

VITAL SIGNS

Famsville's Life Sciences and Healthcare Bi-Monthly Updates



Table of Contents

Introduction

Regulatory Updates

NAFDAC's 2025 Roadmap to Strengthen Regulatory Oversight

Government Absorption of 28,000 Health Workers

Mandatory Inclusion of Bioequivalence Data in Dossier Submissions

Retirement Age Extension for Healthcare Workers

Nigeria Secures \$300 Million World Bank Loan to Strengthen Health Security Infrastructure

Industry and Policy Insights

Contacts

Introduction

Happy 2025 from the Famsville Life Sciences and Healthcare Team!

As Nigeria's healthcare and pharmaceutical industries evolve, regulatory developments and policy changes continue to shape the landscape. In this edition of Vital Signs, we provide a concise and insightful overview of the most critical updates, including legislative advancements, executive approvals, and regulatory shifts.

From NAFDAC's strategic roadmap for regulatory oversight to the Nigerian government's increased funding for the healthcare sector, this issue highlights significant developments that impact stakeholders across the industry. Additionally, we cover the landmark executive order extending the retirement age for healthcare professionals and the mandatory inclusion of bioequivalence data in dossier submissions for generic drugs.

Whether you are a healthcare provider, legal professional, or pharmaceutical industry stakeholder, staying informed is crucial. We invite you to explore these updates and their implications, ensuring you remain well-equipped to navigate Nigeria's dynamic healthcare landscape.

If you would like to discuss any of these developments or seek legal guidance, please do not hesitate to contact us. We look forward to engaging with you.

Welcome to the maiden edition of Vital Signs, Famsville's magazine providing essential updates in Nigeria's health and pharmaceutical sectors. From regulatory developments to executive approvals shaping the industry, we bring you key insights into the evolving legal landscape.

Get in Touch

DAYO ADU

Managing Partner,

Famsville,

Dayo.adu@famsvillelaw.com

Regulatory Updates



1. NAFDAC's 2025 Roadmap to Strengthen Regulatory Oversight

In a bold move to enhance regulatory oversight and uphold the highest standards within Nigeria's pharmaceutical and healthcare sectors, the National Agency for Food and Drug Administration and Control (NAFDAC) unveiled its strategic roadmap for 2025 on 16th January. This initiative underscores the agency's commitment to ensuring the availability of high-quality, safe, and effective health products in Nigeria.

A key aspect of this roadmap is the institutionalisation of best practices aimed at securing World Health Organization (WHO) Listed Authority Status. Achieving this status will align Nigeria's regulatory framework with globally recognised standards, reinforcing consumer confidence in the safety and efficacy of pharmaceutical products circulating within the country.

Another crucial component of the roadmap is the implementation of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) certification. This international certification programme is designed to enhance inspection standards, ensuring that Nigeria's pharmaceutical regulatory systems align with leading global practices. By adopting these rigorous inspection protocols, NAFDAC aims to minimise the risk of substandard and falsified medicines entering the market while fostering trust in the regulatory process.

Additionally, the roadmap prioritises strengthening Nigeria's regulatory framework to facilitate seamless access to high-quality health products. This involves streamlining the approval and monitoring processes for pharmaceutical and medical products, enhancing post-market surveillance, and reinforcing compliance mechanisms for local and international manufacturers. Through these measures, NAFDAC is working to create an enabling environment that supports innovation and growth within the pharmaceutical sector while safeguarding public health.

By implementing this strategic roadmap, NAFDAC reaffirms its dedication to advancing pharmaceutical safety and quality assurance in Nigeria. The agency's efforts reflect a proactive approach to regulatory excellence, ensuring that both healthcare providers and consumers benefit from a more robust and transparent regulatory system. On 16th January, 2025, the National Agency for Food and Drug Administration and Control (NAFDAC) introduced an ambitious plan to improve regulatory inspections and enhance industry standards. Key initiatives include

- Institutionalising best practices to achieve World Health Organization Listed Authority Status.
- Implementing Pharmaceutical Inspection Cooperation Scheme certification for improved inspection standards.
- Strengthening the regulatory framework to ensure access to high-quality health products.

This strategic roadmap aims to reinforce Nigeria's commitment to pharmaceutical safety and quality assurance.¹

2. Legislative Approval of Additional Health Sector Funding

In an effort to address critical challenges facing Nigeria's healthcare sector, the nation's National Assembly has approved an additional \$200 million in funding, a decision that was finalised on 13th February, 2025. This significant financial boost comes at a crucial time, as the healthcare industry grapples with the suspension of USAID health funding, which previously supported numerous public health initiatives.

The newly allocated funds aim to offset the financial shortfalls that have arisen due to the suspension, ensuring that essential healthcare services remain operational. A considerable portion of this budget will be directed toward vaccine procurement, with a strong emphasis

1. National Agency for Food and Drug Administration and Control (NAFDAC), The Year 2025 – NAFDAC Director General's Strategic Plan, <https://nafdac.gov.ng/the-year-2025-nafdac-director-generals-strategic-plan/> accessed last on the 17th February 2025.

on combating epidemic-prone diseases. Given Nigeria's vulnerability to infectious disease outbreaks, such as malaria, cholera, and meningitis, this strategic allocation is intended to enhance national preparedness and strengthen the country's immunisation framework. Furthermore, the funding is expected to support improvements in public health service delivery. This includes expanding healthcare infrastructure, bolstering the supply of essential medicines, and increasing the capacity of medical personnel to ensure that quality healthcare services are accessible to a larger segment of the population. The government's commitment to reinforcing healthcare accessibility aligns with broader efforts to improve health outcomes and reduce mortality rates across the country.

This legislative approval marks a significant milestone in Nigeria's ongoing efforts to fortify its healthcare system. By addressing funding gaps and prioritising critical health initiatives, the government demonstrates its dedication to fostering a more resilient and effective healthcare sector. Stakeholders, including healthcare providers, policymakers, and international partners, will be closely monitoring the impact of this funding to ensure its efficient utilisation for the benefit of the Nigerian population.²

3. Government Absorption of 28,000 Health Workers

On 14th February, 2025, the Nigerian government took decisive action to absorb 28,000 health workers previously funded by USAID. This initiative ensures the continuation of critical healthcare services, particularly in rural and underserved areas where these professionals play a vital role. This intervention ensures continuity in healthcare service delivery, particularly in rural and underserved regions where these professionals play a crucial role in patient care.

The absorption of these health workers reflects the government's commitment to maintaining a robust healthcare workforce. Many of these professionals, including doctors, nurses, and community health workers, were employed under programs aimed at tackling infectious diseases, maternal and child health, and emergency response initiatives. With their contracts now being funded by the federal government, there is renewed hope for stability in the health sector.

A key aspect of this transition is the integration of the absorbed workers into the national payroll system, ensuring prompt salary payments and job security. The government has also introduced measures to streamline the bureaucratic process, reducing delays in employment confirmation and placement. Furthermore, provisions have been made to

2. Reuters "Nigeria makes \$200 million budget provision to fill U.S. aid suspension gaps" <https://www.reuters.com/world/africa/nigeria-makes-200-million-budget-provision-fill-us-aid-suspension-gaps-2025-02-13/> accessed on the 17th February 2025.

facilitate training programs to enhance the skills of these professionals and align them with national healthcare priorities.

Beyond job retention, this move strengthens Nigeria's public healthcare system by ensuring that experienced personnel remain active in-service delivery. Without this intervention, the loss of such a significant number of healthcare workers could have led to increased workloads for existing staff, service disruptions, and worsened health outcomes across the country.

Stakeholders, including labour unions, healthcare advocacy groups, and international partners, have lauded the government's swift action. However, concerns remain about the long-term sustainability of funding these roles, particularly in the face of fluctuating economic conditions. Experts suggest that diversifying funding sources and fostering public-private partnerships will be essential in ensuring that Nigeria's healthcare workforce remains adequately supported.

This initiative marks a crucial step in stabilizing the healthcare workforce and preserving the progress made in public health interventions. The government's continued engagement with stakeholders will be critical in addressing any challenges that arise and ensuring the success of this workforce absorption programme.³

4. Mandatory Inclusion of Bioequivalence Data in Dossier Submissions

As part of its continued efforts to ensure the quality, efficacy, and safety of pharmaceutical products in Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) has implemented a significant regulatory update effective January 2025. Under this new requirement, all dossier submissions for drug products that do not qualify for bio-waivers must now include bioequivalence data.

Bioequivalence testing is a critical component in evaluating the effectiveness of generic drugs, ensuring that they perform at the same level as their branded counterparts in terms of absorption, distribution, metabolism, and elimination within the body. This measure is expected to enhance the credibility of generic pharmaceuticals in Nigeria, reinforcing confidence among healthcare professionals and consumers alike.

By enforcing this regulation, NAFDAC aims to elevate the country's pharmaceutical industry to international standards, aligning with global regulatory authorities such as the World Health Organization (WHO) and the United States Food and Drug Administration (FDA).

3 Channels TV, "FG To Absorb 28,000 Health Workers Affected By USAID Freeze", <https://www.channelstv.com/2025/02/15/fg-to-take-over-salaries-of-28000-health-workers-affected-by-usaid-freeze-health-minister-pate/> Accessed on 17th February 2025.

The requirement is particularly relevant as Nigeria continues to strengthen its local pharmaceutical manufacturing sector, reducing reliance on imported medicines and promoting the production of high-quality generics.

While this regulatory shift is a positive development, stakeholders, including pharmaceutical manufacturers and distributors, must adapt to the new compliance framework. Companies will need to invest in clinical trials, bioequivalence studies, and advanced testing methodologies to meet NAFDAC's stringent approval processes. Additionally, the policy is expected to drive increased collaboration between pharmaceutical companies and research institutions to ensure that generics meet the required therapeutic equivalence.

Ultimately, the mandatory inclusion of bioequivalence data in dossier submissions is a significant milestone in Nigeria's journey toward a more robust and reliable pharmaceutical industry. It underscores NAFDAC's unwavering commitment to ensuring that every medication available in the market is safe, effective, and of high quality.

5. Extension of Retirement Age for Healthcare Workers

On 6th February 2025, President Bola Tinubu approved the extension of the retirement age for clinically skilled healthcare workers from 60 to 65 years. This decision comes as a strategic response to Nigeria's critical shortage of experienced medical professionals, a challenge that has been further intensified by the ongoing brain drain in the healthcare sector.

By allowing healthcare workers to remain in service for an additional five years, the government aims to retain seasoned practitioners whose expertise is essential for high-quality patient care. The policy also ensures that younger medical staff continue to benefit from the mentorship and guidance of senior professionals, thereby strengthening the capacity of Nigeria's healthcare system.

Extending the retirement age also fosters improved knowledge transfer within the sector. Senior healthcare workers play a vital role in training and equipping less experienced colleagues with specialized skills. This move will help bridge the skills gap, ensuring that medical expertise is preserved and passed down effectively to sustain the country's healthcare standards.

Another key advantage of this policy is the promotion of service continuity in hospitals and medical facilities across Nigeria. The retention of experienced personnel ensures that

healthcare delivery remains stable and consistent, reducing the risk of workforce shortages that could negatively impact patient care. With a more experienced and stable workforce, the healthcare sector can maintain operational efficiency and respond more effectively to public health demands.

The approval of this policy was announced by the Coordinating Minister of Health and Social Welfare, Prof. Muhammad Ali Pate, during a meeting with key stakeholders, including the Nigerian Medical Association (NMA), the Medical and Dental Consultants Association of Nigeria, the National Association of Nigerian Nurses and Midwives, and the Joint Health Sector Unions. Prof. Pate emphasised the importance of following due process to formalise the extension, noting that the Ministry will collaborate with the Office of the Head of Civil Service of the Federation and the National Council on Establishment to implement the policy effectively.

The Nigerian Medical Association, represented by its President, Prof. Bala Audu, praised the approval, describing it as a timely and necessary intervention. He noted that retaining experienced healthcare professionals is crucial to the effective delivery of medical services and the continuous development of upcoming medical practitioners.

Beyond workforce retention, this policy shift is expected to alleviate some of the challenges facing Nigeria's healthcare system. The government has reaffirmed its commitment to addressing long-standing issues such as salary arrears, inadequate working conditions, and the need for new remuneration structures. These measures are aimed at improving job satisfaction, reducing healthcare worker emigration, and fostering a more resilient healthcare workforce.

In summary, the extension of the retirement age for healthcare workers represents a proactive and strategic move to stabilize and strengthen Nigeria's health system. By preserving invaluable medical expertise, enhancing knowledge transfer, and ensuring service continuity, this policy is set to have a lasting positive impact on the country's healthcare sector⁴

6. Nigeria Secures \$300 Million World Bank Loan to Strengthen Health Security Infrastructure

In a strategic move to bolster Nigeria's health security, the Federal Government has engaged the World Bank for a new \$300 million loan aimed at enhancing the nation's health emergency response infrastructure. The Nigeria Centre for Disease Control (NCDC) will

⁴ Federal Ministry of Information Press Release "Extension of Retirement Age for Healthcare Workers", <https://fmino.gov.ng/president-tinubu-approves-extension-of-retirement-age-from-60-to-65-for-clinically-skilled-health-workers/> accessed on 17th February, 2025

oversee the implementation of the project, with the Federal Ministry of Finance acting as the borrower on behalf of the government.

According to the World Bank, the loan is designed to “increase regional collaboration and health system capacities to prevent, detect, and respond to health emergencies in the Federal Republic of Nigeria.” The programme will focus on strengthening disease surveillance, improving diagnostic capabilities, and expanding laboratory networks across Nigeria’s 36 states and the Federal Capital Territory.

The project is currently in the pipeline stage, with the disclosure date was scheduled for 6 February 2025. The World Bank Board of Directors is expected to give its final approval on 30th July 2025, following necessary assessments. An appraisal of the programme is set for 14th April 2025, and implementation is scheduled to commence in the 2026 fiscal year.

The Nigeria Health Security Programme (HeSP) aligns with broader government efforts to enhance emergency preparedness and response capabilities. According to the Environmental and Social Review Summary of the project, the programme will facilitate the expansion of molecular laboratory capacity, the upgrade of primary healthcare centres, the establishment of emergency operation centres, and the construction of warehouses to improve logistics and supply chain management for medical resources.

This initiative highlights Nigeria’s commitment to reinforcing its health infrastructure, ensuring a more robust response to public health emergencies, and aligning with international best practices in disease control and prevention.⁵

Industry and Policy Insights

Nigeria’s healthcare sector is undergoing a transformative phase, driven by regulatory advancements, technological innovations, and strategic partnerships. As the government continues to introduce policies aimed at strengthening the healthcare system, stakeholders in both the public and private sectors are actively seeking ways to adapt to these changes and improve healthcare accessibility and quality. Below are some of the key industry insights shaping the future of healthcare in Nigeria.

Digital Health Innovations

Technology is revolutionising healthcare delivery in Nigeria, with digital health innovations playing a crucial role in expanding access to medical services. Telemedicine has seen significant growth, providing patients in remote and underserved areas with the ability to

5. Punch Online News, FG seeks fresh \$300m health security loan from W'Bank, published on 16th February 2025, <https://punchng.com/fg-seeks-fresh-300m-health-security-loan-from-wbank/>, accessed on 17th February 2025

consult with doctors and specialists via digital platforms.

Several digital health platforms are becoming more popular in Nigeria. For example, Reliance HMO Telemedicine allows patients to have virtual consultations, helping to ease pressure on hospitals. Also, companies like Helium Health make it easier for hospitals to manage patient records, leading to better efficiency and coordination of care.

Additionally, the launch of the Nigeria Digital in Health Initiative shows the government's commitment to working with stakeholders to develop policies that balance technology with patient safety and data protection. The initiative also serves as a regulatory body to set up a structured digital health system. Its goal is to create a well-organised digital healthcare network that improves access, makes medical services more affordable, and increases efficiency across Nigeria.

In conclusion, this information accurately reflects how Nigeria is embracing digital health innovations, combining new technology with strong regulations to improve healthcare services.

Public-Private Partnerships (PPPs)

Public-Private Partnerships (PPPs) are increasingly vital in addressing Nigeria's healthcare infrastructure challenges and enhancing service delivery. Thus, recognising the critical role of private sector involvement, the government has fostered joint initiatives aimed at constructing and managing healthcare facilities, providing medical equipment, and funding research and development.

A prominent example is the collaboration between the government and private investors to establish modern diagnostic centres and specialised hospitals. For instance, the Nigerian Sovereign Investment Authority (NSIA)-Umuahia Diagnostic Centre and the NSIA-Kano Diagnostic Centre, established through partnerships with private investors, provide high-quality imaging services and cancer treatment, reducing the need for medical travel abroad. Similarly, the Lagos State Health Scheme (LSHS), a collaboration between the Lagos State Government and private Health Maintenance Organisations (HMOs), has expanded access to affordable healthcare for millions of Lagosians.

PPPs are also making significant strides in pharmaceutical manufacturing, with a focus on local production of essential medicines to reduce reliance on imports and ensure a stable drug supply.

One example is DrugStoc, a private pharmaceutical distribution company working with government hospitals to ensure a steady supply of essential medicines, thereby reducing shortages and preventing the sale of counterfeit drugs.

Additionally, these partnerships have expanded health insurance schemes, improving affordability and access to healthcare for a broader population. The PharmAccess Foundation's collaboration with the Kwara State Government to introduce a community-based health insurance scheme has been recognised as one of Nigeria's most successful healthcare financing models.⁶

The growth of digital health technologies and the strengthening of public-private collaborations are driving Nigeria's healthcare sector forward. For example, Zipline, a private drone logistics company, is partnering with the governments of Kaduna, Cross River, and Bayelsa states to deliver medical supplies to remote areas, significantly improving healthcare access. As regulatory frameworks evolve to support these innovations, the sector is poised for substantial improvements in service delivery, efficiency, and patient outcomes.⁷

Conclusion

Nigeria's healthcare sector is at a critical juncture, with regulatory reforms, technological innovations, and strategic collaborations shaping its future. The adoption of digital health solutions and the expansion of public-private partnerships are paving the way for improved healthcare accessibility and quality. As the sector continues to evolve, stakeholders must remain proactive in aligning with regulatory changes and leveraging emerging opportunities.

For legal consultations or inquiries regarding healthcare regulations and industry trends, please contact Famsville.

For additional information, please contact us on info@famsvillelaw.com.

Stay connected with us on all our social media platforms. *LinkedIn, Instagram, Twitter.*

⁶ <https://www.pharmaccess.org/update/kwara-pharmaccess-strengthen-partnership-to-provide-quality-healthcare/>.
⁷ <https://www.flyzipline.com/newsroom/news/announcements/zipline-announces-nigeria-partnership>

Contacts:



Dayo Adu
Managing Partner
+234 806 280 1020
Dayo.adu@famsvillelaw.com



Uzochukwu Kpaduwa
Associate
+234 906 184 2984
Uzochukwu.kpaduwa@famsvillelaw.com



Victor Abolaji
Associate
+234 916 056 4363
Victor.abolaji@famsvillelaw.com