ASSESSING NIGERIA'S EMERGING CAPACITY FOR LOCAL MANUFACTURING OF MALARIA COMMODITIES

ABSTRACT

Background: Nigeria's continued dependence on imported malaria commodities like Artemisinin-based Combination Therapies (ACTs), Active Pharmaceutical Ingredients (APIs), Long-Lasting Insecticidal Nets (LLINs), and Rapid Diagnostic Tests (RDTs) restricts the growth of local pharmaceutical manufacturing. Recent initiatives like Presidential Initiative for Unlocking the Healthcare Value Chain (PVAC) and National Malaria Elimination Programme (NMEP), have prioritized expanding this, but evidence on Nigeria's manufacturing potential remains scattered across multiple assessments, necessitating a consolidated cross-commodity analysis.

Methods: This study was based on a consultant-led readiness assessment conducted between 2024 and 2025 under the PVAC and NMEP programmes. The data were generated through nationwide facility audits, production-capacity evaluations, regulatory reviews, semi-structured interviews, and procurement and financing assessments across ACT, API, LLIN, and RDT manufacturers. Quantitative indicators such as installed capacity, utilisation rates, WHO PQ progression status, and financing conditions were analysed descriptively, while the findings were supported with desk review of policy briefs and technical review notes. The analysis was based on a framework developed that is triangulated across-commodities.

Findings: The assessment reveals that Nigeria has developed substantial domestic manufacturing capacity, including 16 ACT manufacturers with a combined installed capacity exceeding 60 million doses per month, and emerging RDT manufacturers with projected annual capacity of more than 470 million tests by 2026. LLIN manufacturers and petrochemical producers possess partial upstream readiness that aligns with Nigeria's LLIN Manufacturing Roadmap (2025–2028). However, capacity utilization remains low across sectors, averaging 25–50% due to fragmented procurement systems, donor preferences for imported WHO-prequalified commodities, lack of domestic PQ-enabling laboratory infrastructure, dependence on imported APIs and critical inputs, and limited access to affordable long-term financing. Despite NAFDAC's attainment of WHO GBT Maturity Level 3, manufacturers continue to face regulatory hurdles, particularly regarding WHO PQ pathways. Supply chain vulnerability, high working-capital costs, and inconsistent application of local-content policies further constrain scale-up.

Conclusion: Nigeria's health-commodity manufacturing ecosystems is well advanced, and has the potential to serve local need. However, the realization will require coordinated policy reforms, including multi-year procurement guarantees, blended-financing mechanisms, expanded regulatory and laboratory infrastructure, regional value-chain integration, and strengthened governance coherence.

Keywords: Nigeria; malaria commodities; local manufacturing; ACTs; RDTs; LLINs; APIs; health security; industrial policy; WHO prequalification; procurement reform; pharmaceutical manufacturing; Africa.

1.0 INTRODUCTION

Malaria remains a major global health challenge, with the WHO reporting 263 million cases and 597,000 deaths worldwide in 2023 (World Health Organization, 2024). The WHO further reveals that it is particularly concerning for WHO African Region, where approximately 95% of the deaths occurred. This

has made addressing the inequity in the global malaria response critical, especially in countries where they are endemic.

Nigeria remains a concern in the global efforts to control and eliminate the disease. Nigeria bears a disproportionate malaria burden, contributing an estimated 27% of global cases and 31% of malaria-related deaths (World Health Organization, 2023). This is worsened by the country's reliance on imports of malaria commodities like Artemisinin-based Combination Therapies (ACTs), Active Pharmaceutical Ingredients (APIs), Long-Lasting Insecticidal Nets (LLINs), and Rapid Diagnostic Test (RDT) kits to sustain national prevention and treatment programmes. Countries like India and China, where most medications are gotten have been fingered for substandard and falsified pharmaceutical products (Fatokun, 2016; Beargie, 2019). This often leaves its health system vulnerable to external shocks, including foreign exchange volatility, global supply chain disruptions, long procurement lead-times, and rising logistics costs (Federal Ministry of Health, 2024).

Furthermore, the COVID-19 pandemic reveals the implication of over-reliance on imports for essential health products, as that which can rapidly undermine national health security (Yadav et al., 2022). During this period, Nigeria and many other countries in Africa experienced severe shortages of medicines, diagnostics, and vector control products due to export restrictions from major manufacturing hubs such as India and China (UNIDO, 2021). These disruptions renewed global interest in building more geographically diversified and regionally distributed manufacturing ecosystems for essential health commodities (African Union, 2022; Tirivangani et al., 2021). Nigeria, as Africa's largest economy and the continent's largest malaria-endemic country, occupies a strategic position in this continental industrialization agenda.

In response, Nigeria has initiated wide-ranging reforms to localize pharmaceutical and health product manufacturing. Central to these reforms is the Presidential Initiative for Unlocking the Healthcare Value Chain (PVAC), a high-level coordination mechanism designed to harmonize industrial and health policy efforts and accelerate domestic production of essential medical commodities (Presidential Health Initiative, 2024). Complementary national frameworks, including the National Malaria Elimination Programme (NMEP), the Nigeria Industrial Revolution Plan (NIRP), the Pharmaceutical Manufacturing Transformation Agenda, and NAFDAC's newly strengthened regulatory infrastructure following its attainment of WHO Global Benchmarking Tool Maturity Level 3, have positioned the country to expand local manufacturing capacity (NAFDAC, 2022; Federal Ministry of Industry, Trade & Investment, 2023).

Addressing this ambition should begin with a robust assessment of Nigeria's cross-commodity malaria manufacturing capacity landscape for ACTs, APIs, LLINs and RDTs. Given Nigeria's strategic population size, petrochemical base, regulatory improvements, and current capacity across multiple malaria commodity sectors, the shift from import dependence to domestic resilience is both feasible and timely. Local manufacturing offers significant advantages: strengthening national health security, reducing foreign exchange exposure, creating industrial jobs, and positioning Nigeria as a regional manufacturing hub under frameworks such as the ECOWAS Medicines Regulatory Harmonization (MRH) and the African Continental Free Trade Area (AfCFTA) (ECOWAS, 2023; AfCFTA Secretariat, 2024).

This paper synthesises evidence from a national workstream assessment of manufacturing capacity, procurement systems, regulatory readiness, financing constraints, and localisation feasibility, alongside commodity-specific readiness data for ACTs, APIs, LLINs, and RDTs. Drawing on this integrated evidence, the paper addresses three central questions: 1) What is the current state of domestic manufacturing capacity for ACTs, APIs, LLINs, and RDTs? 2) What systemic constraints inhibit effective utilisation and scale-up of this capacity? 3) What policy, regulatory, and financing reforms are required to support Nigeria's transition from import dependence to domestic resilience?

2.0 METHODOLOGY

2.1. Study Design and area

This readiness assessment utilised a multisite cross-sectional descriptive design, drawing on facility audits, regulatory reviews, and institutional assessments conducted across Nigeria's major manufacturing hubs, with a focus on the national malaria-commodity manufacturing ecosystem in Nigeria, covering pharmaceutical (ACTs, APIs), diagnostic (RDTs), and vector-control (LLIN) product classes. The study design was guided by principles of evidence triangulation, policy analysis, and industrial manufacturing assessment, allowing the authors to consolidate findings from diverse yet complementary data sources into a coherent analytical framework.

The readiness assessment were conducted in states like Lagos, Ogun, Anambra, Oyo, Kano, and the Federal Capital Territory., This area were chosen because they are Nigeria's major pharmaceutical, diagnostic, and LLIN manufacturing sites. Thus, the study area is not a single geographic locality but the entire national health-industrial landscape, comprising domestic manufacturing plants, regulatory institutions, and procurement mechanisms relevant to the production and utilisation of malaria commodities in Nigeria.

2.2 Data Sources

This study drew upon a comprehensive set of nationally validated documents, technical assessments, and regulatory records produced between 2024 and 2025. The primary data sources consisted of data obtained across pharmaceutical, diagnostic, and vector control manufacturing facilities across Nigeria (see table 1). Together, these documents constitute the most extensive and contemporaneous evidence base on Nigeria's malaria commodity manufacturing ecosystem.

2.2.1 Technical Briefs: The technical briefs provided structured insights across multiple domains of malaria commodity manufacturing, including: ACTs, Feasibility and requirements for domestic API production, Market access and procurement challenges for locally manufactured commodities, Current status and potential for LLIN manufacturing in Nigeria, Regulatory readiness and WHO Prequalification pathways, Financing constraints and investment requirements and, RDT manufacturing capacity and quality systems. Each brief synthesized qualitative and quantitative information obtained through key informant interviews, facility audits, market diagnostics, and policy reviews conducted by technical specialists. They included validated statistics on current capacity, utilization rates, regulatory status, supply chain dependence, and identified challenges and opportunities for localization.

2.2.2 Readiness Assessment Report: The readiness assessment report provided granular, facility-level information on ACT manufacturing capacity. The report covered multiple manufacturers across Lagos, Ogun, Anambra, and other industrial clusters, and included: Installed machinery and production capacity, Current production volumes, Workforce competence and technical skills, Supply chain dependencies (APIs, excipients, packaging materials), Compliance with NAFDAC, WHO, and ISO standards, Progress toward WHO Prequalification, and Infrastructure constraints (power, water, HVAC systems). The consultant report also contained qualitative observations from site visits, semi-structured interviews with factory leadership, and validation of self-reported manufacturer data.

2.2.3 Regulatory and Policy Documents: Additional insights were drawn from supporting regulatory and policy documents, including but not limited to: NAFDAC Global Benchmarking Tool (GBT) reports, ISO 13485 certification records for diagnostic manufacturers, WHO PQ Technical Reports, National Malaria Strategic Plan, Federal Ministry of Industry, Trade and Investment (FMITI) industrial policies, ECOWAS Medicines Regulatory Harmonization (MRH) guidelines, Pharmaceutical Manufacturing Transformation Programme (PMTP). These sources were used to validate claims from the briefs and to ensure consistency in regulatory and policy interpretations.

2.2.4 Quantitative Indicators and Secondary Data: The documents provided quantitative indicators such as: Installed production capacity (monthly/annual), Utilization rates (%), National demand estimates for ACTs, LLINs, RDTs, Export potential assessments, Number of PQ-ready facilities, Financing costs and investment requirements, and Import dependency ratios. These indicators were extracted systematically and

entered an analytical matrix to facilitate cross-commodity comparison. The study relied on the validated quantitative metrics already contained in the official assessments.

2.3 Analytical Framework

The analysis was guided by a multi-dimensional health industrialization framework that integrates principles from health systems strengthening, pharmaceutical sector development, and market-shaping theory (see Table 2). This framework enabled a structured examination of Nigeria's evolving malaria-commodity manufacturing ecosystem across four interdependent domains: technical capacity, regulatory readiness, market access, and financing architecture. Synthesizing evidence across these domains made it possible to assess not only Nigeria's current manufacturing capabilities but also the systemic constraints limiting progress toward self-sufficiency.

2.3.1 Technical and Production Capacity Assessment: To evaluate manufacturing capacity, the study applied an adapted version of the WHO Local Production and Technology Transfer Framework, focusing on installed capacity, degree of automation, human resource competence, supply chain structure, and utilization rates. Key indicators extracted from the briefs and consultant report included: Installed monthly output vs. national demand, Machinery configuration and process flow integrity, API and excipient sourcing pathways, Workforce size, specialization, and training profiles, Storage, HVAC, and quality control infrastructure. This allowed a cross-commodity comparison of capacity maturity across ACTs, APIs, LLINs, RDTs, and related products.

2.3.2 Regulatory and Quality Assurance Analysis: Regulatory readiness was examined using the WHO Global Benchmarking Tool (GBT) maturity levels and NAFDAC's documented progress toward international equivalence. The framework assessed: GMP compliance status across manufacturers, Progress toward WHO Prequalification (PQ), ISO 13485 certification and diagnostic QA systems, National laboratory capacity for QC and bioequivalence testing, Regulatory bottlenecks (inspection delays, dossier gaps, PQ documentation burdens). This analysis established the extent to which Nigeria's regulatory oversight and facility-level QA systems align with global market entry requirements.

2.3.3 Market Access and Demand-Side Assessment: The study applied a market-shaping lens to evaluate procurement structures and demand predictability. Analytical dimensions included: Share of national malaria-commodity demand financed by donors, Exclusion of local manufacturers from Global Fund/UNICEF tenders due to PQ gaps, Government procurement cycles and contract reliability, Export potential within ECOWAS MRH and AfCFTA frameworks, Manufacturer experiences with market fragmentation and underutilization. This assessment clarified how procurement rules and market dynamics contribute to persistent idle capacity despite growing technical capability.

2.3.4 Financing and Investment Environment: An investment ecosystem analysis was conducted using principles adapted from blended-finance models in low- and middle-income countries. The review focused on: Cost of capital (commercial vs. concessional), Access to long-term financing for capital expenditure, Availability and uptake of government incentives, Forex constraints and import-dependence cost implications, Appetite of DFIs, donors, and private investors, Emerging pipeline for industrial parks and shared infrastructure. This dimension revealed structural financing weaknesses that limit Nigeria's ability to scale upstream manufacturing (APIs) and achieve WHO PQ for downstream products.

2.3.5 Cross-Domain Synthesis Approach: Finally, findings from all domains were synthesised using a triangulated matrix approach, aligning evidence across: Documented facility-level observations, National policy directives, Quantitative indicators, Stakeholder perspectives. This synthesis enabled a consolidated understanding of Nigeria's manufacturing landscape, highlighting key constraints, opportunities, and transition pathways toward domestic resilience.

3.0 FINDINGS

3.1 Manufacturing Capacity Across Key Malaria Commodities:

The assessment revealed that Nigeria has developed substantial but underutilized manufacturing capacity across the four major malaria commodity categories; Artemisinin-based Combination Therapies (ACTs), Active Pharmaceutical Ingredients (APIs), Long-Lasting Insecticidal Nets (LLINs), and Rapid Diagnostic Test kits (RDTs). Across all sectors, installed technical capacity is significantly higher than current utilization levels, largely due to structural market, regulatory, and financing constraints (see Table 3).

3.1.1 ACT Formulation and Finished-Dose Production: Nigeria hosts 16 licensed local ACT manufacturers, most of whom possess functional production lines for Artemether–Lumefantrine (AL) and other formulations such as DHA–PQP and ASAQ (see Figure 1). Installed national ACT capacity exceeds 1.2 billion doses annually, far higher than average annual national demand. However, utilization rates remain low between 40% and 60% across most facilities due to procurement uncertainty, donor preferences for WHO-prequalified imports, and high dependency on imported APIs. Several manufacturers operate WHO-aligned GMP systems, but none has yet achieved WHO Prequalification (PQ), limiting access to donor-financed tenders.

Characteristic	Licensed Manufacturers	Production Capacity	Utilization Rate	GMP Systems	WHO Prequalification
Description	16 local manufacturers	1.2 billion doses annually	40-60%	WHO-aligned	None

Figure 1: ACT production in Nigeria

3.1.2 Active Pharmaceutical Ingredient (API) Manufacturing Readiness: API production remains Nigeria's weakest point in the malaria commodity value chain. The assessment found no fully operational artemisinin-based API manufacturing plants, and reliance on imports from Asia remains nearly absolute (see Figure 2). Nonetheless, two manufacturers demonstrated partial readiness to begin pilot-scale synthesis of selected APIs, supported by existing chemical engineering infrastructure. The primary constraints include high capital expenditure, lack of guaranteed long-term offtake, unstable forex conditions, and absence of domestic suppliers for key intermediates. API gaps directly affect pricing, production timelines, and the competitiveness of locally produced ACTs.

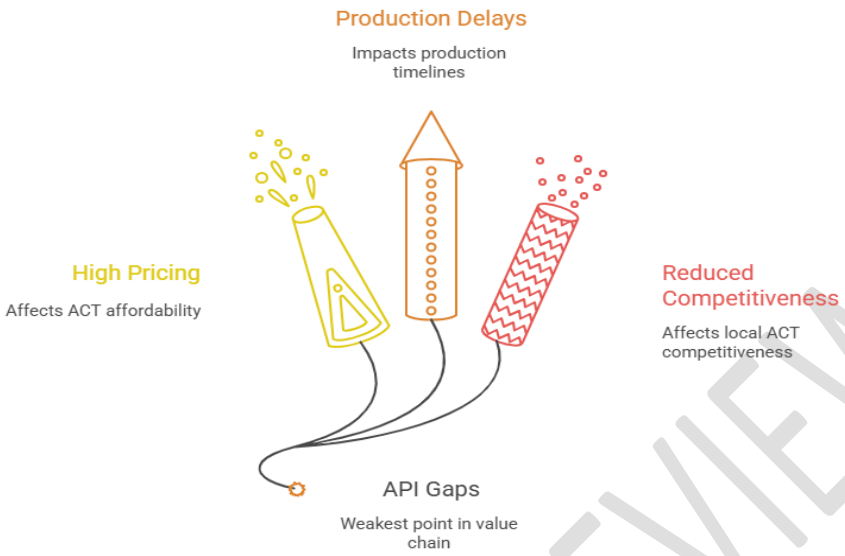

Figure 2: API gaps impact ACT production

3.1.3 LLIN Manufacturing Capacity: The assessment reveals that local LLIN manufacturing capacity is emerging, with several Nigerian textile and polymer-processing companies demonstrating technical readiness to enter the market (see Figure 3). Three companies possess partial infrastructure such as extrusion, knitting, or finishing lines that can be upgraded for full LLIN production. National LLIN demand is estimated at 30–40 million nets per year, but current domestic production is negligible, with nearly 100% of nets imported. The national roadmap proposes a phased transition from local assembly and packaging to full backward integration into polymer extrusion and insecticide coating between 2025 and 2028. Petrochemical giants such as Dangote and Indorama can supply polypropylene feedstock; however, specialized LLIN-grade polymers with specific UV and tensile-strength requirements are not yet manufactured locally. No Nigerian facility has achieved WHO PQ for LLINs, due primarily to limited access to accredited testing and entomology laboratories.

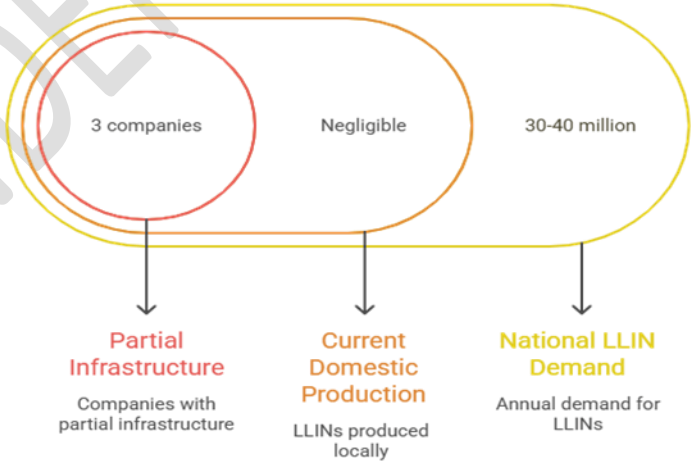

Figure 3: LLIN production capacity in Nigeria

3.1.4 RDT Manufacturing Capacity: RDT manufacturing shows the fastest growth trajectory among all commodity groups (see Figure 4). Seven companies expressed intent or readiness to manufacture malaria RDTs, with three facilities already completed or nearing completion. Combined installed capacity is projected to exceed 470 million test kits per year by 2026, surpassing Nigeria's domestic demand. Two manufacturers have obtained ISO 13485 certification, and at least one is advancing through the WHO Expert Review Panel for Diagnostics (ERPD). Several facilities now possess end-to-end lateral flow assay capabilities, including membrane cutting, antibody coating, strip assembly, desiccant integration, and packaging. However, key input membranes, antibodies, conjugates, nitrocellulose sheets remain entirely imported, introducing supply delays and cost vulnerability. Full WHO PQ has not yet been achieved by any Nigerian RDT producer, reflecting documentation burdens and the absence of accredited national reference laboratories.

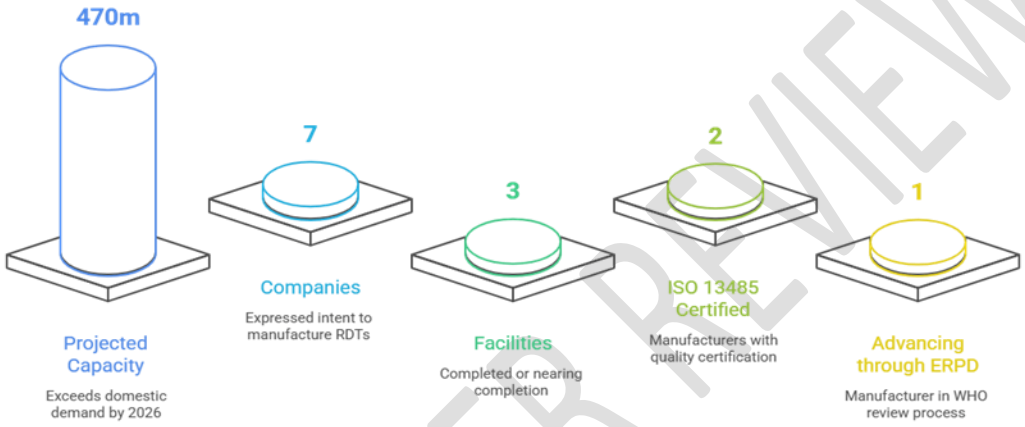

Figure 4: RDT manufacturing capacity in Nigeria

3.2 Market Access and Procurement Constraints

The analysis showed that market access remains the most significant barrier to the scale-up and sustained utilization of Nigeria's local manufacturing capacity for malaria commodities. Across ACTs, LLINs, RDTs, and APIs, procurement processes were found to be fragmented, unpredictable, and heavily skewed toward internationally prequalified imports, despite increasing domestic capacity (see Table 4).

3.2.1 Donor-Dominated Procurement Landscape: Donor-financed programs, including the Global Fund, the U.S. President's Malaria Initiative (PMI), UNICEF, and the World Bank, account for the majority of national procurement for ACTs, LLINs, and RDTs. Because donor procurement frameworks require WHO Prequalification (PQ), and no Nigerian manufacturer has yet achieved PQ for ACTs, LLINs, or RDTs, domestic producers are structurally excluded from the largest and most stable source of demand. As a result, installed capacity remains underused, even in companies that hold NAFDAC approvals, ISO 13485 certification, or GMP compliance.

3.2.2 Fragmented and Irregular Government Procurement: Federal and state procurement cycles were found to be highly irregular, lacking predictable timelines, harmonized specifications, or consolidated national tenders. State-level purchasing through Drug Management Agencies (DMAs) frequently relies on small-volume, short-term tenders that do not support efficient production planning. Delayed payments on fulfilled orders were also reported as a recurring barrier that limits manufacturers' working capital and inhibits scale-up.

3.2.3 Weak Local Content Enforcement: Although several policies reference preferences for locally manufactured health commodities, enforcement remains weak. None of the procurement entities evaluated had implemented clear local-content thresholds, procurement scoring incentives, or monitoring systems.

As a result, domestic manufacturers reported difficulty in competing with imported products, even when they meet required national regulatory standards.

3.2.4 Limited Market Visibility and Demand Forecasting: Manufacturers consistently reported poor visibility of upcoming tenders, donor pipeline plans, or national consumption forecasts. The absence of a centralized demand forecasting system made it difficult for companies to plan investments, secure raw materials, or schedule production. This information asymmetry further exacerbates excess capacity and hinders operational efficiency.

3.2.5 Barriers to Regional Market Entry: Although Nigeria is positioned to supply malaria commodities to ECOWAS countries, the assessment found that duplicative product registration requirements, lack of recognition of NAFDAC approvals, and limited export financing contribute to low regional penetration. Without WHO PQ, manufacturers remain ineligible for most regional pooled procurement mechanisms, limiting export opportunities despite having sizable installed capacity.

3.3 Regulatory Readiness and Quality Assurance Capacity

The assessment revealed substantial variation in regulatory compliance and quality assurance readiness across Nigeria's malaria commodity manufacturing ecosystem. Overall, it showed regulatory maturity at the national level has improved following NAFDAC's attainment of WHO Global Benchmarking Tool (GBT) Maturity Level 3; however, manufacturer-level compliance remains uneven, with only a minority meeting the requirements necessary for WHO Prequalification (PQ) or international donor procurement (see Table 5& 6).

3.3.1 Regulatory Certification Status Across Manufacturers: Across the commodity groups assessed, 94.1% of ACT manufacturers held valid NAFDAC Good Manufacturing Practice (GMP) certification, and all reported routine GMP inspections within the past 24 months (see Figure 5). In contrast, no facility across LLINs, RDTs, or APIs had achieved WHO PQ at the time of assessment. Only 2 RDT manufacturers and 2 LLIN manufacturers had initiated WHO PQ or Expert Review Panel (ERPD) processes, largely at the documentation review or pre-assessment stage.

ISO certification levels differ by commodity. Two RDT manufacturers had obtained ISO 13485:2016 certification, while most ACT producers possessed ISO 9001. No LLIN facility demonstrated full compliance with ISO 9001 or ISO 13485, and none of the assessed manufacturers met ICH Q7 standards required for API production.

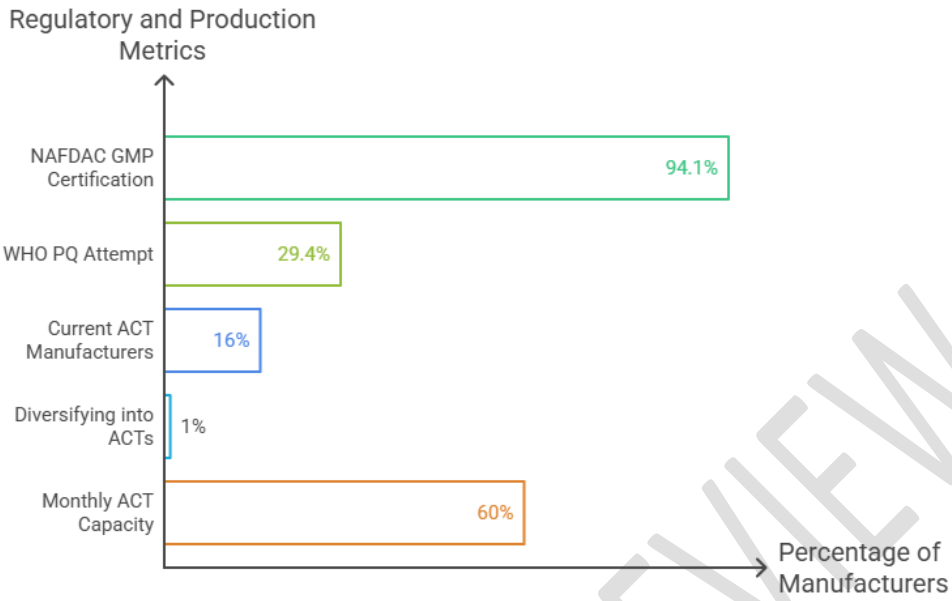

Figure 5: Regulatory readiness of ACT manufacturers

3.3.2 Quality Management Systems (QMS) and QA/QC Infrastructure: All assessed ACT manufacturers operated functional in-house QA/QC laboratories; however, fewer than 20% had internationally accredited testing capability. The majority relied on basic chemical analysis equipment such as HPLCs, dissolution testers, and disintegration units but lacked internationally accredited reference laboratories for method validation.

For RDTs, only two facilities had semi-automated QC lines and maintained adequate environmental controls. None possessed the capacity to conduct full lot-release validation—requiring external evaluation for sensitivity and specificity testing. LLIN manufacturers showed substantial QA gaps: no facility had an ISO-certified quality laboratory, and none could conduct polymer-strength tests, UV degradation analysis, or insecticide retention assays in line with WHO PQ requirements.

National QC infrastructure remains limited. Only one laboratory in Nigeria is WHO-prequalified, and no entomology laboratory meets WHO cone/tunnel testing standards required for LLIN PQ. This gap directly constrains manufacturers, who must outsource PQ-mandated tests to laboratories in East Africa, Europe, or Asia, raising costs and lengthening time-to-market by 6–18 months.

3.3.3 Technical Documentation and PQ Readiness: PQ readiness remains low across commodities. Only 29.4% of ACT firms had initiated PQ documentation within the last three years, while RDT and LLIN firms demonstrated early but incomplete progress. Approximately 80% of assessed companies reported "partial readiness" for CTD-compliant regulatory dossiers. Across all commodity types, firms consistently cited gaps in: stability studies, design history files (for RDTs), entomology and physical durability data (for LLINs), and validated analytical methods (for ACTs and APIs).

For LLINs, the absence of accredited domestic testing capability was the single largest barrier identified, preventing completion of bioefficacy and durability datasets required for PQ.

3.4 Financing and Investment Landscape

The financing environment for local manufacturing of malaria commodities in Nigeria is marked by structural weaknesses that significantly constrain firms' ability to expand production capacity, upgrade quality-management systems, pursue WHO Prequalification (PQ), or compete with established global suppliers (see Table 7). Despite strong national policy emphasis on industrialization and increasing political attention to the localization agenda, manufacturers across ACTs, APIs, LLINs, and RDTs consistently

report that access to affordable and appropriately structured financing remains one of the most critical determinants of competitiveness.

Across all commodity categories, most manufacturers rely predominantly on internal financing particularly retained earnings, personal capital, and incremental reinvestment from operations—rather than external long-term financing instruments. Commercial loans remain the most accessible external option, yet they are widely regarded as unsuitable for the capital-intensive nature of pharmaceutical, diagnostic, and vector-control manufacturing. Interest rates typically range from 18% to 25%, with repayment tenures often limited to two to three years. These conditions sharply contrast with the long investment horizons required for major plant upgrades, installation of automated production lines, or procurement of equipment needed for PQ-relevant quality-control functions. Manufacturers across the briefs emphasize that such credit terms effectively deter investment in modernization and scale-up, forcing firms into incremental, small-scale improvements rather than the transformative upgrades required for global competitiveness.

Although national development finance institutions such as the Bank of Industry (BOI) and the Development Bank of Nigeria (DBN) offer dedicated windows for manufacturing, their uptake remains uneven across commodity groups. ACT and RDT manufacturers appear to have comparatively better access to BOI facilities, though they still report lengthy approval processes, high collateral requirements, and limits in loan size relative to sectoral needs. For LLIN and API manufacturers, the structural mismatch between financing instruments and project requirements is far more pronounced. LLIN production requires substantial upfront investment in extrusion, weaving, and polymer-coating lines often exceeding USD 10–15 million for a single facility upgrade, while API manufacturing demands even larger capital investments for reactors, utilities, effluent-treatment systems, and GMP-grade analytical laboratories. None of the existing financing mechanisms are designed to support investments of this magnitude, and as a result, manufacturers rely heavily on incremental, self-funded investments that slow progress and maintain reliance on imported products.

The assessment further highlights a persistent gap between donor procurement practices and the financial needs of domestic manufacturers. Development partners remain the primary purchasers of malaria commodities in Nigeria especially LLINs, ACTs, and RDTs yet their procurement systems are almost exclusively open only to WHO-prequalified products. While donors do provide technical assistance for PQ preparation, such support rarely includes capital financing or direct investment in manufacturing infrastructure. This creates a structural paradox: local firms cannot access donor-funded markets without achieving PQ, but they cannot achieve PQ without the substantial financial investment that such donors do not provide. As the briefs repeatedly note, this financing trap entrenches import dependence and discourages large-scale investment in domestic manufacturing, even when firms possess the technical capability and infrastructural foundation to expand.

Fiscal incentives intended to stimulate local production exist on paper but are inconsistently implemented in practice. Manufacturers across all commodity groups report difficulty accessing exemptions on import duties for machinery, laboratory equipment, or raw materials. LLIN manufacturers, for instance, highlight inconsistencies in the application of duty waivers for specialized polymer and coating equipment, while ACT manufacturers face challenges accessing foreign exchange at stable rates, increasing the cost of imported APIs and excipients. API manufacturers encounter uncertainty around tax incentives for precursor chemicals, with some reporting double taxation on essential industrial inputs. These inconsistencies weaken investor confidence, create planning uncertainty, and undermine the intended role of fiscal policy as an enabler of industrial growth.

The overall financing landscape therefore presents a system in which manufacturers face high capital costs, limited access to long-term financing, insufficient alignment between financial instruments and industrial requirements, and limited pathways to participate in high-volume donor markets. These constraints collectively inhibit Nigeria's ability to convert its existing manufacturing potential into fully competitive, internationally recognized capacity. The evidence across the briefs and consultant report suggests that

without targeted financing particularly blended mechanisms combining concessional loans, guarantees, and performance-based grants, local manufacturers will continue to struggle to achieve PQ, expand output, or meaningfully substitute imports.

The comparative analysis across commodity groups reflects this variation in readiness. ACT manufacturers, though constrained by cost of capital, are better positioned to mobilize financing for incremental upgrades but remain unable to fund the major investments required for PQ. LLIN manufacturers face the steepest capital demands, particularly in the absence of local PQ-compliant testing laboratories. API manufacturers have the highest financing barriers of all, with their operations remaining far from PQ-readiness due to a combination of infrastructural gaps and limited financing options. RDT manufacturers demonstrate moderate levels of financial readiness, particularly in firms with ISO 13485 certification, but still face high costs associated with clinical validation studies and international laboratory testing.

Taken together, these findings indicate that the financing environment is both a symptom and a driver of Nigeria's limited participation in global health commodity markets. While manufacturers have demonstrated significant resilience and commitment through self-financing and incremental modernization, the systemic constraints within the financial ecosystem continue to limit the sector's ability to scale, compete, and achieve WHO prequalification. As such, financing remains one of the most decisive determinants of Nigeria's ability to transition from partial capacity to full participation in regional and global supply chains for malaria commodities.

3.5 Supply Chain and Input Dependency Patterns

The assessment revealed a consistent pattern of upstream supply chain fragility across all malaria commodities, driven primarily by heavy reliance on imported raw materials, limited domestic supplier ecosystems, and recurrent logistics bottlenecks (See Table 8). These weaknesses significantly affect production timelines, cost stability, product quality assurance, and manufacturers' overall capacity utilization.

3.5.1 Import Dependence Across All Commodities: Input dependence was highest for RDTs and APIs, where manufacturers reported that virtually 100% of critical inputs—membranes, nitrocellulose cards, antibodies, buffer reagents for RDTs; and chemical precursors, solvents, catalysts for APIs—must be imported from Asia or Europe. Lead times for these materials often exceeded 8–16 weeks, with delays exacerbated by customs clearance challenges.

ACT manufacturers were slightly less dependent than API facilities, as they procure finished APIs abroad but source some excipients locally. However, 70–90% of inputs for ACTs remain import-dependent, including APIs, capsules, blister foils, and packaging films. LLIN manufacturers exhibited partial domestic integration for polymer supply through local petrochemical companies, but even here, specialized polypropylene grades required for LLIN yarns (e.g., high-tenacity, UV-resistant variants) are not yet produced in Nigeria. This forces manufacturers to rely on imports for key resin types, stabilizers, and insecticides used in net impregnation.

3.5.2 Supply Chain Delays and Production Slowdowns: All manufacturers reported persistent customs delays, leading to extended input lead times and production stoppages. Several firms described clearance delays of 2–6 weeks, particularly for "sensitive" items such as biological reagents, APIs, and insecticides, which require additional documentation and inspections. These delays were consistently cited as one of the central reasons for underutilization of installed capacity, especially among ACT and RDT manufacturers.

LLIN manufacturers reported shipping delays and global freight volatility as contributors to stalled production during the 2022–2024 period. Many noted that losses from delayed inputs or cancelled production batches discouraged investment in scaling extrusion or coating lines.

3.5.3 Quality Assurance Dependencies: The lack of accredited domestic laboratories forces manufacturers to conduct essential quality and PQ-mandated tests abroad. For example: RDT lot-release

and sensitivity/specificity validation must be performed in foreign WHO-recognized labs, LLIN bioefficacy and durability (cone/tunnel tests, wash-resistance evaluations) must be outsourced to East African or Asian entomology labs, ACT manufacturers must send samples for bioequivalence or API impurity profiling to South Africa, India, or the EU.

These dependencies raise costs by 25–60%, extend regulatory timelines, and complicate inventory planning.

3.5.4 Domestic Supplier Gaps: Across all briefs and consultant assessments, a major supply-chain weakness identified was the near-absence of domestic suppliers for high-grade pharmaceutical excipients, diagnostic-grade reagents, and LLIN-specific polymer additives. Even basic packaging materials must meet international quality thresholds, which many Nigerian suppliers cannot consistently achieve. The result is an ecosystem where domestic manufacturers cannot rely on local sourcing even for seemingly simple components such as desiccants, aluminum foils, or reagent tubes.

Several manufacturers reported that inconsistencies in domestic packaging quality negatively affected PQ documentation efforts, as WHO PQ requires strict traceability of all input suppliers.

3.5.5 Interruption of Production Cycles and Capacity Utilization:

Due to the cumulative effect of supply chain delays, FX constraints, and input shortages, average capacity utilization across commodity groups remained low:

- ACTs: 40–60%
- RDTs: 25–45% for new entrants; up to 60% for semi-automated facilities
- LLINs: <40% for facilities operating only assembly or packaging lines
- APIs: No commercial production due to 100% dependency on imported intermediates

Manufacturers consistently linked underutilization to disrupted production cycles rather than insufficient technical capacity.

4. DISCUSSION

The study sets out to assess local manufacturing landscape for malaria commodities like ACTs, APIs, LLINs and RDT. The findings reveal a challenging but promising landscape for the local manufacturing of malaria commodities in Nigeria. The assessment shows that although progress has been made in regulatory maturity, installed production capacity, and emerging diagnostic and LLIN capabilities, systemic challenges in financing, market access, supply-chain stability, and quality assurance continue to limit Nigeria's ability to translate capacity into sustainable production. These findings mirror broader trends observed across Africa, where manufacturing potential has grown, but structural constraints have hindered competitiveness and global integration (Adebisi et al., 2022; Ekeigwe, 2019; Saied et al., 2022).

4.1 Nigeria's Manufacturing Landscape in Context

The results of this study suggests that Nigeria is well positioned for health-commodity manufacturing. Evidently, the assessment shows that across ACTs, APIs, LLINs, RDTs, and selected vaccine-adjacent components, Nigerian local manufacturers have high level of installed capacity, regulatory progress, and multi-commodity readiness that can compete with those of other regions. Unlike many African countries that possess only small-scale formulation plants or rely almost entirely on imports, Nigeria has developed a relatively diversified manufacturing base, supported by an active private sector and evolving regulatory oversight.

Our findings show that Nigeria hosts one of the continent's largest oral solid dosage (OSD) manufacturing clusters, with an installed ACT capacity exceeding 60 million doses per month under a single shift, enough to meet national annual requirements if fully utilized. This positions Nigeria ahead of several regional peers whose installed capacity remains far below domestic demand (UNIDO, 2020). Similarly, Nigeria's LLIN

manufacturing sector demonstrates a complete pathway—from polymer extrusion to weaving, insecticide treatment, and final stitching—an achievement only matched by a handful of African producers, such as Tanzania and Egypt (Gore & Makhaya, 2020). In RDTs, Nigeria has also made substantive progress, with multiple firms attaining ISO 13485 certification, placing them among the few African producers with credible international quality recognition.

Regulatory readiness further distinguishes Nigeria's landscape. NAFDAC's achievement of WHO Global Benchmarking Tool (GBT) Maturity Level 3, along with the successful WHO PQ of its central QC laboratory, represents a significant milestone not yet attained by most African national regulatory authorities (Ndomondo-Sigonda et al., 2017; WHO, 2021). This regulatory maturity expands Nigeria's potential to participate in regional harmonization efforts, including ECOWAS Medicines Regulatory Harmonization (MRH) and the future African Medicines Agency (AMA). These capabilities provide a unique foundation for Nigeria to serve as a regional regulatory and manufacturing hub, an aspiration echoed in national industrial and health policies.

However, the contextual strength of Nigeria's manufacturing landscape coexists with systemic structural challenges that constrain full utilization. Despite substantial installed capacity, utilization rates across malaria commodities remain low—often between 40% and 60% for ACT production, 30–50% for LLIN lines, and similarly depressed rates for RDT manufacturing. This pattern mirrors the continental paradox in which African manufacturers maintain capacity but operate below optimal output due to procurement fragmentation, donor preferences for imports, and limited domestic demand guarantees (AfDB, 2021; Makinde et al., 2022). The persistent exclusion of locally manufactured ACTs and RDTs from major donor procurement channels due to WHO PQ requirements underscores this challenge and reflects a broader regional trend documented across East and West Africa (Chinganya, 2020; UNCTAD, 2021).

A major contextual limitation is Nigeria's and Africa's heavy dependence on imported inputs. Our findings reveal that manufacturers rely on imports for APIs, excipients, polyester yarns, insecticides, nitrocellulose membranes, antibodies, conjugates, gold nanoparticles, and most QC consumables. This vulnerability aligns closely with regional assessments showing that over 95% of Africa's APIs and a majority of diagnostic and textile-chemical inputs are imported from India and China (UNIDO, 2020), creating systemic exposure to global price shocks, supply disruptions, and exchange-rate volatility. Such dependency structurally elevates production costs in Nigeria, making locally manufactured commodities appear more expensive compared with subsidised imports.

Financing constraints further situate Nigeria within continental patterns. Manufacturers consistently highlighted the burden of 18–25% interest rates, short loan tenures, and inconsistent access to industrial incentives. These findings echo the wider African literature, which identifies high capital costs and weak blended-finance ecosystems as key barriers to pharmaceutical industrialisation (Makinde et al., 2022; African Development Bank, 2021). Although Nigeria demonstrates stronger industrial potential than many regional peers, it faces similar bottlenecks in mobilising long-term, affordable capital.

Taken together, the Nigerian context resembles a hybrid model: the country possesses stronger capacity and more advanced regulation than most of sub-Saharan Africa, yet remains constrained by the same structural limitations, input dependence, financing barriers, certification gaps, and procurement dynamics that impede regional self-sufficiency. This duality positions Nigeria as both a regional leader and a country at a strategic crossroads: with targeted reforms, it has the potential to become West Africa's primary manufacturing and regulatory anchor; without such reforms, capacity gains will remain underutilized and fragile.

4.2 Interpretation in the Context of African and Global Evidence

4.2.1 Local Manufacturing in Sub-Saharan Africa - A Commonly Recognized Challenge: Our findings that Nigeria demonstrates significant installed capacity yet remains constrained by structural bottlenecks align with established evidence across Sub-Saharan Africa (SSA), where local pharmaceutical production

continues to lag despite decades of policy emphasis. Extensive reviews show that Africa produces only 3% of the medicines it consumes, importing nearly 97% of APIs and the majority of finished-dose formulations (UNIDO, 2020; WHO, 2022). The Nigerian case characterized by heavy dependence on imported APIs, LLIN inputs, diagnostic membranes, antibodies, and specialized polymers, therefore mirrors the wider continental reliance on global supply chains.

Across SSA, weaknesses in policy execution, financing mechanisms, input supply, and regulatory oversight have collectively undermined sustained industrial growth. Literature consistently documents that African manufacturers operate at 30–50% of installed capacity, largely due to irregular demand, limited long-term procurement, and financing barriers (McKinsey & Company, 2019; AUDA-NEPAD, 2021). Our finding that Nigeria's manufacturers operate at 40–60% capacity utilization, despite demonstrable technical capability, reinforces this regional pattern. The alignment between these figures suggests that Nigeria is not underperforming relative to peers; rather, it is contending with structural constraints that are systemic across the continent.

Financing challenges constitute a recurring theme in African manufacturing, with several studies noting that pharmaceutical firms in SSA face borrowing costs exceeding 15–25%, compared with 3–7% in South Asia (Akurugu et al., 2022; UNCTAD, 2021). This mirrors our observation that Nigerian firms rely heavily on high-interest commercial loans, which inhibits investment in WHO-prequalification (PQ) upgrades, quality-control systems, and workforce development. In countries such as Kenya, Ethiopia, and Tanzania, similar cost structures have restricted local firms from scaling to compete with global suppliers (Mackintosh et al., 2018). Nigeria's financing constraints therefore reflect well-documented regional dynamics that disproportionately disadvantage African producers in global tenders dominated by Indian and Chinese manufacturers.

The regulatory dimension further contextualizes Nigeria's position within SSA. Numerous studies show that weak regulatory systems have historically impeded African firms from entering donor-funded procurement channels that require stringent WHO PQ or ICH-compliant standards (Hill & Johnson, 2020; WHO, 2020). In this regard, Nigeria stands out: the achievement of WHO Global Benchmarking Tool Maturity Level 3 by NAFDAC positions it among a small number of African regulators—including Tanzania, Ghana, and Egypt—that have achieved this milestone. This confers strategic advantages by improving regulatory credibility, reducing approval timelines, and enhancing investor confidence. In many SSA settings, lack of regulatory maturity has been identified as a primary barrier to PQ readiness; Nigeria's progress therefore places it ahead of many regional peers.

Another unique aspect of the Nigerian landscape, compared with most SSA countries, is its expanding multi-commodity manufacturing base. While many African manufacturers specialize in only one product category—such as LLINs in Tanzania or RDTs in South Africa—Nigeria demonstrates simultaneous capacity across ACTs, RDTs, LLINs, and prospective API production. Comparative analyses show that diversified portfolios confer resilience, enabling firms to withstand procurement shocks and reduce dependence on a single donor-driven market (UNIDO, 2020; PAVM, 2021). The breadth of Nigeria's manufacturing ecosystem therefore represents a competitive advantage relative to the narrower industrial profiles of most West African nations.

However, despite these comparative strengths, Nigeria still faces structural challenges similar to those in other SSA contexts. These include input dependence, energy costs, fragmented procurement, and a limited domestic research-and-development (R&D) ecosystem. Research across East and West Africa shows that technological dependence on Indian and Chinese suppliers particularly for APIs, reagents, and excipients, remains a central bottleneck preventing full industrial self-reliance (Mackintosh et al., 2018). Nigeria's reliance on imported antibodies for RDTs and specialized polymers for LLINs directly reflects this wider technological gap. Without domestic input industries, local manufacturers remain vulnerable to global supply disruptions, exchange-rate fluctuations, and long logistics cycles, as seen during COVID-19 (OECD, 2021).

In sum, the Nigerian experience fits squarely within established regional patterns: strong political ambition, modest industrial progress, but persistent structural constraints. Where Nigeria appears differentiated is in its regulatory maturity, industrial density, and multisectoral potential, which collectively create a platform for accelerated growth. If Nigeria effectively addresses financing, procurement, and regulatory bottlenecks, it may emerge not merely comparable to its peers, but potentially a regional manufacturing anchor, a role supported by its scale, petrochemical feedstock base, and cross-commodity industrial footprint.

These insights highlight that Nigeria's local manufacturing trajectory is consistent with continental challenges, yet distinguishable by unique comparative advantages that, if harnessed, could enable the country to break out of Africa's long-standing dependence on imported health commodities.

4.2.2 Fragmented Procurement Systems and Persistent Market Access Barriers: The persistent market access barriers identified in our findings, particularly irregular procurement cycles, donor-driven market dominance, and limited recognition of national regulatory certifications, mirror long-standing challenges documented in the health systems and industrialization literature across Sub-Saharan Africa (SSA). Numerous studies highlight that the procurement environment in SSA is structurally fragmented, with parallel systems operating at federal, subnational, and partner levels, often without harmonized specifications or aligned planning cycles (Yadav et al., 2021; USAID, 2020). Our finding that Nigerian manufacturers face unpredictable procurement volumes, delayed payments, and limited access to donor-funded tenders is therefore consistent with broader evidence showing that African manufacturers rarely benefit from pooled or coordinated demand structures, even when domestic technical capacity exists.

Donor-financed procurement plays an outsized role in shaping market access in SSA, accounting for **60–80%** of malaria commodity purchases in many countries (Global Fund, 2022; PMI, 2023). This dynamic was evident in our results, where Nigerian firms despite ISO certification, GMP compliance, and in some cases WHO PQ progress, remain excluded from donor procurement channels that rely almost exclusively on globally prequalified suppliers. This reflects a well-established pattern across the continent: even when African manufacturers improve quality systems, the absence of WHO PQ becomes a near-absolute barrier to market participation (Kamunyori et al., 2021). Peer countries such as Kenya, Tanzania, Ethiopia, and Rwanda have documented similar constraints, where local manufacturers operate below 50% capacity because the largest and most predictable buyers—donor programs—procure almost entirely from Asia (Mackintosh et al., 2018; UNIDO, 2020).

Comparative analyses show that fragmented procurement not only undermines manufacturing utilization but also affects sustainability, competitiveness, and investment attractiveness. Evidence from East Africa demonstrates that firms hesitate to invest in PQ upgrades or new production lines without guaranteed offtake agreements lasting **3–5 years**, as required by banks providing long-term capital (AUDA-NEPAD, 2021). In Nigeria, our findings are consistent with this trend: most manufacturers report that without predictable market assurances, investment in PQ, automation, and backward integration is financially unjustifiable. This mirrors observations from Ghana and Zambia, where national procurement unpredictability and lack of multiyear contracting have directly contributed to stalled manufacturing projects in pharmaceuticals and diagnostics (UNCTAD, 2021).

Additionally, Nigeria's experience with market fragmentation is not unique; procurement decentralization across African health systems often results in inconsistent product specifications, multiple procurement authorities, and limited coordination across federal, state, and partner-driven mechanisms. Studies show that more than 30 African countries maintain multiple procurement channels for essential health commodities, leading to inefficiencies, higher prices, and unreliable supplier relationships (USAID, 2020; WHO, 2021). Nigeria's procurement ecosystem—split among the National Malaria Elimination Programme (NMEP), State Drug Management Agencies, the National Primary Health Care Development Agency (NPHCDA), and numerous donor agencies reflects this continental pattern. The result is predictable: manufacturers face a disjointed market with unclear timelines, low procurement transparency, and inconsistent demand signals.

The literature further reinforces that the procurement challenge is not merely logistical but structural. Donor reliance on WHO PQ, while essential for safeguarding quality, inadvertently reproduces global market asymmetries that disadvantage emerging manufacturers in low- and middle-income countries (LMICs). Multiple studies document that African manufacturers face significantly higher barriers to achieving PQ than their Asian counterparts due to financing limitations, documentation complexity, and the cost of maintaining PQ compliance (Waning & Diedrichsen, 2010; Hill & Johnson, 2020). Our findings showing that only a minority of Nigerian manufacturers have attempted PQ in the last three years align with these challenges.

However, Nigeria's positioning within the regional procurement landscape also reveals notable strengths. The country possesses one of the largest domestic health commodity markets in Africa, extensive manufacturing clusters, and advanced regulatory maturity. These attributes align with global evidence suggesting that large, unified national markets are critical for industrial takeoff (UNCTAD, 2021; McKinsey, 2019). If Nigeria were to consolidate its procurement systems, harmonize specifications across agencies, and implement multi-year framework contracts linked to verifiable quality benchmarks, it could generate the scale and predictability needed to unlock domestic investment and improve capacity utilization. Evidence from South Africa's ARV tendering reforms demonstrates that such procurement consolidation can reduce costs by up to 50% while strengthening local participation (Mackintosh et al., 2018).

Taken together, the literature indicates that Nigeria's procurement-related challenges are part of a wider continental pattern characterized by fragmented demand, donor dominance, and weak policy execution. Yet Nigeria's size, manufacturing density, and regulatory advancements provide a unique opportunity to transition from a fragmented to a structured procurement ecosystem, an approach which global evidence shows is essential for catalyzing local manufacturing competitiveness in LMICs. Aligning procurement systems with industrial policy goals, as our findings suggest, will be crucial for translating Nigeria's growing technical capacity into sustained market access, improved utilization, and long-term industrial resilience.

4.2.3 Quality Assurance, PQ Constraints, and Regulatory Gaps: The regulatory and quality assurance patterns observed in our findings—particularly the limited progress toward WHO Prequalification (PQ), the reliance on ISO and national GMP certifications, and the persistent documentation and systems gaps—are consistent with well-documented constraints across African pharmaceutical and diagnostics manufacturing. Numerous studies affirm that regulatory readiness in Sub-Saharan Africa remains uneven, and while national improvements have accelerated in recent years, most manufacturers still face significant structural challenges in meeting global PQ standards (WHO, 2020; Ndomondo-Sigonda et al., 2017). Our findings that only a small subset of Nigerian firms are actively pursuing PQ status, despite notable advancements by NAFDAC, align strongly with this continental trend.

Evidence shows that the barriers to achieving WHO PQ extend beyond technical compliance; they encompass systemic challenges such as high upgrade costs, gaps in quality management systems (QMS), weak documentation culture, and insufficient internal audits (Oladepo et al., 2021). Studies from Kenya, Tanzania, and Ethiopia reveal that PQ implementation frequently requires multi-million-dollar investments in facility redesign, HVAC systems, clean-room retrofitting, and analytical laboratory upgrades, investments that are often unattainable for manufacturers operating at low margins and under 50% capacity (Mackintosh et al., 2018; UNIDO, 2020). Nigeria's manufacturers facing high domestic energy costs, imported input dependence, and high-interest loans therefore encounter the same prohibitive investment barriers identified in other African contexts.

The literature further emphasizes that PQ is a demanding, documentation-intensive process requiring consistent batch data, validated analytical methods, full stability profiles, and internationally harmonized quality systems (WHO, 2021). Our findings that Nigerian manufacturers struggle with documentation rigor, data traceability, and audit readiness mirror challenges described in multiple LMIC studies. For instance,

research in East African Community (EAC) countries shows that even well-established firms often fail PQ audits due to incomplete batch documentation, inadequate change-control procedures, and insufficient quality-risk-management frameworks (Ndomondo-Sigonda et al., 2017). Nigeria's manufacturers appear to be navigating similar hurdles, suggesting that quality assurance gaps are not a reflection of technical incapacity but rather systemic limitations in QMS maturity and human-resource depth.

Regional evidence also highlights the absence of functional, internationally accredited public laboratories as a binding constraint for Africa's PQ prospects. Several studies note that the scarcity of ISO/IEC 17025–accredited laboratories capable of performing required confirmatory testing delays PQ submissions and increases reliance on costly overseas testing services (UNCTAD, 2021; AUDA-NEPAD, 2021). Our findings that Nigeria lacks adequate GLP-compliant or accredited reference laboratories for malaria APIs, RDT components, and LLIN polymer testing align precisely with this pattern. Countries such as Ethiopia and Tanzania have similarly documented laboratory bottlenecks as primary barriers preventing local firms from generating the analytical evidence required for PQ dossiers (Mackintosh et al., 2018).

Furthermore, donor procurement policies that require WHO PQ create an inherent structural disadvantage for African manufacturers at early stages of regulatory maturity. Studies show that more than 90% of PQ-approved suppliers for malaria commodities are located in India and China (Global Fund, 2022; Waning & Diedrichsen, 2010). This geographical concentration of PQ suppliers reflects decades of targeted industrial policies, export incentives, and state-backed financing in Asia—conditions that remain limited across African markets. Our findings highlight that Nigerian firms, despite NAFDAC's WHO Maturity Level 3 status, still face systemic disadvantages in accessing donor markets. This aligns with research showing that African manufacturers often demonstrate high technical competence but remain structurally excluded from global tenders due to the lack of PQ (Kamunyori et al., 2021).

Despite these challenges, Nigeria's regulatory landscape exhibits notable strengths relative to many African peers. The achievement of WHO GBT Maturity Level 3 positions NAFDAC among the most advanced regulators on the continent, alongside Tanzania, Ghana, and Egypt. Literature indicates that ML3 attainment accelerates dossier review timelines, improves regulatory predictability, and enhances industry confidence (WHO, 2020; Hill & Johnson, 2020). Nigeria's growing ecosystem of ISO-certified firms, combined with NAFDAC's regulatory enhancements, therefore represents a solid foundation for future PQ progress.

Several studies also suggest that countries with strong regulatory institutions experience more rapid industrial upgrading and greater traction in global markets (UNIDO, 2020; McKinsey, 2019). In this context, Nigeria's progress in GMP inspections, post-market surveillance, and digitalized regulatory processes may translate into competitive advantages over other West African countries where regulatory reforms remain slower. The presence of multiple firms producing ACTs, RDTs, and LLINs under structured QMS further indicates that Nigeria is closer to the PQ threshold than many SSA peers.

The alignment between our findings and global evidence underscores that Nigeria's PQ and regulatory gaps reflect broader continental constraints but are occurring within a context of meaningful national progress. While the systemic challenges such as high upgrade costs, documentation weaknesses, limited accredited labs, and restrictive donor requirements are widely recognized across Africa, Nigeria's more advanced regulatory status and strong manufacturing base provide a unique opportunity for accelerated progress. If the identified regulatory bottlenecks are addressed through targeted technical assistance, laboratory strengthening, and strategic financing, Nigeria could feasibly emerge as one of the first West African nations to achieve multi-commodity PQ at scale.

4.3 Implications for Policy and Practice

The findings of this study present clear implications for Nigeria's industrialization strategy, health security agenda, and broader policy frameworks aimed at fostering sustainable local manufacturing. The results demonstrate that while Nigeria possesses one of the most advanced health-commodity manufacturing ecosystems in sub-Saharan Africa, several structural and systemic constraints continue to limit output, deter

investment, and weaken competitiveness. Addressing these challenges requires targeted, sequenced, and multi-sectoral policy action that integrates industrial policy, procurement reform, regulatory strengthening, and supply chain transformation.

4.3.1 Strengthening Procurement and Market-Shaping Mechanisms: Perhaps the strongest implication from this study is the need to institutionalize predictable and transparent procurement systems that guarantee minimum offtake for local manufacturers. Our findings show that utilization rates across ACTs, LLINs, and RDTs remain far below installed capacity, largely because public procurement cycles are inconsistent, donor preferences favour prequalified imports, and national demand is fragmented across federal, state, and donor-led channels. This mirrors global evidence indicating that weak and unpredictable demand is one of the most significant barriers to African pharmaceutical industrialization (UNCTAD, 2021; Makinde et al., 2022).

Nigeria's policy environment must therefore transition from short-term, transactional purchasing to multi-year framework agreements with guaranteed minimum offtake volumes. These agreements should include clear, tiered eligibility pathways beginning with NAFDAC- or ISO-certified products, progressing to ERPD-listed products, and culminating in WHO-prequalified commodities eligible for donor financing. Joint procurement compacts between the Federal Government and major donors are essential to aligning market incentives with local-manufacturing goals. Such market-shaping instruments have been successful in other contexts such as vaccines and diagnostics procurement in East Africa and should be adapted to Nigeria's malaria-commodity ecosystem.

4.3.2 Expanding Regulatory and Quality-Assurance Infrastructure: Although Nigeria has made remarkable progress particularly with NAFDAC achieving WHO GBT Maturity Level 3, our findings show that regulatory pathways remain a bottleneck. Most domestic manufacturers still depend on external laboratories for bioefficacy, stability, and entomology testing, slowing WHO PQ readiness and increasing production costs. The implication is clear: Nigeria must expand its national regulatory and quality-assurance infrastructure, including accredited entomology labs for LLIN testing, diagnostic reference labs for RDT validation, and bioequivalence centres for pharmaceuticals. Strengthening this ecosystem will reduce reliance on foreign testing, shorten PQ timelines, and increase local manufacturers' competitiveness outcomes consistently highlighted in global analyses of African regulatory systems (Ndomondo-Sigonda et al., 2017; WHO, 2021).

4.3.3 Developing a Coherent Industrial Financing Architecture: The study's financing findings show that access to affordable long-term capital remains one of the most significant constraints. Manufacturers face interest rates between 18–25%, high collateral requirements, and inconsistent implementation of existing fiscal incentives. These constraints replicate regional financing challenges documented across African pharmaceutical markets (African Development Bank, 2021; Makinde et al., 2022). Nigeria needs an integrated financing framework consisting of: blended-finance facilities (grants + concessional loans) for scale-up and PQ-readiness, working capital windows dedicated to local health-commodity manufacturers, guaranteed buyer-backed financing instruments tied to multi-year procurement and tax relief and duty waivers for imported inputs essential for LLIN, RDT, and ACT production. A coordinated financing policy jointly supported by BOI, NEXIM, development banks, and donor partners would significantly strengthen Nigeria's ability to attract sustained private investment and accelerate industrial maturation.

4.3.4 Mitigating Input Dependency through Regional Value Chain Integration: Our analysis highlights a central systemic risk: almost all inputs for ACTs, LLINs, and RDTs remain imported. This includes APIs, insecticides, membranes, antibodies, conjugates, nitrocellulose, excipients, and most QC consumables. Such dependence exposes Nigeria to global supply-chain shocks and escalates production costs. The implication for policy is the need to strategically integrate Nigeria into regional and continental value chains, including ECOWAS MRH, AfCFTA, and the African CDC's PAVM initiative. Critical steps include: promoting joint ventures for local/regional production of nitrocellulose, antibodies, and polymer

yarns, supporting petrochemical manufacturers (e.g., Dangote, Indorama) to develop LLIN-grade polypropylene, attracting reagent manufacturers into designated free trade zones through fiscal incentives, and leveraging AfCFTA rules of origin to expand export opportunities for PQ-ready products. Such strategies mirror successful regional industrialization models in East Africa and Asia.

4.3.5 Enhancing Institutional Coordination and Governance: The study emphasizes governance fragmentation as a cross-cutting constraint. Multiple agencies including, NMEP, NAFDAC, SON, NPSCMP, BOI, FMITI, FMoH interact with manufacturers, yet coordination remains weak. International evidence shows that countries that succeed in pharmaceutical industrialisation (e.g., India, Bangladesh, South Korea) typically centralise governance through a single coordinating body (UNIDO, 2020). Nigeria must therefore institutionalise a National Coordination Platform on Local Manufacturing, with quarterly government–donor–industry engagements responsible for tracking: Local-content compliance, PQ progress, procurement performance, financing access, and capacity utilisation across commodity groups. This body should have clear authority to resolve bottlenecks and align incentives across government and external partners.

6. CONCLUSION

Nigeria stands at a defining juncture in its pursuit of health security and industrial self-reliance. This study has demonstrated that the country possesses one of the most advanced and diversified health-commodity manufacturing ecosystems in sub-Saharan Africa, with significant installed capacity across ACTs, LLINs, RDTs, APIs, and related commodity groups. The progress observed in regulatory strengthening particularly NAFDAC's attainment of WHO Maturity Level 3 and the expanding ISO 13485 footprint among manufacturers further distinguishes Nigeria from many regional peers and creates a strong foundation for deeper industrialization. These domestic strengths provide real opportunities for Nigeria to transition from its current import-dependent system to a more resilient, self-sustaining, and regionally competitive manufacturing hub.

Yet, the study also highlights persistent systemic constraints that undermine the realization of this potential. Capacity across all commodity groups remains significantly underutilized due to fragmented procurement systems, unpredictable demand, donor preferences for imported PQ-certified products, and the absence of long-term framework contracts. Likewise, heavy dependence on imported inputs ranging from APIs and insecticides to membranes and antibodies creates structural vulnerabilities that elevate production costs and expose manufacturers to global supply-chain shocks. Regulatory bottlenecks, including limited domestic testing infrastructure for PQ validation, further delay market entry and restrict access to donor-funded procurement channels.

These findings highlight the need for coordinated, multi-sectoral reforms that directly address Nigeria's structural barriers. Achieving sustainable industrial growth will require strengthening procurement governance, institutionalizing multi-year offtake agreements, expanding domestic laboratory and regulatory infrastructure, deploying blended-finance mechanisms, and reducing input dependence through targeted regional value-chain development. Importantly, Nigeria's emerging capacity aligns with continental aspirations under the African Union's Pharmaceutical Manufacturing Plan for Africa, signaling opportunities for regional market integration and export readiness once PQ milestones are achieved.

Ultimately, this study reinforces that Nigeria's transition toward domestic manufacturing resilience is both feasible and urgent. With well-coordinated policy action, Nigeria can reposition itself as a regional manufacturing leader, enhance national preparedness against global supply disruptions, reduce long-term procurement costs, and generate high-value employment. The path forward requires deliberate and sustained commitment, but the evidence presented here demonstrates that the foundation for transformation

already exists and that Nigeria is uniquely positioned to lead West Africa toward greater pharmaceutical and health-commodity self-sufficiency.

5. LIMITATION

This study has limitations. First, some of the data obtanined were self-reported which are subject to bias. For example, the capacity utilization figures are manufacturer-reported and were not independently verified through production records. Second, the study does not include cost-competitiveness analysis or detailed price comparisons with imported products. Fourth, while we assess financing constraints qualitatively, we did not conduct formal financial modeling of investment requirements. Finally, the study focuses on technical and systemic constraints but does not deeply examine political economic factors or stakeholder incentive structures that may influence implementation of recommended reforms.

Ethical Approval Statement: Ethical approval was not required for this study as it relied exclusively on secondary data from institutional capacity assessments, manufacturer audits, and policy documents, and did not involve human participants or the collection of personal or sensitive data.

Availability of Data and Materials: All data used in this study were obtained from national technical briefs and a consultant assessment conducted under the PVAC–NMEP–World Bank IMPACT Project. These materials are not publicly archived but may be made available upon reasonable request to the National Malaria Elimination Programme (NMEP) and the Presidential Initiative for Unlocking the Healthcare Value Chain (PVAC).

COMPETING INTERESTS DISCLAIMER:

Authors have declared that they have no known competing financial interests OR non-financial interests OR personal relationships that could have appeared to influence the work reported in this paper.

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Table 1: Detailed Description of Data Sources Used in the Study

Data Source	Type of Data	Specific Variables / Elements Extracted	Usefulness / Rationale for Inclusion	How It Was Used in the Analysis
Brief 1 – ACT Manufacturing Capacity Assessment	Mixed (Quantitative + Qualitative)	Installed ACT capacity; utilization rates; manufacturer distribution; GMP status; PQ progress; API sourcing; ACT formulations (AL, DHA-PQP, ASAQ)	Provides core evidence on Nigeria's ACT manufacturing technical capability and bottlenecks	Used to evaluate Domain 1 (Technical Capacity) & Domain 2 (Regulatory Readiness)
Brief 2 – API Manufacturing Assessment	Qualitative + Technical Landscape	Existing API capacity; infrastructure gaps; cost-of-production drivers; workforce readiness; policy environment; financing gaps	API data is central to upstream manufacturing analysis; shows Nigeria's dependence on imported APIs	Used for supply chain dependency analysis; informs financing and policy constraints
Brief 3 – Financing Landscape for Health Manufacturing	Financial + Policy	Lending rates; loan tenures; FX exposure; incentive uptake; capital expenditure estimates; donor-procurement financing dynamics	Shows core financing constraints that undermine PQ upgrades and expansion	Used to build the Financing Architecture section of analytical framework

Brief 4 – LLIN Manufacturing Assessment	Technical + Market	Local LLIN capacity; yarn sourcing; weaving & finishing capacity; PQ pathway challenges; textile-testing constraints	Adds cross-commodity comparison with vector control products	Used in cross-domain synthesis of local manufacturing maturity
Brief 5 – Regulatory & PQ Pathways	Regulatory	NAFDAC ML3 maturity; PQ documentation burden; ISO 13485 compliance; QC lab gaps	Clarifies readiness for access to donor-funded markets	Used for the Regulatory Readiness matrix
Brief 6 – Market Access & Procurement Assessment	Market + Procurement Data	Government procurement cycles; donor market share; local vs. import preferences; demand stability; payment delays	Explains underutilisation and demand unpredictability	Used to evaluate market-shaping constraints and build results on idle capacity
Brief 7 – RDT Manufacturing Assessment	Technical + QA/QC	RDT production lines; ISO 13485 status; material sourcing; lab-testing capacity; regulatory bottlenecks	Helps compare diagnostics sector to pharma and vector control	Used for cross-sector maturity comparison in Results
Readiness Assessment Report	High-resolution Quantitative + Qualitative	Facility-level installed capacity; equipment inventory; automation; workforce profiles; HVAC/utility status; supply chain details; QC systems; GMP alignment; challenges	Most granular source; validates self-reported data; provides real-world facility insight	Used for triangulation & robust validation of Brief 1; strengthens technical and regulatory findings
NAFDAC Global Benchmarking Tool (GBT) Reports	Regulatory Scoring	Agency maturity level; regulatory functions; inspection timelines; dossier evaluation capacity; PQ-support readiness	Shows regulatory environment strength and gaps	Used to assess national readiness for PQ scale-up
WHO PQ Technical Reports	Regulatory	PQ requirements; documentation gaps; timelines; pre-submission checks	Provides standard against which Nigerian facilities were assessed	Used to define PQ readiness indicators

ISO 13485 Certification Records (Diagnostics)	Compliance Records	Certification dates; audit outcomes; scope of certification	Ensures objectivity when assessing RDT QA systems	Used to verify claims in Brief 7
FMITI Industrialization Policies (NIRP, PMTP)	Policy Documents	Local-content mandates; tax incentives; duty waivers; industrial park plans; sector priorities	Shows policy intent and execution gaps	Used to support policy analysis domain
ECOWAS MRH & AfCFTA Export Guidelines	Regional Trade + Regulatory	Regional certification harmonization; export pathways; documentary requirements	Adds export dimension to market access assessment	Used in export readiness analysis
NMEP National Demand Data	Quantitative	Annual malaria commodity demand; consumption forecasts; gap analysis	Provides denominator for utilization calculations	Used to compare installed capacity vs. national demand
BOI, DBN & DFI Financing Instruments	Financial	Eligible financing instruments; interest rates; loan tenures; credit guarantees	Provides realistic financing environment	Used in financing gap analysis
Manufacturer Self-Assessment Questionnaires	Primary Self-Reported Data	Technical equipment; staffing; QA systems; PQ interest; operational bottlenecks	Complements consultant report and adds self-perception data	Used to triangulate findings from site visits
Stakeholder Interviews	Qualitative	Policy alignment; regulatory constraints; coordination issues; industry expectations	Adds contextual interpretation from decision-makers	Used in thematic analysis for cross-domain synthesis

Table 2: Analytical Framework for Assessing Nigeria's Local Manufacturing Capacity for Malaria Commodities

Domain of Analysis	Key Indicators / Variables	Primary Data Sources	Rationale for Inclusion	Outputs of Analysis
1. Technical & Production Capacity	Installed production capacity (monthly/annual) - Utilisation rate (%) - Plant	Brief 1, Brief 2, Consultant Report	Determines the country's ability to produce malaria	Comparative capacity profile across ACTs,

	layout & degree of automation - Workforce size & technical skills - API/excipient sourcing pathways - Packaging & logistics readiness		commodities at scale and with consistency	APIs, LLINs, RDTs
2. Quality & Regulatory Readiness	GMP/NAFDAC compliance - WHO PQ status & progress - ISO 13485 status (diagnostics) - QA/QC infrastructure (labs, bioequivalence capacity) - Documentation readiness	Briefs 1, 2, 5; NAFDAC GBT Report; WHO PQ documents	Establishes eligibility for donor markets and international procurement channels	Regulatory readiness index & PQ pathway mapping
3. Supply Chain & Input Dependencies	API dependence ratios - Import delays - Local availability of packaging materials - Cost of utilities (power, water, steam) - Foreign exchange exposure	Brief 2, Consultant Report, FMITI policy documents	Clarifies vulnerabilities that undermine competitiveness and supply resilience	Input dependency profile and supply chain risk map
4. Market Access & Demand Structure	Distribution of national demand (government vs. donor vs. private sector) - Access to Global Fund/UNICEF tenders - Procurement timelines & payment cycles - Export readiness (ECOWAS MRH, AfCFTA)	Briefs 3, 6, 7; NMEP procurement data	Determines revenue predictability and utilisation of installed capacity	Market-access barriers matrix & demand stability assessment
5. Financing Landscape & Investment Readiness	Cost of capital (interest rates) - Loan tenures - Access to BOI/DBN/DFI instruments - Incentive utilisation (tax waivers, duty exemptions) - CAPEX and working capital needs	Brief 3, FMITI, BOI, PMTP (2025–2030)	Identifies why manufacturers cannot scale or pursue PQ despite technical readiness	Financing constraint map & blended finance opportunity profile
6. Policy Environment & Institutional Alignment	National industrialisation policies (NIRP, PMTP) - Local content provisions - Coordination across FMoH–FMITI–NAFDAC–BOI - Execution gaps vs. policy commitments	Briefs 1–7; Government policy documents	Shows whether Nigeria's policy environment supports or inhibits industrialisation	Institutional alignment score & policy execution gap analysis

7. Cross-Domain Integration	-Triangulation of quantitative and qualitative findings - Linkages between technical, regulatory, market, and financing constraints	All documents	Enables synthesis to determine overall system readiness	Final systems-level readiness model for local manufacturing

Table 3: Summary of Manufacturing Capacity Across Key Malaria Commodities in Nigeria

Commodity Category	**Number of Identified Manufacturers**	**Installed Technical Capacity**	**Current Utilization Level**	**Quality/Regulatory Status**	**Key Input Dependencies**	**Major Bottlenecks Identified**
ACTs (Artemisinin-based Combination Therapies)	16 licensed formulators	>1.2 billion doses/year	40–60% utilization	Several GMP-compliant; none WHO PQ	APIs entirely imported; packaging materials partly local	Procurement unpredictability; donor preference for PQ imports; API forex exposure
APIs (Artemisinin derivatives & other antimalarial APIs)	0 fully operational; 1–2 partially ready	Pilot-scale potential only	Not applicable	No PQ; no GMP-graded API facility	100% import of intermediates & solvents	High capital cost; no guaranteed offtake; unstable forex; limited chemical ecosystem
LLINs (Long-Lasting Insecticidal Nets)	3 potential manufacturers with partial infrastructure	Capacity for assembly; no full-scale national output	<5% of national demand	None WHO PQ; no accredited entomology labs	Specialized PP yarns, insecticides, UV-stable polymers all imported	Lack of PQ labs; high machinery cost; absence of offtake guarantees
RDTs (Rapid Diagnostic Test Kits)	7 identified; 3 facilities near operational	>470 million tests/year by 2026	20–40% utilisation (expected)	2 manufacturers ISO 13485; progressing to ERPD/PQ	Membranes, antibodies, nitrocellulose, conjugates all imported	No PQ; high input import dependency; limited lab validation capacity

Table 4: Summary of Market Access and Procurement Constraints Across Malaria Commodities

Constraint Category	ACTs	APIs	LLINs	RDTs
Eligibility for Donor Procurement	Not eligible (no PQ)	Not applicable	Not eligible (no PQ)	Not eligible (no PQ)
Dependence on Donor Market	High	None	Very high	High
Government Procurement Predictability	Low	Low	Low	Low
Local Content Preference Implementation	Weak / non-operational	Weak	Weak	Weak
Tenders Fragmentation (Federal/State)	High	High	High	High
Payment Delays (Government)	Frequent	Frequent	Frequent	Frequent
Market Visibility and Forecasting	Limited	Limited	Limited	Limited
Ability to Access Regional Markets	Low (no PQ)	None	Low (no PQ)	Low (no PQ)
Binding Offtake Agreements Available	None	None	None	None

Table 5: Nigeria regulatory readiness & quality assurance capacity landscape

Category	ACT Manufacturers (n=4)	API Manufacturers (n=3)	LLIN Manufacturers (n=3)	RDT Manufacturers (n=7)
Regulatory Certifications	- All hold NAFDAC GMP - 2 hold ISO 9001 - 1 initiating WHO PQ dossier	- Partial NAFDAC GMP - No API PQ processes started	- 2 hold ISO 9001 - No WHO PQ - Pre-assessment ongoing for 1 facility	- 2 hold ISO 13485 - 1 completed ERPD pre-assessment
NAFDAC Inspection Status	Frequent inspections; partial compliance with cGMP	Frequent but lower compliance	Moderate; lacking cGMP for coating lines	High for 2 firms; low for emerging firms
WHO PQ Readiness (Technical)	Medium (documentation gaps, weak stability data)	Very low	Low (lack of PQ testing labs)	Medium–High (one nearing dossier submission)

QMS Implementation	Full SOPs, CAPA, deviation logs	Partial SOPs; no eQMS	SOPs exist but incomplete	ISO-aligned QMS for 2; manual systems for others
Process Validation	Cleaning & batch validation documented	Basic validation; incomplete	No validated LLIN coating or extrusion	Strip assembly validated in 2 plants
Supplier Qualification	Strong systems for excipients, APIs, packaging	Weak (heavy China/India dependence)	Weak (no polymer validation pathway)	Medium (antibody & membrane procurement validated)
Internal Laboratory Capacity	Assay, dissolution, stability (partial)	Basic QC only	No LLIN wash-resistance or UV-aging labs	Limited: some rapid tests, small QC labs
External Lab Dependence	High for PQ analyses	Total	Total	High for ERPD and PQ validation
Existence of GLP Labs	None	None	None	None
Bioequivalence Capability	None domestically	Not applicable	Not applicable	Not required
Documentation & Record Systems	Electronic & paper-based	Paper-based	Paper-based	Electronic (2 firms), manual (others)
Regulatory Gaps Identified	PQ dossier quality, data integrity, GMP audit findings	API traceability, impurity profiling	LLIN entomology, durability testing	Clinical validation gaps
Overall Regulatory Maturity Rating	**Moderate**	**Low**	**Low–Moderate**	**Moderate–High** (in 2 facilities)

Table 6: Summary of regulatory readiness and QA/QC capacity across malaria commodities

Commodity	No. of Identified Manufacturers	NAFDAC GMP Compliance	ISO Certification Status	WHO PQ / ERPD Progress	QA/QC Laboratory Capacity	Key Regulatory Gaps
ACTs	16 current manufacture	94.1% fully	Majority ISO 9001;	*29.4%* initiated	Functional QC labs in	Lack of CTD dossier

	rs; 1 planning entry	GMP-certified	none ISO 13485	PQ; no PQ completed	all firms; limited accreditation	completeness; insufficient method validation
APIs	0 operational for antimalarial APIs; 4 potential	Not applicable	None meet ICH Q7	No PQ attempts	No API-grade QC labs	No regulatory framework; no validated API processes
RDTs	7 identified; 4 engaged; 3 near operational	All NAFDAC-licensed; inspections ongoing	2 ISO 13485:2016 certified	2 in ERPD/PQ discussion; none PQ-ready	Limited environmental controls; no in-country lot testing	Lack of full design files; dependence on foreign validation labs
LLINs	Several with partial infrastructure	NAFDAC compliance through routine inspection	No LLIN manufacturer ISO-certified	2 early-stage PQ engagement	No entomology or durability-testing capability	No WHO-standard lab for bioefficacy/durability; incomplete QA systems

Table 7: Financing and Investment Landscape Across Malaria Commodity Manufacturers in Nigeria

Financing Dimension	**ACT Manufacturers (n=4)**	**API Manufacturers (n=3)**	**LLIN Manufacturers (n=3)**	**RDT Manufacturers (n=7)**
Primary Funding Sources	Retained earnings; short-term loans	Private capital; small equity; limited loans	Private equity; feasibility grants	Self-financing; small donor TA grants
Interest Rates Accessed	18–25%	20–28%	18–23%	18–22%
Loan Tenure	2–3 years	1–2 years	2–3 years	2–3 years
BOI/DBN Access	Moderate; many eligible	Low; API chemistry considered high-risk	Low; LLIN equipment expensive	Moderate; 2 firms received BOI facility

Capital Requirements	Medium (automation, QA upgrades)	Very High (reactors, utilities, effluent systems)	Very High (extrusion, weaving, coating lines)	Medium–High (automated lamination lines)
Working Capital Needs	High (API imports)	Very High (precursors, solvents)	Medium (polymers, coating chemicals)	High (membranes, antibodies, cassettes)
Foreign Exchange Exposure	Very High	Extremely High	High	High
Donor Funding Access	Very low (no PQ)	None	None	Low–Moderate (TA only)
PQ Financing Gap	High — stability chambers, BE studies	Extremely high — no PQ pathway	High — PQT-VC cost prohibitive	Medium — ERPD advanced but costly
Incentive Uptake	Partial, inconsistent	Very low	Low	Moderate (input duty waivers)
Key Bottlenecks	FX volatility; delayed govt. payments	High collateral; long payback not viable	High equipment cost; PQ lab absence	Raw material import delays; no PQ financing
Overall Financial Readiness	**Moderate–Low**	**Very Low**	**Low**	**Moderate** (in 2 firms)

Table 8: Supply chain dependency and input constraints across commodity groups

Commodity	Degree of Import Dependence	Key Imported Inputs	Domestic Inputs Available	Typical Lead Times	Major Supply Chain Constraints	Impact on Production
ACTs	**70–90%** of inputs imported	APIs, blister foils, capsules, stabilizers	Limited excipients, some packaging	6–12 weeks	FX volatility, customs delays, LC issuance	40–60% capacity utilization; batch delays due to API arrival
APIs	**~100%** import dependence	Chemical precursors, catalysts,	None	8–16 weeks	No domestic precursor supply; high	No commercial-scale production;

		solvents, lab reagents			cost of import	stalled pilot trials
RDTs	**~100%** import dependence	Membranes, antibodies, conjugates, buffers, cassettes	Minimal (secondary packaging)	8–12 weeks	"Sensitive goods" clearance delays; reagent expiry risks	Production stoppages; limited scale-up despite facility readiness
LLINs	60–90% depending on process level	Specialized PP pellets, UV stabilizers, insecticides	Basic PP resin from petrochemical firms	12–20 weeks	No domestic grades for LLIN yarn; foreign lab delays	Manufacturing stalls; PQ documentation gaps; low utilization (<40%)