Health and Phamaceuticals Stakeholders' Report

2026
Stakeholders'
Report

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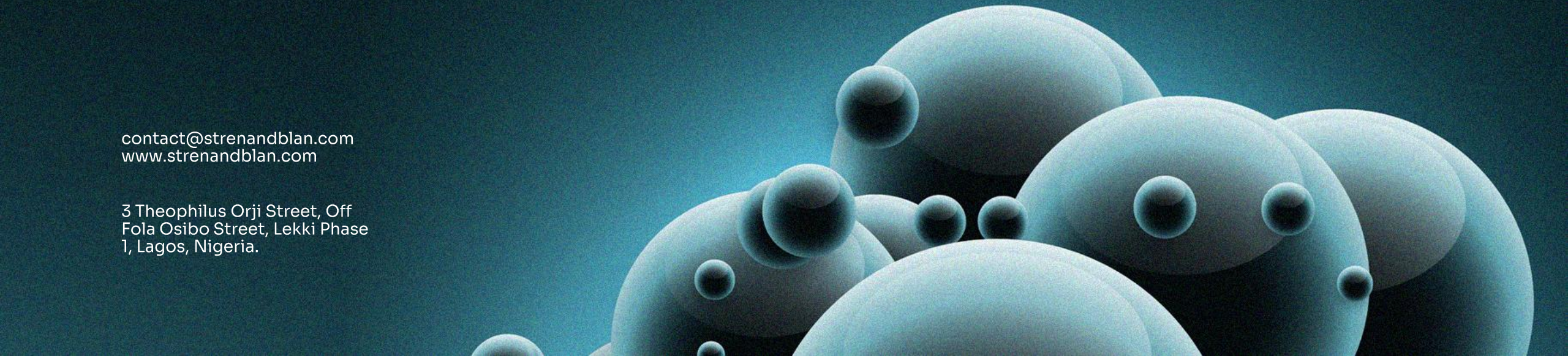

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Introduction

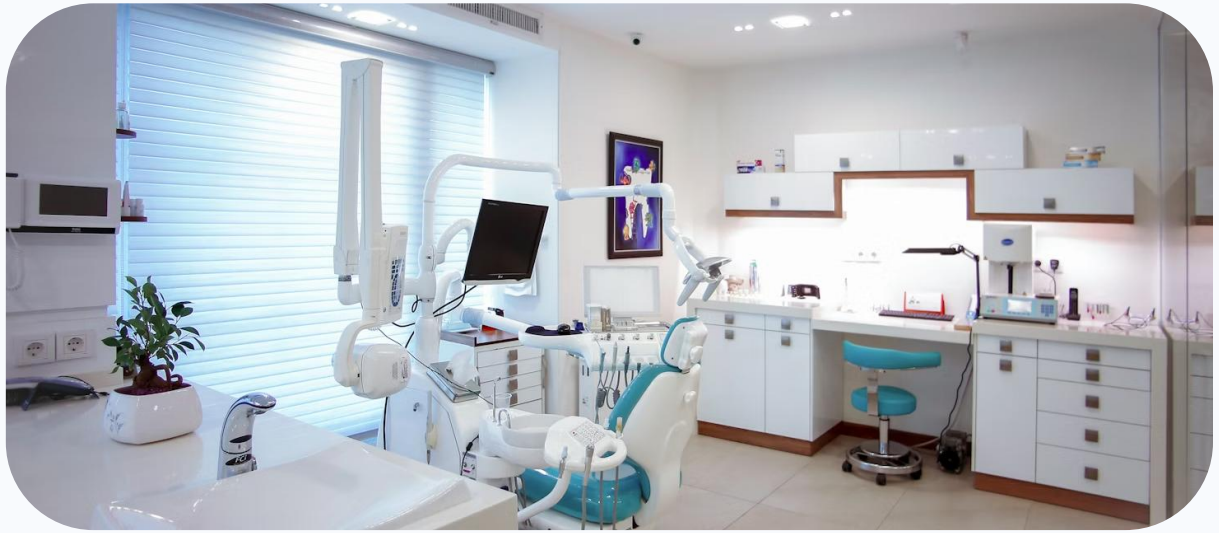
This Stakeholders' Report provides a comprehensive analysis of key regulatory developments and legislative changes affecting Nigeria's health and pharmaceutical sector during the year 2025 (the "Report Period"). The report focuses on regulatory advancements that impact pharmaceutical manufacturers, distributors, healthcare providers, investors, and other stakeholders within the sector.

The year 2025 marked a transformative period characterized by unprecedented regulatory advancement, strategic infrastructure investments, and a renewed commitment to aligning domestic healthcare standards with international best practices. Nigeria's achievement as the first African nation to sustain the World Health Organisation's (WHO) Maturity Level 3 (ML3) status stands as a testament to years of systematic regulatory strengthening and institutional capacity building.

This milestone, coupled with the gazetting of comprehensive pharmaceutical traceability regulations and the operationalization of specialized cancer treatment facilities, signals a maturing ecosystem where quality assurance, patient safety, and therapeutic access converge as policy priorities.

Yet these achievements must be viewed against persistent structural constraints. While the health sector's budgetary allocation is historically significant in nominal terms (₦2.48 trillion for 2026), it remains below the 15% benchmark prescribed under the Abuja Declaration.[1] The 2026 allocation represents approximately 6% of the total national budget.

Executive Summary



This Stakeholders' Report for the health and pharmaceutical sector outlines critical regulatory changes and strategic developments that occurred during 2025. These developments have significant implications for all stakeholders, including manufacturers, distributors, healthcare providers, and investors.

Summary of New Legislation and Regulatory Developments

During the Report Period, several significant legislative and regulatory developments impacted the health and pharmaceutical sector.

NAFDAC Traceability Regulations (Government Notice No. 54)

The NAFDAC Traceability Regulations were officially gazetted, establishing legally binding requirements for pharmaceutical product traceability throughout the supply chain. The regulations mandate unique serialized identifiers for each sellable unit, utilization of GS1 global standards including 2D Data Matrix barcodes, and comprehensive data sharing with NAFDAC covering production, distribution, and sales. Discrepancies must be reported within 48 hours. The framework aligns with the National Pharmaceutical Traceability Strategy (May 2020) and the Africa Strategy for Pharmaceutical Traceability.[2]

PCN E-Pharmacy Guidelines

The Pharmacists Council of Nigeria finalized comprehensive e-pharmacy guidelines in November 2025, establishing mandatory licensing requirements for digital platforms engaged in online medicine sales. The guidelines aim to prevent drug abuse, ensure quality control, and formalize the digital pharmaceutical distribution channel. All digital medicine platforms must obtain appropriate licenses and comply with storage, dispensing, and record-keeping requirements applicable to traditional pharmacies.[3]

Executive Order on Pharmaceutical Raw Materials

The 2024/25 Executive Order removed Value Added Tax (VAT) and import tariffs on pharmaceutical raw materials and active pharmaceutical ingredients (APIs). This policy intervention aims to reduce production costs for local manufacturers, enhance competitiveness, and support the government's local manufacturing drive, targeting 70% local pharmaceutical production by 2030.

National Cancer Control Plan (2026-2030)

The government finalized a new National Cancer Control Plan covering the period 2026-2030, focusing on establishing regional diagnostic hubs, expanding radiotherapy capacity, and improving early detection programs. The plan acknowledges Nigeria's severe radiotherapy deficit (requiring a minimum of 280 machines for the population but having fewer than 10 functional government-funded units) and sets ambitious targets for infrastructure development.

US-Nigeria Health Sector Technical Cooperation MoU

A landmark Memorandum of Understanding signed in December 2025 secures nearly $2 billion in US grant funding for Nigeria's health sector between 2026 and 2030. In exchange, Nigeria committed to allocating at least 6% of its annual budget to health, representing a significant step toward the Abuja Declaration's 15% target, though still falling short of the benchmark.

Key Highlights of 2025

Nigeria Sustains WHO Maturity Level 3 Status

The World Health Organisation officially reaffirmed Nigeria's Maturity Level 3 (ML3) status for the regulation of medicines and vaccines, effective 30 June 2025. This recognition followed WHO's formal re-benchmarking exercise conducted in Abuja and Lagos (25-29 November 2024) and five Institutional Development Plan follow-up meetings held between February and May 2025.

What ML3 Status Means

ML3 designation confirms that NAFDAC operates a stable, well-functioning, and integrated regulatory system evaluated across eight core regulatory functions: National Regulatory System, Registration and Market Authorization, Market Surveillance and Control, Regulatory Inspection, Clinical Trial Oversight, Laboratory Testing, Vigilance (pharmacovigilance), and Licensing Establishments. The designation means Nigeria can manufacture vaccines (a country must achieve ML3 to produce vaccines with international credibility), export pharmaceuticals to markets relying on regulatory reliance mechanisms, attract foreign direct investment based on regulatory confidence, and work toward ML4 status, which would qualify Nigeria as a WHO Listed Authority enabling global pharmaceutical trade.

Strategic Implications

For manufacturers and investors, ML3 status reduces regulatory risk, streamlines approval processes for companies with robust quality management systems, positions Nigeria as a viable regional manufacturing hub, and creates competitive advantages through regulatory credibility. NAFDAC is actively working toward ML4, having closed 27 of 57 indicators, representing approximately 47% progress toward the highest maturity level.[4]

NAFDAC Traceability Regulations Gazetted

The gazetting of NAFDAC Traceability Regulations under Government Notice No. 54 establishes legally binding requirements for supply chain visibility. The regulations mandate serialized identification of each sellable pharmaceutical unit using GS1 global standards (including 2D Data Matrix barcodes and Global Trade Item Numbers), comprehensive data capture at every transaction point from manufacture through retail dispensing, mandatory data sharing with NAFDAC's centralized repository covering production, distribution and sales, 48-hour reporting requirements for data discrepancies, and authentication mechanisms enabling healthcare providers and patients to verify product authenticity.

Compliance Requirements

Stakeholders must implement compliant digital traceability systems, engage with accredited GS1 solution providers in Nigeria, serialize products across all sellable packaging levels, establish data-sharing protocols with NAFDAC's centralized repository, train personnel on traceability compliance, and prepare for inspections verifying system functionality. Non-compliance carries significant penalties, including fines up to N5,000,000 for corporate bodies, potential imprisonment for individuals, and asset forfeiture linked to offences.

Strategic Opportunities

Early investment in compliant systems yields operational efficiencies, including improved inventory control, reduced diversion and counterfeiting, enhanced pharmacovigilance capabilities, brand protection, and demonstration of regulatory responsibility. Companies with integrated traceability infrastructure become more attractive to investors due to reduced regulatory and reputational risk.[5]

PCN Pharmacy Practice Reforms

The Pharmacists Council of Nigeria accelerated reforms to formalize the drug supply chain. The finalization of E-Pharmacy Guidelines in November 2025 now regulates online medicine sales, requiring licensing for digital platforms to prevent drug abuse and ensure quality standards.

The PCN signed irreversible MoUs with stakeholders in Lagos, Onitsha, and Aba to transition from chaotic open drug markets to Coordinated Wholesale Centres (CWCs) by 2026, marking a fundamental restructuring of pharmaceutical distribution. In Q4 2025, PCN task forces intensified surveillance raids on drug hawkers and unlicensed retail outlets in Abuja (Garki), Lagos, and other metropolitan centres.

Compliance Requirements

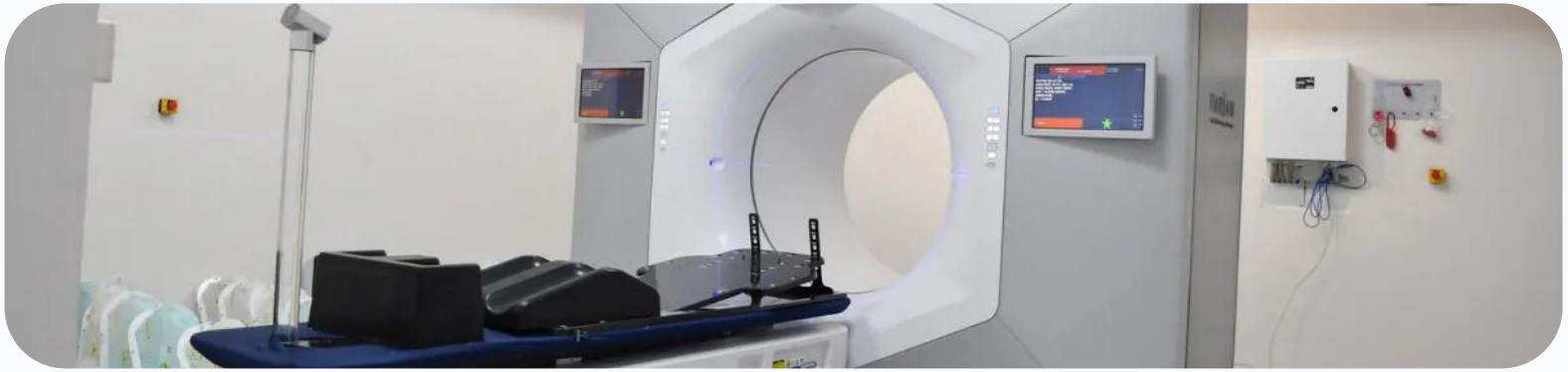
Pharmacists, pharmacies, and stakeholders must adhere to the updated Code of Ethics, implement digital systems for e-pharmacy operations, including secure data handling and patient verification, obtain accreditation for online platforms, discontinue non-approved training programs, and undergo regular inspections for regulatory compliance. Training personnel on digital tools and ethical standards is mandatory, with penalties for non-compliance including license suspension, fines, or legal action.

Strategic Opportunities

Adopting these reforms enables operational efficiencies through digitized inventory and supply chain management, expanded access to pharmaceutical services via e-pharmacy for remote areas, reduced counterfeit drugs via better regulation, enhanced collaboration with government and international partners, and positioning Nigerian pharmacies as leaders in African healthcare innovation, attracting investments and improving patient outcomes.[6]

Cancer Treatment Infrastructure

In 2025, significant progress was made in addressing Nigeria's radiotherapy capacity deficit. The NSIA-LUTH Cancer Treatment Centre in Lagos, operationalized through a public-private partnership between the Nigerian Sovereign Investment Authority and Lagos University Teaching Hospital, treated over 10,064 patients by 2024, providing 8,528 radiotherapy sessions, 6,733 chemotherapy treatments, and 215 high-dose rate 3D brachytherapy sessions. The center is equipped with Varian's Halcyon, a state-of-the-art cancer therapy system designed to enhance treatment accuracy while reducing electricity and water usage by 50%.



Additionally, facilities were commissioned or upgraded at National Hospital Abuja (NHA), University College Hospital Ibadan, and Federal Teaching Hospital Gombe, though Nigeria's overall radiotherapy capacity remains critically insufficient, with fewer than 10 functional machines serving a population exceeding 220 million.

Compliance Requirements

Healthcare providers and institutions must integrate new oncology standards, ensure staff complete mandated training programs, maintain equipment according to NSIA and ministry guidelines, report patient data to national registries, and comply with quality assurance protocols for diagnosis and treatment. Facilities are subject to inspections, with requirements for accreditation, ethical patient care, and alignment with the National Cancer Control Plan, facing penalties like funding cuts or operational restrictions for violations.

Strategic Opportunities

Investments in infrastructure open avenues for reduced healthcare costs through local treatment, economic retention by curbing outbound medical tourism, partnerships with international organizations for technology transfer, enhanced research and training to build a skilled workforce, and private-sector involvement via funds like the Cancer Intervention Fund, ultimately improving survival rates and positioning Nigeria as a regional hub for cancer care.[7]

Nuclear Medicine Policy Development

In 2025, Nigeria advanced the development of a national nuclear medicine policy to modernize healthcare delivery through advanced diagnostics and targeted therapies. Nuclear medicine applications, including PET scans, radioisotope therapies, and precision diagnostic imaging, require sophisticated regulatory oversight due to technical complexity and safety implications. The policy development process involves NAFDAC, the Nigeria Atomic Energy Commission, and the Federal Ministry of Health, establishing frameworks for licensing nuclear medicine facilities, managing radioactive materials, training specialized personnel, and ensuring patient safety protocols.

While still under development, the policy signals Nigeria's commitment to expanding diagnostic and therapeutic capabilities in oncology and other specialties.

Compliance Requirements

Stakeholders, including healthcare providers, must adhere to safety protocols for radioactive materials, obtain certifications for nuclear medicine operations, report incidents within specified timelines, train personnel through approved programs, and integrate data sharing with national health systems. Facilities require IAEA-aligned inspections, with penalties for non-compliance including fines, license revocation, or legal proceedings under national health policies.

Strategic Opportunities

The policy facilitates advanced diagnostics and treatments, reducing reliance on foreign care, fostering Pan-African collaborations for resource sharing, attracting investments in training and equipment, enhancing pharmacovigilance through better detection, and integrating with insurance schemes like the National Cancer Health Fund to protect patients financially, ultimately boosting Nigeria's healthcare sovereignty and research capabilities.[8]

Operationalization of Medipool

Approved in early 2025, Medipool moved into full operationalization in Q4 2025. Medipool functions as a Group Purchasing Organization (GPO) designed to aggregate demand from the Basic Health Care Provision Fund (BHCPF). By consolidating purchasing power, Medipool negotiates bulk procurement contracts for essential medicines and medical supplies, achieving significant cost reductions through economies of scale.

Stakeholder Impact

Local manufacturers now have predictable offtake mechanisms for essential medicines, reducing market uncertainty and enabling production planning. Public health centres benefit from lower, negotiated prices and improved supply reliability. However, manufacturers must meet stringent quality standards and delivery timelines specified in Medipool contracts. The "Nigeria First" procurement preference embedded in Medipool operations favours locally manufactured products, potentially disadvantaging importers unless foreign manufacturers establish local production facilities.[9]

Health Workforce Migration Policy

Formalized in late 2025, the Health Workforce Migration Policy addresses Nigeria's "brain drain" challenge through managed migration frameworks. The policy establishes ethical recruitment MoUs with destination countries (particularly the United Kingdom, United States, Canada, and Gulf states), introduces financial incentives and "return-to-practice" programs for health professionals deployed to underserved rural areas, creates bonding requirements for medical professionals benefiting from government-sponsored training, establishes a database tracking health worker migration patterns, and develops retention strategies including improved working conditions, competitive remuneration, and professional development opportunities.

Stakeholder Impact

The policy represents government acknowledgment that complete prevention of health worker emigration is unrealistic in a globalized labour market. Instead, the focus shifts to managed migration, ensuring Nigeria retains sufficient capacity while allowing controlled outflow. Healthcare facilities, particularly private sector providers, must adapt to potential workforce constraints by investing in retention programs, competitive compensation structures, and creating attractive work environments. Pharmaceutical companies relying on trained pharmacists and pharmacy technicians should similarly focus on retention strategies.[10]

US-Nigeria Technical Cooperation and Budget Commitments

The landmark Memorandum of Understanding signed in December 2025 secures **nearly $2 billion in United States grant funding for Nigeria's health sector** between 2026 and 2030. The funding targets HIV/AIDS programs, tuberculosis control, maternal and child health, malaria prevention, health system strengthening, and healthcare infrastructure development.

Nigeria's Regulatory Commitment

In exchange for US funding, Nigeria pledged to allocate at least 6% of its annual budget to health, representing a significant step toward the Abuja Declaration's 15% benchmark, though still falling short. The 2026 budget allocates N2.48 trillion (approximately 6% of the N58.47 trillion total budget) to health, up from N1.33 trillion in 2024 and N1.17 trillion in 2023.

While progress is evident, Nigeria continues to underperform compared to countries like Rwanda and South Africa, which have consistently met the 15% target. The phased budget increase approach aims to gradually approach the Abuja Declaration benchmark over the MoU's five-year period.[11]

Economic Impact and Stakeholder Benefits

01. Local Manufacturers

Local pharmaceutical manufacturers benefited from the 2024/25 Executive Order removing VAT and import tariffs on pharmaceutical raw materials and active pharmaceutical ingredients (APIs). Industry reports indicate this policy intervention reduced average production costs by approximately 12%, enhancing the competitiveness of locally manufactured products.[12] The government's target of achieving 70% local pharmaceutical production by 2030 creates opportunities for capacity expansion, technology transfer partnerships with Brazilian and Chinese manufacturers, and increased domestic market share.

02. International Investors

Nigeria's sustained ML3 status and progress toward ML4 significantly boost foreign direct investment confidence. MoUs signed with firms such as EMS Brazil for WHO-GMP compliant facilities ("Project Oaks") demonstrate international investor appetite. The regulatory credibility provided by the ML3 designation, combined with policy incentives for local manufacturing, creates an attractive investment environment for pharmaceutical manufacturing, distribution infrastructure, and healthcare service delivery.

03. Retailers and Pharmacists

Stricter enforcement of storage conditions, mandatory digital registration of premises, and transition to Coordinated Wholesale Centres require retail pharmacists to upgrade infrastructure and formalize operations. The E-Pharmacy Guidelines create opportunities for licensed digital platforms while imposing compliance obligations. Overall, these developments professionalize the retail pharmacy sector and reduce unfair competition from unlicensed operators.

04. Healthcare Providers and Patients

Improved access to cancer treatment facilities, traceability systems reducing counterfeit drugs, and increased local production capacity benefit healthcare providers and patients. However, market prices for essential medicines, including insulin and anti-hypertensives, remained volatile in Q3 2025 due to inflationary pressures, despite the Executive Order's cost reduction effects. The transition to the Nigerian Digital Health Initiative (NDHI) for electronic medical records creates efficiency gains but requires infrastructure investment from healthcare facilities.

Conclusion

The regulatory developments and legislative changes outlined in this Report reflect Nigeria's commitment to strengthening its health and pharmaceutical sector infrastructure, aligning with international best practices, and creating an enabling environment for investment and growth.

The sustained WHO ML3 status, progression toward ML4, gazetting of traceability regulations, and significant infrastructure investments signal a maturing regulatory ecosystem offering both opportunities and obligations for stakeholders.

Endnotes

1. *The Abuja Declaration was adopted by African Union member states in 2001, committing signatories to allocate at least 15% of their annual national budgets to the health sector. See African Union, "Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases" (2001).*

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8. https://tribuneonlineng.com/fg-experts-push-for-stricter-safety-in-medical-use-of-radioactive-substances/ <accessed on 26 January 2026>

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