</p>

As seen above, the Nigerian approach to inspection is one of brute force. The regulator has unchecked powers of ingress and egress into the online pharmacy's premises, online and offline. The exercise of such powers not only affects the online pharmacies but as privacy implications on the records of customers stored on the backend and the operations of their hosting provider, who may end up being pulled into this to grant access or shut the site.

The Regulations consider none of this, making it problematic and a ready tool for executive high-handedness.

On the other hand, the UK Framework encourages self-regulation and gives clear examples to guide pharmacies on steps to implement and inspect things to look out for. Although not mentioned above, the UK's Framework also considers the hygiene of the pharmacy,<sup>6</sup> their security measures online and onsite,<sup>7</sup> ventilation,<sup>8</sup> medicine storage<sup>9</sup> and more, all of which are relevant for inspecting pharmacies. Some of these are not considered in Nigeria's inspection framework under the Regulation, leaving room to question the priorities of the sector regulator.

## Operations

Rule 11 requires online pharmacies to operate in line with best practices and relevant regulations in the telecoms industry. The telecoms sector regulator is the Nigerian Communications Commission (NCC), an agency under the Ministry of Communications and Digital Economy. This Regulation is issued under the authority of the Minister of Health. Ordinarily, there is no correlation between the health and telecoms sectors. If the Regulations seek to expand the scope of liability to include telecoms legislation, they ought to expressly refer to the regulations in question.

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<sup>6</sup> Inspection Decision Framework 2019, General Pharmaceutical Council, Principle 3, Standard 3.1

<sup>7</sup> Ibid, Standard 3.4

<sup>8</sup> Ibid, Standard 3.5

<sup>9</sup> Ibid



To investigate if there was a sound basis for requiring online pharmacies to comply with telecoms regulations, this writer reviewed some of the regulations issued by the NCC. In all instances, it was expressly stated that these regulations only applied to licensees (of the NCC)

and other entities that provide communication services. Some of the regulations considered were:

- Consumer Code of Practice Regulations
- Lawful Interception of Communications Regulations
- Competition Practices Regulations
- Universal Access and Universal Service Regulations
- Licensing Regulations
- Guidelines on Advertisements & Promotions
- Guidelines for the Provision of Internet Service

Online pharmacies are not licensed by the NCC and provide communication services. Therefore, attempting to extend Regulation to healthcare will only create problems. The provisions of Rule 11 are absurd and should be expunged. Alternatively, the Regulation drafters should refer to the telecoms regulation they have in mind and define its scope of applicability.

## Communications

Rule 12 of the Regulations provides that every internet-based pharmaceutical service provider should make their site user-friendly and interactive for the following purposes:

- Consultancy services to patients or clients
- Educating patients regarding the medications and disease states
- Contacting patients regarding delays in delivering prescriptions as well as feedback and recalls;
- Reporting adverse drug reactions and medication errors

This section considers the UI/UX of websites used by online pharmacies. It does not consider the human component behind the delivery of the services. While patients will appreciate easy access to medical consultancy, they will be more reassured if they can verify that the advice supplied by

the website comes from someone qualified to do so. The GPhC requires that where a person can be prescribed medication online, the website must state the following:<sup>10</sup>

- the name and address of the prescribing service and the country it is located
- the name and registration number of the prescriber
- status of the prescriber (doctor, nurse, pharmacist, physiotherapist, dentist)
- name and address of the prescriber's regulatory authority
- information on how to check the prescriber's registration status

Something similar should be incorporated into the Regulations. Doing so would deliver the following benefits;

- help to ascertain the veracity of the prescription
- aid patients and their medical consultants in continuing prescription where the patient goes on to seek medical consultation either offline or from another website
- ensure that quacks and suspended medical personnel do not resort to using the internet to ply the trade.

Both the Nigerian and UK Regulation fail to consider dark patterns in the user interface of websites belonging to online pharmacies. Dark patterns refer to a design mechanism that misleads users into making decisions that are not in their immediate interest<sup>11</sup> - involving the use of urgency, where a deadline is imposed on the sale of a particular drug or drugs to compel users to make purchases. For example, it could imply scarcity by telling users that there is limited medicine stock, thus compelling them to buy it before it 'runs out'. The user interface could also make it easy for the consumer to check out a drug but difficult to cancel an order (known as obstruction).<sup>12</sup>

Dark patterns generally impact the free will and choices of the consumer. In a field as sensitive as healthcare, the implications of deploying dark patterns in online pharmacies can put the life and wellbeing of patients in danger. Before such instances arise, they should be nipped in the bud, and a review of the Regulations to expressly ban the various manifestations of dark patterns will be a step in the right direction. It will also place Nigeria as a frontier nation regarding dark pattern legislation. Other jurisdictions with dark pattern legislation include the USA with the *Deceptive Experiences To Online Users Reduction Act, 2019 (DETOUR Act)*, the *Filter Bubble Transparency Act (FBTA)*, and the *EU Consumer Rights Directive*.<sup>13</sup>

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<sup>10</sup>Ibid 4, para. 9

<sup>11</sup> Manyame, A., Oloyede, R., *Dark Design: The Art of Deception by Design*, Digital Law Haus & Tech Hive Advisory <https://techhiveadvisory.org.ng/dark-design-the-art-of-deception-by-design/> p. 4

<sup>12</sup> Ibid, pp. 5 - 6

<sup>13</sup> Ibid, pp. 7 - 8



## Dispensing Prescription-Only Medicines

The Regulations seek to curtail the scope of telemedicine in Nigeria before it takes off. Rule 13(c) restricts online pharmacies from dispensing prescription-only medication based on telephonic or online medical consultations. Prescription-only medication can only be dispensed based on a physical prescription.<sup>14</sup>

This restriction is unnecessary because the Regulation already requires the presence of a qualified Superintendent Pharmacist in the management and running of the online pharmacy.<sup>15</sup> Where the pharmacist is deemed not qualified to issue prescriptions, the Rules could require the involvement of a medical professional qualified to issue prescriptions, unlike an outright ban that limits the service range of online pharmacies and their capacity to support the health needs of Nigerians.

Nigeria's position is similar to that of the USA under the *Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act)*. Section 2 of this law prevents dispensing of controlled substances by online pharmacies, except there is a valid prescription (defined as involving in-person or physical evaluation). However, considering the period when this law was enacted and the advances made in telemedicine, it cannot be said to be in line with modern trends and is restrictive. Therefore, Nigeria should not follow the American example in this respect.

In the UK, however, online pharmacies can dispense prescription-only medicines. They must, however, provide the following information:<sup>16</sup>

- the name of the prescriber and address of prescribing service;
- the prescriber's registration number and country of registration;
- status of prescriber – doctor, pharmacist, nurse, physiotherapist;
- information on how to check the registration status of the prescriber.

The UK regulation further specifies several categories of drugs and how they should be treated. For instance, antibiotics are only to be dispensed according to good practice guidance and the patient's location. The same applies to drugs liable for abuse, misuse, overuse, or addiction, such as opiates, sedatives, laxatives, pregabalin, and gabapentin.<sup>17</sup>

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<sup>14</sup> Ibid 1, Rule 13(b)

<sup>15</sup> Ibid, Rules 2 & 3

<sup>16</sup> Ibid 3, Principle 3.2, p. 14

<sup>17</sup> Ibid, Principle 4.2, p. 17

This approach is preferable as it does not make light of prescription medication status and provides an avenue for verifying or seeking redress where applicable, instead of an outright ban.

## Storage and Delivery of Drugs

Regarding the storage and delivery of drugs, Rule 17(e) requires internet-based pharmaceutical service providers to develop a full audit trail for medication delivery, including requiring a signature upon delivery. However, this audit requirement is narrow compared to that under the GPhC's *Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet*, issued in April 2019.

Audits for online pharmacies in the UK are expected to be corporation-wide, not just limited to the delivery process of drugs, like under the Nigerian rules. Audits in the UK are expected to cover the following:<sup>18</sup>

- staffing levels and their training
- communication methods with suppliers within the organisation and with customers
- systems and processes for handling prescriptions
- records of decisions to make or refuse a sale
- systems of delivery of medication
- information about the pharmacy's services
- cybersecurity and data protection compliance
- customer feedback
- concerns and complaints received
- activities of third parties, agents or contractors.

Rule 17 further provides that internet-based pharmaceutical service providers should provide systems for safe and secure delivery of medications. They must ensure that drugs are kept at the right temperature and tamper-proof and transported according to good distribution practice, in tandem with Principle 4.3 of the GPhC's *Guidance for registered pharmacies providing pharmacy services at a distance including on the internet*.

The Guidance further provides that online pharmacies should track and monitor the package to ensure it gets to the right person and consider laws governing the export of medicines if the recipient is outside the UK. Incorporating similar provisions into the Nigerian Regulations would ensure enhanced compliance with consumer rights.

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<sup>18</sup> Ibid, Principle 1.2, p. 10

## The PCN Emblem

Rule 21 (wrongly numbered as '20' in the Regulations) provides that the Council may prescribe an emblem for its members to use. The emblem is the Council Registered Online Pharmacy Sites Emblem (ROPSE).<sup>19</sup>

Authorised online pharmacies must use this emblem. When an unauthorised online pharmacy uses it, the site or platform will be shut down. Only the emblem approved should be displayed; otherwise, a fine not less than N250,000 in addition to shutting down the site or platform.

Rule 21(5) provides that a pharmacist shall only register one internet-based platform, online pharmacy, or premises. Attempting to register more than one will lead to the online site being shut down, referred to the Investigative Panel and Disciplinary Tribunal, subject to the resolution of the Investigative Panel.

This provision, however, does not neatly tie in with the earlier provisions and marginal notes about Rule 21. It is unclear if pharmacists are barred from registering more than one online pharmacy concerning the emblem or generally barred from registering more than one pharmacy. The introduction of the term 'premises' implies a physical pharmacy and further compounds the confusion, as the rest of Rule 21 only referred to internet-based platforms or pharmacies. There is a need for this Rule to be redrafted with emphasis on clarity and precise use of terminology.

Generally, the Regulations mandate online pharmacies to use the PCN emblem. This position is similar to the GPhC of the UK and Paragraph 25 of the EU *Falsified Medicines Directive (FMD)*. The FMD mandates the European Commission (EC) to create a common logo throughout the Union, to be displayed by all websites offering medicinal products. Paragraph 25 of the FMD further provides that such websites should link to the website of competent member state authorities and that of the European Medicines Agency (EMA).<sup>20</sup> This requirement is absent under the Regulations and, if incorporated, can help to distinguish between authorised and unauthorised online pharmacies.

It may be possible for unauthorised online pharmacies to obtain the logo and place it on their website, thus deceiving unsuspecting customers. Therefore, the FMD, under Article 85c, para. 4, mandates member states to set up a website that provides information on the common logo and the list of persons approved to sell at a distance (online pharmacies) and links to their website addresses. If adopted into the Regulations, this approach will aid with cross-verification and enhance trust in online pharmacies.

The GPhC logo can be used on multiple websites listed on one application by an online pharmacy,<sup>21</sup> in contrast with the Nigerian position under Rule 21(5) if we assume that the proper interpretation of that section is that pharmacists can only register one online platform. If that is the case, this Rule may be described as unduly restrictive on business and the legitimate desire

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<sup>19</sup> Ibid 1, Rule 4(3)

<sup>20</sup> *Falsified Medicines Directive, Directive 2011/62/EU* of the European Parliament and of the Council of 8 June 2011, Official Journal of the European Union

<sup>21</sup> Ibid 4, para. 1

of entrepreneurs to segment their market into niches. They can do this by marketing different classes of drugs on different websites so that consumers can quickly find what they need and gain a competitive edge. In its current confusing form, rule 21(5) seeks to introduce stumbling blocks.

The GPhC further prescribes that online pharmacies must comply with e-commerce regulations and laws on advertising medicines to the public.<sup>22</sup> However, the Regulations have no such requirement, which should not be the case as existing legislation can support the Council's aspirations for ensuring online pharmacies meet the same standards as physical pharmacies. Such legislation includes the Food & Drugs Act, the Federal Competition & Consumer Protection Act (FCCPA) 2018, and the SON Guidelines for E-Commerce 2020.

The GPhC also requires any website displaying the logo to display the following information:<sup>23</sup>

- Name of the owner of the registered pharmacy
- Name of the superintendent pharmacy (if applicable) and their registration number
- Name and address of the pharmacy or pharmacies that supply the medicines
- The pharmacy's GPhC registration number
- The phone number and email address of the pharmacy
- Details of other pharmacies that may be involved in labelling and assembling, if applicable
- Information on how to check the registration status of the involved pharmacies and the superintendent pharmacist
- Terms and conditions of the pharmacy service
- Feedback and complaints procedure

The Regulations should be reviewed to require online pharmacies to state these details.

## Interpretation

Rule 23 defines online pharmacies to mean internet-dependent pharmaceutical services. This definition seems to capture a wide range of businesses engaged in pharmaceutical services, either as their core activity or as one of several services, e.g., e-commerce platforms. The Second Schedule to the Regulations further corroborates this as it sets out the application for new premises or sites registration. It lists the categories of applicants, which include manufacturers, importers, wholesalers, distributors, retailing and dispensing. As long as any participant in the pharmaceutical value chain depends on the internet, the Regulation would seem to deem them an online pharmacy.

The Regulation fails to define what it means to depend on the internet. For example, May & Baker, a prominent pharmaceutical company in Nigeria, advertises its pharmaceutical offerings on its website,<sup>24</sup> although purchases cannot be made there. Emzor Pharmaceuticals and Fidson

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<sup>22</sup> Ibid, para. 6

<sup>23</sup> Ibid, para. 8

<sup>24</sup> May & Baker Nigeria Plc <https://may-baker.com/products/pharmaceuticals/anti-malaria/>



Healthcare are also internet-dependent in the same way. If this is the case, this should be stated in the Regulations rather than leaving it to conjecture.

What about where the company only depends on the internet partly, where some drugs like multivitamins can be purchased online and onsite, while antibiotics are strictly onsite. Can they be considered internet-dependent due to the online option for multivitamins, especially if it contributes to a significant portion of their revenue? Is internet dependency a question of revenue, online traffic, or the extent of physical outlay? These are the kinds of questions and debates that can come up in the course of enforcement that can be altogether avoided if a precise definition is given to 'internet-dependent'.

Luckily, we don't have to go too far for a template definition. The American Ryan Haight Act defines what it means to be internet-dependent: *any delivery, distribution, or dispensing of a controlled substance caused or facilitated using the internet.*<sup>25</sup> Meaning that it is internet-dependent in so far as a transaction concerning drugs is carried out over the internet. Internet dependence is thus a question of the particular transaction, not the company itself.

The Act defines what an online pharmacy is (and is not). An online pharmacy is a person, entity, or internet site, whether in the US or abroad, that knowingly or intentionally delivers, distributes, dispenses, or offers to attempts to deliver, distribute, or dispense a controlled substance using the internet. It then goes further to expressly state the activities that do not qualify as an online pharmacy, namely:<sup>26</sup>

- Manufacturing and distributing
- Non-pharmaceutical practitioners who are otherwise registered
- Hospitals or medical facilities in the USA, public or private
- Healthcare facility owned or operated by a tribal organisation
- Agent or employee of a hospital or healthcare facility, in so far as they are acting within the scope of their employment
- Mere advertisement that does not facilitate a transaction involving a controlled substance
- A person, entity, or internet site outside the US and does not facilitate delivery, distribution, or dispensing of controlled substances via the internet to persons in the US
- Pharmacies that solely refill or fill new prescriptions via the internet

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<sup>25</sup> Ryan Haight Online Pharmacy Consumer Protection Act of 2008, section 3(a)

<sup>26</sup> *ibid*

- Any person that the Attorney-General and Secretary (equivalent to the Minister in Nigeria) have jointly found to be consistent with controls against diversion and consistent with public safety, to be granted exemption from the definition of an online pharmacy

To the extent that these exceptions can easily be extended to the Nigerian context, manufacturers, wholesalers, and distributors should be exempted. Only importers, retailers, dispensers and B2C e-commerce platforms offering medicines and medical devices should be deemed online pharmacies.

Summarily, the Nigerian position on an online pharmacy is fixed and broad to capture the entire value chain. In contrast, the American position on online pharmacies is fluid, depending on the transaction, and narrow, focusing mainly on entities that directly interact with end-users.

The Nigerian definition of an online pharmacy seems to tie internet dependency to the service provider, unlike the American position where internet dependency is a question of the particular transaction. A pharmacy may be considered an online pharmacy where a transaction is carried out over the internet, but it may not be deemed an online pharmacy in another physical transaction.



## Recommendations

The Online Pharmacy Regulations 2021 are grossly inadequate and fail to adequately foster the growth of online pharmacies and telemedicine in Nigeria. It seems to be intentionally vaguely worded and broadly written to capture a wide range of services to extract revenue from inspection, registration, and renewal fees. As shown above, the Regulations are short on many aspects compared to similar legislation in the UK, the US, and the EU. It is, however, not beyond redemption. In this review, recommendations have been presented for improving it. These recommendations will be retold here for easy reference.

1. Rule 8 of the Regulations should be reviewed to temporarily permit online pharmacies to close without paying renewal fees.
2. Rule 10 should be reviewed to require that inspectors can only access the backend of an online pharmacy or its premises to examine any article, record, documents and make copies under a validly obtained court order.
3. The inspection framework under Rule 10 should be expanded to accommodate issues about the health, safety, and wellbeing of patients and the public. For example, it should require standard operating procedures (SOPs) for data management, regular self-review, and an internal whistleblower policy. In addition, all medicines and medical devices should be obtained from licensed suppliers, access to patient data restricted, and hygiene standards defined.
4. The requirement to comply with telecoms regulations under Rule 11 should be deleted, or the relevant telecoms regulations should be expressly mentioned, with the scope of their applicability defined.
5. Rule 12 should be reviewed to mandate online pharmacies to provide details of the prescriber following an online consultation.
6. The use of dark patterns should be proactively banned under Rule 12
7. Online pharmacies should be permitted to dispense prescription-only medication, subject to providing details about the prescriber and adhering to good practice guidance regarding all categories of controlled substances.
8. The scope of audits under Rule 17 should be expanded to include matters like staffing, communication methods, handling prescriptions, records of decisions, systems for delivering medication, the pharmacy's services, cybersecurity and data protection compliance, customer feedback, and activities of third parties.
9. Online pharmacies should be mandated to track medication delivery and consider export laws when delivering medication outside Nigeria.
10. The numbering of Rule 21 as Rule 20 should be corrected.

11. The restriction on pharmacists to register a single internet-based platform under Rule 21 should be relaxed to permit more than one registration.
12. The term 'premises' under Rule 21 creates confusion about whether pharmacists can only register one physical pharmacy or an online pharmacy. Therefore, this provision should be clarified.
13. The PSN should be mandated to set up a website with links to all registered online pharmacies that have the right to use its emblem. The online pharmacies should also do the same and link to the website.
14. The Regulations should expressly mandate online pharmacies to comply with relevant provisions of the Food & Drugs Act, the Federal Competition & Consumer Protection Act (FCCPA) 2018, and the SON Guidelines for E-Commerce 2020
15. Online pharmacies should be mandated to provide details about their ownership, the superintendent pharmacist, address of suppliers, the online pharmacy's registration number, contact details, associated pharmacies involved in labelling and assembling, information on how to check the registration status of the involved pharmacies and the superintendent pharmacist, terms and conditions, and feedback mechanisms.
16. The definition of online pharmacies under Rule 23 should be reviewed in line with the American position to associate internet dependence with the transaction in question, not the pharmacy itself. The definition should also be reviewed to exclude manufacturers, wholesalers, and distributors, focusing only on pharmaceutical businesses interacting with the end-user, such as retailers, importers, and B2C e-commerce platforms.



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