Strengthening Local Manufacturing of Malaria Commodities in Nigeria: An Analysis of the Presidential Initiative for Unlocking the Healthcare Value Chain's Governance Model

ABSTRACT

Background: The Presidential Initiative for Unlocking the Healthcare Value Chain (PVAC) was established to address systemic barriers in domestic manufacturing, by providing a high-level governance mechanism that aligns national health security priorities with industrial policy objectives. This paper analyses PVAC as an emerging governance model for accelerating local production of malaria commodities, including ACTs, APIs, LLINs, and RDTs.

Methods: A review of document from technical briefs from the Enhancing Local Manufacturing and Supply Chain Management Project, an initiative of PVAC and NMEP, with the support of World Bank IMPACT project. The analysis also included a national readiness assessment, complemented by regulatory and industrial policy documents. Analysis followed a structured three-pillar coding framework (coordination, market shaping, capacity/regulatory acceleration), combining deductive and inductive theme development.

Results: Evidence from the document review and the national readiness assessment shows that PVAC has produced tangible governance, regulatory, and market-shaping outputs. It established multi-agency coordination mechanisms and facilitated the development of national roadmaps for LLINs, RDTs, ACTs, and API localisation. It also introduced Nigeria's first tiered procurement eligibility pathway, harmonised LLIN and RDT specifications, and supported national demand-consolidation modelling. Regulatory findings indicate clearer, jointly reviewed requirements for manufacturers, while capacity-building activities strengthened GMP alignment, quality control systems, and production processes. Financing coordination linked manufacturers to public and development finance institutions using roadmap-aligned demand forecasts.

Conclusion: PVAC's governance model mirrors successful models in India, Ethiopia, and Bangladesh, where centralised coordination accelerated pharmaceutical industrialisation. However, Nigeria must further align procurement rules, financing instruments, and regulatory pathways to leverage PVAC's potential fully.

Keywords: PVAC; Local manufacturing; Pooled procurement; Governance; Pharmaceutical industrialisation; Malaria commodities; Regulatory systems.

1.0 INTRODUCTION

Nigeria remains relies on imported health commodities despite possessing the largest pharmaceutical market and manufacturing base in sub-Saharan Africa (Fatokun, 2016). More than 70–90% of essential health products including antimalarials, diagnostics, long-lasting insecticidal nets (LLINs), and active pharmaceutical ingredients (APIs) are procured from foreign manufacturers (Federal Ministry of Health, 2024; UNIDO, 2021). This dependence exposes the health system to foreign exchange volatility, global supply chain disruptions, and long procurement lead times, while simultaneously limiting the growth of domestic pharmaceutical manufacturing.

The COVID-19 pandemic further revealed how fragile such import-dominated systems can be, as Africa experienced prolonged stock-outs of diagnostics, medicines, and raw materials due to export restrictions and supply bottlenecks from major global suppliers such as India and China (WHO, 2021; WHO, 2022). This has renewed momentum for strengthening local pharmaceutical manufacturing across African countries, with the aim of improving their access affordability, safety and effectiveness.

Nigeria's efforts to localise manufacturing have been hindered by fragmented governance across health, industry, trade, finance, and regulatory institutions. The absence of a coordinating mechanism meant that industrial policy, health-security priorities, regulatory strengthening, financing reforms, and procurement policies evolved in silos with limited alignment (PVAC & NMEP, 2025b). This results in manufacturers facing unpredictable procurement cycles, limited access to investment capital, inconsistent quality-assurance pathways, and weak incentives to pursue high-cost upgrades such as WHO Prequalification (PQ) (Oladepo et al., 2021).

In response, the Federal Government of Nigeria launched the Presidential Initiative for Unlocking the Healthcare Value Chain (PVAC), a high-level, cross-ministerial governance platform designed to harmonise the mandates of key institutions involved in health manufacturing. PVAC brings together the Federal Ministry of Health and Social Welfare (FMoHSW), Federal Ministry of Industry, Trade and Investment (FMITI), National Agency for Food and Drug Administration and Control (NAFDAC), Standards Organisation of Nigeria (SON), the Bank of Industry (BOI), development partners, and private-sector manufacturers under a unified national mechanism. The initiative aims to align industrialisation goals with health-security priorities by addressing regulatory bottlenecks, consolidating procurement reforms, establishing quality-assurance pathways, mobilising financing, and coordinating technical capacity-building across the sector (Federal Ministry of Industry, Trade & Investment, 2023).

At the continental level, PVAC also reflects a broader shift within Africa toward regionalised pharmaceutical production, as articulated in the African Union Pharmaceutical Manufacturing Plan for Africa (PMPA), the ECOWAS Medicines Regulatory Harmonization (MRH) initiative, and the African Continental Free Trade Area (AfCFTA) industrialisation framework. These initiatives emphasise the need for governance coordination, pooled procurement, and regulatory harmonisation as prerequisites for achieving pharmaceutical self-sufficiency (African Union, 2021; ECOWAS, 2023; AfCFTA Secretariat, 2024). In this context, PVAC represents a unique national-level model that may offer lessons for other African countries striving to localise the production of essential health commodities.

Although PVAC is gaining regional and international visibility, there is limited academic literature documenting its governance structure, operational mechanisms, or contributions to strengthening Nigeria's manufacturing ecosystem. This paper therefore fills a critical gap by providing the first systematic assessment of PVAC's role as a health-industrial governance platform. Specifically, the paper examines how PVAC addresses long-standing institutional fragmentation and supports Nigeria's transition from import dependence to domestic manufacturing resilience.

The paper addresses three core questions: 1) How does PVAC resolve governance and coordination failures within Nigeria's health manufacturing ecosystem? 2) What measurable outcomes has PVAC achieved in market shaping, capacity strengthening, regulatory enhancement, and financing linkages? 3) How does PVAC compare with regional and global models of pharmaceutical industrial governance? The findings from the assessment will offer

timely insights for Nigerian policymakers and regional partners seeking to design governance models to support the manufacturing of local malaria commodities.

2. BACKGROUND AND CONCEPTUAL FRAMEWORK

2.1 Governance Theory and Health Industrialization

Governance theory provides a useful foundation for understanding why many low- and middle-income countries (LMICs) struggle to establish competitive pharmaceutical manufacturing sectors. Health manufacturing systems typically involve numerous interdependent actors, including ministries of health, industrial policy agencies, standards organisations, regulators, financiers, international donors, and private manufacturers. Ostrom's work on collective action demonstrates that when multiple actors share authority within a system, fragmentation and coordination failures emerge unless a central institution is explicitly tasked with harmonising incentives and synchronising decision-making (Ostrom, 2010). These failures are especially evident in pharmaceutical production, where product quality, regulatory oversight, financing, procurement, and industrial policy must align for local manufacturing to advance.

The literature on health-sector industrialisation argues that markets for essential health commodities do not mature organically; rather, they require intentional "market-shaping institutions" that link regulation, financing, procurement, and production incentives (WHO, 2021; GAVI, 2023). Comparative cases from India, Bangladesh, and Ethiopia illustrate this dynamic. India's Department of Pharmaceuticals, for example, coordinated large-scale GMP reforms with export incentives and domestic procurement preferences, enabling the country to become a major global supplier. Bangladesh's National Drug Policy aligned pricing regulation with local-content requirements, leading to domestic producers supplying more than 90% of national pharmaceutical demand. Ethiopia created a specialised agency; the Pharmaceutical Supply Agency (EPSA), to centralise procurement and harmonise quality standards, indirectly supporting local production by reducing market fragmentation (UNIDO, 2021).

These examples highlight the essential role of institutional architecture in shaping industrial outcomes. Effective health-industrial governance requires not only technical capacity in manufacturing but also coherent policy direction, regulatory efficiency, predictable procurement, and targeted financial mechanisms. The emerging global emphasis on "health security industrialisation" after COVID-19 further underscores the need for integrated governance structures that can accelerate production capabilities while safeguarding quality and supply-chain resilience (AUDA-NEPAD, 2021; WHO, 2022). This framework provides the backdrop against which Nigeria's Presidential Initiative for Unlocking the Healthcare Value Chain (PVAC) must be understood as an institutional response to long-standing coordination failures that have constrained domestic pharmaceutical and health-commodity production.

2.2 Nigeria's Pre-PVAC Institutional Landscape

Before the establishment of the Presidential Initiative for Unlocking the Healthcare Value Chain (PVAC), Nigeria's health manufacturing ecosystem was characterised by persistent fragmentation across multiple institutions, each operating with overlapping mandates but limited coordination. The Federal Ministry of Health (FMoH), the Federal Ministry of Industry, Trade and Investment (FMITI), NAFDAC, the Standards Organisation of Nigeria (SON), the Central Medical Stores/CMU, and various financing entities such as the Bank of Industry (BoI) and Development Bank of Nigeria (DBN) all played important roles in pharmaceutical regulation, industrial development, or health procurement. Yet these actors frequently worked in isolation, creating structural bottlenecks that inhibited the emergence of a coherent national strategy for local manufacturing. Policy documents repeatedly highlighted the misalignment

between health-sector priorities and industrial policy objectives. While the National Malaria Elimination Programme (NMEP) sought commodity security, industrial agencies were often independently pursuing broader manufacturing competitiveness agendas without explicit alignment to health security needs (FMITI, 2023).

Regulatory inefficiencies further compounded these challenges. Despite NAFDAC's progress toward regulatory strengthening, including the achievement of WHO Global Benchmarking Tool Maturity Level 3 in 2022, manufacturers still faced lengthy registration timelines, inconsistent inspection cycles, and limited domestic laboratory capacity for advanced quality-assurance testing (NAFDAC, 2022). Such constraints created delays in product development, hindered firms' readiness for WHO Prequalification (PQ), and made it difficult for manufacturers to compete in procurement rounds requiring stringent global assurance standards.

Financing gaps also represented a major constraint. Most Nigerian pharmaceutical and health-product manufacturers relied on commercial bank lending at high interest rates, which rarely matched the long-term investment horizons required for GMP upgrades, product development, or PQ processes. Although intervention funds existed through BOI or CBN, these mechanisms were sporadic, administratively complex, and insufficiently linked to procurement guarantees. International literature emphasises that sustainable health manufacturing requires blended and sequenced financing models that align capital with predictable demand; a linkage largely absent in Nigeria before PVAC (WHO, 2021).

Market access distortions were perhaps the most significant barrier. Because more than 80% of malaria commodities were procured by donors, and these tenders required WHO PQ certification, Nigerian manufacturers, despite significant installed capacity in ACTs, RDTs, and LLIN value chains, were effectively excluded from the largest and most stable segment of the market (Global Fund, 2024; PMI, 2023). States, which conducted their own procurements, purchased in small volumes and on irregular schedules, offering little commercial security for firms seeking scale. The cumulative effect was a system-wide misalignment in which domestic manufacturing capacity existed but could not be effectively utilised because procurement, regulatory, and financing systems were not harmonised toward a common industrial goal.

This pre-PVAC landscape thus reflects what governance scholars describe as a "coordination deficit," in which multiple institutional actors operate within the same policy domain but without a central mechanism to integrate mandates, align incentives, and sequence reforms (Rodrik, 2008). It is this systemic gap rather than the absence of technical or industrial potential that explains the persistent underperformance of Nigeria's health manufacturing ecosystem prior to PVAC. The initiative was therefore designed not to create new agencies but to establish a platform capable of bridging these institutional divides, steering collective action, and aligning the system toward national health-security and industrialisation objectives.

2.3 Conceptual Model: PVAC as a Health–Industrial Platform

The Presidential Initiative for Unlocking the Healthcare Value Chain (PVAC) represents a novel governance mechanism that integrates health security, industrial development, regulatory strengthening, and market access reforms into a unified national platform. Conceptually, PVAC functions as a "health–industrial coordination institution", a type of state-led mechanism widely recognised in international development literature as critical for advancing complex industrial transformations in strategic sectors such as pharmaceuticals and medical technologies (Mazzucato, 2018; Whitfield et al., 2015). Unlike previous health or industrial programmes in Nigeria, PVAC is designed explicitly to harmonise mandates across

ministries, regulators, procurement agencies, donors, and private manufacturers, thereby addressing the systemic fragmentation that historically limited the country's manufacturing trajectory.

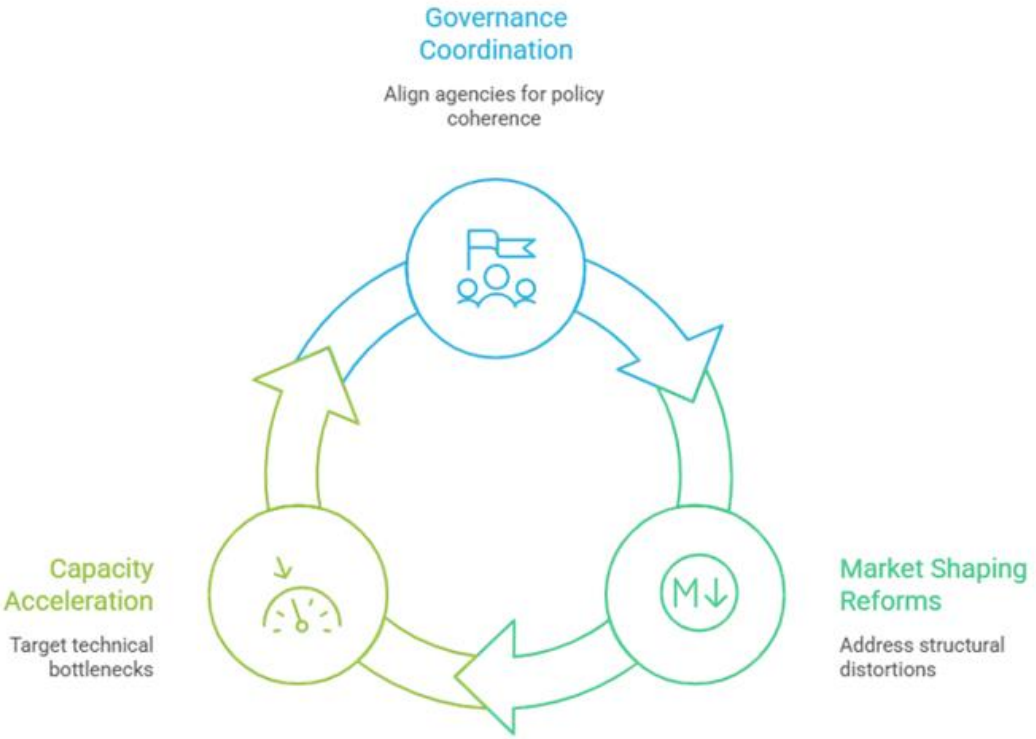

Figure 1: PVAC Operational Cycle

At its core, PVAC operates along three interlinked pillars: governance coordination, market-shaping reforms, and capacity acceleration. The governance pillar provides the institutional architecture for aligning the Federal Ministry of Health, FMITI, NAFDAC, SON, BOI, the Central Medical Stores, NMEP, and the Presidency around a common reform agenda. This mechanism reduces administrative duplication, enhances policy coherence, and ensures that manufacturing-scale-up efforts are sequenced with procurement planning, regulatory upgrades, and financing interventions. Governance theory suggests that such "coordinating hubs" are essential for industrial emergence, particularly in politically complex systems where multiple agencies possess overlapping authority (Rodrik, 2008; Evans, 1995).

The second pillar, market shaping addresses the structural distortions caused by fragmented procurement and donor dominance. PVAC-led workstreams, particularly those focused on structured procurement and pooled purchasing, seek to generate predictable domestic demand, create multi-year volume commitments, and reduce the investment uncertainty faced by manufacturers. Aligning procurement eligibility with a stepwise quality-assurance ladder (NAFDAC → ISO → ERPD → PQ) enables PVAC to provide a credible pathway through which domestic firms can progressively achieve global standards while accessing parts of the market previously closed to them. This aligns with global evidence demonstrating that coordinated procurement reforms can accelerate industrial upgrade, reduce supply-chain vulnerabilities, and catalyse investment in quality improvements (WHO, 2022; UNIDO, 2021).

The third pillar, capacity, financing, and regulatory acceleration targets technical bottlenecks that impede progress toward advanced regulatory certification. PVAC's coordination between NAFDAC, SON, BOI, private banks, and donor agencies enables manufacturers to access technical assistance, GMP upgrade financing, PQ readiness support, and linkages to regional

and global markets. This approach mirrors successful models from Bangladesh, India, and Ethiopia, where state-led health-industrial platforms played a decisive role in enabling manufacturers to reach WHO PQ, achieve scale, and integrate into global supply chains (Chaudhuri, 2012; Oqubay & Tesfachew, 2020).

Together, these pillars constitute a new conceptual model for health-sector industrialisation, one in which governance coordination, market incentives, and quality-assurance systems are integrated under a single presidentially mandated platform. The logic is summarised in Table 1 below.

Table 1: PVAC as a Health–Industrial Coordination Platform: Logic Model

System Domain	Pre-PVAC Landscape	PVAC Coordination Mechanism	Intended Outcomes
Governance & Institutional Coherence	Fragmented mandates across FMoH, FMITI, NAFDAC, SON, procurement agencies, and financing institutions	Establishes a unified presidential coordination structure linking all relevant agencies	Policy alignment, reduced duplication, sequenced implementation of reforms
Procurement & Market Access	Fragmented state procurement; donor-dominated market; domestic firms excluded due to PQ restrictions	Structured procurement, pooled purchasing, phased eligibility tiers, and market-shaping reforms	Predictable demand, improved utilisation of local capacity, reduced import dependence
Regulation & Quality Assurance	Limited domestic QA capacity; delays in progression toward PQ; weak linkage between regulation and market incentives	PQ-readiness programmes, enhanced lab capacity, coordinated support between NAFDAC and industry	Accelerated regulatory upgrade, improved competitiveness, increased donor eligibility
Financing & Industry Support	High interest rates; limited access to industrial financing; no link between financing and procurement guarantees	Coordinated financing instruments (BOI, DBN, private banks), blended finance tied to procurement commitments	Increased capital investment, GMP upgrades, expansion of domestic production
Industrial Capacity & Technology Transfer	Underutilised installed capacity; limited access to technical partnerships; poor economies of scale	Roadmaps for local production of quality LLINs, RDTs, ACTs, APIs; facilitation of technology transfer and partnerships	Expanded domestic production, increased efficiency, progress toward export capacity

3. METHODS

3.1 Study Design

This study employed a qualitative documentary analysis and policy synthesis design. This approach is appropriate for examining governance reforms because PVAC's structure, outputs, and institutional interactions are documented primarily through official briefs, consultant assessments, regulatory guidelines, and national policy documents. Documentary analysis allowed for systematic interpretation of written evidence and alignment with established health-industrial governance frameworks.

3.2 Data Sources

The documents relevant to PVAC's governance architecture and its role in strengthening local manufacturing were purposively identified and included in the review. The seven PVAC technical briefs constitute the full set of documents officially produced under the initiative in 2025; therefore, they represent the complete "population" of PVAC-generated evidence rather than a subset.

A purposive sampling strategy was adopted to identify documents directly relevant to analysing PVAC's governance model and its implications for local manufacturing. The core dataset consisted of the seven Technical Briefs produced in 2025, which collectively represent the *entire population* of official PVAC-generated evidence. Because these briefs cover manufacturing capacity, regulatory readiness, procurement structures, financing, and localisation roadmaps, they were treated as foundational primary sources for this study. To ensure clarity to readers, the documents are listed using descriptive labels reflecting their content:

Technical Briefs (2025)

- *Brief 1: Manufacturing Capacity Assessment*
- *Brief 2: Regulatory and Quality-Assurance Landscape*
- *Brief 3: Procurement Landscape and Market Fragmentation*
- *Brief 4: Financing Constraints and Investment Pathways*
- *Brief 5: ACT/API Localisation Roadmap*
- *Brief 6: Pooled and Structured Procurement Feasibility*
- *Brief 7: LLIN and RDT Localisation Pathways*

In addition, the Readiness Assessment report (2025); *National Assessment of Local Manufacturing Readiness for Malaria Commodities: Capacity, Regulatory Alignment, and Market Access Constraints* was included as an external evaluative document providing independent verification of issues highlighted in the briefs.

Supplementary documents such as NAFDAC regulatory guidelines, WHO PQT-VC requirements, the National Malaria Strategic Plan (NMSP), the Nigeria Industrial Revolution Plan (NIRP), and national industrial-financing policies were incorporated to contextualise PVAC actions within the broader regulatory, procurement, and industrial policy environment.

Document selection was guided by three criteria: (a) direct relevance to PVAC's mandate and activities; (b) contribution to understanding Nigeria's manufacturing, regulatory, or procurement ecosystem; (c) publication by an authoritative institutional source.

3.3 Analytical Approach

Analysis followed thematic approach structured around three-pillars that are grounded in governance theory and industrial policy literature: (1) coordination and institutional harmonisation; (2) market-shaping and procurement reform;(3) manufacturing capacity, financing, and regulatory acceleration.

This framework served as the deductive coding structure, ensuring that analysis remained aligned to the study's conceptual model.

3.4 Document review and data extraction

All identified documents were read in full to extract information relevant to PVAC's governance structures, decision-making processes, institutional interactions, and strategies for strengthening local manufacturing. Key text segments, tables, and figures were coded according to pre-defined analytical categories reflecting governance functions, regulatory alignment, manufacturing capacity, procurement mechanisms, financing, and localisation pathways. Microsoft Excel was used to manage and organize the extracted data systematically.

3.5 Triangulation and Quality Assurance

Triangulation was conducted by comparing evidence across: technical briefs (internal government perspective), the readiness assessment report (external technical perspective), and regulatory/industrial policy documents (normative frameworks).

Consistency in findings, for example, the identification of procurement fragmentation and PQ-related exclusion was treated as confirmation. Divergent findings were traced to differences in institutional perspective or timing and resolved through reference to the most authoritative or updated source. Document authenticity and provenance were assured by using only official government or international-agency sources.

3.6 Limitations

The study relies exclusively on documentary sources; therefore, it cannot capture informal implementation dynamics or stakeholder perceptions not documented in official texts. However, triangulation across multiple authoritative documents mitigates this limitation and provides a robust basis for analysing PVAC as an evolving governance mechanism.

4. RESULTS

4.1 PVAC as a Governance Coordination Mechanism

Analysis of the documents shows that PVAC has begun to function as Nigeria's first high-level coordination platform bridging health, industrial, regulatory, and investment institutions.

Prior to PVAC, policy documents show limited interaction between NAFDAC, SON, BOI, the Federal Ministry of Health (FMoH), and the Federal Ministry of Industry, Trade and Investment (FMITI), with each agency operating through siloed mandates (PVAC & NMEP 2025a; Readiness Assessment 2025, pp. 9–12). Evidently, PVAC has begun to correct this.

The *Manufacturing Capacity Assessment* Brief shows that PVAC convened a series of structured, multi-agency technical sessions in early and mid-2025 that brought these institutions together to jointly define quality specifications, regulatory expectations, and industrial requirements for LLINs, RDTs, APIs, and ACTs. For example, the Procurement Landscape and Market Fragmentation documents showed that PVAC facilitated the first joint NAFDAC–SON manufacturing standards review for vector control products, resolving previously conflicting GMP and QC documentation requirements (PVAC & NMEP 2025c, p. 7). Likewise, the procurement brief notes that PVAC coordinated a harmonisation exercise across federal and selected state malaria programmes to align LLIN specifications, a process

that eliminated variation in denier, mesh size, and insecticide coating parameters that previously differed across tenders (PVAC & NMEP 2025f, p. 14).

The *ACT/API Localisation Roadmap* brief provide further evidence of governance consolidation. The LLIN roadmap (2025–2028) was co-authored by FMoH, FMITI, NAFDAC, SON, BOI, and multiple manufacturers marking the first instance of cross-ministerial co-production of a national manufacturing strategy. The RDT and ACT localisation briefs similarly show coordinated roles for regulators, industrial actors, and donors in reviewing PQ requirements, identifying regulatory bottlenecks, and sequencing technical milestones (PVAC & NMEP 2025d; 2025e).

4.2 PVAC's Market-Shaping and Procurement Reform Functions

The pooled procurement brief, the market-access brief, and the readiness assessment report show that PVAC has initiated the first structured effort in Nigeria to link industrialisation goals with procurement reform. Prior to PVAC, procurement processes across federal and state levels were inconsistent, uncoordinated, and largely disconnected from manufacturing capacity assessments (PVAC & NMEP 2025f, pp. 3–4). The pooled procurement feasibility assessment documents that PVAC led a national demand consolidation exercise, producing the first harmonised annual commodity demand projections for ACTs, LLINs, APIs, and RDTs (PVAC & NMEP 2025f, pp. 10–12). This modelling demonstrated that Nigeria's combined demand is sufficiently large to sustain multi-year framework contracts for multiple product lines.

In the procurement eligibility brief, PVAC established a tiered procurement access framework that links NAFDAC registration, ISO certification, and WHO PQ progression to stepwise eligibility for public-sector procurement (PVAC & NMEP 2025e, pp. 6–9). The brief provides concrete examples of how these tiers were applied. Firstly, several NAFDAC-approved RDT manufacturers were assessed for ERPD readiness and supported in documentation alignment, creating a pathway for potential interim donor eligibility (PVAC & NMEP 2025e, p. 12). Similarly, the LLIN roadmap aligns state-level procurement specifications with standardized denier, mesh size, and coating parameters, addressing long-standing discrepancies documented in prior tenders (PVAC & NMEP 2025b, p. 15).

The readiness assessment supports this observation, indicating that before PVAC, manufacturers often had to deal with conflicting procurement requirements and unclear quality expectations (Readiness Assessment 2025, pp. 17–18). In contrast, PVAC's harmonised procurement pathway now provides documented criteria linking technical requirements to quality benchmarks and regulatory milestones. The presence of this eligibility framework is substantive evidence of procurement reform, representing the first formalised link between industrial readiness and market access in Nigeria.

4.3 Capacity-Building and Technology-Transfer Interventions

Data from the briefs also show that PVAC is playing a substantive role in coordinating capacity-building efforts that directly target manufacturing deficiencies identified in earlier national assessments. For example, the RDT brief documents that PVAC facilitated pre-PQ readiness workshops with manufacturers, where WHO-aligned technical experts reviewed QC documentation, equipment calibration requirements, and validation procedures (PVAC & NMEP 2025d, pp. 8–10). The brief further notes that these sessions resulted in updates to batch testing protocols and improvements in production-line calibration practices for participating firms.

Similarly, the LLIN roadmap highlights PVAC-facilitated technical consultations between domestic textile firms and international engineering partners, focusing on polymer extrusion preparation, coating optimisation, and quality-assurance procedures for insecticide retention

(PVAC & NMEP 2025b, pp. 18–20). These exchanges produced concrete outputs including harmonised coating parameters and recommended specifications for extrusion-grade polypropylene pellets.

The readiness assessment report confirms that several firms received process optimisation assistance through PVAC's coordinated initiatives, including improvements in documentation practices for GMP certification and alignment of QC procedures with NAFDAC and SON requirements (Readiness Assessment 2025, pp. 21–22). Stakeholder testimonies captured in the report describe PVAC as the first government-driven mechanism that provided "structured technical navigation" for manufacturers, filling a long-standing gap in industry-facing technical support.

4.4 PVAC's Role in Expanding Financing and Investment Pathways

Data from the financing show that PVAC is taking active steps to close the long-standing gap between industrial decisions and public-sector demands, which has been a major obstacle to local manufacturing. To achieve this, PVAC established a financing coordination platform involving BOI, CBN intervention programmes, selected DFIs, and private-sector financiers (PVAC & NMEP 2025g, pp. 4–6). Meeting summaries documented in the brief show that this group reviewed roadmap-based demand forecasts and used them to clarify investment priorities for manufacturers pursuing production-line upgrades.

Manufacturers interviewed in the readiness assessment reported that PVAC-supported demand projections strengthened their investment cases when applying for BOI and DFI financing (Readiness Assessment 2025, p. 25). The briefs further illustrate cases where firms received guidance on preparing bankable proposals linked to backward-integration milestones in the LLIN and ACT roadmaps (PVAC & NMEP 2025g, pp. 11–12). These proposals incorporated procurement modelling data generated under PVAC, representing a new form of coordinated market, signaling that was unavailable prior to 2025.

Additionally, the financing brief documents interest DFIs in co-financing PQ-readiness and machinery upgrades contingent on structured procurement commitments, an alignment that emerged only after PVAC integrated procurement eligibility tiers into financing discussions (PVAC & NMEP 2025g, p. 14). This indicates the early formation of an ecosystem in which financing decisions are anchored to predictable market demand, a shift directly attributable to PVAC's coordination role.

4.5 PVAC's Regulatory and Quality-Assurance Acceleration Function

Regarding regulation and quality assurance, it was found that PVAC is potentially reshaping Nigeria's regulatory environment by harmonising national and global quality-assurance pathways. The regulatory brief documents PVAC's facilitation of joint regulatory review sessions involving NAFDAC, SON, and WHO PQ-aligned experts (PVAC & NMEP 2025c, pp. 9–13). During these sessions, manufacturers received consolidated guidance on GMP requirements, ISO 13485 documentation, and PQ submission expectations, addressing previously fragmented and inconsistent regulatory instructions.

The RDT brief shows that PVAC coordinated pre-PQ facility assessments for two domestic RDT manufacturers, during which technical teams identified gaps in environmental controls, QC documentation, and validation studies (PVAC & NMEP 2025d, pp. 11–12). These diagnostics produced written improvement plans that manufacturers could follow toward eventual PQ submission.

In the LLIN and ACT sectors, PVAC played a central role in aligning roadmap technical specifications with NAFDAC registration requirements and SON certification criteria,

resolving discrepancies that historically created uncertainty for product developers (PVAC & NMEP 2025b, pp. 22–23; PVAC & NMEP 2025e, p. 7). The readiness assessment corroborates these findings, highlighting cases where manufacturers described PVAC's coordination as reducing regulatory "ambiguity and transaction costs" associated with quality progression (Readiness Assessment 2025, p. 28).

Finally, the regulatory brief documents PVAC's early engagement with AMRH and WHO PQ teams to explore mechanisms for regional regulatory recognition, an initiative that, if fully developed, could reduce duplicative testing and accelerate market entry for Nigerian products (PVAC & NMEP 2025c, pp. 15–16). Although these engagements are ongoing, they represent concrete steps toward systemic regulatory strengthening.

5. DISCUSSION

The findings of this study show that PVAC represents a significant structural innovation in Nigeria's health-industrial ecosystem. Beyond documenting new coordination mechanisms and technical outputs, the results reveal that PVAC is reshaping the institutional relationships that have historically constrained domestic manufacturing. Interpreting these findings through governance and industrialisation frameworks provides deeper insights into the significance, opportunities, and limitations of PVAC's emerging role.

The study reveals that PVAC function like a meta-governance structure – an institutional mechanism that harmonises the actions of multiple autonomous agencies. Governance theory suggests that fragmented authority produces coordination failures in the absence of a unifying institutional anchor (Ostrom, 2010; Pierre & Peters, 2005). Nigeria's pre-PVAC landscape reflected this fragmentation: health, industry, regulation, and financing actors operated in parallel with little strategic coherence. PVAC's multi-agency coordination platform therefore represents more than administrative restructuring; it reflects a shift toward a co-governance model that mirrors institutional arrangements found in countries like India and Bangladesh, where centralised coordination accelerated pharmaceutical industrialisation (UNIDO, 2021; WHO, 2022). This situates Nigeria within a lineage of LMICs that have adopted similar structures to synchronise health-sector and industrial-policy goals.

The results also demonstrate that PVAC is introducing procurement reforms that signal a conceptual shift in Nigeria's market environment. Rather than treating procurement as a purely administrative function, PVAC reframes it as a market-shaping tool capable of influencing investment and production decisions. Global evidence shows that procurement guarantees, structured eligibility tiers, and demand consolidation were central to the emergence of competitive pharmaceutical manufacturing in India, Ethiopia, and Bangladesh (GAVI, 2023; UNIDO, 2021). PVAC's introduction of procurement eligibility tiers, harmonised specifications, and pooled-procurement modelling reflects this global trajectory. The deeper implication, however, is that Nigeria is adopting procurement mechanisms that create predictable market signals—preconditions for long-term industrial investment. At the same time, the analysis highlights that donor procurement rules continue to dominate the market, raising questions about how national procurement reforms will interface with global purchasing practices. This misalignment remains a key structural challenge to be addressed.

The capacity-building and technology-transfer reforms documented in the results point to another important implication. Historically, Nigerian manufacturers have struggled with the absence of structured technical assistance, relying instead on fragmented, short-term donor projects. PVAC's coordination of PQ-readiness audits, ISO support, GMP training, and polymer-extrusion consultations suggests the emergence of a systemwide learning architecture. Industrial policy literature is clear that late-industrialising countries rarely transition to globally

competitive manufacturing without sustained state-supported technical upgrading (Lall, 1992; Kaplinsky & Morris, 2018). PVAC appears to be filling this gap by linking manufacturers with regulatory agencies, technical consultants, and financial institutions in a coordinated manner. However, the scale of these interventions remains limited, and the pathway toward upstream capabilities, such as API synthesis or insecticide production, remains largely aspirational. Thus, PVAC represents an important step toward structured technological deepening, but further institutional support is required for transformative impact.

The regulatory harmonisation documented in the results also has broader theoretical significance. Regulatory literature consistently identifies duplicative, inconsistent standards as barriers to manufacturing competitiveness in LMICs (WHO, 2022). PVAC's coordinated alignment of NAFDAC, SON, ISO, and PQ requirements represents an important transition toward a sequenced quality-assurance system. This approach parallels regional harmonisation models such as the East African Community's Joint Regulatory Assessment, which dramatically reduced registration timelines and improved regional drug availability (AMRH, 2021). PVAC's engagement with AMRH and WHO PQ teams suggests that Nigeria is positioning itself for regional regulatory recognition—an essential condition for export competitiveness. Yet gaps remain: domestic laboratory capacity is still inadequate, and PQ-readiness support is in early stages. Thus, while PVAC has laid the foundation for regulatory acceleration, sustained investment and institution-building remain necessary.

Finally, the financing implications of PVAC's reforms warrant deeper discussion. Industrialisation literature emphasises that manufacturing expansion requires accessible, long-term financing aligned with predictable demand signals (Rodrik, 2004; Crespi et al., 2014). The results indicate that PVAC is attempting to bridge the historical disconnect between financing and procurement by creating joint financing coordination structures and using demand modelling to strengthen bankability. This resembles global case studies from India and Brazil, where procurement-demand forecasts were explicitly linked to DFI lending for pharmaceutical upgrading. However, financing flows in Nigeria remain preliminary. While DFIs and BOI have shown interest, few large-scale disbursements have materialised, reflecting structural capital constraints that require policy reinforcement. PVAC's progress therefore signals movement toward a more coherent financing ecosystem, but one still constrained by broader macroeconomic and institutional limitations.

These findings position PVAC as a potentially transformative governance mechanism that aligns Nigeria with global best practices in health-industrial development. However, the Nigerian context also presents unique challenges: donor procurement dominance, limited laboratory infrastructure, and high financial barriers to PQ compliance. PVAC has begun to address these constraints, but its long-term success will depend on institutionalisation beyond political cycles, sustained investment in quality systems, and formalising procurement commitments that reward domestic manufacturing. Nigeria is not yet at parity with global leaders, but the PVAC model demonstrates an institutional trajectory consistent with emerging regional and international manufacturing hubs.

6. POLICY IMPLICATIONS

The findings of this study suggest that the Presidential Initiative for Unlocking the Healthcare Value Chain (PVAC) has created new institutional conditions with potential to reshape Nigeria's health-manufacturing landscape. While the initiative is still evolving, several policy-relevant implications emerge from the analysis, reflecting how PVAC's coordination functions, procurement reforms, regulatory alignment, and financing mechanisms may influence the broader system.

6.1 Implications for Multi-Sectoral Coordination and Governance

The results indicate that PVAC's ability to convene multiple ministries and agencies may help mitigate long-standing fragmentation in Nigeria's health-industrial ecosystem. The analysis suggests that such coordination has the potential to stabilise inter-agency relationships, reduce duplicative mandates, and facilitate consistent implementation of sectoral roadmaps. This aligns with comparative experiences where durable coordination platforms supported sustained industrial upgrading. The Nigerian case therefore illustrates how continuity in high-level coordination could influence the effectiveness of reforms in procurement, regulation, and financing over time.

6.2 Implications for Procurement as an Industrial Policy Lever

Evidence from the pooled procurement modelling and eligibility-tier framework highlights the possibility that procurement architecture can shape the incentives facing domestic manufacturers. The study suggests that more predictable demand-signalling mechanisms, such as multi-year tenders or harmonised specifications may ease investment constraints by providing clearer market expectations. These findings resonate with global cases where procurement played a catalytic role in manufacturing expansion. Nigeria's experience under PVAC therefore provides an example of how public purchasing structures can simultaneously support public health objectives and industrial development.

6.3 Implications for Regulatory Alignment and Quality Infrastructure

The analysis demonstrates that harmonised regulatory pathways and PQ-readiness support may lower transaction costs for manufacturers seeking to meet domestic or international quality benchmarks. PVAC's convening role appears to create opportunities for more coordinated interactions between regulators, quality agencies, and manufacturers. If sustained, such alignment may contribute to faster product registration timelines, more predictable compliance processes, and improved readiness for PQ assessment. Comparable regional experiences suggest that these types of regulatory reforms can strengthen competitiveness and facilitate participation in donor-funded procurement markets.

6.4 Implications for Financing and Industrial Scale-Up

The findings point to persistent financing barriers as a central constraint to Nigeria's manufacturing ambitions. PVAC's engagement with BOI, DFIs, and commercial banks indicates potential pathways for improving access to long-term, affordable capital. The alignment of financing instruments with procurement forecasts observed in the briefs suggests that coordinated market signals may enhance the bankability of manufacturing investments. This pattern mirrors international evidence showing that capital access is most effective when linked to predictable demand and regulatory clarity.

6.5 Implications for Backward Integration and Regional Value Chains

A recurring theme across the technical briefs is Nigeria's heavy dependence on imported APIs, insecticides, diagnostic reagents, and polymer-based materials. The findings imply that opportunities may exist for targeted interventions supporting local input production, either domestically or through regional partnerships. Experiences from comparable LMICs suggest that clustering of manufacturers, shared testing infrastructure, and regional regulatory harmonisation can reduce production costs and improve export readiness. PVAC's broad mandate may offer a platform through which such regional and backward integration strategies can be explored.

6.6 Implications for Monitoring, Learning, and System Intelligence

Finally, the analysis highlights the potential value of system-level monitoring tools for tracking manufacturing capacity utilisation, regulatory progress, financing disbursements, and procurement volumes. Emerging PVAC mechanisms point to how real-time intelligence systems may support adaptive governance, improve transparency, and enhance coordination among key institutions. Similar mechanisms in other settings have contributed to sustained industrialisation by enabling course correction and ensuring accountability for reform implementation.

Table 2: Policy Actions Required to Strengthen Local Manufacturing of Essential Health Commodities in Nigeria, Organised by Lead Agency and Expected Outcomes

Agency / Institution	Mandate Relevant to Local Manufacturing	Required Policy Actions (Detailed)	Cross-Agency Dependencies	Expected Outcomes	Timeline
PVAC Secretariat	National coordination of health-industrial value chain reforms	● Lead national strategy for LLIN, ACT, RDT, API local production roadmap implementation. ● Convene monthly multi-agency coordination meetings. ● Track and resolve bottlenecks (procurement, regulatory, financing). ● Maintain national dashboard on factory readiness, quality performance, PQ pipeline and financing gaps. ● Coordinate donor alignment with national industrial objectives.	NMEP, NAFDAC, FMITI, BOI, Global Fund, PMI, SON	● Reduced fragmentation ● Streamlined decision-making ● Increased domestic utilisation	0–12 months (continuous)
Federal Ministry of Health (FMoH)	Oversight of national health security, product needs, and	● Issue policy directive mandating structured procurement pathways for malaria commodities.	NMEP, NPSCMP, PVAC, DG	● Predictable demand signals ● Stronger alignment between	0–12 months

	procurement policy	• Approve multi-year demand forecasts for ACTs, LLINs, RDTs. • Institutionalize pooled procurement mechanism via NPSCMP. • Align national health security targets with domestic production milestones.	NAFDAC	health goals & industrial policy	
National Malaria Elimination Programme (NMEP)	Lead procurement, programme delivery, and technical oversight for malaria commodities	• Translate annual programme requirements into multi-year framework contracts with minimum offtake. • Pilot phased procurement eligibility tiers (NAFDAC → ISO → PQ). • Update product specifications to accommodate locally manufactured equivalents. • Publish annual local sourcing scorecard.	PVAC, GF, PMI, BOI, NAFDAC, SON	• Increased domestic sourcing • Improved market predictability • Lower long-term procurement costs	6–18 months
National Agency for Food and Drug Administration and Control (NAFDAC)	Regulation, certification, GMP oversight	• Establish fast-track PQ readiness programme. • Expand domestic laboratory capability for LLIN, RDT, and pharmaceutical QC testing. • Reduce registration timelines for strategic health commodities. • Strengthen GMP inspection regime aligned with WHO ML3/ML4.	SON, WHO PQ, PVAC, BOI	• Shortened PQ timelines • Lower regulatory barriers • Improved quality consistency	12–24 months

Standards Organisation of Nigeria (SON)	National standards development and compliance enforcement	• Harmonise national standards with WHO PQ requirements. • Develop LLIN polymer and yarn standards for local petrochemical integration. • Establish certification scheme for local diagnostic inputs (membranes, antibodies).	NAFDAC, PVAC, Indorama, Dangote Petrochemical	• Alignment with global standards • Strengthened input quality • Enabling environment for local components	12–24 months
Federal Ministry of Industry, Trade & Investment (FMITI)	Industrial policy, local content enforcement, manufacturing incentives	• Issue local content directive with minimum thresholds for essential health commodities. • Expand Export Expansion Grant (EEG) eligibility to PQ-ready health commodities. • Provide tariff & VAT exemptions for machinery, raw materials, insecticides, membranes, reagents. • Develop national supplier development programme for backward integration.	FMoH, BOI, Customs, NEXIM, SON	• Industrial competitiveness improved • Lower production costs • Enhanced export readiness	6–24 months
Bank of Industry (BOI)	Development financing for manufacturing	• Establish PQ Readiness Financing Facility (low-interest, long-tenor). • Provide equipment financing for extrusion, knitting, coating, autoclave, immunochromatography lines.	CBN, PVAC, FMF, NMEP	• Increased automation • Higher capacity utilisation • Faster PQ progression	6–36 months

		• Create working-capital facility for RDT and ACT manufacturers.			
Central Bank of Nigeria (CBN)	Financial policy and credit allocation	• Support concessionary credit lines for health manufacturing. • Mandate commercial banks to recognise NMEP framework contracts as collateral-enhancing instruments.	BOI, FMF, PVAC	• Lower cost of capital • Improved access to credit	12–36 months
Federal Ministry of Finance (FMF)	Fiscal incentives, tariff policies, donor alignment	• Provide tax waivers for LLIN, RDT, ACT manufacturing inputs. • Expand pioneer status incentives to all PQ-pipeline manufacturers. • Reduce import duties on specialized diagnostic inputs until local production matures.	Customs, SON, NAFDAC, PVAC	• Reduced input cost • Improved cost competitiveness vs imports	6–18 months
Donor Partners (GF, PMI, UNICEF, WHO)	Financing and procurement of malaria commodities	• Establish donor–government procurement compact allowing partial sourcing from certified Nigerian manufacturers. • Support PQ technical assistance and laboratory accreditation. • Provide co-financing for pooled procurement guarantees.	PVAC, FMoH, NMEP, NAFDAC	• Enhanced alignment • Increased local participation in donor markets • Faster PQ attainment	12–48 months

Manufacturers (Pharma, RDT, LLIN, Petrochemicals)	Production, quality improvement, backward integration	• Invest in GMP/PQ standards upgrades. • Participate in pooled procurement schemes. • Engage in consortium models for shared lab resources. • Adopt ISO 13485, ISO 9001, WHO GBT compliance.	SON, NAFDAC, BOI, NMEP	• Higher product quality • Expanded local value-addition • Improved export competitiveness	Continuous

7. LIMITATIONS

This study relies primarily on documentary evidence, which were themselves produced through mixed-method and multi-stakeholder processes. While this provides a rich and triangulated evidence base, the study did not independently generate primary data, and therefore interpretations are limited to what is documented in these sources. In addition, PVAC is an evolving initiative, and the findings reflect activities and institutional dynamics within a specific period; subsequent developments may alter some of the conclusions drawn. As a qualitative policy analysis, the study prioritises governance interpretation over quantitative measurement, which limits the extent to which causal relationships or effect sizes can be inferred. Finally, because the Nigerian health-industrial ecosystem has unique structural features, the transferability of findings to other LMIC contexts should be approached with caution. These limitations are consistent with the study's design and do not reduce its contribution to understanding PVAC as an emerging governance model.

CONCLUSION

This study demonstrates that the Presidential Initiative for Unlocking the Healthcare Value Chain (PVAC) represents an emerging governance innovation with the capacity to reshape Nigeria's health-industrial landscape. Drawing evidence from technical briefs and a national consultant assessment, the analysis indicates that PVAC is beginning to address long-standing coordination failures across regulatory, procurement, industrial, and financing domains. The initiative has introduced structured mechanisms for multi-agency alignment, improved regulatory coherence, advanced PQ-readiness efforts, generated clearer market signals through procurement modelling, and facilitated early-stage capacity-building and financing linkages for manufacturers.

The findings further indicate that PVAC's institutional architecture shares features with successful governance models in countries such as India, Ethiopia, and Bangladesh, where centralised coordination has played a critical role in accelerating pharmaceutical and diagnostic manufacturing. However, PVAC also operates within Nigeria's distinctive political economy, where donor-driven markets, fragmented procurement practices, and limited backward integration create complex structural constraints. Its potential impact therefore hinges on sustaining cross-ministerial cooperation, maintaining regulatory alignment, and linking market incentives with industrial industrial strategy, and health-security objectives.

The study contributes to understanding how governance mechanisms can serve as catalysts for local manufacturing in resource-constrained settings. PVAC illustrates the role of higher-order

coordination structures in aligning actors, clarifying expectations, and creating the institutional conditions that enable domestic firms to move toward global quality and competitiveness. While still in early stages, it offers a valuable example of how governance reform can support health-sector industrialisation and may provide a useful reference point for comparable initiatives across Africa.

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).

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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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