The Pharma Legal Handbook

Nigeria

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs

PHARMA BOARDROOM

Nigeria

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Nigeria.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with Olaniwun Ajayi LP, a leading Nigerian law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

*** THIS REPORT WAS ORIGINALLY PUBLISHED IN OCTOBER 2019 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**

OLANIWUN AJAYI

Olaniwun Ajayi LP is a leading Nigerian law firm with nearly 60 years' experience in assisting organisations and individuals as well as government entities achieve their goals. The Firm has established a sterling reputation for a wide range of regulatory and compliance advisory, intellectual property rights protection, general corporate and commercial transactions, tax advisory and compliance (to name a few). This fact is more particularly highlighted by our track record of involvement in some of the largest and most complex transactions in the dynamic sectors of the Nigerian economy.

The Firm comprises 13 (thirteen) practice areas, to wit: Enterprise and Corporate Governance Practice, Intellectual Property Practice, Tax Practice, Technology Innovation and Fintech, Oil & Gas Practice, Finance & Capital Markets Practice, Power and Infrastructure Practice, Government Business Practice, Mergers & Acquisition and Private Equity Practice, Entertainment Media and Leisure Practice, Mining Practice, Emerging Areas Practice, and the Dispute Resolution Practice.

The Firm is particularly proficient in all areas of the law pertaining to the pharmaceutical industry and through its Enterprise Practice Group, provides regulatory and compliance advisory and support to both private and public companies.

The Firm's unparalleled capacity to handle complex legal issues is the bedrock of our practice, and our clients rely on us to help translate their vision into reality. Our diverse client list and background has solidified our appreciation of client nuance, which ensures that we quickly appreciate the demands of major projects and clients' needs.

The Firm has over 90 lawyers which are some of the most diligent and creative lawyers in Nigeria – serving over 30 business sectors, bound together by a singular passion to help our clients achieve their objectives. Commercially savvy and erudite, we continuously pursue knowledge with the aim of ensuring that the advice proffered to our clients is the subject of strategic thinking and diligent digging, to the end that our clients are protected from actual and potential pitfalls in their diverse business relationships.

Lagos
The Adunola
401 Close,
Banana Island,
Ikoyi, Lagos
Nigeria

Abuja
4th Floor Leadway House
Plot 1061, Cadastral Avenue,
Central Business District,
Abuja,
Nigeria

Port Harcourt
Flat 5, BICS Suites,
25 Herbert Macaulay Street,
Old GRA, Port Harcourt,
Rivers State,
Nigeria

Website: www.olaniwunajayi.net
Telephone: +234 1 270 2551

THE AUTHORS

MICHAEL AMADI

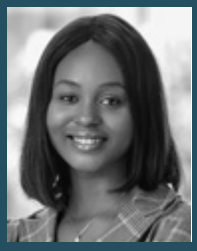
SENIOR ASSOCIATE,
OLANIWUN AJAYI LP

Michael heads Olaniwun Ajayi LP's new Port Harcourt Practice. He has over a decade experience in advising local and international companies on corporate law, compliance and regulatory matters, employment and labour matters, he routinely advises various Boards and the management of several public and private companies on regulatory and compliance matters.

Michael is a graduate of the University of Nigeria, Nsukka, and a scholar of Durham University, United Kingdom. He previously served as Special Assistant to Chief Executive Officer of the Nigerian Investment Promotion Commission, where he coordinated the legal, regulatory, and compliance portfolio of the Commission. He also served as a member of the Ministerial Committee on the review of Pioneer Status Administration in Nigeria. His experience has positioned him to reflect with eagle

Education:
- LL.M Durham University, United Kingdom (Distinction)
- B.L Nigeria Law School Lagos
- LL.B (Hons) University of Nigeria

Email: mamadi@olaniwunajayi.net
Telephone: +234(0)8033255838



FUNMILAYO FENWA

ASSOCIATE,
OLANIWUN AJAYI LP

Funmilayo is an Associate in the Firm's Oil and Gas Practice in Olaniwun Ajayi LP. She advises on a wide range of finance matters across several sectors including corporate & project finance and security arrangements.

Funmilayo was a member of the Firm's Enterprise and Corporate Governance Practice where she garnered substantial experience in regulatory and compliance matters as well as intellectual property protection.

Education:
- B.L., Nigerian Law School
- LL.B Nottingham Trent University

Email: ffenwa@olaniwunajayi.net
Telephone: +234(0)8023733814

JOHN UDOH

ASSOCIATE,
OLANIWUN AJAYI LP

John is an Associate in the Firm's Enterprise and Corporate Governance Practice from where he regularly walks individuals and corporations through the dynamics of the Nigerian corporate, regulatory, and compliance regime. He has a deep-seated understanding of the regulatory environment within which client businesses operate and is thus able to wield this commercial foresight in advising against potential pitfalls.

Education:
- B.L., Nigerian Law School (Distinction)
- LL.B University of Uyo.

Email: judoh@olaniwunajayi.net
Telephone: +234(0)7084511874

OLANIWUN AJAYI

www.olaniwunajayi.net
Olaniwun Ajayi LP
Olaniwun Ajayi LP
Olaniwun Ajayi LP
@Olaniwun Ajayi LP
@Olaniwun Ajayi LP

CONTENTS

01

REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

3. What are the steps to obtaining authorization to develop, test, and market a product?

4. What are the approximate fees for each authorization?

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

8. How is compliance with regulation monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

9. What is the potential range of penalties for noncompliance?

10. Is there a national healthcare system? If so, how is it administered and funded?

11. How does the government (or public) healthcare system function with private sector healthcare?

12. Are prices of drugs and devices regulated and, if so, how?

13. How are drugs and devices used by patients paid for? What roles do public and private payers play?

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The regulatory authorities with jurisdiction over drugs, biologicals and medical devices in Nigeria are: (i) The National Agency for Food and Drug Administration and Control (**NAFDAC**); (ii) The National Drug Law Enforcement Agency (**NDLEA**); and (iii) The Federal Ministry of Health.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

The regulatory framework for the authorization of drugs, biologicals and medical devices is the National Agency for Food and Drug Administration and Control Act Cap N1 LFN 2004 (the **NAFDAC Act**). The NAFDAC Act empowers NAFDAC to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals.

NAFDAC has also issued various guidelines which supplement the NAFDAC Act.

As regards pricing and reimbursement of drugs, biologicals and medical devices, there is currently no fixed mechanism in place for drug price control or reimbursement in Nigeria.

3. What are the steps to obtaining authorization to develop, test, and market a product?

The process to development, test and marketing of products is regulated by NAFDAC through the NAFDAC Act and Guidelines made pursuant to it.

The NAFDAC Guidelines for Clinical Trial Application in Nigeria (NAFDAC Clinical Trial Guidelines) provides to the effect that no person shall commence a clinical trial or cause a clinical trial to be commenced or conduct a clinical trial, unless a written authorization in relation to the clinical trial has been granted NAFDAC.

The relevant application form for obtaining the authorization is available on the NAFDAC website (http://www.nafdac.gov.ng/). The NAFDAC Clinical Trial Guidelines provides detailed information on documents and information required for the application.

The accompanying documents for the application include but are not limited to the following: Informed Consent Form; Evidence of Accreditation of Ethics Committee by the National Health Research Ethics Committee; Ethics Committee Approval from participating centers; Minutes of Meeting held to approve the protocol and Informed Consent Form by the Ethics Committee; and Evidence of insurance cover for the trial participants.

Marketing of a product in Nigeria entails the registration of the product with NAFDAC; the advertising and labelling of the product.

For the purpose of registration, it is important to note that where the manufacturer is a foreign entity, a Power of Attorney, authorizing a local agent in Nigeria, to submit the application on its behalf would be required. The Power of Attorney must be valid for at least five (5) years and notarized by the Notary Public in the country of manufacture.

As it relates to advertisement of the products in Nigeria, the manufacturer must ensure an advertisement approval is obtained from NAFDAC, as well as a vetting approval from APCON prior to airing of the advert. Failure to obtain the necessary approvals may result in liability for the manufacturer.

In relation to labelling of a product, NAFDAC is required to first approve the label or artwork of the product before an application for its registration is submitted. Labelling is regulated by the relevant NAFDAC guidelines on the registration of medicine or medical device in Nigeria and is easily accessible on the NAFDAC website.

4. What are the approximate fees for each authorization?

Fees/Tariffs for different applications differ. The fees are set out in the NAFDAC Guidelines for the product type/category sought to be registered.

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

Once the application for the registration of a product is successful, NAFDAC issues a Certificate of Registration to the successful applicant. The registration of a product shall, unless cancelled earlier, be valid for a period of five (5) years and may be renewed for the same period.

An application for renewal of product registration certificate shall be made on the applicant's letterhead addressed to Director of Registration and Regulatory Affairs Directorate at NAFDAC. The application is to be accompanied by supporting documents and evidence of payment of prescribed fees.

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

The application for registration of a brand name and generic product can be done through a single application process. The NAFDAC Guidelines for Registration of drugs, medical devices or other regulated products (be it imported or locally manufactured) prescribe the application process and supporting documents for the application and the guidelines is available on the NAFDAC website.

There is a requirement that the written application for registration of a product contains both the generic name and the brand name of the product (where it is applicable).

Further, the application process is slightly different for foreign manufacturers. A foreign manufacturer would in addition to documents required from a local manufacturer be required to provide the following:

- a Power of Attorney, authorizing a local agent in Nigeria, to submit the application on behalf of the foreign manufacturer. The Power of Attorney must be valid for at least five (5) years and notarized by the Notary Public in the country of manufacture;

- evidence that the foreign manufacturer is licensed to manufacture the product for sale in the country of origin;
- evidence from the competent Health Authority in the country of manufacture that the sale of the product does not constitute a contravention of the drug laws of the foreign country;
- the current Good Manufacturing Practice (**GMP**) of the manufacturing facility which must be authenticated by the Nigerian Embassy in the country of origin. In countries where no Nigerian Embassy exists, any Commonwealth or ECOWAS country can authenticate the document; and
- a Letter of Invitation for GMP Inspection of the factory where the products are being manufactured.

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

In Nigeria, the registration or the consideration for registration of combination drug products are prohibited by NAFDAC unless where there is proven scientific documented evidence that such product has clinical advantage over the single drug available for the same indication(s) (Clause 10.2 of the NAFDAC Guidelines for Registration of Imported Drug Products in Nigeria).

Where registration is permissible for the combination products, the general procedure for registration of drugs with NAFDAC (as highlighted above) will apply.

8. How is compliance with regulations monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

Compliance with regulation is monitored by the Investigation and Enforcement Directorate (the **Directorate**) of NAFDAC. It is a department of NAFDAC charged with the responsibility of ensuring compliance with NAFDAC's mandate on regulatory activities.

The Directorate receives and investigates complaints and carries out/supervises the destruction of defective, dangerous, fake, counterfeit, substandard, expired, adulterated and/or unwholesome NAFDAC regulated products.

9. What is the potential range of penalties for noncompliance?

Section 25 of the NAFDAC Act provides for penalties for non-compliance with provisions of the Act. It provides that where there is a contravention of any NAFDAC Regulation (whether for registration, advertising, etc.), the person who contravenes shall be guilty of an offence and liable on conviction to the penalties specified in the regulation. However, where no penalty is specified in the regulation, the person shall be liable to a fine of ₦50,000 or imprisonment for a term of one year or both.

Further, where the offence is committed by a body corporate and it is proved to have been committed with the consent or connivance of, or to be attributable to a neglect on the part of any director, manager, secretary or other similar officer of the body corporate or any person purporting to act in any of those capacities, such person as well as the body corporate shall be guilty of the offence and liable on conviction to a fine of ₦100,000.