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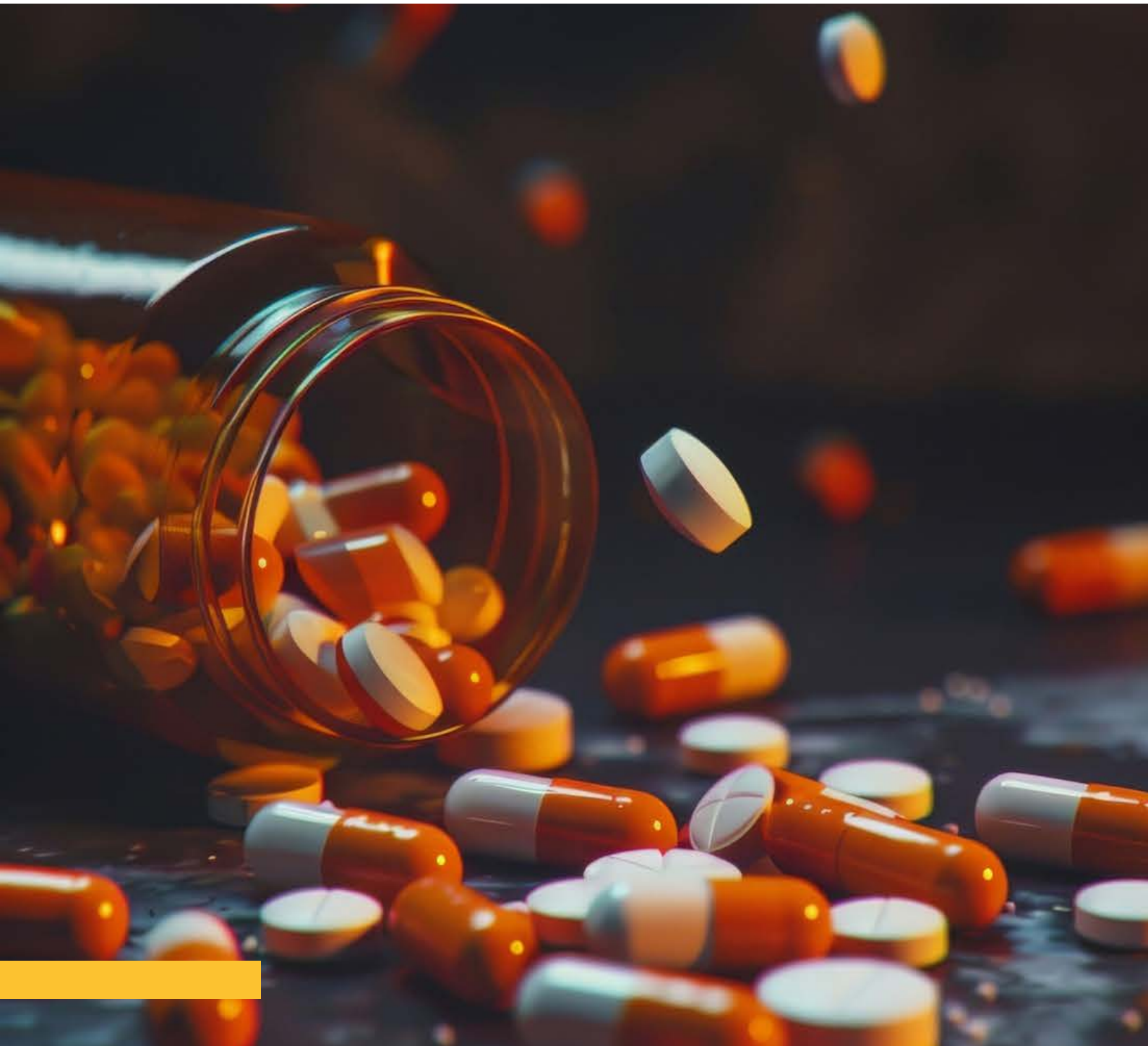
Review of the Drug and Related Products Advertisement Regulations, 2021



1. Introduction

In an era where drug advertisements flood both traditional and digital media like Instagram, Facebook and X, the need for strong regulatory oversight has never been more urgent. Misleading claims and unverified promotions pose serious risks to public health, especially in a country as diverse and populous as Nigeria. In response, the **Drug and Related Products Advertisement Regulations, 2021**, introduced by the **National Agency for Food and Drug Administration and Control (NAFDAC)**, marks a decisive effort to bring clarity, accountability, and safety to the marketing of drug products.

Officially published in the Federal Republic of Nigeria Official Gazette on **July 7, 2021**, the regulations are grounded in the authority of the **NAFDAC Act (Cap. N1, LFN 2004)** and the **Food, Drug and Related Products (Registration, Etc.) Act (Cap. F33, LFN 2004)**. These rules set out to transform how prescription and over-the-counter drugs are advertised, prioritizing truth, transparency, and the protection of consumers over promotional hype.

This review evaluates the regulations' structure, content, legal implications, strengths, weaknesses, and potential areas for improvement, focusing on their clarity, enforceability, and alignment with Nigeria's broader public health and legal frameworks.

2. Regulations Overview

The regulations, comprising 33 provisions and a schedule, provide a comprehensive framework for overseeing the advertisement of prescription and over-the-counter (OTC) drug products in Nigeria. Structured to cover the scope of application, approval processes, content requirements, restrictions, and enforcement mechanisms, the regulations apply to all drug products manufactured, imported, exported, sold, distributed, or used in Nigeria. The document seeks to promote credibility, trust, and informed decision-making among consumers and healthcare professionals.

2.1 Goals and Objectives of the Regulations

The primary goal of the regulations, as implied in Regulation 3, is to ensure that drug advertisements are accurate, complete, clear, and designed to promote credibility and trust. Key objectives include:

a. Prohibiting the advertisement of unregistered drug products or unapproved advertisements as provided by Regulation 2(1) (a-b).

b. Preventing misleading claims or consumer promotions that could exploit public vulnerabilities for example giving free samples of drug or related products to the consuming public as provided in Regulations 2(1) (c), and 4(b).

c. Ensuring balanced presentation of risks, benefits, side effects, and contraindications (as provided in Regulation 9).

d. Restricting prescription drug advertisements to scientific and medical journals to target healthcare professionals (as provided in Regulation 13).

e. Prohibiting advertisements claiming treatment for specific serious diseases listed in the Schedule (as provided in Regulation 21).

2.2 Key Components

2.2.1 Scope and Application

Regulation 1 defines the scope, applying to all drug advertisements in Nigeria, while Regulation 2 prohibits advertising unregistered drugs, unapproved advertisements, or engaging in consumer promotions such as free samples or gifts. This ensures stringent oversight by NAFDAC.

2.2.2 Advertisement Approval Process

Regulations 5–7 detail the application process for advertisement approval, requiring submissions such as brand/generic names, dosage forms, manufacturer details, and scientific justification for claims as stated in Regulation 6. Applications must be authenticated by the Superintendent Pharmacist and Chief Executive. Approvals are valid for one year initially, renewable for two years if unchanged. Pursuant to regulations 7 (3), Consumer promotions, where permitted, have a 15-week validity.

2.2.3 Content Requirements

Content requirements in this context refers to the substance of the advertisements. Regulations 9–20 emphasize evidence-based and balanced advertisements. Also, pursuant to regulations 16-18, prescription drug advertisements must include therapeutic classification, indications, dosages, adverse reactions, contraindications, and references to scientific sources. Claims of efficacy or superiority must be substantiated with clinical studies, and superlative claims like “most effective”, and “least toxic” are restricted unless supported by evidence.

2.2.4 Restrictions and Special Provisions

Regulation 12 prohibits false, misleading, or vague claims and bans prescription drug advertisements in mass media like television, radio, or social media. Regulation 21 prohibits advertising drugs as treatments for 66 specified diseases (e.g., cancer, diabetes, alcoholism, tuberculosis) listed in the Schedule, safeguarding against misleading cure claims. Regulation 10 mandates boxed warnings for drugs with serious safety risks.

3. Legal Analysis

3.1 Alignment with Existing Laws

The regulations are firmly rooted in the **National Agency for Food and Drug Administration and Control Act (Cap. N1, LFN) 2004** and the **Food, Drug and Related Products (Registration, Etc.) Act (Cap. F33, LFN) 2004,** aligning with NAFDAC's mandate to regulate drug safety and advertising. They complement the **Drug Labelling Regulations** (referenced in Regulations 13 and 24) by ensuring consistent labeling and advertising standards.

However, potential overlaps with other laws, such as the **Federal Competition and Consumer Protection Act 2018**. For example, NAFDAC's Regulation 12 prohibits false or misleading drug advertisement claims, Regulation 11 restricts unsubstantiated superlative claims (e.g., "most effective"), and Regulation 9 mandates balanced risk-benefit information, while FCCPA's Section 123(1) bans false or deceptive representations about goods, Section 124 prohibits misleading advertisements, and Section 125 requires substantiation for claims. Both laws address deceptive drug advertisements (e.g., unverified efficacy claims), but NAFDAC's focus on health-specific standards (e.g., clinical evidence in Regulation 11(6)) contrasts with FCCPA's broader consumer protection scope, risking duplicative enforcement by NAFDAC and the FCCPC without clear coordination, which could lead to inconsistent standards or penalties.

3.2 Enforceability

3.2.1 Sanctions and Penalties

Pursuant to Regulation 28, there are penalties for non-compliance, with individuals facing up to one year imprisonment or a fine of N800,000 or both, and corporations facing fines up to N5,000,000. Also, Regulation 29 provides for forfeiture of assets linked to offenses. The assets shall be forfeited to the Federal Government. The body tasked with the enforcement of these provisions is the NAFDAC as provided in Regulation 31. However, the lack of detailed procedures for investigations, hearings, or appeals may undermine consistent enforcement.

3.2.2 Approval and Withdrawal Mechanisms

Regulation 8 allows NAFDAC to withdraw approvals for false claims, non-compliance, new scientific evidence, or court orders, providing flexibility to adapt to emerging risks. However, the absence of a defined appeals process for withdrawn approvals could lead to disputes or perceptions of unfairness.

3.2.3 Stakeholder Responsibilities

The regulations in regulations 6 clearly delineate responsibilities for NAFDAC, manufacturers, distributors, and advertising companies, with authentication requirements ensuring accountability. However, the lack of a centralized registry for approved advertisements or advertisers may complicate monitoring and compliance across Nigeria's diverse media landscape.

4. Strengths of the Regulations

1. Comprehensive Coverage: The regulations apply to all drug products and advertising platforms, including digital and social media, ensuring that it applies to every medium of advertisement in today's world.

2. Evidence-Based Standards: In the medical field, evidence is critical for ensuring transparency and consumer protection. Regulations 11 and 15 enforce this by requiring substantiated claims and balanced risk-benefit information in advertisements, promoting informed decision-making and safeguarding consumers from misleading claims.

3. Public Safety Emphasis: The restrictions on advertising a drug or related product as treatment, prevention or cure for any disease for serious diseases (as provided in Regulation 21) and prohibitions on superlative or fear-inducing claims (as provided in Regulations 4, 11) prioritize patient safety and rational drug use.

4. Robust Enforcement Mechanisms: Significant fines, imprisonment, and forfeiture provisions (Regulations 28–29), coupled with NAFDAC's enforcement authority (Regulation 31), deter violations and ensure accountability.

5. Weaknesses of the Regulations

1. Limited Digital Media Guidance: Although Regulation 32 includes digital and social media within the definition of "media," it lacks specific guidelines for regulating online advertisements, which are increasingly common and vulnerable to misinformation. For instance, fake drug advertisements proliferate on platforms like Facebook and Instagram, yet there is no clear procedure to hold perpetrators accountable.

2. Unclear Appeals Process: The absence of detailed procedures for appealing withdrawn approvals or penalties may lead to disputes or perceptions of regulatory unfairness.

3. Resource Constraints: NAFDAC's capacity to monitor advertisements across diverse platforms, particularly digital media, may be limited by funding, personnel, and technological constraints.

4. Lack of Public Awareness Provisions: The regulations do not mandate public education campaigns to help consumers identify misleading advertisements, which could enhance compliance and consumer protection.

6. Recommendations

To improve the effectiveness and adaptability of the Drug and Related Products Advertisement Regulations, 2021, the following proposals are advanced to address current limitations and ensure alignment with Nigeria's public health and regulatory priorities:

1. Strengthen Oversight of Digital Media

Although Regulation 32 acknowledges digital platforms, it does not sufficiently address the specific challenges posed by social media advertising, such as viral misinformation and influencer endorsements. NAFDAC should develop dedicated guidelines for online content, deploy automated monitoring tools, and establish cooperation with technology platforms to detect and remove misleading advertisements swiftly. These steps are essential to safeguard consumers in an increasingly digital environment.

2. Introduce a Clear Appeals Process

The absence of an articulated appeals framework following the withdrawal of advertisement approvals under Regulation 8 may undermine trust in regulatory decisions. A transparent process featuring defined timelines, an impartial review panel, and objective criteria would strengthen procedural fairness and reinforce public and industry confidence in NAFDAC's authority.

3. Improve Enforcement Capacity

Limited resources constrain NAFDAC's ability to oversee advertising, especially in rural and digital contexts. Targeted investment in technology, including AI-based monitoring systems, and increased staffing for field operations would improve oversight. A centralized, publicly accessible database of approved advertisements and licensed advertisers would further support compliance and empower consumers.

4. Coordinate with Consumer Protection Institutions

The potential overlap between these regulations and the Federal Competition and Consumer Protection Act 2018 could lead to inconsistent enforcement. A collaborative framework between NAFDAC and the FCCPC would clarify responsibilities, align enforcement standards, and harmonize penalties, providing clarity for stakeholders and enhancing regulatory coherence.

5. Expand Public Education Initiatives

While the regulations focus on industry obligations, public awareness remains limited. NAFDAC should partner with relevant stakeholders to conduct nationwide education campaigns on identifying legitimate advertisements and reporting infractions. Efforts should prioritize underserved rural communities to improve health literacy and support regulatory objectives.

6. Establish a Mechanism for Periodic Review

Given the rapid evolution of media and healthcare practices, the regulations should not remain static. A triennial review process, involving key stakeholders, would ensure that the regulatory framework stays responsive to emerging trends and continues to protect public health effectively.

7. Conclusion

The Drug and Related Products Advertisement Regulations, 2021, mark a significant effort by NAFDAC to bring greater control and accountability to drug advertising in Nigeria. Through a focus on evidence-based claims, restrictions on misleading promotions, and consistency with the country's legal framework, the regulations aim to promote public health and build trust within the pharmaceutical sector. Nonetheless, the effectiveness of the framework is hindered by gaps in digital media oversight, limited enforcement resources, and insufficient public engagement. Addressing these challenges will require practical steps such as improved digital monitoring systems, a clear and accessible appeals process, stronger enforcement capacity, strategic partnerships with consumer protection bodies, broad public education initiatives, and regular reviews of the regulatory framework. These improvements will help ensure the regulations continue to protect consumers from false or harmful claims while supporting informed health choices and reinforcing NAFDAC's role in safeguarding public health.

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