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NAVIGATING NIGERIA'S HEALTH AND PHARMACEUTICAL SECTOR: KEY UPDATES

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INTRODUCTION

Nigeria accounts for 60% of the health products consumed in the Economic Community of West African States (ECOWAS) by volume and with an estimated population of about 600 million, it represents a huge potential market for investors. According to the May 2023 report from the National Bureau of Statistics, the health sector in Nigeria saw a growth rate of 3.20% in Q1 2023, marking a decrease from the 13.35% growth reported in the same quarter of 2022.[1]

The contribution to the nominal GDP was 0.55% in Q1 2023, slightly lower than the 0.60% recorded in Q1 2022 but an increase from the 0.54% in Q4 2022.[2] The expansion in the health and pharmaceutical sector in Nigeria is primarily attributed to heightened investments from both public and private sector entities. These investments were part of the measures to combat the poor state of the sector and address other emerging needs in the market. In the wake of prominent global pharmaceutical companies exiting the Nigerian market between Q4 2023 and Q1 2023, the Nigerian government has heightened its efforts to actively implement policies and strategies facilitating the success of private players within the sector.

These governmental initiatives have played a significant role in the recent advancements observed in the sector. Notably, the National Agency for Food Drugs Administration and Control (NAFDAC) reported a $2 billion investment in the sector for the erection and completion of WHO-compliant facilities that manufacture quality pharmaceutical products and an impressive 12% increase in the number of local manufacturers who have received approval for the construction and erection of drug manufacturing facilities in Nigeria.[3]

Additionally, the $40 million equity investment contract agreement between the African Finance Corporation (AFC) and the African Export-Import (AFREXIM) Bank to establish the African Medical Centre of Excellence in Abuja highlights substantial investment opportunities within the sector. With these developments in mind, both existing and potential investors in the sector may want to consider certain key legal issues that may impact their businesses in Nigeria, whether they are doing business directly or through a third party.

[1]Nigerian Bureau of Statistics, "Nigerian Gross Domestic Product Report Q1 2023" May 2023.
[2]ibid
[3]Mariam Ileyemi, PREMIUM TIMES, 12th February 2024 As multinational pharmaceutical companies exit Nigeria, NAFDAC says local manufacturers increase by 12% (premiumtimesng.com) [accessed 29th February, 2024]

ESG RISKS AND COPING STRATEGIES IN NIGERIA'S HEALTH AND PHARMACEUTICAL SECTOR

In the past, most of the pressure to disclose Environmental, Social and Governance (ESG) data was on financial institutions. Today, as stakeholders expect organizations to not only disclose, but act on, issues related to ESG, greenhouse gas (GHG) emissions, and climate risk, the focus has shifted to non-financial sectors that include the healthcare and pharmaceutical sector. The Director General of the National Agency for Food Drugs Administration and Control (NAFDAC) had reiterated in her speech delivered at Kings University Ode Omu, Osun State Nigeria, that the goals and targets of sustainable development are universal and apply to all countries in the world including Nigeria. She went further to add that reaching this goal requires action on all fronts by government, businesses, civil society and people everywhere.[4]

Healthcare and pharmaceutical corporations inherently grapple with various dimensions of sustainability, encompassing concerns like the environmental impact of drugs, disparities in access to medicines, and unethical sales practices. Regulators in Nigeria's health and pharmaceutical sector are currently giving focused attention to ESG issues, necessitating a sense of urgency for healthcare and pharmaceutical corporations to improve efforts in this regard. For example, the Federal Competition and Consumer Protection Commission (FCCPC) in its business guidelines introduced in 2020 stated its commitment to providing a framework to legally support businesses that need to coordinate or combine efforts to ensure that the supply and distribution of scarce products and services that attend to the health, safety, and subsistence need of consumers are not compromised.[5] This effort is focused on limiting the negative effects associated with poor ESG measure implementation on supply chain security.

Furthermore, the National Agency for Food, Drugs, Administration and Control (NAFDAC) has intensified its recent endeavors to enforce the Regulation on Good Distribution Practice for Pharmaceutical Products. This regulation was introduced to establish the minimum standards for good distribution practices in both the public and private sectors concerning finished pharmaceutical products. It is therefore expedient for companies in the health and pharmaceutical sector in Nigeria to regularly conduct compliance audits and develop a comprehensive compliance matrix to help keep track of mandatory practice requirements.

[4] Sustainable Development and Growth for the Millennial Entrepreneur: the Role of Regulatory Agencies – NAFDAC
[5] FCCPC Business Guidelines 2020 Untitled-1 (fccpc.gov.ng)

Top management individuals in various health and pharmaceutical corporations are saddled with the responsibility to pay adequate attention to sustainability issues within their organization by monitoring the implementation of SDG policies within their organizations and report on the extent of compliance with same.

Addressing governance concerns, the Nigerian Code of Corporate Governance, 2018 (NCCG), serves as the paramount legislation. It stipulates that companies, including those within the healthcare and pharmaceutical sector, must uphold principles such as promoting board diversity[6]; conducting regular corporate governance evaluations[7]; fair, responsible, and transparent remuneration[8]; and regular shareholder engagement[9]. Adherence to the NCCG code by healthcare and pharmaceutical companies not only reinforces ethical practices but also cultivates transparency, accountability, and trust by the wider population, thereby contributing to the overall robustness of the industry.

REGULATORY EFFORTS ON ISSUES RELATING TO PRODUCT LIABILITY IN THE HEALTH AND PHARMACEUTICAL SECTOR IN NIGERIA

The notable legislative instruments in Nigeria that seek to limit the incidence of harmful or fake drug and pharmaceutical products on consumers are the National Agency for Food, Drugs, Administration and Control (NAFDAC) Act, CAP N1 LFN 2004, and the Counterfeit Fake Drugs and Unwholesome Processed Foods Act. Also, the introduction of the Good Manufacturing Practice for Pharmaceutical Products Guidelines, 2021 as developed by NAFDAC further reinforces the commitment of the agency to ensure that pharmaceutical products meet the requirements of safety, quality and efficacy they purport or are represented to possess. This regulation stipulates the minimum standards that manufacturers are required to adhere to ensure the quality of pharmaceutical products.

[6] Nigerian Code of Corporate Governance, 2018 (NCCG), Principle 2
[7] NCCG, Principle 15
[8] NCCG, Principle 16
[9] NCCG, Principle 21

According to Section 5 of the NAFDAC Act, Cap N1, LFN 2004, one of the primary duties of the NAFDAC is the duty to compile standards specifications and guidelines for drugs and medical products in Nigeria, among others. As such, NAFDAC as a regulatory agency, regularly releases standards and guidelines for these products before they are allowed into circulation. The failure to reach these standards will prevent the registration of the product and even where a registered product ceases to meet the standards imposed by the NAFDAC, NAFDAC has the powers to recall these products, prosecute the manufacturers, and demand the payment of fines jointly or severally under the Recall, Handling, and Disposal of Substandard and Falsified Medical Products Regulations, 2021.

In 2023, NAFDAC oversaw the recall of at least ten (10) health products from circulation in Nigeria. The reasons for these recalls ranged from finding foreign materials in the products to discovering counterfeits of the products. In the first quarter of 2023, NAFDAC recalled three pharmaceutical products from the market. By Public Alert No. 010/2023, NAFDAC notified the public of the recall of Norvasc 5mg tablets after iron wires were found in the drugs. By December 2023, NAFDAC had overseen the recall of a batch of Ozempic (semaglutide) pens, counterfeit Meronem 1g Injections, fake Anthrax vaccines, and Dostinex among others found to be falsified in Nigeria. While none of the manufacturers were fined or prosecuted, largely because the manufacturers in most instances informed NAFDAC of the existence of counterfeits or initiated the recalls themselves, NAFDAC has shown that it takes the health and safety of Nigerians quite seriously.

While product recalls in themselves are not actionable in Nigerian Courts, they may serve as evidence that the products may have some form of defects, A manufacturer whose products have been recalled by NAFDAC may find it difficult to prove that it is not liable to pay damages for a product liability claim especially if there is evidence of damage by the Claimant, hence the need for proactive engagement with consumers minimise the risk of future claims. Likewise, the non-registration of a product with NAFDAC serves as proof that the products are substandard and reinforces a consumer's product liability claims. Consumers may bring an action against the manufacturers of unregistered drug products such as the Original Chest and Lung Tablets (which the NAFDAC issued a Public Notice against on 21st June, 2023). Such manufacturers may face an uphill task in convincing the Courts that their drugs and their manufacturing processes are flawless.

While there may have been a dearth of product liability claims brought by NAFDAC or based on the provisions of the NAFDAC Act and Regulations, the NAFDAC has taken considerable enforcement actions to recall defective products from the market. Therefore, with the number of recalls done by the NAFDAC in 2023 alone, consumers who experience health challenges as a result of using these products before the recall or even after, may bring an action against the manufacturers for the payment of damages.

Similarly, Claimants may choose to bring their complaints before the NAFDAC, who have shown to be adept at handling these complaints, and after exercising its investigative powers provided for under the NAFDAC Act, NAFDAC may recall the products and fine the manufacturers.

With the uptick in NAFDAC's efforts towards recalling products in 2023, we anticipate that in 2024 the NAFDAC will take a step further in its enforcement actions by ensuring the prosecution of the manufacturers and the compensation of the consumers affected by the manufacturer's products.

The activities of NAFDAC as well as an increasing awareness of consumer rights highlight a critical need for health and pharma companies to thoroughly review and strengthen their internal compliance programs, by bringing in external Law Firms with expertise in this regard. This proactive step is essential to minimize the risk of costly and damaging product liability claims.

Key areas to prioritize within your compliance framework include:

Rigorous Quality Control: Implement and meticulously document adherence to the highest manufacturing standards, quality testing protocols, and storage/transport guidelines. This ensures product safety and provides strong evidence in the case of potential disputes.

Transparent Labeling and Instructions: Provide clear, accurate, and Nigeria-specific information on product composition, potential side effects, contraindications, and proper dosage instructions. Ensure this information is accessible in relevant local languages.

Post-Market Surveillance: Establish a robust system to monitor product performance, track potential adverse events, and take swift corrective action when necessary. Collaborate with NAFDAC for reporting and recall coordination.

Comprehensive Record Keeping: Maintain detailed records of all manufacturing processes, quality control measures, distribution channels, customer feedback, and adverse event reports. This documentation is crucial for defending against potential claims.

Liability Insurance: Secure adequate liability insurance coverage to protect your company in the event of unforeseen product-related incidents.

Staff Training: Invest in regular compliance training for all employees involved in product development, manufacturing, marketing, and distribution. Emphasize the importance of ethical practices and adherence to Nigerian regulations.

REGULATORY EFFORTS ON ISSUES RELATING TO WHITE COLLAR CRIMES IN THE HEALTH AND PHARMACEUTICAL SECTOR IN NIGERIA & AFRICA AT LARGE

White-collar crime, acts of financial dishonesty committed by professionals, poses a severe threat to the health and well-being of Nigerians. Within the pharmaceutical sector, these crimes can have a devastating ripple effect.

Here is a closer look at the harmful effects:

Compromised Drug Quality: Bribery and corruption can incentivize the sale of counterfeit or substandard drugs. These lack proper ingredients or potency, leading to ineffective treatment or even serious health complications.

Reduced Access to Essential Medicines: Embezzlement of public healthcare funds hinders the procurement of vital medications. This disproportionately affects low-income Nigerians who rely on public healthcare systems.

Erosion of Trust in Healthcare Professionals: Unethical practices by medical professionals, such as fraudulent billing or kickbacks for prescribing certain drugs, damage public trust in the healthcare system. This discourages people from seeking necessary medical attention.

Weakened Public Health Initiatives: White-collar crimes can divert resources away from public health programs like disease prevention or vaccination campaigns. This can have long-term consequences for controlling the spread of infectious diseases.

Impunity and a Culture of Corruption: A lack of effective prosecution for white-collar crimes creates an environment where such practices are seen as less risky. This discourages ethical behaviour and perpetuates a cycle of corruption.

To tackle these issues, the National Agency for Food and Drug Administration and Control (NAFDAC) has taken proactive measures. Recently, the organization conducted a training program titled 'Anti-corruption and Leadership in the 21st Century' to raise awareness among its staff about the detrimental effects of corruption. This initiative not only aimed at sensitizing employees but also served as a forum for the agency to formulate effective strategies in addressing prevalent challenges related to bribery and corruption within the sector.

CONCLUSION

In conclusion, as the landscape in Nigeria's health and pharmaceutical sector evolves, the complexities associated with these issues intensify, posing potential risks to businesses operating in the sector. Recognizing the urgency to navigate these challenges effectively, seeking professional advice becomes not only a prudent course of action but a critical imperative for sustainable business practices.

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Stren & Blan Partners is a full-service commercial Law Firm that provides legal services to diverse local and multinational corporations. We have developed a clear vision for anticipating our clients' business needs and surpassing their expectations, and we do this with an uncompromising commitment to Client service and legal excellence.

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