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REVIEW ARTICLE

Landscape of Medical Device Regulation in Nigeria: A Perspective

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ABSTRACT

Regulating medical devices is essential to guarantee their safety, effectiveness, and quality. While developed countries have established robust regulatory frameworks, many developing countries, including Nigeria, face challenges in regulating both imported and locally manufactured medical devices. This article explores the regulatory framework of medical devices in developed countries using the case of the Medical Device framework in the EU and FDA in the US. An overview of medical device regulations in African countries was also provided, with the most focus on NAFDAC and SON in Nigeria. We found that while Nigeria has made progress in strengthening its regulatory framework, it still faces challenges in enforcement, compliance, and aligning with international standards. In addition, the intellectual property landscape and potential conflicts of interest in collaborations with industry players also require attention with the advent of medical devices locally produced in the country. Future directions include; enhanced training of personnel and alignment with international standards. Reforms focusing on technological advancements, and collaborative efforts among stakeholders to guarantee the security and efficacy of medical devices.

Keywords: Medical device regulation, Healthcare practice regulatory, NAFDAC, Africa, Regulatory body in Nigeria

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INTRODUCTION

Medical devices are crucial for diagnosing and treating diseases, and their regulation is crucial to enhance safety, efficacy, and quality.[1,2] Effective regulation of these devices has a profound impact on healthcare delivery in the world at large. Essentially, properly regulated devices ensure patient safety, improve clinical outcomes and boost public confidence in the healthcare system. In addition, economically, stringent regulations can attract foreign manufacturers, fostering local production and creating job opportunities.[3]

The FDA in the USA and the Medical Device framework in the EU are two examples of supervisory agencies that have been established to oversee the medical device business.[4] However, Nigeria like many nations in Africa, grapples with the complexities of regulating medical devices, especially those being imported into the country and those locally manufactured.

In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) is responsible for regulating and controlling the manufacture, importation, exportation, advertisement, distribution, sale, and use of food, drugs, cosmetics, medical devices, chemicals, and packaged water [5]. However, unlike the FDA's oversight of the Medical Devices guide which is detailed on what is expected of medical devices, the NAFDAC's guide available in Nigeria isn't, thereby resulting in a lack of details. This could have been influenced partially by the steady, yet low rate of locally manufactured medical devices and equipment in the country. Consequently, several companies/entities specialize in servicing and remanufacturing clinical devices with no document serving as a guide for both their safety and practices.

Reiterating the importance of a robust regulatory framework is imperative to ascertain the safety, efficiency, and quality of medical devices in Nigeria. Therefore, this

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perspective article aims to explore the regulatory landscape of Medical Devices in developed countries (using the case of the UK and the US), in Africa, and a streamlined focus on Nigeria. In the subsequent sections, we will examine what has been in existence, what holds now, and make recommendations for the future. We will extend our discussions to highlight the roles of key agencies like the Standards Organization of Nigeria (SON) and (NAFDAC) in strengthening medical device regulation in the country.

Regulatory Requirements for Medical Devices in Developed Countries

In a world where the safety and efficacy of Medical Devices are paramount, nations across the globe, especially advanced countries, have established intricate systems to ensure that every device used in healthcare meets the highest standards. The heart of this regulatory framework often lies within the grand halls of the National Regulatory Authority (NRA). This esteemed institution, with its clear powers and responsibilities, stands as the guardian of public health, ensuring that every medical device is scrutinized before it reaches the hands of healthcare professionals[6].

One of the keystones for medical device regulation is characterization based on their purpose and possible consequences from malfunction or operation within the human body. Typically, medical devices are carefully categorized in industrialized nations, such as the US, Japan, and Canada according to the level of risk posed from low to high [7,8]. Every class denotes a distinct risk level, ranging from the safe to the perhaps dangerous. This classification system is akin to a vigilant watchtower, guiding the allocation of regulatory resources and controls, and ensuring that the most critical devices receive the most stringent oversight.

To achieve the optimal result of the regulatory framework, a new device must go through the process of pre-market approval before it is introduced to the market[9]. At the basic level, manufacturers must present a declaration of conformity, to ensure their device meets all safety and performance requirements. While complex devices go through an arduous process, the "simpler" ones may only require presenting proper technical documentation to the regulatory authority, in addition to conducting thorough audits of the manufacturer's quality control system (QMS). Importantly, the device must be authorized by the regulatory body, irrespective of how "simple" before its introduction to the medical market.

The activities of the regulatory body do not end with only approval, the body is also saddled with the responsibility of continuously monitoring the compliance of the manufacturers and users to ethics of usage and practice through a robust post-market surveillance system. According to WHO, 2020 [10], the regulatory authority conducts market surveillance activities to issue safety alerts to users when necessary, ensuring that potential risks are swiftly addressed. At the core of this regulatory framework lies the requirement for manufacturers to develop and sustain a quality management system, such as ISO 13485. This system is the backbone of the device's lifecycle, ensuring that quality, safety, and performance are upheld from conception to decommissioning. [11]

In the UK, for instance, the Medicines and Healthcare Products Regulatory Agency (MHRA) is responsible for regulating medical devices. Medical devices must be registered with the MHRA before it can be placed on the Great Britain market [12]. Furthermore, manufacturers based outside the UK wishing to place a device on the Great Britain market need to appoint a UK representative, who acts on behalf of the manufacturer for all its devices. In addition, as a result of Brexit, that is, the UK leaving the EU following a referendum held on 23 June 2016 and officially taking place on 31 January 2020,[13] the UK government has introduced measures that give a provision for CE (Conformité Européene) mark which is a valid mark that enables medical device to be placed on the EU market. Consequently, the following conditions hold for medical devices placed on the Great Britain market[14]:

i. general medical devices compliant with the EU medical devices directive (EU MDD) or EU active implantable medical devices directive (AIMDD) with a valid declaration and CE marking can be placed on the Great Britain market up until the sooner of expiry of the certificate of 30 June 2028
ii. in-vitro diagnostic medical devices (IVDs) compliant with the EU in vitro diagnostic medical devices directive (IVDD) can be placed on Great Britain market up until the sooner expiry of the certificate of 30 June 2030, and
iii. general medical devices including custom-made devices, compliant with the EU medical devices regulation (EU MDR) and IVDs compliant with the EU in vitro diagnostic medical devices regulation (EU IVDR) can be placed on Great Britain market up until 30 June 2030.
iv. The EU no longer recognizes UK Notified Bodies.
v. UK Notified Bodies are not able to issue CE certificates - and have become UK Approved Bodies.

In the United States, the Food and Drug Administration (FDA) in particular its Center for Devices and Radiological Health (CDRH), is in charge of regulating medical devices. From pre-market submission to post-market surveillance, the FDA's regulatory framework covers every stage of a device's lifetime with the goal of ensuring safety, efficacy, and performance criteria [15]. During the pre-market regulation, based on complexity and risk, the FDA divided medical devices into three classifications (I, II, and III). While Class III devices, which support or sustain life or pose potential threats to patients, require extensive testing and FDA clearance, Class I devices are the least dangerous and frequently require no regulatory monitoring [15,16]. During the pre-market pathway, manufacturers may use the 510(k) pre-market submission for products that are judged to be "substantially equivalent" to those that are already on the market.[15-17] Manufacturers must prove that their device is comparable to an existing product in order to pass this comparatively simplified process, which is applicable to the majority of Class II devices. The next stage is often the pre-market approval (PMA), where,

for Class III devices, this stringent procedure is required. It entails presenting scientific proof and data from clinical trials to back up the device's efficacy and safety [16,18]. PMA is necessary for devices that have no previous equivalents and requires a lot of evidence, which makes it expensive and time-consuming. Should the device be novel, the FDA provides a pathway for devices that offer significant benefits or treatment improvements by offering the De Novo classification for novel devices that do not have a substantially equivalent current device [18].

Furthermore, since most novel devices and those intended for continuous use in the human body need to be justified through clinical trials, Manufacturers are required to file for an Investigational Device Exemption (IDE) for products that need clinical data, especially those that fall under the PMA process.[18,19] With this approval, clinical trials can be conducted to test the device's efficacy and safety in regulated, real-world settings. To ensure patient safety throughout testing, the FDA closely monitors the IDE approval process. Irrespective of the device class, strict labeling regulations enforced by the FDA guarantee that all marketed devices bear the proper usage instructions, cautions, and instructions. The FDA's quality system regulation (QSR), which mandates uniform manufacturing procedures to preserve quality throughout the production process, must also be followed by manufacturers.[20]

Post-market surveillance, as earlier mentioned, is a core aspect of the responsibilities of the FDA in the US. For instance, following approval, the FDA uses Medical Device Reporting (MDR) to keep an eye on a device's performance, requiring makers and healthcare providers to report any negative outcomes or malfunctions.[15,19] Potential problems that might not have been apparent during pre-market testing are found with the use of this post-market surveillance. Sometimes, to gather more information on long-term performance, safety, and patient outcomes, the FDA may mandate post-approval studies. Furthermore, as RWE becomes more and more important, manufacturers can be expected to provide data from actual usage to support clinical trial results and enhance the risk-benefit analysis of the device [21.] More noteworthy is that the FDA has the power to impose recalls if a device is shown to be dangerous after being on sale. If patient safety is in jeopardy, the FDA may issue public warnings and work with manufacturers on corrective measures.[21,22]

The European Union Medical Device Regulation, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC established the rules for the placing on the market, making available, and putting into service medical devices and accessories in the EU.

This also applies to certain products without a medical purpose, such as contact lenses and liposuction equipment.

There are general obligations required of manufacturers which include the necessity of devices to be designed and manufactured in accordance with the Regulation's requirements, ensuring the establishment of a risk management system, conducting clinical evaluations, and preparing technical documentation. Manufacturers must also affix the CE marking of conformity and register their devices and economic operators while a person responsible for regulatory compliance must be appointed, and post-market surveillance implemented. Additionally, devices from outside the EU must have an authorized representative established in the EU with importers and distributors verifying the compliance of devices before making them available on the market. These contributor's obligations include storage, traceability, reporting, and cooperation with competent authorities.

Another important factor is the unique device identification (UDI) System which devices must bear for identification and traceability. The Commission designates entities to operate the UDI system and manage the UDI database. Economic operators and health institutions must store the UDI of certain devices. Member States of the EU must designate authorities responsible for assessing, designating, and monitoring notified bodies who must fulfill organizational, quality management, and other requirements to carry out conformity assessment procedures.

Furthermore, the regulation allows for the reprocessing of single-use devices under certain conditions. Manufacturers are required to provide an implant card and information to patients with implanted devices. It establishes the European database on medical devices (Eudamed) for information sharing and traceability. This regulation aims to ensure the safety and performance of medical devices placed on the EU market through a comprehensive regulatory framework.[23]

Regulatory Requirements for Medical Devices in Africa

A study in 2019 by Saidi and Douglas[24] provided information on medical device legislation in Africa, emphasizing important elements and ramifications for the growth of the medical device sector on the continent concentrating on regulation in ten African nations (Kenya, Egypt, Sudan, Morocco, Angola, Algeria, Tanzania, Ethiopia, and South Africa with Nigeria), which have the greatest GDPs. The key finding was that the regulations in these countries have a strong focus on imports, as they heavily rely on medical devices from developed countries. This has led to lengthy and non-transparent approval processes, which can hinder access to medical care. Furthermore, regulations and regulations of solely medical devices are nonexistent in any of the countries[25]. Rather, a wide range of items, including foods, cosmetics, medications, and related chemicals, are covered by the laws, which may result in a lack of resources and skilled personnel to effectively regulate the medical device industry. Africa's medical device laws are based on the same structure as developed nations, including the US FDA, the Australian Hybrid Therapeutic Goods Administration, and the European CE Mark. The industry's and regulators' coordination and harmonization depend on this alignment with international standards.[26]

In addition to enforcing regulations, African governments can take significant steps to support the growth of their

medical device industries. Some of these initiatives include giving preference to locally made devices when purchasing them and offering technical support to improve the industry's technical capabilities. Hence the necessity for establishing comprehensive and effective medical device regulations in Africa, as well as the need for broader policy considerations to assist the growth of the domestic medical care industry.

Prior studies showed that the South African Health Products Regulatory Authority (SAHPRA) is responsible for regulating medical devices, as South Africa boasts one of the continent's most advanced medical device regulatory frameworks[27]. Similar to the European Union, the nation uses a risk-based categorization system to group devices into four groups (A, B, C, and D) according to the possible risk they pose to patients [28]. In addition, medical device regulation in Kenya is the purview of the Pharmacy and Poisons Board (PPB) of Kenya. Kenya introduced new laws in 2019 requiring all medical devices must be registered before they can be marketed in the country.[29] The system classifies devices into four risk categories, similar to the EU model. Egypt's medical device regulations are overseen by the Egyptian Drug Authority (EDA). The nation has been making efforts to bring its regulatory structure into compliance with global norms, especially the International Medical Device Regulators Forum's (IMDRF) standards.[11] Similarly, Medical device regulation is overseen by the Food and Drugs Authority (FDA) in Ghana. Ghana, too, has strengthened its regulatory structure in recent years, introducing a risk-based classification system among other notable achievements.[30]

However, research has revealed that East, Central, and Southern Africa have a complicated, and frequently undeveloped medical device regulatory environment. Only half of the fourteen member countries of the College of Surgeons of East, Central, and Southern Africa (COSECSA) now have medical device regulatory mechanisms in place, and the other half do not have any formal processes in place, even though 11 of the countries have laws requiring the regulation of medical devices involves several critical elements, including the legal framework, regulatory bodies, a risk-based device classification system, essential principles and standards, conformity assessment, registration requirements, import controls, and post-market oversight[26,31]. There are differences in the degree of implementation of these components between the COSECSA countries and South Africa. While some countries lack formal regulatory mechanisms (Level 3), South Africa has the most developed regulatory framework (Level 1).

While there are some forms of progress, many African countries have underdeveloped regulatory frameworks. One of the factors influencing this, in our opinion, could be distortion in the technological development from the legacy of colonialism and economic factors ranging from suppression and discouragement in order to limit Africans from challenging colonial economic and political dominance. Internally, it could be attributed to resource constraints, shorter history of medical device regulation, and different healthcare priorities in a developing country context.

Regulatory Requirements for Medical Devices in Nigeria

Over the previous few decades, Nigeria's medical device regulations have seen significant change. Medical devices were frequently governed by general pharmaceutical legislation in the early years since there were no particular regulatory frameworks in place. A significant turning point was the creation of the National Agency for Food and Drug Administration and Control (NAFDAC) in 1993, which gave Nigerian medical device regulation a more organized framework [32]. The agency is tasked with the responsibility of registering, ensuring quality, and conducting post-market surveillance of medical devices. Concurrently, SON, governed by the Standards Organization of Nigeria Act No 14, 2015, is tasked with developing and enforcing national standards, encompassing a wide array of products, including Medical Devices[32,33].

Despite their pivotal roles, questions emerge regarding the adequacy of these agencies in adapting to the swiftly evolving landscape of biomedical technologies. The Standards Organization of Nigeria Act No 14, 2015, empowers SON to establish and implement standards for quality and performance. However, the agility of these standards to keep pace with advancements in medical devices raises concerns, emphasizing the need for constant evaluation and potential updates.

Currently in Nigeria, a provision is in place for the medical equipment manufactured in the country under three basic government agencies (NAFDAC, SON, and FMOH).

NAFDAC, being the primary regulatory agency is responsible for registering and controlling medical devices in Nigeria ensuring that medical devices meet safety, efficacy, and quality standards before they are distributed and used within the country[8] by enforcing the following procedures: First, an application is submitted which makes a provision for comprehensive information about the medical device, including its technical specifications, intended use, manufacturing processes, and labeling. Thereafter, the document provided is to ascertain compliance of the medical device with relevant regulations, standards, and guidelines. This includes evaluating the safety, effectiveness, and quality of the device.[34]

Furthermore, laboratory testing is requested to be carried out based on the risk factor and classification of the device to verify its safety and performance characteristics. [8] Accredited laboratories conduct these tests to ensure accurate and reliable results. Finally, a facility Inspection is conducted in the case of certain medical devices, NAFDAC may conduct inspections of the manufacturing facilities to assess compliance with Good Manufacturing Practices (GMP) and quality control processes. If the medical device meets all these regulatory requirements, NAFDAC approves and registers the device. A unique identification number is assigned, and the device is listed in the NAFDAC database as authorized for importation, distribution, and use in Nigeria.

The regulation of medical devices in Nigeria presents significant opportunities for improvement, particularly in establishing a comprehensive framework that ensures safety,

efficacy, and quality. A multi-faceted approach is necessary to address existing challenges and enhance regulatory processes since existing guidelines are insufficient, with limited pre-market testing and reliance on international certifications. Furthermore, there is a lack of funding, skilled personnel, and technical expertise to effectively perform regulatory functions[25] and current processes for monitoring and reporting adverse events are weak, leading to potential safety risks.

Hence it is essential to establish a clear regulatory framework aligned with international standards such as implementing a classification system for medical devices based on risk levels can streamline regulatory processes and involve various stakeholders, including healthcare providers and manufacturers, to foster collaboration and innovation[35].

While these improvements are crucial, there is also a need to consider alternative approaches, such as Open Source Medical Devices, which may offer innovative solutions to regulatory challenges and enhance access to medical technologies in Nigeria[36].

Standards and Regulations for the Importation of Medical Devices in Nigeria

Since Nigeria majorly depends on the use of imported medical devices, it has been observed that due to the unaffordability of new devices, most healthcare facilities often rely on the importation of used devices, which necessitates ensuring compliance of such devices with standards to ascertain that such devices still maintain their integrity [26]. If this area is unsuccessful, it will inevitably result in improper regulation of some diagnostic instruments, which will spread the use of subpar equipment and negatively impact patient outcomes. Consequently, NAFDAC uses the Nigerian medical device import registration system, which is governed by a set of established principles and rules by international organizations like the World Health Organization (WHO), the International Electrotechnical Commission (IEC), and the International Organization for Standardization (ISO) for quality, safety, and performance.

The manufacturer or designated representative proceeds by submitting a registration application to NAFDAC, by

Table 1: Regulatory frameworks of selected nations

Country	*Regulatory Body*	*Legal Framework*	*Essential Registration Required*	*Risk-based Classification System*	*Post-Market Controls*	*Import Controls*
USA	FDA	Medical Device Amendments of 1976, and FDA regulations (21 CFR)	Yes	Class I, II, III	Yes	Yes
Japan	MHLW/ PMDA	Ministerial Ordinance on Standards for Medical Devices, and MHLW/PMDA guidelines	Yes	Class I, II, III, IV	Yes	Yes
Canada	MDB	Medical Devices Regulations (SOR/98-282), Food and Drugs Act, and Health Canada guidance	Yes	Class I, II, III, IV	Yes	Yes
UK	MHRA	Medical Devices Regulations 2002 (SI 2002/618), EU Medical Device Regulation (MDR) 2017/745 (until Brexit), and MHRA guidance	Yes	Class I, IIa, IIb, III	Yes	Yes
Australia	TGA	Therapeutic Goods Act 1989, Therapeutic Goods (Medical Devices) Regulations 2002, and TGA guidance	Yes	Class I, IIa, IIb, III	Yes	Yes
Nigeria	NAFDAC/ SON	SON Act No 14, 2015	Yes	Class A,B,C	Yes but inadequate	Yes
Ghana	*Food and Drugs Authority (FDA) Ghana)*	Medical Devices Regulations, 2019 (L.I. 2406)	Yes	Class A,B,C,D	Yes but inadequate	Yes but inadequate
Egypt	EDA	Law 127/1955 on Pharmaceutical Affairs, Ministerial Decree 271/2005 on Medical Devices, and EDA guidelines	Yes	Class A,B,C	Yes	Yes
South Africa	SAHPRA	Medicines and Related Substances Act 101/1965, Medical Devices Regulations 2016, and SAHPRA guidance.	Yes	Class A,B,C	Yes	Yes
Kenya	Kenya Pharmacy and Poisons Board (PPB)	Kenya Standard for Medical Devices (KS 2931:2019)	Yes	Class I, IIa, IIb III, IV	Yes but inadequate	Yes but inadequate

offering comprehensive details regarding the item, such as its intended purpose, technical parameters, production methods, clinical information, classifications according to their intended purpose, possible risk, and level of interaction with the human body. The level of inspection and documentation needed for registration is determined by the categorization of the device while identification of the best regulatory pathway, the risk assessment entails assessing the possible risks and hazards connected to the device and its components. The device's specifications, production procedures, labeling, usage instructions, sterilization techniques, and performance data are then recorded. To guarantee the constant quality of their medical equipment, importers need to set up and keep up a strong quality management system (QMS), this compliance with the QMS standards demonstrates the importer's commitment to quality and regulatory compliance. In addition, performance testing should be conducted to assess the device's functionality, reliability, and durability to aid verification of the device's appropriateness for its intended use and confirmation that it meets the required standards. Post-market monitoring is then put in place, this involves gathering and examining data on device safety, performance, and adverse events, where importers are expected to collaborate with the already existing health system to report any adverse events or product defects to NAFDAC promptly. Finally, foreign manufacturers intending to import medical devices to Nigeria must appoint a local authorized representative who serves as a liaison between the manufacturer and NAFDAC and is responsible for submitting the registration application, maintaining regulatory compliance, and handling post-market surveillance activities on behalf of the manufacturer. The regulatory frameworks of various selected nations are compared in Table 1, which highlights important regulatory organizations, legal requirements, crucial registration procedures, risk-based classification systems, import controls, and post-market controls.

CONCLUSION AND FUTURE DIRECTIONS

Conclusion

In this paper, we examined the landscape of medical device regulation in Nigeria, taking insights from the established frameworks of the likes of regulation in UK, FDA in the US, and the EUMDR. The US FDA and EU Medical Device Regulation which have established robust frameworks that categorize medical devices based on risk, ensuring safety, efficacy, and quality through stringent pre-market approval and post-market surveillance processes serve as benchmarks for developing countries like Nigeria to align their regulatory systems.

We further provided an overview of the current state of medical device regulations in Africa, and further streamlined our discussion to Nigeria where NAFDAC and SON play pivotal roles in ensuring compliance with standards. While the regulation of medical devices in Nigeria has progressed significantly, considerable challenges remain such as reliance on imported medical devices, lack of trained personnel, and lack of attention to emerging healthcare technologies within the country. In general, the regulatory scope and responsiveness of NAFDAC to emerging technologies necessitate continuous evaluation as failure to do so can lead to enforcement and compliance challenges resulting in the use of unsafe Medical Devices. Also, reliance on imports can delay access to essential technologies.

Comparisons made with the EU and US regulatory frameworks revealed gaps in Nigeria's oversight, particularly in pre-market approval processes and post-market surveillance. While developed nations have implemented risk-based classification and stringent quality control mechanisms, Nigeria's regulatory environment remains largely reactive, focusing more on import controls than a holistic device lifecycle approach. A key limitation as identified in relation to the above challenge is the reliance on imported medical devices, often without rigorous local validation raises concerns about the safety and efficacy of devices used in Nigeria, as international approvals do not always account for local infrastructural and environmental differences. Moreover, the lack of skilled personnel, inadequate funding, and the absence of harmonized policies across African countries further complicate regulatory efficiency. The underdeveloped post-market surveillance system means potential adverse effects of medical devices may go unreported, increasing patient risks.

To advance medical device regulation in Nigeria, a shift from mere compliance-based regulation to a dynamic, innovation-driven framework is required. This involves expanding local manufacturing capabilities through incentivized partnerships between biomedical engineers, regulatory bodies, and research institutions. Establishing a regional regulatory harmonization strategy, akin to the EU model, enhancing oversight and facilitating intra-African trade in medical technologies. Ultimately, Nigeria must move beyond traditional regulatory models and embrace technology-driven, globally competitive strategies to ensure patient safety and innovation in healthcare.

Consequently, we provided recommendations, which include strengthening enforcement, expanding training, and aligning more closely with international standards. We believe that these are key steps toward enhancing the regulatory framework in Nigeria, thereby creating a more effective regulatory system that adapts to technological advancements and meets evolving healthcare needs.

Future Directions

Attention to Intellectual Property and Patent Concerns

Innovation is the lifeblood of every industry. Medical device development cannot be left out as well, as it often entails groundbreaking research and breakthroughs. With the recent introduction of degree-awarding Biomedical Engineering and Biomedical Technology curriculum into the Nigerian education system, several notable research activities have been recorded. In the near future, locally produced devices will

stem from the knowledge gained, necessitating the need for an application for Intellectual property (IP) rights particularly patents to become integral in safeguarding these innovations. Currently in Nigeria, the regulatory landscape surrounding IP poses challenges for product developers. The legal framework governing IP rights, as outlined in acts such as the NAFDAC Act Cap N1 LFN 2004[37] and the Federal Competition and Consumer Protection Act 2018, needs to be robust to stimulate investment in research and development. The regulatory complexity surrounding patents raises questions about the effectiveness of the legal framework in supporting the development and protection of innovative devices. A critical examination of these regulations is essential to encourage a conducive environment for research and development in the biomedical field, strengthening patent laws and legal frameworks will encourage research and development of indigenous medical devices while safeguarding intellectual property rights.

Collaborations Among Regulatory Bodies

Collaborations between healthcare institutions, especially hospitals, and industry players are pivotal for the development and deployment of medical devices. However, such collaborations introduce potential conflicts of interest that demand careful consideration. Balancing the pursuit of advancements in medical technology with the need to maintain objectivity and prioritize patient welfare is a delicate challenge. While the Federal Competition and Consumer Protection Act 2018 addresses certain aspects of competition, lingering concerns persist regarding transparency and ethical considerations in collaborations. Striking the right balance between fostering innovation and safeguarding against conflicts of interest remains an ongoing challenge for regulators and stakeholders in the healthcare sector.

A notable observation from this discourse is the concentration of administrative responsibilities within a single agency, NAFDAC. While various Acts create committees, councils, and inspectors, their implementation is centralized, raising questions about the distribution of regulatory authority and potential limitations in addressing the dynamic landscape of the Food and Drug Administration in Nigeria. SON, on the other hand, primarily focuses on maintaining high-quality standards for the certification of products entering and emanating from Nigeria. With a clear mandate, SON contributes significantly to guaranteeing the quality and safety of products within the Nigerian medical sector. Hence, Nigeria's regulatory framework consists of specialized agencies, but a more distributed, collaborative approach may be needed to address challenges, including the recent rise in counterfeit products[38].

Focus on Regulatory Reforms for Medical Devices

Despite the regulatory structure in place, Nigeria faces significant challenges due to limited infrastructure, resources, enforcement, and compliance. Additionally, a shortage of trained staff further hinders efficiency, causing delays in regulatory processes[39,40]. Rapid advancements in medical technology, such as digital health devices and AI, have also outpaced current regulations, leaving gaps in oversight. Moving forward, Nigeria must prioritize comprehensive regulatory reforms to modernize its framework and reduce the time between reviews (e.g., the NAFDAC framework set for 2026). Enhanced stakeholder collaboration across public, private, and international sectors is also essential to strengthening regulatory infrastructure and capacity.

Assessment of Effectiveness of Current Regulations

Empirical studies should assess the impact of existing regulations on medical device safety, market dynamics, and patient outcomes in Nigeria and also research ways of exploring the effectiveness of Nigeria's post-market surveillance framework and proposing data-driven enhancements to mitigate risks. Feasibility studies should also be used to analyze the cost-benefit dynamics of producing medical devices locally versus reliance on imports. Cross-country studies comparing Nigeria's medical device regulations with those of other African nations can also provide insights into best practices for regional harmonization.

Conclusively, healthcare professionals and medical device manufacturers in Nigeria must align their practices with evolving regulatory requirements to ensure patient safety and device efficacy while the need to train stakeholders concerned such as biomedical engineers, regulatory officers, and healthcare providers on global best practices for medical device regulation, including post-market surveillance and risk assessment should be seen as a matter of urgency and top priority.

Nigerian healthcare institutions should adopt stricter evaluation criteria for medical devices, including lifecycle assessments and performance validation, to mitigate risks associated with substandard imports. A need to integrate its medical device regulations with WHO, FDA, and EU standards to ensure compatibility with global trade and safety benchmarks such as creating a national repository for approved medical devices, adverse event reporting, and manufacturer compliance status should be created to enhance transparency and oversight.

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Oyebola Oni: Conceptualization, Writing - Original Draft, Writing - Review and Editing; Ifeanyi Ogbodo: Writing - Original Draft; Joseph Agboola: Writing - Original Draft; Ayodele James Oyejide: Writing - Review and Editing

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