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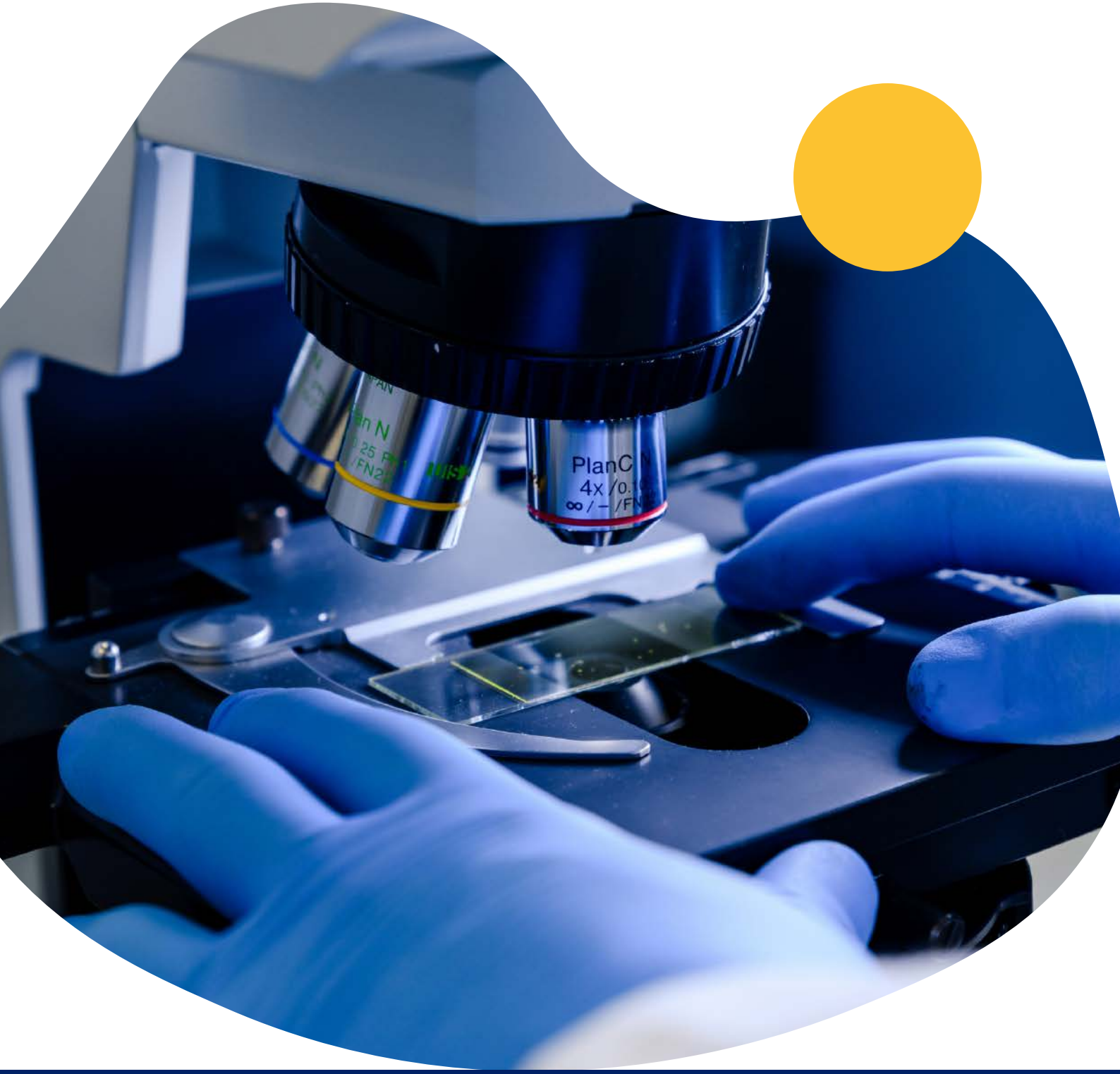
Review of the Medical Devices, In Vitro Diagnostics and Related Products Advertisement Regulations, 2023



1. Introduction

Medical devices, such as thermometers and x-ray machines, and in vitro diagnostics (IVDs), like pregnancy tests and cholesterol tests, are critical tools for diagnosing, treating, and monitoring diseases all over the world. Related products, such as diagnostic software and calibration tools, support their functionality. In Nigeria, where the growing medical device market faces challenges like counterfeit products and misleading advertisements, the National Agency for Food and Drug Administration and Control (NAFDAC) introduced the Medical Devices, In Vitro Diagnostics and Related Products Advertisement Regulations, 2023, under the NAFDAC Act and the Food, Drugs and Related Products Act (Cap. N1 and F33, LFN 2004). These regulations aim to ensure that advertisements are accurate, ethical, and non-misleading to protect public health and maintain trust in the medical device industry. This review evaluates the regulations' goals and objectives, key components, alignment with existing laws, strengths, weaknesses, and areas for improvement.

2. Goals and Objectives of the Regulation

The main goal of the regulation as provided in Regulations 5 is that advertisements of medical devices, IVDs and related products for advertisement shall be accurate, complete, clear and designed to promote credibility and trust by the general public.

Some of the objectives include:

a. Prohibiting advertisements of unregistered medical devices, IVDs and related products except they are become registered and the advert material approved by the Agency. This is provided in Regulation 2.

b. Ensuring that advertisements are written as to accurately interpret vald and representative research findings, and also balanced information i.e the claim would contain both the negative and positive findings which are readily verifiable by the Agency (as provided in Regulations 12–13, 16).

c. Preventing misleading, fear-inducing, or unethical advertisements. This is provided in Regulations 6, 11, 14, and 17.

d. Restricting advertisements for professional-use devices to scientific journals and healthcare professionals. This is provided by Regulation 19.

3. Analysis of Key Components of the Regulation

3.1 Scope and Application

Pursuant to Regulation 1, the regulation applies to all advertisements of medical devices, IVDs, and related products that are manufactured, imported, exported, sold, distributed or used in Nigeria.

3.2 Advertisement Approval Process

The process for application for approval of advertisement are provided in Regulation 3. The advertisement material shall be submitted along with an application and accompanying documents in a manner as may be prescribed by the NAFDAC. Thereafter, the submitted materials shall be authenticated by the Chief Executive or the appropriate technical person of the medical device and related product company sponsoring the advertisement. Some of the contents of the application to be submitted are; brand name of the medical device and related product (if any), the place of importation or local manufacturer, the name and address of the manufacturer, the name and address of the advertising company etc

Regulations 7 provides that, approvals are valid for one year initially, renewable for two years if unchanged, with consumer promotions limited to 15 weeks. Also, Regulations 9 allows NAFDAC to withdraw approvals for false grounds, non-compliance, or new scientific evidence, ensuring adaptability. Regulation 8 voids approvals for unauthorized alterations.

3.3 Restrictions and Ethical Standards

Pursuant to Regulation 17, advertisements of medical device, IVD and related products shall not contain false and misleading information, Incomplete truths, inadequate qualifications and limitations regarding safety or effectiveness of the medical device, IVD and related product. Also, vague and unsubstantiated statements, or suggestions of superiority over competing products are prohibited.

Even terms like “magic” or “miracle” or “best tolerated” that induce unnecessary daily or continuous use of the medical device or related product outside of its intended use are prohibited. Regulation 14 ensures advertisements align with healthcare ethical standards, while Regulation 15 prohibits disparaging competitors. Regulation 19 restricts advertisements for professional-use devices to scientific journals and healthcare professionals.

3.4 Enforcement and Penalties

Regulation 22 outlines penalties, with individuals facing up to one year imprisonment or a N800,000 fine, and corporations facing fines up to N5,000,000. As it concerns corporations or other association of individuals, every personnel such as a director, manager, secretary or partner of a firm or trustee of the body concerned would be liable to be proceeded against and punished in the same manner as if he had himself committed the offence, unless he prove that the act or omission constituting the offence took place without his knowledge, consent or connivance. This provision is a practical example of when the veil of incorporation of a company would be lifted.

Lastly, Regulation 23 mandates forfeiture of assets linked to offenses to the Federal Government. NAFDAC is solely responsible for enforcement.

4. Alignment with Existing Laws

The regulations are grounded in the NAFDAC Act (Cap. N1, LFN) 2004 and the Food, Drugs and Related Products (Registration, Etc.) Act (Cap. F33, LFN) 2004, aligning with NAFDAC's mandate to regulate medical devices and IVDs. Also, they complement the Medical Devices In Vitro Diagnostics and Related Products Labelling Regulations (as provided in Regulation 4). However, potential overlaps with the Federal Competition and Consumer Protection Act 2018, which governs general advertising, are not addressed, risking jurisdictional conflicts with the Federal Competition and Consumer Protection Commission (FCCPC).

5. Strengths of the Regulations

1. **Extensive Coverage:** By encompassing all medical devices, IVDs, and related products across various media, including digital platforms (Regulation 25), the regulations address the diverse advertising landscape in Nigeria. This ensures that whether an advertisement appears on television, radio, or social media, it must meet the same rigorous standards, protecting consumers across urban and rural areas.
2. **Substantiated Claims and Transparent Findings:** Regulations 12–13, 16, and 20 require advertisers to back claims with verifiable research and present balanced findings, including potential risks alongside benefits. This transparency helps consumers make informed decisions and reduces the likelihood of exaggerated or deceptive marketing, enhancing trust in the medical device industry.
3. **Commitment to Ethical Advertising:** By prohibiting misleading, fear-inducing, or unethical advertisements (as provided in Regulations 6, 14, 17), the regulations uphold high ethical standards. For instance, banning terms like "miracle" prevents companies from exploiting vulnerable consumers especially the overly religious ones, while restrictions on disparaging competitors (as provided in Regulation 15) foster fair competition and maintain industry integrity.
4. **Structured Approval Process:** Regulation 3 provides clear application requirements, and Regulation 7 sets defined validity periods, making compliance straightforward for manufacturers and advertisers. This clarity reduces ambiguity, encourages adherence, and ensures NAFDAC can efficiently review and approve advertisements.
5. **Strong Deterrence Through Enforcement:** The penalties outlined in Regulation 22, combined with asset forfeiture (as provided in Regulation 23) and NAFDAC's enforcement authority (Regulation 24), create a robust framework for accountability. Holding corporate officers personally liable ensures that companies prioritize compliance, deterring violations and protecting public health.

6. Weaknesses of the Regulations

1. **Inadequate Guidance for Digital Media:** Although Regulation 25 includes digital media within the scope, the regulations fail to provide detailed guidelines for online advertisements. With the rapid growth of social media platforms like X and other digital channels, misleading ads can spread quickly, exploiting gaps in oversight. This lack of specificity leaves NAFDAC ill-equipped to tackle the unique challenges of digital misinformation, such as targeted ads or influencer promotions.
2. **Failure to Address Urban-Rural Disparities:** The regulations do not account for Nigeria's significant urban-rural divide, where rural communities often face limited access to healthcare and lower literacy levels. These populations are more susceptible to misleading advertisements, as they may lack the resources or knowledge to verify claims, making them prime targets for unscrupulous marketers.
3. **Enforcement Challenges Due to Resource Constraints:** NAFDAC's ability to monitor and enforce compliance, particularly across digital platforms, is likely hindered by limited funding, personnel, and technological tools. Without adequate resources, the agency may struggle to keep up with the volume of advertisements, especially in a rapidly evolving digital landscape.
4. **Absence of Public Awareness Initiatives:** The regulations do not mandate campaigns to educate consumers about identifying misleading advertisements. This gap leaves the public, particularly vulnerable groups, without the tools to critically assess marketing claims, reducing the regulations' overall impact on consumer protection.

7. Recommendations

To strengthen the regulations and ensure they effectively protect consumers while adapting to Nigeria's healthcare and legal landscape, the following measures are proposed:

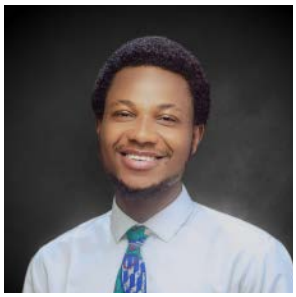
1. **Develop Clear Guidelines for Digital Media:** NAFDAC should create specific rules for online advertisements, particularly on platforms like X, where misinformation can spread rapidly. These guidelines could include requirements for clear disclosure of sponsored content, restrictions on influencer marketing, and tools for real-time monitoring of digital ads. This would help NAFDAC address the unique challenges of digital platforms and curb misleading promotions effectively.
2. **Target Rural Vulnerabilities with Education:** NAFDAC should launch public education campaigns tailored to rural communities, where limited healthcare access and low literacy increase susceptibility to deceptive ads. These campaigns could use radio, community leaders, and local languages to teach people how to spot false claims and verify product legitimacy, empowering them to make informed decisions.
3. **Boost Enforcement Capacity:** The government should allocate more funding to NAFDAC to hire additional staff, train them in digital monitoring, and invest in technology for tracking advertisements. Creating a centralized, publicly accessible registry of approved ads would also make it easier to verify compliance and hold violators accountable.
4. **Align with Broader Consumer Protection Laws:** NAFDAC should work with the Federal Competition and Consumer Protection Commission (FCCPC) to clarify roles and avoid overlaps with the Federal Competition and Consumer Protection Act 2018. Joint guidelines or a memorandum of understanding could streamline enforcement and ensure consistent standards across all advertising sectors.
5. **Promote Public Awareness Campaigns:** NAFDAC and manufacturers should be required to fund and run campaigns that educate consumers on identifying misleading ads. These could include TV and radio spots, social media content, and community workshops, focusing on teaching the public to check for NAFDAC approval and report suspicious claims, enhancing consumer protection.
6. **Implement a Regular Review Schedule:** To keep the regulations relevant, NAFDAC should commit to reviewing them every three years. This would allow updates to address new technologies, such as AI-driven advertising, and fix implementation issues, ensuring the regulations remain effective in a fast-changing environment.

8. Conclusion

The 2023 regulations on the advertisement of medical devices, in vitro diagnostics, and related products represent a timely and important effort to promote responsible marketing and safeguard public health in Nigeria. By setting clear standards for accuracy, ethics, and transparency, the framework helps reduce the risk of misleading claims and builds greater trust in the medical device industry. Still, effective implementation remains key. To fully achieve their goals, the regulations need stronger enforcement mechanisms, clearer guidance for digital platforms, and targeted public awareness campaigns, especially for rural and vulnerable populations. Regular reviews will also be necessary to keep pace with emerging technologies and evolving consumer behavior. If these gaps are addressed, the regulations will not only protect consumers but also strengthen the credibility of the healthcare sector as it continues to grow.

AUTHORS

Dayo Adu
Managing Partner



Uche Thompson
Trainee Associate

FAMSVILLE

CONTACT US

+234 (0) 90 68909 300

+234 (0) 80 62801 020

info@famsvillesolicitors.com

214B, Eti Osa Way, Dolphin Estate
Ikoyi Lagos